DIGISTAT® Smart Central

DIGISTAT® Version 4.1

User Manual

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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.

1. Contents

2. Using the manual

2.1. 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

1) The appearance of the page (a page may appear different from that shown here).
2) The functions (certain operations may or may not be enabled).
3) 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.

2.2. Charcters 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 (see Appendix **A**).

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 5.4", 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.

2.3. 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.

3. 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.

3.1. 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 in different times, and in a way that is agreed with the user. The resultant software suite fits to the specific user needs and can change in time, according to the possible changes in the user needs.

3.2. Intended use

The product "DIGISTAT®" (hereafter "PRODUCT") is a medical device composed only of software that is licensed exclusively to create an electronic copy of certain data and recording of the unit's activity in order to provide:

- electronic documentation of the activity in the unit;
- information on the use of human resources and materials;
- deferred statistics for quality control;
- support to the diagnostic and therapeutic activities, within the limits of what specified herein below;
- support to the management of alarms coming from the connected medical devices;

- display of information to remote users for non-clinical purposes.

The PRODUCT is not aimed to administer or exchange energy to or from the human body or to transmit medicines, liquids or other substances to or from the human body.
The PRODUCT is not aimed to allow direct diagnosis or monitoring of vital physiological processes (by way of example cardiac performance, respiration or activity of CNS) and therefore the therapeutic or diagnostic procedure or maneuver, if any, deemed necessary by the User, shall be performed by him/her solely as consequence of the direct examination and of the scientific correspondence of the specific case with the data obtained through the use of the PRODUCT.
Based on the above features, the PRODUCT, even if designed to provide the maximum reliability, cannot guarantee the perfect correspondence of the provided data, nor can it substitute the direct verification of the same by the User.
In any case, the PRODUCT must be used in compliance with the safety procedures reported in the user manual accompanying the Product.

Always check that the information supplied is correct. It is under exclusive responsibility of the User to make correct use of the information supplied.

The PRODUCT can be used close to the patient and to the medical devices in order to speed up the data entry, to decrease the chances 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 it is necessary to double-check that the patient identity, hospitalization department and bed displayed in DIGISTAT® are correct.
This is utterly important in case of critical actions as, for instance, drug administration.

The User must implement adequate procedures to guarantee that potential errors occurring in 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 User.
Only printouts that are signed (with digital signature or autograph) by authorized physicians or medical operators shall be considered valid clinical documents. 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.

Only printouts signed by the authorized physicians or medical operators shall be considered valid clinical documents.

The PRODUCT may provide, depending on the configuration, access to information on drugs. It is responsibility of the User to initially and periodically verify that this information is current and updated.
The PRODUCT can be connected to other medical devices in order to import data therefrom but is not aimed to control, monitor or influence the performances of the medical devices with which it is connected.
The PRODUCT may provide, depending on the modules installed, visual and acoustic indication of the status and operating conditions of the approved devices connected to the PRODUCT thus providing a support to the management of the alarms and to the planning of nursing workflow.
The information displayed by the PRODUCT is not meant to replace or replicate the original display of data, messages and alarms of the medical devices. The PRODUCT does not and is not intended to control, affect or modify the normal use of those connected devices.
The PRODUCT does not substitute a "Nurse Call" system and it is not a "Distributed Alarm System" (as defined by the standard EN 60601-1-8). 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 and to the nature and limitations of the hospital local network.

DIGISTAT® is not a "Distribuited Alarm System".

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.

3.2.1. Intended users

The PRODUCT must be used by properly trained physicians, nurses, administrative staff, system administrators, biomedical engineers and technicians.
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 ASCOM UMS or ASCOM UMS distributors and 2) in possession of the professional qualifications to correctly interpret the information supplied and to implement the appropriate safety procedures.

Use of DIGISTAT® must be granted only to professionally qualified and properly trained personnel.

Limited parts of the PRODUCT may be used by other categories of users for non-clinical purposes, to access a limited set of information and without the ability to alter existing information or enter new ones. For example patient's family member can access information of their relative.

3.2.2. Intended environment

The PRODUCT can be used inside medical facilities in intensive care units, wards, operating blocks, operating theatres and other departments.
The PRODUCT is software-only medical device that can be run on a computer connected to the hospital local network and must be adequately protected against cyber-attacks.
The PRODUCT must be installed only on recommended PCs and/or operating systems.

DIGISTAT® must be installed only on recommended PCs and/or operating systems.

In using the PRODUCT, the User declares to have understood and accepted the characteristics, limits and responsibilities contained herein and in the user manual. Should the User consider any of these clauses to be unacceptable, he must immediately stop using the PRODUCT and inform promptly the system administrator.

3.2.3. "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".

3.3. 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.

> ***WARNING!***
>
> ***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.***

3.4. 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 labelling (either paper label provided at installation time or "About box" displayed within the product – see paragraph 6.8.5).
In case of doubts/questions about product labelling and/or product identification please contact ASCOM UMS/Distributor technical assistance (for contacts see paragraph 10).

3.5. 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 authorised dealer.

The device details can be found on its labelling.

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

3.6. 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 in keeping technical documentation and provide technical support.

3.7. 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.

4. 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).

4.1. Bedside

4.1.1. Hardware

According to the IEC 60601-1 regulation, for "bedside" PCs, or for PCs positioned within the "Patient Area", the use of "Medical grade" devices is required. In these places medical grade PANEL PCs are often used. If explicitely requested, ASCOM UMS is able to provide information on some suitable devices of this kind.

Minimum hardware requirements:

- Intel® processor with Intel® dual-core technology (or faster)
- Memory: 2 GB RAM (4 GB suggested)
- Hard Disk: at least 20 GB of available space
- Monitor: 1024 x 768 or higher (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- Windows® compatible printer
- Ethernet interface 100 Mb/s (or higher)
- CD/DVD Drive or possibility to copy the installation files

4.1.2. Operating System

Supported operating systems:

Microsoft Corporation Windows® XP SP3 32 bit
Microsoft Corporation Windows® XP SP3 64 bit
Microsoft Corporation Windows® 7 32 bit
Microsoft Corporation Windows® 7 64 bit
Microsoft Corporation Windows® 7 SP1 32 bit
Microsoft Corporation Windows® 7 SP1 64 bit
Microsoft Corporation Windows® 8 32 bit
Microsoft Corporation Windows® 8 64 bit
Microsoft Corporation Windows® 8.1 32 bit
Microsoft Corporation Windows® 8.1 64 bit

4.2. Central

4.2.1. Hardware

Minimum hardware requirements:

- Intel® processor with Intel® dual-core technology (or faster)
- Memory: 2 GB RAM (4 GB suggested)
- Hard Disk: at least 20 GB of available space
- Monitor: 1024 x 768 or higher (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- Windows® compatible printer
- Ethernet interface 100 Mb/s (or higher)
- CD/DVD Drive or possibility to copy the installation files

4.2.2. Operating System

Supported operating systems:

Microsoft Corporation Windows® XP SP3 32 bit
Microsoft Corporation Windows® XP SP3 64 bit
Microsoft Corporation Windows® 7 32 bit
Microsoft Corporation Windows® 7 64 bit
Microsoft Corporation Windows® 7 SP1 32 bit
Microsoft Corporation Windows® 7 SP1 64 bit
Microsoft Corporation Windows® 8 32 bit
Microsoft Corporation Windows® 8 64 bit
Microsoft Corporation Windows® 8.1 32 bit
Microsoft Corporation Windows® 8.1 64 bit

4.3. Server

4.3.1. Hardware

Minimum hardware requirements:

- Intel® Xeon® E series processor (or faster)
- Memory: 4 GB RAM (8 GB recommended)
- Hard Disk: at least 80 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

4.3.2. Operating System

Microsoft Corporation Windows Server 2012 R2 x64 Standard/Enterprise Ed. latest available SP.
Microsoft Corporation Windows Server 2008 R2 x64 Standard/Enterprise Ed. latest available SP.

4.3.3. System Software

Microsoft SQL Server 2012 R2 x64 Standard/Enterprise Ed. latest available SP.
Microsoft SQL Server 2008 R2 x64 Standard/Enterprise Ed. latest available SP.

WARNING!

To correctly use DIGISTAT®, the Microsoft Windows Display Scaling must be set to 100%. Different settings may prevent the product from starting or cause malfuctions in the way DIGISTAT® is visually displaied. Please refer to the Microsoft Windows documentation for instructions on the Display Scaling settings.

WARNING!

The minimum vertical resolution of 768 is supported only if DIGISTAT® is configured to run in full-screen mode or if the Windows traybar is in Auto-hide mode.

WARNING!

The computers must comply with the regulations regarding the environment where they are installed. Check compliance with competent authorized personnel.

WARNING!

In compliance with on-going product improvement policies pursued by ASCOM UMS, this User Manual's specifications can be changed at any moment. Please contact the Firm's authorized representative concerning market availability of the product range presented in this User Manual.

WARNING!

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. The personnel in charge should perform the adequate compliance checks.

WARNING!

It is recommended 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.

WARNING!

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

4.4. 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.

WARNING!

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.

WARNING!

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.

4.5. 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 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.

ATTENTION!

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.

ATTENTION!

In case a WiFi network is in use, given the possible intermittence 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.

4.5.1. 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 analyse 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

5. Before starting

5.1. 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 other 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 bearing the CE mark.
- Only use devices approved by ASCOM UMS. It is not possible to install devices without proper training.
- Only use devices approved by ASCOM UMS. 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 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).

5.2. 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®.

5.3. 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.

5.3.1. Electrical safety

The hardware devices used together with DIGISTAT® (PC, display, barcode reader, etc...) must comply with therelevant 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 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.

5.3.2. Patient Area

The term “Patient Area” or “Patient Environment” means the space in which intentional or unintentional contact may take place between the patient and parts of the system (any device) or between the patient and other people who may come into contact with parts of the system (e.g., a physician who touches the patient and other devices at the same time). This definition applies when the patient’s position is pre-determined: in other cases, all the possible positions of the patient must be taken into consideration.

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

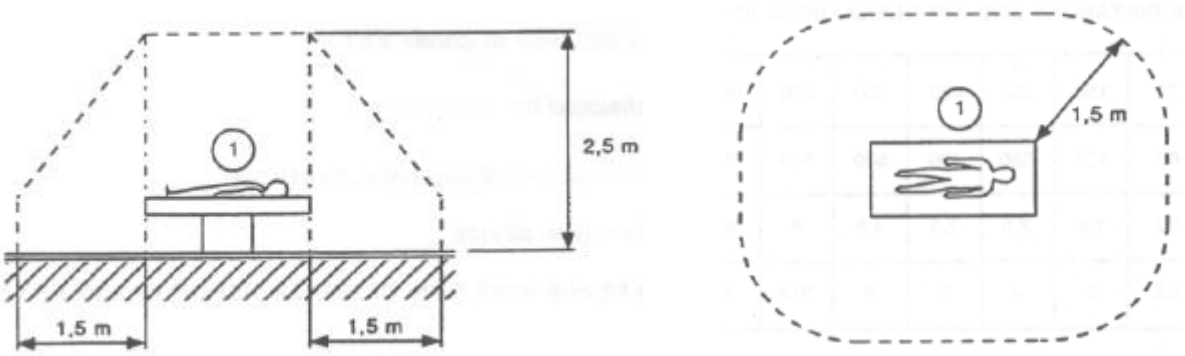


Fig 1

It is the direct responsibility of the hardware licensee (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.

WARNING!

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.

5.3.3. 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.

5.3.4. 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.).

5.4. 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 personsal political opinions, the support to political parties and/or trade unions and/or associations and organizations having political, religious or philosophical aims. Moreover, "sensibile 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 6.5 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 6.5.2). Automatic log out allows to protect 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 phisycally secure. An example of this kind of transmission are the HL7 communications. The Responsible Organization is responsible to provide adequate security measures to comply with the local privacy laws and regulations.

5.4.1. 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 for 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 6.8.4 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.

5.4.2. 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.

5.4.3. 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.

5.5. 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.

5.6. 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 substituion 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 or room to the workstation and create this way the possibility to select a wrong patient.

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 apllications 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: guasto

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 prepare d as "sustitution equipment"

The instruction on how to enable/disable and replace a DIGISTAT® workstation, reserved to system administrators, are in the DIGISTAT® configuration manual.

5.6.1. 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.

5.7. 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 function of system complexity. In case of high complexity it is suggested to perform maintenances more often, up to twice a year.

This is the maintenence 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 configuraed.
- 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 thet 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 5.4.

Connection to devices

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

Instruction for use

- Chck 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.

5.8. Compatible devices

Some DIGISTAT® modules work together with the medical devices connected to the patient (as, for instance, infusion pumps, blood-gas analyzers etc…).

The updated list of all the compatible devices can be found on the ASCOM UMS website, at the following address

http://www.unitedms.com/ing/prodotto.asp?ID=9

It is possibile to make request of the updated list of those devices to ASCOM UMS. Please use for this purpose the references (tel, e-mail, fax…) printed on the cover of this manual.

5.9. 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 10 for the contacts list).

There are extrema cases, rare but possible, in which it is phisically 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 5.5).

WARNING!

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 10 for the contacts list.

6. "Control Bar" and DIGISTAT® environment

6.1. 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.

6.2. Touch screen

DIGISTAT® can run both on touch and non-touch workstations. The same procedures 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

6.3. 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

6.4. DIGISTAT® Work Area

The DIGISTAT® Work Area is defined and delimited by Control Bar, a tool that is common to all and every possible DIGISTAT® installation (Fig 5).
Control Bar manages the installed modules and systems, the patients and their data, the users and their permissions etc.
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 shows Control Bar with no module installed.

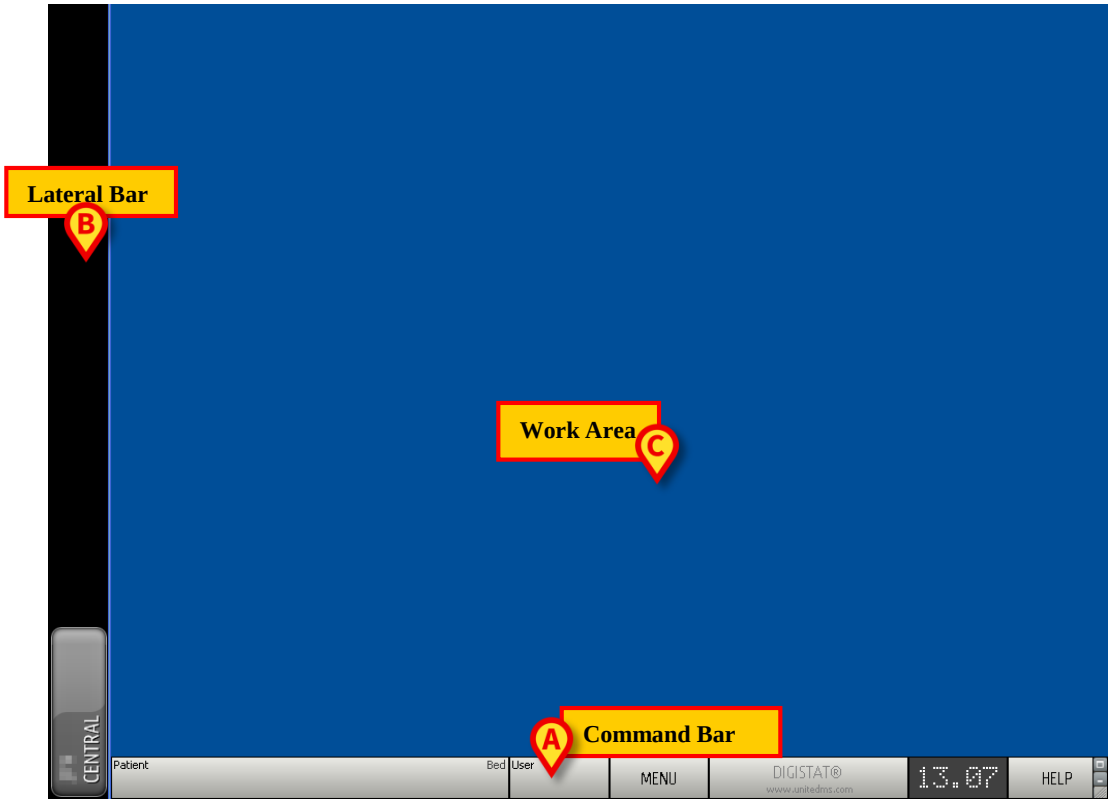


Fig 5

The command bar (Fig 5 **A**) will be described in paragraph 6.4.1 (and subsequent).

The lateral bar displays the icons of the currently available modules. See, for instance, Fig 6, that refers to a configuration comprising the "Image Bank" and "Clinical Forms" modules.

Fig 6

The module currently selected is highlighted (yellow).

6.4.1. 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 possibile to select a specific module only after the user log in (paragraph 6.5).

6.5. 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 either using 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

WARNING!

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.

WARNING!

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.

6.5.1. Barcode log in

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

To use this functionionality, 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.***

6.5.2. 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**)

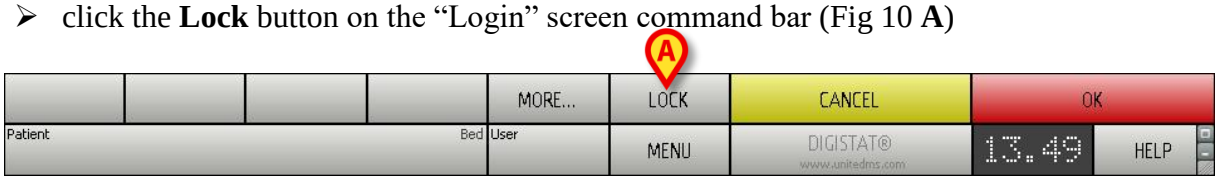


Fig 10

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.***

6.5.3. Recent users

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

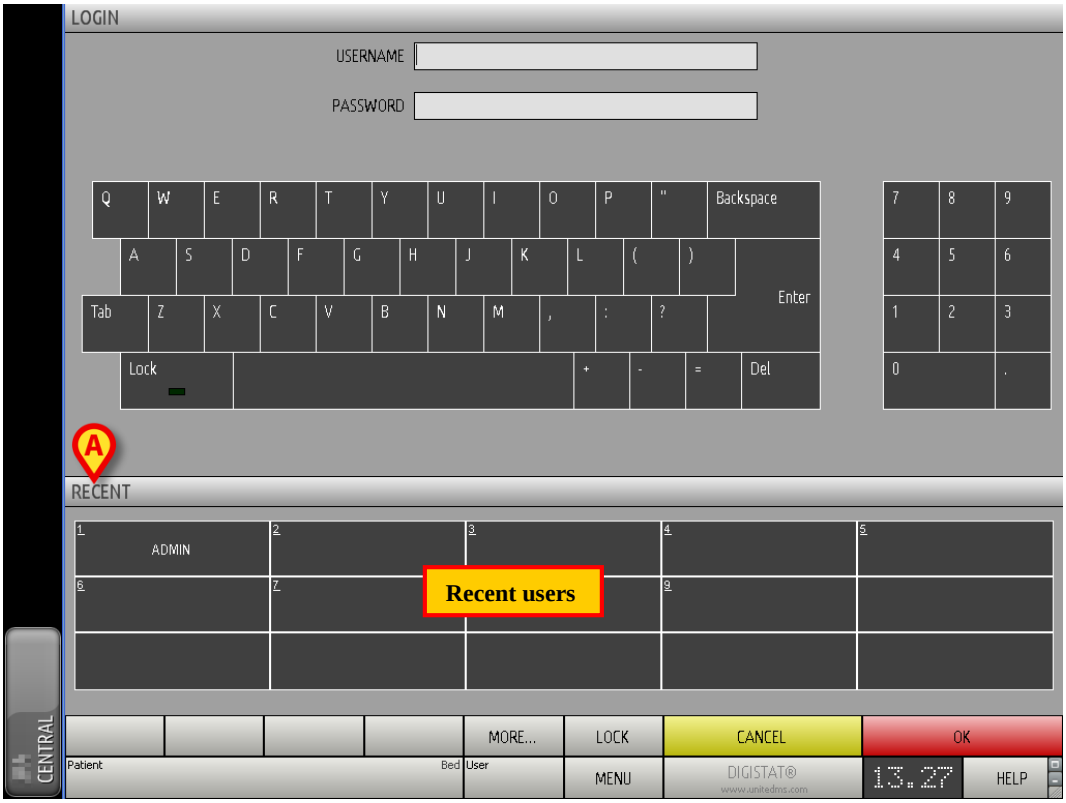


Fig 12

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.

6.5.4. 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.

6.6. 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.

6.6.1. 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).

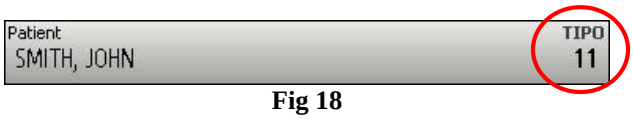


Fig 18

The department name and the bed number are black if the patient is located in a department associated to the workstation on which the user is working (see Fig 18).
The department name and the bed number are red if the patient is located in a department that was not associated to the workstation on which the user is working (Fig 19 - the workstation/department link depends on configuration choices).

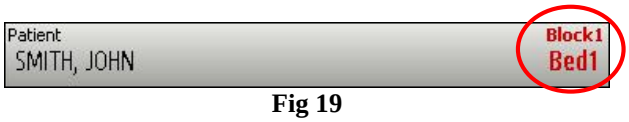


Fig 19

Every workstation is associated by configuration to one or more departments. The user is allowed to perform certain specific actions only if the patient is admitted to one of the associated departments. The red colour in the **Patient** *button is used to advise the user that he/she is working with a patient that is outside the associated departments.*

The signal “Other location” (Fig 20) appears when,

Fig 20

at patient admission time, in the bed selection window (Fig 21), the user specified that the patient is not in one of the configured departments. The user therefore selected the “Other location” option in the window dispayed in Fig 21.

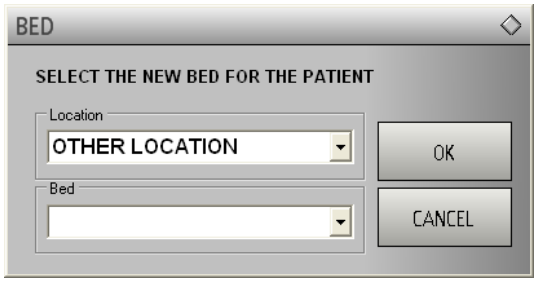


Fig 21

See the specific module’s documentation for the patient admission procedure.

When the  icon is displayed alongside the patient name, it means that the user is not enabled to edit that patient’s data.

Fig 22

Patient management.

The patient archives management tools can change depending on the modules installed, on the user needs, on the chosen configuration etc. The related procedures change accordingly.

The DIGISTAT® module “Patient Explorer” was explicitly created to manage the patient archives. Please refer to the “Patient Explorer” module documentation for the related procedures.

If the DIGISTAT® module “Patient Explorer” is not installed the patient management functions are performed by “Control Bar”. When this is the case, the related procedures are described in the specific documentation.

If the patient archives management tool in use is not part of the DIGISTAT® environment please refer the relevant technical documentation.

WARNING!

When entering patient-relating data it is necessary to double-check that the patient identity, hospitalization department and bed displayed in DIGISTAT® match with the actual ones.
This is utterly important in case of critical actions as, for instance, drug administration.

6.7. Help

Click the **Help** button on Control Bar (Fig 15 **E**) to access the on-line documentation available. The page shown in Fig 23, or an analogous one, depending on the available documentation, will open.

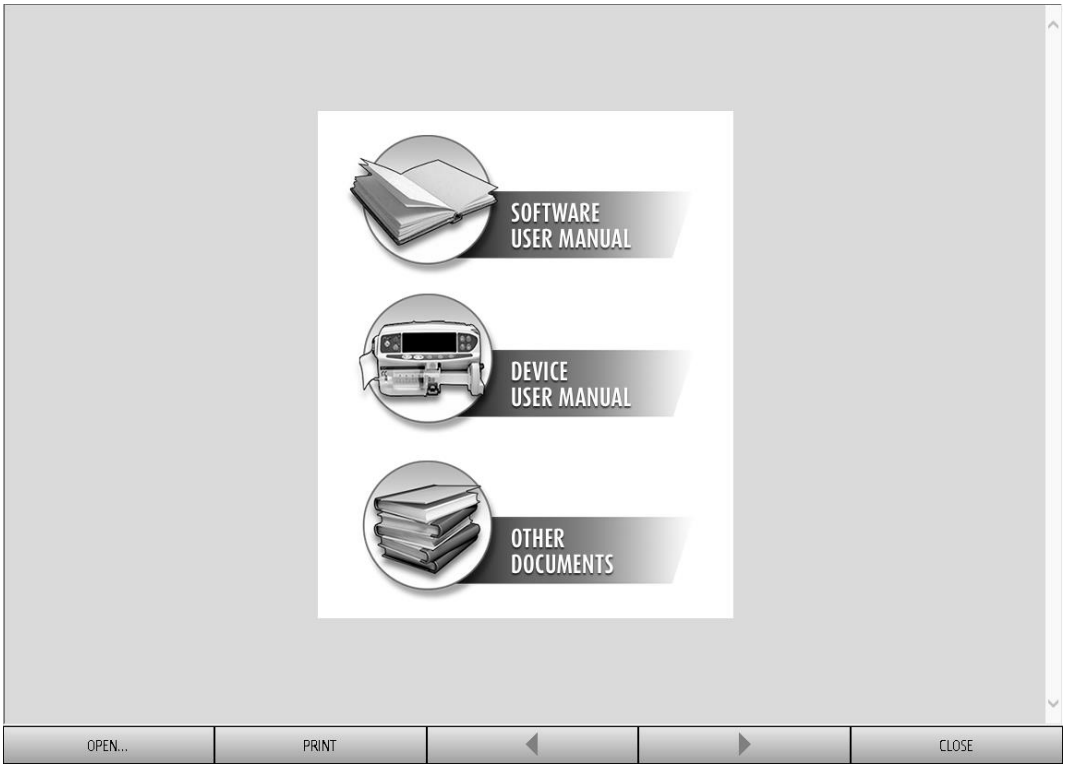


Fig 23

The command bar (Fig 24) offers some navigation possibilities.

Fig 24

- 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.

6.8. DIGISTAT® Main Menu

The **Menu** button placed on the DIGISTAT® Control Bar (Fig 25)

Fig 25

opens a menu containing several options (Fig 26).

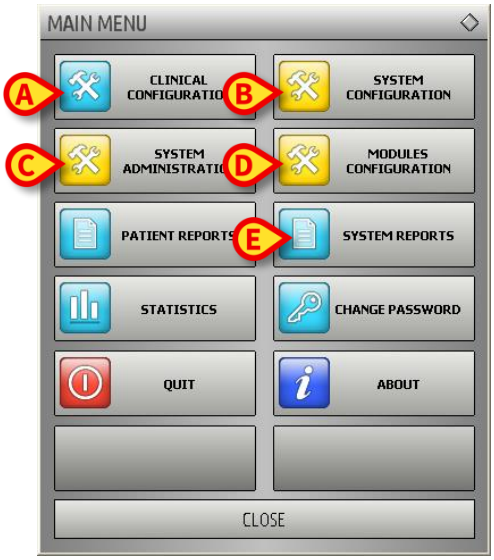


Fig 26

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

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

Clinical configuration - (Fig 26 **A**)

System configuration - (Fig 26 **B**)

System administration - (Fig 26 **C**)

Modules configuration- (Fig 26 **D**)

System reports - (Fig 26 **E**)

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

The other buttons, indicated in Fig 27, 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.

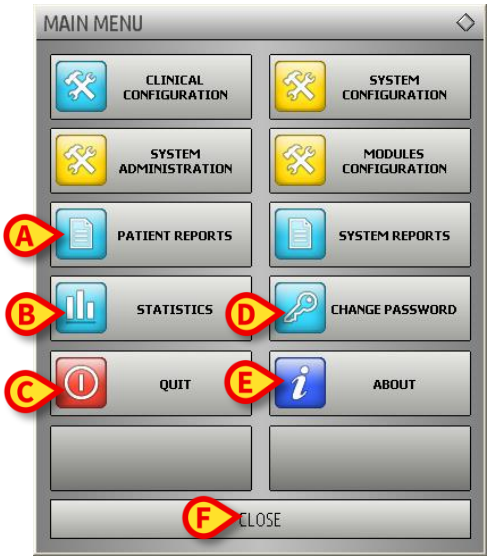


Fig 27

Patient reports - (Fig 27 **A**, paragraph 6.8.1)

Statistics - (Fig 27 **B**, paragraph 6.8.3)

Quit - (Fig 27 **C**, paragraph 6.8.6)

Change Password - (Fig 27 **D**, paragraph 6.8.4)

About - (Fig 27 **E**, paragraph 6.8.5)

The **Close** button (Fig 27 **F**) closes the “Main menu” window (Fig 27).

6.8.1. Patient reports

The "**Patient reports**" button (Fig 27 **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 (Fig 28).

Fig 28

The number and kind of available reports depend on the modules installed and the configuration in use. Therefore the number and kind of buttons on this menu (Fig 28) change according to the configuration in use.

6.8.2. Print reports

Use the buttons on the menu displayed in Fig 28 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 29).

Some DIGISTAT® modules show at this stage another module-specific window making it possible to further define the print report (i.e.infusion type, date filter, event type. See the specific module documentation for the description of these functionalities.

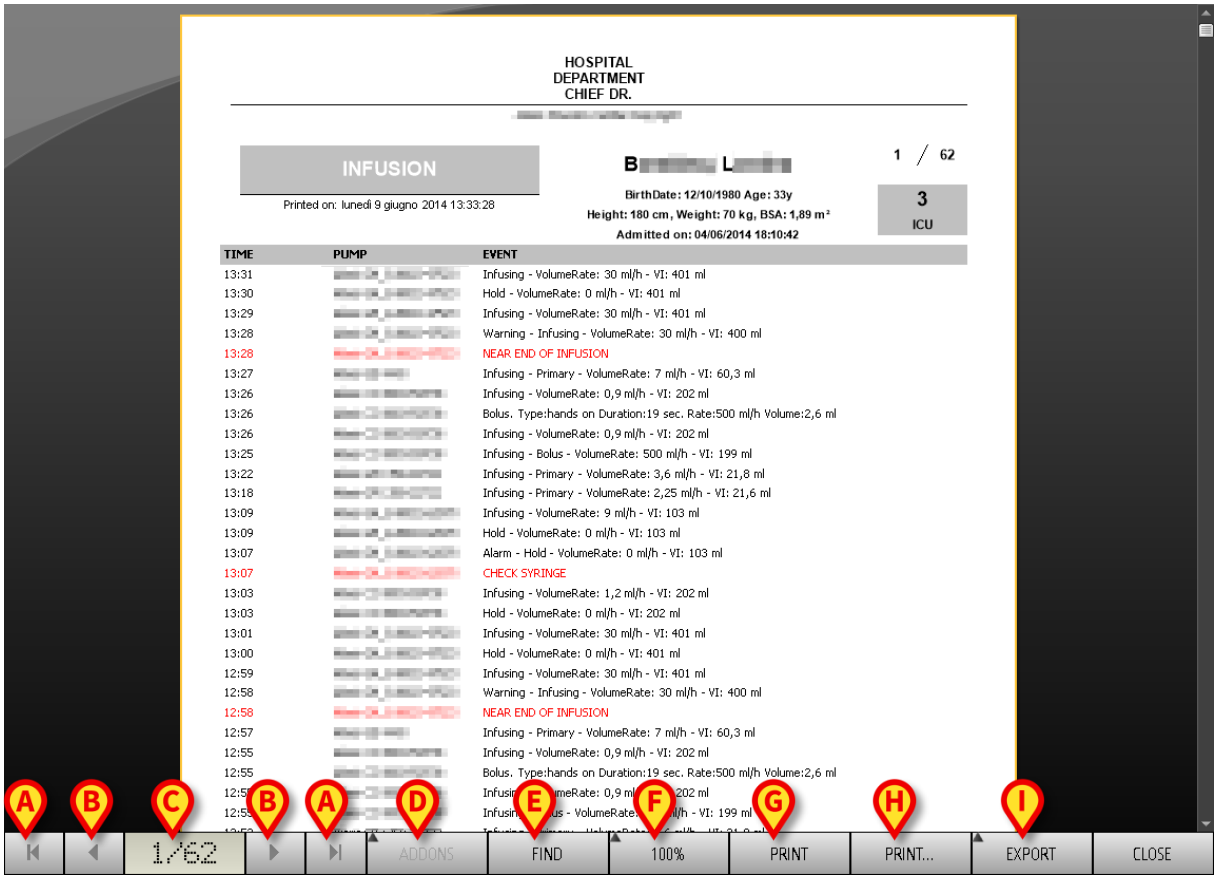


Fig 29

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

A - Use the  and  buttons (Fig 29 **A**) to reach the beginning and the end of the document.

B - Use the  and  buttons (Fig 29 **B**) to go to the previous or the next page.

C - The display  (Fig 29 **C**) indicates the current page number.

D - The **Addons** button (Fig 29 **D**) activates the possible additional print management options (in this configuration the "Watermarks" option is available - see paragraph 6.8.2.1 for a description of these options).

E - The **Find** button (Fig 29 **E**) makes it possible to search the displayed document. See paragraph 6.8.2.2 for more instructions.

F – The button indicating the **100%** percentage (Fig 29 **F**) is a zoom, making it possible to change the display mode. See paragraph 6.8.2.3 for more instructions.

G - Use the **Print** button (Fig 29 **G**) to print the report.

H - Use the **Print…** button (Fig 29 **H**) to display the print options window (Fig 35). See paragraph 6.8.2.4 for a description of this window and the related procedures.

I - Use the **Export** button (Fig 29 **I**) to export the document contents to different file extensions. See paragraph 6.8.2.5 for more instructions.

L - Use the **Close** button to close the "Print preview" screen.

6.8.2.1. Addons

The **Addons** button (Fig 29 **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 30).

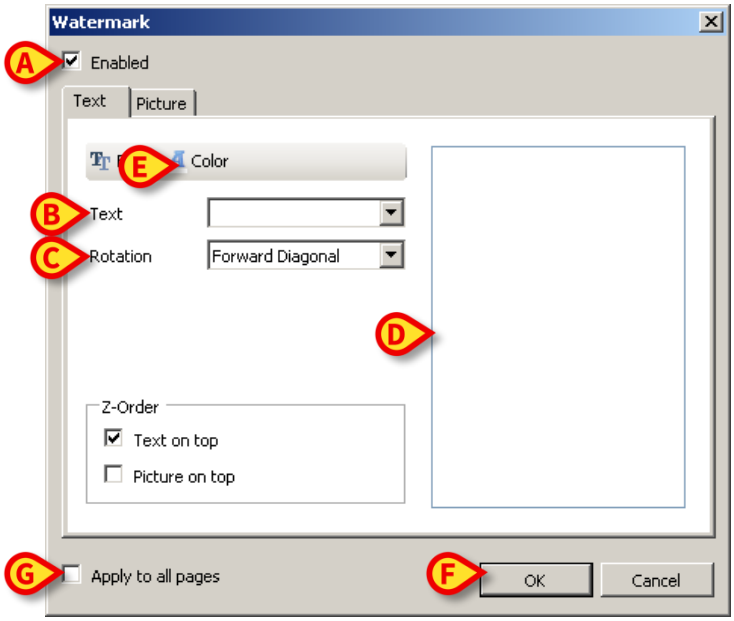


Fig 30

To add a textual watermark,

- Ensure that the "**Enabled**" checkbox is checked (Fig 30 **A**). If not, the window's contents cannot be edited.
- Insert the text in the "**Text**" field (Fig 30 **B**).
- Use the "**Rotation**" menu (Fig 30 **C**) to specify the watermark orientation (diagonal, horizontal, vertical).

A print preview is displayed in the area indicated in Fig 30 **D**.

- Use the buttons indicated in Fig 30 **E** to select the watermark font and color.
- Click the **Ok** button (Fig 30 **F**).

The text is this way inserted as watermark.

If the "**Apply to all pages**" checkbox is selected (Fig 30 **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 31 **A**.

The following window is displayed (Fig 31).

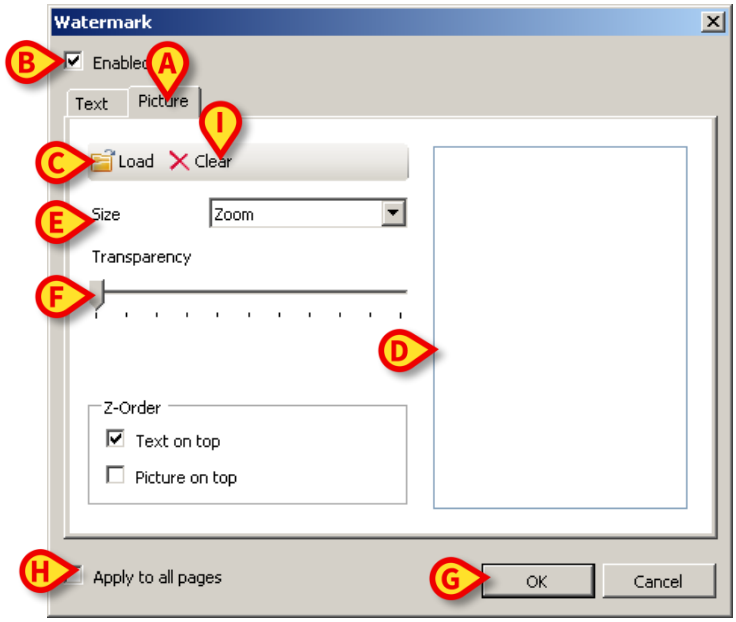


Fig 31

Follow these steps to insert an image as watermark,

- Ensure that the "**Enabled**" checkbox is checked (Fig 31 **B**). If not, the window's contents cannot be edited.

- Click the "**Load**" button indicated in Fig 31 **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 31 **D**.

- Use the "**Size**" drop-down menu to set the size of the image (Fig 31 **E**).
- Use the "**Transparency**" cursor to set the transparency level of the watermark image (Fig 31 **F** - maximum transparency when the cursor is aon the left).
- Click the **Ok** button (Fig 31 **G**). The watermark image is this way inserted.

If the "**Apply to all pages**" checkbox is selected (Fig 31 **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 31 **I**.

6.8.2.2. Find

The **Find** button (Fig 29 **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 32).

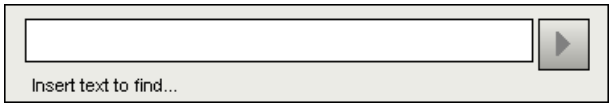


Fig 32

- Insert in the window the text to be found in the print report (Fig 33 **A**).

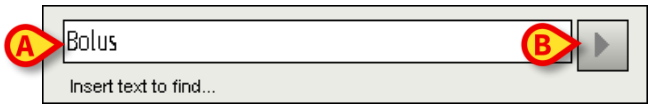


Fig 33

- Click the  button (Fig 33 **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.

6.8.2.3. Zoom

The **Zoom** button (on which, by default, the **100%** size is displayed - Fig 29 **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 34).

Fig 34

- Click the wanted option on the menu.

The page is displayed anccordingly. 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.

6.8.2.4. Print

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

- Click the **Print…** button (Fig 29 **H**) to display the print options window (Fig 35)

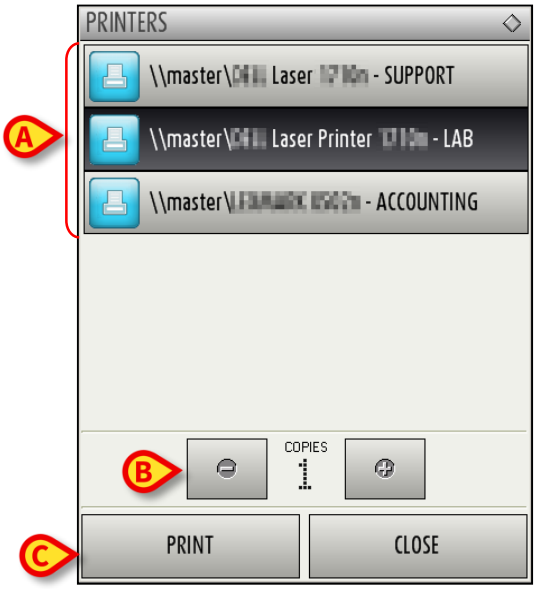


Fig 35

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 35 **A**).
- Use the  (one less copy) and the  (one more copy) buttons to specify the number of copies (Fig 35 **B**).
- Click the **Print** button (Fig 35 **C**) to print the report.

6.8.2.5. Export

The **Export** button (Fig 29 **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.

6.8.3. Statistics

The **Statistics** button on the main menu (Fig 36) makes it possible to access the system's statistical calculation tools.

Fig 36

The button opens another menu (Fig 37) 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 to 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 paragraph 6.8.3.1.

Fig 37

6.8.3.1. Query Assistant

The **Query Assistant** button (Fig 37) accesses a tool making it possible to create, save and execute queries on the DIGISTAT® database (Fig 38).

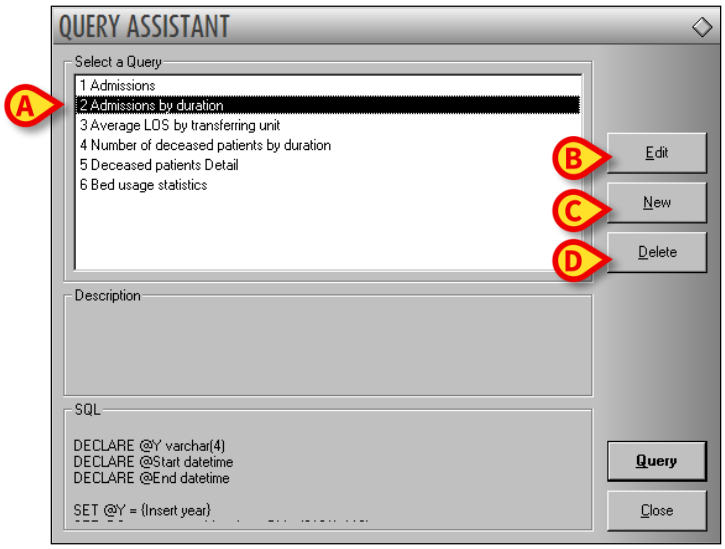


Fig 38

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 38 **A**).

To run a query

- click the corresponding name on the list,

The name will be highlighted (Fig 39 **A**).

A textual description of the query is displayed in the "Description" area (Fig 39 **B**).
The "SQL" area (indicated in Fig 39 **C**) displays the content of the query in SQL language (Structured Query Language).

The "edit", "cancel" and "new" query options are reserved to the system administrators.

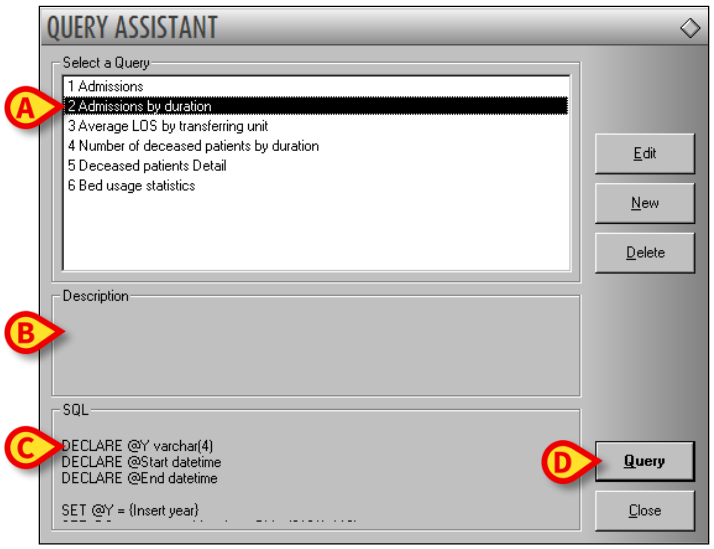


Fig 39

To run the query

- click the **Query** button (Fig 39 **D** - bottom-right).

The results are displayed in a new window, as a table (Fig 40).

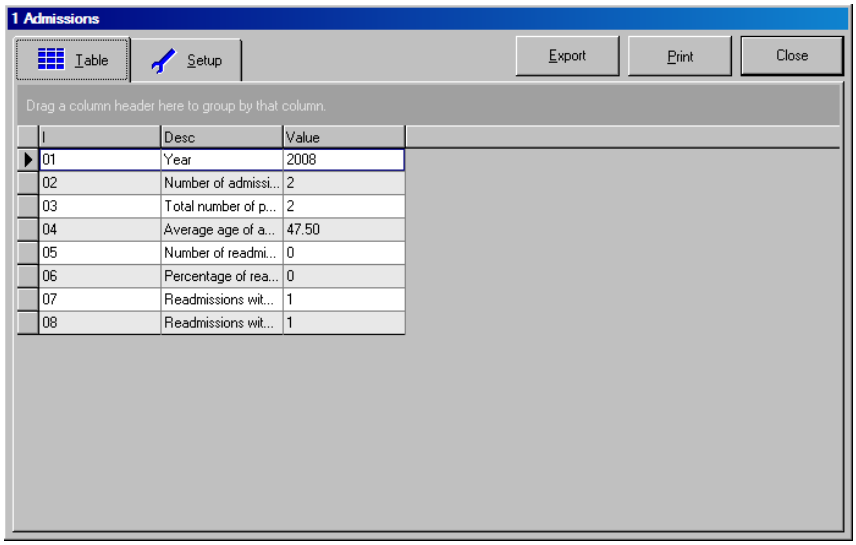


Fig 40

The **Edit** button placed on the right of the "Query Assistant" window (Fig 38 **B**) makes it possible to edit an existing query.

The **New** button placed on the right of the "Query Assistant" window (Fig 38 **C**) makes it possible to create a new query.

The **Delete** button placed on the right of the "Query Assistant" window (Fig 38 **D**) makes it possible to cancel an existing query.

6.8.4. Change password

The **Change Password** button on the DIGISTAT® main menu (Fig 41 **A**) opens a window making it possible to change the password of the user currently logged to the system.

Fig 41

To change the user password

- click the **Change Password** button (Fig 41 A).

The "Change password" window will open.

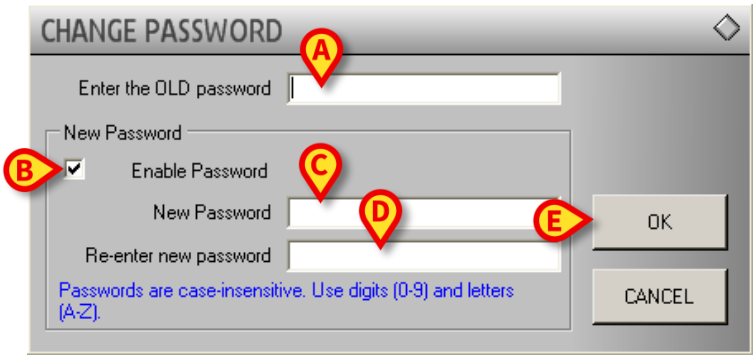


Fig 42

- Type the current password in the "**Enter the OLD password**" field (Fig 42 **A**).
- Verify that the "**Enable password**" checkbox (Fig 42 **B**) is selected.
- Type the new password in the field indicated in Fig 42 **C**.
- Type again the new password in the field "**Re-emter new password**" (Fig 42 **D**).
- Click the **Ok** button (Fig 42 **E**).

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

6.8.5. About DIGISTAT®

The **About** button on the DIGISTAT® main menu (Fig 41 **B**) displays a window containing information on the DIGISTAT® version installed and the related licences (Fig 43).

Fig 43

6.8.6. Quit DIGISTAT®

The **Quit** button on the DIGISTAT® main menu (Fig 45 **A**) makes it possible to quit the DIGISTAT® environment.

To quit DIGISTAT®

- click the **Menu** button on the control bar (Fig 44).

Fig 44

The DIGISTAT® main menu will open (Fig 45).

Fig 45

- Click the **Quit** button (Fig 45 **A**).

Another menu is displayed (Fig 46).

Fig 46

- Click the **Quit** button again (Fig 46 **A**).

User confirmation is required (Fig 47).

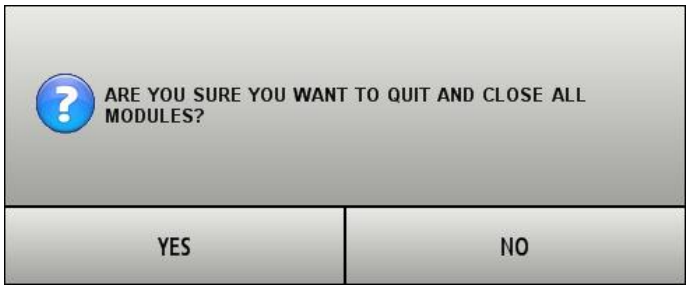


Fig 47

- Click **Yes** to exit DIGISTAT®.

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

6.9. Warning messages

Different types of pop-up windows are used throughout the DIGISTAT® environment to provide information or warnings regarding the correct use of the software. Also, when a critical operation is being performed, they are used to request confirmation of the operation.

The possible messages are communicated by 4 different types of window, here explained.

1) Timer window with single option (Fig 48).

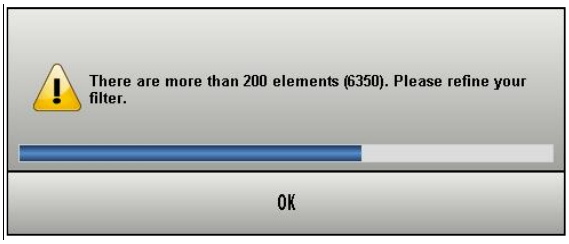


Fig 48

This type of window is generally used to issue warnings or error messages to the user. The bar indicated in Fig 48 is a timer indicating how much time the window remains on screen. The blue part of the bar gets shorter as time goes by.
When the blue part reaches the left side of the bar the window disappears.
To make the window disappear immediately, click the **Ok** button.

2) Timer window with double choice (YES or NO - Fig 49).

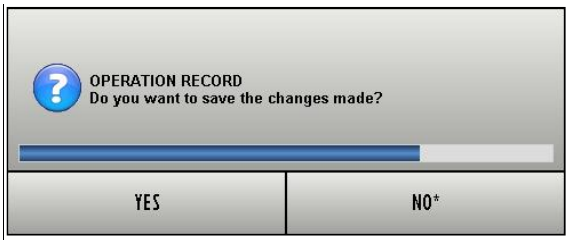


Fig 49

This window offers two options, usually related to an action which has just been performed. Click the **Yes** button to perform the action, click the **No** button to cancel the action.
The bar indicated in Fig 49 is a timer. The blue part of the bar gets shorter as time goes by.
When the blue part reaches the left side of the bar the window disappears. When this happens the system automatically makes a choice depending on the type of question and the context in which the message appears.

3) Window without timer with double choice (YES or NO - Fig 50).

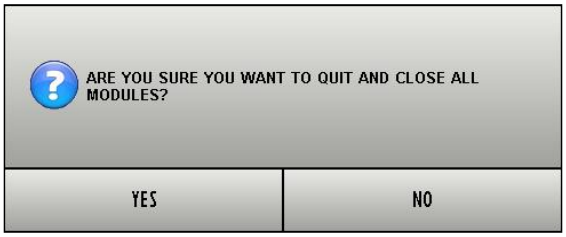


Fig 50

The window shown in Fig 50, as the previous one, requires a choice between the options **Yes** and **No** in relation to an operation which has just been performed. Click the **Yes** button to perform the action, click the **No** button to cancel the action. This type of window has no timer and remains on screen until a choice is made.

4) Window without timer with single option (Fig 51)

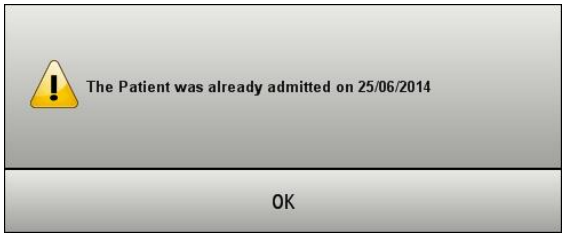


Fig 51

The window shown in Fig 51 provides information regarding a procedure error. No timer here, the kind of information provided requires a reading confirmation from the user (click **Ok**).

The presence or absence of the timer in a window depends on the context it appears in. Certain messages only make sense momentarily and with reference to the operation the user is performing. These messages have a timer and disappear after a certain time.
Other messages must be received by anyone using the system, even after some time, and require a reading confirmation. These messages have no timer.

The messages provided by the DIGISTAT® environment are complete and comprehensible. There is no need to refer to special codes in order to understand them. In case of unclear messages, please inform your ASCOM UMS referent as soon as possible, for reporting and clarity improvement purposes.

7. DIGISTAT® Smart Central

7.1. Introduction

The DIGISTAT® "Smart Central" system acquires online data from the devices connected to the patient (i.e. infusion pumps, monitors, heart-lung machines and so on). It is designed to provide a clear view on the devices status, highlighting alarms and/or warnings possibly occurring on any connected device.
The purpose of the system is to help the alarm/warnings management and shall not be used as a remote alarm system or as an alarm replicator.

DIGISTAT® "Smart Central" is intended to provide visual and acoustic indication of the status and operating conditions of the approved devices connected to DIGISTAT®.
DIGISTAT® "Smart Central" informs the users at a central workstation about all connected devices, displays an overview of multiple beds in one screen, provides device alarm management support, reduces alarm stress for nursing staff and patients and helps to plan the nursing workflow.

The intended environments are Intensive Care Units inside hospitals or healthcare facilities.
The DIGISTAT® "Smart Central" is a software only module that shall run on a computer located on the hospital network where the DIGISTAT® suite is installed.

The Product shall be used by:

- Nurses
- Physicians
- Biomedical engineers
- System Administrators

Nurses
Nurse in the Hospital can use DIGISTAT® "Smart Central" to check the status of the devices, verify that they are connected, operating and sending data to the electronic patient record. They can plan their workflow on the basis of the information presented on the display. Nurses can define their set of patients to monitor and have them grouped in a single screen. They can review the history of events (alarms, warnings, change of settings) occurred.

Physicians
Physicians can review the history of events occurred to a patient.

Biomedical engineers
Biomeds can control the connection and acquisition of data from the connected devices, can identify technical alarms and evaluate the need for device maintenance.

System Administrators
System Administrators can configure the system, this include configuration of the devices ports, drivers, users, permissions, parameters to display, etc.

7.1.1. Information for the user

Please read carefully the following warnings.

WARNING!

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.

WARNING!

DIGISTAT® "Smart Central" must not be used to replace the monitoring of the device alarms.

WARNING!

DIGISTAT® "Smart Central" is not designed to verify that the devices are working correctly but rather to acquire and catalogue clinical data.

WARNING!

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 <u>not</u> recovered by "Smart Central" after reconnection.

WARNING!

DIGISTAT® "Smart Central" does not replace a Nurse Call system.

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

7.2. Module selection

To select the DIGISTAT® "Smart Central" module

- click the corresponding icon on the lateral bar (Fig 52).

Fig 52

The "Smart Central" screen, shown in Fig 53, 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.

7.3. DIGISTAT® “Smart Central”

The “Smart Central” screen displays a schematic representation of the situation of each patient in the ward (Fig 53).

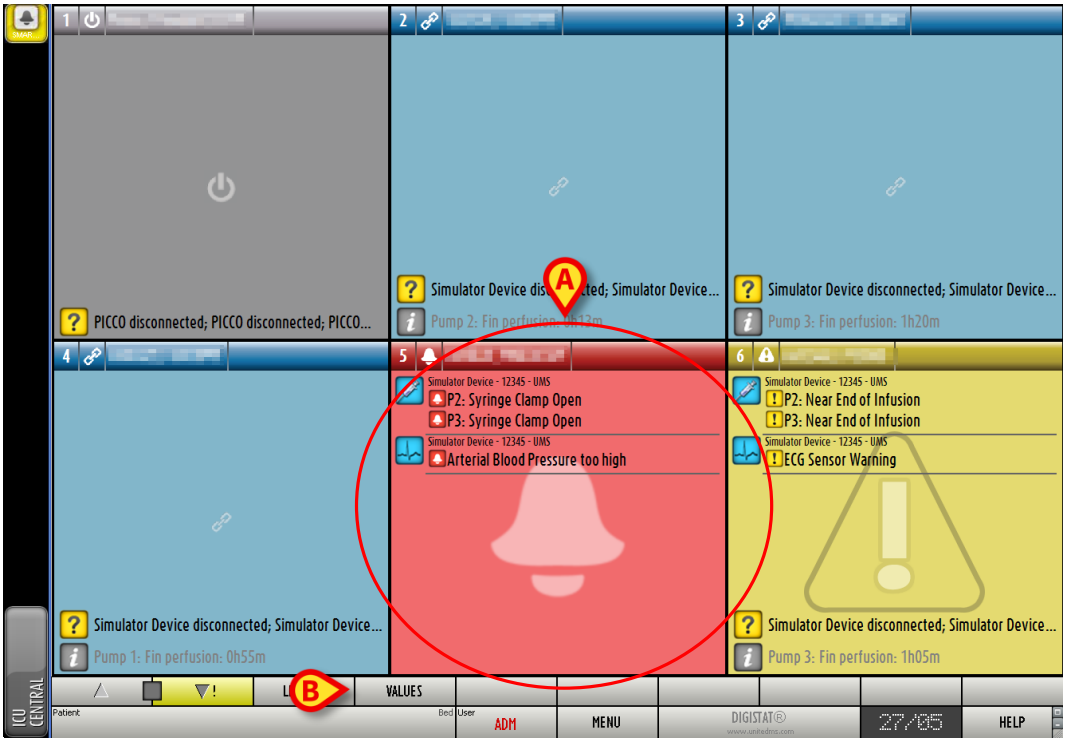


Fig 53

The screen is divided into rectangular areas, named “Bed areas” (Fig 53 **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 55), 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 53 **B**).

To display all the available data

- Click the **Values** button on the command bar (Fig 53 **B**).

The button will be selected. The available information will be displayed as in Fig 54.

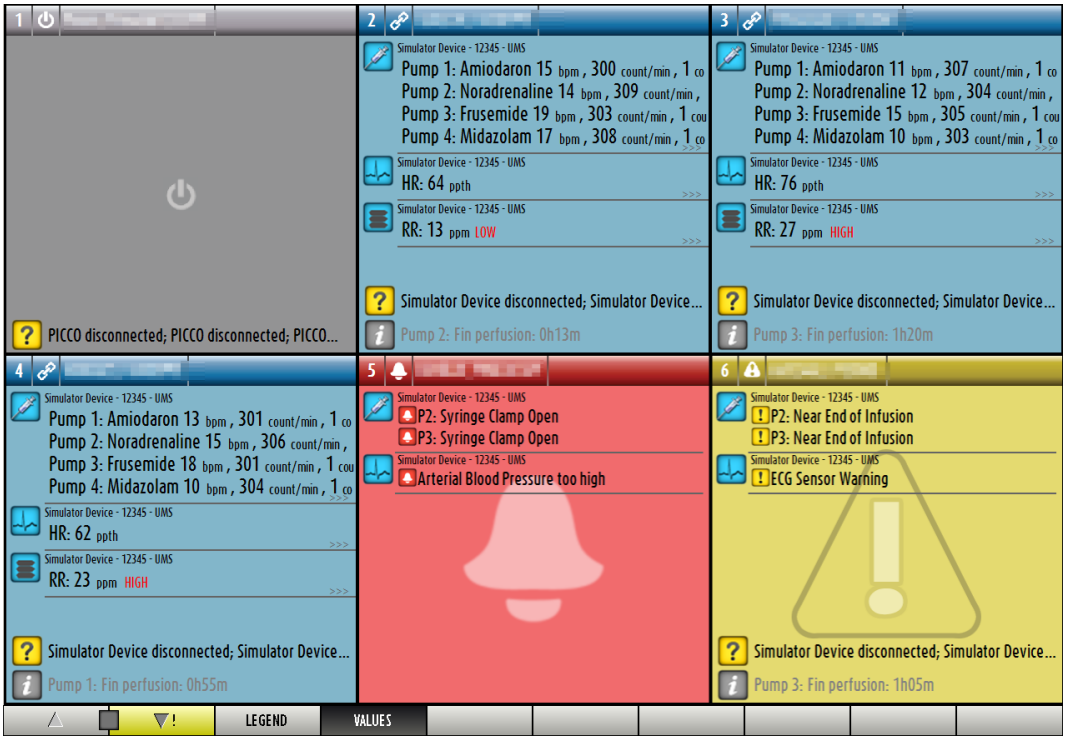


Fig 54

7.4. Bed areas

Each “Bed area” displays some of the data provided by the devices connected to the patient (Fig 55). The kind of data displayed depends on the way the device is designed and configured.

Fig 55

If the “Bed area” is yellow, as in Fig 55, 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 56, it means that at least one of the connected devices is in alarm state.

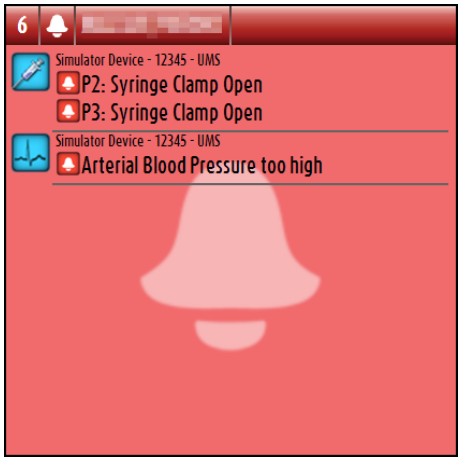


Fig 56

The connected beds from which neither alarms nor warnings are received appear as in Fig 57. No device data is here displayed to facilitate reading possible alarms and warnings occurring on the other beds.

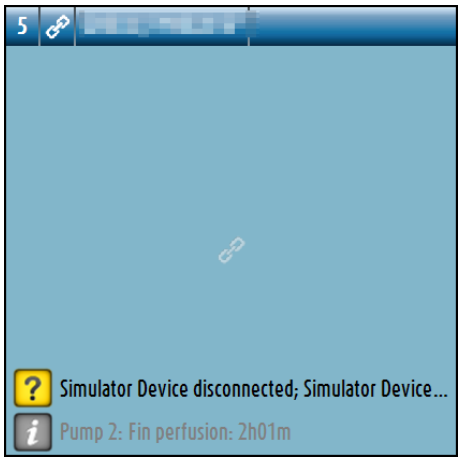


Fig 57

To display device data on these pumps click the **Values** button on the command bar (Fig 53 **B**). The "Bed area" will appear as in Fig 58.

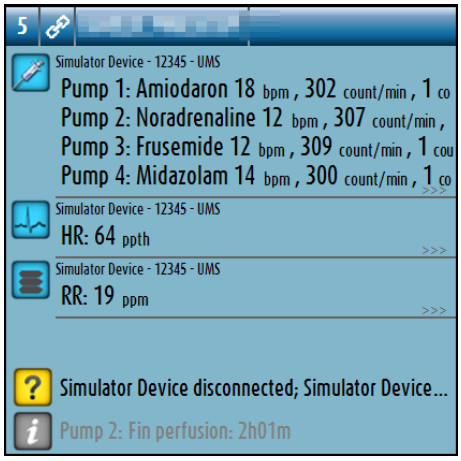


Fig 58

Disconnected beds are displayed as in Fig 59.

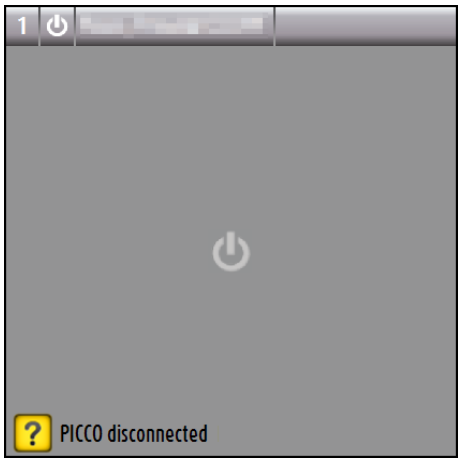


Fig 59

7.4.1. 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 60 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 60

The information in the bed area is divided by "Device type". Each device type is characterized by a specific icon (Fig 61 **A**).

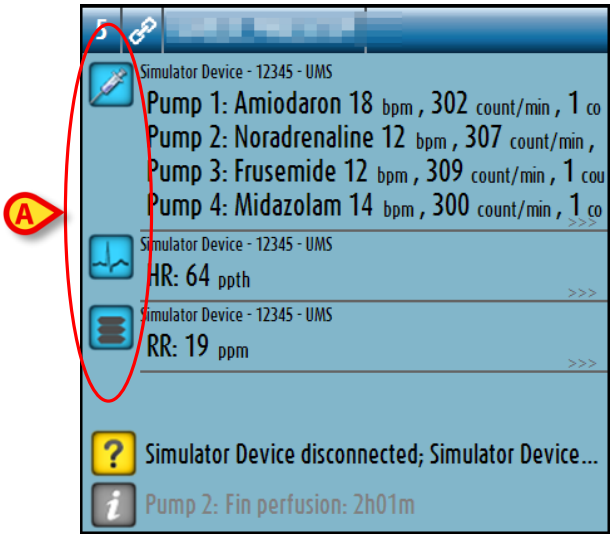


Fig 61

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 7.5.1 for a detailed description.

Data coming from the same kind of device are grouped together. In Fig 62, for instance, three groups are indicated: pulmonary ventilator, infusion pumps and patient monitor.

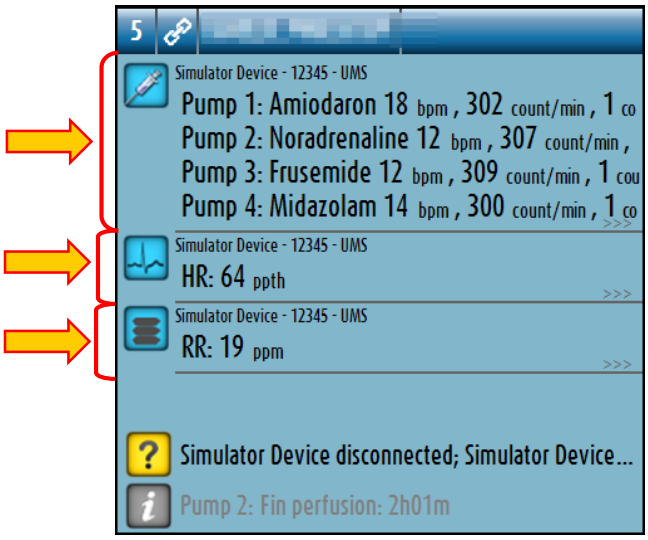


Fig 62

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 63 **A**).

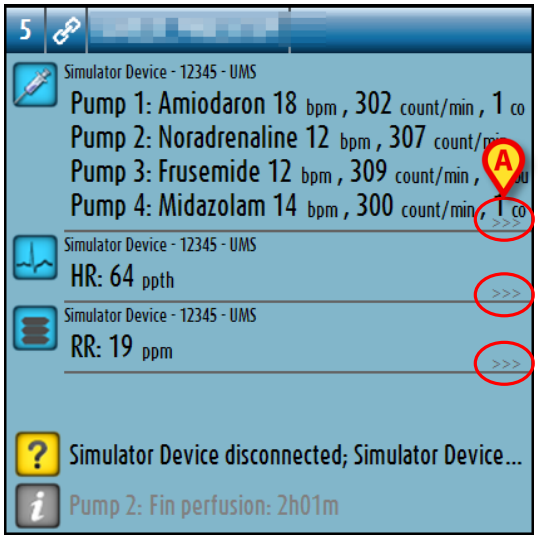


Fig 63

Hidden data can be displayed by clicking the “Bed area”, which is this way enlarged to full screen mode (Fig 64). All the available information is this way displayed.

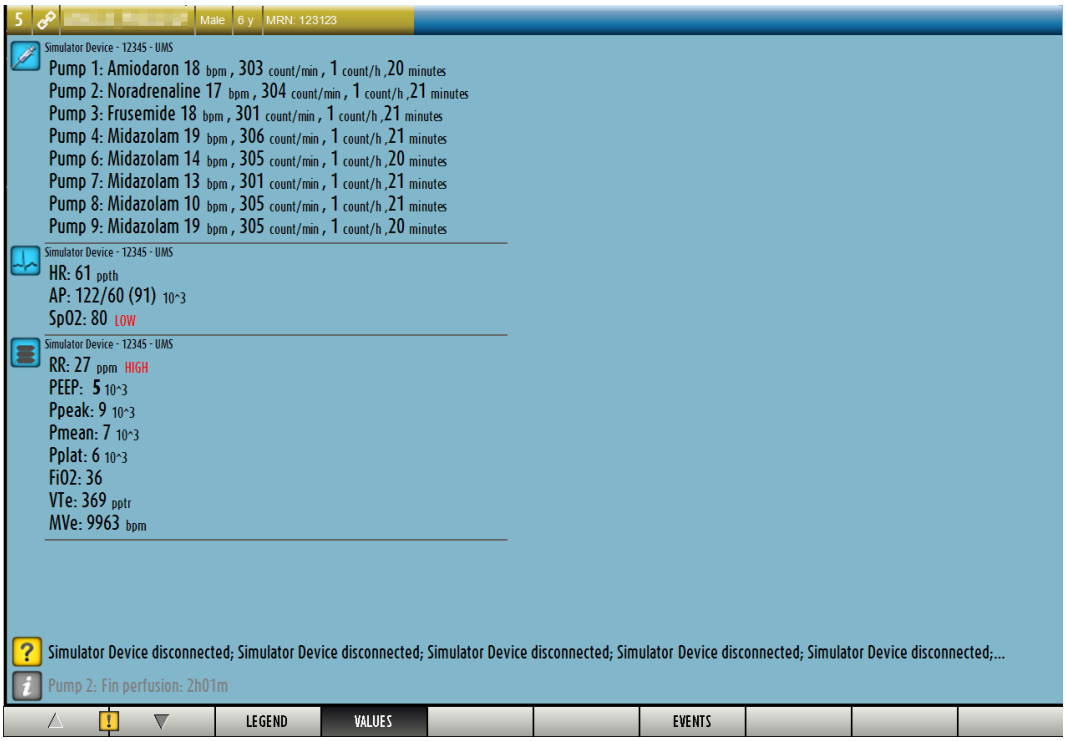


Fig 64

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 65).

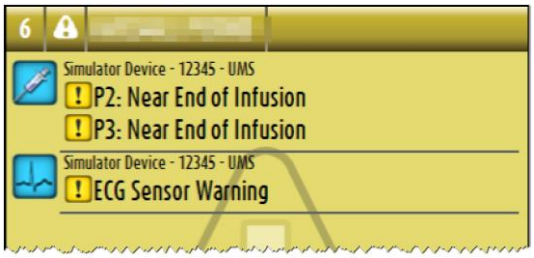


Fig 65

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 66).

Fig 66

Additional information on the connected devices and the list of the possible disconnected devices are displayed at the bottom of the "Bed area" (Fig 67 **A**). Disconnected devices are indicated by the icon. Additional information is indicated by the icon.

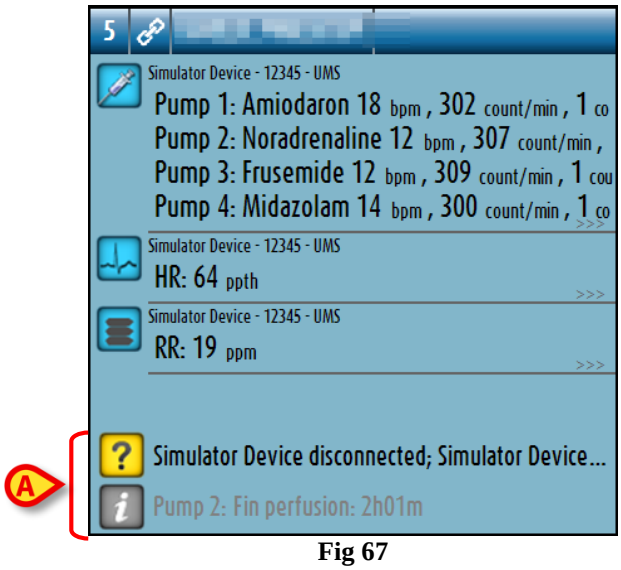


Fig 67

It is possible, by configuration, to associate a message to the displayed values. I.e. it is possible to define a range of values which is "normal" and configure the system to inform the user if the collected values are outside this range. See for instance Fig 68 **A**, in which the values are defined as "Low".

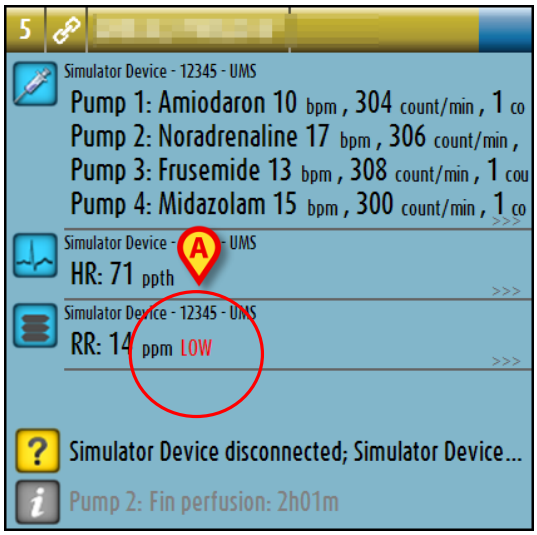


Fig 68

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.

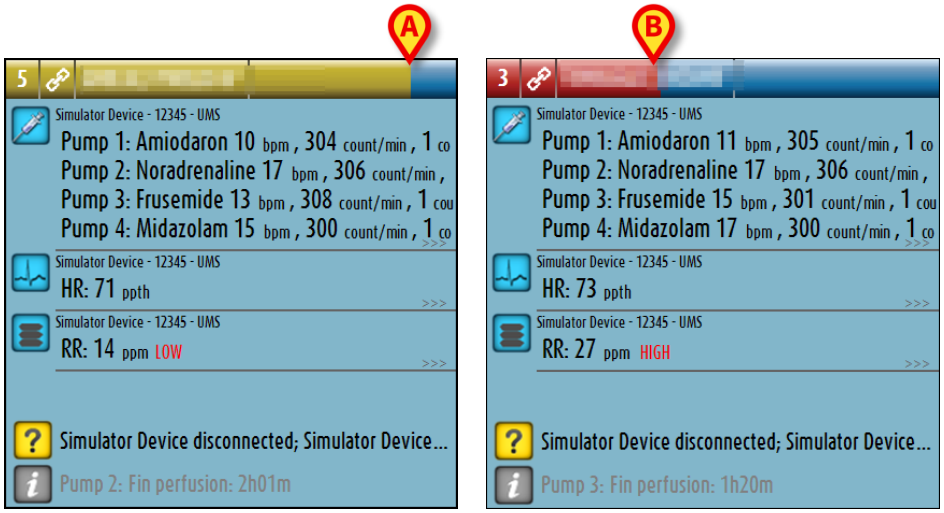


Fig 69 a/b

When the state of a bed area changes to a lower level alarm (or no alarm), the color relating to the prevoius state remains on the heading bar for a certain configurable time. In Fig 69 **A** the yellow bar is fading to the left, meaning that the previous state was a warning state. In Fig 69 **B** the red bar is fading to the left, meaning that the previous state was an alarm state.

7.5. The “Smart Central” command bar

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

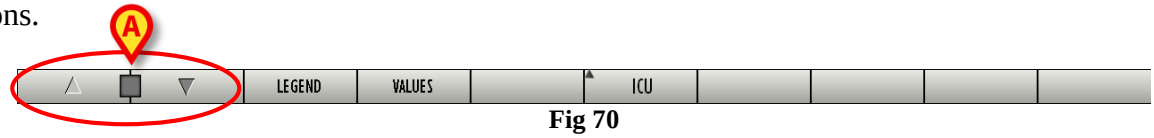


Fig 70

The arrow buttons on the left (Fig 70 **A**) make it possibile to scroll up and down the screen when it is not possibile 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 71) 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 exlamation 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.

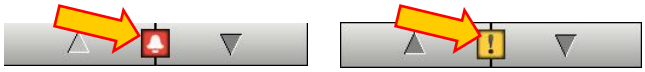


Fig 71

When the alarm/warning is taken in charge the bell-icon/exclamation mark icon disappears, still remaining the yellow/red colour inside the box (Fig 72).

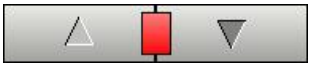


Fig 72

See paragraph 7.7 (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 7.5.1).

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 73).

Fig 73

- 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 64) an additional button – **Events** - is present on the command bar (Fig 74).

Fig 74

- Click this button to display the detailed list of all the events occurred to the devices connected to the selected bed (see paragraph 7.6).

7.5.1. 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 75).

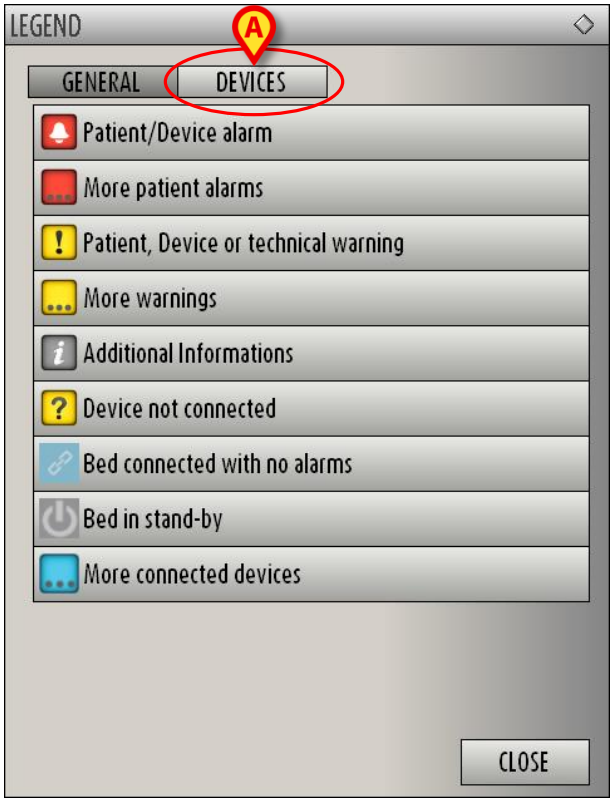


Fig 75

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 75 **A**.

To see the "Device" icons

- Click the **Devices** button indicated in Fig 75 **A**.

The "Devices" legend is this way displayed (Fig 76)

Fig 76

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).

7.6. 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 77).

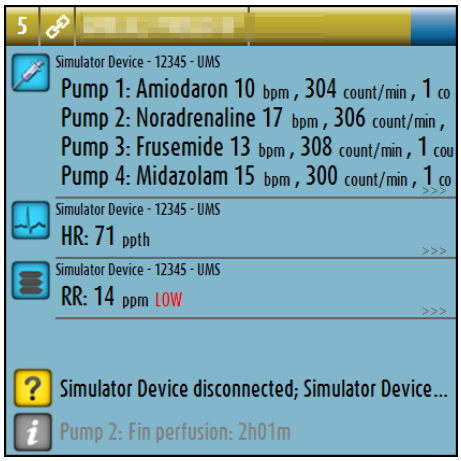


Fig 77

The bed area is this way enlarged to full screen mode (Fig 78).

- Click the **Events** button on the command bar (Fig 78 **A**).

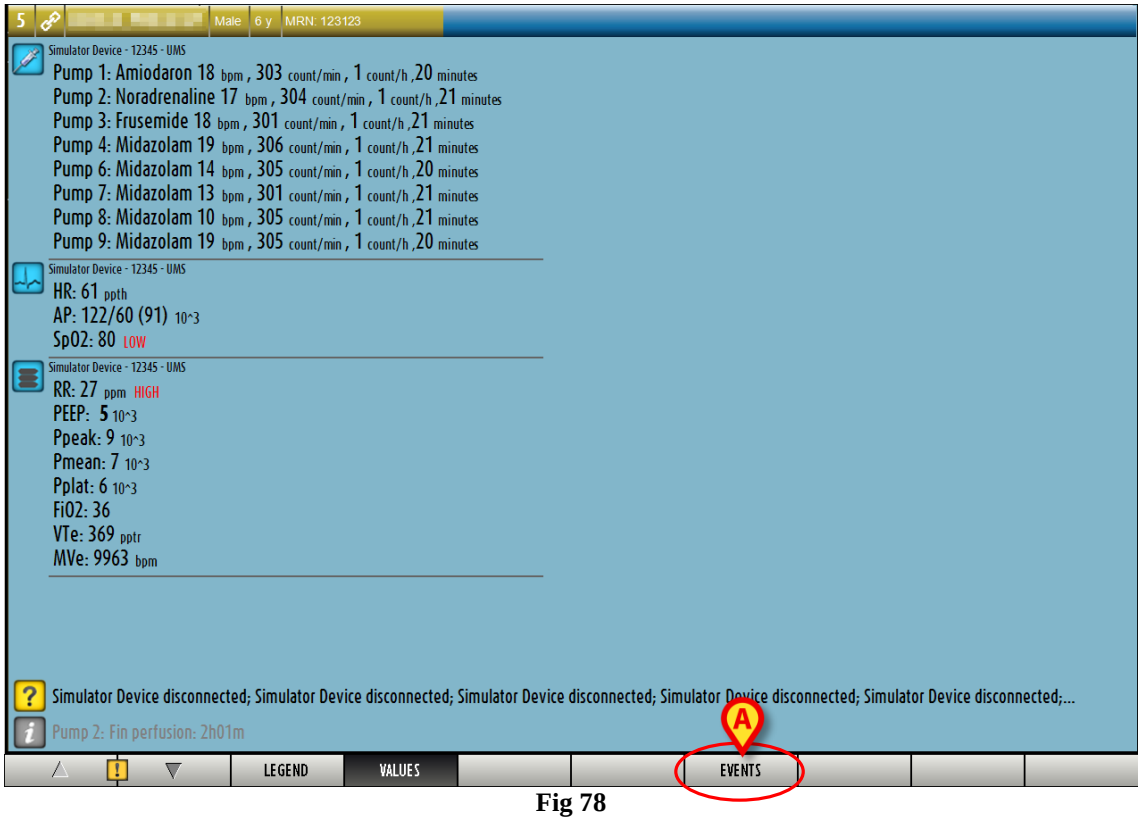


Fig 78

The events list will be displayed on the right (Fig 79).

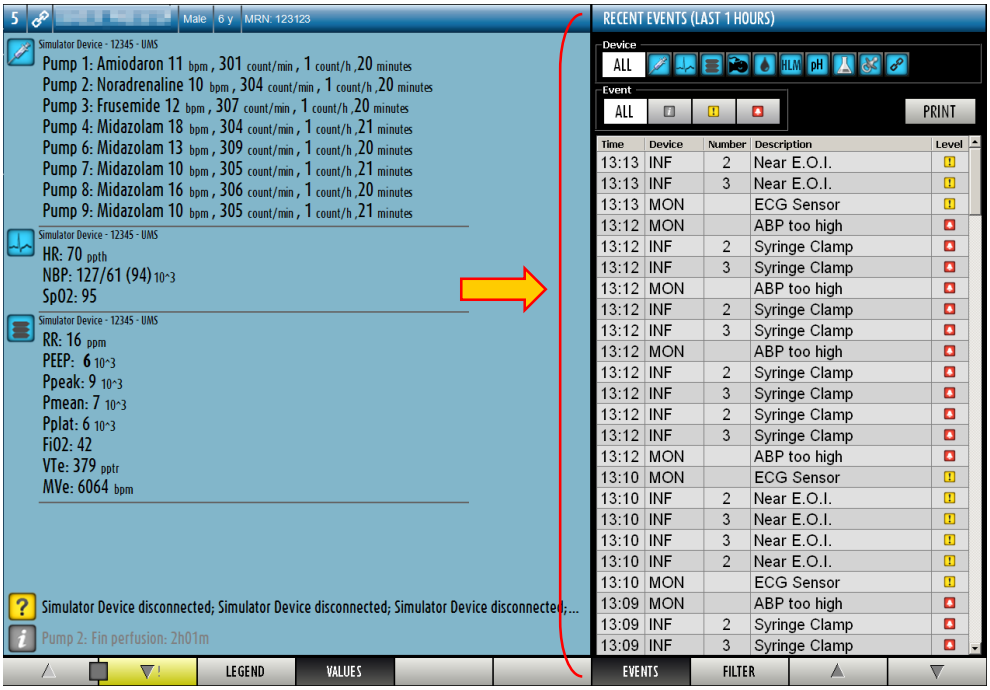


Fig 79

7.6.1. Events list description

The table shown in Fig 80 contains the list of all the events occurred on all the devices connected to the selected patient during his/her stay.

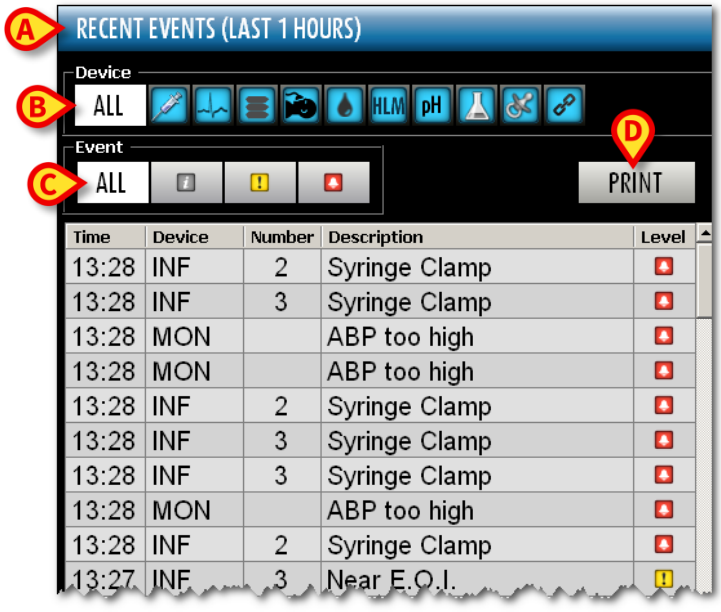


Fig 80

The headline “Recent events” (Fig 80 **A**) can also display, if chosen by configuration, the time period to which the events list refers.

The “Dispositif” buttons indicated in Fig 80 **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 7.5.1). Multiple selection is possible to display the events referring to two or more devices at the same time.

The “Événement” buttons indicated in Fig 80 **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 selection is possible to display two kinds of events at the same time (i.e. only alarms and warnings).

The **Print** button indicated in Fig 80 **D** makes it possible to print the list of events displayed (Fig 81).

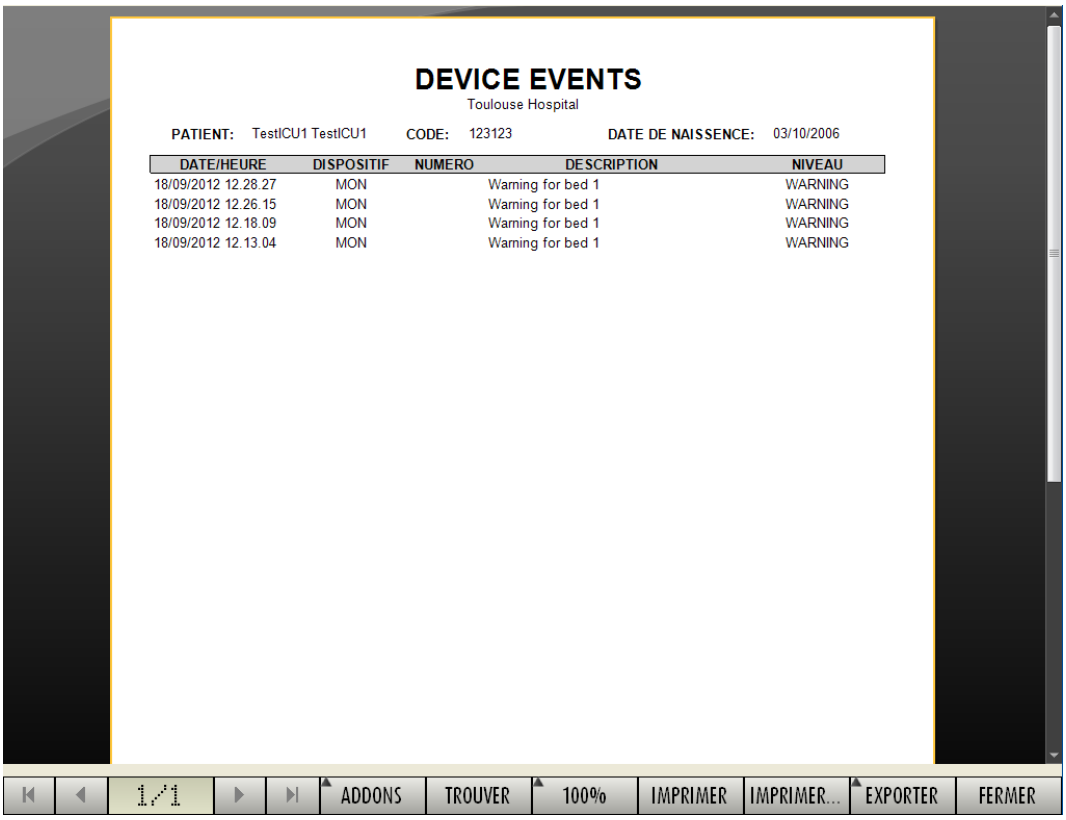


Fig 81

See paragraph 6.8.2 for the system’s print functionalities.

The events table is displayed below (Fig 82).

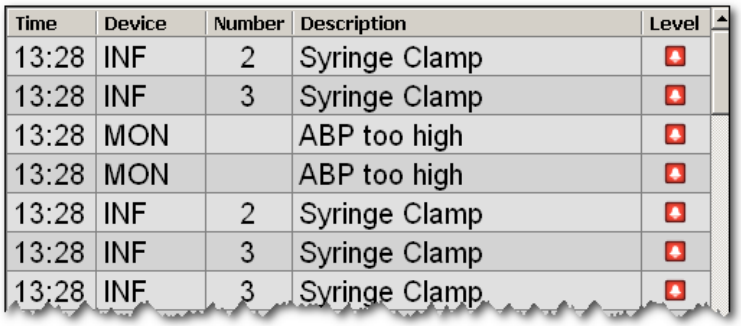


Fig 82

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).

7.6.2. 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 83).

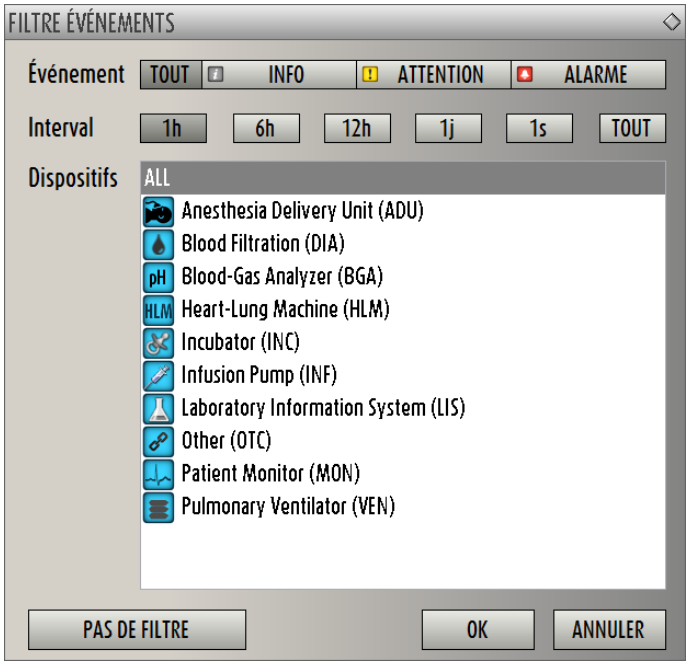


Fig 83

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).
- Dispositif – 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 disply 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 83 is displayed.

- Click the **Clear Filters** button on the window
- Click **Ok**.

The unfiltered list is this way displayed again.

7.7. Alarms and Warnings notification

WARNING!

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 84, where five connected “Beds” are displayed and no device on no bed is alarmed or in warning state.

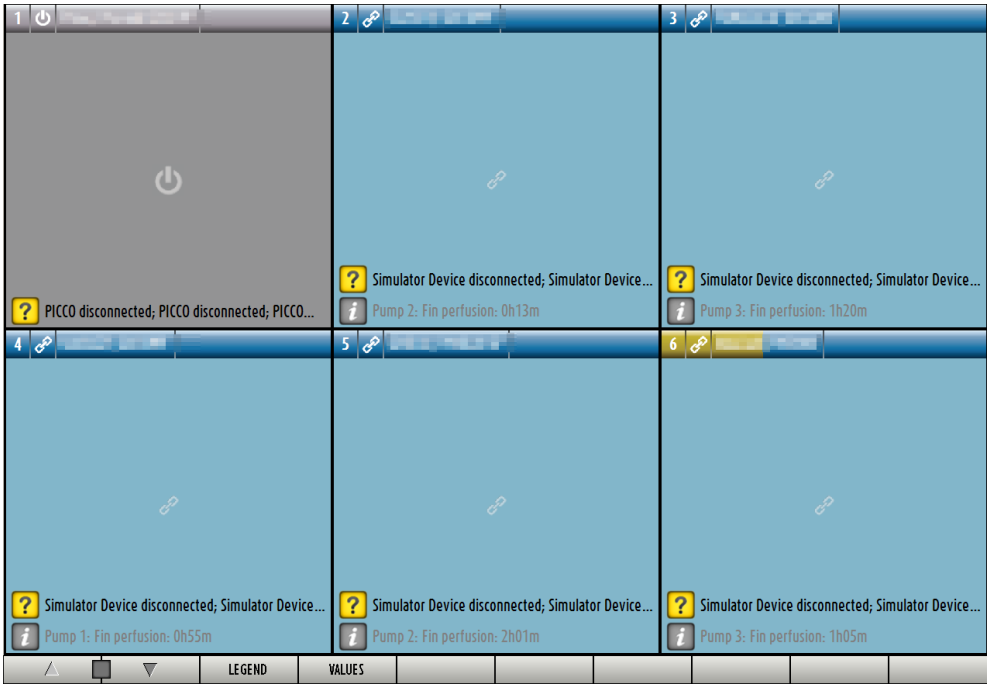


Fig 84

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 85, 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.

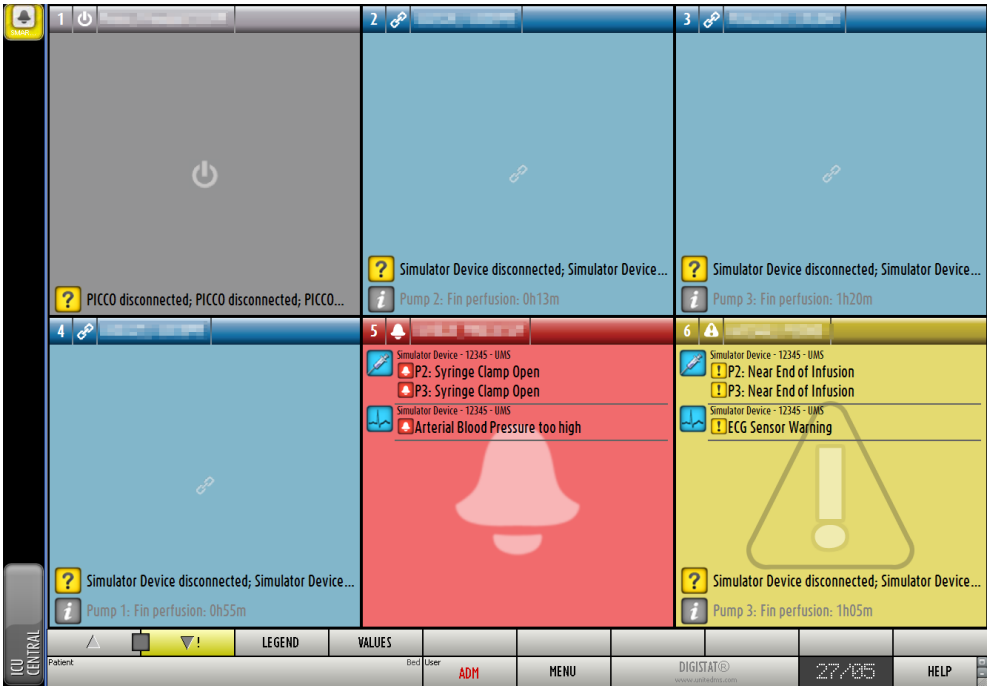


Fig 85

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 86. Notice the icons in the background (a bell for the alarm, an exclamation mark for the warning).

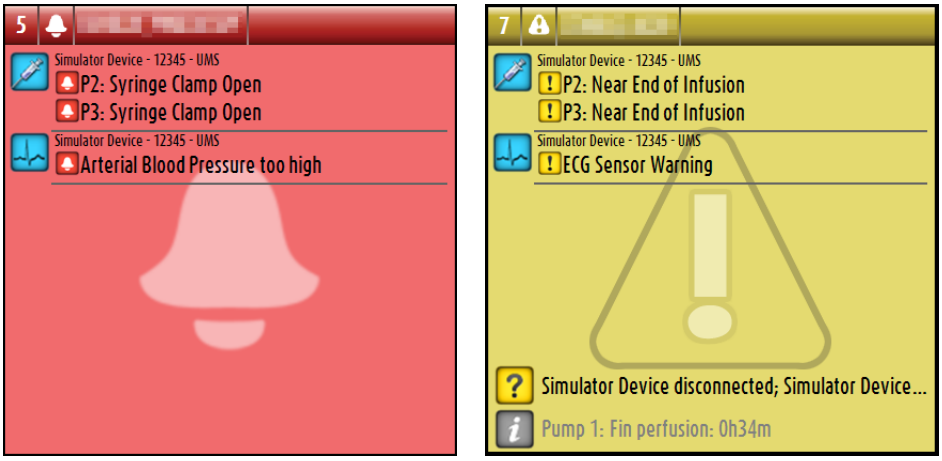


Fig 86

When the "Bed areas" are in the state shown in Fig 86 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 87

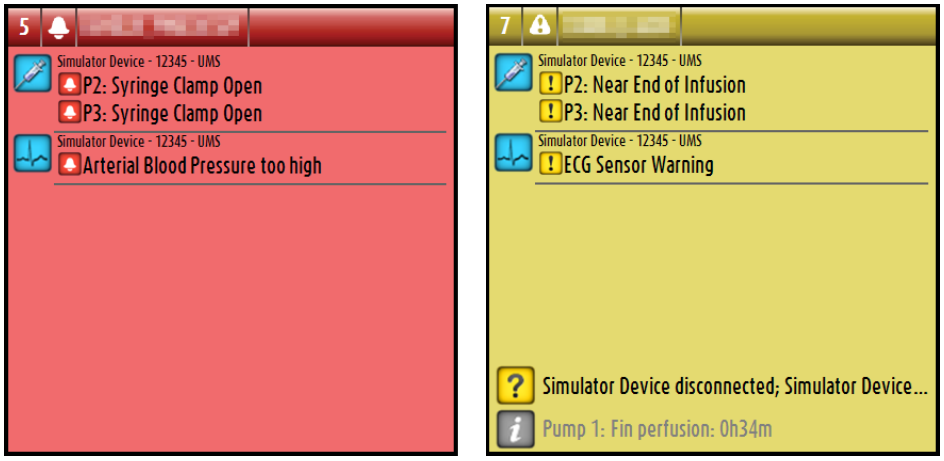


Fig 87

The occurrence of alarms/warnings is also notified on the command bar by the arrow-buttons indicated in Fig 88 and Fig 89.

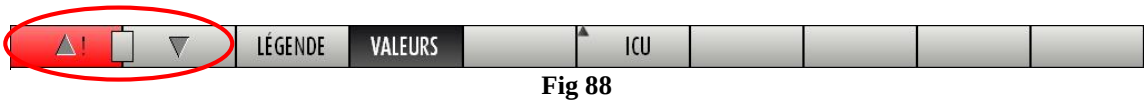


Fig 88

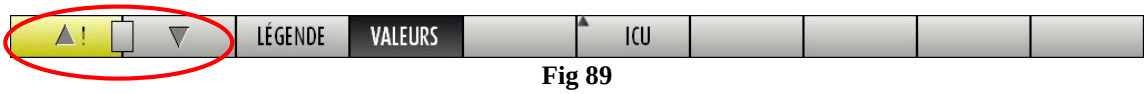


Fig 89

These buttons make it possibile to scroll up and down the screen when it is not possibile 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 90) 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 90

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

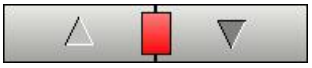


Fig 91

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.

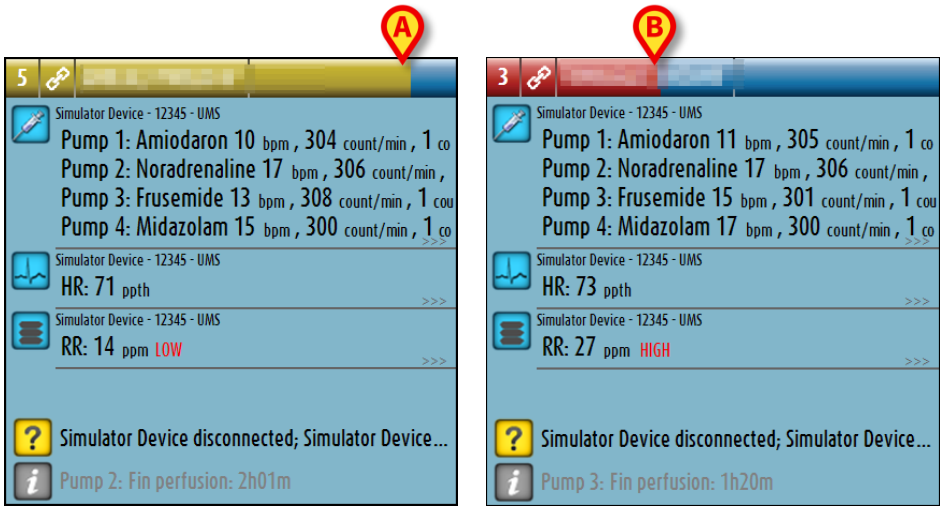


Fig 92 a/b

When the state of a bed area changes to a lower level alarm (or no alarm), the color relating to the prevoius state remains on the heading bar for a certain configurable time. In Fig 92 **A** the yellow bar is fading to the left, meaning that the previous state was a warning state. In Fig 92 **B** the red bar is fading to the left, meaning that the previous state was an alarm state.

7.8. Sound Check procedure

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 93).

Fig 93

The following menu is displayed (Fig 94).

Fig 94

- Click on **Modules Configuration** (Fig 94 **A**).

The following menu opens (Fig 95).

Fig 95

- Click on **Sound Check** (Fig 95 **A**).

The following pop-up window opens, asking whether a sound is heard or not from speakers (Fig 96).

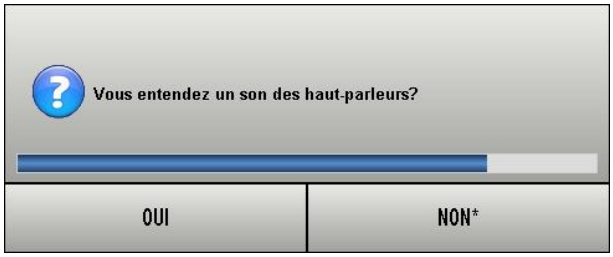


Fig 96

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 97 and Fig 98).

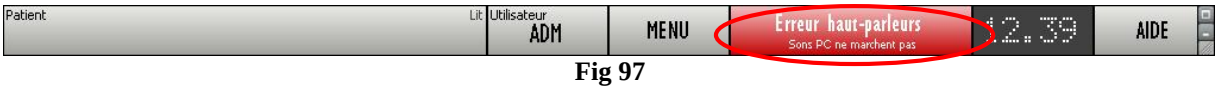


Fig 97

Fig 98

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.

7.9. 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 99 **A** and Fig 100)

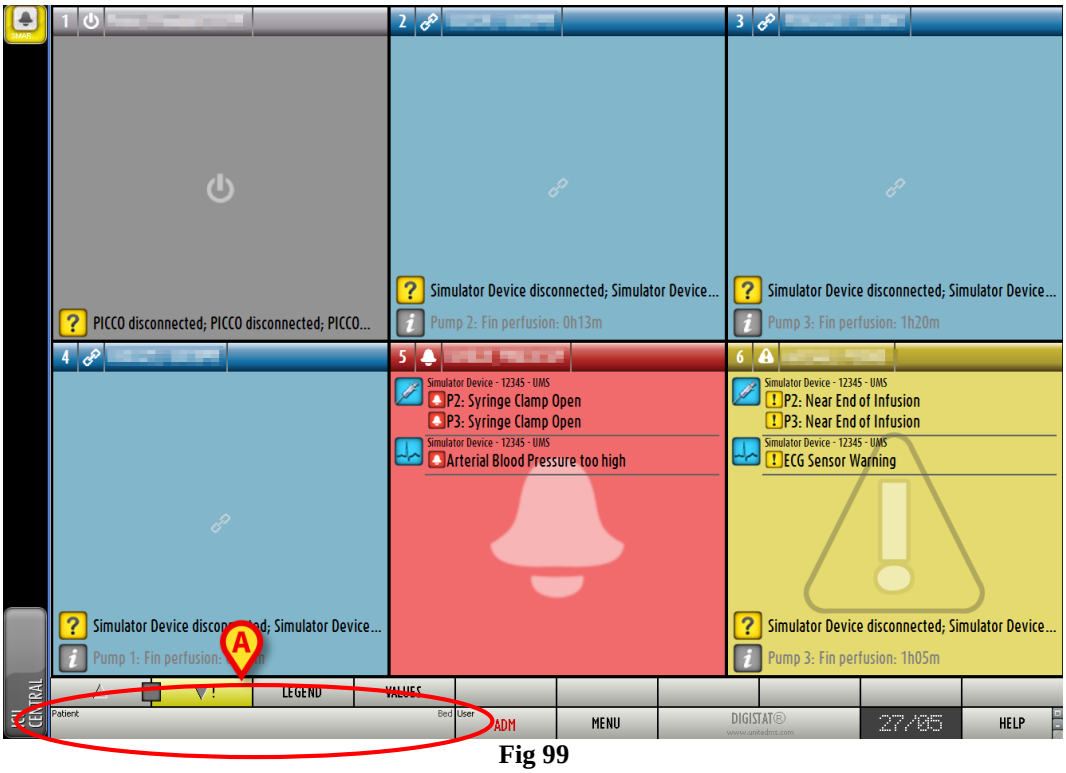


Fig 99

Fig 100

The following screen will open (Fig 101).

Fig 101

The rectangular buttons on the screen (Fig 101 **A**) represent the beds in the ward. If a patient is admitted to a bed, the patient name is displayed on the area (Fig 102 **A**). Below the patient name you can read the admission date. Areas with no name correspond to empty beds (Fig 102 **B**).

Fig 102

- 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 103).

Fig 103

The system displays the current situation of the patient on the "Smart Central" (i.e. the corresponding "Bed area") in full screen mode (Fig 104).

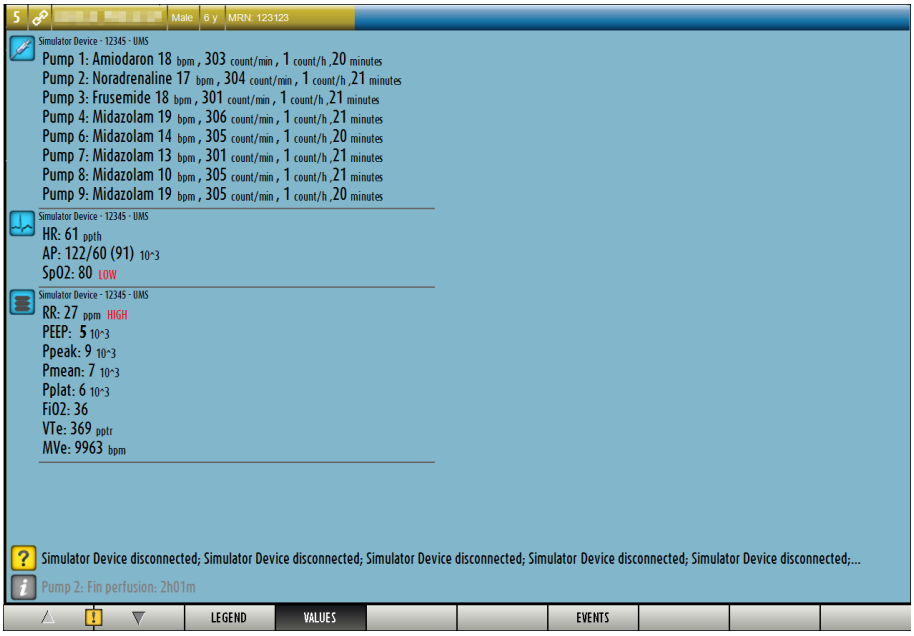


Fig 104

7.10. 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 PATIENTS RECHERCHER button indicated in Fig 105 **A**

Fig 105

The following screen will open (Fig 106).

Fig 106

The search fields in the upper area make it possible to specify the relevant patient's information (Fig 107).

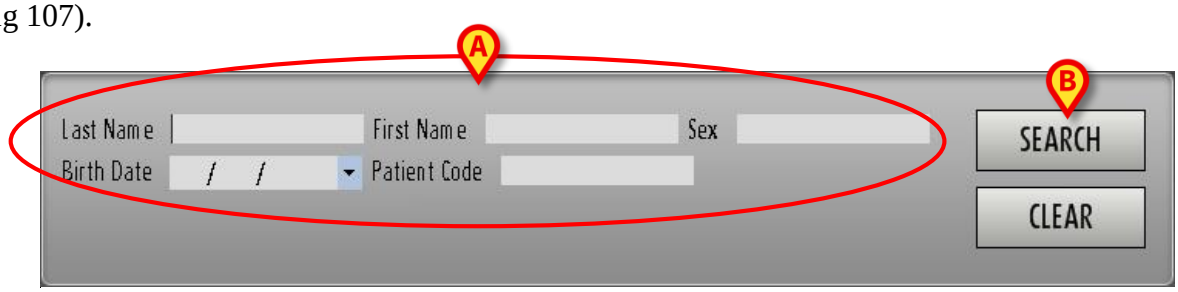


Fig 107

To search for a patient

- enter the data of the patient you are searching for in one or more fields (Fig 107 **A**).
- Click the **Search** button (Fig 107 **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.

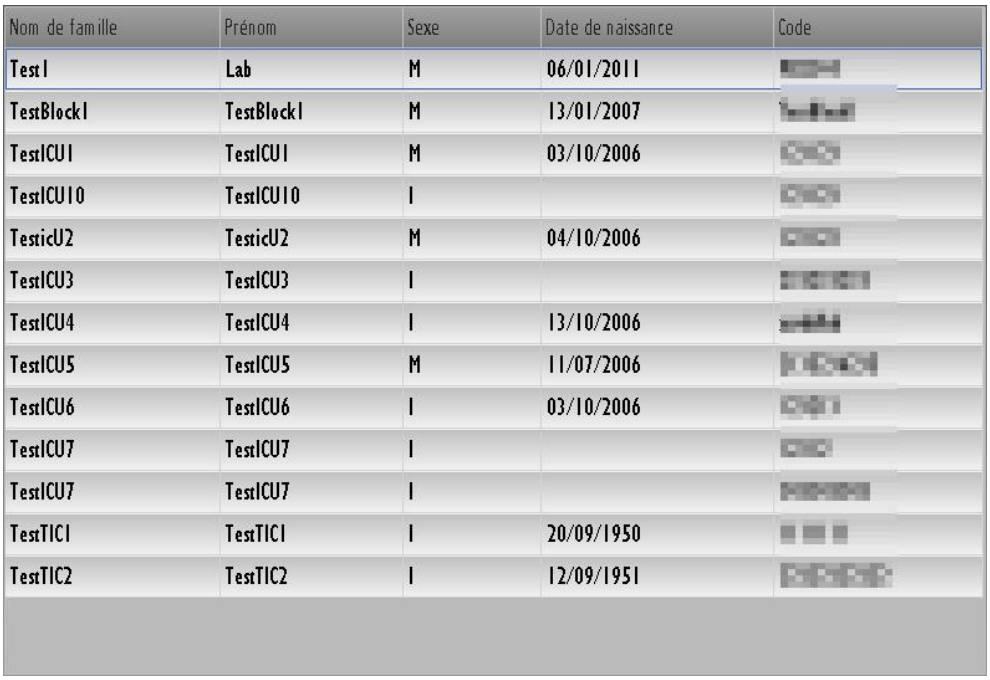
For example: if a search is performed by entering the patient's birthdate, the result is the list of all patients born on that date. If a search is performed by entering the patient's birthdate **and** sex the result is the list of only the men or women born on that date.

- 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.

7.10.1. The search results

The search results are shown in the central part of the screen (Fig 108).



Nom de famille	Prénom	Sexe	Date de naissance	Code
Test	Lab	M	06/01/2011	
TestBlock	TestBlock	M	13/01/2007	
TestICU	TestICU	M	03/10/2006	
TestICU10	TestICU10	I		
TesticU2	TesticU2	M	04/10/2006	
TestICU3	TestICU3	I		
TestICU4	TestICU4	I	13/10/2006	
TestICU5	TestICU5	M	11/07/2006	
TestICU6	TestICU6	I	03/10/2006	
TestICU7	TestICU7	I		
TestICU7	TestICU7	I		
TestTIC	TestTIC	I	20/09/1950	
TestTIC2	TestTIC2	I	12/09/1951	

Fig 108

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 108 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.

7.11. The command bar

The command bar (Fig 109) contains buttons making it possible to perform different actions.

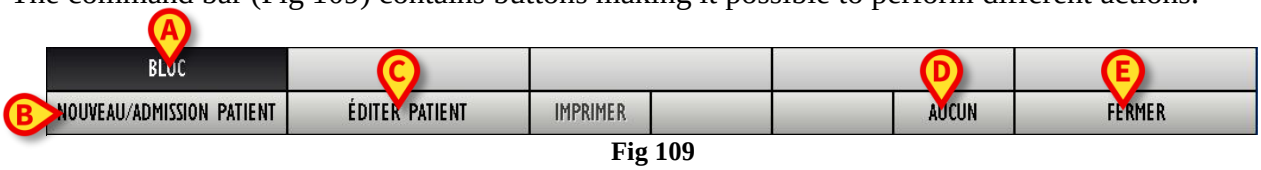


Fig 109

1) **Block** (Fig 109 **A**) – This button indicates the current ward or department.

2) **New/Admit Patient** (Fig 109 **B**) – This button makes it possible to enter a new patient in the database and to admit him/her to a bed (see paragraph 7.11.1 for the detailed procedure).

3) **Edit Patient** (Fig 109 **C**) – This button makes it possible to edit the patient's data (see paragraph 7.11.2).

4) **None** (Fig 109 **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 7.11.3).

5) **Close** (Fig 109 **E**) – This button closes the search page (see paragraph 7.11.4).

7.11.1. New/Admit patient

The **New/Admit Patient** button (Fig 110) makes it possible to enter a new patient in the database and to admit him/her to a bed.

Fig 110 - Command bar

To enter a new patient

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

The following window opens (Fig 111).

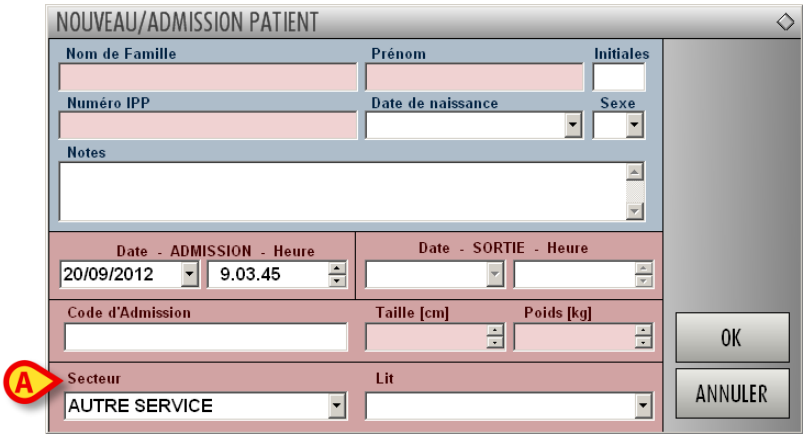


Fig 111

- 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 "Secteur" and "Lit" fields (Fig 111).

7.11.2. Edit patient

The **Edit Patient** button (Fig 112) makes it possible to edit the data of a selected patient.

Fig 112

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 113).

The "edit" operations performed are always referred to the patient whose name appears on the **Patient** button (Fig 113).

Fig 113

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 114).

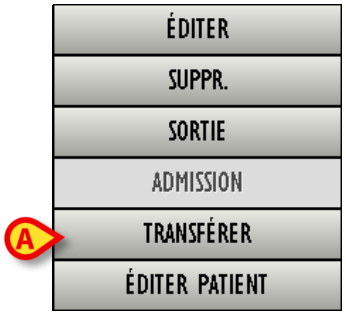


Fig 114

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.

7.11.2.1. Move

The **Move** button (Fig 114 **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 114).

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

The following window opens (Fig 115).

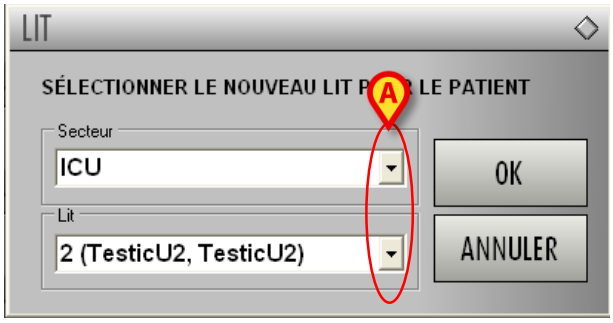


Fig 115

- Use the arrow buttons (Fig 115 **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.

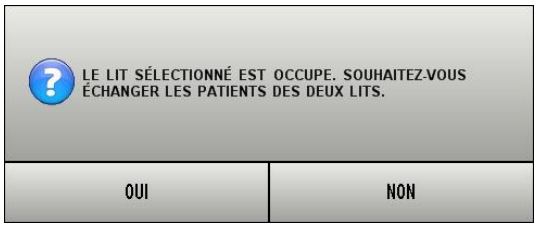


Fig 116

7.11.2.2. Admit

The admission button is disabled. The admission procedure is performed together with the "New patient" recording procedure. See paragraph 7.11.1.

7.11.2.3. 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 117).

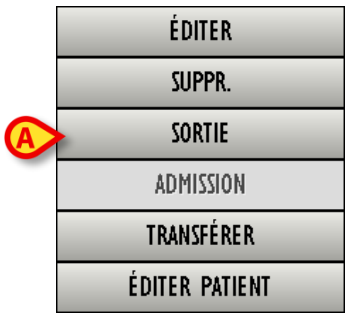


Fig 117

- Click the **Discharge** button (Fig 117 **A**).

A pop-up message requesting confirmation of the operation opens (Fig 118).

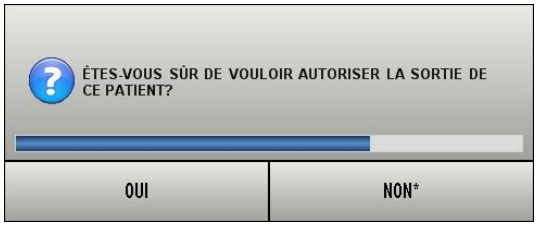


Fig 118 – Discharge patient

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

This action opens the window containing the patient's data (Fig 119 – unlike the window shown in Fig 111, here you can change the date and time of discharge).

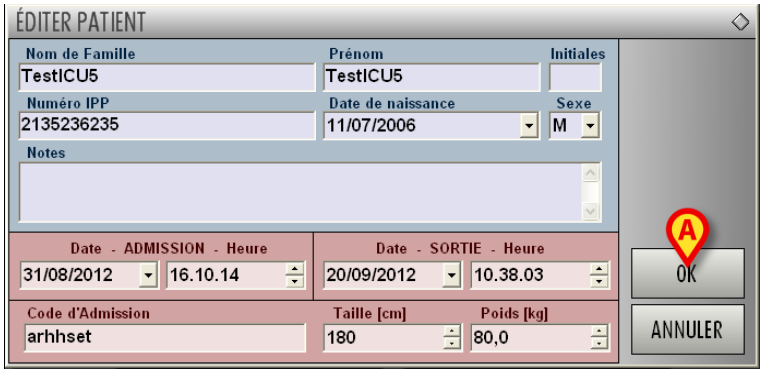


Fig 119

- Click **Ok** to complete the discharge procedure (Fig 119 A)

7.11.2.4. 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 120).

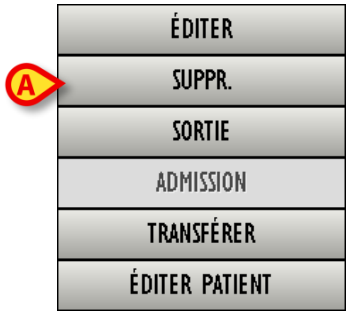


Fig 120

- Click the **Delete** button (Fig 120 **A**).

A pop-up message requesting confirmation is provided (Fig 121).

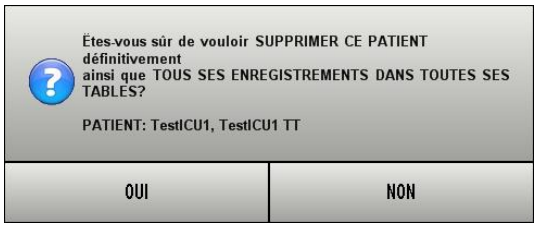


Fig 121

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

WARNING!

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.

7.11.2.5. 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 122).

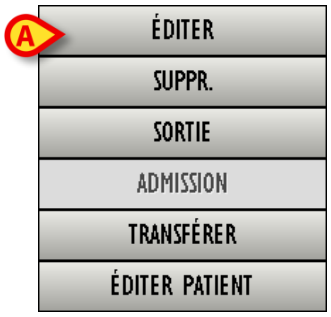


Fig 122

- Click the **Edit** button (Fig 120 **A**).

A window containing the patient's data opens (Fig 123).

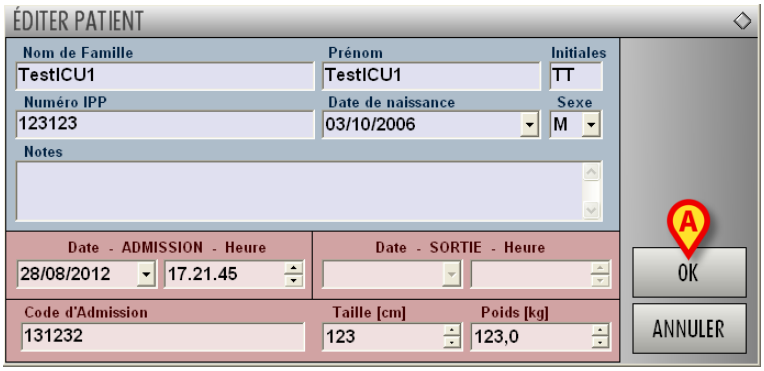


Fig 123 – Edit patient

- Edit the patient's data.
- Click **Ok** to confirm (Fig 123 **A**).

7.11.3. Deselect patient

The **None** button (Fig 124) makes it possible to deselect the selected patient (whose name is shown on the PATIENT button).

Fig 124 - Command bar

To deselect a patient

- click the **None** button (Fig 124).

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

7.11.4. Close

The **Close** button (Fig 125) makes it possible to close the search screen.

Fig 125 - Command bar

To close the patient search screen

- click the **Close** button on the page (Fig 125).

8. 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 126 the workstation is locked to bed 1.

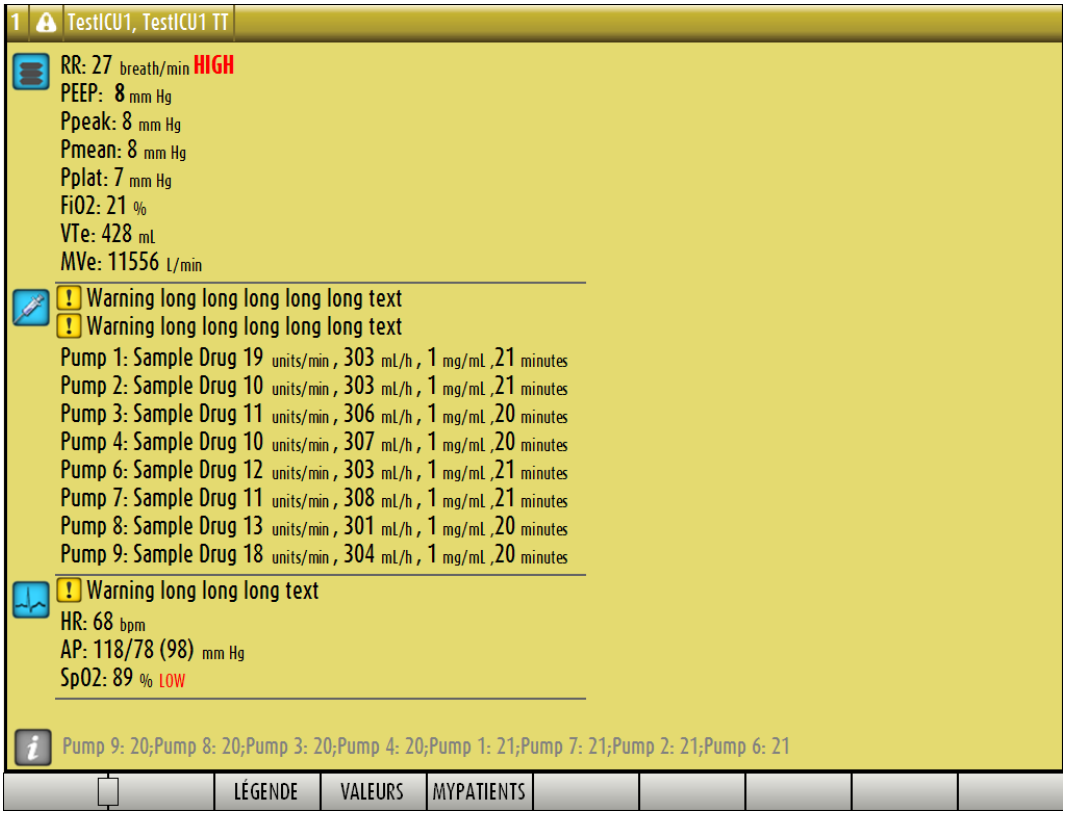


Fig 126

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 7.5.1).
Use the **Values** button to display the device values when no alarm/warning is provided (see paragraph 7.4.1).
Use the **MyPatients** button to select other beds to be displayed on screen (see paragraph 8.1).

8.1. 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 127).

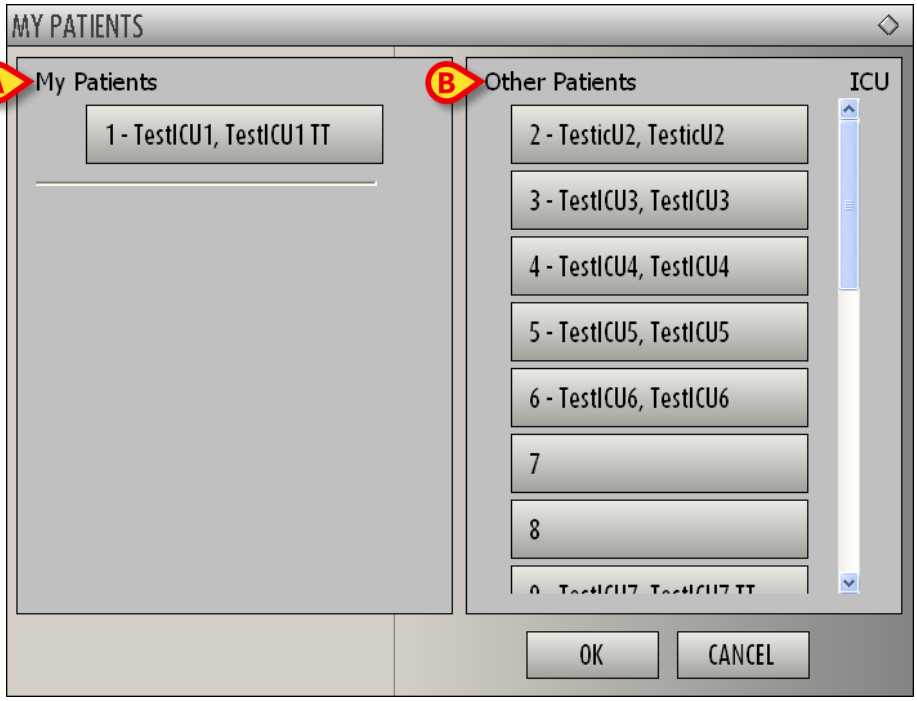


Fig 127

On the left, on the "My patients" column, is the list of "Bed areas" currently displayed (Fig 127 **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 undisplayed "Bed areas" are listed (Fig 127 **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.

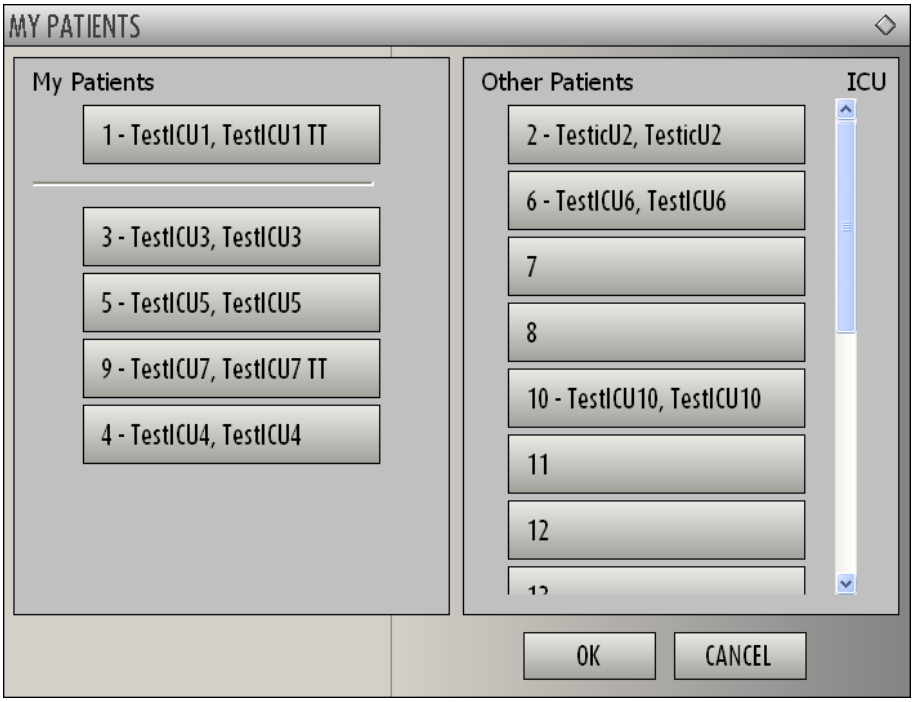


Fig 128

In Fig 128 “Bed areas” 3, 5, 9 and 4 are selected.

- Then click the **Ok** button.

The “Smart Central” screen appears like in Fig 129.

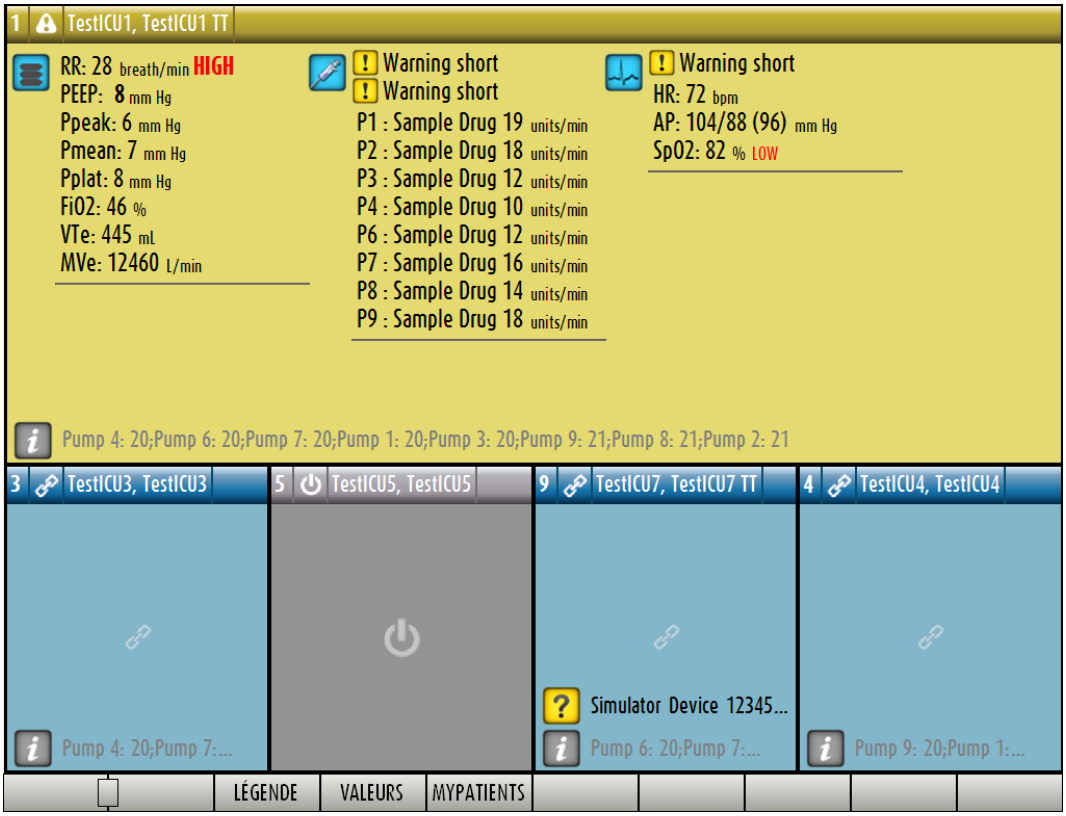


Fig 129

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 128).

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.

9. Enclosed Documentation

The following documents are enclosed

1. *End-user licence agreement*. To be fully read, signed and sent to ASCOM UMS

END-USER LICENSE AGREEMENT
FOR "DIGISTAT®", A ASCOM UMS PRODUCT

IMPORTANT—READ CAREFULLY. This ASCOM UMS End-User License Agreement ("Contract") is a Contract between the User (either a natural or corporate person) and the Firm ASCOM UMS S.r.l. unipersonale ("ASCOM UMS") for the "DIGISTAT®" System produced by ASCOM UMS. The product "DIGISTAT®" ("PRODUCT") comprises computer software and may include associated storage media, printed materials and "online" or electronic documentation. The PRODUCT also contains updates, if any, and integrative components for the original PRODUCT supplied by ASCOM UMS. Any software supplied with the PRODUCT and associated with a separate End-User License is licensed to the User in compliance with the said Contract's terms and conditions. By installing, copying, downloading, viewing or otherwise using the PRODUCT, the User agrees to be bound by the terms of this Contract. If the User does not agree to the terms and conditions of this Contract, he is not authorized to use the PRODUCT and must immediately stop using it.

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2. **OTHER RIGHTS AND LIMITATIONS**

   - **Limitations on Reverse Engineering, Decompilation, and Disassembly.** The User may not reverse engineer, decompile, or disassemble the PRODUCT, except and only to the extent that such activity is expressly permitted by applicable law notwithstanding this limitation.

   - **Separation of Components.** The PRODUCT is licensed as a single product. Its component parts may not be separated for use on more than one computer.

   - **Trademarks.** This Contract does not grant the User any rights on any trademarks or ASCOM UMS registered trademarks.

   - **Sub-license and Rental.** The User may not rent, sub-license, lease, or lend the PRODUCT.

   - **Technical Assistance Service.** ASCOM UMS may provide the User with a Technical Assistance Service for the PRODUCT ("Technical Assistance Service"). Use of the Technical Assistance Service is governed by ASCOM UMS policies and programs, which are provided on request. Any additional software code provided to the User as part of the Technical Assistance Service shall be considered as part of the PRODUCT and subject to the terms and conditions of this Contract. Concerning technical information the User may give ASCOM UMS during the Technical Assistance Service, ASCOM UMS may use such information for its business purposes, including product support and development.

- **Termination.** Without prejudice to any other rights, ASCOM UMS may terminate this Contract if the User fails to comply with the terms and conditions of the same. In such an event, the User must destroy all copies of the PRODUCT and all its component parts.

3. **UPGRADES** - If the PRODUCT is labeled as an upgrade ("Upgrade"), the User must be properly licensed to use a product identified by ASCOM UMS as being eligible for upgrades required to use the PRODUCT. A PRODUCT labeled as an upgrade replaces and/or supplements (and can deactivate) the PRODUCT that forms the basis for your eligibility for the upgrade. The User may use the resulting upgraded PRODUCT only in compliance with the terms of this Contract. If the PRODUCT is an upgrade for a component of a software program package licensed to the User as a single PRODUCT, the PRODUCT may be used and transferred only as part of that single PRODUCT package and may not be separated for use on more than one COMPUTER.

4. **COPYRIGHT** - PRODUCT rights and copyright (including, but not only, every image, photo, animation, video, audio, music, text and "applet" integrated with the PRODUCT), annexed printed material and any copy of the PRODUCT are the property of either ASCOM UMS or its suppliers. Intellectual property title and rights on the contents the User may access by using the PRODUCT are the property of the respective owners and can be protected by copyright or by other laws and treaties on intellectual property. This Contract does not grant the right to use such contents. If the PRODUCT contains documentation supplied only in electronic format, the User is authorized to print a copy of the abovementioned electronic documentation. The User may not copy the printed material annexed to the PRODUCT.

5. **BACKUP COPY** - After installing a copy of the PRODUCT in compliance with the terms of this Contract, the User may preserve the original media on which ASCOM UMS supplied him the PRODUCT only for backup or storage purposes. If he needs the original media to use the PRODUCT, he may create only one copy of the PRODUCT for backup or storage purposes. Except for this Contract'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 its published specifications.
Except for the above specifications, the PRODUCT is supplied "just as it 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, notwithstanding its performance of the due checks and its preparation of upgrades based on the best knowledge and experience in existence from time to time, that the PRODUCT or other equipment systems, or the network itself on which the PRODUCT is used, will be invulnerable 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.)

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 ASCOM UMS instructions, (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 Client. UNDER NO CIRCUMSTANCE WILL THESE GENERAL CONTRACT CONDITIONS INVOLVE ACKNOWLEDGEMENT OF ASCOM UMS OR

ITS SUPPLIERS' RESPONSIBILITY IN CASE OF DECEASE OR PERSONAL LESIONS 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 WHICH DO NOT ALLOW LIMITATION OR EXCLUSION OF INCIDENTAL OR CONSEQUENTIAL DAMAGE.

This Contract 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 Contract 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 Contract 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 shipment of the PRODUCT by ASCOM UMS is recorded in the shipment documentation or in the PRODUCT delivery documentation.

INTENDED USE

The PRODUCT is a medical device composed only by software that is licensed exclusively to create an electronic copy of certain patients' data and recording of the unit's activity in order to provide:

- electronic documentation of the activity in the unit;
- information on the use of human resources and materials;
- deferred statistics for quality control;
- support to the diagnostic and therapeutic activities, within the limits of what specified herein below;
- support to the management of alarm coming from the connected medical devices;
- display of information to remote users for non-clinical purposes.

The PRODUCT is not aimed to administer or exchange energy to or from the human body or to transmit medicines, liquids or other substances to or from the human body.
The PRODUCT is not aimed to allow direct diagnosis or monitoring of vital physiological processes (by way of example cardiac performance, respiration or activity of CNS) and therefore the therapeutic or diagnostic procedure or maneuver, if any, deemed necessary by the user, shall be performed by him/her solely as consequence of the direct examination and of the scientific correspondence of the specific case with the data obtained through the use of the PRODUCT.

Based on the above features, the PRODUCT, even if designed to provide the maximum reliability, cannot guarantee the perfect correspondence of the provided data, nor can it substitute the direct verification of the same by the user.
In any case, the PRODUCT must be used in compliance with the safety procedures reported in the user manual accompanying the Product.

The PRODUCT can be used close to the patient and to the medical devices in order to speed up the data entry, to decrease the chances of errors and to allow the user to verify the correctness of the data through the immediate comparison with the actual data and activities.

The user must implement adequate procedures to guarantee that potential errors occurring in 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 user.

Only printouts that are signed (with digital signature or autograph) by authorized physicians or medical operators shall be considered valid clinical documents. 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 may provide, depending on the modules installed, access to information on drugs. This information is taken from official publications. It is responsibility of the user to periodically verify that this information is current and updated.

The PRODUCT can be connected to other medical devices in order to import data therefrom but is not aimed to control, monitor or influence the performances of the medical devices with which it is connected.

The PRODUCT may provide, depending on the modules installed, visual and acoustic indication of the status and operating conditions of the approved devices connected to the PRODUCT thus providing a support to the management of the alarms and to the planning of nursing workflow.
The information displayed by the PRODUCT is not meant to replace or replicate the original display of data, messages and alarms of the medical devices. The PRODUCT is not intended to control, affect or modify the normal use of those devices.

The PRODUCT does not substitute a "Nurse Call" system and it is not a "Distributed Alarm System" (as defined by the regulation EN 60601-1-8). 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 and to the nature and limitations of the hospital local network.

INTENDED USERS
The PRODUCT must be used by properly trained physicians, nurses, administrative staff, system administrators, biomedical engineers and technicians.
Use of the system must be granted, by means of specific configuration of the passwords and active surveillance, only to trained personnel in possession of the professional qualifications to correctly interpret the information supplied and to implement the appropriate safety procedures.

Limited parts of the PRODUCT may be used by other categories of users for non-clinical purposes, to access a limited set of information and without the ability to alter existing information or enter new ones. For example patient's family member can access information of their relative.

INTENDED ENVIRONMENT
The PRODUCT can be used inside medical facilities in intensive care units, wards, operating blocks, operating theatres and other departments.

The PRODUCT is software-only medical device that can be run on a computer connected to the hospital local network and must be adequately protected against cyber-attacks.
The PRODUCT must be installed only on recommended PCs and/or operating systems.

In using the PRODUCT, the user declares to have understood and accepted the characteristics, limits and responsibilities contained herein and in the user manual.

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 Contract which are not compatible with them, it being understood that all the remaining terms of this Contract shall remain fully valid and the enforceable.

* * * * *

Should you have any questions concerning this End-User License Contract, please contact the ASCOM UMS representative in your area or write to ASCOM UMS srl, Customer Service, Via di Mucciana 19, 50026 San Casciano in Val di Pesa (Firenze), Italy (or use contacts listed below).

Date Signature

SPECIFIC ACCEPTANCE OF CERTAIN PROVISIONS IN THIS CONTRACT

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 ASCOM UMS End-User License Contract concerning the product "DIGISTAT®":

- COPYRIGHT

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

Date Signature

10. Contacts

- **ASCOM UMS srl unipersonale**

Via Amilcare Ponchielli 29, 50018, Scandicci (FI), Italy
Tel. (+39) 055 0512161
Fax (+39) 055 8290392

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support@unitedms.com

800999715 (toll free, Italy only)

- **Sales and products information**

sales@unitedms.com

- **General info**

info@unitedms.com

Appendix A: glossary

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.

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ALARM MESSAGE

An “Alarm message” coming from any one of the devices in use warns the user about an immediate danger for the patient or the users of the device. Alarm messages are of vital importance and must be managed with the highest priority.

BUTTONS

- **Function buttons**

  Buttons which, when clicked, make it possible to perform different operations or access different functions of the software. In Figure 2 the active function buttons are **New**, **Show**, **Delete**, **Change** and **Reports**.

- **Active button**

  Button which, in the context present, can be clicked and makes it possible to perform operations or access particular functions.

- **Inactive button**

  Button which, in the context present, cannot be clicked.

- **Make button active**

  Perform an operation which means that a certain button becomes clickable.

CHECKBOX

Small box, usually square, which can be clicked to select an option. It can also be called a “selection box”.

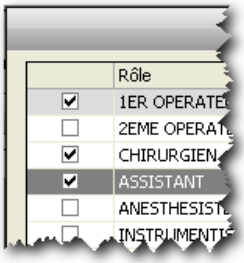

Figure 1 - Checkbox

- **Selection box**

  See “Checkbox”.

CLICK

Move the mouse over a specific object and press one of the buttons (the left one unless otherwise specified).

- **Double Click**

  Click twice in rapid succession.

CLIENT

A computer connected to a server (see) in an information network that requests the server for one or more services.

COMMAND BAR

Term used to generically indicate a portion of screen containing different function buttons (Figure 2).

Figure 2

CONFIGURATION

The configuration of a software product is a series of operations and choices which determine the general set-up of the software and its operation and appearance. The configuration is not to be performed by the user (see) but by a system technician/administrator (see).

CONTROL BAR

The external portion of each page on the DIGISTAT® environment, comprised a control bar at the bottom and a side control bar. “Control Bar” is used to manage, among other things, access to the system (login - see), exit from the system (logout - see) and selection of the module required.

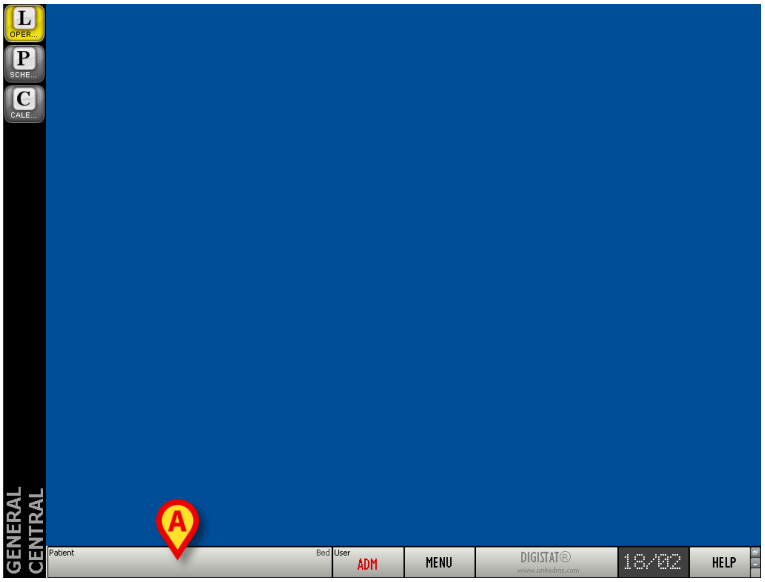

Figure 3

CURSOR

Moving mark indicating a position. It is often a short blinking vertical line indicatine where the user is inserting data.

DATABASE

A database is a collection of data organized so that it is easily accessible. The data in a database can be consulted, edited and updated.

DEFAULT

A value is classed as being "by default" when it is automatically used by the system if the user does not specify any other values.

DIGISTAT®

- **DIGISTAT® Module**

  Software designed and developed to offer a solution to a specific series of needs and problems.

- **DIGISTAT® System**

  A series of DIGISTAT® modules that work in an integrated, synchronized and interdependent way.

- **DIGISTAT® Environment**

  The combination that encompasses and characterizes all DIGISTAT® modules and systems

DRAG

To “drag an item” means to move to an object with the cursor of the mouse, click and, keeping the button pressed, move the cursor across the page. The object moves with the cursor. The “dragged” items stops when you release the left button.

DRAG AND DROP

“Drag and drop” is the act of dragging an item to move it to a different point of the screen (see “drag”).

EDIT

Modify the data on a screen.

- **Edit Mode**

  A screen is said to be in edit mode when it can be edited by the user.

- **Edit state**

  See “Edit Mode”.

EVENTS

In the OranJ system, an event is a significant occurrence in the operating process which must be documented. The number and kind of possible events depend on the user needs and are set by configuration.

FIELD

Portion of screen in which you can enter data (digits, letters or both - Figure 4).

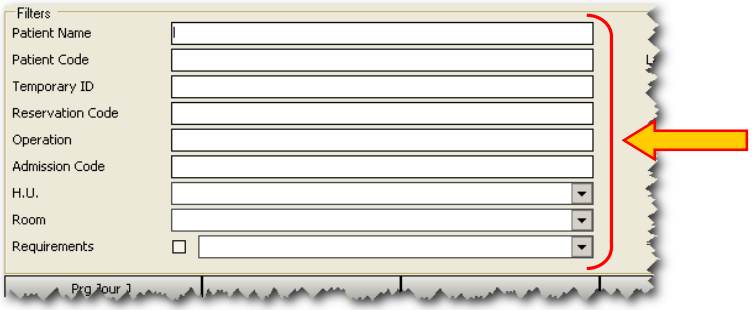

Figure 4 - Fields

❖ **Free field**

A field is “free” when you can enter any type of text or digit and it is not restricted to a series of pre-defined options.

LOCATION

The term “Location”, when used within the DIGISTAT® environment, indicates the area (fo instance a department, or a ward) for which the system is configured.

LOG

Item recording in real-time and chronologically certain operations defined as “meaningful”.

LOGIN (procedure)

The act of accessing (by means of username and password - see) the system.

❖ **Logout**

The act of exiting the system.

MARKER

In the OranJ system, markers are events which are defined as characterizing every operating event. The number and nature of markers, as well as the logic of succession, can be configured to suit the user’s needs. The OranJ system envisages 6 markers as standard:

1. Entrance to the block (the patient has undergone block check-in)
2. Entrance to the room (the patient has undergone room check-in)
3. Skin incision
4. Suture
5. Exit from the room (Operation done)
6. Exit from the block

MESSAGE CENTER

A software that manages the messages and the licences within the DIGISTAT® environment (see). The use of “Message Center” is reserved to the system administrators (see).

PAGE

Term used to indicate what can be seen on the screen in a specific moment.

PASSWORD

A password is a sequence of numbers and/or letters used to access a protected area. It should only be known to the user concerned.

PATIENT

- **Admitted Patient**

  Within the DIGISTAT® environment, the expression "admitted patient" means that the patient has been admitted to the hospital structure. The admission of a patient involves the assignment of a bed and a location. When a patient is admitted, the number of his/her bed appears alongside his/her name on the **Patient** button on the ControlBar (see Figure 3 **A**).

- **Patient registered in the database**

  The expression means that the name and data of a patient appear in the archive that we are consulting.

- **Patient Selected**

  Within the DIGISTAT® environment, when the patient is selected, his/her name appears on the **Patient** button on the ControlBar (see Figure 3 **A**).

POP-UP

Window containing a message for the user (see) which appears following the performance of any operation.

QUERY

A database interrogation performed to obtain a specific set of data.

RADIOBUTTON

Selection tool enabling to select one among many available options and having the feature:  . The selection of an option excludes the other options. See, for instance, the radiobuttons shown in Figure 5.

Figure 5

READ-ONLY

This expression means that a series of data cannot be edited by the user.

RECORD

A series of data organized rationally and composed of coherent items. An example of a record could be the patient data composed of name, last name, address, code, etc.

RESERVE

In the OranJ and Smart Scheduler systems, reserves are those operations which have not been assigned a time, block or room but which have been included in the daily schedule.
The "reserve" concept has been introduced to enable the immediate scheduling of emergency operations which become necessary from one minute to the next. The criterion observed for these urgent cases is "as soon as a place is free, the operation goes ahead".

SCREEN

Term used to indicate what can be seen on the computer screen in a specific moment.

SERVER

An informatic component (a computer, for instance) providing services to other components (tipically named "clients" - see) in an information network.

SLOT

In the Smart Scheduler system, the term "slot" indicates the range of time in which an operating room is available to a hospital unit for scheduling. From the graphic point of view, on the scheduling grid, the slot is one of the ochre yellow colored areas (Figure 6).

Figure 6 - slot

STATE (of the operation)

In the OranJ and Smart Scheduler systems, the "operation state" is the "stages" in which an operation is, in relation to the process necessary to its completion. There are 6 visible operation states in the two systems. These are

1) Foreseen – It has been decided that an operation must be performed for a specific patient.

2) Requested – It has been declared that the operation can be included in the schedule of the structure where you are operating, therefore its scheduling has been requested.

3) Scheduled – The operation has been included in the schedule of the structure where you are operating. The location and time of the operation have been decided.

4) Ready - The patient has undergone check-in and is inside the surgical block.

5) In progress – The patient has undergone room check-in. The operation is being performed.

6) Completed - The patient is out of the operating room. The operation is over.

The Smart Scheduler system manages operations up to scheduling, i.e., in the three states described here. The OranJ system manages the operations from scheduling up to completion (the last 4 states). Within OranJ the states are characterized by different colors. The "scheduled" state is light gray; the "ready" state is green; the "in progress" state is blue; the "completed" state is dark gray.

SYSTEM ADMINISTRATOR

Specialized technician responsible for managing the IT system used. This is the first person to contact if you have any kind of problem.

TAB

Tabs like those of an address book, which you click to access a different page (Figure 7).

Figure 7 - Tab

TOOLTIP

A tooltip is an area containing information about one of the items displayed on screen. The tooltip appears when the mouse pointer passes over the specific item (clicking is not necessary).

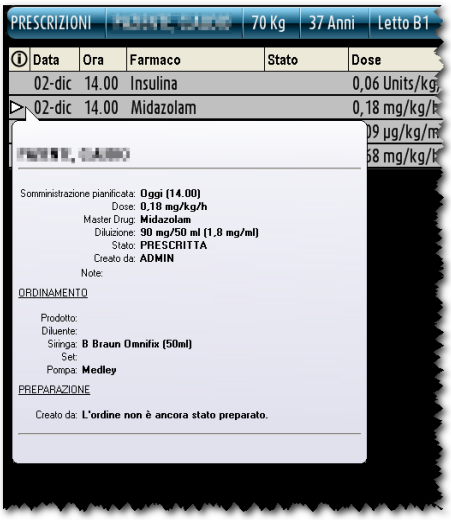

Figure 8 - Tooltip

TOUCH SCREEN

Particular type of screen in which the operations usually performed using the mouse are performed by touching the surface of the glass.

USER

The person using the system.

- **User Connected**

  See “User Logged In”.

- **User Logged In**

  User who has accessed the system (login - see) by entering his/her username and password and is therefore authorized to access some of its functions. The user logged in is also known as the “user connected”.

- **User Logged-out**

  User who has not accessed the system (login) or who has exited the system (intentionally or otherwise) and cannot therefore access his/her functions without logging in again.

USERNAME

The name which identifies the user of a system. It can be composed of letters, numbers or both together.

WARNING MESSAGE

A “Warning message” warns the user that an ongoing situation or procedure could lead to a danger for the users or the patient. Warning messages are very important and must be managed as soon as possible.

WORKSTATION

In this manual the word “workstation” indicates the computer on which the software or part of it is installed.

Appendix B – 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 accettable 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.