DIGISTAT® On Line

DIGISTAT® Version 4.0

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. 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 UMS srl
http://www.unitedms.com
DIGISTAT® is a Trademark of 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.

UMS is certified under the UNI EN ISO 9001:2008 and UNI CEI EN ISO 13485:2012 standards for software engineering, development, production, installation and assistance.

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 UMS technical support service.
Remember that, by specific request, UMS is able to provide custom-made documentation for every specific type of procedure and/or configuration.
Please remember that DIGISTAT® must only be used by authorized and trained users, as specified in the "Intended users" paragraph.

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 in upper case and highlighted in grey. For example, in expressions like.

- Click the XYZ button,

XYZ is a button featured on the page being described.

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

"DIGISTAT®" 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.
"DIGISTAT®" 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 "DIGISTAT®".

Based on the above features, "DIGISTAT®", 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 "DIGISTAT®" 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 complete and exclusive responsibility of the user to make correct use of the information supplied and check every time that they are correct.

"DIGISTAT®" 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 "DIGISTAT®" 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.

"DIGISTAT®" 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.

"DIGISTAT®**"** 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 information displayed by "DIGISTAT®" is not meant to replace or replicate the original display of data, messages and alarms of the medical devices. "DIGISTAT®" is not intended to control, affect or modify the normal use of those devices.

"DIGISTAT®" 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.

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

"DIGISTAT®**"** must be used by properly trained physicians, nurses, administrative staff 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.

Use of the system 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.

"DIGISTAT®" is software-only medical device that can be run on a computer connected to the hospital local network and must be adeguately protected against cyber-attacks.

"DIGISTAT®" 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 described in this user manual. Should the user consider any of these clauses to be unacceptable, he must stop using "DIGISTAT®" immediately and inform promptly the system administrator.

3.3. Manufacturer's responsibility

The CE seal is a safety warranty of the product introduced on the market.
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 UMS authorized personnel;
- 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 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 UMS, one of its branches or the nearest authorised dealer about any ownership transfer either by duly filling in the "Product Tracking Form" published in the final pages of the present document or by giving written notice with the same data requested in the abovementioned form.

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 7.5.5).
In case of doubts/questions about product labelling and/or product identification please contact UMS technical assistance (for contacts see paragraph 6)

3.5. CE mark and regulation conformity

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.

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

3.6. Post-market surveillance

The CE marked device is subject to a post-market surveillance - which 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 UMS, one of its branches or nearest authorised dealer.

The device details can be found on its labelling.

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

3.7. Product life

The life time of the product does not depend on wearing or other factors that could compromise safety. It is influenced by the obsolescence of the hardware and software (PC and server) and is therefore assessed as 5 years from the date of the product's specific version release, period during which the manufacturer is committed in keeping technical documentation and providing technical support.

4. Software and hardware specifications

4.1. Bedside

4.1.1. Hardware

For bedside workstations, if a medical grade PANEL PC is required, UMS suggests the following solutions:

Recommended: ONYX 1721 2 Gb RAM (4GB suggested), 80GB HD
Recommended : AxiomTek MPC170-831 2 Gb RAM (4GB suggested), 80GB HD
Supported: POC 174 2 Gb RAM (4GB suggested), 80GB HD.

4.1.2. Operating System

Microsoft Corporation Windows 7 x86 Professional - Recommended.
Microsoft Corporation Windows XP x86 Professional with SP3 - Supported.

4.2. Central

4.2.1. Hardware

Recommended: DELL Optiplex 745 or above (Small Form Factor Chassis).

Hardware requirements:

- Intel® Celeron® processor with Intel® dual-core technology (or faster)
- Memory: 2 GB RAM (4 GB recommended)
- 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 7/XP compatible printer (optional)
- Ethernet interface 10/100 Mb/s (or higher)
- CD/DVD Drive (optional)

4.2.2. Operating System

Microsoft Corporation Windows 7 x86 Professional - Recommended.
Microsoft Corporation Windows XP x86 Professional - Supported.

4.3. Server

4.3.1. Hardware

Minimum hardware requirements:

- Intel® Pentium® processor with Intel® dual-core technology (or faster)
- Memory: 2 GB RAM (4 GB recommended)
- Hard Disk: at least 80 GB of available space
- Monitor: 1024 x 768 or higher (65.000 colors minimum)
- Mouse or other compatible device
- Windows compatible printer
- Ethernet interface 10/100 Mb/s (or higher)
- CD/DVD Drive

RECOMMENDED SERVER IN A CLUSTER ENVIRONMENT:

- 1 Blade center H or higher
- 2 Blades HS22 INTEL XEON 5400 or higher connected in failover cluster
- 1 SAN Ibm DS 4000 series or higher
- 2 switch Fiber Channel 4Gbit connected in failover to the SAN and with redundant1Gbit connection to the Network Fiber Channel.
- 8 gbyte Ram for each blade
- 100 GB reserved data area on the SAN

4.3.2. Operating System

Microsoft Windows Server 2008 R2 Standard/Enterprise Ed. with SP1 - Recommended.
Microsoft Corporation Windows Server 2008 – Supported.
Microsoft Windows 2003 Server - Supported.

4.3.3. System Software

Microsoft SQL Server 2008 R2 Standard/Enterprise Ed. - Recommended.
Microsoft SQL Server 2012 Standard/Enterprise Ed. - Supported.
Microsoft SQL Server 2008 Standard/Enterprise Ed. - Supported.
Microsoft SQL Server 2005 Standard/Enterprise Ed. - Supported.

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 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!

It is recommended to consult UMS srl before any Operating System or SQL Server update.

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.

4.4. 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 UMS the maintenance calendar in order to let UMS 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 gradualòly deteriorates until timeout errors occur. The system may finally switch to "Recovery" mode.

4.4.1. 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 UMS staff and any other person specifically trained and authorized by UMS. Similarly, maintenance interventions and repairs on DIGISTAT® must absolutely be performed according to the UMS company guidelines only by UMS personnel or other person specifically trained and authorized by UMS.

DIGISTAT® must absolutely be installed and configured by specifically trained and authorized personnel. This includes UMS staff and any other person specifically trained and authorized by UMS.

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

5.3.1. Precautions

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.

5.3.2. Warnings

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

- **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 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.

- **Patient Area**

The term "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.

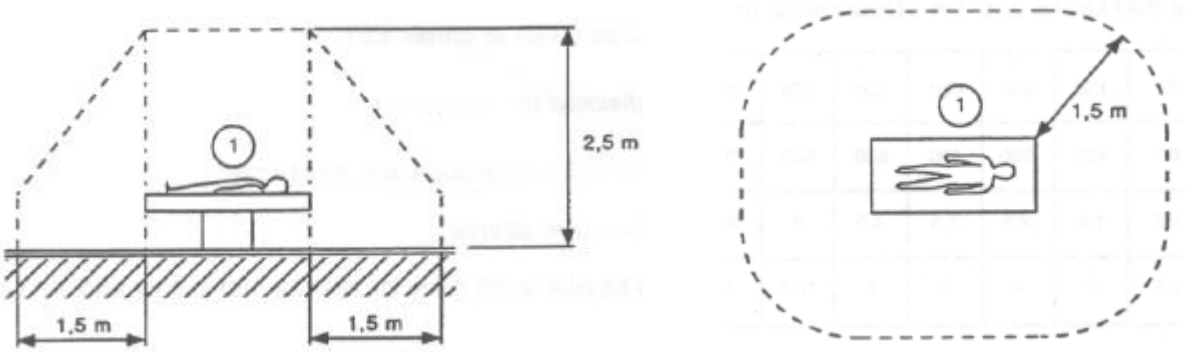


Fig 1 – Patient Area

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 UMS performed in whole or in part the wiring and the necessary connections.

- **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.

- **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 7.2 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). Automatic log out allows to protect the system from unauthorized accesses.

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 (see paragraph 7.5.4 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

UMS 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.
UMS srl, 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 UMS technical staff is configured as "System Administrator" for the DIGISTAT® system (see regulation of 25/11/2008 of the Privacy Guarantor on "System Administrators"). UMS 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.
UMS 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 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.
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 UMS staff and any other person specifically trained and explicitly authorized by UMS. Missing an explicit, direct authorization from UMS, 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 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 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 UMS and requests the "substitution equipment" activation

3) The UMS 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 UMS and schedule the substitution/reconfiguration procedure to allow 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 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 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 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 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).

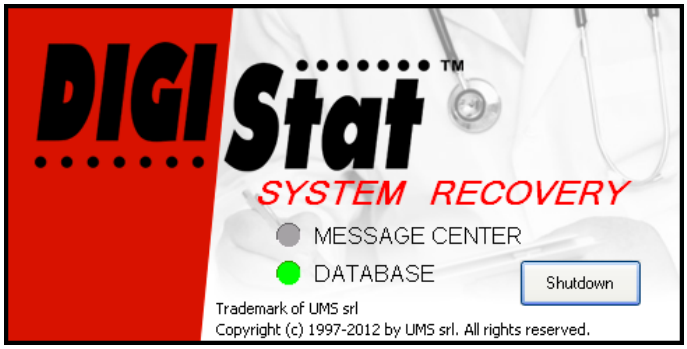


Fig 2

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 6 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.

UMS offers full support for the definition of the above mentioned procedure.

See paragraph 6 for the contacts list.

6. Contacts

- **UMS srl - United Medical Software**

Via di Mucciana 19, 50026 San Casciano in Val di Pesa (FI)
Tel. (+39) 055 0512161
Fax (+39) 055 8290392

- **Technical assistance**

support@unitedms.com

800999715 (toll free, Italy only)

- **Sales and products information**

sales@unitedms.com

- **General info**

info@unitedms.com

7. “Control Bar” and DIGISTAT® environment

7.1. 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.

7.1.1. 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

7.1.2. 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.

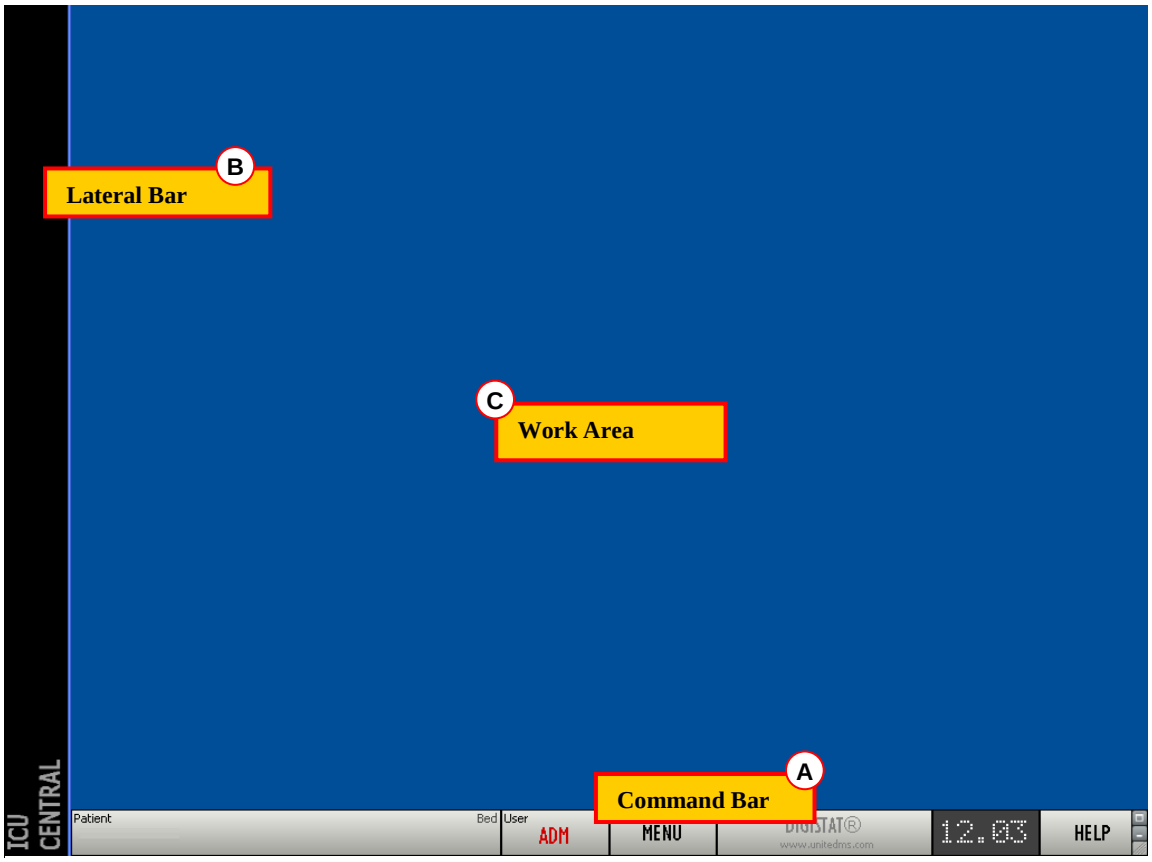


Fig 5 - Control Bar

The command bar (Fig 5 **A**) will be described in paragraph 7.1.3 (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 - Two available modules

The module currently selected is highlighted (yellow).

7.1.3. 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 7.2).

7.2. 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 appears.

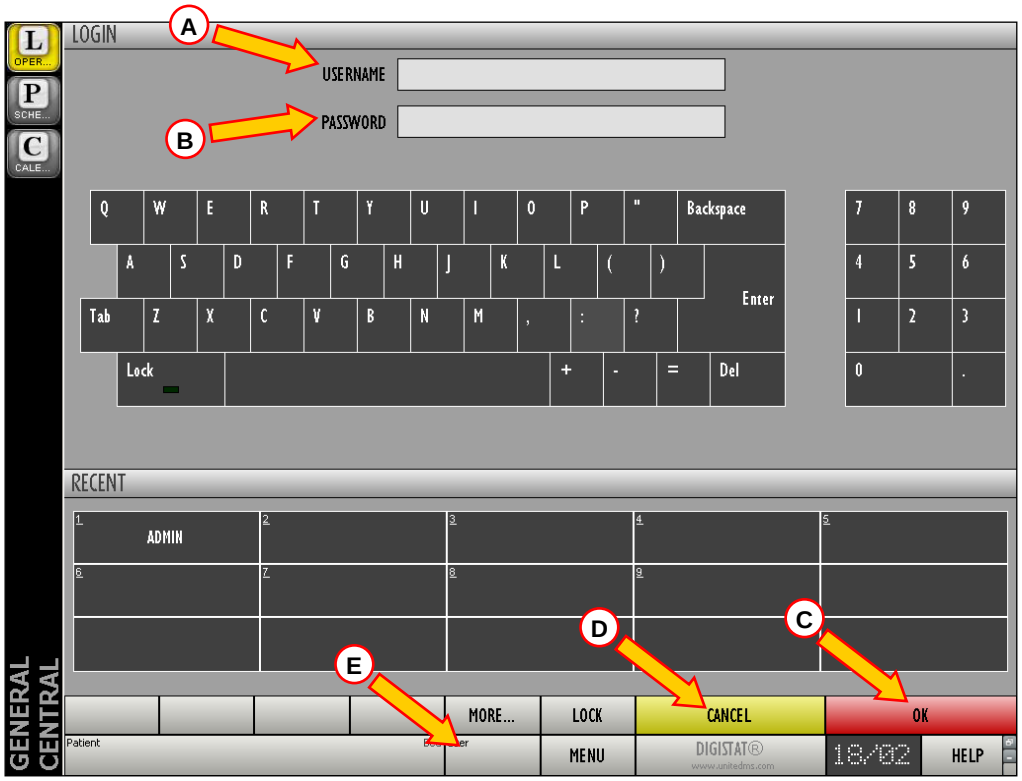


Fig 7 – Access to the system

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 – User connected

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.

7.2.1. 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 - Barcode reader (example)

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.

7.2.2. 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 – Control Bar

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

Fig 11 – User Locked

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

7.2.3. 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.

7.2.4. 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 – Opening the “User List”

To display the “User List”,

- click the MORE button.

The following window appears (Fig 14).

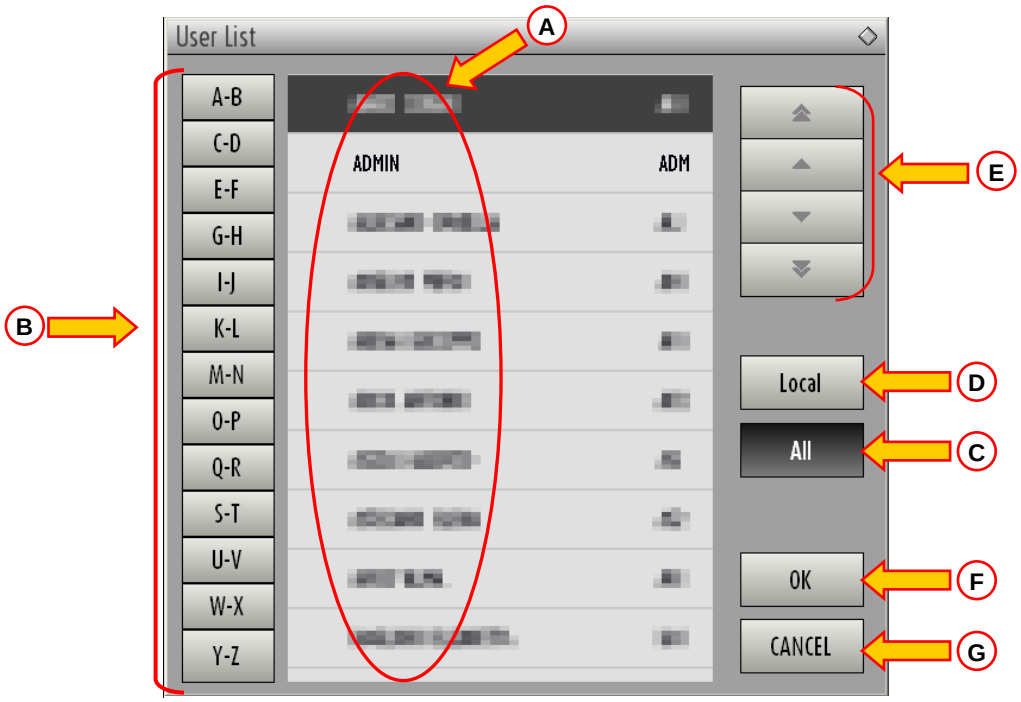


Fig 14 – User List

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.

7.3. 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 - Control Bar

- 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 – Main Menu

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

- The display indicated in Fig 15 **D** alternately shows the current date and time.
- Use the HELP button (Fig 15 **E**) to access the on-line documentation available.
- The small buttons highlighted in Fig 15 **F** 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.

- The button quoting the DIGISTAT® brand name and the UMS srl web address (Fig 15 **G**) 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.

7.3.1. 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.

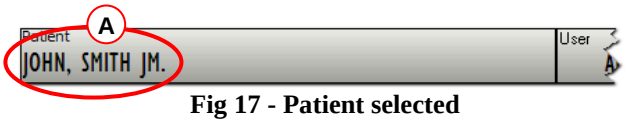


Fig 17 - Patient selected

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 - Patient Admitted

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.

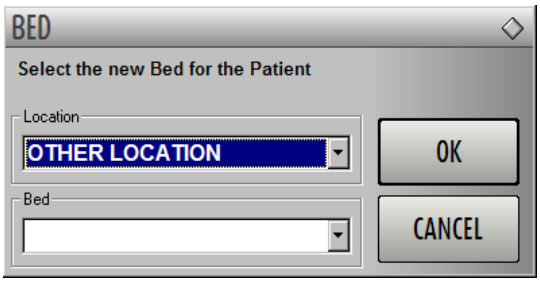


Fig 21 - Bed selection window

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

Workstation locked to bed

When the  icon is displayed alongside the patient name, it means that the workstation is locked to that specific bed, i.e. it only displays data relating to a single bed specified by configuration (Fig 22).

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.

7.4. Help

Click the HELP button on Control Bar (Fig 15 **E**) to access the on-line documentation available. The page shown in Fig 23 will open.

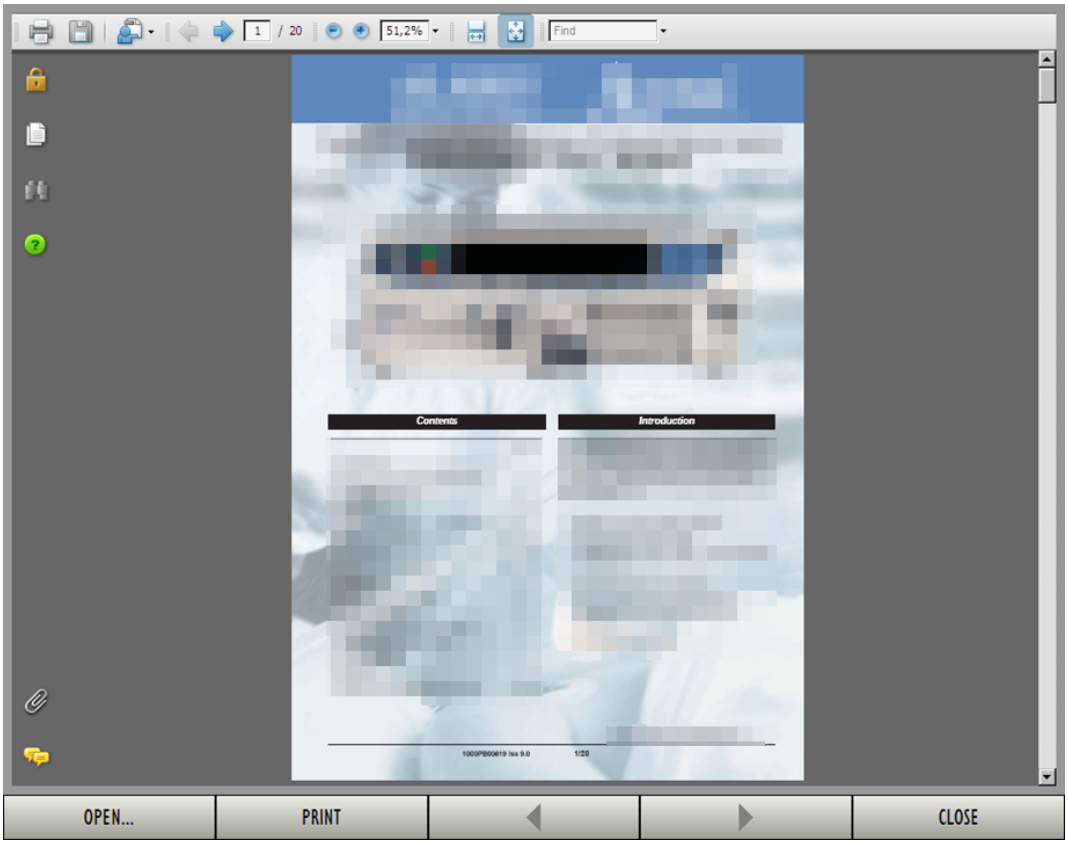


Fig 23

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  button closes the on-line help.

7.5. DIGISTAT® Main Menu

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

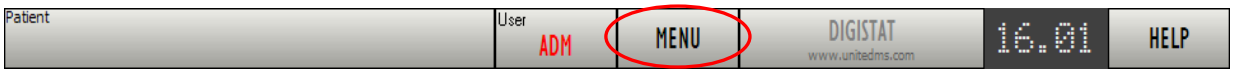


Fig 25

opens a menu containing several options (Fig 26).

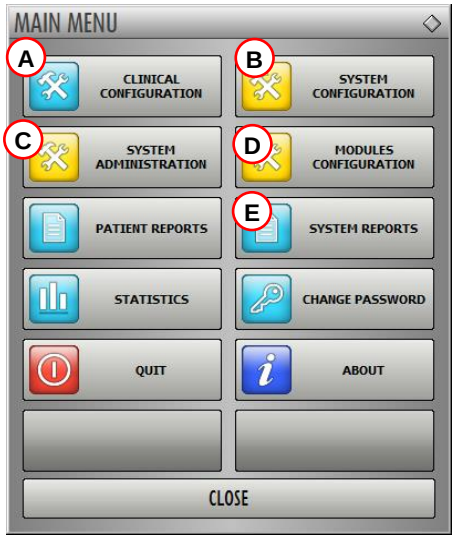


Fig 26 - Configuration functions

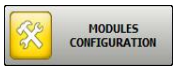
Each button on the menu accesses a specific set of functions.

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

 - (Fig 26 **A**)

 - (Fig 26 **B**)

 - (Fig 26 **C**)

 - (Fig 26 **D**)

- (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.

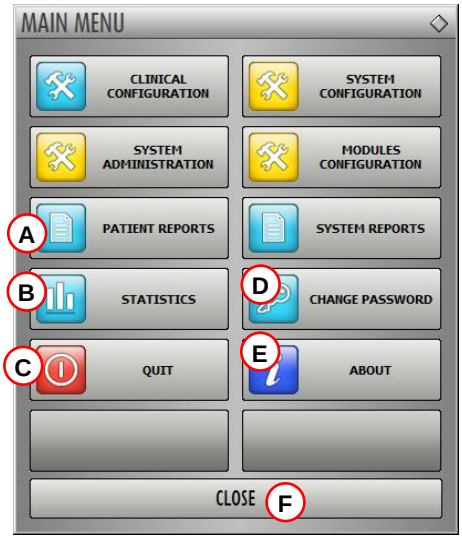


Fig 27 - Functions for the user

- (Fig 27 **A**, paragraph 7.5.1)

- (Fig 27 **B**, paragraph 7.5.3)

- (Fig 27 **C**, paragraph 7.5.6)

- (Fig 27 **D**, paragraph 7.5.4)

- (Fig 27 **E**, paragraph 7.5.5)

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

7.5.1. Patient reports

The “Patient reports” button - 

(Fig 27 **A**) - accesses 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 - Patient reports

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.

7.5.2. 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 (for example 

).

A print preview will open (Fig 29).

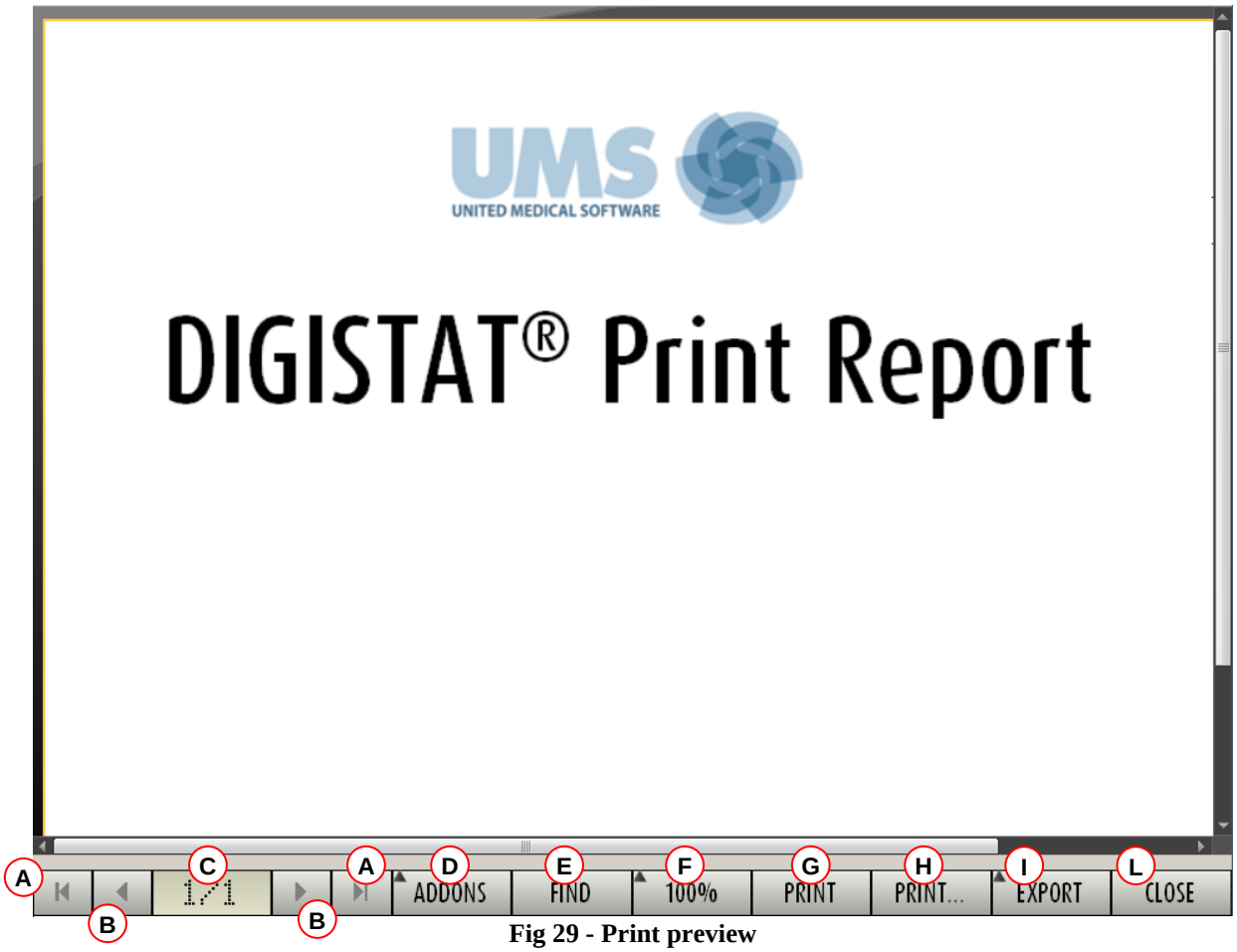


Fig 29 - Print preview

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  button (Fig 29 **D**) activates the possible additional print management options (in this configuration the "Watermarks" option is available - see paragraph 7.5.2.1 for a description of these options).

E - The  button (Fig 29 **E**) makes it possible to search the displayed document. See paragraph 7.5.2.2 for more instructions.

F - The  button (Fig 29 **F**) is a zoom, making it possible to change the display mode. See paragraph 7.5.2.3 for more instructions.

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

H - Use the PRINT... button (Fig 29 **F**) to display the print options window (Fig 36). See paragraph 7.5.2.4 for a description of this window and the related procedures.

I - Use the EXPORT button (Fig 29 **G**) to export the document contents to different file extensions. See paragraph 7.5.2.5 for more instructions.

L - Use the CLOSE button (Fig 29 **H**) to close the "Print preview" screen.

7.5.2.1. Addons

The ADDONS button (Fig 29 **D**) activates the possible additional print management options.

To display the available options,

- Click the ADDONS button.

A menu opens upon it. In Fig 30 the "Watermark" option is available.

Fig 30

- Click the button corresponding to the functionality you want to activate.

Addons - Watermark

To add watermarks to the print report (either text or image),

- Click the MARK button.

The following window is displayed (Fig 31).

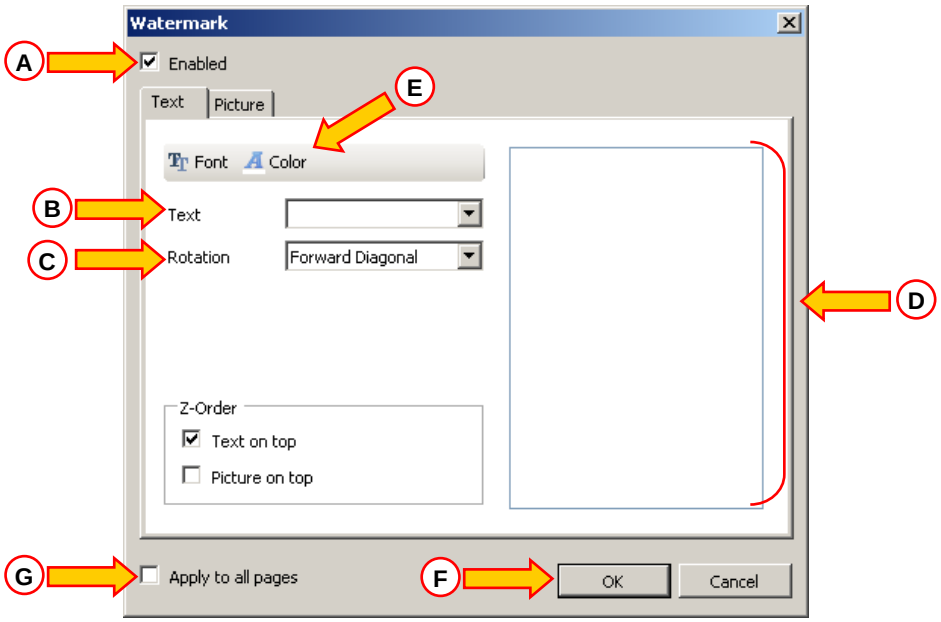


Fig 31

To add a textual watermark,

- Ensure that the "Enabled" checkbox is checked (Fig 31 **A**). If not, the window's contents cannot be edited.
- Insert the text in the "Text" field (Fig 31 **B**).
- Use the "Rotation" menu (Fig 31 **C**) to specify the watermark orientation (diagonal, horizontal, vertical).

A print preview is displayed in the area indicated in Fig 31 **D**.

- Use the buttons indicated in Fig 31 **E** to select the watermark font and color.
- Click the OK button (Fig 31 **F**).

The text is this way inserted as watermark.

If the "Apply to all pages" checkbox is selected (Fig 31 **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 32 **A**.

The following window is displayed (Fig 32).

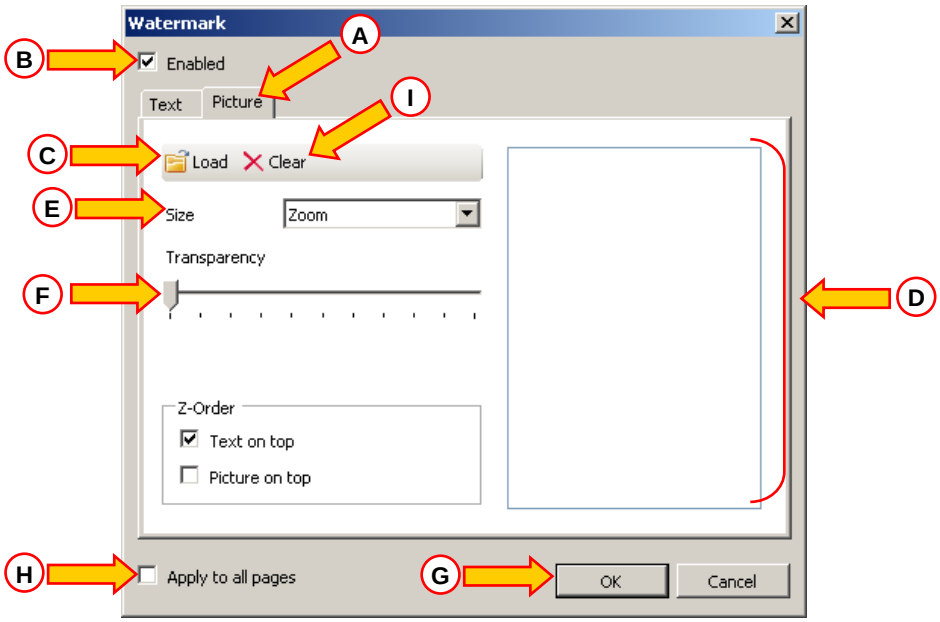


Fig 32

Follow these steps to insert an image as watermark,

- Ensure that the "Enabled" checkbox is checked (Fig 32 **B**). If not, the window's contents cannot be edited.
- Click the "Load" button indicated in Fig 32 **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 32 **D**.

- Use the "Size" drop-down menu to set the size of the image (Fig 32 **E**).
- Use the "Transparency" cursor to set the transparency level of the watermark image (Fig 32 **F** - maximum transparency when the cursor is aon the left).
- Click the OK button (Fig 32 **G**).

The watermark image is this way inserted.

If the "Apply to all pages" checkbox is selected (Fig 32 **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 32 **I**.

7.5.2.2. 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 33).

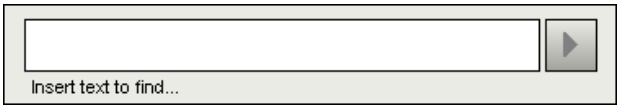


Fig 33

- Insert in the window the text to be found in the print report (Fig 34 **A**).

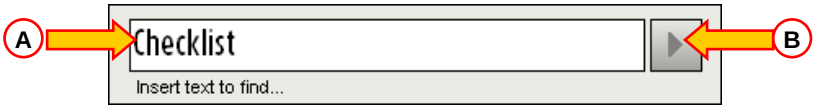


Fig 34

- Click the button (Fig 34 **B**).

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

- Click the button again to search for the following instances of the text.

7.5.2.3. Zoom

The 100% button (Fig 29 **F**) is a zoom, making it possible to change the display size and mode.

To change the display mode,

- click the 100% button. The following menu is displayed (Fig 35).

Fig 35

- 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 100% button on the command bar after selection.

7.5.2.4. 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 36)

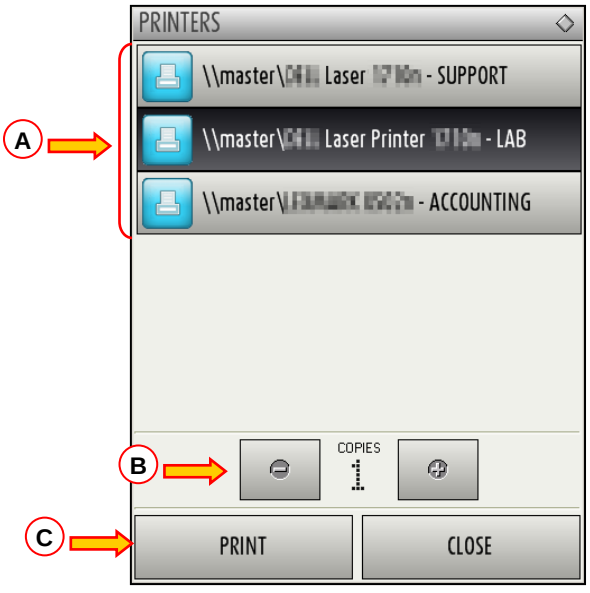


Fig 36

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 36 **A**).

- Use the  (one less copy) and the  (one more copy) buttons to specify the number of copies (Fig 36 **B**).

- Click the  button (Fig 36 **C**) to print the report.

7.5.2.5. Export

The  button (Fig 29 **I**) makes it possible to export the displayed document contents to different file extensions.

- Click the  button to display the following menu (Fig 37).

Fig 37

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.

7.5.3. Statistics

The 

button on the main menu (Fig 38) makes it possible to access the system's statistical calculation tools.

Fig 38

The button opens another menu (Fig 39) 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 7.5.3.1.

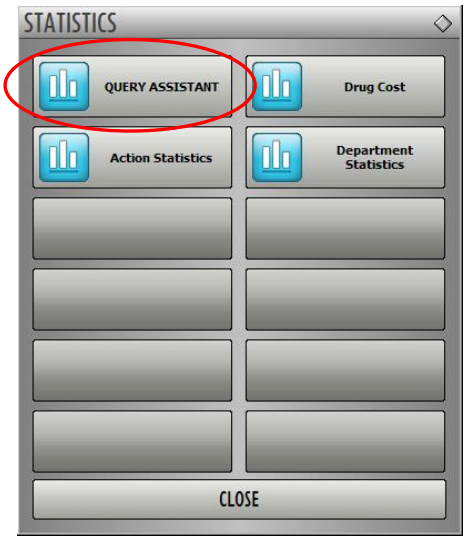


Fig 39

7.5.3.1. Query Assistant

The 

button (Fig 39) accesses a tool making it possible to create, save and execute queries on the DIGISTAT® database (Fig 40).

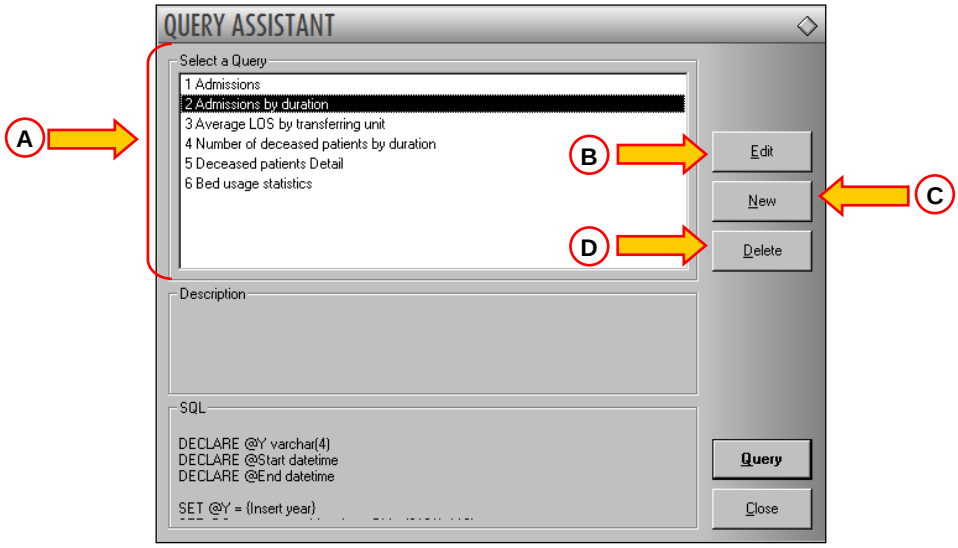


Fig 40 - Query Assistant

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 40 **A**).

To run a query

- click the corresponding name on the list,

The name will be highlighted (Fig 41 **A**).

A textual description of the query is displayed in the "Description" area (Fig 41 **B**).
The "SQL" area (indicated in Fig 41 **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.

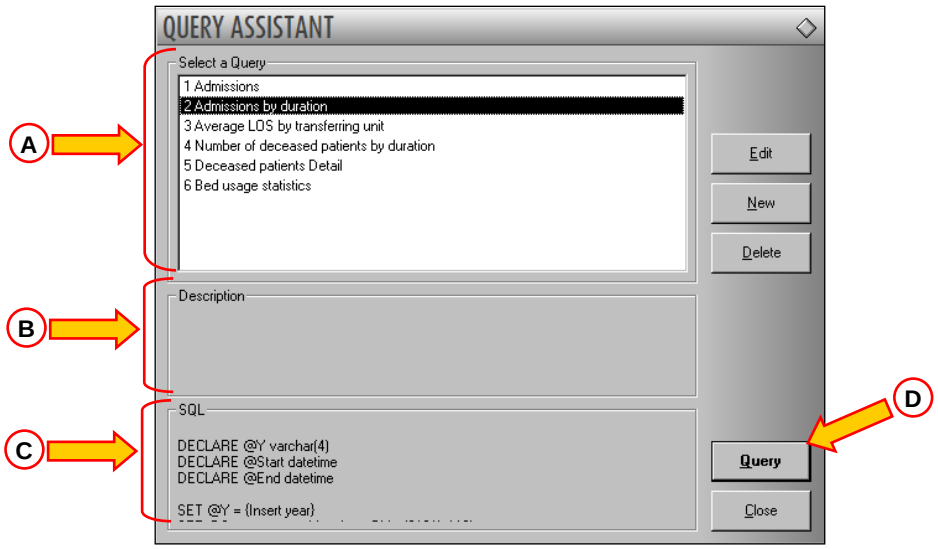


Fig 41 - Selected query

To run the query

- click the QUERY button (Fig 41 **D** - bottom-right).

The results are displayed in a new window, as a table (Fig 42).

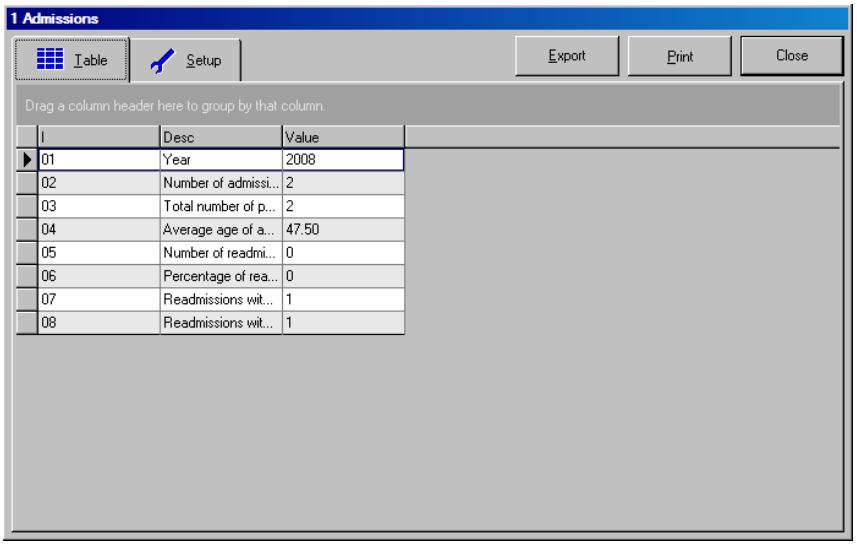


Fig 42 - Results

The EDIT button placed on the right of the "Query Assistant" window (Fig 40 **B**) makes it possible to edit an existing query.

The NEW button placed on the right of the "Query Assistant" window (Fig 40 **C**) makes it possible to create a new query.

The DELETE button placed on the right of the "Query Assistant" window (Fig 40 **D**) makes it possible to cancel an existing query.

7.5.4. Change password

The 

button on the DIGISTAT® main menu (Fig 43 **A**) opens a window making it possible to change the password of the user currently logged to the system.

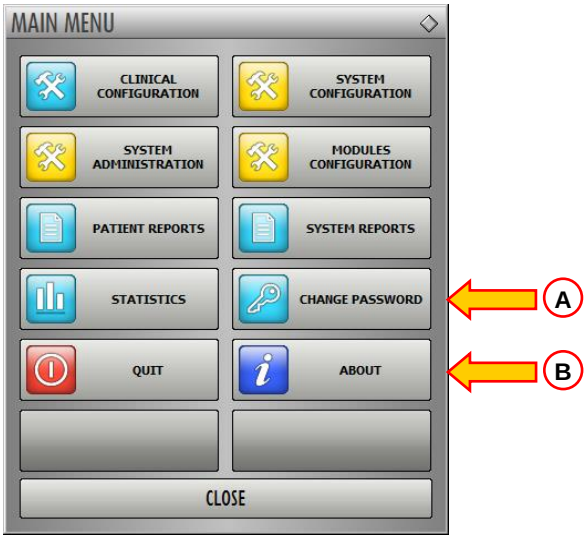


Fig 43

To change the user password

- click the 

button (Fig 43 A).

The "Change password" window will open.

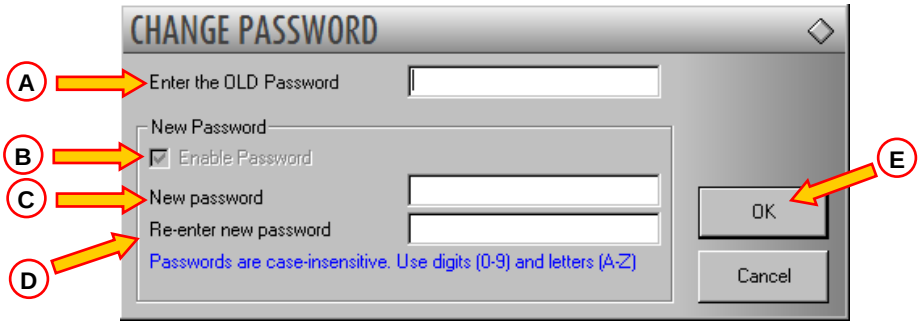


Fig 44 - Change password

- Type the current password in the "Enter the OLD password" field (Fig 44 **A**).
- Verify that the "Enable password" checkbox (Fig 44 **B**) is selected.
- Type the new password in the field indicated in Fig 44 **C**.
- Type again the new password in the field "Re-emter new password" (Fig 44 **D**).
- Click the OK button (Fig 44 **E**).

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

7.5.5. About DIGISTAT®

The 

button on the DIGISTAT® main menu (Fig 43 **B**) displays a window containing information on the DIGISTAT® version installed and the related licences (Fig 45).

Fig 45

7.5.6. Quit DIGISTAT®

The 

button on the DIGISTAT® main menu (Fig 47 **A**) makes it possible to quit the DIGISTAT® environment.

To quit DIGISTAT®

- click the MENU button on the control bar (Fig 46).

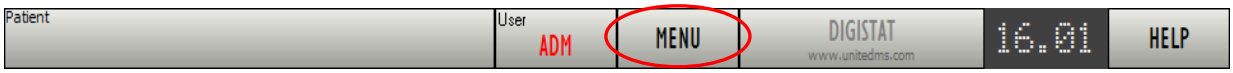


Fig 46

The DIGISTAT® main menu will open (Fig 47).

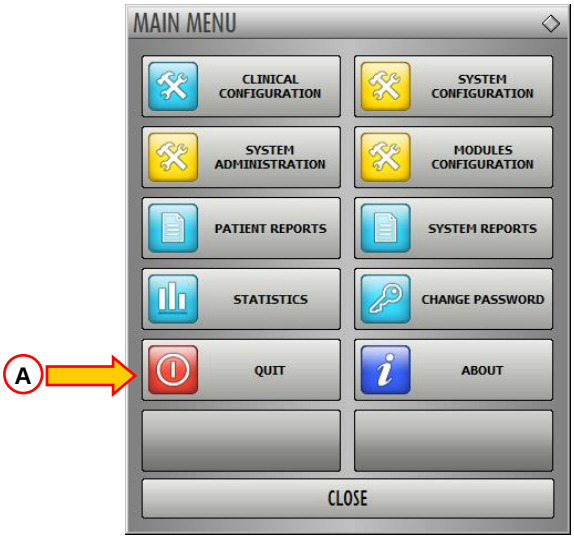


Fig 47 - Main menu

- Click the QUIT button (Fig 47 **A**).

Another menu is displayed (Fig 48).

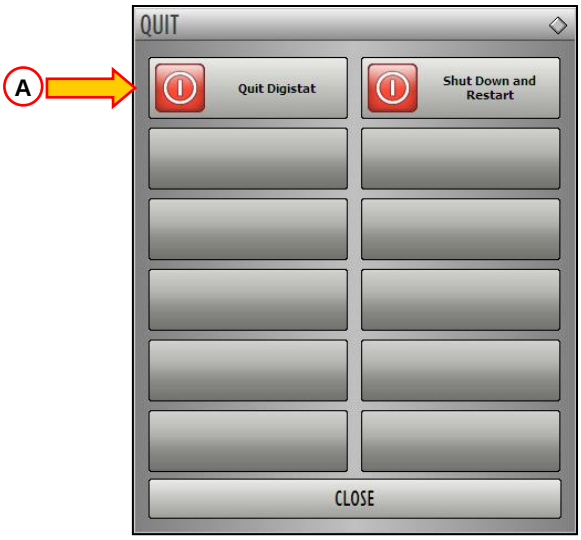


Fig 48

- Click the QUIT button again (Fig 48 **A**).

A confirmation is requested (Fig 49).

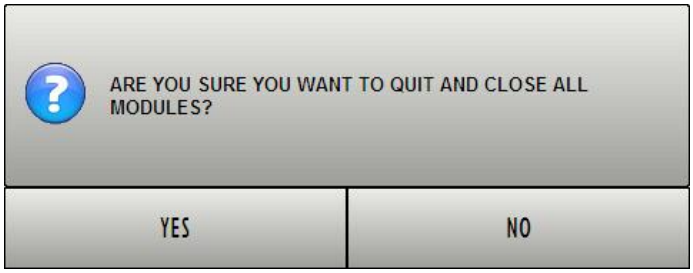


Fig 49

- Click YES to exit DIGISTAT®.

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

7.6. Side toolbar

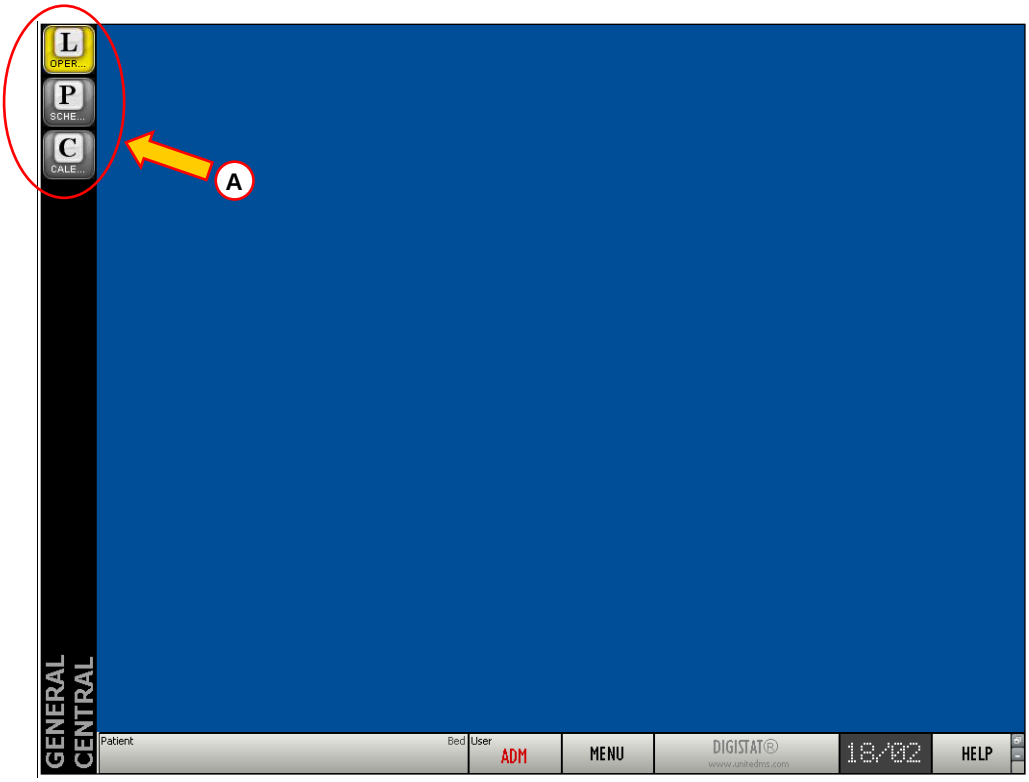


Fig 50- Side Toolbar

When the system is operating, the icons relating to the installed modules are displayed on the side toolbar on the left of the screen (Fig 50 **A**, Fig 51).

Fig 51 – Module icons

The icons on the side toolbar represent the available modules.

To activate one of the system modules

- click the corresponding icon on the side toolbar (Fig 51).

The icon corresponding to the currently selected module is highlighted yellow  .

7.7. 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 52).

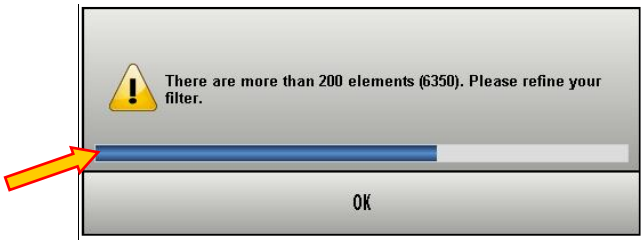


Fig 52 – Timer window with single option

This type of window is generally used to issue warnings or error messages to the user. The bar indicated in Fig 52 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 53).

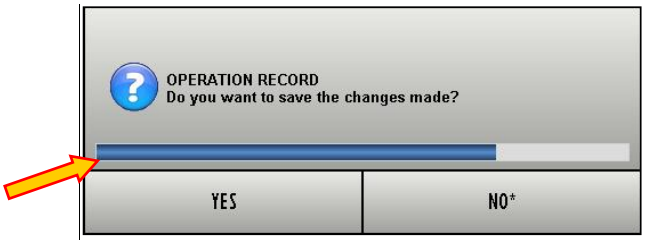


Fig 53 – Timer window with Yes/No choice

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 53 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 54).

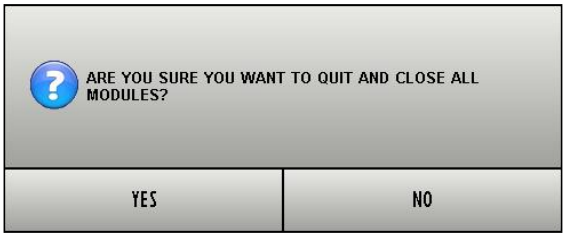


Fig 54 – Window without timer with double choice

The window shown in Fig 54, 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 55)

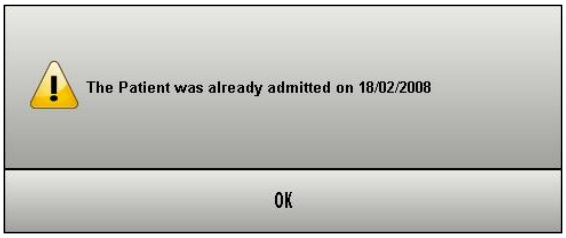


Fig 55 – Window without timer with single option

The window shown in Fig 55 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 UMS referent as soon as possible, for reporting and clarity improvement purposes.

8. On Line

8.1. Introduction

The DIGISTAT® "On Line" module manages the large amount of incoming data from the medical devices connected to the patient (monitor, ventilator, BGA etc.) and from the laboratory.

Virtually any medical device equipped with an interface for pc (RS-232, Ethernet or other) and a documented, available communication protocol can be connected to DIGISTAT® "On Line" and therefore communicate its data drectly to the patient record.

The workload of the medical staff is this way diminished, being both instrumental and laboratory data collection, summary and correlation authomatized

Moreover, automatic data acquisition helps reducing the manual documentation errors.

8.1.1. Data display

The information managed by the "On Line" module can be viewed as either tables or charts.

The different module's screen are widely configurable: several display windows can be created and configured with the needed items (tables and/or charts).

The specific kind of data acquired and the sample rate are configurable.

Information acquired by other DIGISTAT® modules (for example Therapy or Infusion) can be automatically displayed.

Specific configuration parameters make it possible to select the colours of the different items displayed on the various screens (i.e. backgrounds, fonts, tables, charts etc…). This feature makes it possible to customize the system according to the preferences and the needs of the specific structures using it. The figures shown in this manual can therefore display different colors from those actually in use in your structure. Refer to your system administrator for further information.

8.1.2. Data acquisition

Data can be acquired in two ways:

1) parameters can be manually entered by the user (see paragraph 8.8.5 for the procedures related to manual data entry);

2) data can be automatically acquired by the system.

Automatic acquisition is reserved for parameters generated by interfaceable medical equipment (ventilators, monitors, laboratory instruments), or by a central laboratory.

These data, automatically acquired and inserted in the DIGISTAT® database, can contain "artifacts" (caused, for example, by sudden patient movements, by accidental disconnections etc.). Therefore, the clinical staff has to check, evaluate and accept these data. Data this way filtered are "validated". The validation procedure is summarized in paragraph 8.9.

8.2. Module selection

To select the "On line" module:

- click the corresponding icon on the lateral bar (Fig 56).

Fig 56

A screen analogous to that shown in Fig 57 appears. In Fig 57 no patient is selected, therefore the screen contains no data.
When a patient is selected the screen contains the selected patient's data.

The DIGISTAT® "On Line" module is widely configurable. The screens shown in this manual can therefore be different from those in use in your Healthcare Structure.
The procedures and the functionalities of the "On Line" module, described in this manual, remain the same in every configuration. What changes is the way the various screens appear and the specific contents (for instance the kind of data considered).

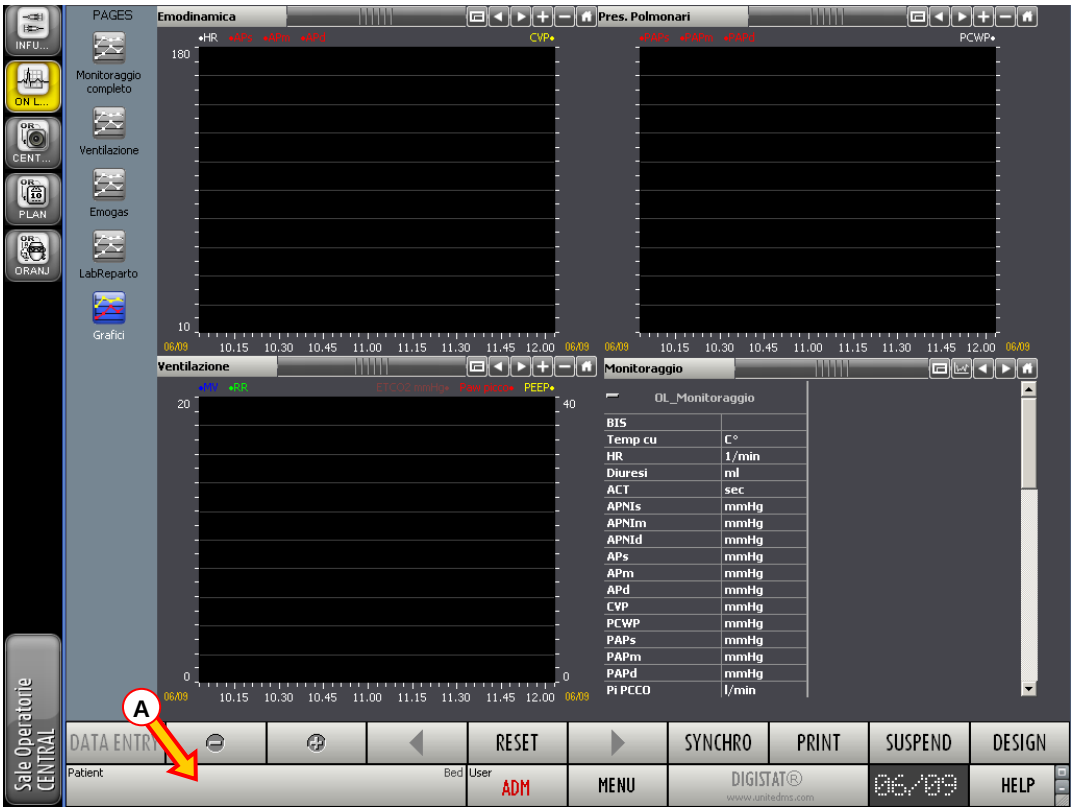


Fig 57 - Example of data display screen - no patient selected

8.3. Patient selection

To select a patient, if you are using for this purpose a DIGISTAT® software,

- click the PATIENT button on the Control Bar (Fig 57 **A**)

The DIGISTAT® Patient Explorer module opens if the module is present in the system in use; otherwise the patient search and selection functions are accomplished by Control Bar. See the related technical documentation to know the specific search and selection procedures.

If the software in use is not a DIGISTAT® software see the related documentation.

If your Healthcare Structure doesn't use a DIGISTAT® software for the patient search and selection, please refer to the specific related documentation.

When a patient is selected the module displays the data of the selected patient.

8.4. Data display screen structure

The screen shown in Fig 58 dispalys in chart and tables the data acquired. This is the "Data display" screen of the "On line" module. It is widely configurable, i.e. the number and kind of charts and tables displayed depend on the user needs. Nonetheless the structure of the screen is fixed.
This section describres the page structure, that is formed of three main parts:

1) the list of selectable pages (Fig 58 **A**);
2) the "data display" area (displaying the chart and tables - Fig 58 **B**);
3) the command bar (Fig 58 **C**).

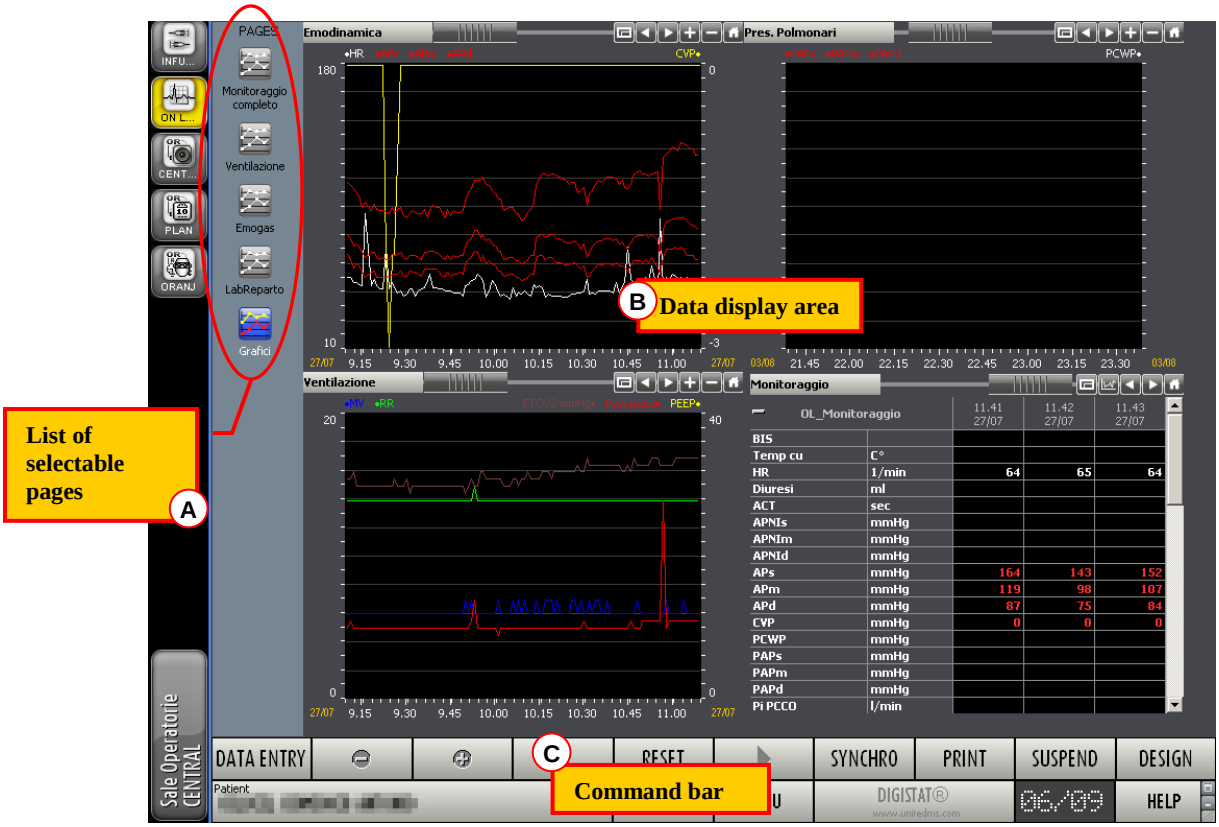


Fig 58 - Data display screen - Patient selected

8.5. List of selectable pages

The vertical area on the left (Fig 58 **A**, Fig 59) displays the list of all the available pages in the configuration in use.

The number and kind of selectable pages is configurable. Many features of each page (as the parameters displayed, the number of charts and tables on it etc…) are decided according to the user needs.

Fig 59 - Selectable pages

Each page is indicated by an icon and a name (the names shown in the figure are “Monitoraggio completo”, “Ventilazione” and “Emogas”).

The icon corresponding to the page currently displayed is highlighted - 

.

To select a page,

- click the corresponding icon.

The selected page appears on the “data display” area (Fig 58 **A**).

8.6. “Data display” area

The “data display” area is the central part of each screen. Charts and tables are here displayed.

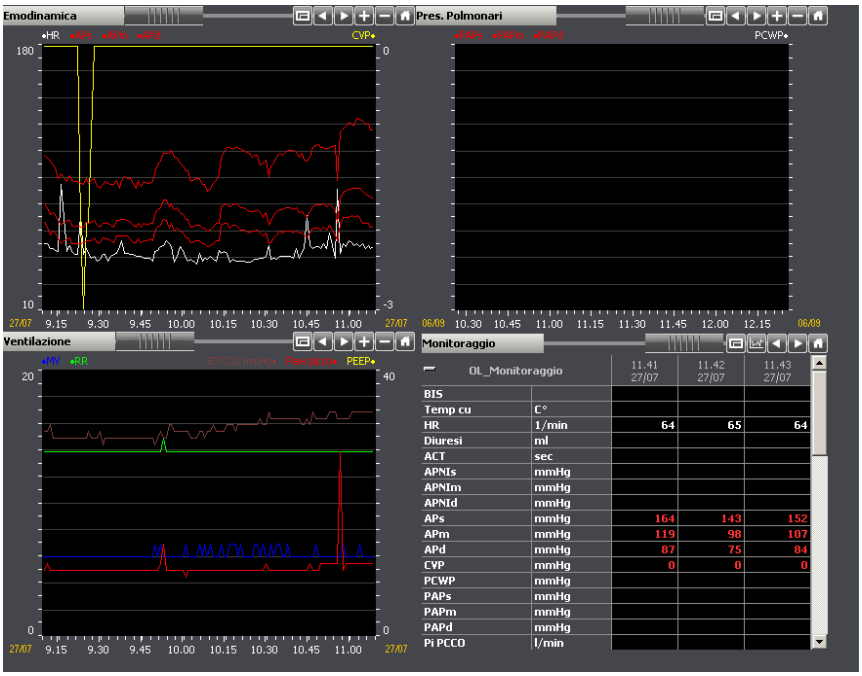


Fig 60 - Data display area

8.6.1. Charts

The “On line” module makes it possible to display in charts the trends of selected parameters.

This section provides the user with the instructions to read the module’s charts.

8.6.1.1. Chart general structure

The horizontal axis of the chart represents time. The time unit of measure (days, minutes, hours) depends on the length of the time span represented on the chart.

The vertical axis indicates the value of the represented parameters.
Two scales of values can be used: one on the left (Fig 61 **A**, going from 0 to 20 in the example); one on the right (Fig 61 **B**, from 0 to 40, in the example). The names of the represented parameters are displayed above the chart. On the left are displayed the names of the parameters whose values can be read on the left (in Fig 61 these are “MV” and “RR”). On the right are displayed the names of the parameters whose values can be read on the right (in Fig 61 these are “ETCO2 Ven”, “Paw picco” and “PEEP”).

Fig 61

The color of the parameter name is the color of the corresponding chart. In Fig 62, for example, the charts of the parameters named “MV” and “RR” are drawn in blue and in green.

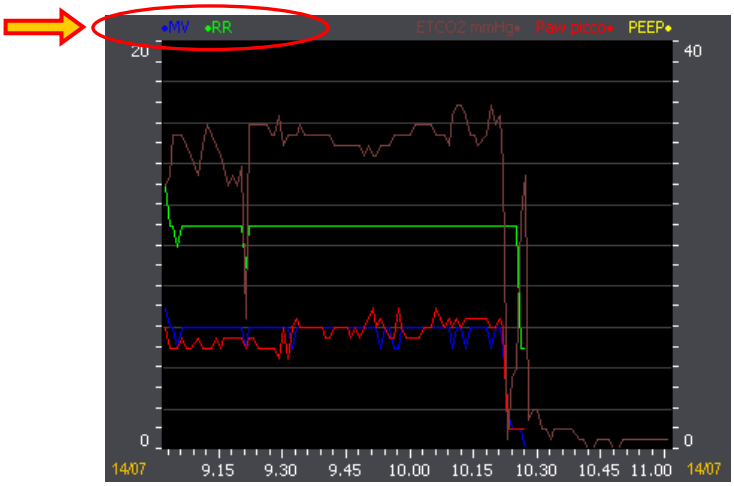


Fig 62

8.6.1.2. Charts command bar

Above every chart there is a command bar (Fig 63 **A**, Fig 64).

Fig 63 - Charts

The command bar makes it possible to change the chart display mode. The functions of the different buttons are described below.

Fig 64 - Command bar

- The chart's name is displayed on the left, in the box highlighted in Fig 64 **A**. The name in the example is "Ventilazione".

 - This object, indicated in Fig 64 **B**, is named "rollbar". It makes it possible to move back and forth on the time axis. Drag the rollbar to the left to display a chart area referring to a preceding time; drag the rollbar to the right to display a chart area referring to a subsequent time.

The buttons highlighted in Fig 64 **C** make it possible to perform the following actions:

 - **Full screen display** - Use this button to display the chart in "full screen" mode. A second click brings the chart back to the original proportions.

 - **Back** - Use this button to display a chart portion referring to a time preceding the time currently displayed.

 - **Forward** - Use this button to display a chart portion referring to a time following the time currently displayed.

 - **Enlarge** - Use this button to select an area to be enlarged on the chart. To do that,

- click the  button.
- Move the mouse pointer on the chart.

The mouse pointer changes to: 

- Click the point corresponding to the left limit of the area to be enlarged.

On the chart a vertical bar appears, indicating the left limitselected point. The corresponding time is indicated under the bar.

- Click the point corresponding to the right limit of the area to be enlarged.

The area comprised between the clicked points is this way enlarged in the chart

 - **Minimize** - Use this button to minimize the displayed chart. The time span displayed increases while the chart appears smaller.

 - **Original proportions** - Use this button to bring the chart back to the proportions it had before any change was performed in the display mode.

8.6.1.3. Chart cursor

- Click the chart area to display a yellow vertical line ("Chart cursor", Fig 65).

Fig 65 - Chart cursor

The time corresponding to the point indicated by the cursor can be read below the cursor itself (9:53, 23/06 in Fig 65 **A**; when the point corresponds to a date different from the current date the date is displayed as well).

On the bottom corners (either left or right, depending on the position of the cursor) several boxes appear, displaying the exact chart parameters values at the time indicated by the cursor (in Fig 65 **B**, for example, the parameter named "MV" has a 6 value, the parameter named "RR" has a 14 value etc… This means that those were the parameters values at 9:53 on the 23rd of June).
If the mouse pointer is dragged on the chart area keeping the left button clicked the values indicated by the cursor change with the movement.

- Click any point along the vertical axis to display a horizontal cursor. The values corresponding to the clicked point are displayed at the cursor extremities (Fig 66).

- Move the mouse pointer up or down keeping the left button clicked to drag the horizontal cursor. The values displayed change with the movement.

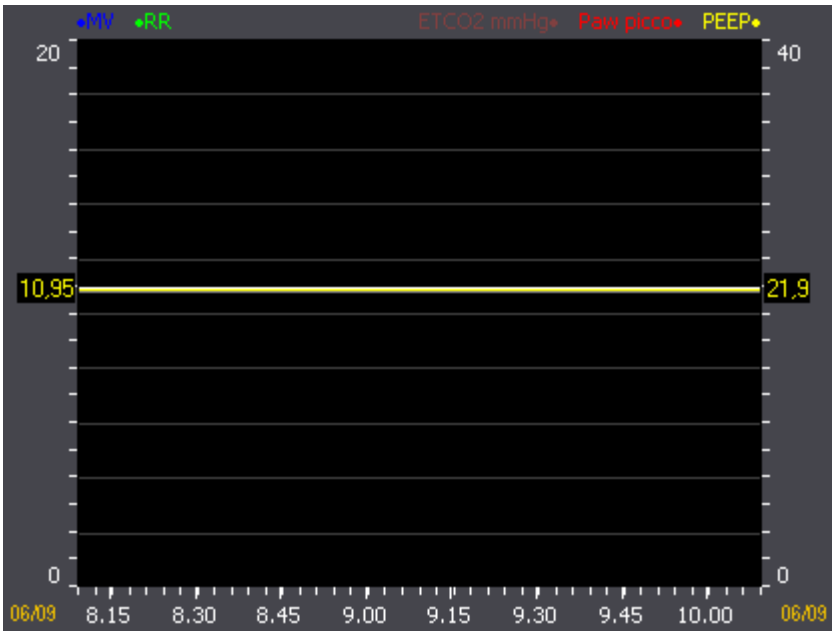
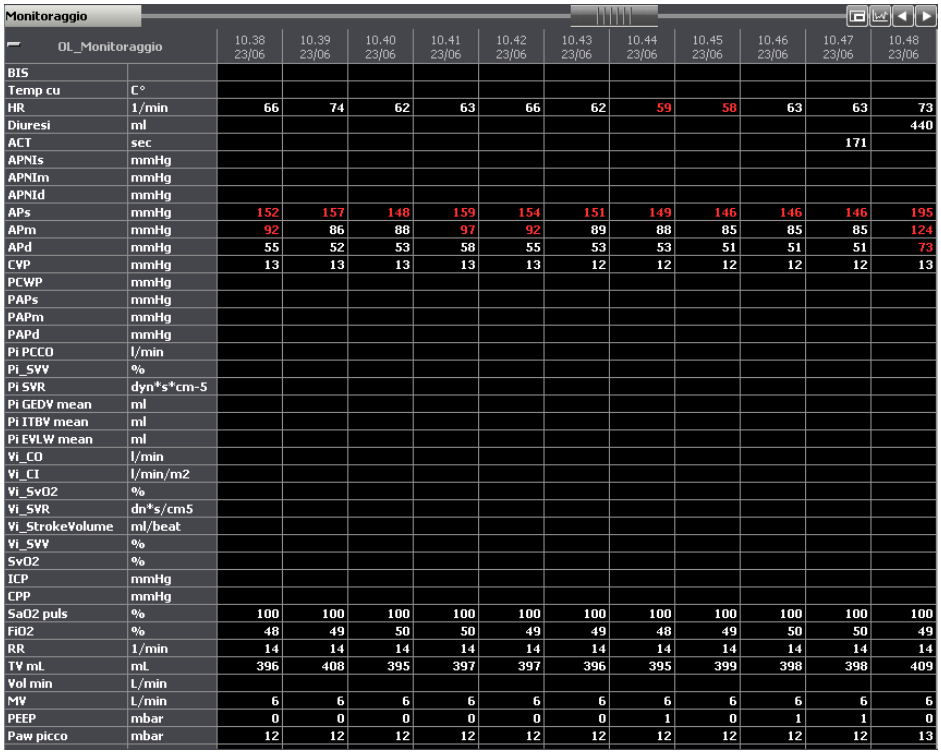


Fig 66 - Horizontal Cursor

When the SYNCHRO *button on the command bar is selected (Fig 83) one click on one of the charts on the page displays a cursor on all the charts (all cursors indicating the same time). Also, the corresponding column is highlighted on all the tables. See paragraph 8.6.3 for a more detailed description of the synchronization functionalities.*

8.6.2. Tables

The tables on the various pages contain textual and/or numeric data. Data can be either manually inserted by the user or automatically acquired by the system and later validated by the physician



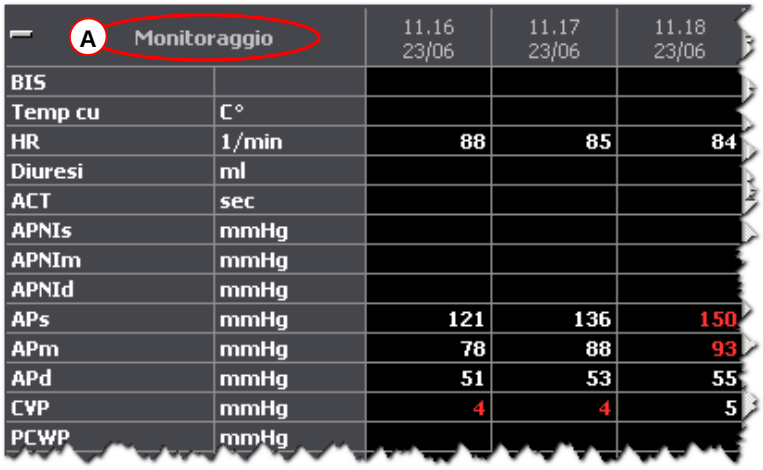
Monitoraggio

OL_Monitoraggio		10.38 23/06	10.39 23/06	10.40 23/06	10.41 23/06	10.42 23/06	10.43 23/06	10.44 23/06	10.45 23/06	10.46 23/06	10.47 23/06	10.48 23/06
BIS												
Temp cu	C°											
HR	1/min	66	74	62	63	66	62	59	58	63	63	73
Diuresi	ml											440
ACT	sec										171	
APNIs	mmHg											
APNIm	mmHg											
APNId	mmHg											
APs	mmHg	152	157	148	159	154	151	149	146	146	146	195
APm	mmHg	92	86	88	97	92	89	88	85	85	85	124
APd	mmHg	55	52	53	58	55	53	53	51	51	51	73
CVP	mmHg	13	13	13	13	13	12	12	12	12	12	13
PCWP	mmHg											
PAPs	mmHg											
PAPm	mmHg											
PAPd	mmHg											
Pi PCCO	l/min											
Pi_SVV	%											
Pi SVR	dyn*s*cm-5											
Pi GEDV mean	ml											
Pi ITBV mean	ml											
Pi EVLW mean	ml											
Vi_CO	l/min											
Vi_CI	l/min/m2											
Vi_SvO2	%											
Vi_SVR	dn*s/cm5											
Vi_StrokeVolume	ml/beat											
Vi_SVV	%											
SvO2	%											
ICP	mmHg											
CPP	mmHg											
SaO2 puls	%	100	100	100	100	100	100	100	100	100	100	100
FiO2	%	48	49	50	50	49	49	48	49	50	50	49
RR	1/min	14	14	14	14	14	14	14	14	14	14	14
TV mL	mL	396	408	395	397	397	396	395	399	398	398	409
Vol min	L/min											
MV	L/min	6	6	6	6	6	6	6	6	6	6	6
PEEP	mbar	0	0	0	0	0	0	1	0	1	1	0
Paw picco	mbar	12	12	12	12	12	12	12	12	12	12	13

Fig 67 - Table

8.6.2.1. Tables general features

The first column of each table displays, in the first cell on top, the name of the table. In Fig 68 **A** the name is “Mixed parameters”.



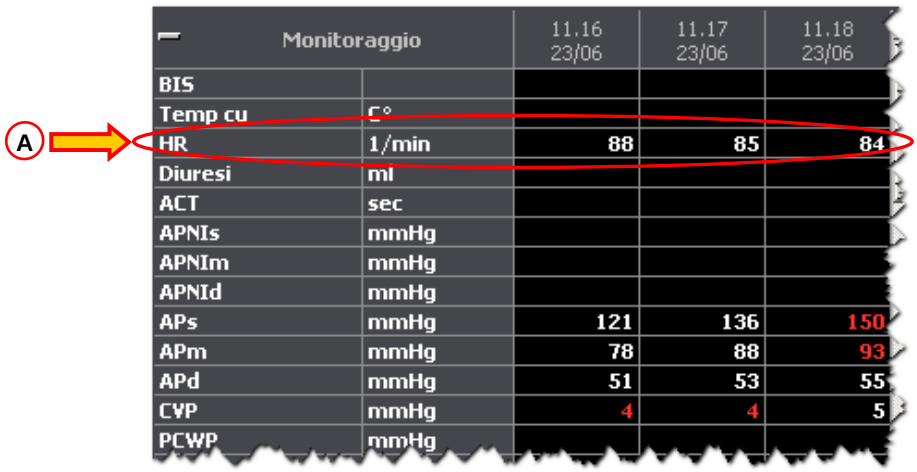
A Monitoraggio		11.16 23/06	11.17 23/06	11.18 23/06
BIS				
Temp cu	C°			
HR	1/min	88	85	84
Diuresi	ml			
ACT	sec			
APNIs	mmHg			
APNIm	mmHg			
APNId	mmHg			
APs	mmHg	121	136	150
APm	mmHg	78	88	93
APd	mmHg	51	53	55
CVP	mmHg	4	4	5
PCWP	mmHg			

Fig 68 - Table name and parameters

The cells placed beneath the title display the names of the relevant parameters considered (“BIS”, “Temp cu”, “HR”, “Diuresi” etc… in Fig 68).

The second column specifies, for each parameter, the unit of measure in use.

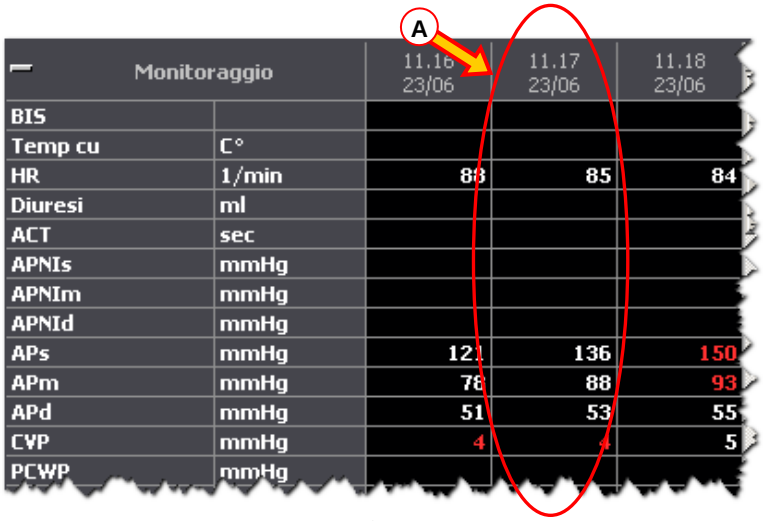
The values of a specific parameter can be read on the corresponding row. Therefore each row shows the way a specific parameter changes in time. In Fig 69 **A**, for example, the changes in the patient's heart rate are highlighted.



Monitoraggio		11.16 23/06	11.17 23/06	11.18 23/06
BIS				
Temp cu	C°			
HR	1/min	88	85	84
Diuresi	ml			
ACT	sec			
APNIs	mmHg			
APNIm	mmHg			
APNId	mmHg			
APs	mmHg	121	136	150
APm	mmHg	78	88	93
APd	mmHg	51	53	55
CVP	mmHg	4	4	5
PCWP	mmHg			

Fig 69

Each column corresponds either to a validation performed by the clinical staff or to a manual data specification.
The data specification and the data validation procedures are described in paragraph 8.9.



Monitoraggio		11.16 23/06	11.17 23/06	11.18 23/06
BIS				
Temp cu	C°			
HR	1/min	88	85	84
Diuresi	ml			
ACT	sec			
APNIs	mmHg			
APNIm	mmHg			
APNId	mmHg			
APs	mmHg	121	136	150
APm	mmHg	78	88	93
APd	mmHg	51	53	55
CVP	mmHg	4	4	5
PCWP	mmHg			

Fig 70

The cell on top of each column displays the time of data specification/validation (the date is specified when it's different from the current date). Each column displays the value of the specified parameters at a certain time. The column highlighted in Fig 70 **A**, for example, displays the values of all the parameters at 11.17 of the 23rd of June.

The button highlighted Fig 71 ( ) minimizes the table.

Fig 71

Click the button to minimize the table (as in Fig 72). Click the button to bring the table back to the original proportions.

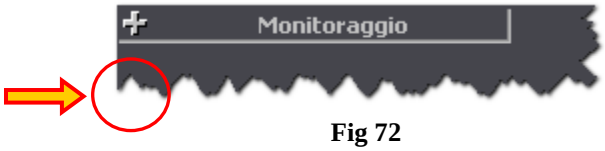


Fig 72

The same table can be divided in different sections. Fig 73 shows a table containing two distinct sections ("Venoso" and "Ventilazione"). The features and the procedures described since apply to each section of the table.

Venoso						
vHCO3	mMol/L					
vCO2	Vol %					
vpCO2	mmHg					
vpH						
vpO2	mmHg					
vSatO2	%					
vSBE	mMol/L					
Ventilazione		10.06 26/08	10.07 26/08	10.08 26/08	10.09 26/08	10.10 26/08
FiO2	%					
SaO2 puls	%	98	99	99	98	98
RR	1/min					
SIMV freq	1/min					
Vol min	L/min					
PEEP	mbar					
ETCO2 mmHg	mmHg					
PSup above PEEP	mbar					

Fig 73 - Two sections

Move the mouse pointer over the values on the table to display a tooltip containing information on the specific value (parameter name, date and time of specification, range of normality - when specified - Fig 74).

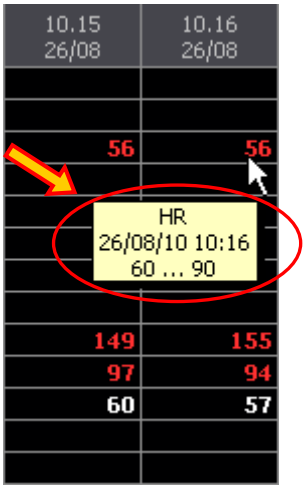


Fig 74

When a small red triangle is displayed on the top-left corner of a cell it means that the value is too long to be displayed entirely (Fig 75). The value is displayed completely in a tooltip when the mouse pointer is moved over the cell.

Fig 75 - Partial value

When a small yellow triangle is displayed on the top-left corner of the column heading (Fig 76) it means that there is a textual note associated to the data specified in the column. The note, together with the acronym of the user who added it, is displayed in a tooltip when the mouse pointer is passed over the specific column heading.

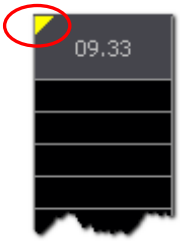


Fig 76 - Note

The red values on the table are out of the range of normality set by configuration (Fig 77).

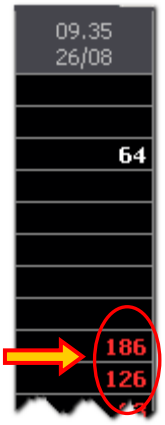


Fig 77

8.6.2.2. Parameter tables' command bar

A command bar is present above each table (Fig 78 **A**, Fig 79).

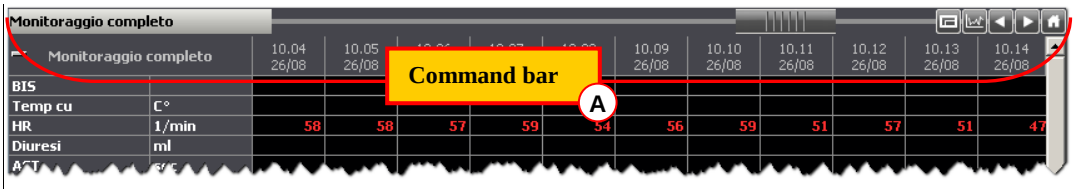


Fig 78 - Table

The command bar makes it possible to change the table display mode. The functions of the different buttons on the command bar are described below.

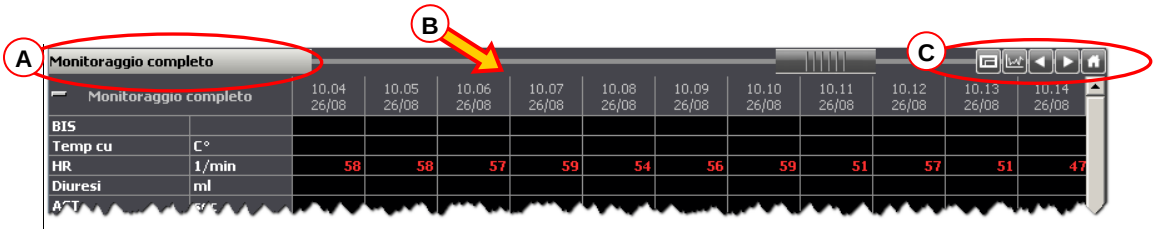


Fig 79 - Command bar

- On the left, in the box highlighted in Fig 79 **A**, is displayed the name of the table. The name in the example is "Monitoraggio completo" ("Complete monitoring").

- This object, indicated in Fig 79 **B**, is named "rollbar". It makes it possible to move back and forth on the table. Drag the rollbar to the left to display the columns referring to a time preceding the time currently displayed. Drag the rollbar to the right to display the columns referring to a time following the time currently displayed.

The buttons indicated in Fig 79 **C** make it possible to perform the following actions:

 - **Full screen display** - Use this button to display the table in "full screen" mode. A second click brings the table back to the original proportions.

 - **Back** - Use this button to display a table portion referring to to a time preceding the time currently displayed.

 - **Forward** - Use this button to display a table portion referring to a time following the time currently displayed.

 - **Original proportions** - Use this button to bring the table back to the proportions it had before any change was performed.

 - **Chart parameter picker** - Use this button to open a tool making it possible to rapidly crate a chart. This tool is described in paragraph 8.6.2.3.

8.6.2.3. Chart popup parameter picker

Click the  button placed above each table to open the tool displayed in Fig 80, named "Chart popup parameter picker".

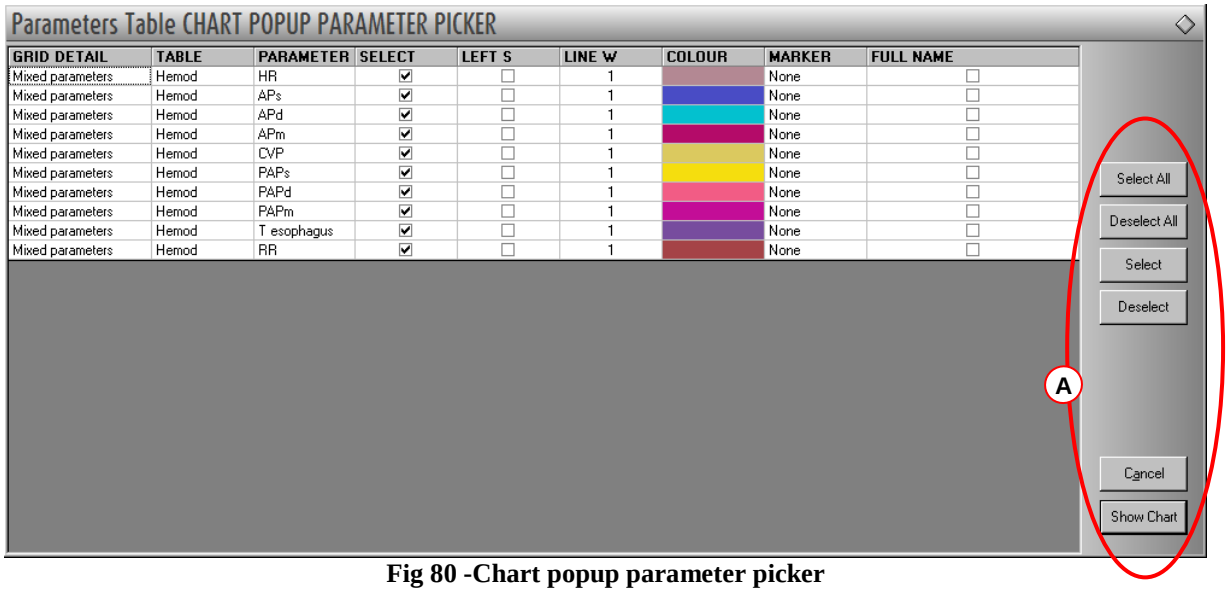


Fig 80 -Chart popup parameter picker

The "parameter picker" makes it possible to display in a separate popup window a chart that is entirely user-defined.

"Parameters picker" description

The "parameters picker" displays a table listing all the relevant parameters (Fig 81).

GRID DETAIL	TABLE	PARAMETER	SELECT	LEFT S	LINE W	COLOUR	MARKER	FULL NAME
Mixed parameters	Hemod	HR	☑	☐	1		None	☐
Mixed parameters	Hemod	APs	☑	☐	1		None	☐
Mixed parameters	Hemod	APd	☑	☐	1		None	☐
Mixed parameters	Hemod	APm	☑	☐	1		None	☐
Mixed parameters	Hemod	CVP	☑	☐	1		None	☐
Mixed parameters	Hemod	PAPs	☑	☐	1		None	☐
Mixed parameters	Hemod	PAPd	☑	☐	1		None	☐
Mixed parameters	Hemod	PAPm	☑	☐	1		None	☐
Mixed parameters	Hemod	T esophagus	☑	☐	1		None	☐
Mixed parameters	Hemod	RR	☑	☐	1		None	☐

Fig 81 - Parameters table

Each row corresponds to one of the parameters of the original table (i.e. the table on which the  button was clicked).

Grid detail
Table
Parameter — These three items identify the specific parameter

Select — Use this checkbox to specify whether representing or not the corresponding parameter on the chart you are creating.

Left S Check this box if you want to display the specific parameter scale of values on the left of the chart. Do not check it if you want to display it on the right.

Line W This cell specifies the width of the line drawn in the chart.

Colour This cell indicates the color of the line.

Marker This cell specifies whether a marker is drawn or not when the chart line changes direction. It is also possible to select the kind of marker (square, triangle, circle etc…).

Full name Check this box to display the parameter's full name on the chart.

On the the right of the "Parameters picker" window there are various buttons (Fig 80 **A**). These are their functionalities:

Select All selects all the parameters on the table.

Deselect All deselects all the parameters on the table.

Select makes it possible to select a chosen set of parameters. To do that:

- click the row corresponding to a parameter.

The row is this way highlighted.

- Move the mouse pointer either upwards or downwards keeping the left button clicked, until you reach a row corresponding to another parameter.

All the rows in between are this way highlighted.

- Click the Select button.

All the checkboxes corresponding to the highlighted lines are this way selected in the "Select" column on the table.

Deselect makes it possible to deselect a chosen set of (previously selected) parameters. To do that:

- click the row corresponding to a parameter.

The row is this way highlighted.

- Move the mouse pointer either upwards or downwards keeping the left button clicked, until you reach a row corresponding to another parameter.

All the rows in between are this way highlighted.

- Click the Deselect button.

All the checkboxes corresponding to the highlighted lines are this way deselected in the "Select" column on the table.

Use the Cancel button to abort the chart creation procedure and close the "Parameter picker" window.

Use the Show Chart button to display in a popup window the chart having the chosen features.

Chart creation procedure

To create a chart using the "parameters picker popup window"

- Click the  button.

The "Parameters picker popup window" opens (Fig 80).

- Select, on the parameters table (Fig 81), the parameters to be displayed (and specify their features).

- Click the Show Chart button.

A popup window containing the defined chart shows up. In the example shown in Fig 82 two parameters are displayed ("APs" in magenta and "HR" in green; two different markers were chosen).

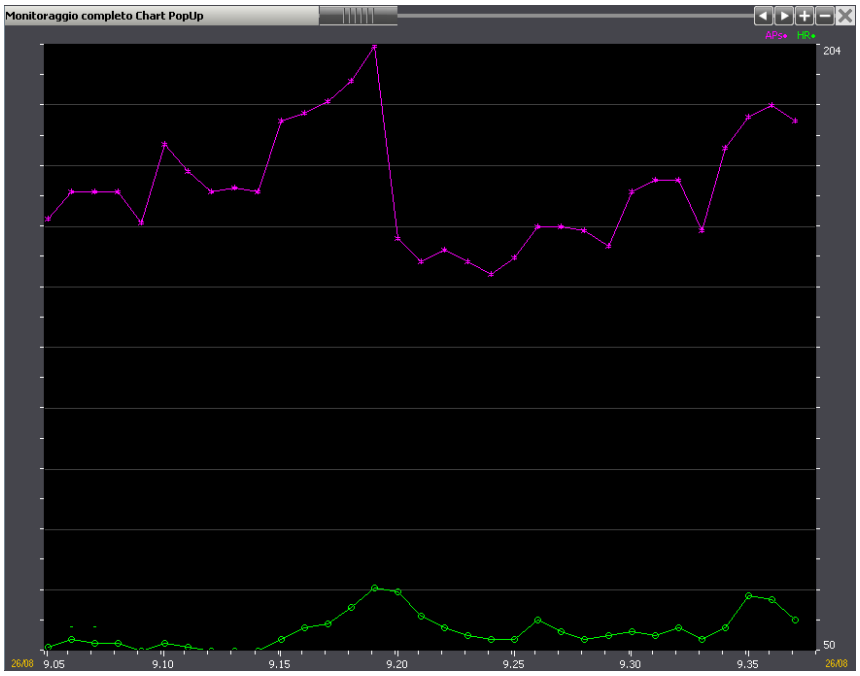


Fig 82 - Pop-up chart

The chart's command bar is described in paragraph 8.6.1.2.

8.6.3. Charts and tables sinchronization

It is possible to synchronize charts and tables.

The syncronization functionality is active when the SYNCHRO button on the command bar is selected (Fig 83).

Fig 83 - Command Bar

It is an ON/OFF button. When selected it looks like this: SYNCHRO.

Click it again to disactivate the charts and tables synchronization.

When the synchronization functionality is active, one click on one of the charts displays the chart cursor (the vertical yellow cursor, see Fig 65) on all the charts on the page. The cursors all indicate the same time. The column corresponding to the same time is highlighted on the possible tables on the same page.

No column is selected if, at the time corresponding to the cursor position on the chart, no data is available on the table.

Similarly, the selection of a column on a table displays the yellow cursor on all the charts on the page, in the position corresponding to the time specified on the column heading.

To selected a column on a table,

- click the column to be selected.

The column is this way highlighted (Fig 84).

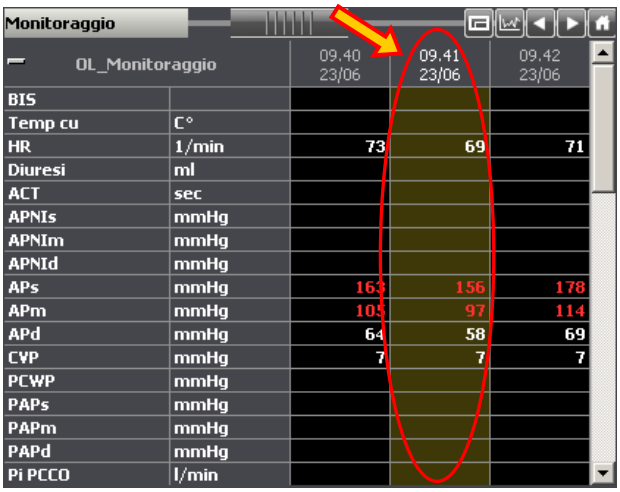


Fig 84 - Selected column

Fig 85 shows the synchronization between a chart and a table: the highlighted column, referring to the 09:41 of the 23rd of June, corresponds to the cursors in the charts.

Fig 85 - Synchronization between charts and tables

8.7. Main page command bar

The command bar of the "On line" module main page (Fig 86) is formed of several buttons. Each button makes it possible to perform a specific action. The various functionalities are listed in this paragraph. They are described in detail in the paragraphs indicated.

Fig 86 - Command bar

Use this button to access the "Data entry" screen (Fig 88), used both for manual data entry and data validation purposes.
The validation procedure makes it possible to control the data automatically acquired and to filter the possible artifacts.
The validation procedure is described in paragraph 8.9.

Use this button to double the time span displayed on the charts. If, for instance, 8 hours are displayed, one click on this button displays 16 hours.
This kind of change in the display mode is temporary. The chart goes back to the normal display mode if another page is accessed or another patient is selected.

Use this button to halve the time span displayed on the charts. If, for instance, 8 hours are displayed, one click on this button displays 4 hours.
This kind of change in the display mode is temporary. The chart goes back to the normal display mode if another page is accessed or another patient is selected.

Use this button to scroll back all the tables and the charts displayed on screen.

Use this button to scroll fortward all the tables and the charts displayed on screen.

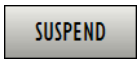
Use this button to bring the page back to its original display mode (scale, values). The page displays the latest values acquired (either manually or automatically).

Use this button to activate the charts and tables synchronization functionality. It is an ON/OFF button that remains selected once clicked.

The synchronization functionality is described in paragraph 8.6.3.

Use this button to access the system's print functionalities. See paragraph 8.10 for a description of these functionalities.

This button opens a tool making it possible to either design new pages or to modify the structure of the existing ones. These functionalities are reserved to the system administrators (or person with an equivalent permissions level). If the logged user is not allowed to access these functionalities the button is either absent or disabled.



Use this button to suspend the automatic data acquisition from the medical devices connected to the patient. See paragraph 8.11.

8.8. Manual data entry and data validation

The data automatically acquired from the medical devices can contain “artifacts” (caused, for example, by sudden patient movements, by accidental disconnections etc.). These data are called “raw data”. The clinical staff has to evaluate these “raw data” in order to either accept or refuse them. This paragraph describes the validation procedure.

Click the DATA ENTRY button on the main screen command bar (Fig 87) to access the data entry and validation functionalities.

Fig 87 - Command bar

The following screen opens (Fig 88):

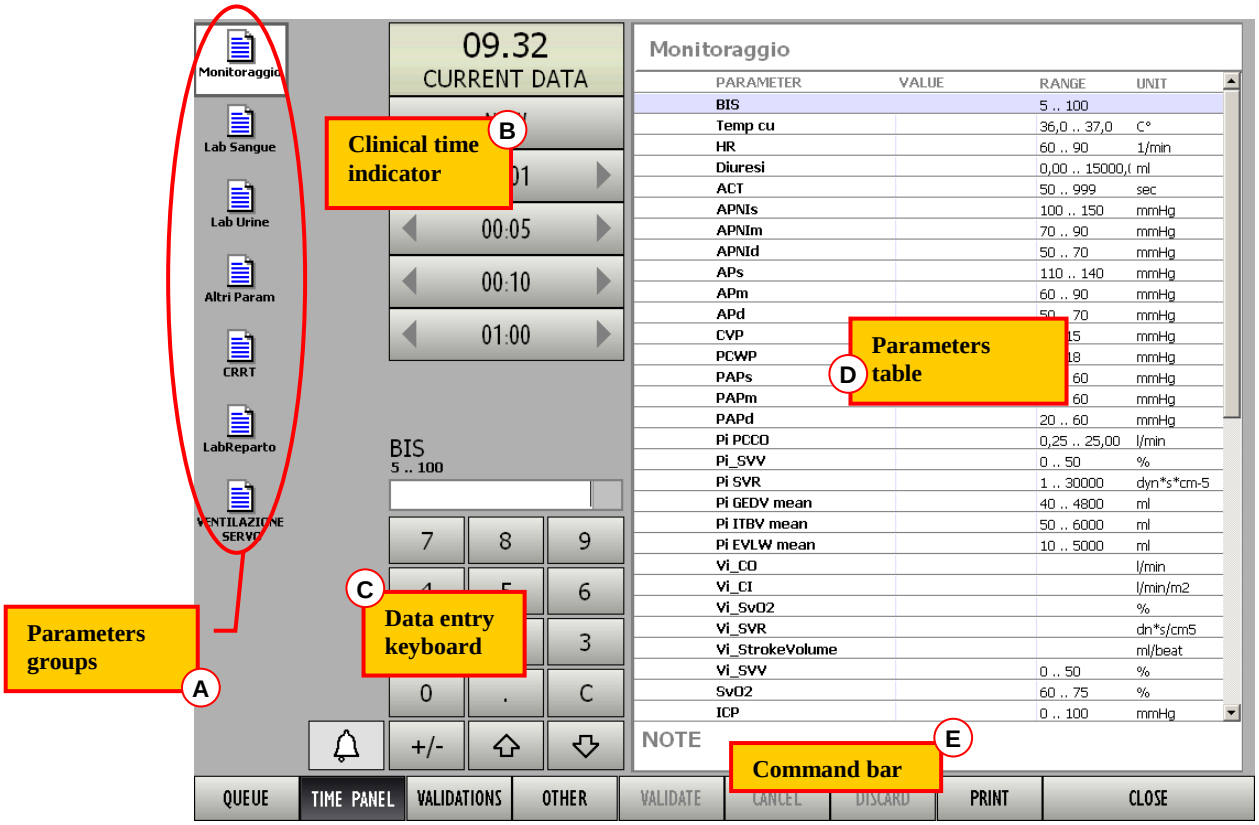


Fig 88 - Data entry screen

This screen is formed of five main parts:

1) the list of parameters groups (described in paragraph 8.8.1);
2) the clinical time indicator (described in paragraph 8.8.2);
3) the data entry keyboard (described in paragraph 8.8.4);
4) the parameters table (described in paragraph 8.8.3);
5) the command bar (described in paragraph 8.8.6).

The data validation procedure is summarized in paragraph 8.9.

8.8.1. Parameters groups

The icons on the left (Fig 88 **A**, Fig 89) represent the existing groups of parameters.

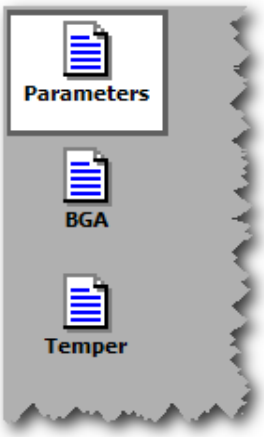


Fig 89 - Parameters groups

Each icon refers to a different group of parameters. The number of groups and their type are set by configuration.

To display the data of a specific group

- click the corresponding icon.

The clicked icon appears as highlighted (it is the group named “Parameters” in Fig 89).

On the right of the screen, the parameters table (Fig 88 **D**) displays the values of the selected group.

8.8.2. Clinical time indicator

The panel indicated in Fig 88 **C** and enlarged in Fig 90 makes it possible to read and set the clinical time. The data displayed on the table on the right refer to the time here displayed (Fig 88 **D**, Fig 93). The buttons on the panel can be used to change the time displayed and show this way the data referring to a different time.

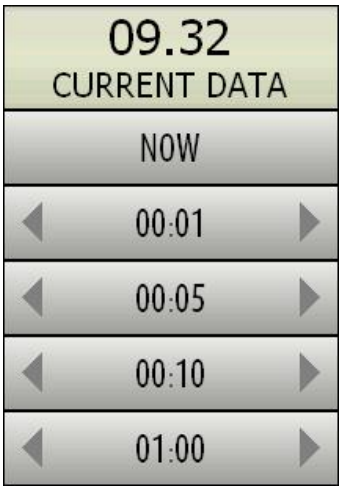
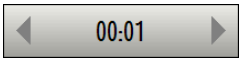


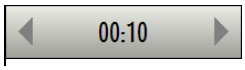
Fig 90 - Clinical time indicator

On top the time is displayed (it is 09:32 in the figure). When the time displayed is the current time the indication "CURRENT DATA" appears in the panel (as in Fig 90).

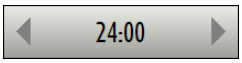
The buttons placed below the time indication make it possible to change the clinical time.

Use the 

button to move back and forward on the time-line one minute per click (left arrow is the back button).

Use the 

button to move back and forward on the time-line ten minutes per click (left arrow is the back button).

Use the 

button to move back and forward on the time-line one day per click (left arrow is the back button).

Use the 

button to display the current time.

WARNING!

The data displayed on screen refer to the time displayed on the clinical time indicator.

The data displayed on screen refer to the time displayed on the clinical time indicator. Therefore the changes in the time displayed on the time indicator change the data displayed on the table on the right (Fig 88 **D**, Fig 93). That is, for example: if the clinical time displayed is 09:30 the data displayed on the table are those acquired at 09:30; if the clinical time displayed is 08:30 the data displayed on the table are those acquired at 08:30. This feature makes it possible, if necessary, to validate past data.

For instance: in case the results of a laboratory exam relating to a sample taken hours before the current time are delivered to the system, it is better to set the clinical time to the time of the sample.

If, before accessing the validation screen, a cursor is activated either on a table or a chart, when accessing the validation screen an additional button is displayed on the time panel, referring to the time indicated by the cursor. This makes it possible to rapidly edit any value already existing on the tables.

8.8.2.1. Previous validations list

It is possible to display the list of all the previous validations under the clinical time indicator.

To do that

- click the VALIDATIONS button on the command bar (Fig 91).

Fig 91 - Command bar

The list of all the previous validations appears under the clinical time indicator (Fig 92).

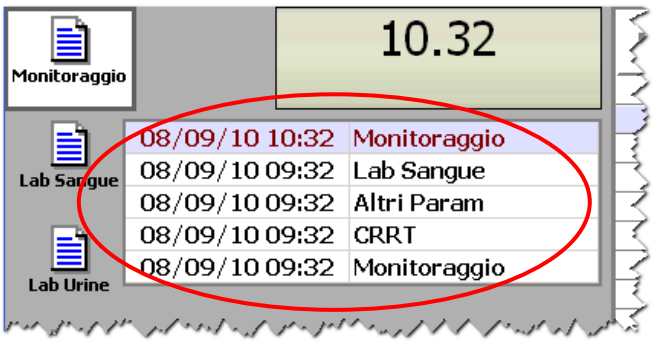


Fig 92 - Validations list

Each line corresponds to a validation. For each validation are specified the date, the time and the group.

- Click the line corresponding to a past validation to display the corresponding data on the table on the right (Fig 88 **D**).

8.8.3. Parameters table description

The table indicated in Fig 88 **D** and highlighted in Fig 93 displays all the parameters configured in the system belonging to the selected group.

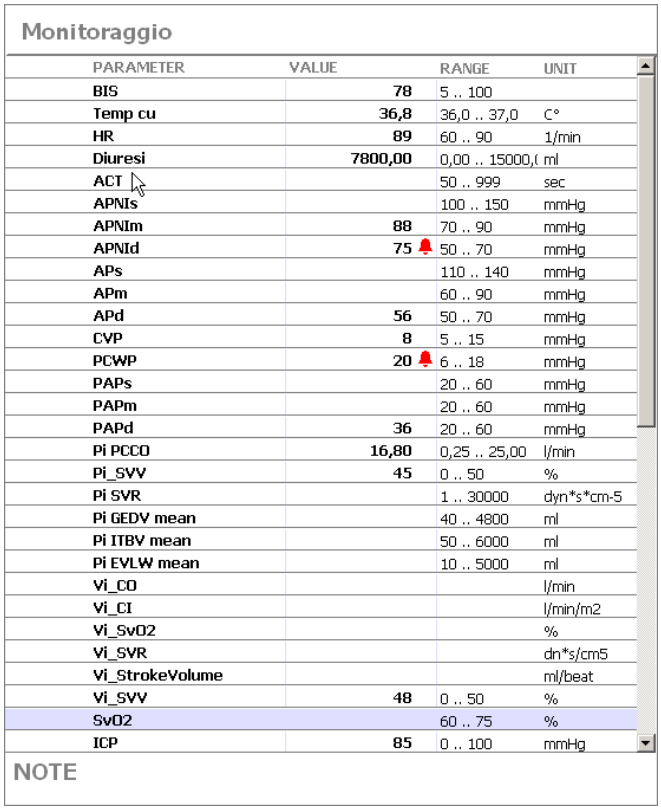


Fig 93 - Parameters table

Each line corresponds to a parameter.

There are four columns on the table:

- The “Parameter” column displays the name of the parameter;
- The “Value” column displays, when specified, the parameter value;
- The “Range” column displays, when specified, the range of normality for the values of the corresponding parameter;
- The “Unit” column displays the unit of measure of the corresponding parameter.

The “Note” area placed below the table makes it possible to add a note about a specific data set validation.

To add a note

- ➢ click the “Note” area.

A blinking cursor appears.

- Type the note (Fig 94).

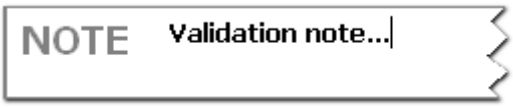


Fig 94

When a textual note is associated to a validation a specific yellow marker is displayed on the corresponding column on the "Data display" table (Fig 95).

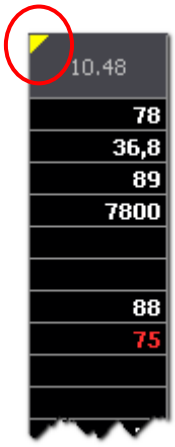


Fig 95

The data entry procedure is described in paragraph 8.8.5.

The validation procedure is described in paragraph 8.9.

8.8.4. Data entry keyboard

The keyboard indicated in Fig 88 **C** and enlarged in Fig 96 makes it possible to insert numeric and textual (depending on the parameter) data in the parameters table (Fig 88 **D**, Fig 93).

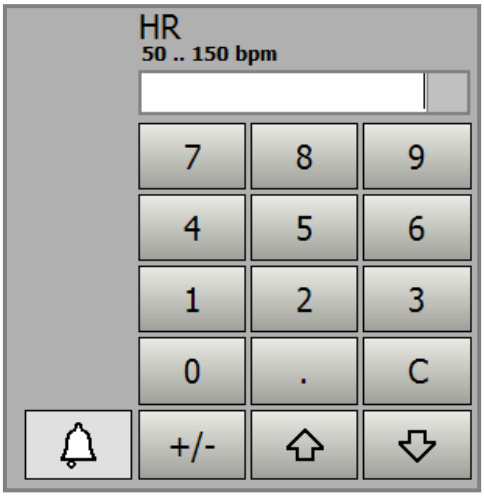


Fig 96 - Data entry keyboard

- Click the buttons on the keyboard to insert numeric data.

Textual data are usually selected on a menu containing a list of pre-defined options. When this is the case the button appears near the field. This button opens the list of options (Fig 97).

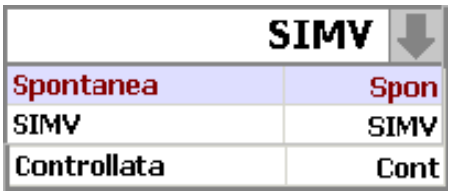


Fig 97 - Options

- Click the relevant option to select it and add it to the table.

8.8.5. How to enter data

To enter data

- set the clinical time that you want to associate to the data you are entering (see paragraph 8.8.2 for the clinical time selection procedure).

The table on the right displays the values acquired at the selected time. When the clinical time displayed is the current time the table displays the current data (Fig 98).

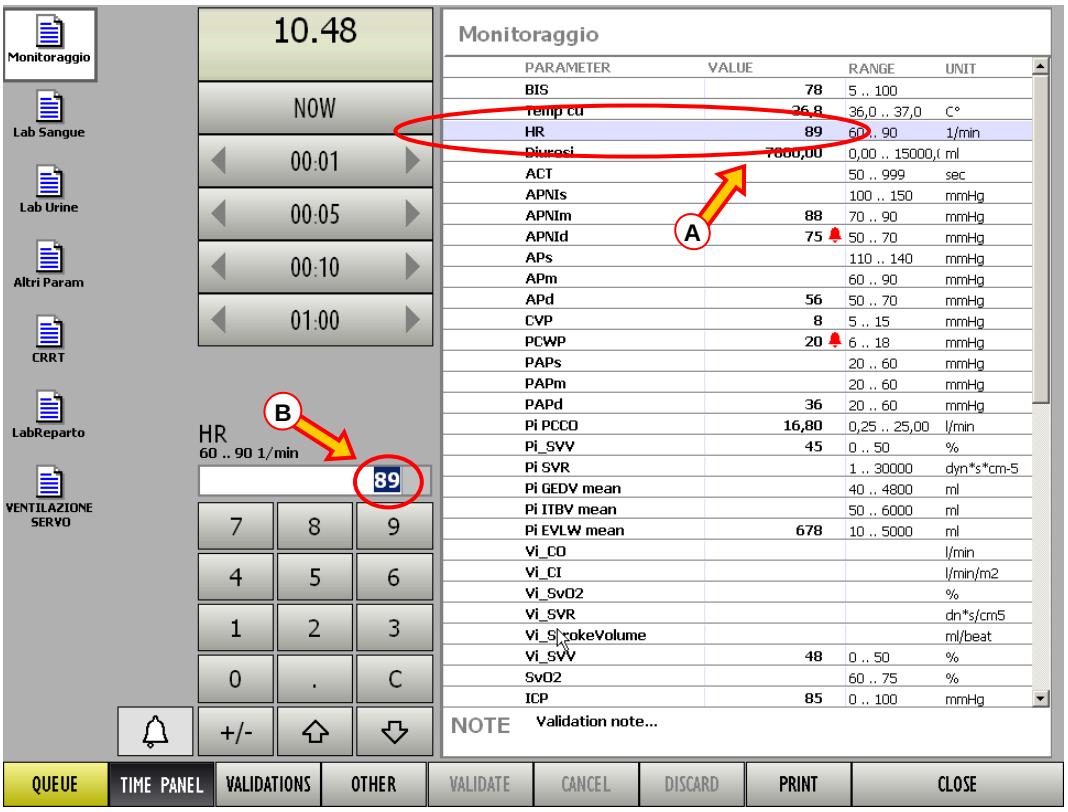


Fig 98 - Data entry

One of the rows is highlighted, corresponding to one of the parameters. The value specified on the highlighted row (if a value is specified - Fig 98 **A**) is displayed in the data entry field, above the numeric keyboard (Fig 98 **B**).

- Use the arrow buttons on the keyboard (and) to select the row corresponding to the parameter to be specified. Otherwise click the relevant row.

The parameter value (if present) is displayed in the data entry field, otherwise no value appears in the field.

- Use the data entry keyboard to enter the new value (Fig 99)

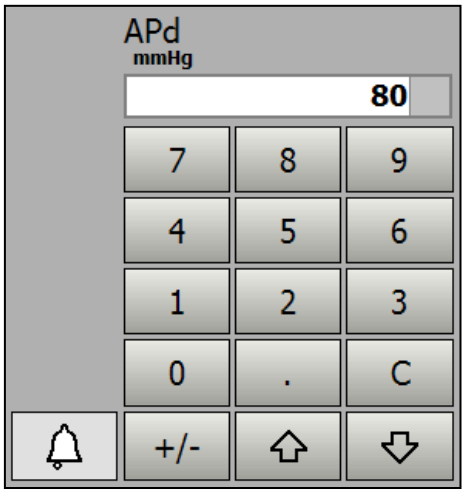


Fig 99 - New value added

- Use the arrow buttons on the keyboard (and) to select either the previous or the following row. Otherwise click the RETURN key on the workstation keyboard.

The new value is diplayed (Fig 100).

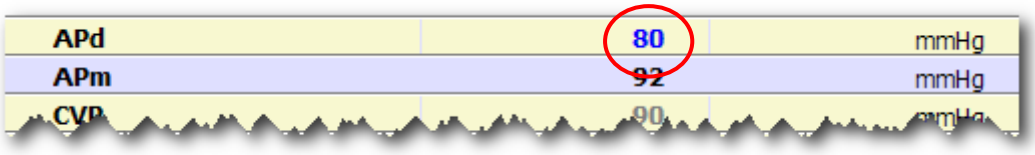


Fig 100

For some parameters a "normality" range is specified. When the value, either acquired by the system or specified by the user, is out of the normality range the icon appears alongside the value. See for instance Fig 101, in which the value of the parameter "NBPD" is 58 mmHg when the normality range specified is 60 to 160 mmHg. In this case the icon appears alongside the value.

Fig 101

When a row corresponding to a value that is out of the normality range is selected, the  button placed alongside the numeric keyboard becomes red. In Fig 102 the "NBPD" value is selected and the button is red.

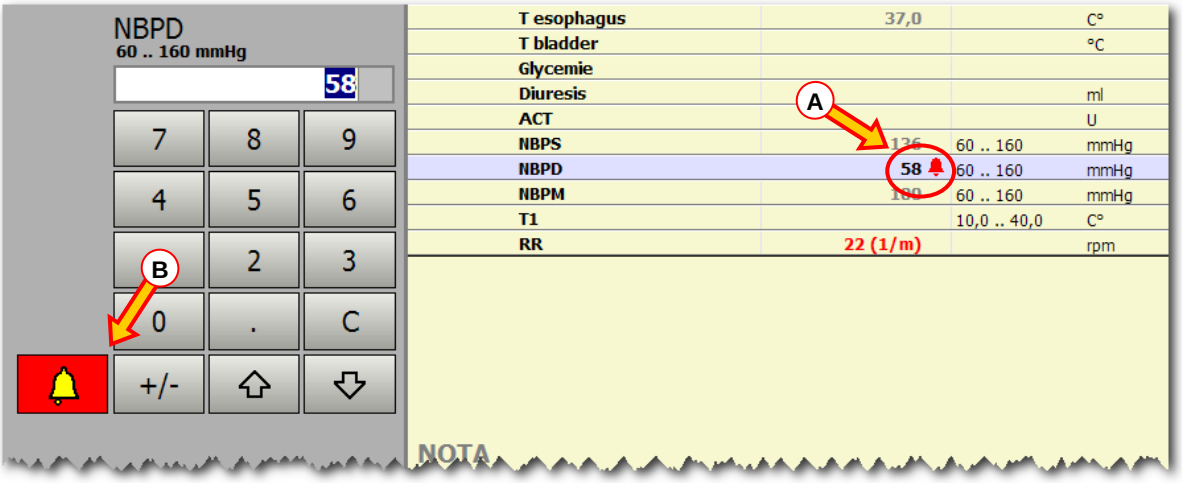


Fig 102

The values that are out of the normality range, after the validation, are displayed in red on the "data display" table on the main screen (Fig 103) unless the  button is clicked before the validation. If the  button is clicked it turns grey again -  . The corresponding value is consequently displayed in black on all the module's screens.

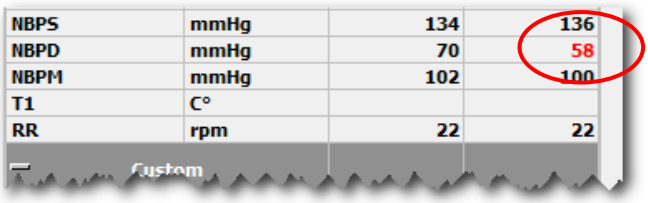


Fig 103

When an impossible value is specified (a value that is out of specific plausibility criteria) the "On line" module inhibit the operation and informs the user with a specific pop-up message (Fig 104).

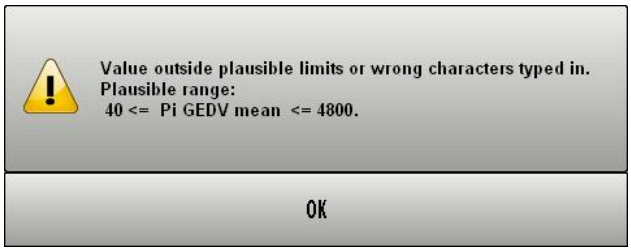


Fig 104

8.8.6. The command bar of the data entry screen

The command bar of the data entry screen is formed of various buttons making it possible to perform specific procedures.
The different functionalities of the buttons are listed in the present paragraph and, when necessary, explained in more detail in the indicated paragraphs.

Fig 105 - Command bar

This button displays the list of items that are part of the validation queue. See paragraph 8.8.7 for a description of the validation queue. When the button is grey there is no queue
When the button is yellow there is a queue. Click the button to display the items in the queue.

When this button is selected the area indicated in Fig 90 and Fig 88 **B** (the "Clinical time" area) displays the buttons making it possible to edit the clinical time (see paragraph 8.8.2 for the procedure). The selection of this button excludes the possibility to select the "Validations" and "Other" buttons.

When this button is selected the area indicated in Fig 90 e Fig 88 **B** (the "Clinical time" area) displays the list of all the past validations (see paragraph 8.8.2.1 for the procedure). The selection of this button excludes the possibility to select the "Time panel" and "Other" buttons.

This button has the general purpose to display any list that the Healthcare Structure using the "On line" module may find useful. The list is displayed in the area indicated in Fig 90 and Fig 88 **B** (the "Clinical time" area). For instance, the system administrators can define a *Query* identifying a certain kind of validations and use the "Other" button to immediately display the query results.

The selection of this button excludes the possibility to select the "Time panel" and "Validations" buttons.

Use this button to validate the data displayed on screen. See paragraph 8.9 for the data validation procedure.

Use this button to bring the values of the parameters displayed on screen to their original values. All the changes possibly performed are annulled.

This button is only enabled when the validation queue is displayed. Use this button to discard one of the data sets on the queue. See paragraph 8.8.7 for the detailed procedure.

Use this button to print the parameters' values.

Use this button to close the "Data entry" screen.

8.8.7. Validation queue

Some parameters can be configured to be stored in a validation queue as soon as they are acquired. These are the cases of data whose acquisition must be immediately communicated to the medical staff (as, for instance, the laboratory exams or the emogas analysis) .

If there are data in the validation queue the QUEUE button on the command bar changes its color to QUEUE.

- Click the button to display the the validation queue.

These data can be either analyzed, edited, validated or discarded. In all cases this kind of data must be viewed by a physician.

The validation procedure is the same used for the other parameters, described in paragraph 8.9.

To display and validate the data in the "validation queue"

- click the QUEUE button.

A list of icons appears on screen (Fig 106 **A**). Each icon corresponds to a set of data waiting for validation ("queued" data).

When the validation queue is displayed the QUEUE button appears like this: QUEUE (Fig 106 **B**).

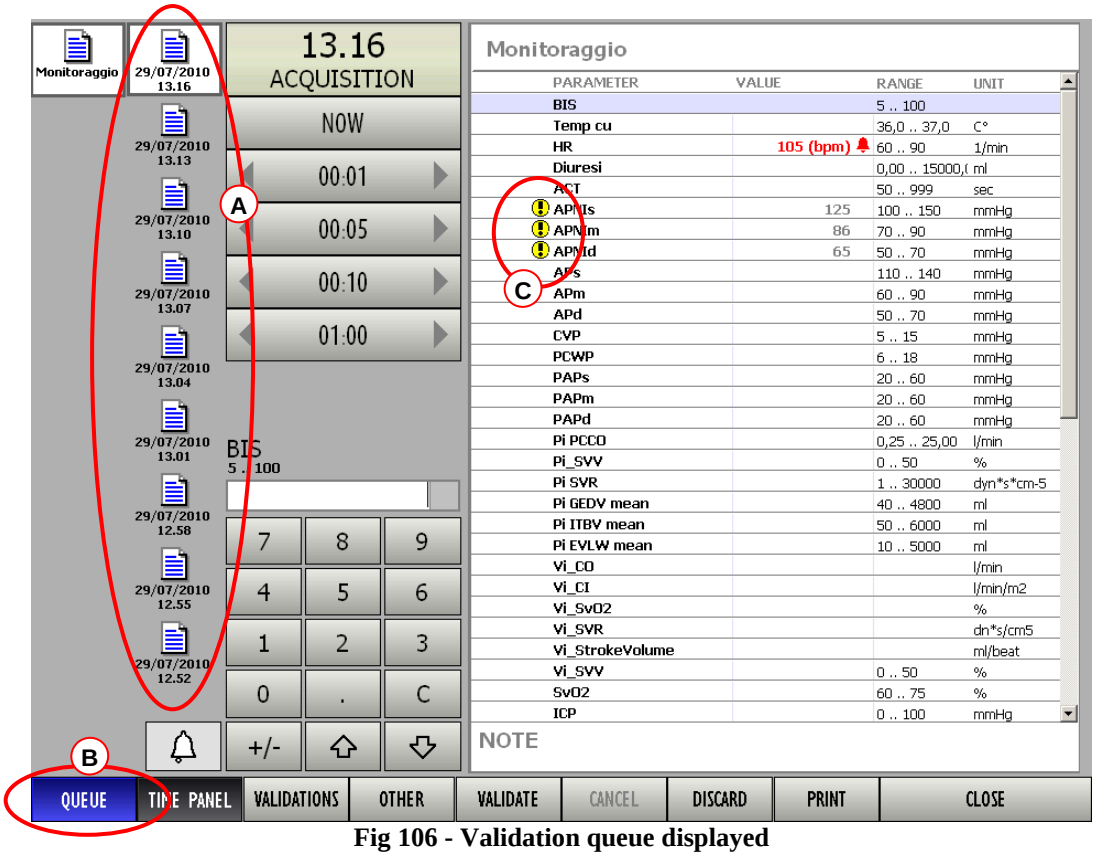


Fig 106 - Validation queue displayed

The time of acquisition of the corresponding data is specified beneath each icon.

- Click the icon corresponding to the data to be validated.

The icon is this way highlighted (Fig 107).

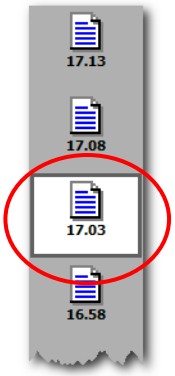


Fig 107

The parameters table on the right displays the parameters and the values corresponding to the clicked icon.

- Review and (in case) edit the data on the table (the procedure is described in paragraph 8.8.5).

- Click the VALIDATE button to validate the data and add them to the patient documentation.

Otherwise,

- click the DISCARD button to reject the data and cancel them definitively.

In both cases the icon corresponding to the set of data disappears from the validation queue.

When the ⓘ icon appears alongside the parameter name (as, for instance, in Fig 106 **C***) it means that the corresponding parameter was acquired before the acquisition time indicated under the icon.*
For example: there are ten parameters, 6 of them are acquired at 10:30 and the remaining 4 parameters are acquired at 11:00. When the 11:00 o'clock acquisition is displayed the ⓘ icon appears alongside the 6 parameters acquired at 10:30.

8.9. Data validation procedure

This paragraph summarizes the data validation procedure.

On the “On Line” data display screen (Fig 108),

1. click the DATA ENTRY button on the command bar (Fig 108 **A**).

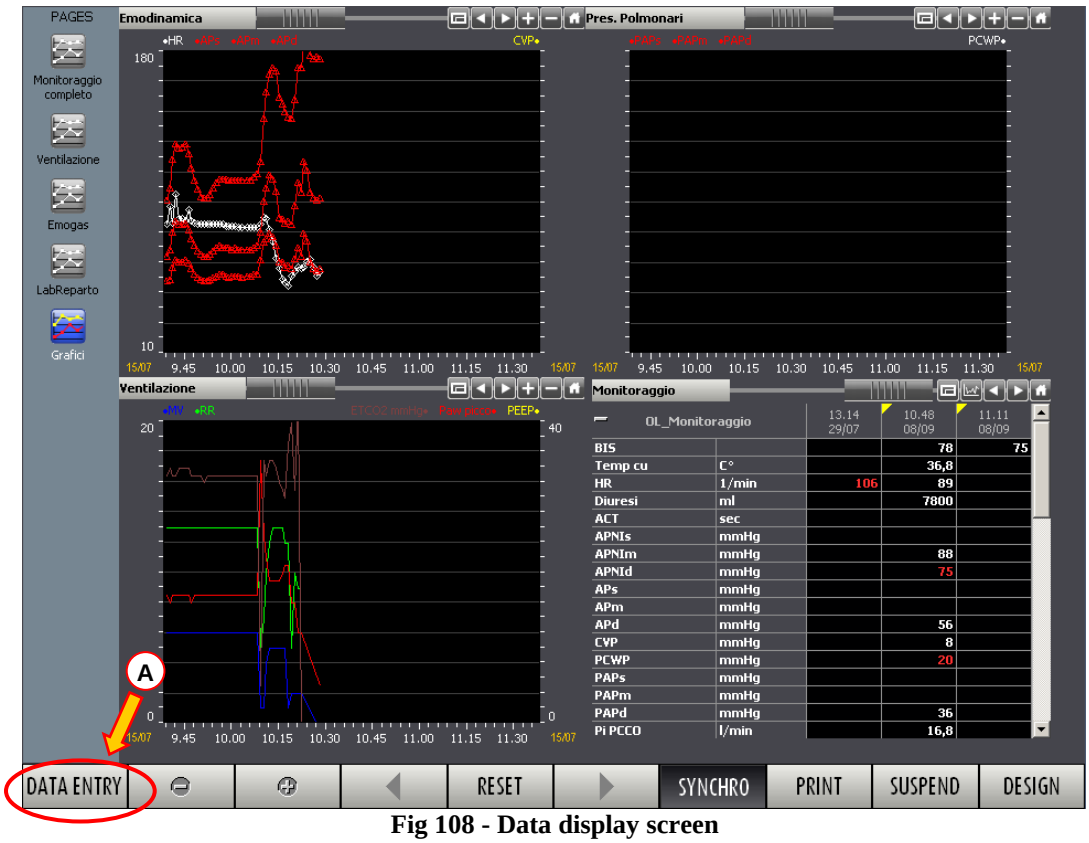


Fig 108 - Data display screen

The “Data entry” screen opens (Fig 109).

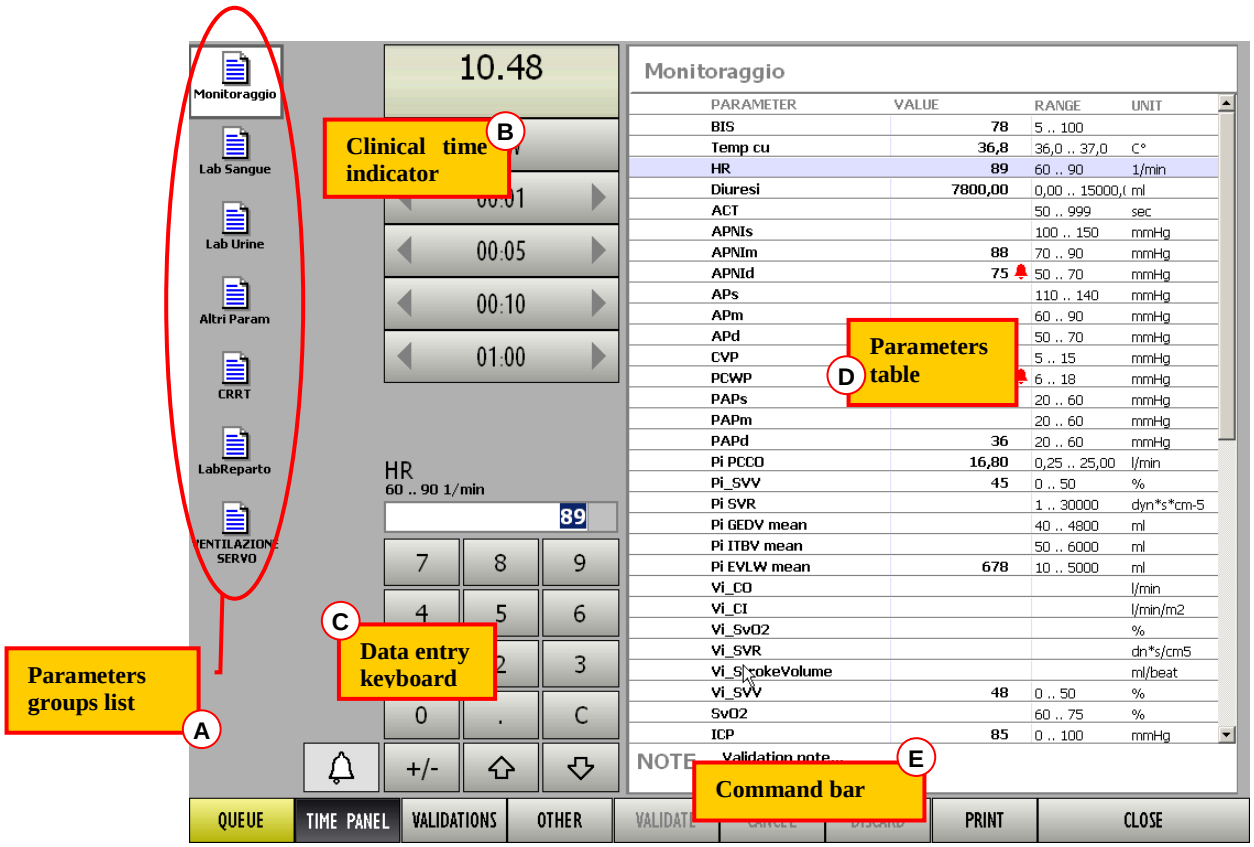


Fig 109 - Data entry screen

2. Click the icon corresponding to the group of parameters to be validated (Fig 109 **A**).

The icon is this way highlighted. The parameters and values of the selected group at the time indicated by the clinical time indicator appear on the parameters table (Fig 109 **D**). See paragraph 8.8.1 for a detailed description of the parameters group selection procedure.

3. Set the clinical time (using the appropriate buttons - Fig 109 **B**) in case you need to validate data referring to a time preceding the current time.

The parameters table displays the values corresponding to the selected time. See paragraph 8.8.2 for a description of the time setting procedure.

4. Enter data using the data entry keyboard (Fig 109 **C**). See paragraph 8.8.5 for a description of the data entry procedure.

5. Click the VALIDATE button on the command bar (Fig 109 **E**) to confirm the data entered.

Otherwise, to abort the procedure,

5. click the CANCEL button.

6. Repeat steps 1 to 5 for each group of parameters to be validated.

7. Click the CLOSE button to go back to the “On line” data display screen (Fig 108).

See paragraph 8.8.7 for the queue validation procedure.

8.10. Print functionalities

To access the “On Line” module’s print functionalities.

- click the PRINT button on the command bar (Fig 110).

Fig 110 - Command bar

A specific window opens, making it possible to define the features of the report to be printed (Fig 111).

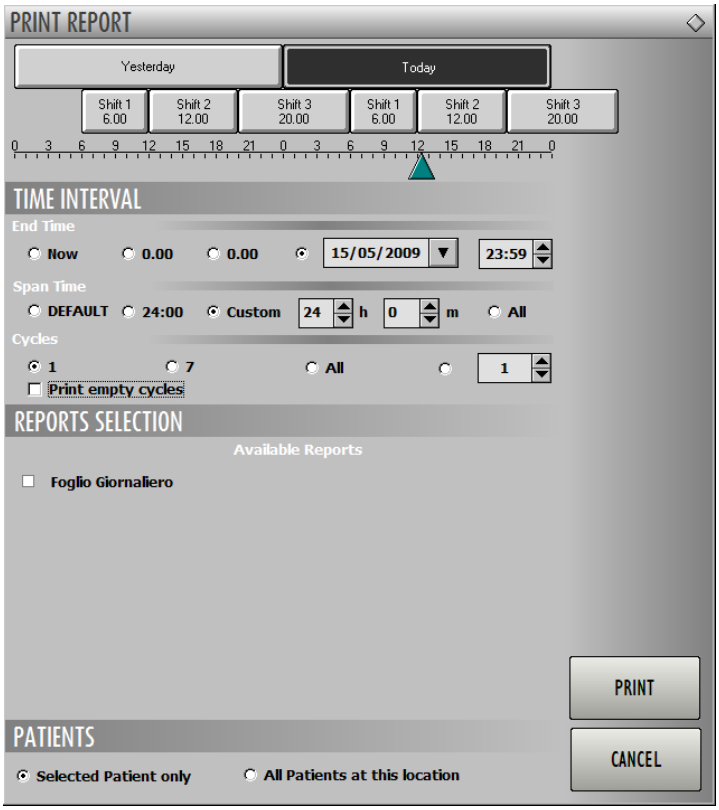
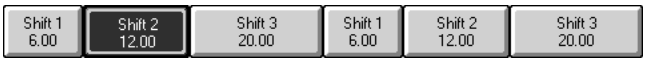
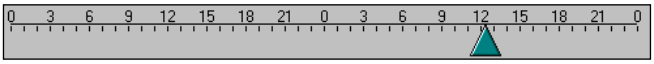


Fig 111 - Print reports definition

Use the Yesterday Today buttons to print either yesterday’s or today’s data.

Use the 

buttons to select the shift to which the print reports refer.

The bar 

indicates the current time (in the figure it is 12:00 o'clock approximately).

The area shown in Fig 112 makes it possible to select the time interval to which the print reports refer.

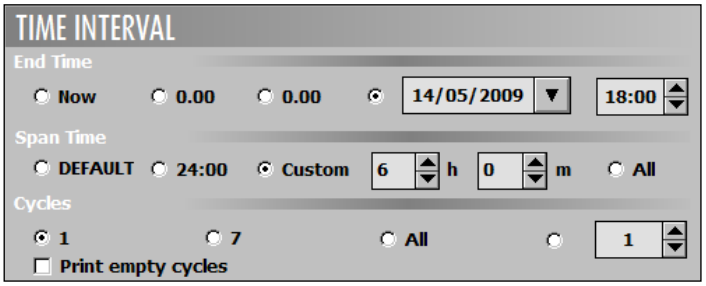


Fig 112 - Time interval selection

The area shown in Fig 113 makes it possible to select one of the available reports. The number and kind of available reports is defined by configuration through the integrated "On Line reports maker" editor (to access this tool enter the Clinical Configuration functionalities on the DIGISTAT® main menu - Fig 26 **A**).

Fig 113 - Available reports selection

The area shown in Fig 114 makes it possible to decide whether printing the data of a single patient or the data of all the patients in the location.

Fig 114 - Patient selection

After report definition,

- click the 

button to create the report.

A print preview can be displayed. The print preview screen features are described in paragraph 7.5.2.

8.11. Data acquisition suspension

The SUSPEND button on the command bar of the data display screen (Fig 115) makes it possible to either suspend or stop the direct data acquisition from the medical devices.

Fig 115 - Command bar

To either suspend or stop the data acquisition

- click the SUSPEND button.

Various options are available (Fig 116)

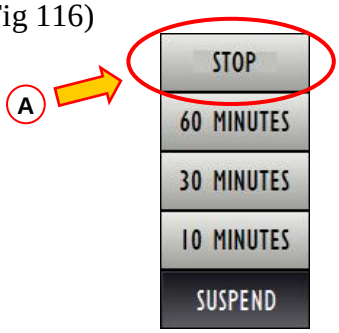


Fig 116

The 10 MINUTES button suspends the data acquisition for 10 minutes.
The 30 MINUTES button suspends the data acquisition for 30 minutes.
The 60 MINUTES button suspends the data acquisition for 60 minutes.
The STOP button suspends the data acquisition for an undetermined time.

When one of the three temporary suspension options (10, 30 and 60 minutes) is selected, a popup window appears to remind the user of the acquisition restart time (Fig 117).

Fig 117 - Acquisition suspended

The STOP button (Fig 116 **A**) displays a different popup window (Fig 118).

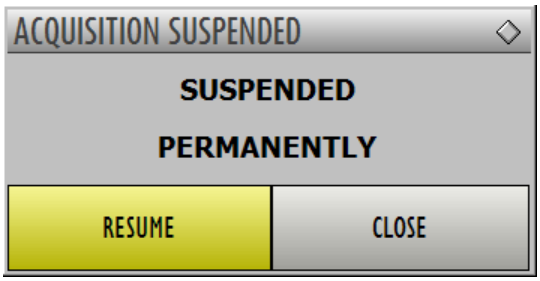
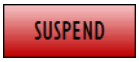


Fig 118 - Acquisition suspended permanently

On both windows,

The RESUME button (Fig 117 **A**) makes data acquisition start again;
The CLOSE button (Fig 117 **B**) closes the acquisition suspension confirmation window.

When data acquisition is suspended the 

button is red.

- Click the red button to display the following options:

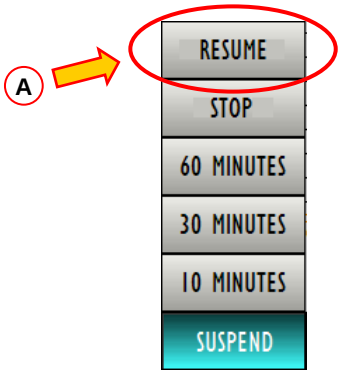


Fig 119

The RESUME option (Fig 119 **A**) is added to the options displayed in Fig 116.

- Click the RESUME button to start data acquisition again.

9. Enclosed Documentation

The following documents are enclosed

1. *Product tracking form*. To be filled and sent to UMS in case the device is moved to another place.

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

PRODUCT TRACKING FORM

Return to:

UMS SRL
Quality Assurance Department
Via di Mucciana 19
50026 San casciano in Val di Pesa (Firenze)

Italy

Tel: 800 999715
Tel: +39 055 0512161
Fax +39 055 8290392

Name of product/system _____

Code (REF) _____

Serial Number (SN) _____

Name and address of the former owner:

Name and address of the new owner:

Date: _____ Signature and Stamp

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FOR "DIGISTAT®", A UMS PRODUCT

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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 authorised by UMS, (b) has not been used in compliance with 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 UMS receives no payment as license fee.

Limitation of Liability. IN NO CASE WILL 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 UMS OR ITS SUPPLIERS WERE INFORMED ABOUT THE POSSIBILITY THAT SUCH DAMAGES COULD OCCUR. Under no circumstance will either 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 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 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 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.

INTENDED USERS
The PRODUCT must be used by properly trained physicians, nurses, administrative staff 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 adeguately 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 provisions and the limitations contained herein.

CONFLICTING TERMS
Should the User and 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 UMS representative in your area or write to UMS srl, Customer Service, Via di Mucciana 17, 50026 San Casciano in Val di Pesa (Firenze), Italy.

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 UMS End-User License Contract concerning the product “DIGISTAT®”:

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

Date Signature

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.

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

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 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”.

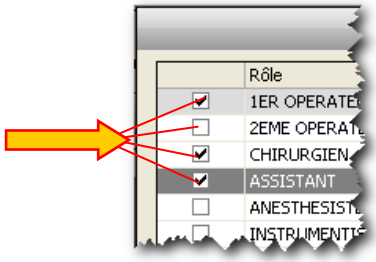

Figure 1 - Checkboxes

- **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 – Command Bar

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. “Controlbar” 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.

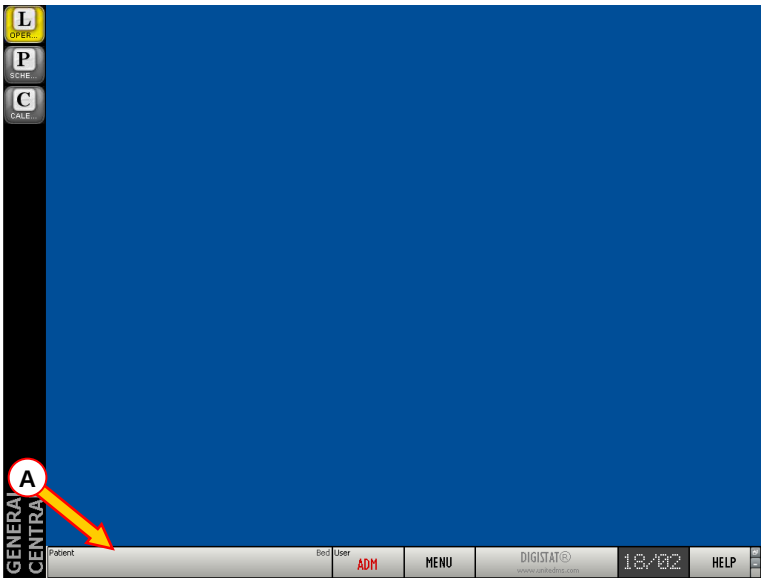

Figure 3 - Control Bar

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).

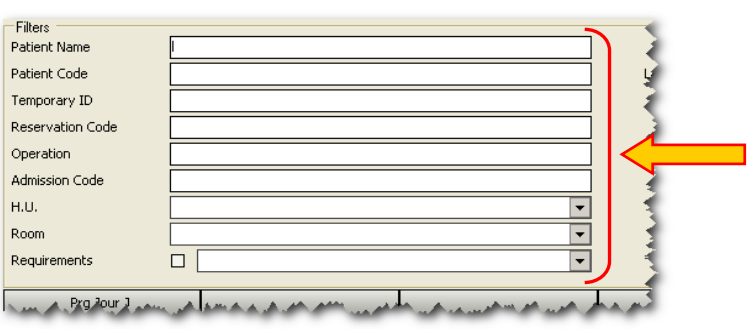

Figure 4 - Fields

❖ **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 indicated in Figure 5.

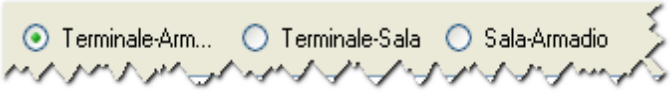

Figure 5

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 **A**).

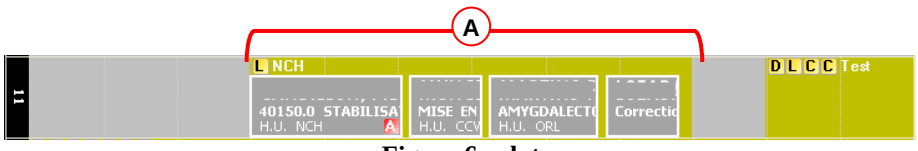

Figure 6 - slot

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).

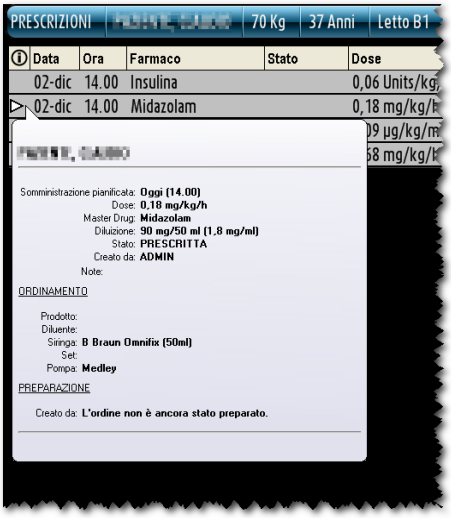

Figure 8 - Tooltip

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.