DIGISTAT® Forms

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.

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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.

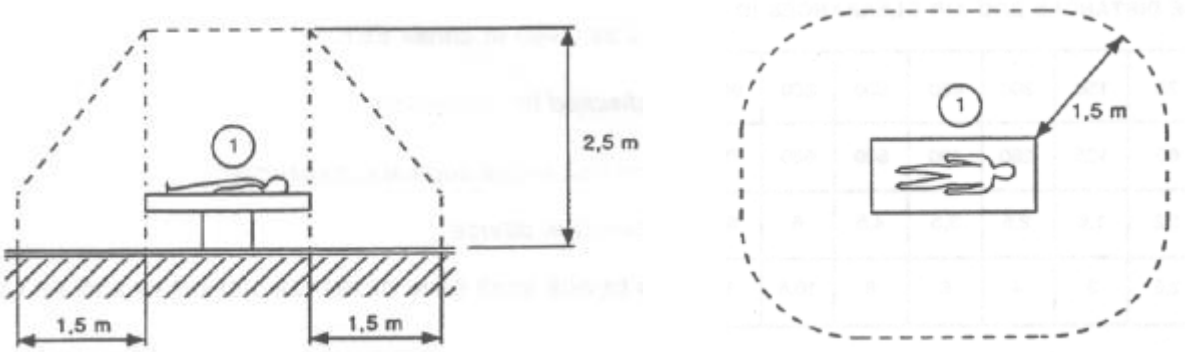


Fig 1 – Patient Area

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).

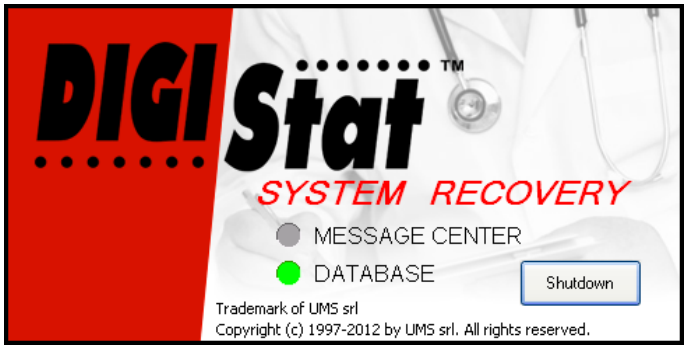


Fig 2

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.

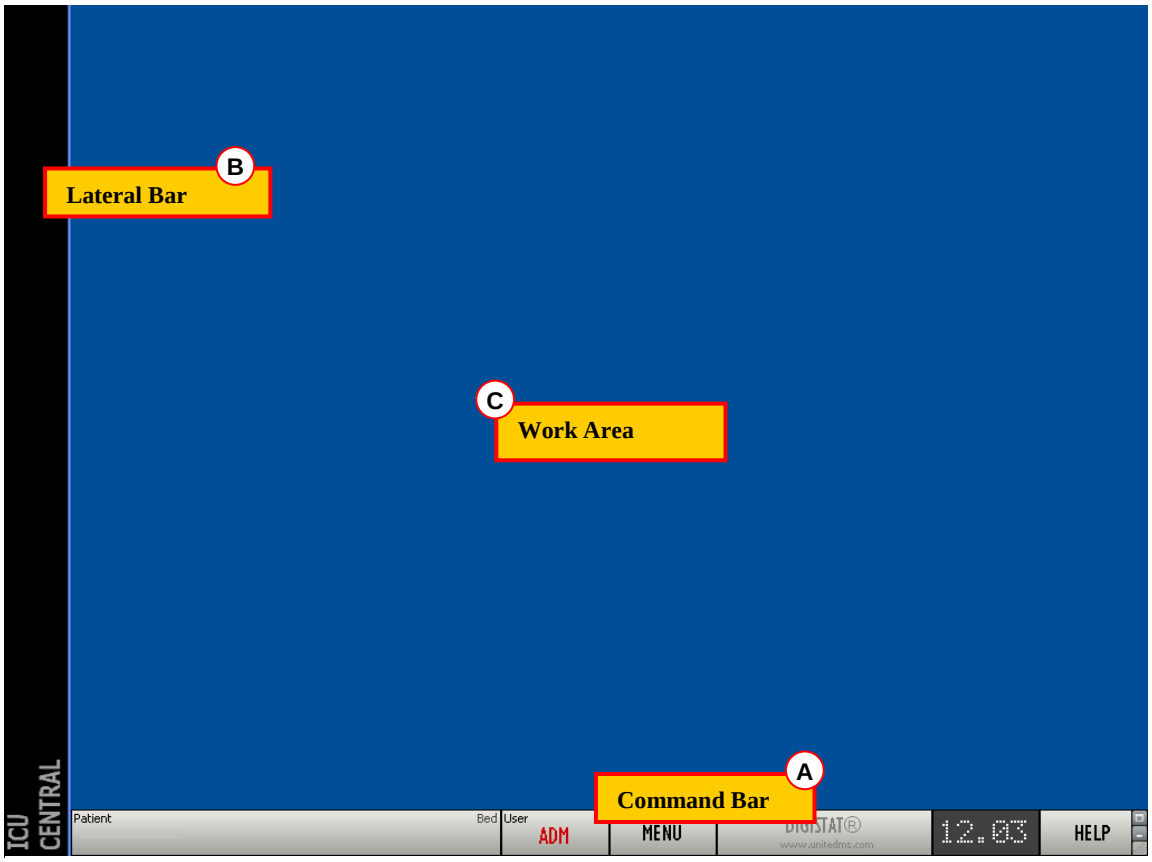


Fig 5 - Control Bar

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.

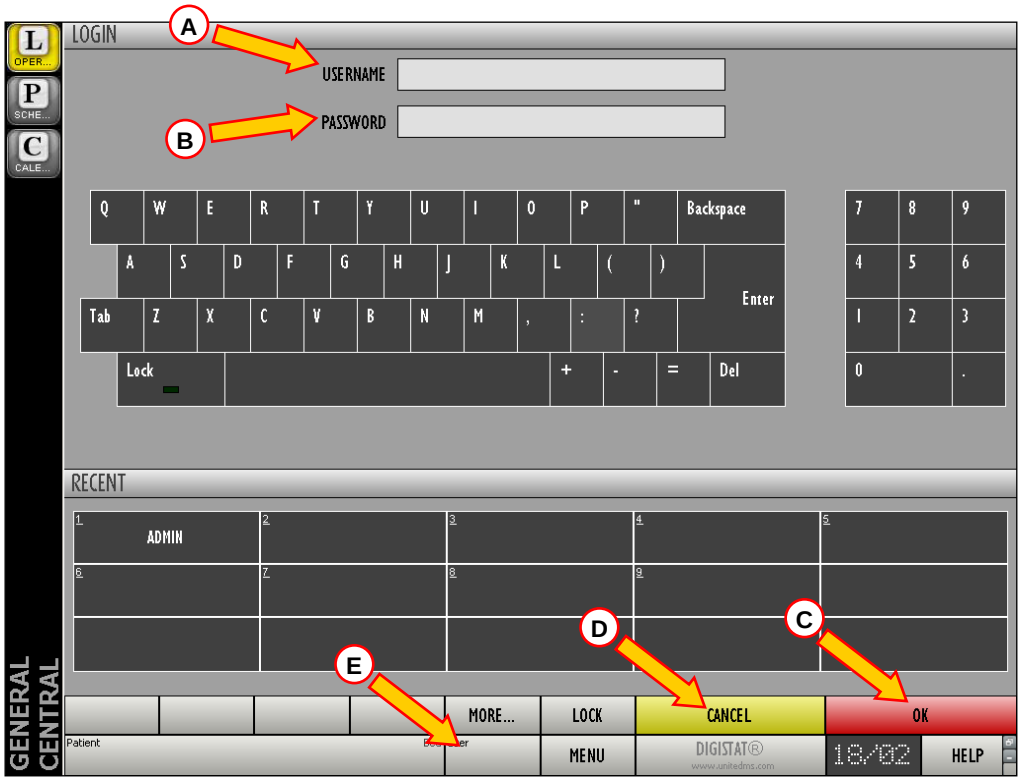


Fig 7 – Access to the system

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).

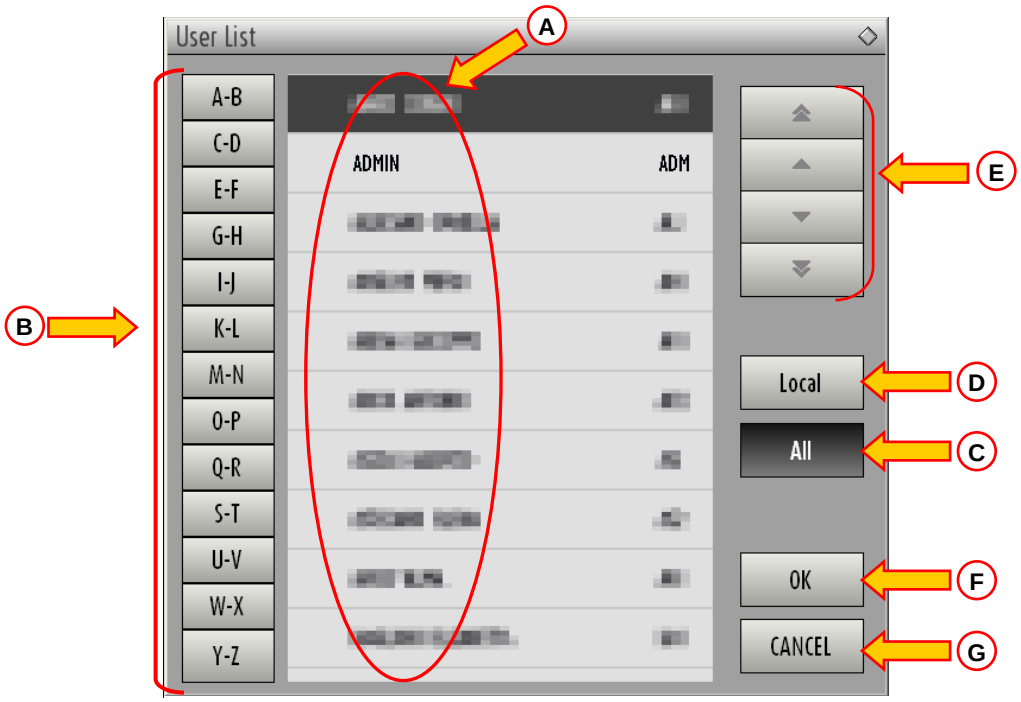


Fig 14 – User List

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.

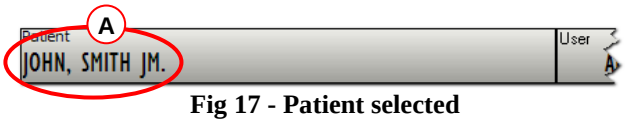


Fig 17 - Patient selected

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.

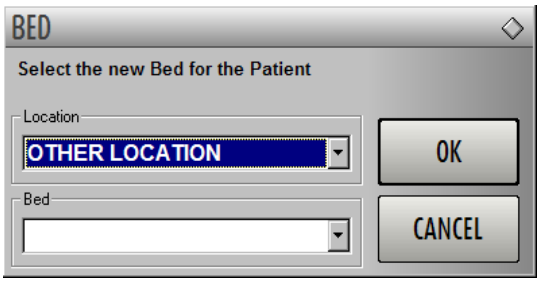


Fig 21 - Bed selection window

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.

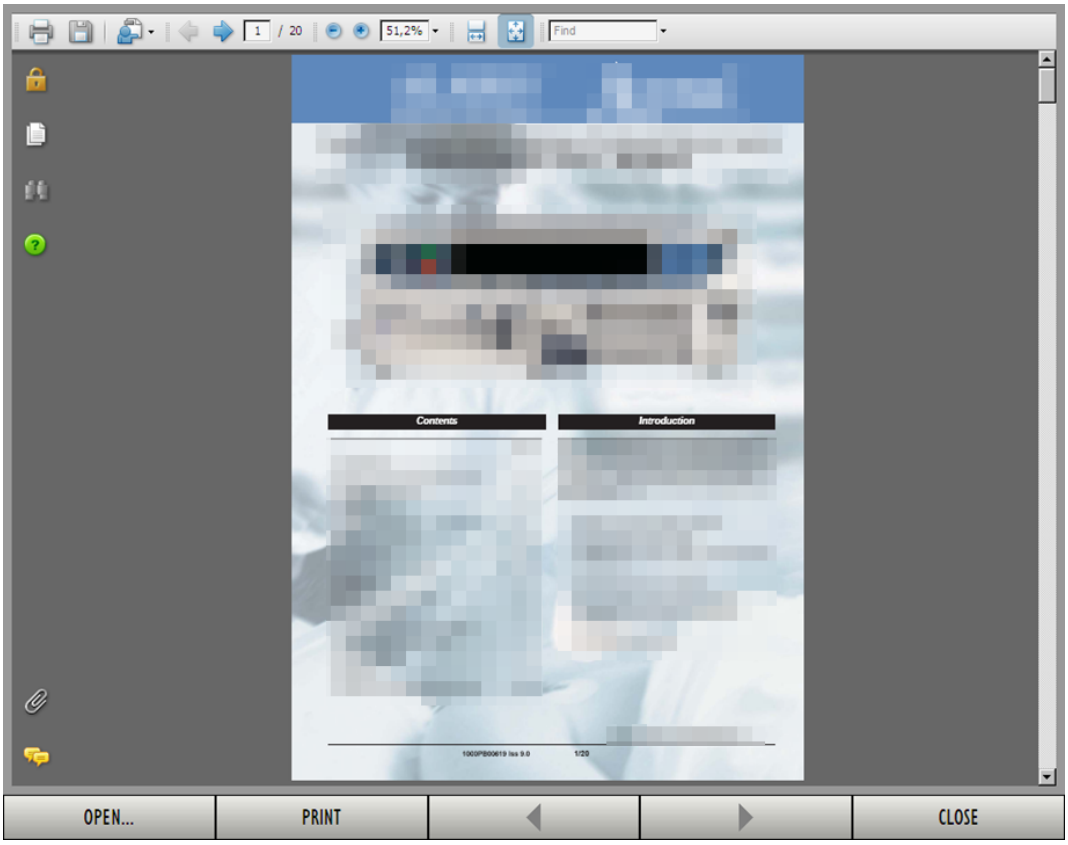


Fig 23

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)

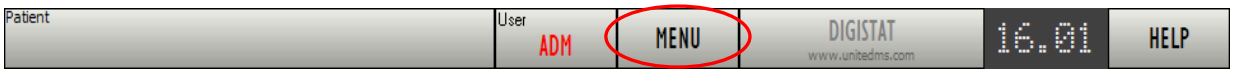


Fig 25

opens a menu containing several options (Fig 26).

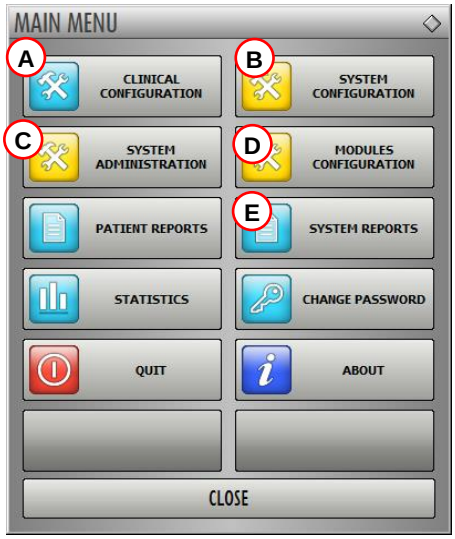


Fig 26 - Configuration functions

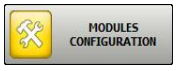
Each button on the menu accesses a specific set of functions.

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.

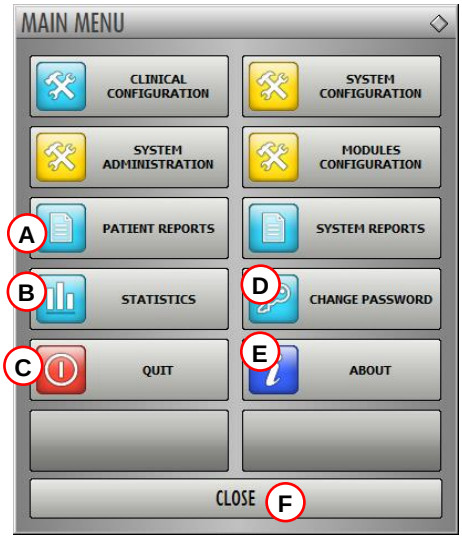


Fig 27 - Functions for the user

- (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).

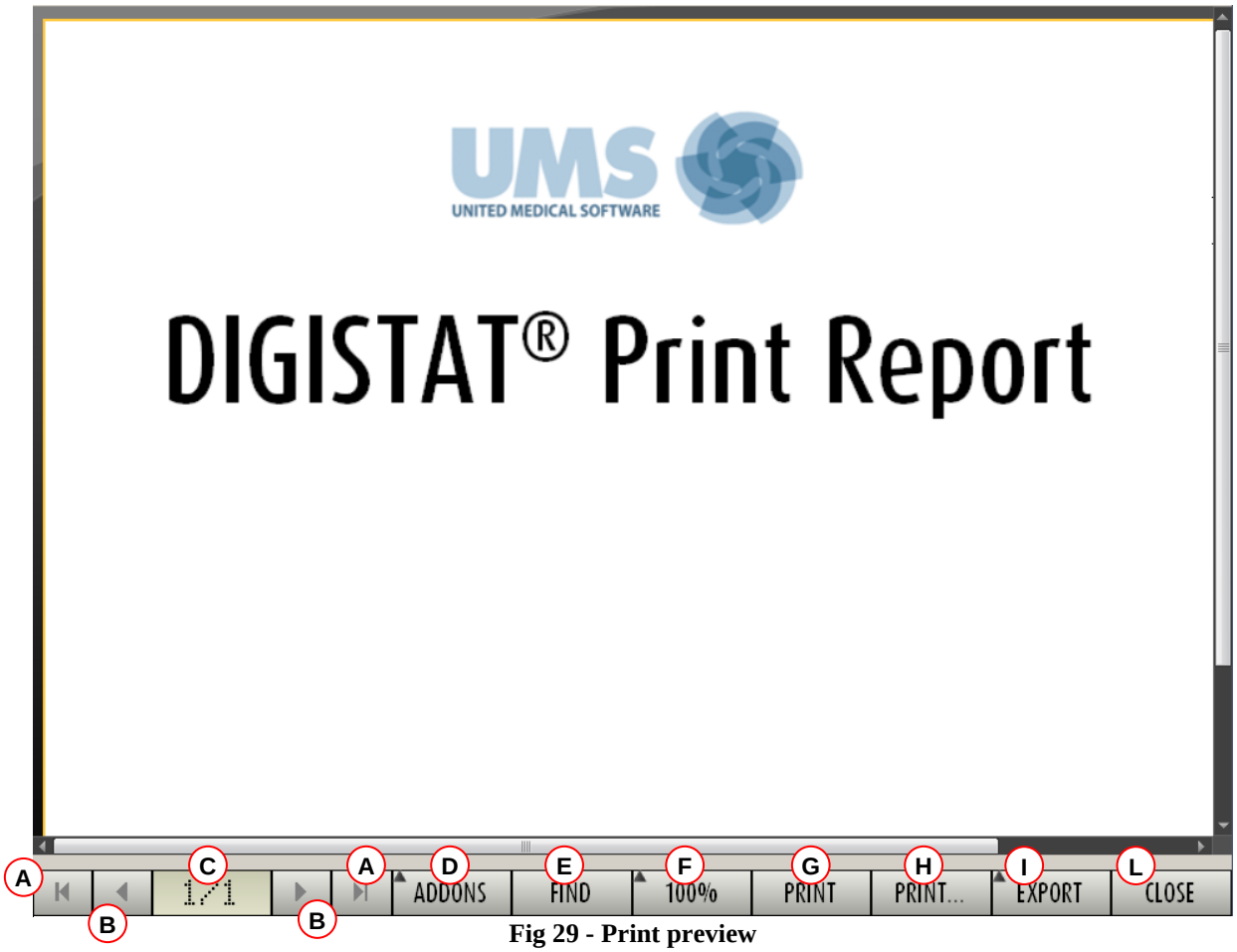


Fig 29 - Print preview

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).

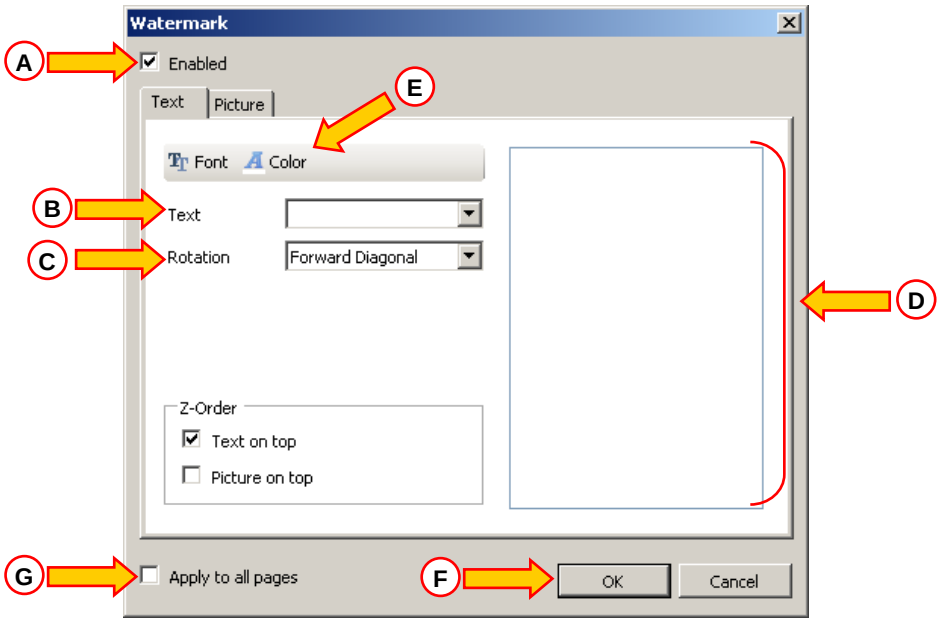


Fig 31

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).

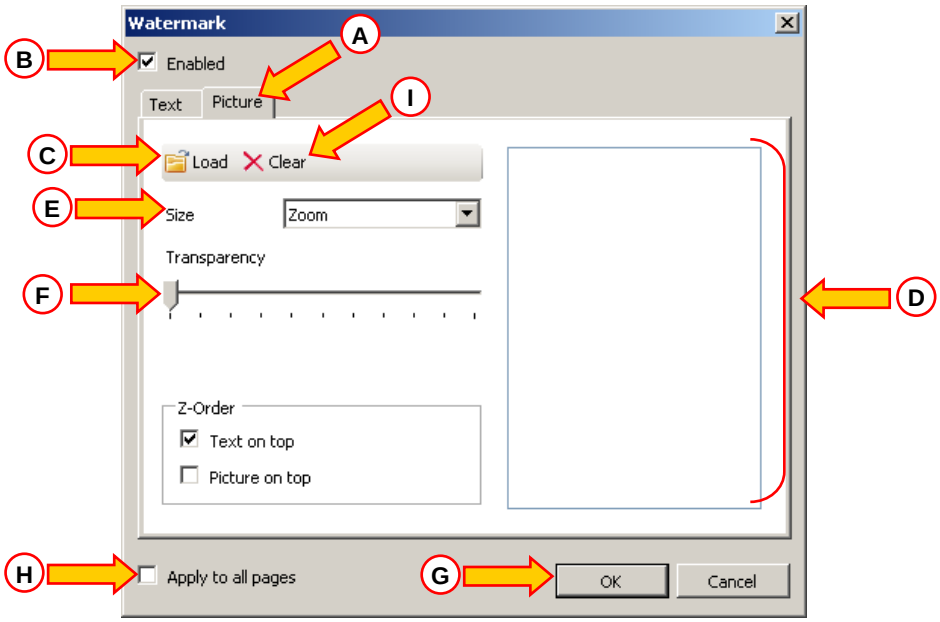


Fig 32

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).

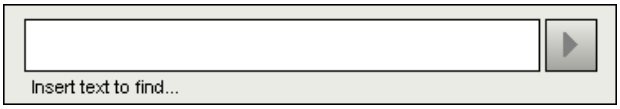


Fig 33

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

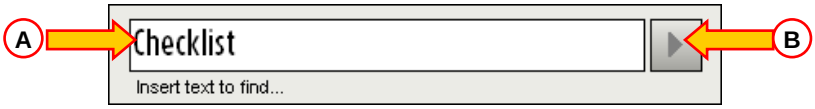


Fig 34

- 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)

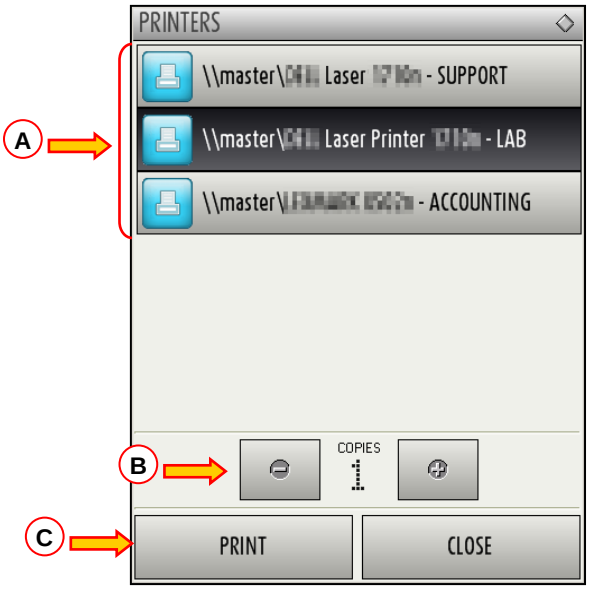


Fig 36

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.

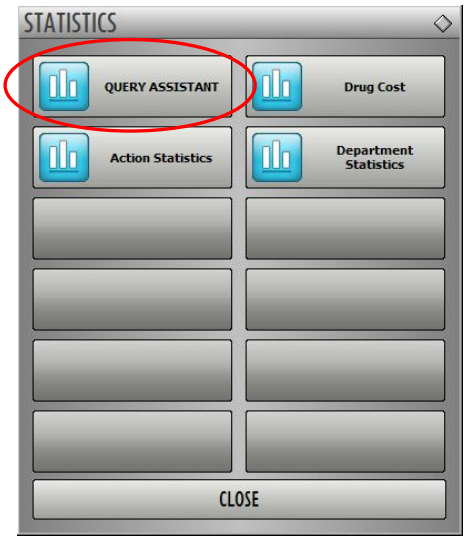


Fig 39

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).

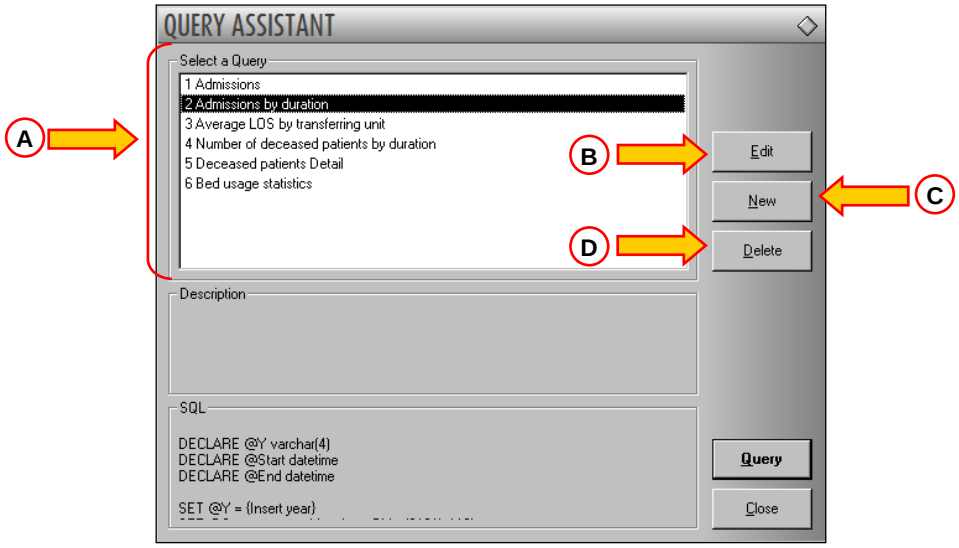


Fig 40 - Query Assistant

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.

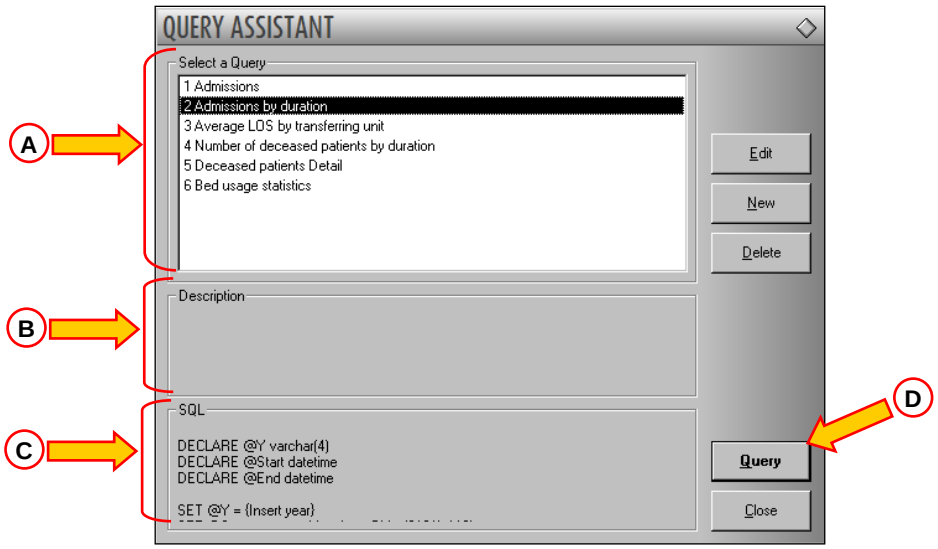


Fig 41 - Selected query

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).

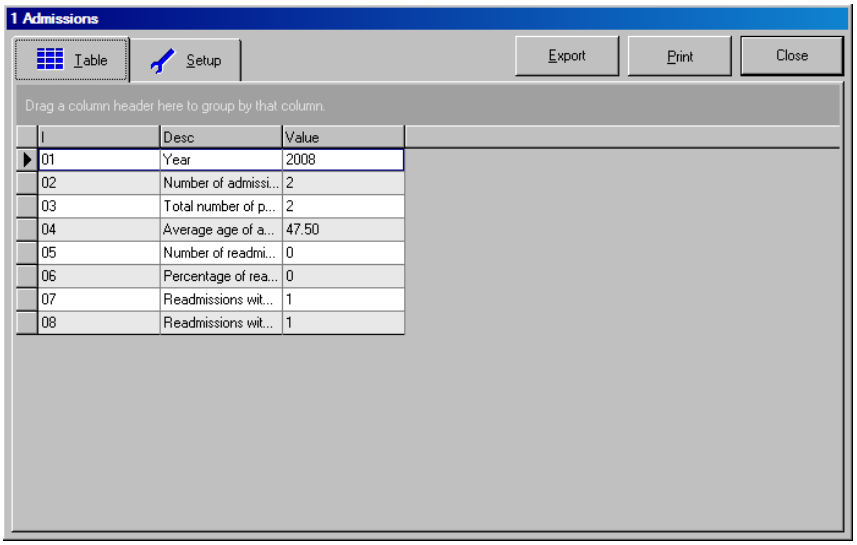


Fig 42 - Results

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.

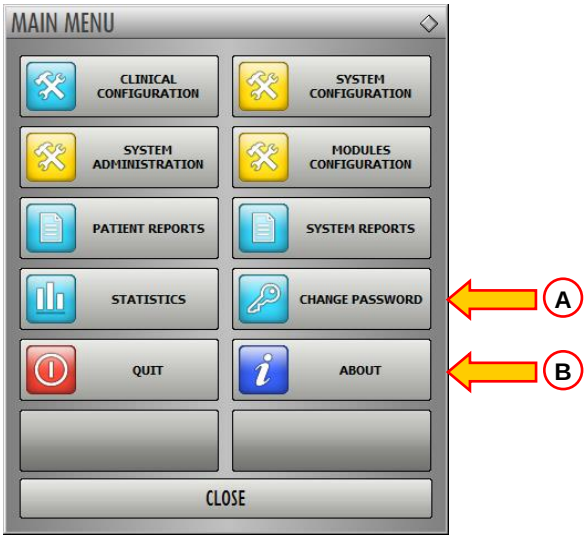


Fig 43

To change the user password

- click the 

button (Fig 43 A).

The "Change password" window will open.

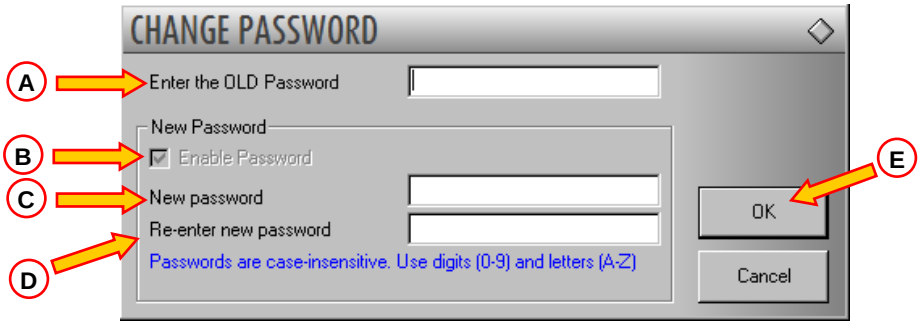


Fig 44 - Change password

- 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).

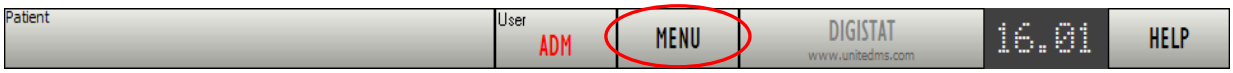


Fig 46

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

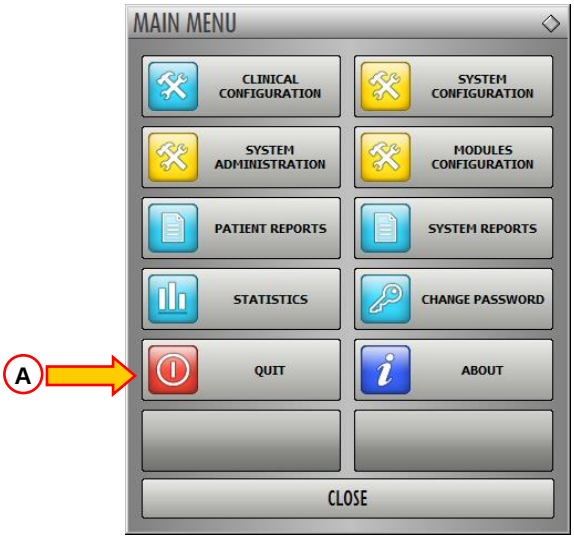


Fig 47 - Main menu

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

Another menu is displayed (Fig 48).

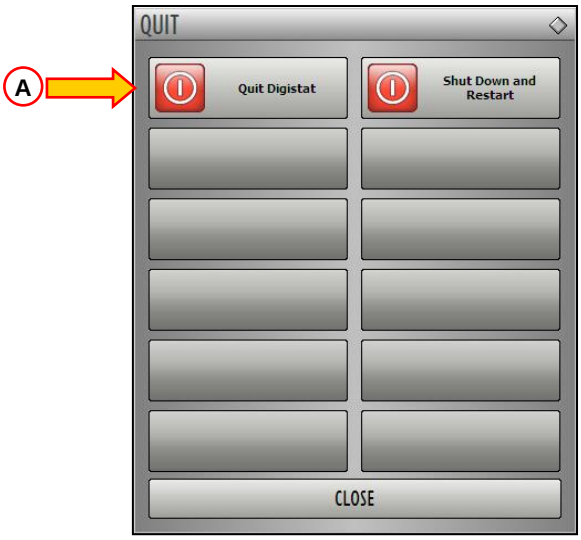


Fig 48

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

A confirmation is requested (Fig 49).

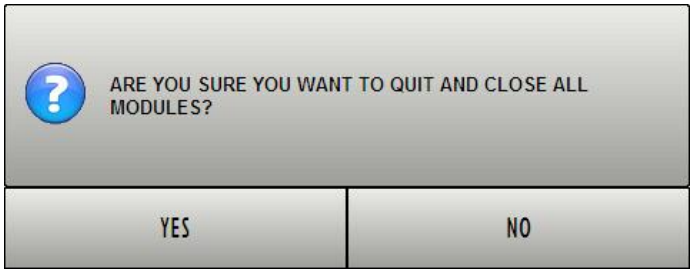


Fig 49

- Click YES to exit DIGISTAT®.

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

7.6. Side toolbar

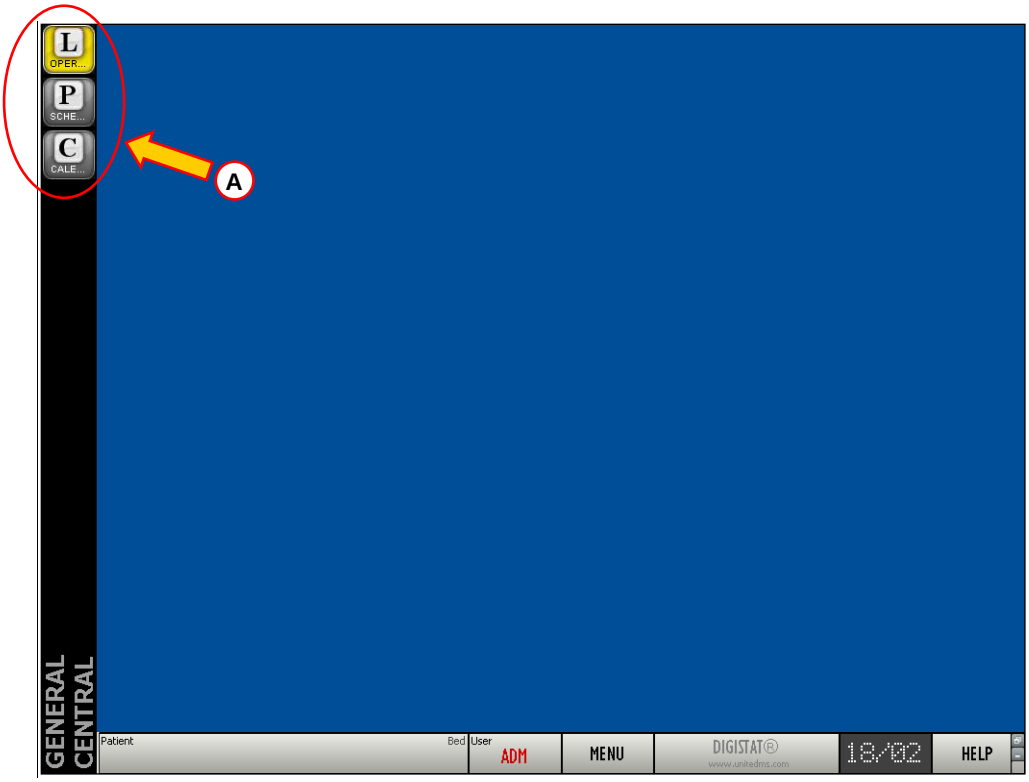


Fig 50- Side Toolbar

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).

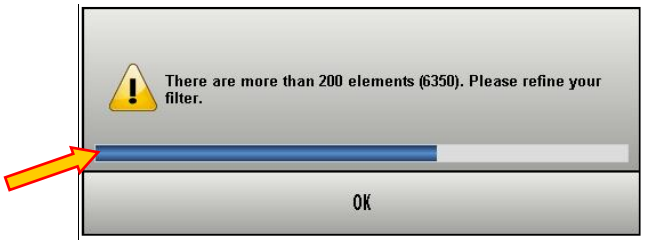


Fig 52 – Timer window with single option

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).

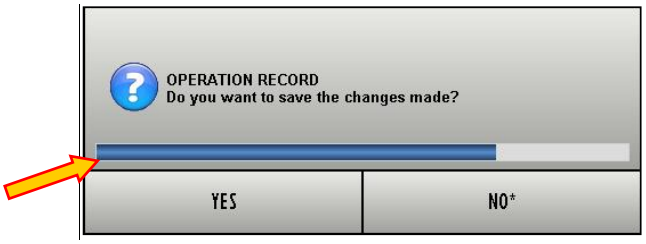


Fig 53 – Timer window with Yes/No choice

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).

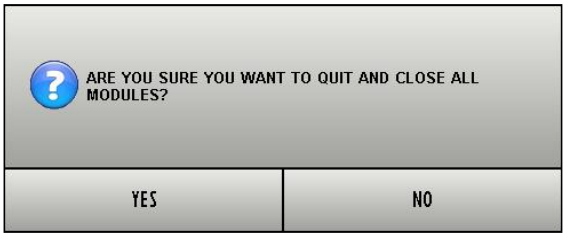


Fig 54 – Window without timer with double choice

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)

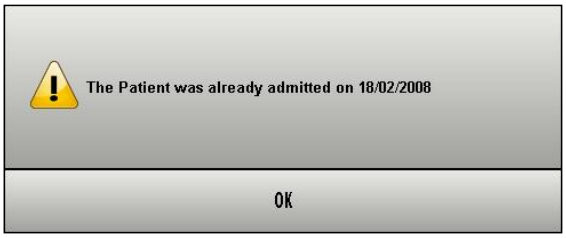


Fig 55 – Window without timer with single option

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. Clinical Forms

8.1. Customizable digital patient documentation

The DIGISTAT® Clinical Forms module provides fully customizable forms to offer easy and efficient ways of entering, viewing, querying and printing patient data.

The patient records can be exported to other softwares (as, for example, Microsoft © Excel and Word), and printed to create a complete and clear documentation that is specifically directed to the department needs.

The DIGISTAT® Clinical Forms module is widely customizable. This manual describes, as examples, some standard configurations that are chosen among the numerous possible ones.

The look of the screens used in your healthcare structure can therefore be different from that here described.

8.2. Module selection

To select the "Clinical Forms" module

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

Fig 56 - "Clinical Forms" module icon

The kind of screen displayed after the module selection depends on the configuration in use.
If no patient is selected no data are displayed on screen. If a patient is selected the screen displays the selected patient data.

8.3. Patient search and selection

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

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

The DIGISTAT® Patient Explorer module will open 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 does not use a DIGISTAT® software for the patient search and selection, please refer to the specific related documentation.

8.4. Screen structure

The different screens of the "Clinical Forms" module are characterized by a structure that remains the same independently from the screen's specific contents. This sctructure is highlighted in Fig 57. Fig 57 shows a screen containing the patient's personal data and the possible patient contacts.

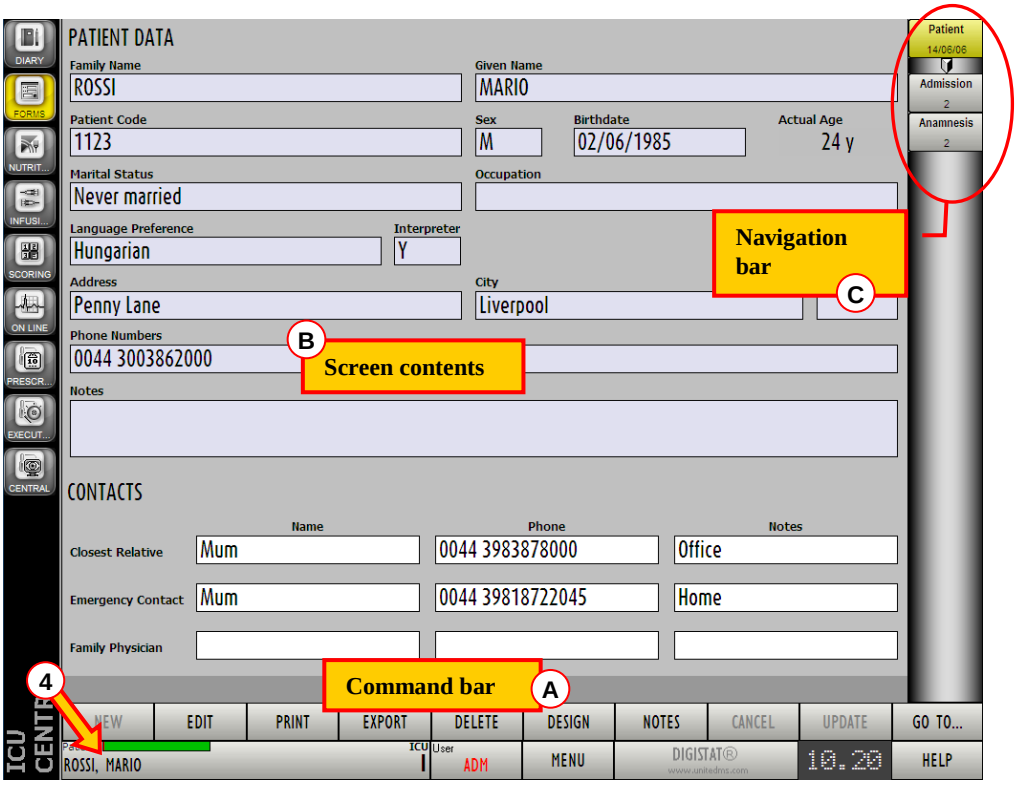


Fig 57

Three main components can be highlighted on every screen:

1) the command bar (Fig 57 **A**);
2) the screen contents (Fig 57 **B**);
3) the navigation bar (Fig 57 **C**).

8.5. Screen contents

The central part of every screen contains the information related to the specific functions of the configuration in use. The screen displayed in Fig 57 contains the patient data; other screens (i.e. other "forms") contain data of a different kind. Fig 58, for example, refers to the patient anamnesis.

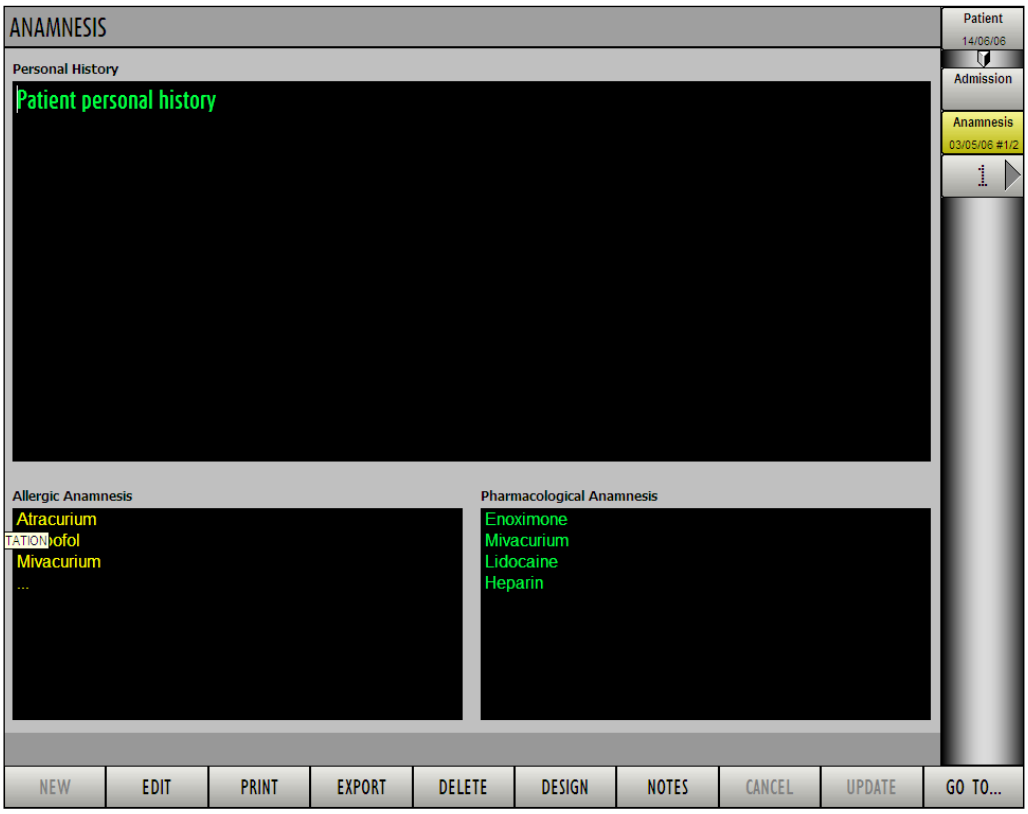


Fig 58 - Patient anamnesis

8.6. Command bar

The command bar (Fig 59) placed at the bottom of every screen is formed by several buttons. Each button makes it possible to perform a specific procedure. The buttons can be either enabled or disabled depending on the current screen and the related contents.

The functions of the different buttons are summarized in this paragraph. Each function will be described later in more detail in the paragraphs indicated.

Fig 59 - Command bar

NEW This button creates a new form of a specific kind. See paragraph 8.6.1.

EDIT This button makes it possible to change the contents of the screen currently displayed. Click this button to turn the screen to "edit mode", enabling this way data entry (see paragraph 8.6.3 for the possible "data entry" procedures).

PRINT This button makes it possible to print the screen contents. Click this button to display a print preview of the relevant document (See paragraph 7.5.2 for a description of the system's print functionalities).

EXPORT This button makes it possible to export the data displayed to a text file. See paragraph 8.6.5 for the detailed procedure.

DELETE This button deletes the current record and all the records depending on it. See paragraph 8.6.6.

DESIGN This button opens the "Form editor", a tool making it possible to design new forms (or to modify the structure of the existing ones). This function is reserved to the system administrator. Please contact the UMS technical assistance for more information on this functionality.

NOTES This button makes it possible to add a note relating to the selected patient (See paragraph 8.6.8 for the detailed procedure).

GO TO... This button opens a smart navigation tool (See paragraph 8.6.9 for the detailed procedure).

8.6.1. How to create a new record

The NEW button (Fig 60 **A**) on the command bar makes it possible to create a new, empty record of a specific kind.

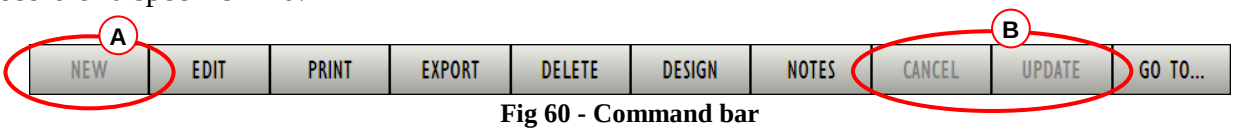


Fig 60 - Command bar

To create a new record

- click the NEW button on the command bar.

A new, empty record of the same kind of that currently displayed opens. I.e: when the "Patient visits" record is displayed the "New" button creates a new empty "Patient visits" record; when the "Exams" record is displayed the "New" button creates a new empty "Exams" record.

No data are on the record created this way. The record is in "Edit mode" (data entry enabled).

- Specify the data on the new record.

The buttons CANCEL and UPDATE (Fig 60 **B**) activate.

When these buttons are active the command bar appears as in Fig 61:

Fig 61

After data entry, either

- click the UPDATE button to save the new record

or

- click the CANCEL button to cancel without saving.

When the NEW button is disabled the new record creation procedure is not available.

8.6.2. Data editing

The EDIT button on the command bar (Fig 62 **A**) makes it possible to change the contents of an existing record.

Fig 62 - Command bar

To edit an existing record,

- access the record to be edited.
- Click the EDIT button on the command bar.

The record turns to "Edit" mode. Data entry is this way enabled.

The CANCEL and UPDATE buttons (Fig 62 **B**) activate.

When these buttons are active the command bar appears as in Fig 63:

Fig 63

- Edit the record data.
- either click the 

button to save the changes

or

- click the 

button to cancel without saving.

8.6.3. Data editing procedures

The different fields on the "Clinical Forms" module screens are characterized by different data specification procedures. This paragraph describes some common examples.

1) Checkbox selection

Fig 64 - Checkbox

- Click the checkbox (or the checkboxes) corresponding to the option that must be present/enabled/active.

In Fig 64, for instance, the user indicated that the current record refers to an emergency.

2) Free text

Fig 65 - Free text

- Type the required information.

3) *Drop down menu*

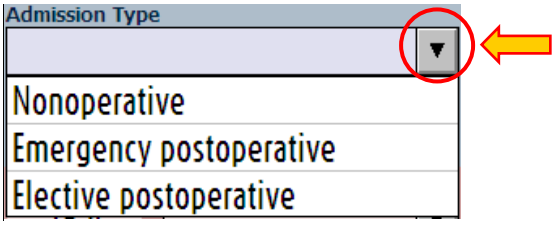


Fig 66 - Drop down menu

- Click the button placed alongside the relevant field (Fig 66).

A menu containing several pre-defined options will opens.

- Click the wanted option.

The chosen option is displayed in the field.

4) *Codefinder module*

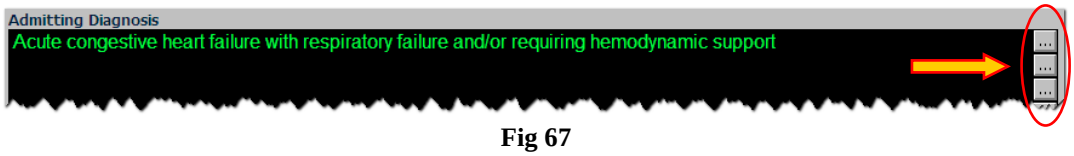


Fig 67

- Click the button placed alongside the field (Fig 67).

The DIGISTAT® Codefinder module opens (Fig 68).

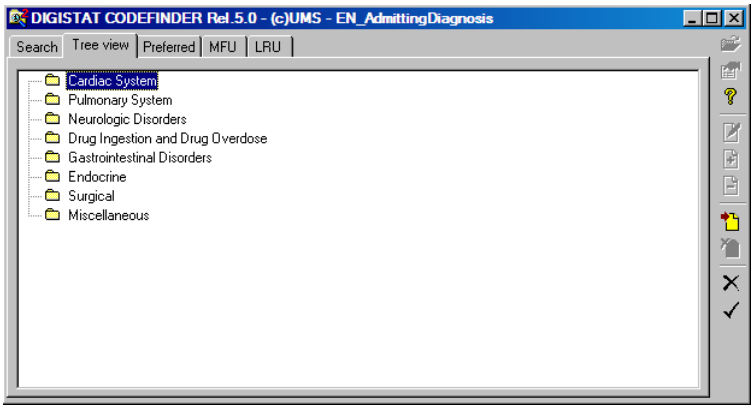


Fig 68 - Codefinder

- Use the module's search and selection functions to specify the required information.

See the "Codefinder" module's user manual for a detailed description of these functionalities.

8.6.4. Print

The PRINT button on the command bar (Fig 69) makes it possible to print the patient documentation.

The format and the contents of the print reports are in part customizable. Please refer to your system administrators for more information about the print reports configuration.

Fig 69 - Command bar

To do that

- click the PRINT button.

A print preview opens. The system's print functionalities are described in paragraph 7.5.2.

8.6.5. Data export

The EXPORT button on the Command bar (Fig 70) makes it possible to export the data of one or more tables to a text file.

Fig 70 - Command bar

To do that

- click the EXPORT button.

The window shown in Fig 71 will open.

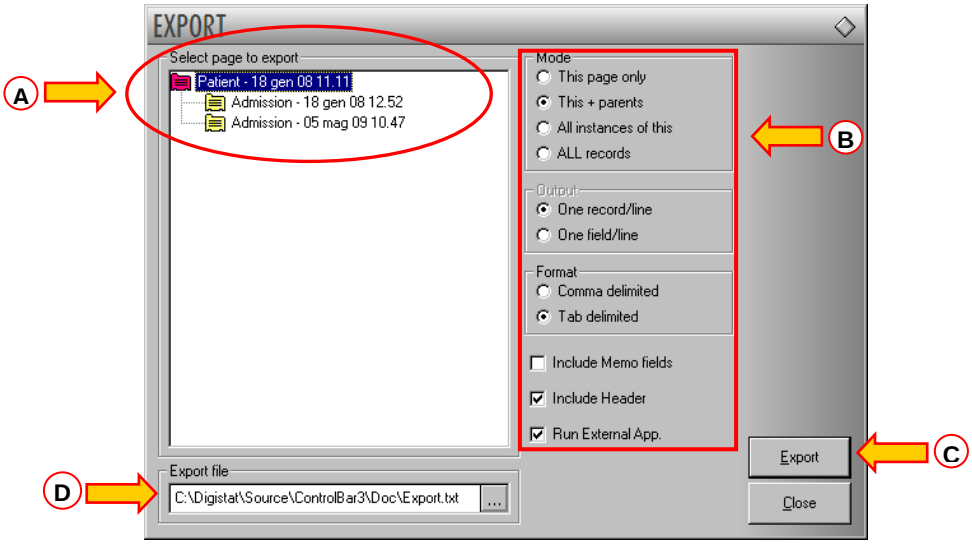


Fig 71 - Data export

The "Export" window makes it possible to define:

1 - the set of data to be exported,
2 - the export modality,
3 - the destination of the file created.

On the left of the window, under the title "Select page to export" (Fig 71 **A**), a tree graph represents the structure of the patient's pages (see paragraph 8.7 for an explanation of the page organization within the "Clinical Forms" module).

Every "leaf" of the "tree graph" represents a page. Each page is characterized by the page title, the page creation date and time.

Click a line on the graph to select the corresponding page. In the figure the "Patient" page is selected (the corresponding line is highlighted).

On the right of the window (Fig 71 **B**) there are several options regarding the way the page is exported (for instance: export only the selected page vs. export the selected page and the parent pages - export one record per line vs. export one field per line etc…).

The box indicated in Fig 71 **D** specifies the destination of the export file created. Click the ... button to open a window making it possible to specify the destination file.

To export the data of a specific page,

- click the EXPORT button on the command bar (Fig 70)**.**

The window shown in Fig 71 opens.

- Click the line corresponding to the page containing the data to be exported (Fig 71 **A**).

The line is highlighted.

- Click the Export button placed at the bottom-right of the window (Fig 71 **C**).

The data of the selected page are this exported to a text file.

The pages selected to be exported are characterized by a magenta icon on the tree-graph on the left of the window (Fig 71 **A***).*

8.6.6. How to delete a record

The DELETE button on the command bar (Fig 70) makes it possible to delete a record. All its "children records" are deleted as well. See paragraph 8.7 for an explanation of the page organization within the "Clinical Forms" module.

Fig 72 - Command bar

To delete a record

- access the record to be deleted.
- Click the DELETE button.

The system asks for a confirmation with the following pop-up message.

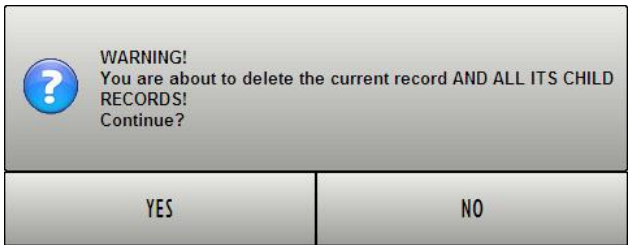


Fig 73

- Click YES to delete the current record and all its "children records"

The deletion of a record is a critical and irreversible action. Only the system administrator, or person having an analogous permissions level, is enabled to perform it. Otherwise the DELETE ***button is disabled.***

It is also possible to delete a record using the CANCEL button on the "Smart navigation window". See paragraph 8.6.9 for more details.

8.6.7. Forms design functions

The DESIGN button (Fig 74) opens the "Form editor", a tool making it possible to design new forms (or to modify the structure of the existing ones). This functionality is reserved to the system administrators. Please contact the technical assistance for more information. The button is either disabled or not present if the user is not allowed to access the "design" functions.

Fig 74 - Command bar

8.6.8. How to add a patient note

The NOTES button on the command bar (Fig 75) makes it possible to add a patient note.

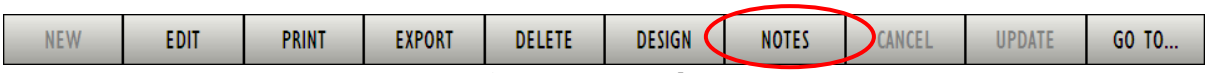


Fig 75 - Command Bar

To add a note

- click the NOTES button.

The following window opens.

Fig 76 - "Notes" window

- Click the Edit button (Fig 76 **A**).

The window changes in the following way. Data entry is enabled (Fig 77).

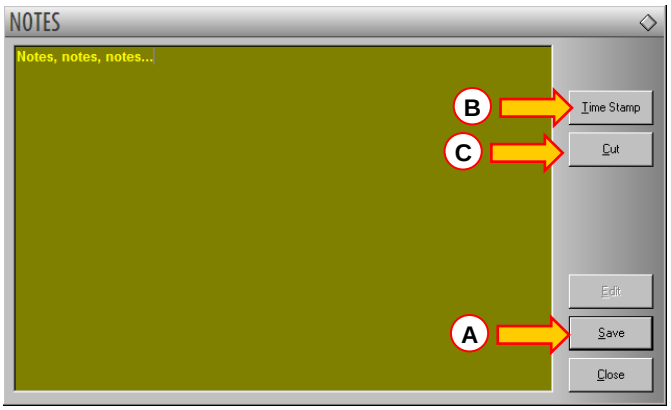


Fig 77 - "Notes" window (edit mode)

- Type the note. The text appears on the window.
- Click the Save button to save the note (Fig 77 **A**).

The window closes automatically; the presence of a note is indicated by the color of the button on the command bar, that is now yellow (NOTES). Click the button again to display the note again.

Use the Time Stamp button indicated in Fig 77 **B** to display the date, time and the acronym of the user who is adding the note (Fig 78).

Fig 78 - Date and time

Use the Cut button (Fig 77 **C**) to cut a selected text portion of the note.

To cut a text portion

- click the Edit button (Fig 76 **A**).
- Select the text to be cut using the mouse device or the workstation keyboard.
- Click the Cut button (Fig 76 **C**).

The selected text will disappears from the "Notes" window.

The notes inserted this way are visible on every DIGISTAT® module possibly installed implementino the NOTE *button.*

8.6.9. Smart navigation functions

The GO TO... button on the command bar (Fig 79) opens a tool enabling a quick, smart navigation through the Clinical Forms records.

Fig 79 - Command Bar

To open the "Smart navigation window"

- click the GO TO... button**.**

The window shown in Fig 80 opens.

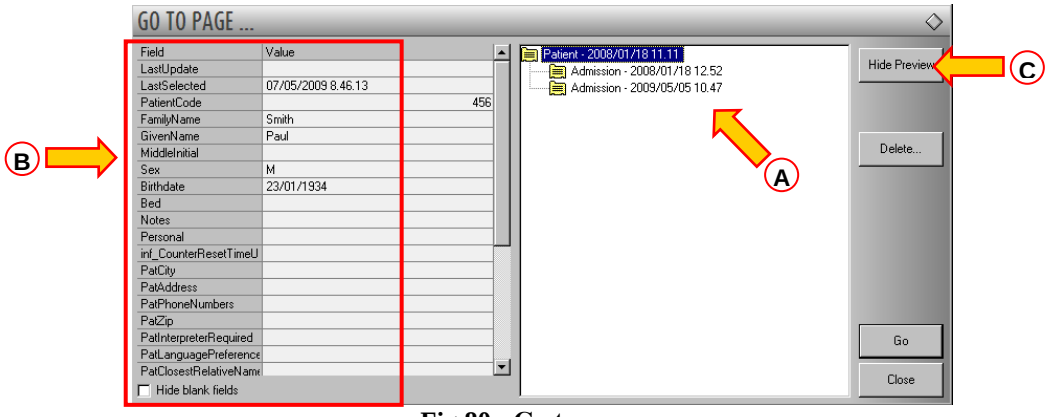


Fig 80 - Go to page…

On the right of the window (Fig 80 A) it is displayed the records structure in the form of a tree-graph (see paragraph 8.7 for a description of the way the various records are structured).
On the left it is displayed the content of the various fields on the selected page (Fig 80 **B**).

Click one of the lines on the right to display (on the left) the information of the corresponding record).

The Hide Preview button (Fig 80 C) displays only the structure (the left part is hidden - Fig 81).

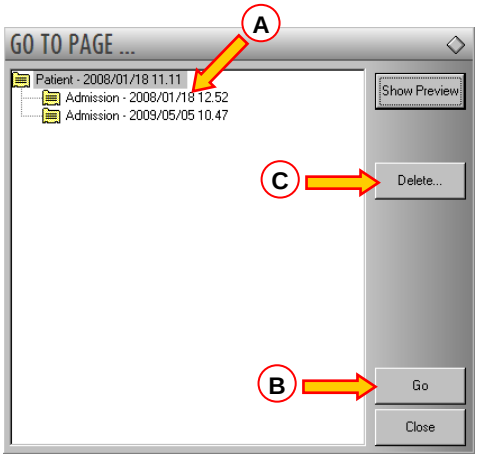


Fig 81

To access a record

- click the line corresponding to the record.

The line is highlighted (Fig 81 **A**)

- Click the Go button (Fig 81 **B**).

Double click the line to access the corresponding record directly.

Use the Delete... button (Fig 81 **C**) to delete the selected page. When the button is clicked the system asks for confirmation with the following pop-up message (Fig 82).

Fig 82

- Click YES to delete the current record and all its "children".

8.7. The navigation bar / Records logical structure

The figures in this paragraph (8.7) are taken from a "Clinical Forms" configuration that is in use in an Italian obstetrics departments. Hence the functions and the names of the different screens ("Gravidanze", "Intrapartum", "Partogramma" etc…). Please remember that the "Clinical Forms" module contents change according to the user needs and that the screens described in this manual <u>are an example</u> that explains the module structure and the use of the navigation bar.

The navigation bar placed on the right of every Clinical Forms page (Fig 83, Fig 57 **C**) is a tool that makes it possible to access the different screens and functions of the module.

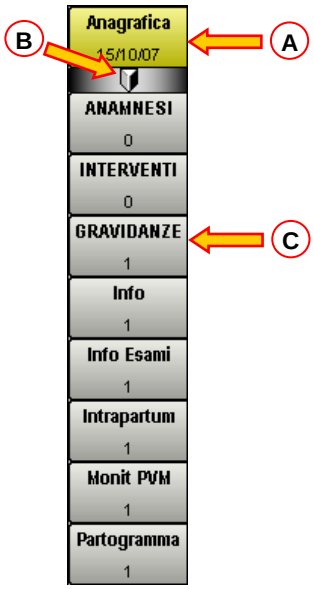


Fig 83

The structure of the navigation bar reflects the logical organization of the records (that is a tree graph). Every record is represented by a box. Click one of the boxes to access the corresponding record. The record currently displayed is highlighted yellow (Fig 83 **A**).

Patient data are recorded and displayed on a record named "Patient" in the present configuration. This record is the root, the starting point on which all the other records of the same patient are based. This record is represented on the lateral bar by the first box on top (Fig 83 **A**). The record date of creation is displayed in the box.

The symbol, indicated in Fig 83 **B**, says that all the subsequent records are at a lower level. This structure can be represented in a tree graph in the following way.

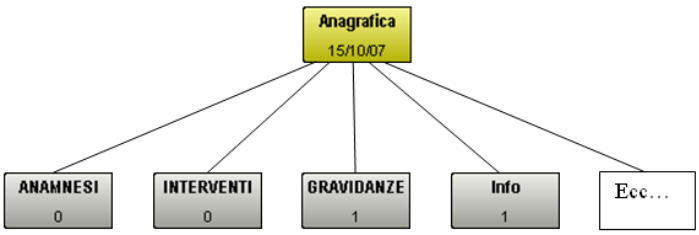


Fig 84

The number inside each box indicates the number of existing records of that specific kind. The example displayed in Fig 84 shows that there are 1 "Gravidanze" record, 1 "Info" record and 0 "Anamnesi" and "Interventi" records.

The present paragraph describes, as example, one of the possible navigations through the patient records and describes therefore one of the possible ways to use the navigation bar.

Click the GRAVIDANZE box to display the data referring to the pregnancies of a patient (Fig 83 **C** - remember that the present configuration is in use in an obstetrics department).

The lateral bar noe looks as in Fig 85.

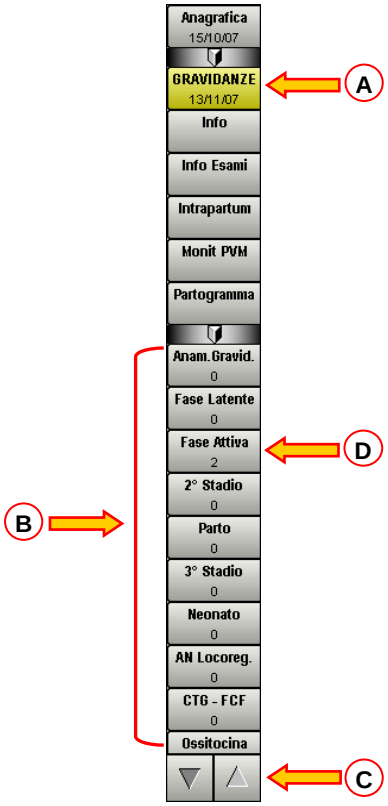


Fig 85

The patient's pregnancy record is displayed on screen (corresponding to the selected box, now yellow - Fig 85 **A**). All the boxes corresponding to the records containing the details of the selected pregnancy appear on the bar, grouped in a lower level (Fig 85 **B**).
The arrows indicated in Fig 85 **C** mean that there are further boxes on the bar that are not displayed. Click the arrows to scroll the bar up and down and display the hidden boxes.

The chosen path can be represented in a "tree" graph (Fig 86).

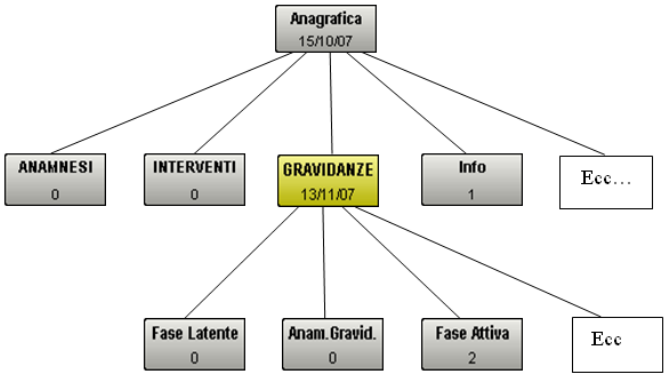


Fig 86

The user chooses to display the records relating to the "Active phase" of delivery. He/she thus clicks the FASE ATTIVA box (Fig 85 **D**).The navigation bar changes in the following way (Fig 87).

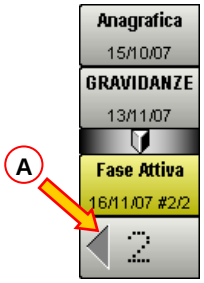


Fig 87

On the bar are now displayed only the boxes related to the chosen path ("Anagrafica", then "Gravidanze", then "Fase attiva"). The number "2" indicated in the figure means that there are two records regarding the active phase of delivery. One of the two records is displayed on screen. Click the arrow indicated in Fig 87 **A** to display the other record.

The "tree" representation of the chosen path is the following.

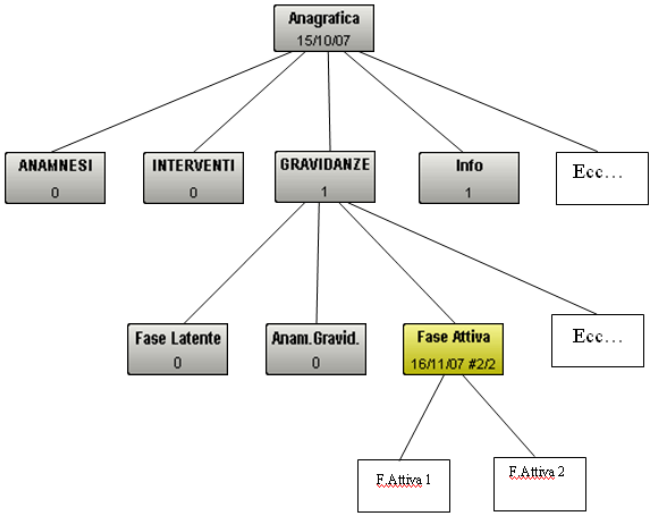


Fig 88

The navigation bar makes this way possible to move easily and quickly from a record to another.

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

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

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

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OTHER RIGHTS AND LIMITATIONS
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Sub-license and Rental. The User may not rent, sub-license, lease, or lend the PRODUCT.

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

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

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

LIMITED WARRANTY
UMS warrants for a period of twelve (12) months from the date of delivery of the PRODUCT to the User that: (a) the media on which the PRODUCT is supplied shall be free of material and of manufacturing defects under normal conditions of use; and (b) the PRODUCT shall perform substantially in accordance with its published specifications.
Except for the above specifications, the PRODUCT is supplied "just as it is". This Limited Warranty shall apply only to the initial User/licensee.
The sole obligation of UMS under this warranty shall be, to the discretion of UMS, either to repair or replace the PRODUCT or to refund the price paid for the purchase of the PRODUCT, provided that the defect of the PRODUCT is technically attributable to UMS and that UMS has authorized its return.
Responsibility for loss or damages suffered by the PRODUCT during its shipment in connection with this warranty shall vest on the party shipping the PRODUCT.
UMS does not guarantee that the PRODUCT will be free from errors or that the User can operate the system without problems or interruptions.
Furthermore, due to the ongoing development of intrusion methods and attacks of networks, UMS does not guarantee, notwithstanding its performance of the due checks and its preparation of upgrades based on the best knowledge and experience in existence from time to time, that the PRODUCT or other equipment systems, or the network itself on which the PRODUCT is used, will be invulnerable to intrusions and attacks.
It is the responsibility of the User to install and to maintain software means for the protection against intrusions or attacks (i.e. antivirus, firewall, etc.)

Limitations. This warranty does not apply if the PRODUCT: (a) has been installed, repaired, maintained or in any other way altered by persons not 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”.

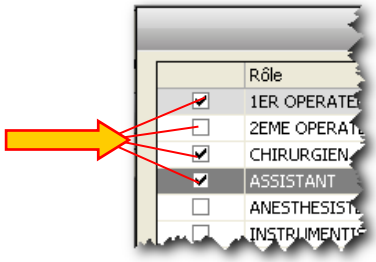

Figure 1 - Checkboxes

- **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.

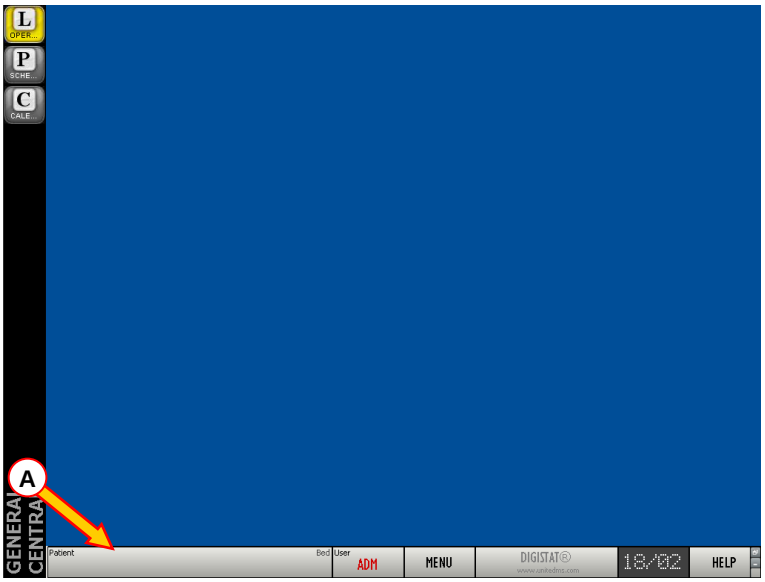

Figure 3 - Control Bar

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).

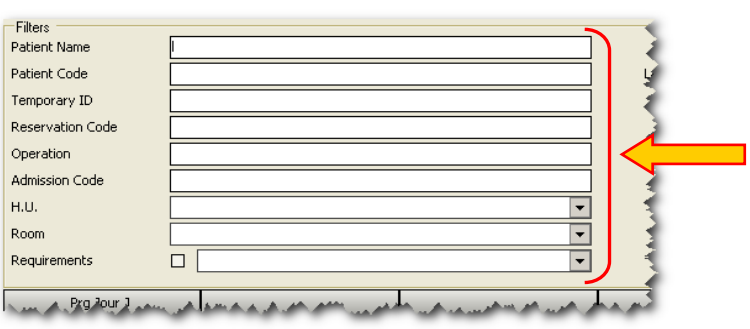

Figure 4 - Fields

❖ **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.

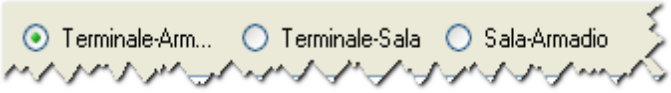

Figure 5

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**).

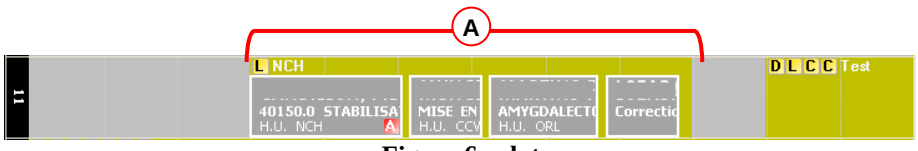

Figure 6 - slot

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).

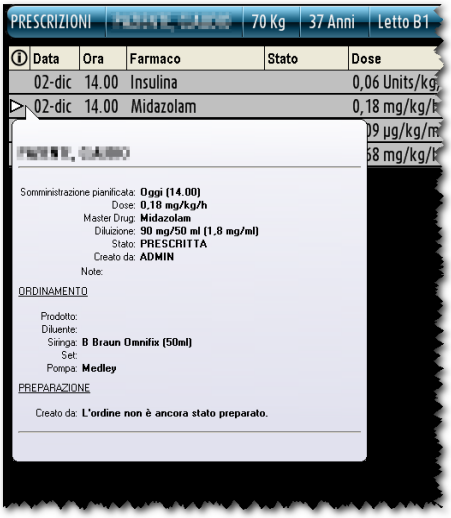

Figure 8 - Tooltip

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.