DIGISTAT® Fluid Balance

DIGISTAT® Version 4.1

User Manual

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ASCOM UMS srl unipersonale
Via Amilcare Ponchielli 29, 50018, Scandicci (FI), Italy
Tel. (+39) 055 0512161 – Fax (+39) 055 829030
www.unitedms.com

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WARNING

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DIGISTAT® is a Trademark of ASCOM UMS srl
Information is accurate at the time of release.
All other trademarks are the property of their respective owners.

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

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

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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 ASCOM UMS technical support service.
Remember that, by specific request, ASCOM UMS is able to provide custom-made documentation for every specific type of procedure and/or configuration.

2.2. Charcters used and terminology

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

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

When consulting the on-line version as opposed to the paper version, cross references in the document work like hypertextual links. This means that every time you come across the reference to a picture ("Fig 7", for example) or to a paragraph ("paragraph 5.4", for example), you can click the reference to directly access that particular figure or that particular paragraph.

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

- Click the "**Update**" button,

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

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

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

2.3. Symbols

The following symbols are used in this manual.

Useful information

This symbol appears alongside additional information concerning the characteristics and use of DIGISTAT®. This may be explanatory examples, alternative procedures or any "extra" information considered useful to a better understanding of the product.

Caution!

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

3. Introduction to DIGISTAT®

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

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

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

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

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

3.1. Modular architecture

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

3.2. Intended use

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

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

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

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

!

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

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

!

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

The User must implement adequate procedures to guarantee that potential errors occurring in the PRODUCT are promptly detected and corrected and do not constitute a risk to the patient and the operator.
These procedures depend on the configuration of the PRODUCT and the method of use preferred by the User.
Only printouts that are signed (with digital signature or autograph) by authorized physicians or medical operators shall be considered valid clinical documents. In signing the aforementioned printouts, the User certifies that he/she has checked the correctness and completeness of the data present in the document.
Only these signed documents are a valid source of information for diagnostic or therapeutic processes and/or procedures.

!

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

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

! ***DIGISTAT® is not a "Distribuited Alarm System".***

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

3.2.1. Intended users

The PRODUCT must be used by properly trained physicians, nurses, administrative staff, system administrators, biomedical engineers and technicians.
Use of the PRODUCT must be granted, by means of specific configuration of the passwords and active surveillance, only to User 1) trained according to PRODUCT indications by personnel authorized by ASCOM UMS or ASCOM UMS distributors and 2) in possession of the professional qualifications to correctly interpret the information supplied and to implement the appropriate safety procedures.

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

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

3.2.2. Intended environment

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

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

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

3.2.3. "Off-label" use of the Product

Every use of the Product outside what explicitly stated in the "Intended use" (usually referred to as "off-label" use) is under the full discretion and responsibility of the user and of the Responsible Organization. The manufacturer does not guarantee in any form the Product safety and suitability for any purpose when the Product is used outside what explicitly stated by the "Intended use".

3.3. Manufacturer's responsibility

The CE seal is a safety warranty of the product introduced on the market.
ASCOM UMS is responsible for the product's safety, reliability and performance only if:

- Use and maintenance comply with User Manual instructions;
- This Manual is stored in good conditions and all sections are readable;
- Configurations, changes and repairs are only performed by personnel formed and authorized by ASCOM UMS ;
- The Product's usage environment complies with safety regulations;
- The environment's wiring system is highly efficient and complies with related regulations.

!

WARNING!

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

3.4. Product tracking

In order to ensure device tracking and on-going safety and efficiency checks on site, in compliance with ISO 9001 and EN 13485 quality standards and European law on medical devices 93/42/EEC, amended by the directive 2007/47/EC, the former owner is recommended to inform ASCOM UMS/Distributor about any ownership transfer by giving written notice stating the product, former owner and new owner identification data.
Device data can be found in the product labelling (either paper label provided at installation time or "About box" displayed within the product – see paragraph 6.8.5).
In case of doubts/questions about product labelling and/or product identification please contact ASCOM UMS/Distributor technical assistance (for contacts see paragraph 9).

3.5. Post-market surveillance

The CE marked device is subject to a post-market surveillance - which ASCOM UMS, its distributors and dealers must provide for each marketed copy - concerning actual and potential risks, either for the patient or the User, during the Product's life cycle.
In case of deterioration of the device characteristics, poor performance or inadequate user instructions that have been or could be a hazard to either the patient or User' health or to environmental safety, the User must immediately give notice to either ASCOM UMS, one of its branches or nearest authorised dealer.

The device details can be found on its labelling.

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

3.6. Product life

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

3.7. CE mark and regulation conformity

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

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

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

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

4. Software/Hardware specifications

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

4.1. Bedside

4.1.1. Hardware

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

Minimum hardware requirements:

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

4.1.2. Operating System

Supported operating systems:

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

4.2. Central

4.2.1. Hardware

Minimum hardware requirements:

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

4.2.2. Operating System

Supported operating systems:

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

4.3. Server

4.3.1. Hardware

Minimum hardware requirements:

- Intel® Xeon® E series processor (or faster)
- Memory: 4 GB RAM (8 GB recommended)
- Hard Disk: at least 80 GB of available space
- Monitor: 1024 x 768 or higher (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- Ethernet interface 100 Mb/s (or higher)
- CD/DVD Drive or possibility to copy the installation files

4.3.2. Operating System

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

4.3.3. System Software

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

The computers and the other connected devices must be suitable for the environment in which they are used and must therefore comply with the relevant regulations. The personnel in charge should perform the adequate compliance checks.

WARNING!

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

WARNING!

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

4.4. Firewall and Antivirus

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

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

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

!

WARNING!

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

!

WARNING!

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

4.5. Local network features

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

- DIGISTAT® uses a TCP/IP traffic protocol.
- The LAN must not be congested and/or full loaded.
- DIGISTAT® requires at least a 100 Mbps LAN available to the end user. 1 Gbps backbones would be worthwhile.
- There must not be filters in the TCP/IP traffic between workstations, server and secondary devices.
- If the devices (server, workstations and secondary devices) are connected to different subnets there must be routing in these subnets.
- It is recommended to adopt redundancy strategies to ensure network service availability in case of malfunction.
- It is recommended to schedule together with ASCOM UMS the maintenance calendar in order to let ASCOM UMS or the authorized Distributor efficiently support the healthcare structure in managing the possible disservices caused by maintenance activities.

ATTENTION!

If the network does not match the requested features, DIGISTAT® performance gradually deteriorates until timeout errors occur. The system may finally switch to "Recovery" mode.

ATTENTION!

In case a WiFi network is in use, given the possible intermittence of the WiFi connection, network disconnections are possible, that cause the activation of the "Recovery Mode" and the consequent system unavailability. The Responsible Organization shall ensure an optimal network coverage and stability, and train the personnel in the management of these temporary disconnections.

4.5.1. DIGISTAT® impact on the hospital network

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

The bandwidth used by a DIGISTAT® system depends on many different factors. The most important are:

- Number of workstations,
- Number of workstations configured as central stations,
- Number and type of devices dedicated to data acquisition (either only or as well dedicated).
- Interfaces with external systems,
- DIGISTAT® configuration and mode of use.

In a configuration with 100 clients the following bandwidth occupation values can be indicatively predicted

Average: 0.8 – 6 Mbit/s

Pitch: 5 – 25 Mbit/s

5. Before starting

5.1. Installation and maintenance warnings

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

DIGISTAT® must absolutely be installed and configured by specifically trained and authorized personnel. This includes ASCOM UMS (or authorized Distributor) staff and any other person specifically trained and authorized by ASCOM UMS/Distributor. Similarly, maintenance interventions and repairs on DIGISTAT® must absolutely be performed according to the ASCOM UMS company guidelines only by ASCOM UMS/Distributor personnel or other person specifically trained and authorized by ASCOM UMS/Distributor.

!

DIGISTAT® must absolutely be installed and configured by specifically trained and authorized personnel. This includes ASCOM UMS (or authorized Distributor) staff and any other person specifically trained and authorized by ASCOM UMS/Distributor.

- Only use devices approved by ASCOM UMS bearing the CE mark.
- Only use devices approved by ASCOM UMS. It is not possible to install devices without proper training.
- Only use devices approved by ASCOM UMS. There is a risk of injury to the patient and operators.
- Scrupulously observe the manufacturer's instructions for the hardware installation.
- Make provision for regular maintenance of the inner disk and checks on the operating system.
- The DIGISTAT® USB dongle must be stored and used in eligible environmental conditions (temperature, humidity, electromagnetic fields etc.), as specified by the dongle manufacturer. These conditions are equivalent to those required by common office electronic devices.
- Within "Patient Area" (see Fig 1) it is recommended to use washable waterproof devices.
- Within "Patient Area" (see Fig 1) it is recommended to use washable, sterilizable rubber keyboards and mouse devices. For "touch screens" capacitive technology (insensitive if used with gloves) is recommended because it discourages using gloves (sometimes contaminated).

5.2. Cleaning

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

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

5.3. Precautions and warnings

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

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

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

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

5.3.1. Electrical safety

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

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

!

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

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

!

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

5.3.2. Patient Area

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

!

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

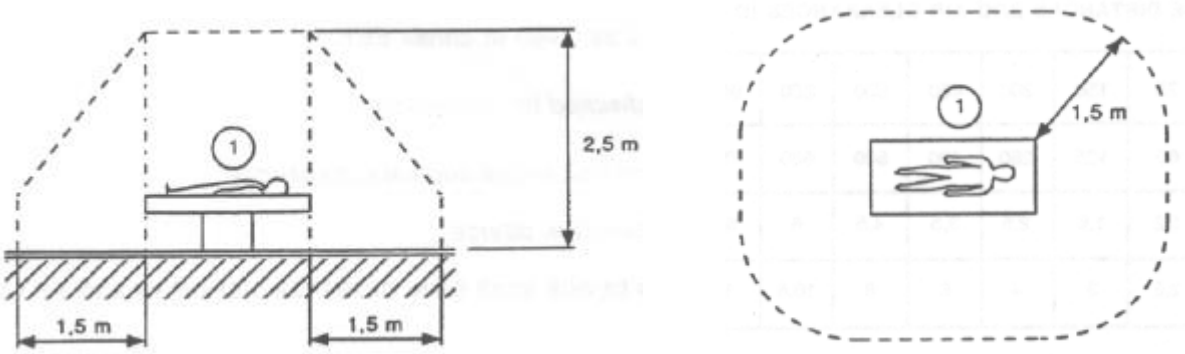


Fig 1

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

!

WARNING!

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

5.3.3. Electromagnetic compatibility

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

5.3.4. Devices eligibility

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

5.4. Privacy Policy

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

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

Please read the following precautions carefully and strictly observe them.

- The workstations must not be left unattended and accessible during work sessions. It is recommended to log out when leaving a workstation. See paragraph 6.5 for log out procedure.

- Sensible data saved in the system, as passwords or users' and patients' personal data, must be protected from possible unauthorized access attempts through adequate protection software (antivirus and firewall). It is the hospital structure responsibility to implement this software and keep them updated.

- The user is advised against the frequent use of the lock function (paragraph 6.5.2). Automatic log out allows to protect the system from unauthorized accesses.

In some circumstances personal and/or sensible data are transmitted in non-encrypted format and using a connection which is not phisycally secure. An example of this kind of transmission are the HL7 communications. The Responsible Organization is responsible to provide adequate security measures to comply with the local privacy laws and regulations.

5.4.1. User credentials features and use

This paragraph explains the user's DIGISTAT® credentials (username and password) features, use and update policy.

- Every precaution must be taken in order to keep personal username and password secret.

- Username and password must be kept private. Do not let anybody know your username and password.

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

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

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

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

- Each user is characterized by a profile enabling him/her to access only the functionalities that are relevant for his/her working tasks. The system administrator must assign an appropriate user profile when creating the user account. The profile must be reviewed at least once a year. This revision can also be performed for classes of users. The user profile definition procedures are described in the DIGISTAT® configuration manual.

- Password must be at least 8 characters.

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

- The password is given by the system administrator at user account creation time. It must be changed by the user at first access in case this procedure is defined by configuration (see paragraph 6.8.4 for the password modification procedure).

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

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

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

The following information is reserved to system administrators:

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

See DIGISTAT®configuration manual for detailed information on user account creation procedures and password configuration.

5.4.2. System administrators

ASCOM UMS/Distributor technical staff, when performing installation, updates and/or technical assistance may have access to and deal with personal sensible data stored in the DIGISTAT® database.
ASCOM UMS srl or Distributor, for issues relating to management of personal sensible data, adopts procedures and working instructions complying with the current privacy regulation (D.Lgs 196/2003 of the 30th of June 2003).
In performing the abovementioned activities the ASCOM UMS/Distributor technical staff is configured as "System Administrator" for the DIGISTAT® system (see regulation of 25/11/2008 of the Privacy Guarantor on "System Administrators"). ASCOM UMS/Distributor staff performing this kind of procedures is appropriately trained on privacy issues and, in particular, in sensible data treatment issues.

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

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

5.4.3. System logs

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

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

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

5.5. Back up policy

!

It is recommended to regularly perform system backups.

The responsible healthcare structure using DIGISTAT® system must define a backup policy that best suits its data safety requirements.
ASCOM UMS/Distributor is available to help and support in implementing the chosen policy.

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

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

5.6. Out-of-order procedure

This paragraph describes the policy suggested by ASCOM UMS in case a DIGISTAT® workstation gets out of order. The goal of the procedure here described is to minimize the time required to replace the out-of-order workstation with one properly working.
ASCOM UMS suggests for this purpose to have at disposal, as substitute equipment, an additional PC on which DIGISTAT® is already installed.
In case of a DIGISTAT® workstation is out-of order, the substitute equipment can promptly replace the DIGISTAT® workstation.
Always remember that DIGISTAT® must only be installed by trained authorized personnel. This includes ASCOM UMS/Distributors staff and any other person specifically trained and explicitly authorized by ASCOM UMS/Distributor. Missing an explicit, direct authorization from ASCOM UMS/Distributor, the hospital staff is not authorized to perform installation procedures and/or to modify DIGISTAT® configuration.
The risk related to the DIGISTAT® workstation deactivation and substitution is that of associating the workstation with a wrong bed or room. This could lead to a “patient switch”, which is an extremely hazardous condition.
The risk related to the substituion and/or reconfiguration of network equipment involved in the DIGISTAT® data acquisition (i.e port server, docking station, etc...) is that of assigning the acquired data to a wrong patient. The patient-acquired data relation is based on the IP address. Changing it could lead either to data flow interruption or, in severe cases, to assigning data to the wrong patient.

!

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

The risk related to this procedure is that of associating a wrong bed or room to the workstation and create this way the possibility to select a wrong patient.

In case a DIGISTAT® workstation needs to be deactivated and replaced, the hospital staff must promptly call ASCOM UMS (or authorized Distributors) and request the execution of this task.
We suggest the hospital management (or anyone who is in charge) to define for this purpose a clear, univocal operating procedure and to share this procedure with all the staff members involved.

In order to speed up replacement times, we suggest to have at disposal one or more substitution equipment with all the necessary apllications already installed (OS, firewall, antivirus, RDP, ...) and with DIGISTAT® already installed, but disabled (i.e. not executable by a user without the assistance of an ASCOM UMS technician).

In case of out of order of a DIGISTAT® workstation, the substitution equipment availability assures the minimization of restoration times (hardware substitution) an limits at the same time the risk of patient exchange.

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

1) The hospital staff replaces the out of order PC with the “substitution equipment”
2) The hospital staff calls ASCOM UMS/Distributor and requests the “substitution equipment” activation
3) The ASCOM UMS/Distributor staff disables the out of order workstation and correctly configure the “substitution equipment”
4) The out of order PC is repaired and prepare d as “sustitution equipment”

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

5.6.1. Reconfiguration/substitution of network equipment

In case it is necessary to either reconfigure or substitute a network device involved in the DIGISTAT® data acquisition, the hospital staff must promptly call ASCOM UMS/Distributor and schedule the substitution/reconfiguration procedure to allow ASCOM UMS staff to either reconfigure DIGISTAT® as well or provide all the necessary information. It is recommended, for this purpose, to define a clear procedure and share it with all the involved personnel. Some general indications about this are in the DIGISTAT® configuration manual.

5.7. Preventive maintenance

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

This is the maintenence checklist:

Preparatory checks

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

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

- Schedule possible updates with the technical staff

Checks to be performed

Antivirus

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

Database

- Check that an effective DIGISTAT® database clean-up and back-up policy is configuraed.
- Check that the clean-up and back-up store procedures exist (UMSBackupComplete, UMSBackupDifferential, UMSCleanLog, UMSCleanDriver) and the related schedule.
- Check that back-up files exist (both full and differential).
- Check with the hospital technical department that back-up, configuration folders and data folders are correctly copied to another storage device.
- Restore a back-upped DB to verify its correctness.
- Delete the old back-up files (.bak) and the possible files that are not inherent to DIGISTAT® configuration on the network shared path.
- Check that the other jobs on SQL Agent or scheduled tasks (for instance those that are support to integration with third-parties systems) are present, and that their schedule is adequate.
- On SQL Agent check that the different JOBs are executed and that there are not hanging JOBs or JOBs in error.
- Check the SQL Server LOGs.
- Check the DB total size and the number of records in the main tables.
  Script for checking all the tables size:

```
USE [DATABASENAME]
GO

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

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

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

EXEC (@INS);

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

DROP TABLE [#SpaceUsed]
```

Server

- Check the Windows™ server event log.
- Check the permissions on the shared folders (es: Backup folder).
- Useless files and directories clean up to free up space on server disk.
- Check the displays (if any) on the server rack and verify that there are neither visual nor sound alarms.
- Check that on the different disk units there is enough space available.
- Disk check with dedicated tools (checkdisk, defrag, etc.).
- In case there are disks in RAID, check the health conditions of the RAID unit on the RAID management software.
- Check the leds of the non-alarmed RAID units.
- If an UPS is connected, check its health conditions with its management software.
- In case of UPS schedule an electric interruption (an electric failure simulation) and check thet the server is configured ti perform a CLEAN shutdown.

Workstations

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

DIGISTAT®

- Check data presence (SELECT) Patient, Admission, Bed, Location tables and some random others.
- Check on the network table that no workstation has the ALL value in the “modules” field.
- Check and in case clean the service and/or ASCOM UMS Gateway LOG.
- Check and in case clean the DAS LOGs for the Drivers (if enabled).
- Check that the privacy policy is respected as stated in this manual in paragraph 5.4.

Connection to devices

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

Instruction for use

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

5.8. Compatible devices

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

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

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

Please note that new drivers and new connections are created very often, therefore the list published on the website may sometimes not be complete. It is possibile to make request of the updated list of devices to ASCOM UMS. Please use for this purpose the references (tel, e-mail, fax…) listed in paragraph 9.

5.9. System unavailability

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

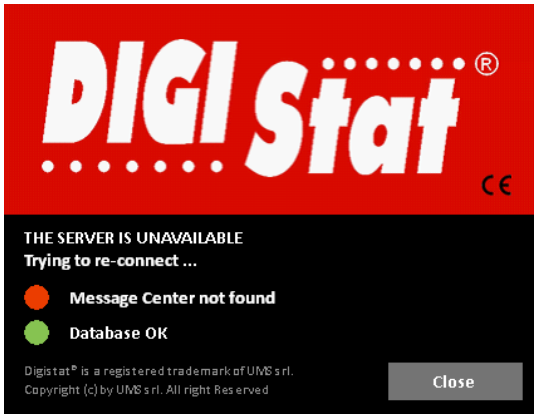


Fig 2

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 9 for the contacts list).

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

It is responsibility of the healthcare structure using DIGISTAT® to define an emergency procedure to put into effect in those cases. This is necessary to

1) Make it possible for the departments to keep on working
2) Restore as soon as possible the system availability (back-up policy is part of this management. See paragraph 5.5).

WARNING!

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

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

See paragraph 9 for the contacts list.

6. "Control Bar" and DIGISTAT® environment

6.1. Introduction

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

6.2. Touch screen

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

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

6.3. Launching DIGISTAT®

To launch DIGISTAT®,

- double click the desktop icon (Fig 3).

Fig 3

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

Fig 4

6.4. DIGISTAT® Work Area

The DIGISTAT® Work Area is defined and delimited by Control Bar, a tool that is common to all and every possible DIGISTAT® installation (Fig 5).
Control Bar manages the installed modules, the patients and their data, the users and their permissions etc.
DIGISTAT® Control Bar is formed by a horizontal command bar (Fig 5 **A**), by a vertical selection bar on the left (Fig 5 **B**) and by a central Work Area. The different screens of the installed modules are displayed within the Work Area (Fig 5 **C**).

Fig 5 shows Control Bar with no module installed.

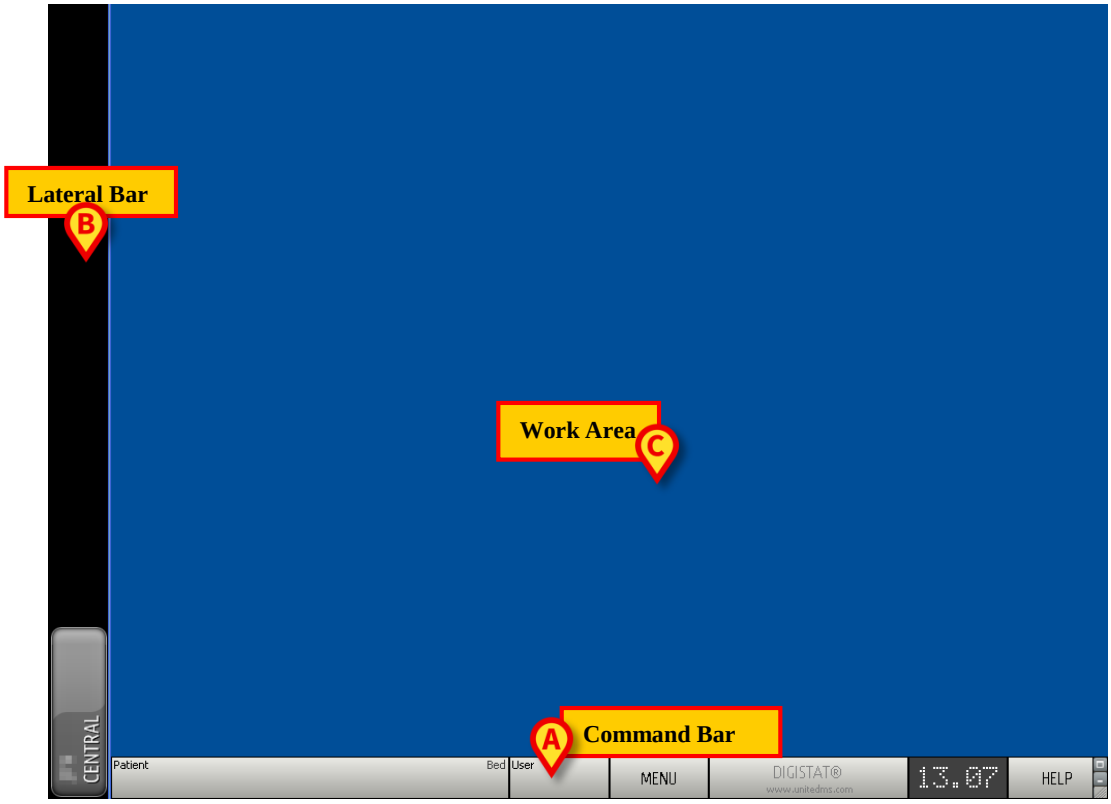


Fig 5

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

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

Fig 6

The module currently selected is highlighted (yellow).

6.4.1. Selecting a module

To select a module

- click the corresponding icon.

The icon is this way highlighted. The module's functionalities are displayed within the Work Area.

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

6.5. Accessing the system

The DIGISTAT® system can only be accessed by entering the personal username and password ("Log in" procedure).
For this reason, at the beginning of every work session, it is necessary to click the **User** button (Fig 7 **A**).

The following page is displayed.

Fig 7

To access the system,

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

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

- click the **Cancel** button (Fig 7 **E**).

The username and password are issued by the system administrator. If you do not have a username and a password you are not authorized to use 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 is displayed on the **User** button on the control bar (the acronym is ADM in Fig 8 **A**).

Fig 8

WARNING!

The user whose credentials are displayed on the* User *button is responsible for all the actions performed on* DIGISTAT®*. It is strongly recommended to log out before leaving the* DIGISTAT® *workstation to avoid improper use of the system.

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

To log in again, click the **User** button again. The page shown in Fig 7 is displayed again.

WARNING!

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

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

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

6.5.1. Barcode log in

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

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

- scan the user's personal barcode.

Fig 9

The user is immediately logged in.

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

6.5.2. Disabling the automatic log out

If the system remains idle for a certain configured time, the user is automatically disconnected (automatic log out).
To stop this from happening it is necessary, when logging in, after username and password specification and before clicking **Ok**, to

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

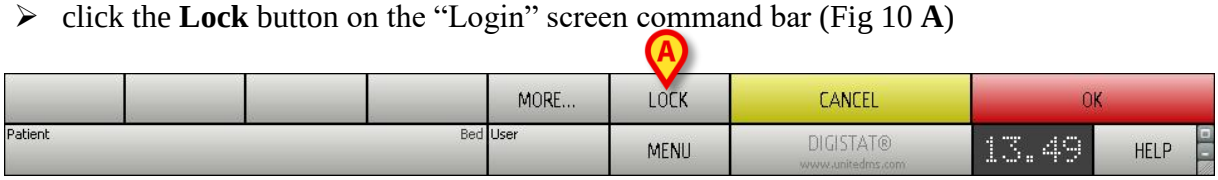


Fig 10

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

Fig 11

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

6.5.3. Recent users

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

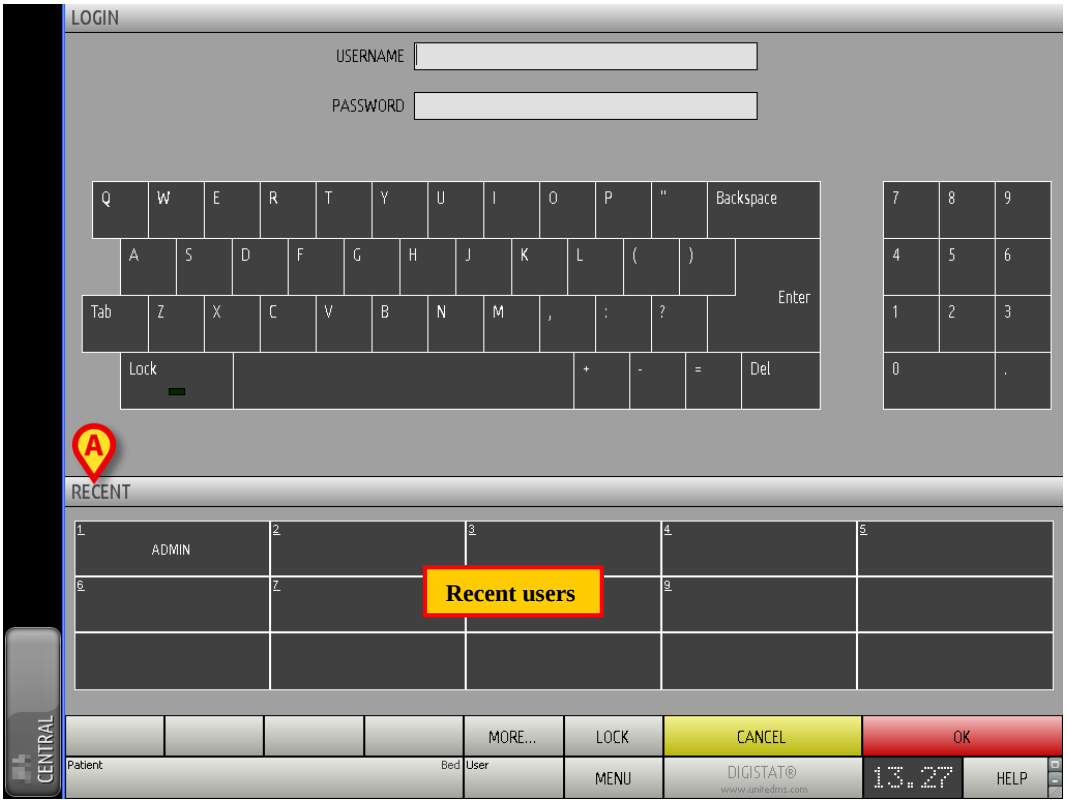


Fig 12

The area is divided into rectangles. The names of the users who accessed the system recently are displayed inside the rectangles. Click one of the rectangles to fill the “Username” field with the name displayed inside the rectangle.

6.5.4. How to use the “User List”

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

Fig 13

To display the “User List”,

- click the **More** button.

The following window is displayed (Fig 14).

Fig 14

The window shown in Fig 14 can be used as an index book enabling to search and select a user in the list of all the possible users.

The central part of the window shows the names of possible users, in alphabetical order (Fig 14 **A**).

The letters on the left side of the window (Fig 14 **B**) work like an index and make it possible to see only the users whose names begin with a specific letter.
For example: click the **C-D** button to see the list of patients whose names begin with the letters **C** or **D**.

Use the **All** button (Fig 14 **C**) to see the list of all possible users.

Use the **Local** button (Fig 14 **D**) to see the list of users that logged in to the 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 is this way highlighted, then

- click the **Ok** button (Fig 14 **F**).

Otherwise it is possible to

- double-click the row displaying the name of the user.

After selection, the "**User list**" window closes and the name of the selected user is displayed in the "**Username**" field on the "**Login**" page (Fig 7 **A**).

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

6.6. DIGISTAT® Control Bar

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

Fig 15

- The **Patient** button (Fig 15 **A**) displays, after a patient is selected, the patient's name and, if the patient is admitted, his/her bed number.

- The **User** button (Fig 15 **B**) shows the name of the logged user. See Fig 8.

- Use the **Menu** button (Fig 15 **C**) to open the following window (Fig 16).

Fig 16

The functionalities accessible from this menu are described later in this manual. (paragraph 6.8).

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

- The display indicated in Fig 15 **E** alternately shows the current date and time.

- Use the **Help** button (Fig 15 **F**) to access the available documentation (user manuals and quick guides).

- The small buttons highlighted in Fig 15 **G** can be used to:
  1. minimize the DIGISTAT® window (button);
  2. select the full screen display mode (button);
  3. select the window display mode (button).

These three buttons are present only if enabled by configuration.

6.6.1. How to read the "Patient" button

Patient selected

When a patient is selected, the **Patient** button displays the name of the selected patient (Fig 17 **A**). See the documentation of the specific modules for the patient selection procedure.

Fig 17

Patient admitted

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

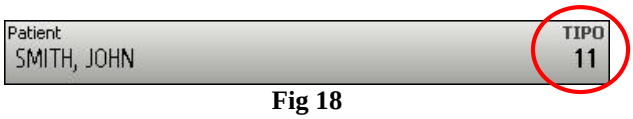


Fig 18

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

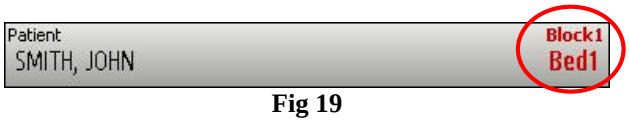


Fig 19

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

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

Fig 20

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

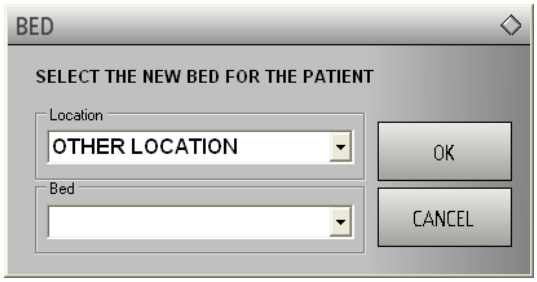


Fig 21

See the specific modules documentation for the patient admission procedure.

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

Fig 22

Patient management.

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

The DIGISTAT® module “Patient Explorer” is dedicated to the patient archives management. 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-related data it is necessary to double-check that the patient identity, hospitalization department and bed displayed in DIGISTAT® match with the actual ones.
This is utterly important in case of critical actions as, for instance, drug administration.

6.7. Help

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

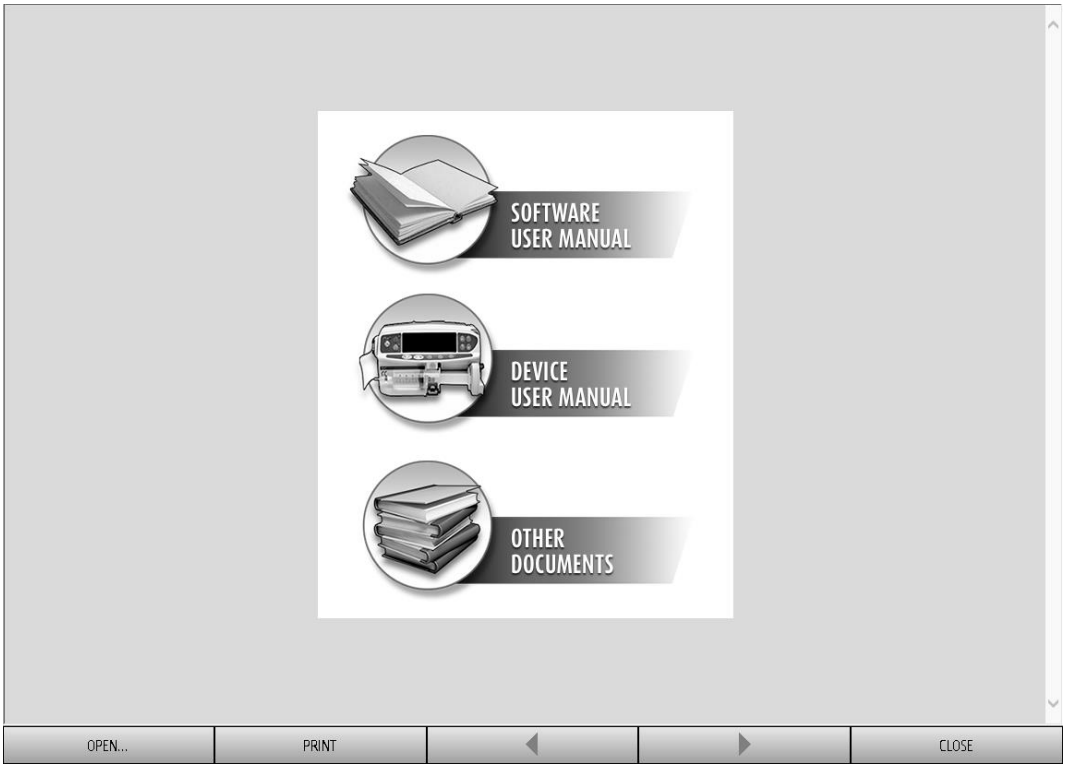


Fig 23

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

Fig 24

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

6.8. DIGISTAT® Main Menu

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

Fig 25

opens a menu containing several options (Fig 26).

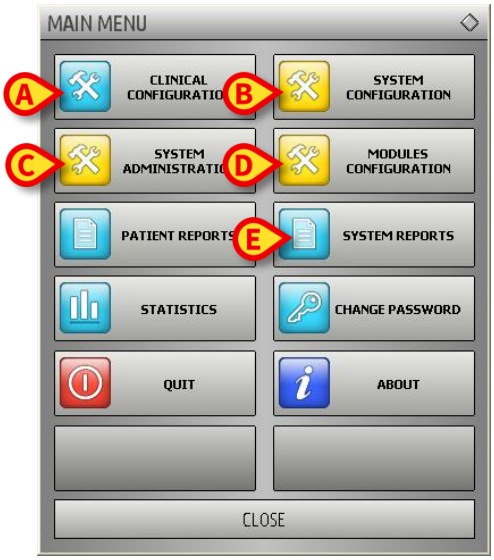


Fig 26

Each button on the menu makes it possible to access a specific set of functions.

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

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

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

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

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

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

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

The other buttons, indicated in Fig 27, make it possible to access features and functions that some users can perform (according to their permission level). These are described in the indicated paragraphs.

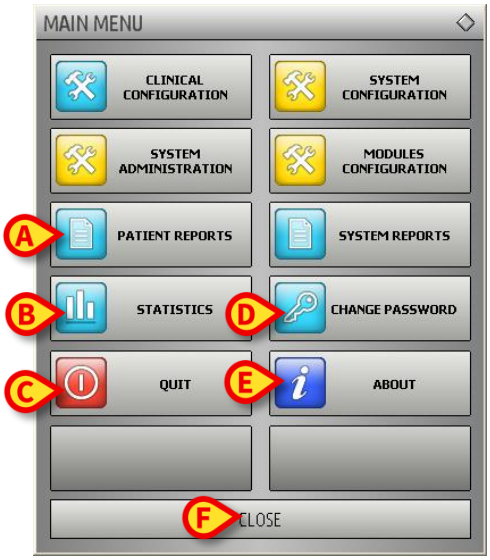


Fig 27

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

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

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

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

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

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

6.8.1. Patient reports

The "**Patient reports**" button (Fig 27 **A**) makes it possible to access a set of options enabling the user to print reports of different kinds for the selected patient.

The button opens a menu containing different options (Fig 28).

Fig 28

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

6.8.2. Print reports

Use the buttons on the menu displayed in Fig 28 to access the system print functionalities.

The layout of some reports is customizable. Please refer to the system administrators for any request regarding the print reports customization.

To print a patient report

- click one of the buttons on the menu**.**

A print preview of the selected document opens (Fig 29).

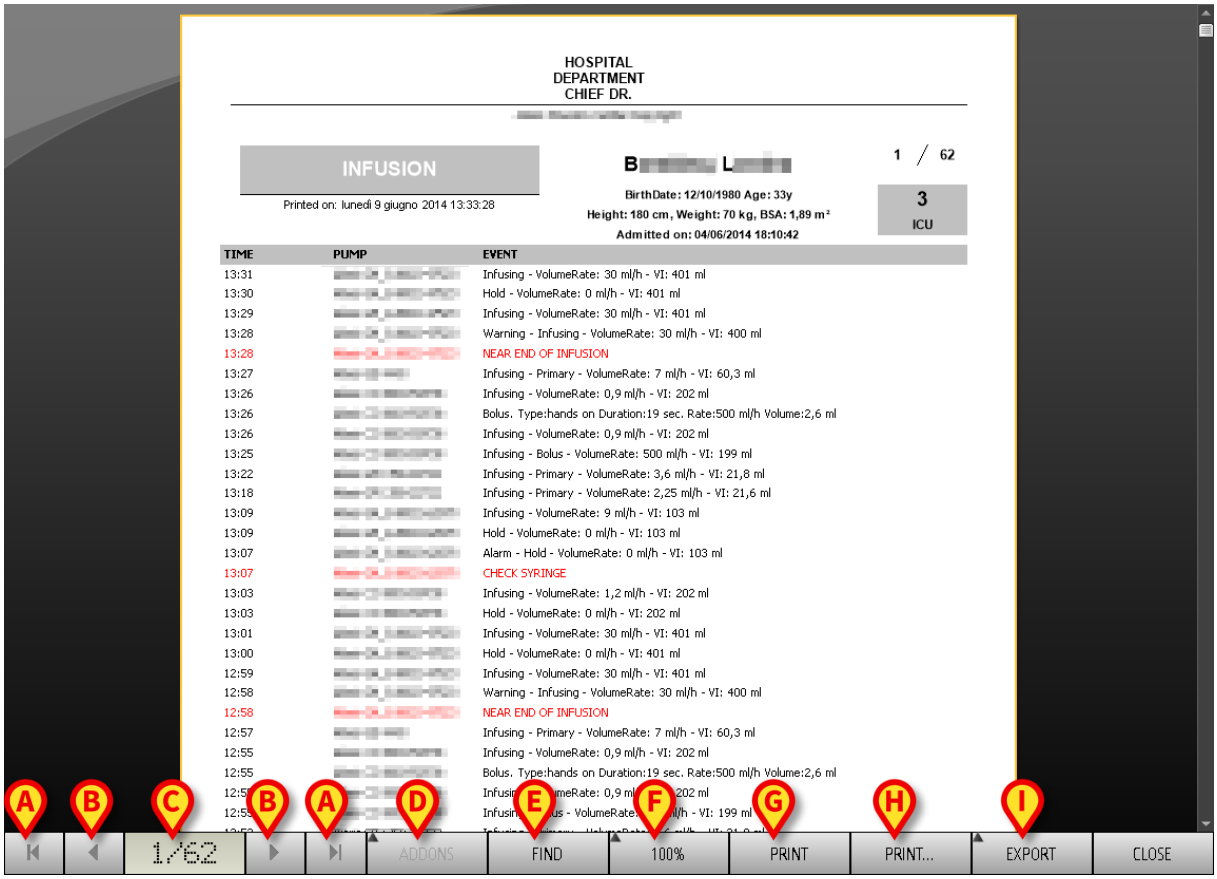


Fig 29

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

A - Use the and buttons (Fig 29 **A**) to go to the beginning or 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 1/1 (Fig 29 **C**) indicates the current page number.

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

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

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

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

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

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

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

6.8.2.1. Addons

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

To display the available options,

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

Addons - Watermark

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

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

The following window is displayed (Fig 30).

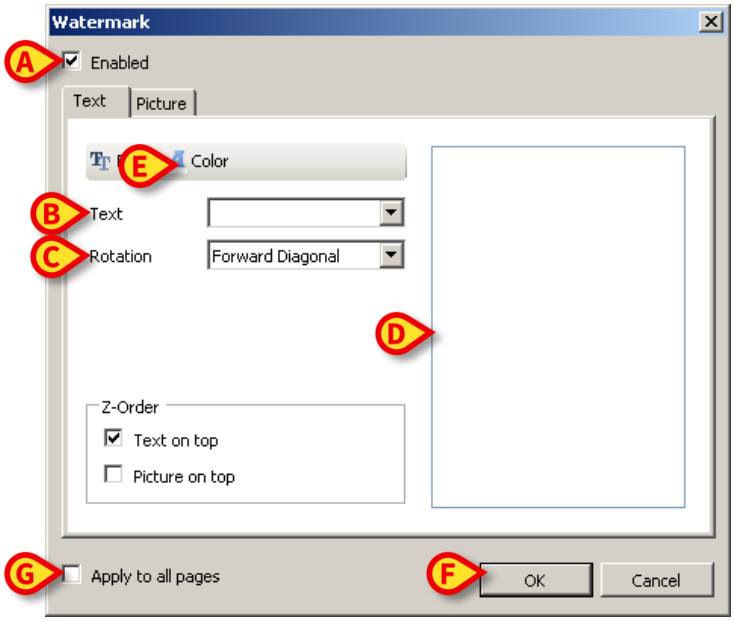


Fig 30

To add a textual watermark,

- Ensure that the "**Enabled**" checkbox is checked (Fig 30 **A**). If not, the contents cannot be edited.
- Insert the text in the "**Text**" field (Fig 30 **B**).

- Use the "**Rotation**" menu (Fig 30 **C**) to specify the watermark orientation (diagonal, horizontal, vertical).

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

- Use the buttons indicated in Fig 30 **E** to select the watermark font and color.

- Click the **Ok** button (Fig 30 **F**).

The text is this way inserted as watermark.

If the "**Apply to all pages**" checkbox is selected (Fig 30 **G**) the watermark is applied to each page in the document, otherwise it is applied only to the current page.

To insert a picture as watermark

- Click the "**Picture**" tab indicated in Fig 31 **A**.

The following window is displayed (Fig 31).

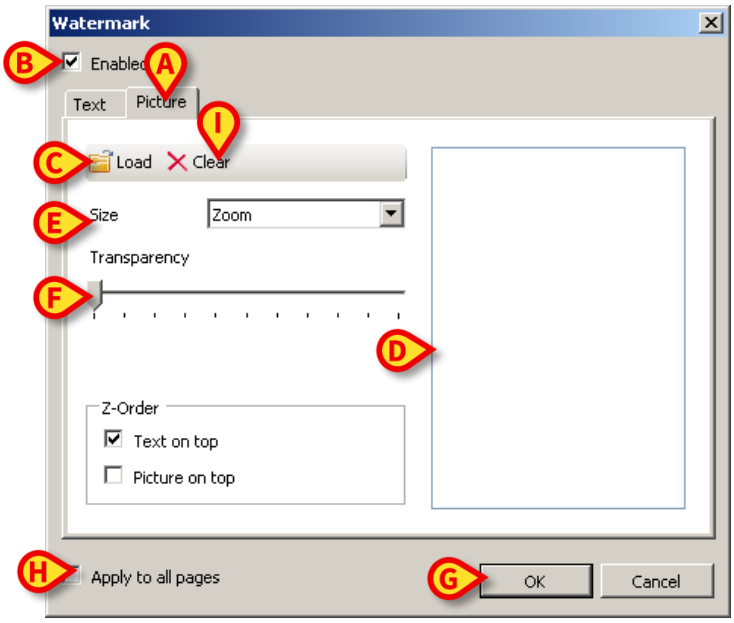


Fig 31

Follow these steps to insert an image as watermark,

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

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

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

- Search and select the image to be uploaded.

The image is displayed in the area indicated in Fig 31 **D**.

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

The watermark image is this way inserted.

If the "**Apply to all pages**" checkbox is selected (Fig 31 **H**) the watermark is applied to each page in the document, otherwise it is applied only to the current page.

To delete an already selected image,

- Click the "**Clear**" button indicated in Fig 31 **I**.

6.8.2.2. Find

The **Find** button (Fig 29 **E**) makes it possible to search the print report currently displayed.

To search the print report,

- Click the **Find** button.

The following window opens (Fig 32).

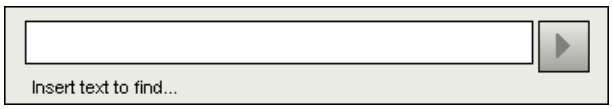


Fig 32

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

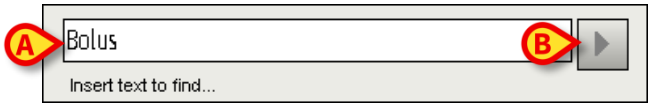


Fig 33

- Click the button (Fig 33 **B**).

The text specified, when found, is highlighted in the print preview.

- Click the button again to search for other instances.

6.8.2.3. Zoom

The **Zoom** button (on which, by default, the **100%** size is displayed - Fig 29 **F**) is a zoom, making it possible to change the display size and mode.

To change the display mode,

- click the Zoom \button. The following menu is displayed (Fig 34).

Fig 34

- Click the wanted option on the menu.

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

The following options are available:

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

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

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

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

the

area contains a cursor that can be used to zoom the page contents (left is zoom out, right is zoom in). The percentage value corresponding to the page size is displayed above the cursor. Values range from 100% to 200%. After selection, the selected value is also displayed on the **Zoom** button on the command bar.

6.8.2.4. Print

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

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

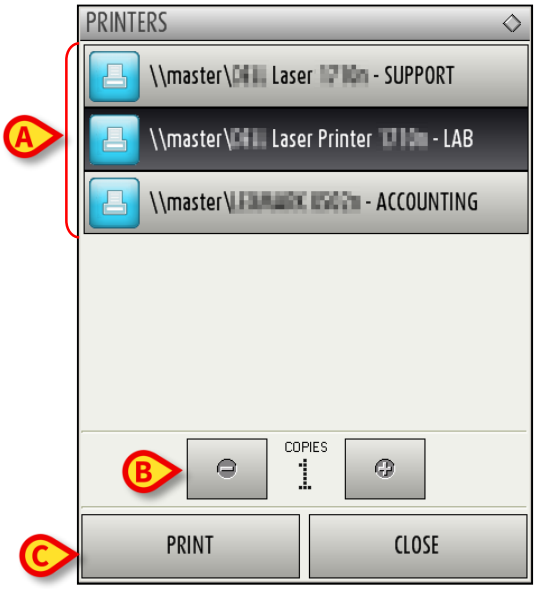


Fig 35

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

- Click the wanted option on the menu to select the printer (Fig 35 **A**).

- Use the (one less copy) and the (one more copy) buttons to specify the number of copies (Fig 35 **B**).

- Click the **Print** button (Fig 35 **C**) to print the report.

6.8.2.5. Export

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

- Click the **Export** button to open the "Export" menu.

The menu displays all the extensions currently supported by the system in use.

- Click the option corresponding to the wanted extension.

The document is this way exported to the corresponding extension.

6.8.3. Statistics

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

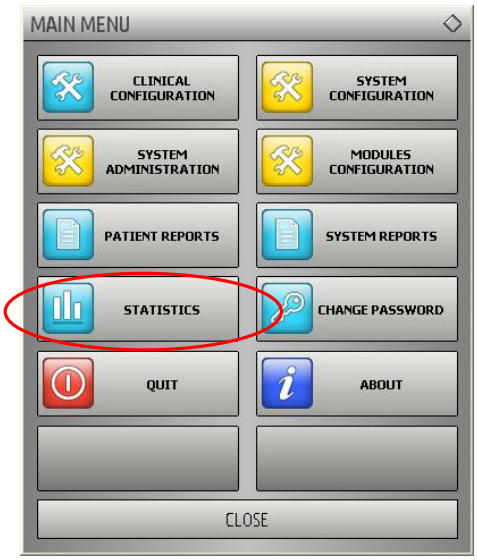


Fig 36

The button opens another menu (Fig 37) listing various tools. The type and number of selectable tools depend on the configuration in use and the specific modules installed. These tools are reserved to the system administrators. See the specific technical documentation for instructions.

The "Query assistant" tool, which is accessible for users having specific permissions and training, is described in paragraph 6.8.3.1.

Fig 37

6.8.3.1. Query Assistant

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

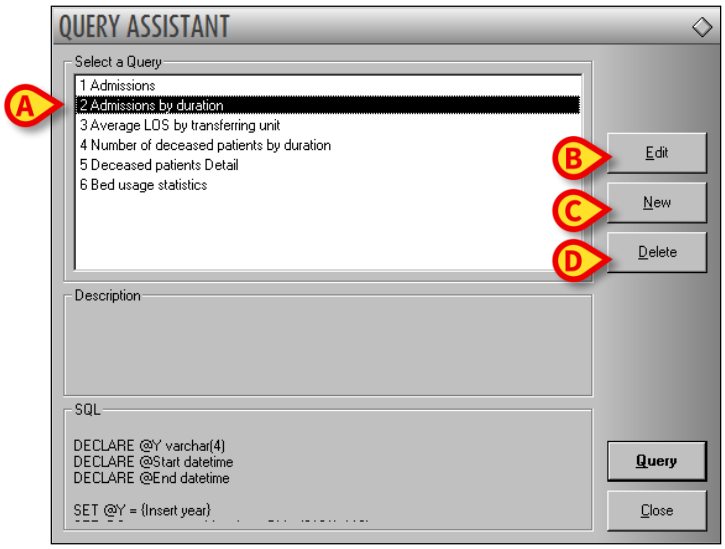


Fig 38

The user can select a query from a list of pre-defined queries, to execute it and display the results in a specific window.
The "Select a Query" area displays the list of all the pre-defined queries (Fig 38 **A**).

To run a query

- click the corresponding name on the list,

The name is this way highlighted (Fig 39 **A**).

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

The "Edit", "Cancel" and "New" query options are reserved to the system administrators.

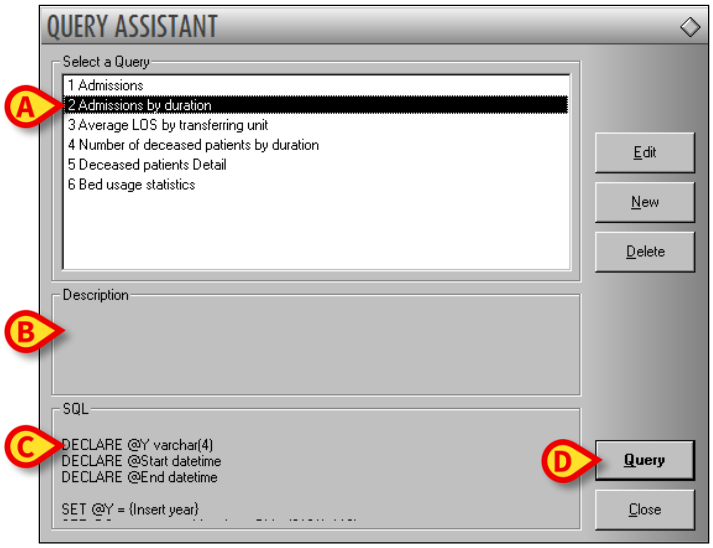


Fig 39

To run the query

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

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

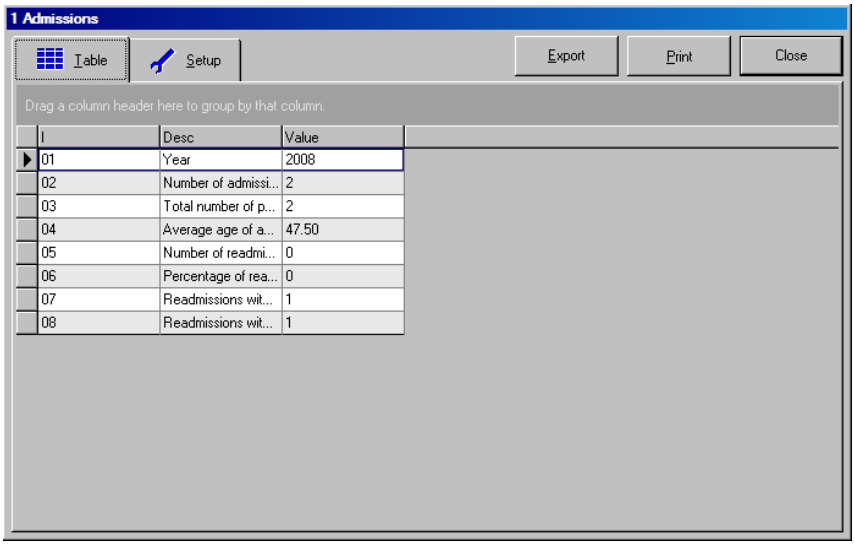


Fig 40

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

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

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

6.8.4. Change password

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

Fig 41

To change the user password

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

The "Change password" window opens.

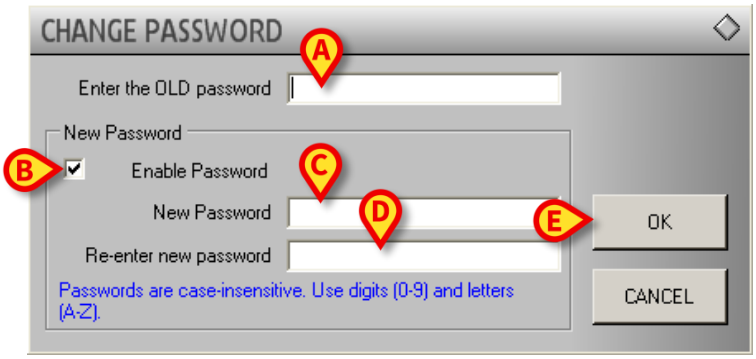


Fig 42

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

The passwords are not sensibile to uppercase and lowercase. Passwords can include numbers (0 to 9) and letters (A-Z).

6.8.5. About DIGISTAT®

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

Fig 43

6.8.6. Quit DIGISTAT®

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

To quit DIGISTAT®

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

Fig 44

The DIGISTAT® main menu opens (Fig 45).

Fig 45

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

Another menu is displayed (Fig 46).

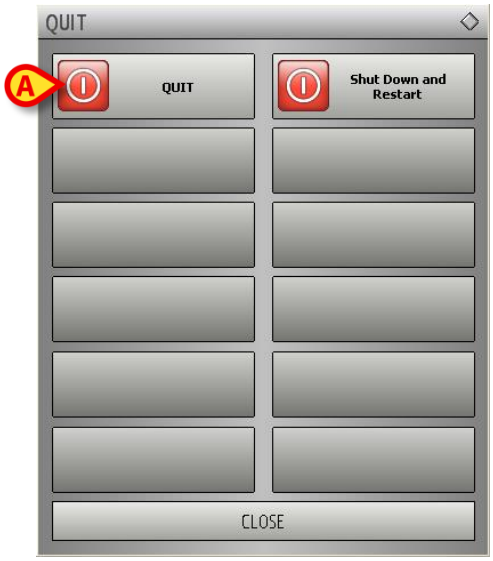


Fig 46

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

User confirmation is required (Fig 47).

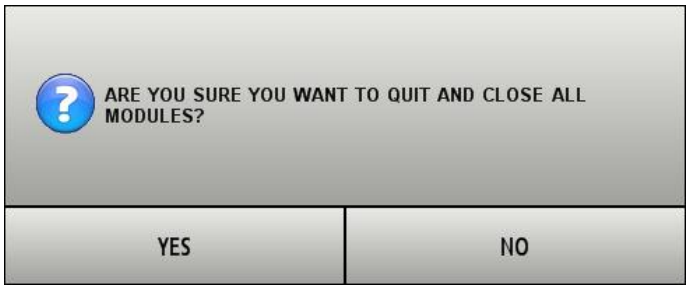


Fig 47

- Click **Yes** to exit DIGISTAT®.

To exit DIGISTAT® users must have the required permissions level.

6.9. Warning messages

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

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

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

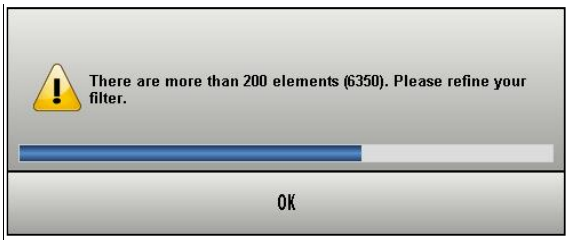


Fig 48

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

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

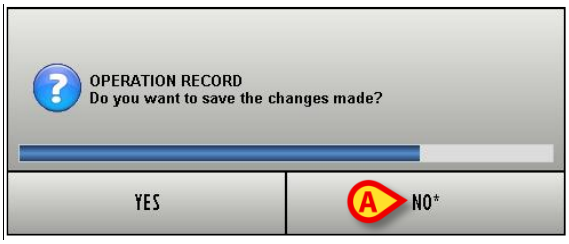


Fig 49

This window offers two options, usually related to an action which has just been performed. Click the **Yes** button to confirm the action, click the **No** button to quit.
The bar on the window 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 chooses either the Yes or No option by default, depending on the context/question. Default selection is set by configuration and indicated by an asterisk (Fig 49 **A**).

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

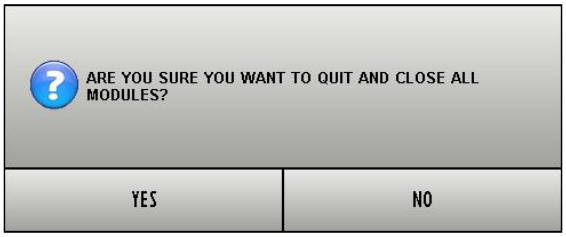


Fig 50

The window shown in Fig 50, as the previous one, requires a choice between the options **Yes** and **No** in relation to a procedure that has just been performed. Click the **Yes** button to perform the action, click the **No** button to quit without performing. This type of window has no timer and remains on screen until a choice is made.

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

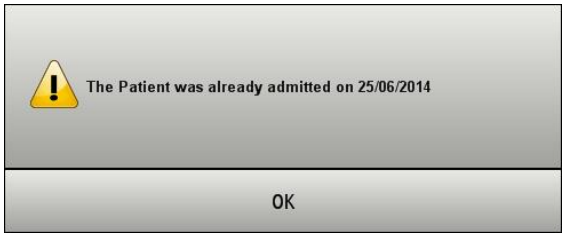


Fig 51

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

The presence or absence of the timer in a window depends on the context it appears in. Certain messages only make sense momentarily and with reference to the operation the user is performing. These messages have a timer and disappear after a certain time.

Other messages must be received by anyone using the system, even after some time, and require a reading confirmation. These messages have no timer.

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

7. Fluid Balance

7.1. Introduction

The DIGISTAT® **Fluid Balance** module gives the patient's precise fluid balance by recording daily fluid input and output. The administered volumes can either be acquired automatically from the configured infusion devices or inserted manually by the clinical staff. The system calculates both partial and total balances. The "in" and "out" items are configurable according to the department's needs.

7.2. Module selection

To select the "Fluid Balance" module

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

Fig 52 -"Fluid Balance" module icon

If no patient is selected the screen shown in Fig 53 is displayed. No data is displayed on the screen shown in Fig 53. When a patient is selected the screen displays the selected patient's data.

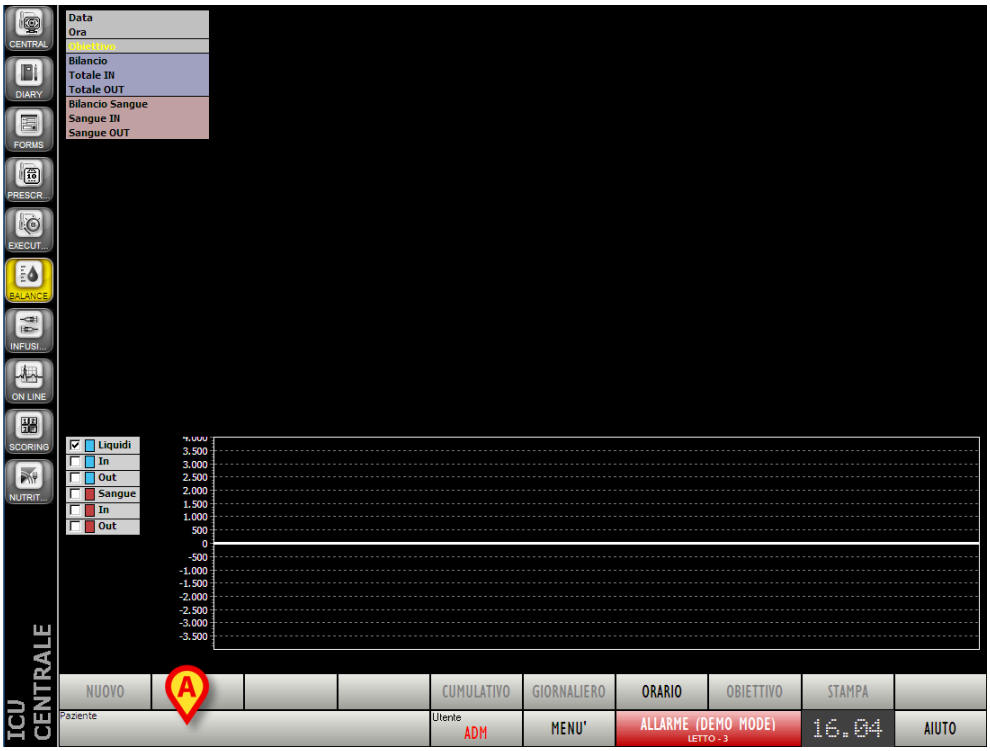


Fig 53 - No patient selected

7.3. Patient selection

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

- click the **Patient** button on the Control Bar (Fig 53 **A**).

The DIGISTAT® Patient Explorer module opens, if the module is in use. Otherwise the patient search and selection functionalities are accomplished by Control Bar. See the related technical documentation to know the specific search and selection procedures. If the software in use is not a DIGISTAT® software see the related documentation.

!

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

When a patient is selected the data displayed on the screen are referred to the selected patient (in Fig 54 a patient is selected).

7.4. "Fluid Balance" main screen

The main screen is formed of three main parts:

- a table (Fig 54 **A**, see paragraph 7.5 for the description),
- a chart (Fig 54 **B** see paragraph 7.6),
- a command bar (Fig 54 **C** see paragraph 7.7).

Fig 54 - Main screen - Patient selected

7.5. Table

The table (Fig 55) displays all the “in” and “out” values of the fluids to and from the patient, providing at the same time total and partial fluid balances.

Date	01/02				02/02				01 feb	02/02											03/02	02 feb
Time	18.03	19.59	21.57	23.54	1.55	4.01	6.05	8.56	9→9	10.12	12.05	14.01	14.03	14.04	14.06	16.13	16.14	17.53	20.03	21.55	0.11	9→9
Total																						
Balance	-84,84	-207,2	-165,6	692,13	-203,9	-159,4	-200,9	379,47	-473,8	-190,6	-140,4	-130,2	51,43	100,72	1,53	-66,4	0,82	-106	-23,03	2,15	9,7	-490,4
Total IN	95,16	292,8	194,4	992,13	196,15	200,6	99,15	879,47	4126,3	49,4	139,59	129,82	51,43	100,72	1,53	153,6	0,82	114,05	156,97	122,15	159,7	1179,8
Total OUT	-180	-500	-360	-300	-400	-360	-300	-500	-4600	-240	-280	-260				-220		-220	-180	-120	-150	-1670
Blood Balance									-50													
Blood IN																						
Blood OUT									-50													
Dopamina									2,64													
INFUSION									0,6	13,2	50,74	46,94	1,43	0,72	1,53	94,4						208,96
MANTENIMENTO	89,2	87	88,5	86,3	90,1	94,3	93	127,4	1047,5	36,2	33,1	32,1				0,7	0,8	72,4	94,8	82	99,7	451,8
Noradrenalina																						
Propofol									13,18													
Furosemide	1,99	1,93	1,97	1,95	2,02	2,1	2,02	0,69	21,74													
Nitroglicerina																						
Dobutamina	3,97	3,87	3,93	3,88	4,03	4,2	4,13	1,38	40,71		0,75	0,78				3,5	0,02	1,65	2,17	0,15		9,02
MANNITOLO		100				100			300					100								100
Plasma exp				500				500	1250													
Farmaci Paracetamolo																						
Farmaci Gentalyn													50									50
CRISTALLOIDI			100	400				200	1200													
Per OS											55	50				55		40	60	40	60	360
Elettroliti KCl		100			100			50	250													
Elettroliti Bicarbonato																						
AUTOTRANS																						
Emazie concentrate																						
Piastrine																						
Plasma																						
Urina	-180	-500	-360	-300	-400	-360	-300	-500	-4600	-240	-280	-260				-220		-220	-180	-120	-150	-1670
SNG																						
PERDITE DRENAGGI TORACI...									-50													

Fig 55

7.5.1. How to read the table - Rows

On the left are the names of the fluid balance items whose values are specified in the table (Fig 55 **A**). The first cell of every row indicates the name of the balance item whose values are displayed in the row itself.

7.5.1.1. Date

The first row indicates the date to which the values on the table refer.

Date	01/02				02/02				01 feb	02/02											03/02	02 feb
Time	18.03	19.59	21.57	23.54	1.55	4.01	6.05	8.56	9→9	10.12	12.05	14.01	14.03	14.04	14.06	16.13	16.14	17.53	20.03	21.55	0.11	9→9

Fig 56

The system considers a 24 hours period (configurable) as one “clinical day”. The “clinical day” usually begins at 9:00 o’clock (configurable). Therefore, a day starts at 9:00 and ends the morning after at 9:00. All the values recorded during this period are assigned by the system to the same clinical day and labelled together. The actual date is anyway displayed for every fluid balance calculation. Fig 56 **A** indicates the actual dates. Fig 56 **B** indicates the “clinical dates”, i.e. the label used by the system to refer to a work day going from 9:00 to 9:00.

7.5.1.2. Time

The second row displays the time of every fluid balance calculation.

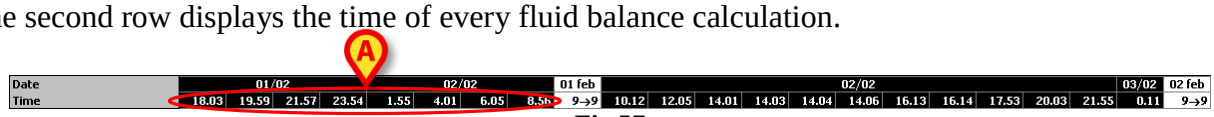


Fig 57

Time is automatically recorded every time a fluid value is recorded. See paragraph 7.14.1 for the fluid balance values recording procedure.

7.5.1.3. Target

The third row displays the daily target, i.e. the target balance indicated for the patient.

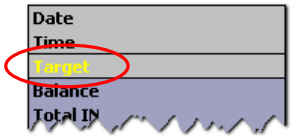


Fig 58 - Target

The daily target can be specified both for the current and for the following day. See paragraph 7.5.1.3 for the daily target setting procedure.

7.5.1.4. Total balances

Three lines, highlighted violet, display the total balances (Fig 59).

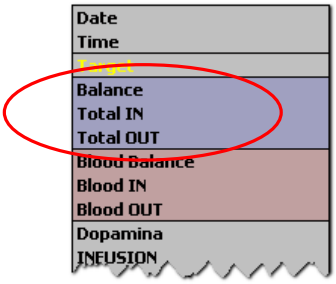


Fig 59 - Total Bilances

The total balance, the total “in” balance and the total “out” balance are displayed (in this order).

7.5.1.5. Blood balance

Three lines, highlighted red, display the blood balances (Fig 60).

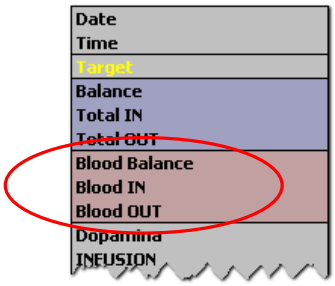


Fig 60 - Blood balance

The blood IN balance, the blood OUT balance and the total blood balance (the sum of "Ins" and "Outs") are displayed. The values "Blood balance", "Blood in" and "Blood out" can be either included or not, depending on a configuration parameter.

7.5.1.6. Detalied IN and OUT values

The rows highlighted light grey display the detailed fluids IN values (Fig 61 **A**).
The rows highlighted dark grey display the detailed fluids OUT values (Fig 61 **B**).

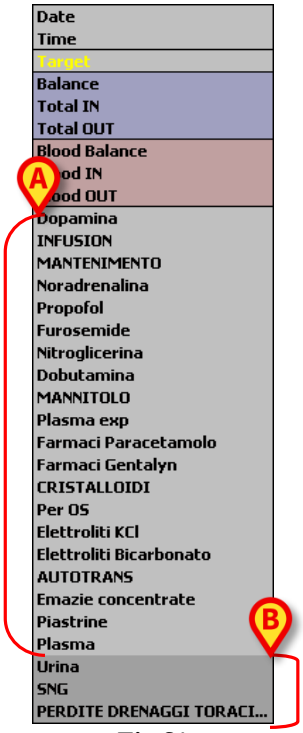


Fig 61

If the DIGISTAT® "Infusion" module is installed the values coming from the infusion pumps are automatically acquired.

7.5.2. How to read the table - columns

A column is added to the table every time a user specifies any fluid values. See paragraph 7.14.1 for the related procedure.
The first cell of every column displays the time the column was added. The time displayed, therefore, is the values insertion time (Fig 62 **A**).

Date		01/02				02/02				01 feb						02/02							03/02	02 feb
Time	A	18.03	19.59	21.57	23.54	1.55	4.01	6.05	8.56	9→9	10.12	12.05	14.01	14.03	14.04	14.06	16.13	16.14	17.53	20.03	21.55	0.11	9→9
Target																							
Balance		-84,84	-207,2	-165,6	692,13	-203,9	-159,4	-200,9	37[illegible],47	-473,8	-190,6	-140,4	-130,2	51,43	100,72	1,53	-66,4	0,82	-106	-23,03	2,15	[illegible]9,7	-490,4
Total IN		95,16	292,8	194,4	992,13	196,15	200,6	99,15	87[illegible],47	4126,3	49,4	139,59	129,82	51,43	100,72	1,53	153,6	0,82	114,05	156,97	122,15	15[illegible]9,7	1179,8
Total OUT		-180	-500	-360	-300	-400	-360	-300	-500	-4600	-240	-280	-260				-220		-220	-180	-120	-[illegible]50	-1670
Blood Balance										-50													
Blood IN																							
Blood OUT										-50													
Dopamina										2,64													
INFUSION										0,6	13,2	50,74	46,94	1,43	0,72	1,53	94,4						208,96
MANTENIMENTO		89,2	87	88,5	86,3	90,1	94,3	9[illegible]	[illegible]7,4	1047,5	36,2	33,1	32,1				0,7	0,8	72,4	94,8	82	9[illegible]9,7	451,8
Noradrenalina																							
Propofol										13,18													
Furosemide		1,99	1,93	1,97	1,95	2,02	2,1	2,02	[illegible],69	21,74													
Nitroglicerina																							
Dobutamina		3,97	3,87	3,93	3,88	4,03	4,2	4,13	[illegible],38	40,71		0,75	0,78				3,5	0,02	1,65	2,17	0,15		9,02
MANNITOLO			100				100			300					100								100
Plasma exp					500				500	1250													
Farmaci Paracetamolo																							
Farmaci Gentalyn														50									50
CRISTALLOIDI				100	400				200	1200													
Per OS												55	50				55		40	60	40	60	360
Elettroliti KCl			100			100			50	250													
Elettroliti Bicarbonato																							
AUTOTRANS																							
Emazie concentrate																							
Piastrine																							
Plasma																							
Urina		-180	-500	-360	-300	-400	-360	-300	-500	-4600	-240	-280	-260				-220		-220	-180	-120	-[illegible]50	-1670
SNG																							
PERDITE DRENAGGI TORACI...										-50													

Fig 62 - Table

The total fluid values referring to the previous day are displayed in a specific column, characterized by lighter colors (Fig 62 **B**). This column is automatically added when the clinical day begins and is updated during the day with the new values specifications. At daily balance closing time the column is "frozen" and a new column is created. The daily balance closing time depends on a configuration parameter. In the configuration here explained the clinical day ends at 9:00. The last column of the table (Fig 62 **C**) displays the total values for the current day updated to the present time.
The first cell of the "Totals" column displays the date to which the total balances refer (Fig 63 **A**); the second cell specifies the relevant time span (Fig 63 **B** - in the present configuration it is 9:00 to 9:00); the third column displays, if specified, the daily target (Fig 63 **C**).

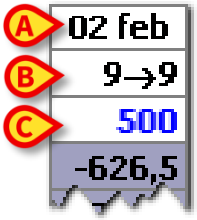


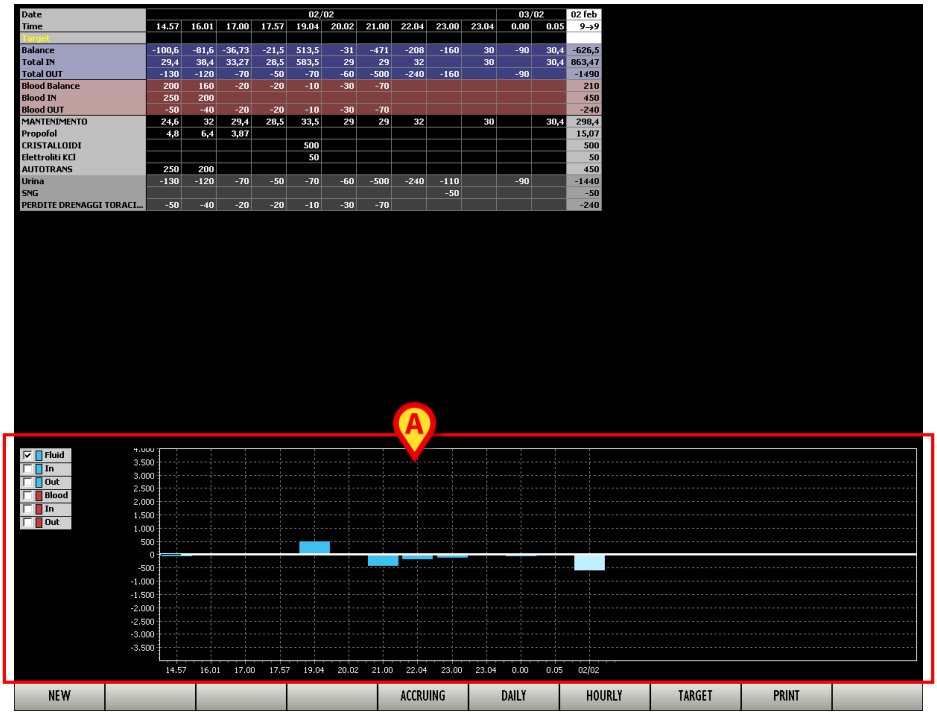
Fig 63

Specific information tooltips are displayed when the mouse pointer indicates the column headings on the table (Fig 64).

Fig 64

7.6. Chart

The lower part of the DIGISTAT® Fluid Balance main screen (Fig 65 **A**) displays in a chart the balance values specified in the table.



Date	02/02										03/02		02 feb
Time	14.57	16.01	17.00	17.57	19.04	20.02	21.00	22.04	23.00	23.04	0.00	0.05	9->9
Balance	-100,6	-81,6	-36,73	-21,5	513,5	-31	-471	-208	-160	30	-90	30,4	-626,5
Total IN	29,4	38,4	33,27	28,5	583,5	29	29	32		30		30,4	863,47
Total OUT	-130	-120	-70	-50	-70	-60	-500	-240	-160		-90		-1490
Blood Balance	200	160	-20	-20	-10	-30	-70						210
Blood IN	250	200											450
Blood OUT	-50	-40	-20	-20	-10	-30	-70						-240
MANTENIMENTO	24,6	32	29,4	28,5	33,5	29	29	32		30		30,4	298,4
Propofol	4,8	6,4	3,87										15,07
CRISTALLOIDI					500								500
Elettroliti KCl					50								50
AUTOTRANS	250	200											450
Urina	-130	-120	-70	-50	-70	-60	-500	-240	-110		-90		-1440
SNG									-50				-50
PERDITE DRENAGGI TORACI...	-50	-40	-20	-20	-10	-30	-70						-240

Fig 65

The fluid IN and OUT quantities can be read on the vertical axis (in ml - Fig 66 **A**).
The fluid variation date and time can be read on the horizontal axis (Fig 66 **B**).

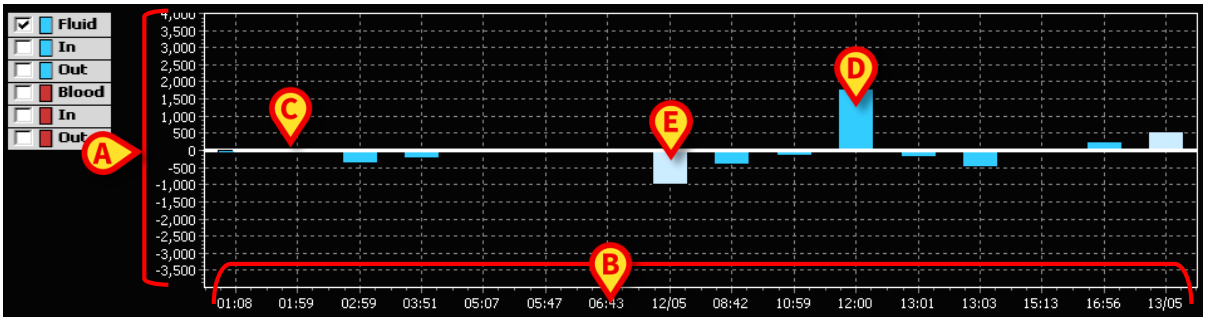


Fig 66 - Chart

The variations in the fluid balance are represented by the blue vertical bars (Fig 66 **D** - the color is red when referred to blood changes, see Fig 69). The white line in the middle of the chart is the zero level (Fig 66 **C**). The bars above the white line represent fluid INs, the bars below the white line represent fluid OUTs.
When the clinical day changes a bar of a lighter color is added to indicate the total fluid balance of the previous day (Fig 66 **E**). This value corresponds to the balance value displayed on the table in the lighter colored column (Fig 62 **B**).

The box on the left (Fig 67) makes it possible to select what kind of values are to be displayed on the chart.

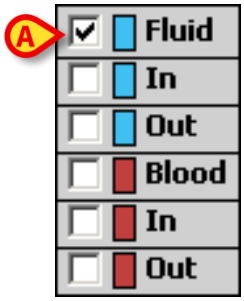


Fig 67

The checkboxes on the left can be either selected or deselected to display on the chart the corresponding values. If, for instance, “Fluid” and “Blood” are selected as in Fig 68,

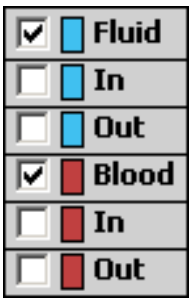


Fig 68

the chart displays the “Fluid” and “Blood” values separately (Fig 69).

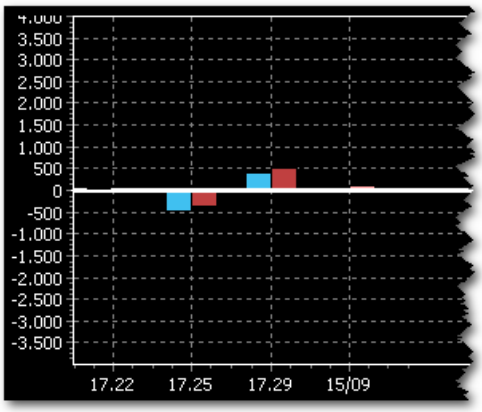


Fig 69

The system makes it possible, by selecting the corresponding boxes, to display in the chart the values relating to the in and out values both of the total fluids and of blood (the corresponding boxes are [“fluid”, “fluid in” and “fluid out”] and [“blood”, “blood in” and “blood out”]).
If the “Fluid”, “Fluid IN” and “Blood”are selected, for instance (Fig 70),

Fig 70

this is the corresponding chart:

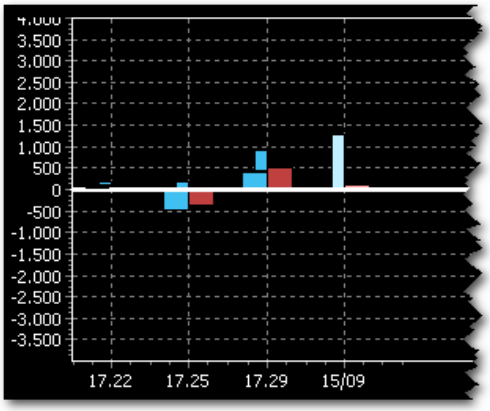


Fig 71

Three different istograms indicate the three values separately (blue-wide for the total fluid; blue - thin for the fluids in; red wide for the total blood).

7.7. The command bar

The buttons on the command bar of the Fluid Balance module main screen make it possible to perform different procedures.

Fig 72 - Command bar

This paragraph briefly describes the functions of the different buttons. The related procedures are described later in the indicated paragraphs.

New - use this button to insert values in the fluid balance table (see paragraph 7.8).

Accruing - use this button to display the fluid balance values in a cumulative mode on every column of the table (see paragraph 7.9).

Daily - use this button to display on the table only the daily total values (see paragraph 7.10).

Hourly - use this button to display on the table the fluid values at 60 minutes intervals. These are approximated values calculated by linear interpolation (see paragraph 7.11).

The presence of the **Hourly** *button depends on a configuration parameter. Please ask your system administrators if you need more details.*

Target - use this button to set the daily target (see paragraph 7.12).

Print - use this button to access the system's print functionalities (see paragraph 7.13).

7.8. Data entry: the “New” button

The **New** button on the command bar (Fig 73) makes it possible to record a change in the patient’s fluid balances (i.e. to insert a fluid balance value - see paragraph 7.14.1 for an example of this functionality).

Fig 73 - Command Bar

Click the **New** button to access the following screen (Fig 74).

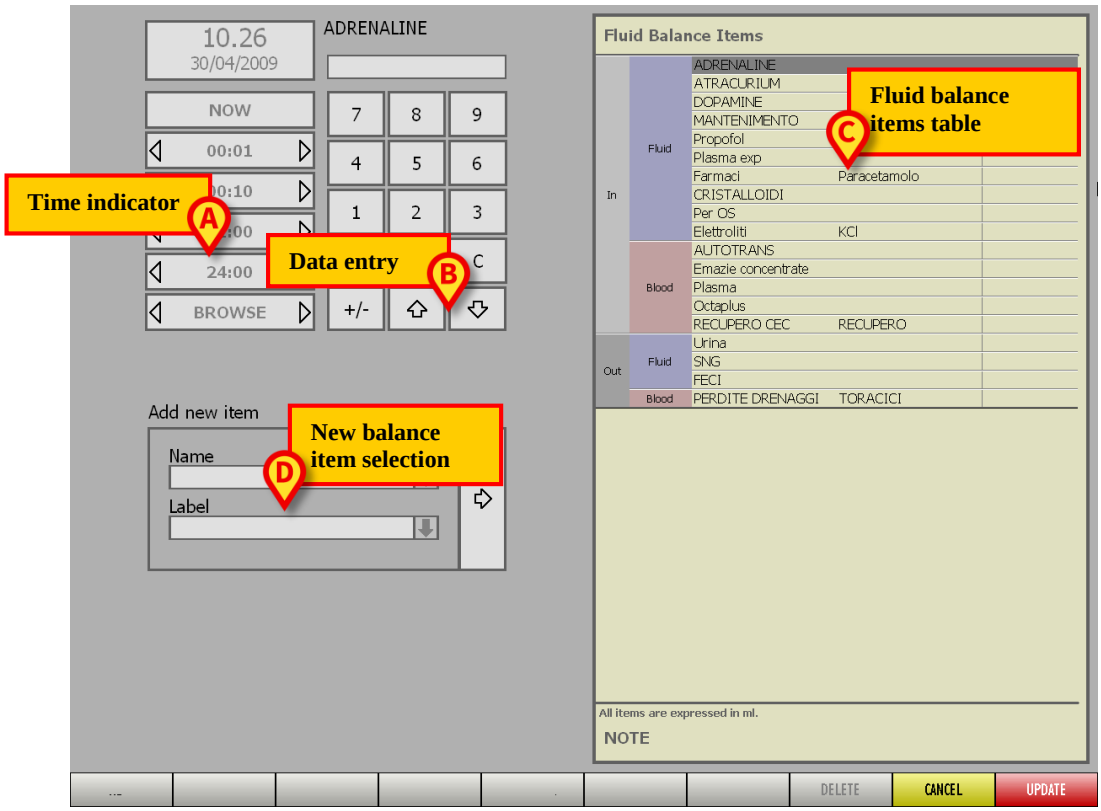


Fig 74 - Add a balance value

The screen is in “edit” mode, i.e. it is possible to edit the data displayed; the **Cancel** and **Update** buttons on the command bar are active. The screen contains various tools:

- a time indicator, enabling to specify the time of data insertion (Fig 74 **A**, see paragraph 7.8.1);
- a numeric data entry keyboard (Fig 74 **B**, see paragraph 7.8.2);
- the balance items table (Fig 74 **C**, see paragraph 7.8.3);
- the new balance items specification panel (Fig 74 **D**, see paragraph 7.8.4).

The different tools are described in the indicated paragraphs.

7.8.1. Time indicator

In the top left corner of the screen a time indicator (indicated in Fig 74 **A** and enlarged in Fig 75), can be used to select the time of data entry.

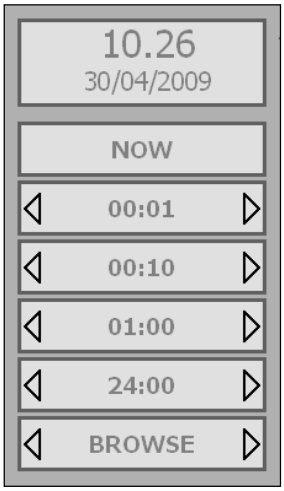


Fig 75 - Time Indicator

The first box, on top, displays the selected time and date. Any value displayed in the table on the right side of the screen (Fig 74 **C**) refers to the date and time selected here. The buttons below the date/time display make it possible to move either forwards or backwards on the time line.

Use the **Now** button to display the current time.

Use the **00:01** button to move one minute back / forward (left arrow is the back button).
Use the **00:10** button to move ten minutes back / forward (left arrow is the back button).
Use the **01:00** button to move one hour back / forward (left arrow is the back button).
Use the **24:00** button to move 24 hours back / forward (left arrow is the back button).
Use the **Browse** button to "jump" directly to the time (preceding or subsequent) in which a set of values was recorded (these "times" correspond to columns on the fluid balance table - Fig 62).

After any editing, click the **Update** button on the command bar to save the changes made.

7.8.2. Fluid balance values specification

On the right of the time specification buttons described in the previous paragraph there is a numeric keyboard making it possible to specify the value of the selected fluid balance item (Fig 74 **B**, Fig 76).

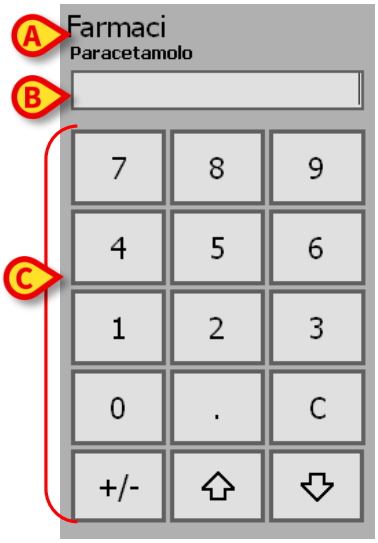


Fig 76

The name of the selected item is displayed above the keyboard (Fig 76 **A**). The example shown in the figure displays "Farmaci (Paracetamolo)". This is the item selected on the "Fluid Balance items" table (Fig 78). When another item on the table is selected the name displayed in Fig 76 **A** changes accordingly. The field indicated in Fig 76 **B** is the field where the values (in ml) of the selected balance item are inserted.
The numeric keyboard indicated in Fig 76 **C** makes it possible to specify the value.

Two arrow-buttons ⇧ ⇩ on the keyboard make it possible to select a different row on the "Fluid Balance items" table (moving the selection up and down the table - Fig 78).

To specify a value on the table,

- use the arrow buttons to select an item on the table, or touch the corresponding row.

The name of the item is highlighted on the table; it is also displayed above the numeric keyboard (Fig 77 **A**).

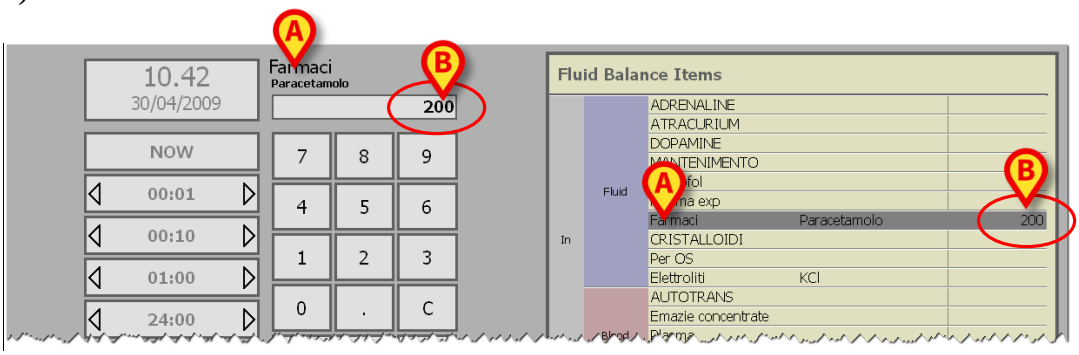


Fig 77 - Value specification

- Click the field indicated in Fig 76 **B**. A cursor appears.
- Use the numeric keyboard to specify the value.
- Click one of the two arrow-buttons ⇧ ⇩.

The preceding or following item is selected on the table. The specified value is displayed in the "Fluid Balance items" table (Fig 77 **B**). After any editing, click the **Update** button on the command bar to save the changes made.

7.8.3. The “Fluid Balance items” table

The table on the right of the screen (Fig 78, Fig 74 **C**) lists the items that can be specified in the fluid balance.

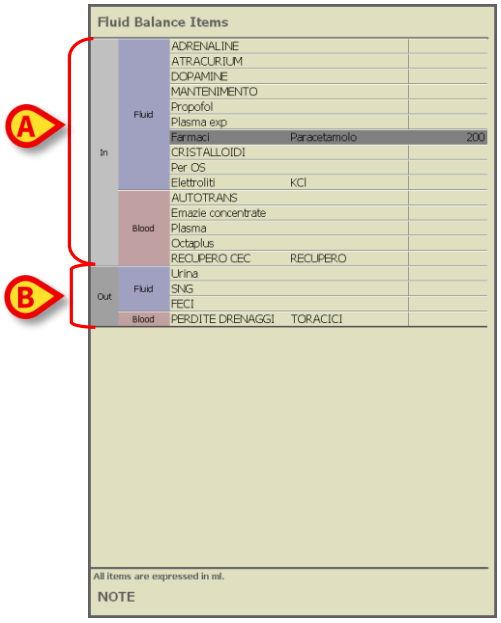


Fig 78 - “Fluid Balance items” table

The items are divided in two groups:
the upper group contains the “IN” items (Fig 78 **A**);
the lower group contains the “OUT” items (Fig 78 **B**).

Each group can be further divided into “Fluid” and “Blood” if necessary. See Fig 79 for an instance.

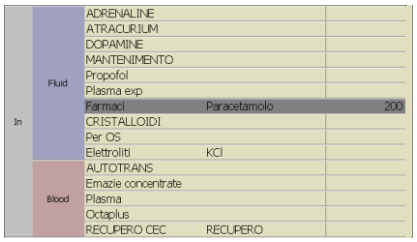


Fig 79

Once the value of a certain item is specified it is displayed on the right (Fig 80). The value specification procedure is described in paragraph 7.8.2.

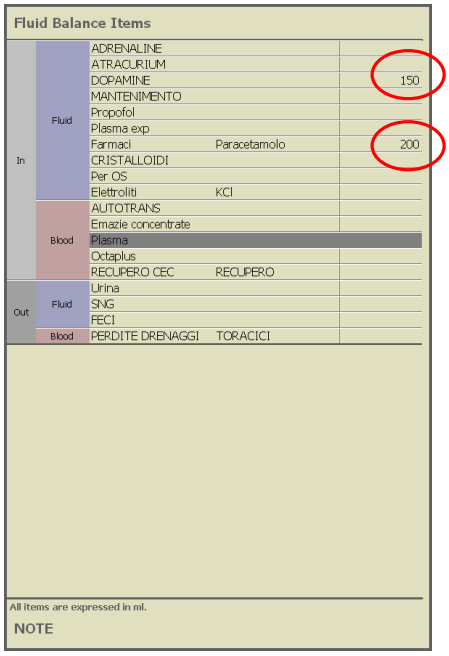


Fig 80

The values automatically acquired by the infusion devices are characterized by a specific icon and are red bordered (Fig 81).

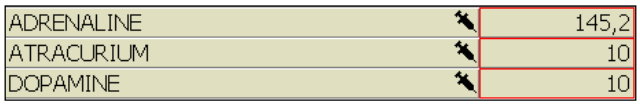


Fig 81

It is possible to add balance items to the table. The balance items addition procedure is described in paragraph 7.8.4.

7.8.4. How to add a balance item

A tool placed on the bottom-left corner of the screen can be used to add an item to those listed in the "Fluid Balance items" table (Fig 74 **D**, Fig 82).

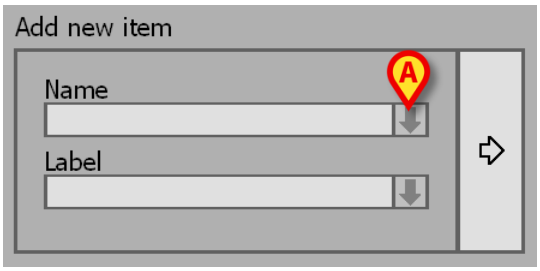


Fig 82 - Add new item

This is the procedure:

- Click the button placed alongside the "Name" field (Fig 82 **A**). A menu containing all the configured items appears (Fig 83 **A**). The items list on the menu is divided in groups ("IN" items and "OUT" items, each one further divided in "Fluid" and "Blood"). The items on the menu are defined by configuration.

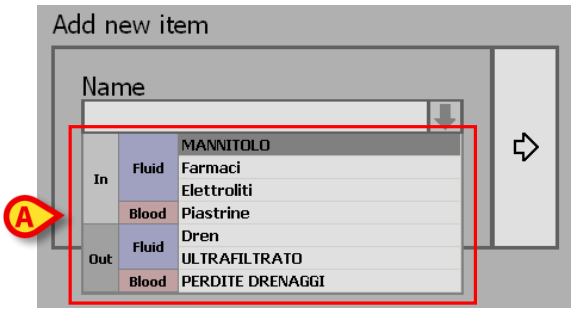


Fig 83 - Select new item

- Click the item you want to add. The name of the clicked item is dislplayed in the field (Fig 84).

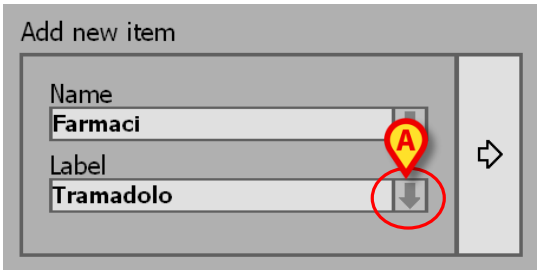


Fig 84 - Selected item

A default value is dislplayed in the "label" field. To change this value

- click the button placed alongside the field (Fig 84 **A**). A menu containing the possible options opens (Fig 85).

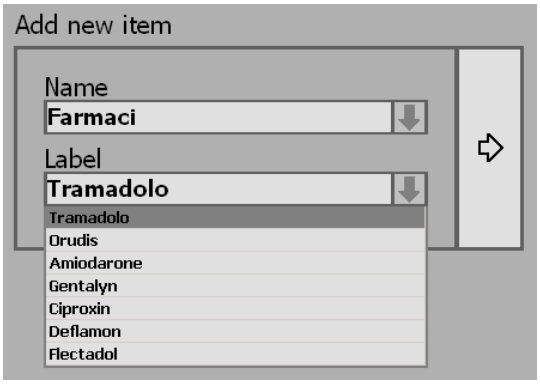


Fig 85 - Label selection

- Click the wanted option. The clicked option is dislplayed in the "Label" field (Fig 86 **A**).

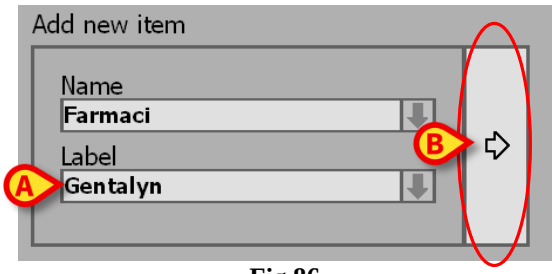


Fig 86

- Click the button indicated in Fig 86 **B**. The selected item is this way displayed in the “Fluid Balance items” table (Fig 87 **A**).

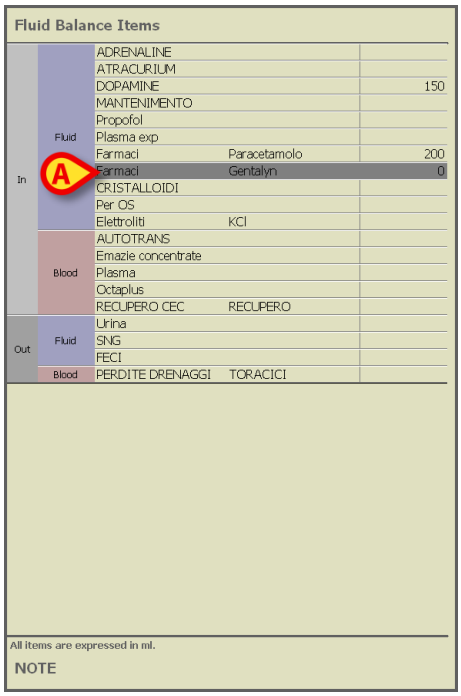


Fig 87

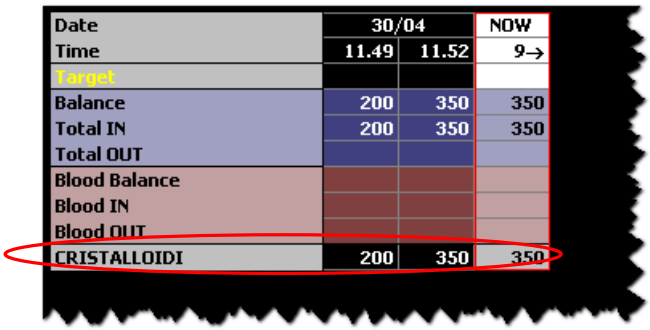
After every editing, click the **Update** button on the command bar to save the changes made.

7.9. “Accruing” fluid balance

The **Accruing** button on the command bar (Fig 88) changes the display mode of the fluid balance values on the main page table (the table shown in Fig 62 and described in paragraph 7.5).

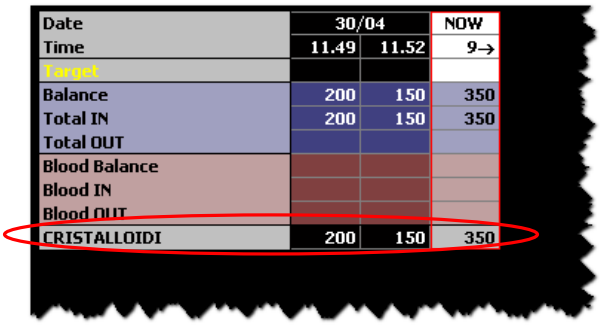
Fig 88

This button, when selected, displays the total values in every column in an “Accruing” mode.
The following example shows the difference between the two display modes (Fig 89 and Fig 90):



Date	30/04		NOW
Time	11.49	11.52	9→
Target			
Balance	200	350	350
Total IN	200	350	350
Total OUT			
Blood Balance			
Blood IN			
Blood OUT			
CRISTALLOIDI	200	350	350

Fig 89 - Accruing mode



Date	30/04		NOW
Time	11.49	11.52	9→
Target			
Balance	200	150	350
Total IN	200	150	350
Total OUT			
Blood Balance			
Blood IN			
Blood OUT			
CRISTALLOIDI	200	150	350

Fig 90 - Normal mode

The two tables displayed in Fig 89 and Fig 90 refer to the same balance. The first one is displayed in “Accruing” mode, the second one is displayed in “Normal” mode.
The table refers to two subsequent data entries. The first one at 11.49 (200 ml cristalloids); the second one at 11:52 (150 ml cristalloids).
Notice, on the tables, the values referring to the cristalloids administration (red circled in the figure).
In Fig 89 (accruing mode), the second column displays the value 350 (200 in the first administration plus 150 in the second administration).
In Fig 90 (normal mode), the second column displays the value 150, referring only to the administration corresponding to the column.
Total values are diaplayed in the third column. They are the same in both figures (350 is the total value administered).
The same kind of difference can be noticed in the “Balance” and “Total IN” rows.

!

WARNING!

When the* Accruing *button is selected the values displayed on the table are not those specified by the user.
A specific warning is therefore displayed on top of the screen every time the “Accruing” mode is activated (Fig 91).

Fig 91 - Warning!

It is also possible to select the **Accruing** and **Daily** buttons at the same time to display the total daily values in "Accruing" mode. See paragraph 7.10 for an explanation of the "Daily" mode.

7.10. "Daily balance" mode

The **Daily** button on the command bar (Fig 92) makes it possible to display only the daily total values.

Fig 92 - Command bar

Namely, only the "lighter colored" columns are displayed, summarizing the balance of the previous day.

For instance, if the normal display mode is the following (Fig 93),

Date	02/02										03/02	02 feb	04/02	04 feb	06/02		06 feb	02/03		02 mar	30/04	NOW
Time	16.59	17.01	17.56	17.58	19.01	19.53	20.49	21.58	22.48	22.53	0.03	9→9	11.54	9→9	11.53	17.03	9→9	12.29	15.28	9→9	11.29	9→
Target																100	100					
Balance	-46,46	2,3	-286,7	2,3	521,3	40,6	-13,8	-18,7	159	-64	12,6	-157,4	-334,8	-334,8	185,2	85,2	270,4	165,2	165,2	330,4	350	350
Total IN	73,54	2,3	163,3	2,3	571,3	110,6	66,2	81,3	159	6	82,6	2062,7	165,2	165,2	185,2	165,2	350,4	165,2	165,2	330,4	350	350
Total OUT	-120		-450		-50	-70	-80	-100		-70	-70	-2220	-500	-500		-80	-80					
Blood Balance	-20		-130		-40	-10	-50	-10				-340						100	200	300		
Blood IN												100						100	200	300		
Blood OUT	-20		-130		-40	-10	-50	-10				-440										
ADRENALINE												145,2	145,2	145,2	145,2	145,2	290,4	145,2	145,2	290,4		
ATRACURIUM												10	10	10	10	10	20	10	10	20		
DOPAMINE												10	10	10	10	10	20	10	10	20	150	150
MANTENIMENTO	69	2,3	63,3	2,3	71,3	60,6	66,2	81,3	59	6	82,6	850,2										
Propofol	4,54											47,27										
Farmaci Paracetamolo			100						100			200									200	200
Farmaci Gentalyn																					0	0
CRISTALLOIDI					500							600										
Elettroliti KCl						50						200			20		20					
Emazie concentrate												100										
Octaplus																		100	200	300		
Urina	-120		-50		-50	-70	-80	-100		-70	-70	-1820	-500	-500								
SNG			-400									-400										
FECI																-80	-80					
PERDITE DRENAGGI TORACI...	-20		-130		-40	-10	-50	-10				-440										

Fig 93

the corresponding daily display mode is shown in Fig 94.

Date	02 feb	04 feb	06 feb	02 mar	NOW
Time	9→9	9→9	9→9	9→9	9→
Target			100		
Balance	-157,4	-334,8	270,4	330,4	350
Total IN	2062,7	165,2	350,4	330,4	350
Total OUT	-2220	-500	-80		
Blood Balance	-340			300	
Blood IN	100			300	
Blood OUT	-440				
ADRENALINE	145,2	145,2	290,4	290,4	
ATRACURIUM	10	10	20	20	
DOPAMINE	10	10	20	20	150
MANTENIMENTO	850,2				
Propofol	47,27				
Farmaci Paracetamolo	200				200
Farmaci Gentalyn					0
CRISTALLOIDI	600				
Elettroliti KCl	200		20		
Emazie concentrate	100				
Octaplus				300	
Urina	-1820	-500			
SNG	-400				
FECI			-80		
PERDITE DRENAGGI TORACI...	-440				

Fig 94

Only the columns containing the daily totals are displayed.

7.11. “Hourly” mode

The **Hourly** button on the command bar (Fig 95) displays in the table an evaluation of the fluid balance variations at 60 minutes intervals. These are expected values obtained by linear interpolation.

Fig 95

Basing on (at least) two values provided by the user for a certain item, the system can calculate an evaluation of the IN or OUT quantities at every full hour for that item.

A configuration parameter either enables or disables the **Hourly** *button. For more information please contact your system administrator.*

If, for example, three values for a certain item are specified at 11.49, at 11.52 and at 14.19, the **Hourly** button can be clicked to display a table in which the values are approximated evaluations of the fluid balance variations at every full hour starting from 12.00 o’clock.

Date	30/04			NOW
Time	11.49	11.52	14.19	9→
Target				
Balance	200	150	175	525
Total IN	200	150	175	525
Total OUT				
Blood Balance				
Blood IN				
Blood OUT				
CRISTALLOIDI	200	150	175	525

Fig 96 - “Normal” display mode

Fig 96 shows a table in “Normal” display mode, while Fig 97 shows the same table in “Hourly” display mode.

Date	30/04			NOW
Time	12.00	13.00	14.00	9→
Target				
Balance	359,52	71,43	71,43	502,38
Total IN	359,52	71,43	71,43	502,38
Total OUT				
Blood Balance				
Blood IN				
Blood OUT				
CRISTALLOIDI	359,52	71,43	71,43	502,38

Fig 97 - “Hourly” display mode

The hourly values can be calculated if there are at least two “actual” values recorded on the table. The time span between the two values must be at least one hour. When, for a certain value on the table, it is not possible to calculate the hourly values and the “hourly” mode is selected, the value remains the same.

The total IN and OUT balances are calculated on the values displayed on the table, when in "Hourly" mode as well. Therefore, being the values in "Hourly" mode different from the actual values, the totals can differ from the actual values.

To know the actual values it is necessary to deselect the* Hourly *button and go back to the "normal" display mode.

WARNING!

When the* Hourly *button is selected the values displayed on the table are not those specified by the user. The values diplayed are expected values not actual ones.
A specific warning appears therefore on top of the screen every time the "Hourly" mode is activated (Fig 98).

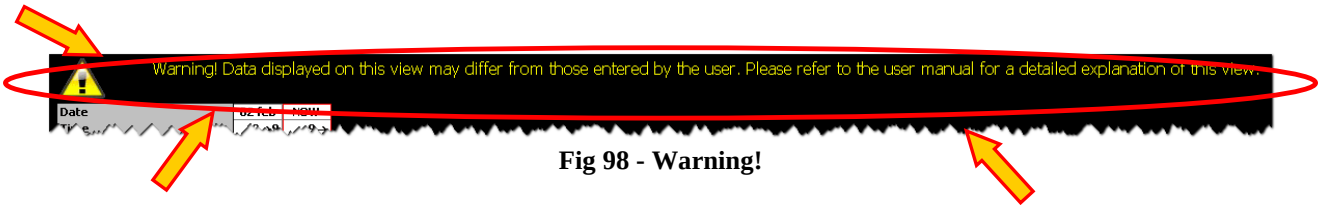


Fig 98 - Warning!

It is also possible to select the **Hourly** and **Accruing** buttons at the same time to display the hourly valuations in "Accruing" mode. See paragraph 7.9 for an explanation of the "Accruing" mode.

7.12. Target

The **Target** button on the command bar (Fig 99) can be used to specify the balance daily target.

Fig 99

The daily target can be specified both for the current day and for the next day. To specify the daily target

- click the **Target** button. The following window opens (Fig 100).

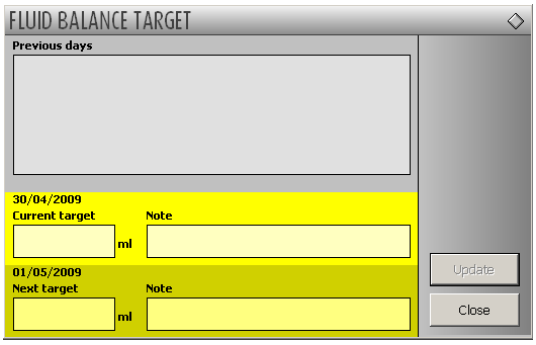


Fig 100 - Fluid balance target

- Type the target value in the "Current target" field (Fig 101 **A**).

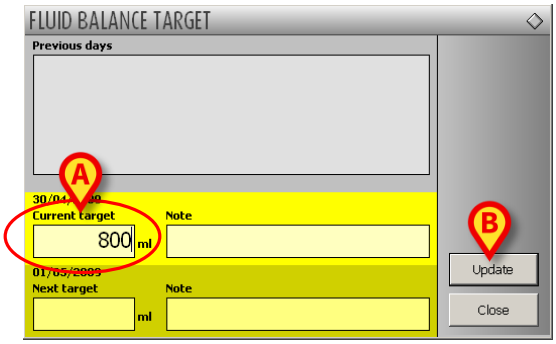


Fig 101 - Target specification

- Click the **Update** button (Fig 101 **B**). The fluid balance target is displayed in the table (Fig 102 **A**).

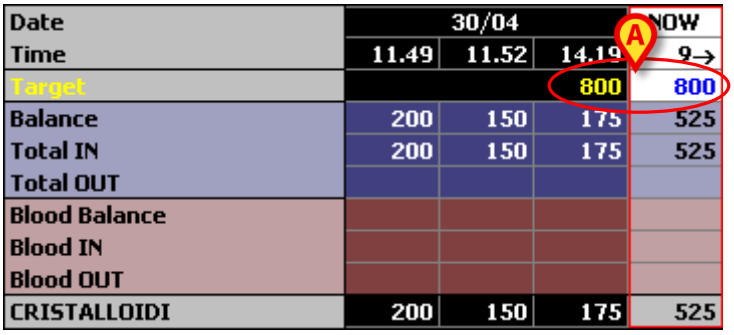


Fig 102 - The target is displayed on the table

7.12.1. "Fluid balance target" window description

The "Fluid balance target" window provide sfurther information.

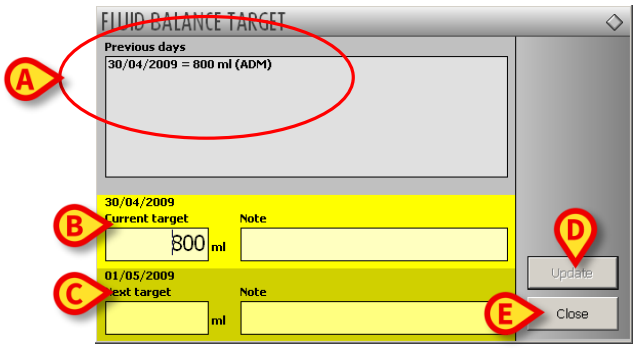


Fig 103 - "Fluid balance target" window

The "Previous days" field (Fig 103 **A**) displays a list of all the targets specified since. The display format is "Date / Target value / Acronym of the user who specified the value". The possible notes are specified in this field as well.
The "Current target" area (Fig 103 **B**) makes it possible to specify the target for the current day. Use the "Note" field to insert a textual note.
The "Next target" area (Fig 103 **C**) makes it possible to specify the target for the next day. Use the "Note" field to insert a textual note.
Both areas display the date to which the specified target refers.

The **Update** button (Fig 103 **D**) records the specified target and inserts it into the fluid balance table.
The **Close** button (Fig 103 **E**) closes the window without saving the changes.

7.13. Print reports

The **Print** button on the command bar makes it possible to create a print report containing the patient's fluid balances data (Fig 104).

Fig 104 - Command bar

To create a print report

- click the **Print** button. The following window is displayed (Fig 105).

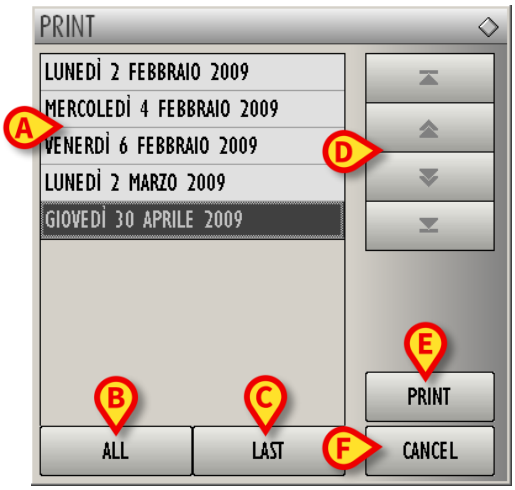


Fig 105 - Day selection

The window lists the days in which balance data were entered (Fig 105 **A**). To select a date, click the corresponding row in the list. The selected row is this way highlighted. Only the data referring to the selected day (or days) are printed. In the example shown in Fig 105 the day "Giovedì 30 Aprile 2009" is selected.
The **All** button (Fig 105 **B**) selects all the days in the list
The **Last** button (Fig 105 **C**) selects the last day in the list.
The arrow buttons on the right of the window (Fig 105 **D**) scroll the list up and down.
The **Cancel** button (Fig 105 **F**) closes the window without printing anything.
The **Print** button (Fig 105 **E**) displays a print preview. See paragraph 6.8.2 for the system's print functionalities.

7.14. Some common procedures

7.14.1. How to record a fluid balance entry

This paragraph describes the procedure making it possible to specify a fluid balance value. In the example shown in Fig 106 there are no values for the selected patient.

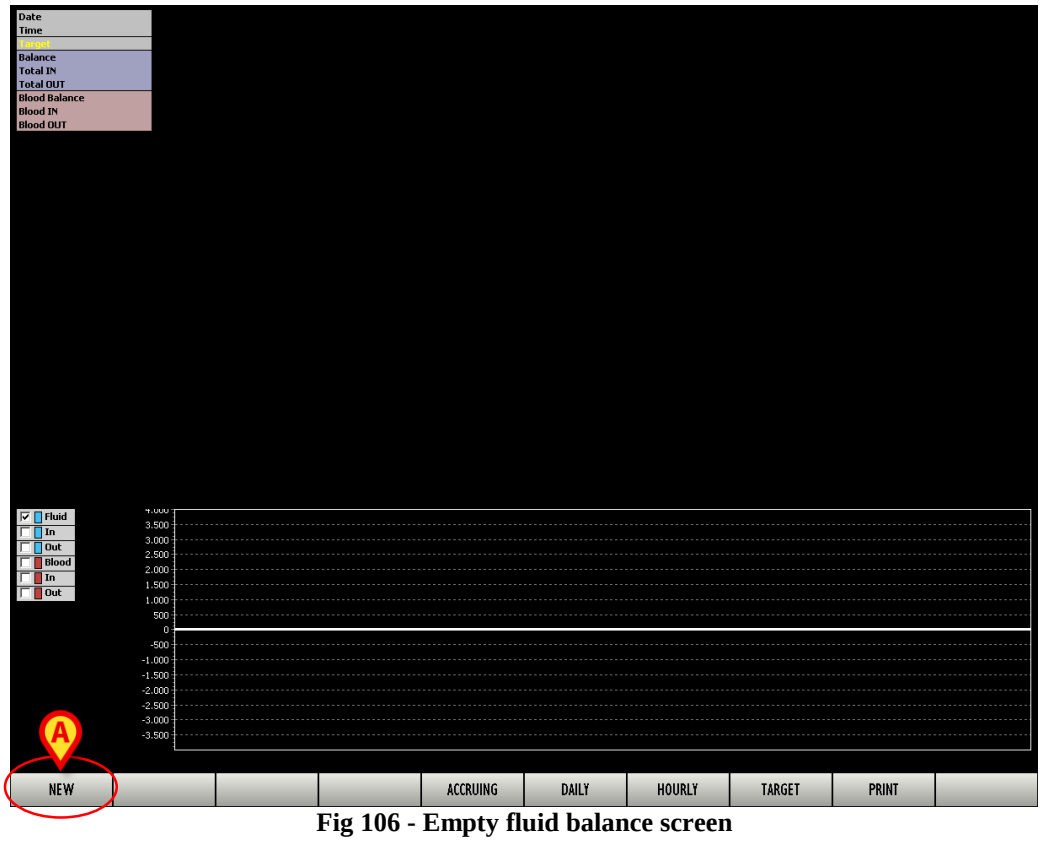


Fig 106 - Empty fluid balance screen

To insert a new value,

- click the **New** button on the command bar (Fig 106 **A**).

A screen making it possible to specify the details of the new value opens (Fig 107 - this screen is described in paragraph 7.8).

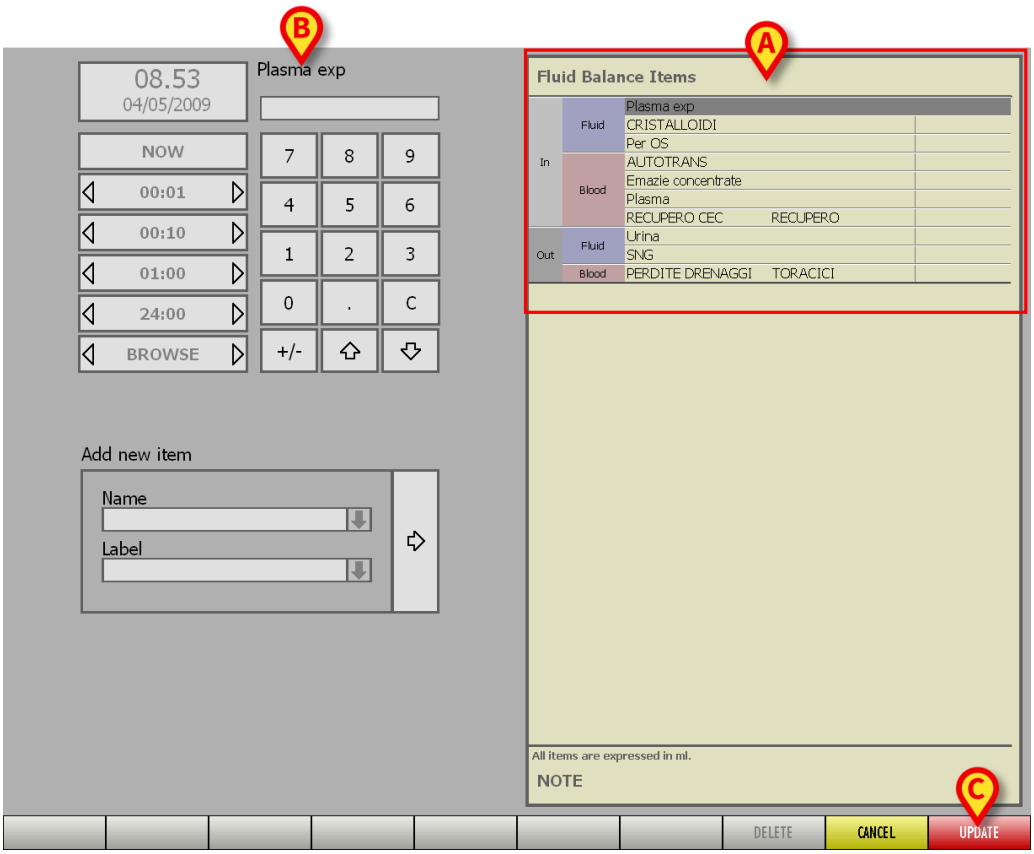


Fig 107 - Balance item specification

- Select, on the table on the right (Fig 107 **A**), the fluid balance item that must be added (click the name of the item to select it).

In Fig 107 the item "Plasma exp" is selected. The name of the selected item is displayed on the left, alongside the date/time indication (Fig 107 **B**). It is now necessary to specify the value of the balance item.

- Click the field indicated in Fig 108 **A**. A cursor blinks inside the field.

- Specify the item's value using either the virtual keyboard on screen (Fig 108 **B**) or the workstation keyboard.

Fig 108

- Click either the **Return** button on the workstation keyboard or the ⇩ button on the virtual keyboard to confirm the specified value. The specified value appears on the table on the right (alongside the selected value - Fig 109 **A**).

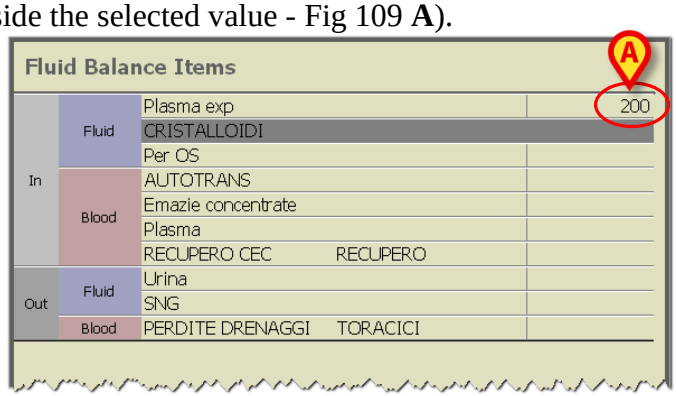


Fig 109

- Repeat the procedure for any other value to be inserted.

- Click the **Update** button on the command bar (Fig 107 **C**). The screen changes in the following way (Fig 110).

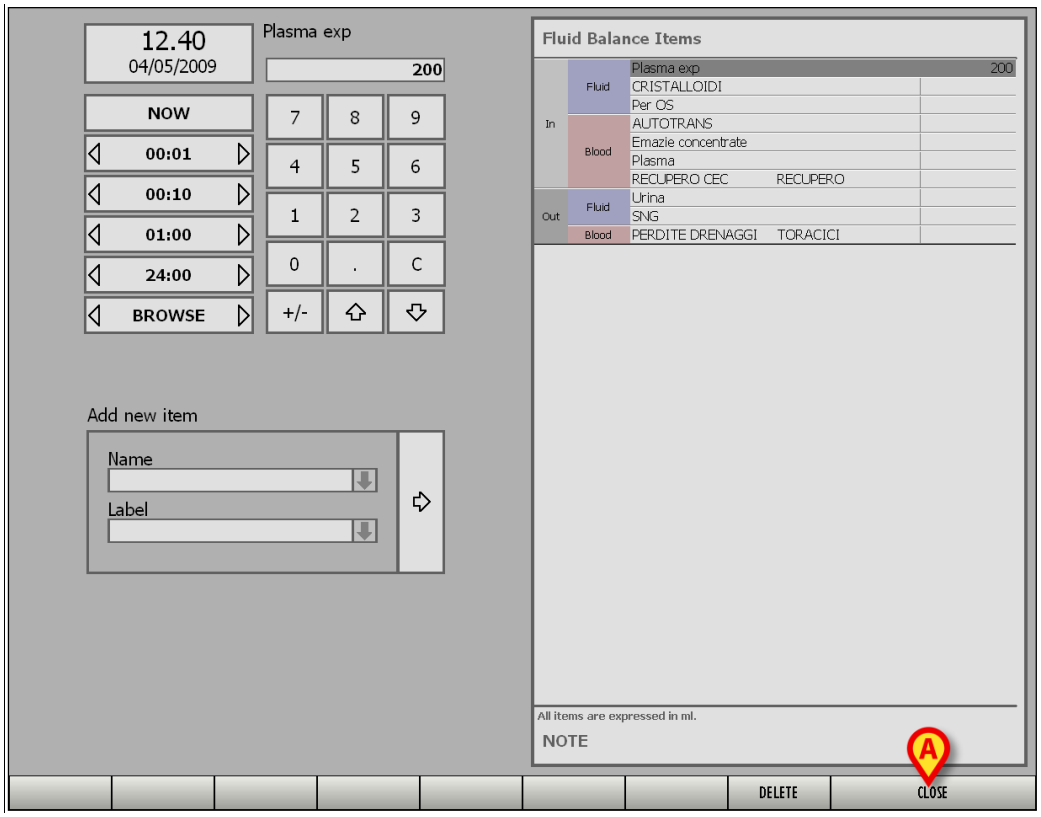


Fig 110

- Click the **Close** button (Fig 110 **A**) to go back to the module's main screen. The new value is displayed on the table (Fig 111).

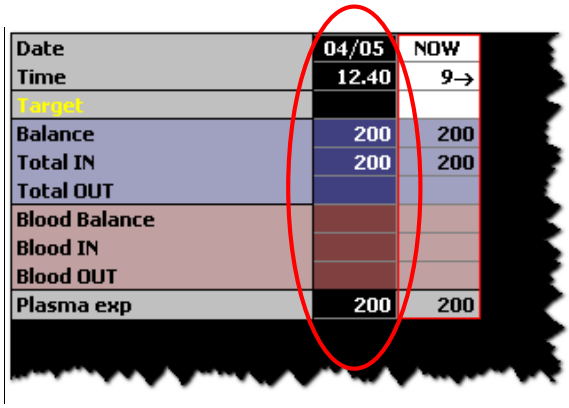


Fig 111

7.14.2. How to edit past fluid balances

It is possible to edit the values of the fluid balance items specified in the past. To do that

- click the **New** button on the command bar (Fig 112).

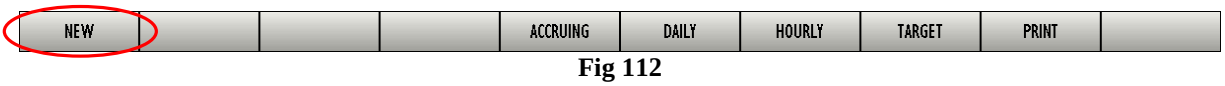


Fig 112

The following screen opens. This screen is described in paragraph 7.8.

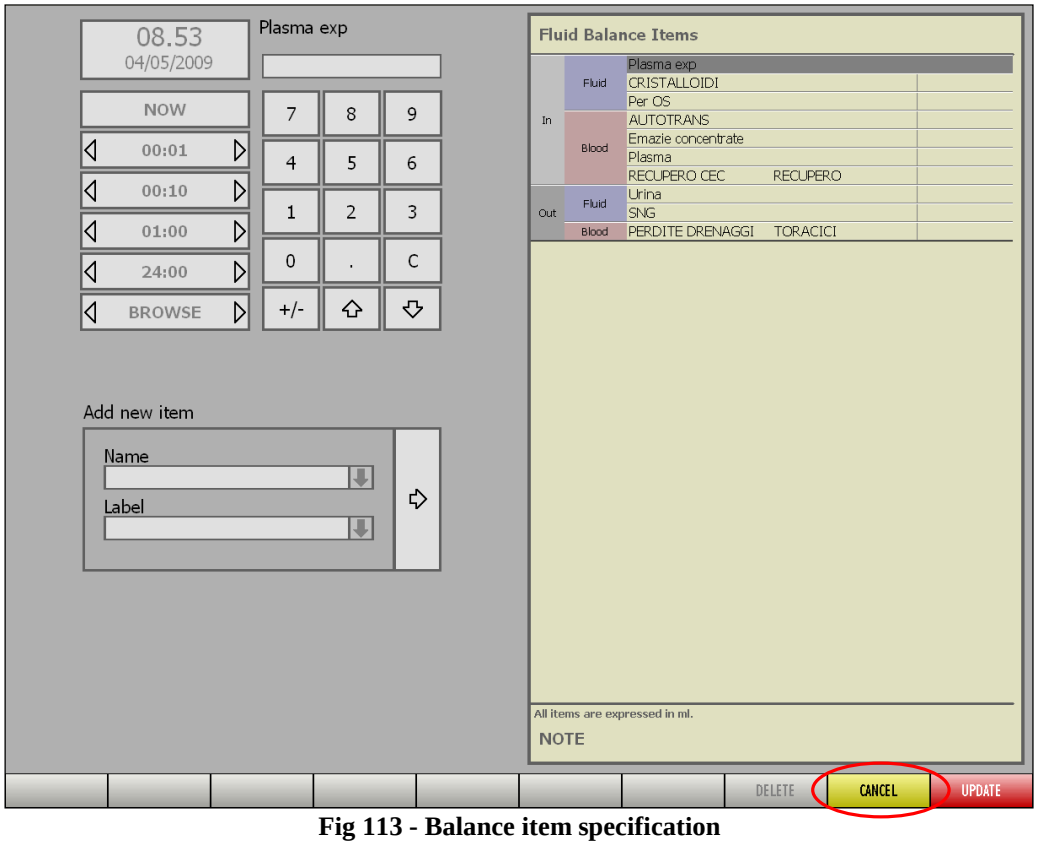


Fig 113 - Balance item specification

- Click the **Cancel** button to exit edit mode (Fig 113). The screen changes in the following way (Fig 114).

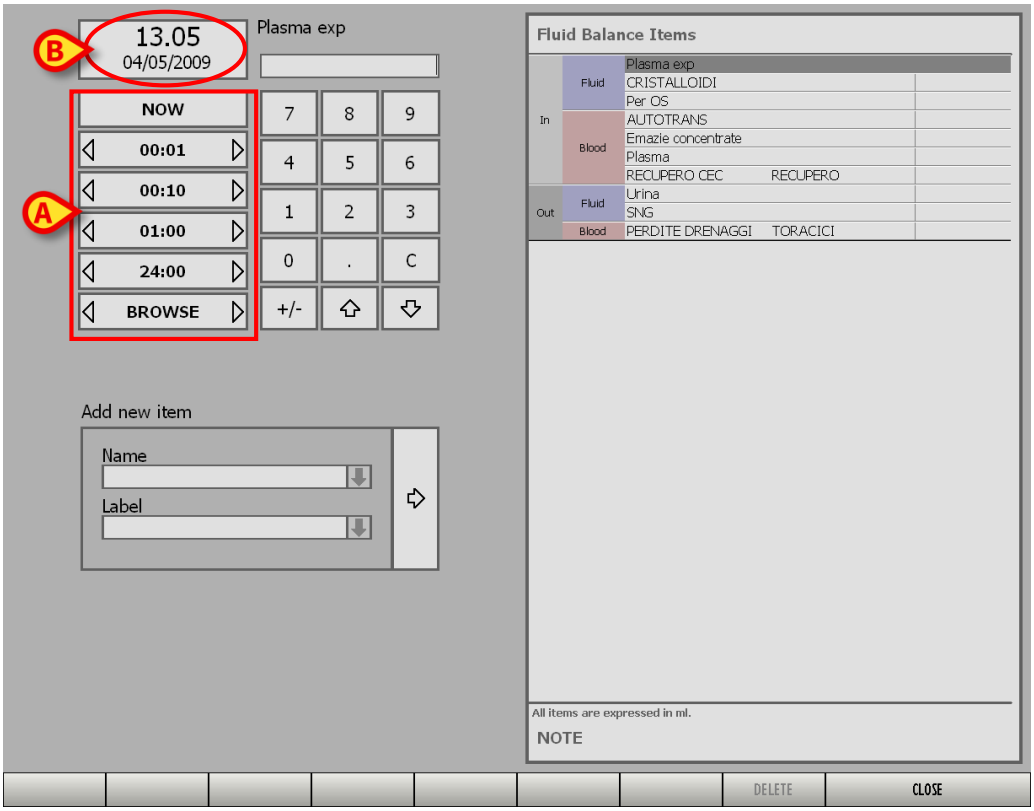


Fig 114

The buttons highlighted in Fig 114 **A** activate. These buttons make it possible to select a time preceding the current time. The **Browse** button makes it possible to "jump" directly to the time at which the value that must be edited was recorded.

- Use either the time-line buttons or the **Browse** button to go to the time in which the value that must be edited was recorded.

All the balance values recorded at the time selected are displayed on the "Fluid Balance Items" table (Fig 115).

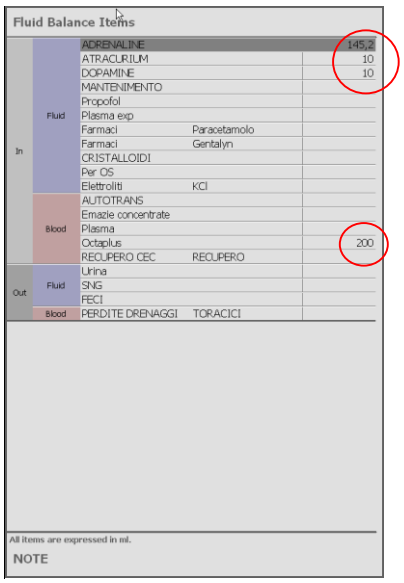


Fig 115 - Fluid balance items

- Click the row containing the value that must be edited. The row is this way highlighted. The corresponding value is displayed in the field indicated in Fig 116.

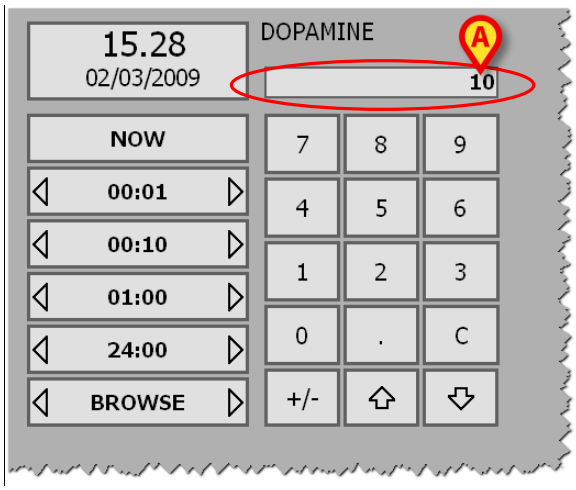


Fig 116

- Specify the new value using the numeric keyboard.

The **Cancel** and **Update** buttons on the command bar activate.

- Click the **Update** button. The value is this way changed.

7.14.3. How to delete a fluid balance insertion

To delete all the values of a past fluid balance specification (i.e. all the values belonging to a same column in the fluid balance table),

- use the procedure described in paragraph 7.14.2 to display the time and the values corresponding to the balance to be deleted.

The relating values are displayed in the "Fluid Balance items" table (Fig 117 **A**). The **Delete** button on the command bar activates (Fig 117 **B**).

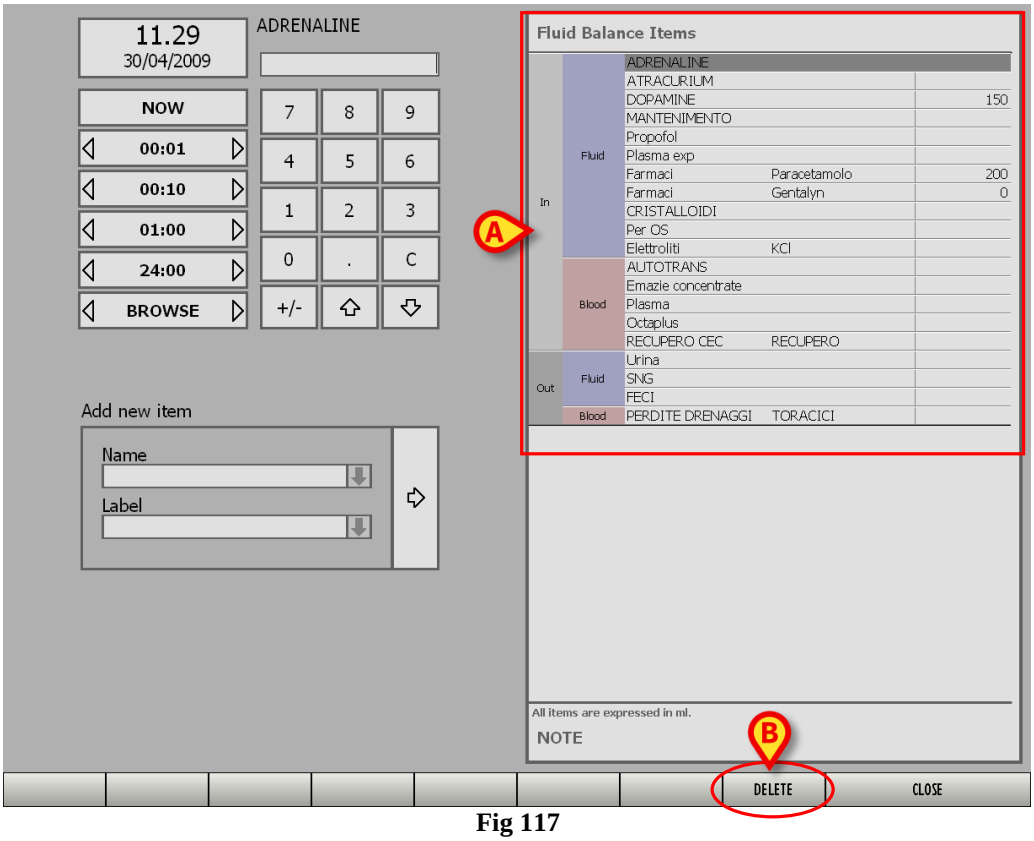


Fig 117

- Click the **Delete** button. User confirmation is required.

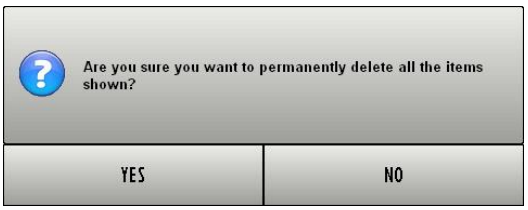


Fig 118

- Click **Yes**. All the items on the "Fluid balance items" table (Fig 117 **A**) are this way deleted. The corresponding column on the table on the main screen is also deleted.

7.14.4. How to change the insertion time

It is possible to associate a time that is different from the current time to a fluid balance specification. I.e., for example, it is possible to specify some balance values at 16:00 and make the system display them as recorded at 14:00. To do that

- click the **New** button on the command bar (Fig 119).

Fig 119

The following screen opens (this screen is described in paragraph 7.8).

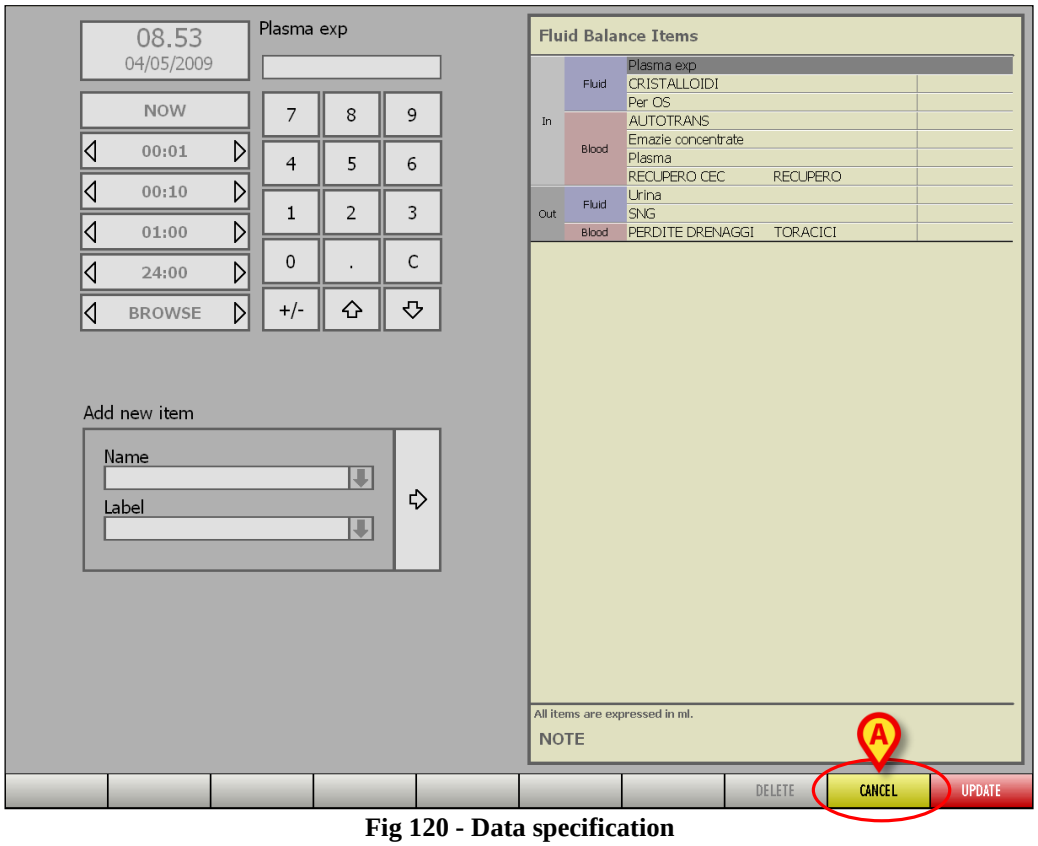


Fig 120 - Data specification

- Click the **Cancel** button to exit edit mode (Fig 120). The screen changes in the following way (Fig 121).

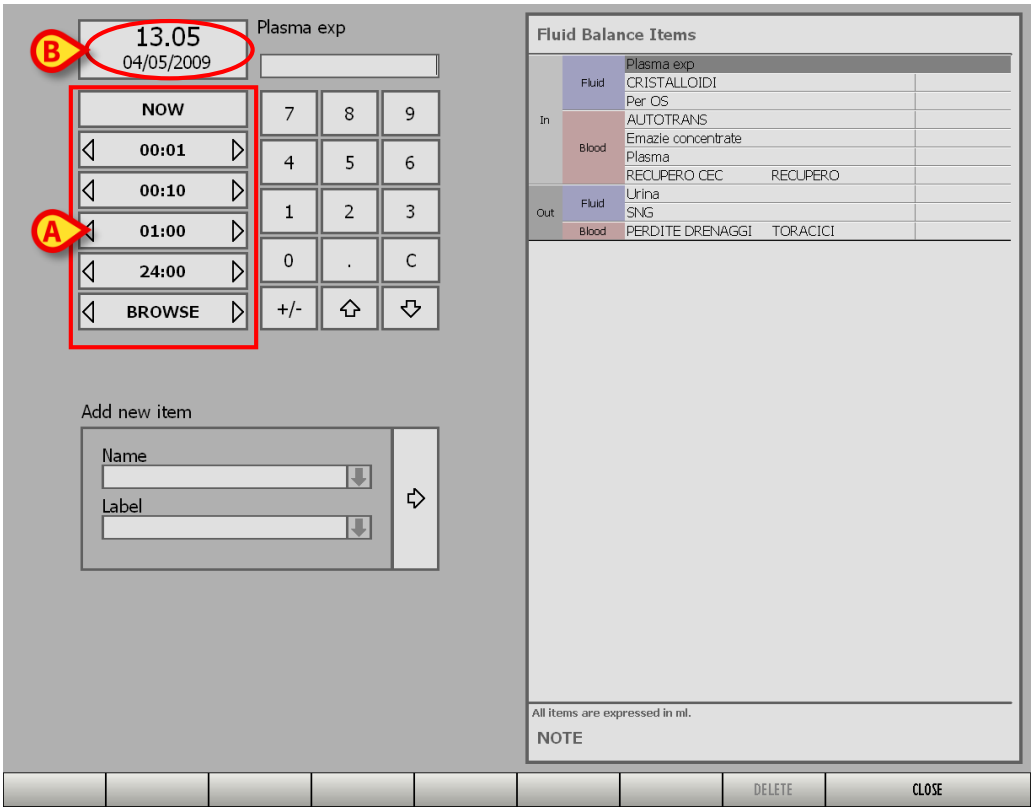


Fig 121

The buttons highlighted in Fig 121 **A** activate. These buttons make it possible to specify a time that is different from the current time.

- Use the buttons to display, in the box indicated in Fig 121 **B**, the time that you want to set as recording time (see paragraph 7.8.1 for an explanation of how these buttons work).

- Specify the fluid balance values (see paragraph 7.14.1 for the values specification procedure).

The **Cancel** and **Update** buttons on the command bar activate.

- Click the **Update** button. The values are this way recorded at the time specified.

8. Enclosed Documentation

The following documents are enclosed

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

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

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

PRODUCT LICENSE
The PRODUCT is protected by copyright laws and international copyright treaties, as well as other intellectual property laws and treaties. The PRODUCT is licensed, not sold.

1. **GRANT OF LICENSE.** This License Contract grants the User the following rights:

   - **Application Software.** The User may install, use, access, view, run or otherwise interact ("RUN") with one copy of the PRODUCT or any previous version for the same operating system on a single computer, workstation, terminal, palmtop computer, pager, "intelligent telephone" or other electronic digital device ("COMPUTER").

   - **Storage/Network Use.** The User may also store or install a copy of the PRODUCT on a storage device, such as a network server, which is only used to RUN the PRODUCT on other computers over an internal network; however, the User must purchase and dedicate a license for each COMPUTER that RUNS the PRODUCT from the storage device. A PRODUCT license may not be concurrently shared or used on different COMPUTERS.

   - **License Pack.** If this package is an ASCOM UMS License Pack, the User is authorized to RUN a number of additional copies of this PRODUCT's software up to the number of copies specified above as "Authorized Copies".

   - **Copyright.** In compliance with legal regulations, ASCOM UMS holds all rights not expressly envisaged in this Contract.

2. **OTHER RIGHTS AND LIMITATIONS**

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

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

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

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

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

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

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

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

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

LIMITED WARRANTY

ASCOM UMS warrants for a period of twelve (12) months from the date of delivery of the PRODUCT to the User that: (a) the media on which the PRODUCT is supplied shall be free of material and of manufacturing defects under normal conditions of use; and (b) the PRODUCT shall perform substantially in accordance with its published specifications.

Except for the above specifications, the PRODUCT is supplied "just as it is". This Limited Warranty shall apply only to the initial User/licensee.

The sole obligation of ASCOM UMS under this warranty shall be, to the discretion of ASCOM UMS, either to repair or replace the PRODUCT or to refund the price paid for the purchase of the PRODUCT, provided that the defect of the PRODUCT is technically attributable to ASCOM UMS and that ASCOM UMS has authorized its return.

Responsibility for loss or damages suffered by the PRODUCT during its shipment in connection with this warranty shall vest on the party shipping the PRODUCT.

ASCOM UMS does not guarantee that the PRODUCT will be free from errors or that the User can operate the system without problems or interruptions.

Furthermore, due to the ongoing development of intrusion methods and attacks of networks, ASCOM UMS does not guarantee, notwithstanding its performance of the due checks and its preparation of upgrades based on the best knowledge and experience in existence from time to time, that the PRODUCT or other equipment systems, or the network itself on which the PRODUCT is used, will be invulnerable to intrusions and attacks.

It is the responsibility of the User to install and to maintain software means for the protection against intrusions or attacks (i.e. antivirus, firewall, etc.)

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

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

ITS SUPPLIERS' RESPONSIBILITY IN CASE OF DECEASE OR PERSONAL LESIONS RESULTING FROM THE USE OF THE PRODUCT. The said limitations shall apply even if this warranty fails to meet its essential purpose. THE ABOVEMENTIONED LIMITATIONS SHALL NOT APPLY IN THE STATES AND IN THE JURISDICTIONS WHICH DO NOT ALLOW LIMITATION OR EXCLUSION OF INCIDENTAL OR CONSEQUENTIAL DAMAGE.

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

INTENDED USE

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

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

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

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

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

The user must implement adequate procedures to guarantee that potential errors occurring in the PRODUCT are promptly detected and corrected and do not constitute a risk to the patient and the operator.
These procedures depend on the configuration of the Product and the method of use preferred by the user.

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

The PRODUCT may provide, depending on the modules installed, access to information on drugs. This information is taken from official publications. It is responsibility of the user to periodically verify that this information is current and updated.

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

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

The PRODUCT does not substitute a "Nurse Call" system and it is not a "Distributed Alarm System" (as defined by the regulation EN 60601-1-8). Therefore, it must not be used in place of the direct monitoring of the alarms generated by the medical devices. This limitation is due, among the other reasons, to the specifications and limitations of the communication protocols of the medical devices and to the nature and limitations of the hospital local network.

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

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

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

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

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

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

* * * * *

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

Date Signature

SPECIFIC ACCEPTANCE OF CERTAIN PROVISIONS IN THIS CONTRACT

IMPORTANT—READ CAREFULLY

In compliance with articles 1341 and 1342 of the Italian Civil Code or to any other equivalent provision applicable in any other jurisdiction, I hereby declare that I have read, fully understood and specifically accept the following clauses of the ASCOM UMS End-User License Contract concerning the product "DIGISTAT®":

- COPYRIGHT

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

Date Signature

9. Contacts

- **ASCOM UMS srl unipersonale**

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

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 active function buttons are **New**, **Show**, **Delete**, **Change** and **Reports**.

- **Active button**

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

- **Inactive button**

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

- **Make button active**

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

CHECKBOX

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

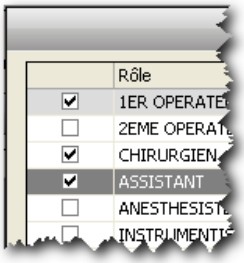


Figure 1 - Checkbox

- **Selection box**

  See “Checkbox”.

CLICK

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

- **Double Click**

Click twice in rapid succession.

CLIENT

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

COMMAND BAR

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

Figure 2

CONFIGURATION

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

CONTROL BAR

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

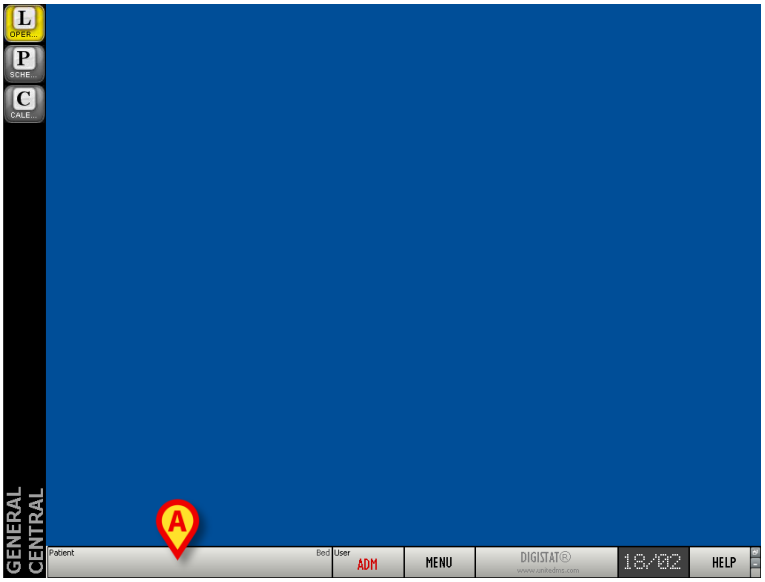


Figure 3

CURSOR

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

DATABASE

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

DEFAULT

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

DIGISTAT®

- **DIGISTAT® Module**

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

- **DIGISTAT® System**

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

- **DIGISTAT® Environment**

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

DRAG

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

DRAG AND DROP

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

EDIT

Modify the data on a screen.

❖ Edit Mode

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

❖ Edit state

See “Edit Mode”.

EVENTS

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

FIELD

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

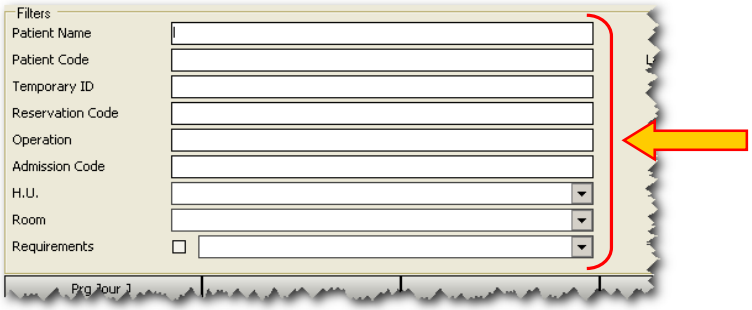


Figure 4 - Fields

- **Free field**

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

LOCATION

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

LOG

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

LOGIN (procedure)

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

- **Logout**

The act of exiting the system.

MARKER

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

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

MESSAGE CENTER

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

PAGE

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

PASSWORD

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

PATIENT

- **Admitted Patient**

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

- **Patient registered in the database**

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

- **Patient Selected**

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

POP-UP

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

QUERY

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

RADIOBUTTON

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

Figure 5

READ-ONLY

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

RECORD

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

RESERVE

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

SCREEN

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

SERVER

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

SLOT

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

Figure 6 - slot

STATE (of the operation)

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

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

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

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

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

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

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

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

SYSTEM ADMINISTRATOR

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

TAB

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

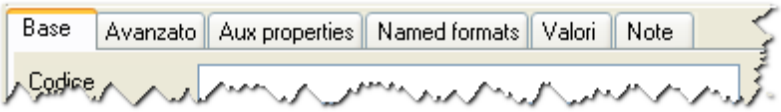


Figure 7 - Tab

TOOLTIP

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

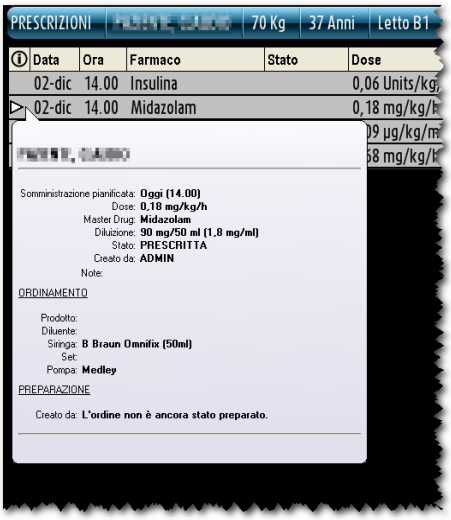


Figure 8 - Tooltip

TOUCH SCREEN

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

USER

The person using the system.

- **User Connected**

  See “User Logged In”.

- **User Logged In**

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

- **User Logged-out**

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

USERNAME

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

WARNING MESSAGE

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

WORKSTATION

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

Appendix B – Residual risks

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

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

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

RISKS RELATING TO THE HARDWARE PLATFORM IN USE

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