DIGISTAT® Scoring Calculator

DIGISTAT® Version 4.2

User Manual

DIG UD SCR IU 0004 ENG V01
06 DIC 2016

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

SOFTWARE LICENSE

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

WARNING

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

LICENSES AND REGISTERED TRADEMARKS

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

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

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

1. Contents

2. Using the manual

2.1. Aims

The effort which has gone into creating this manual aims to offer all the necessary information to guarantee a safe and correct use of the DIGISTAT® system and to allow the manufacturer identification. Furthermore this document aims to describe every single part of the system, it also intends to offer a reference guide to the user who wants to know how to perform a specific operation and a guide to the correct use of the system so that improper and potentially hazardous uses can be avoided.

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

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

To be more precise, the differences may concern

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

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

2.2. Charcters used and terminology

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

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

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

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

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

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

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

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

3.2.1. Safety Advisories

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

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

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

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

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

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

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

In case some devices used for the Product are located in the patient area or are connected to equipment present in the patient area then the responsible organization shall ensure that the whole combination complies with the international standard IEC 60601-1 and any additional requirement established by the local authorities.

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

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

PATIENT POPULATION

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

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.

3.2.2. "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 8).

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).
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.

4.1. Bedside

4.1.1. Hardware

Minimum hardware requirements:

- Intel® I3 processor (or faster)
- Memory: 4 GB RAM
- Hard Disk: at least 60 GB of available space
- Monitor: 1024 x 768 or higher (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- Ethernet interface 100 Mb/s (or higher)
- CD/DVD Drive or possibility to copy the installation files

4.1.2. Operating System

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

4.2. Central

4.2.1. Hardware

Minimum hardware requirements:

- Intel® I3 processor (or faster)
- Memory: 4 GB RAM
- Hard Disk: at least 60 GB of available space
- Monitor: 1024 x 768 or higher (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- Ethernet interface 100 Mb/s (or higher)
- CD/DVD Drive or possibility to copy the installation files

4.2.2. Operating System

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

4.3. Server

4.3.1. Hardware

Minimum hardware requirements:

- Intel® I5 processor (or faster)
- Memory: 4 GB RAM (8 GB recommended)
- Hard Disk: at least 120 GB of available space
- Monitor: 1024 x 768 or higher (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- Ethernet interface 100 Mb/s (or higher)
- CD/DVD Drive or possibility to copy the installation files

4.3.2. Operating System

Microsoft Corporation Windows Server 2012 R2

4.3.3. System Software

Microsoft SQL Server 2012/2014

4.4. Handheld device

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

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.

4.5. 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.

4.6. 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.

4.6.1. 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.

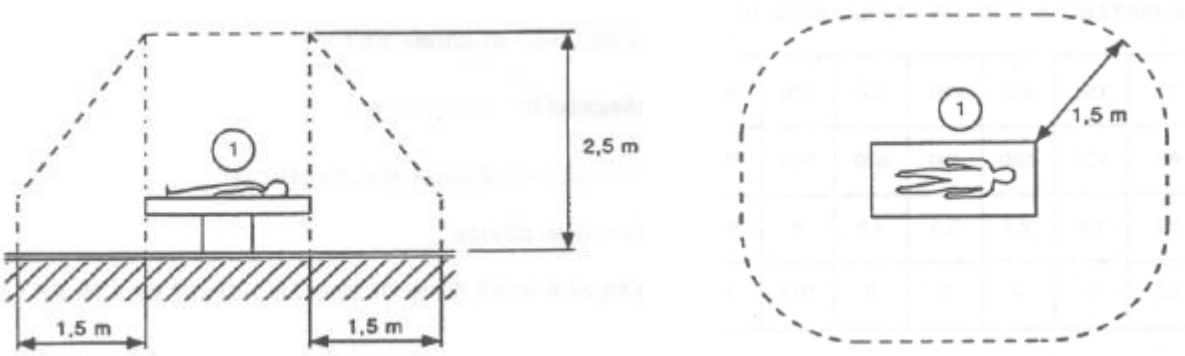


Fig 1

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 applications already installed (OS, firewall, antivirus, RDP, ...) and with DIGISTAT® already installed, but disabled (i.e. not executable by a user without the assistance of an ASCOM UMS technician).

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

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

Please contact Ascom UMS or Distributor for the list of available drivers.

5.9. System unavailability

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

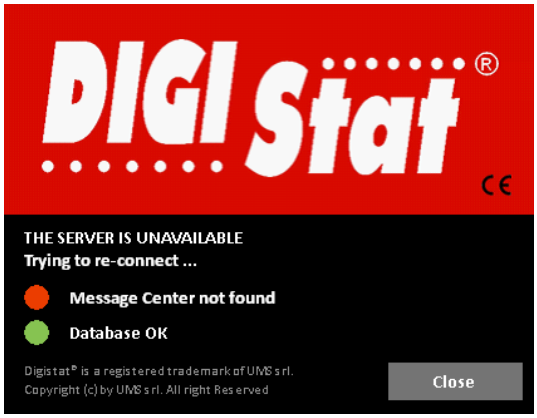


Fig 2

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 8 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 8 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.

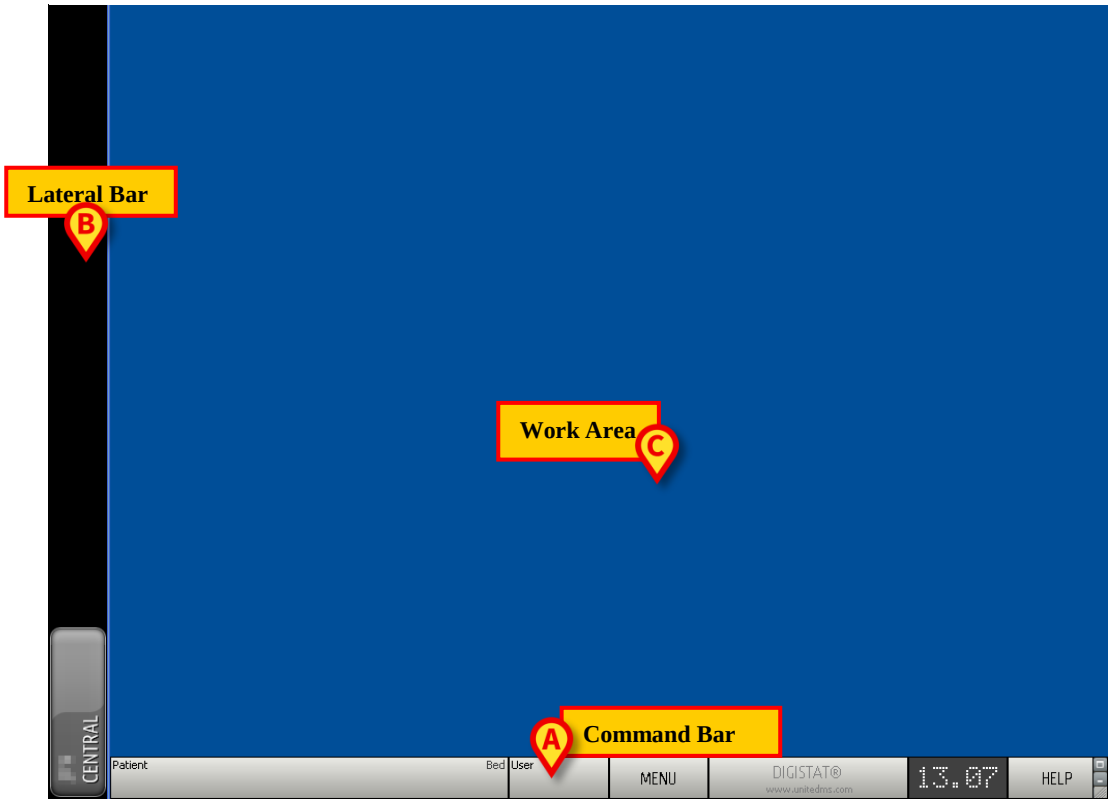


Fig 5

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 your 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 the 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 length of time, the user is automatically disconnected (automatic log out). This length of time depends on a configuration parameter.

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

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

Fig 10

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

Fig 11

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

6.5.3. Recent users

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

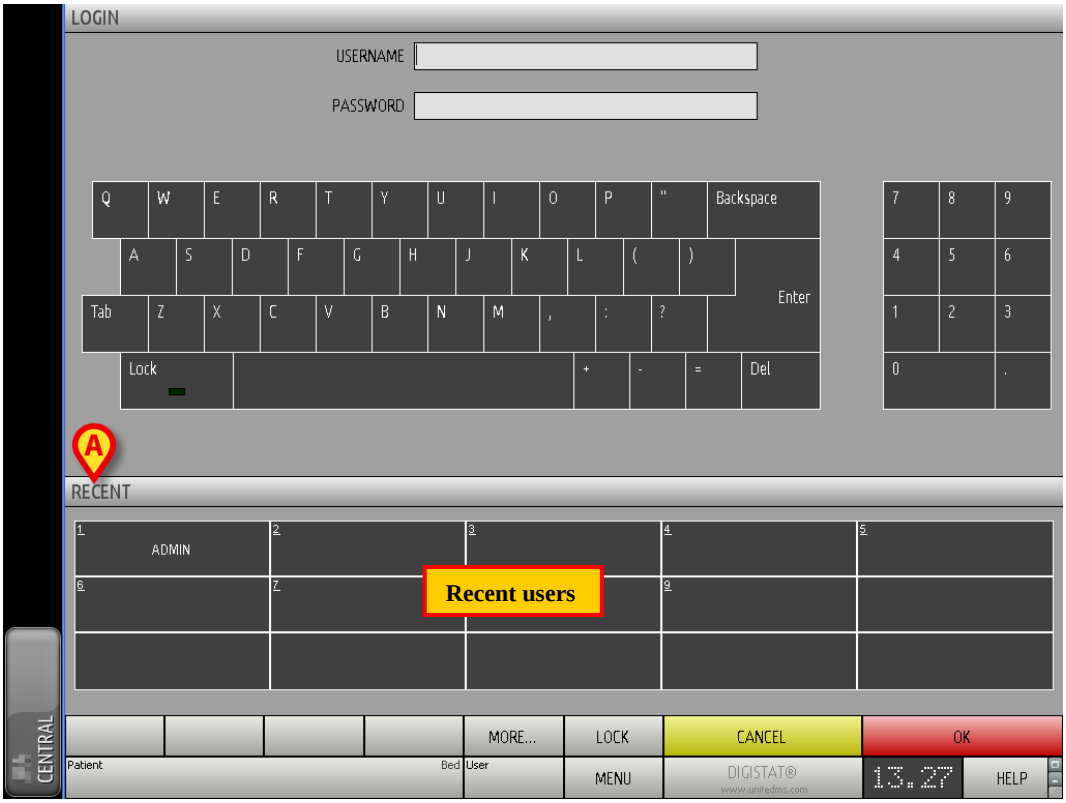


Fig 12

The area is divided into rectangles. The names of the users who accessed the system recently appear inside the rectangles. When any of these rectangles is clicked, the “Username” field is automatically filled with the name appearing inside the rectangle.

6.5.4. How to use the “User List”

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

Fig 13

To display the “User List”,

- click the **More** button.

The following window is displayed (Fig 14).

Fig 14

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

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

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

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

Use the **Local** button (Fig 14 **D**) to see the list of users relating to the specific workstation on which you are currently working.

Use the arrows on the right side of the window (Fig 14 **E**) to scroll up and down the list of users.

To select a user

- click the name of the user.

The name will be highlighted, then

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

Otherwise you can

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

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

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

6.6. DIGISTAT® Control Bar

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

Fig 15

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

Fig 16

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

- The button quoting the DIGISTAT® brand name and the ASCOM UMS srl web address (Fig 15 **D**) is used by the system to signal that there are alarms or warnings going on in one of the modules. This feature is explained in the context of the specific module.
- The display indicated in Fig 15 **E** alternately shows the current date and time.
- Use the **Help** button (Fig 15 **F**) to access the on-line documentation available.

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

These three buttons are present only if enabled by configuration.

6.6.1. How to read the "Patient" button

Patient selected

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

Fig 17

Patient admitted

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

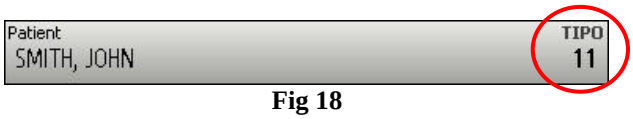


Fig 18

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

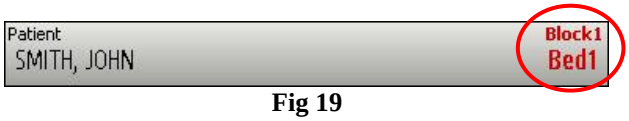


Fig 19

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

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

Fig 20

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

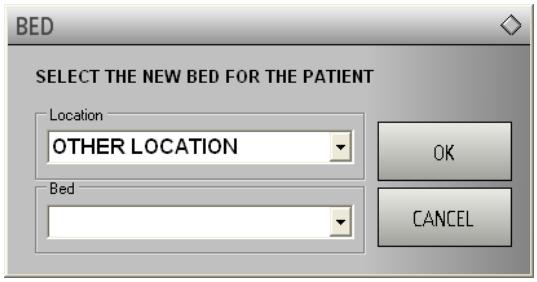


Fig 21

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

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

Fig 22

Patient management.

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

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

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

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

WARNING!

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

6.7. Help

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

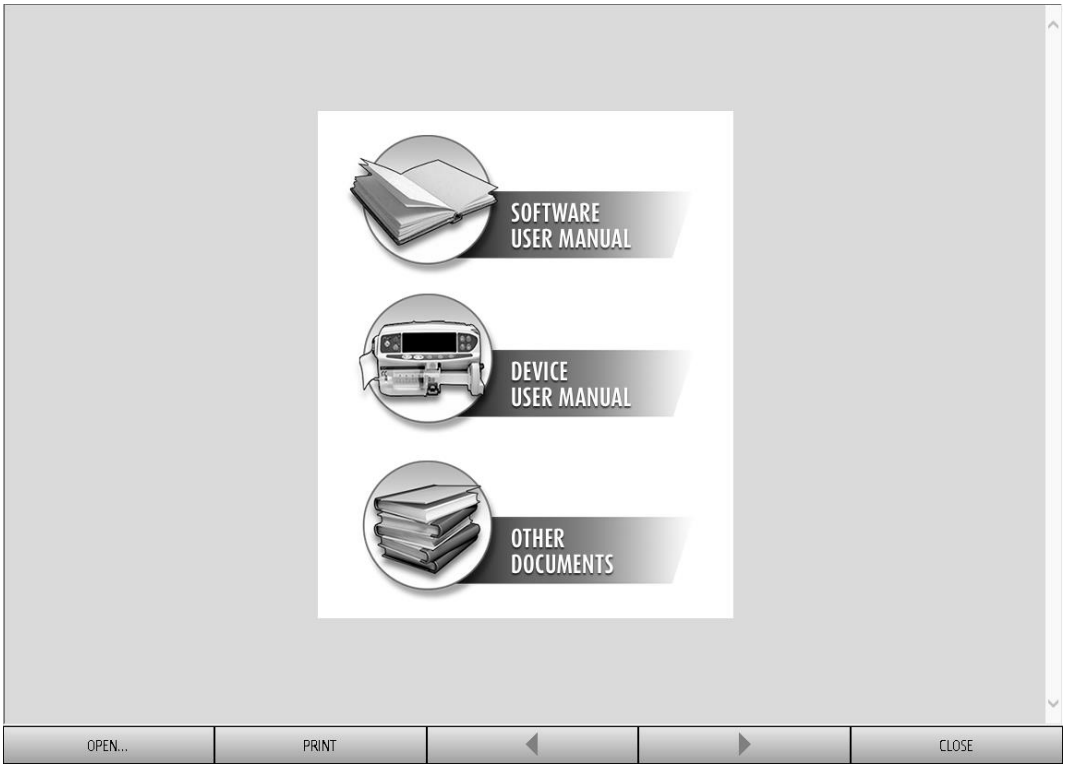


Fig 23

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

Fig 24

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

6.8. DIGISTAT® Main Menu

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

Fig 25

opens a menu containing several options (Fig 26).

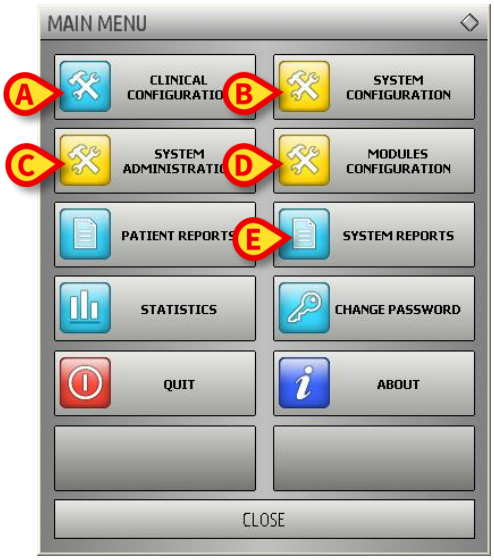


Fig 26

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

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

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

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

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

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

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

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

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

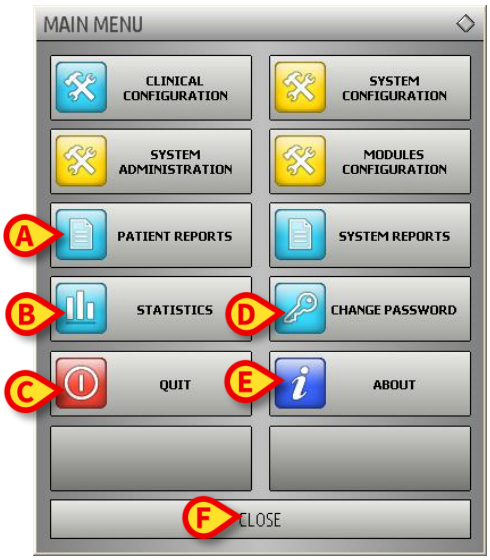


Fig 27

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

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

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

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

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

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

6.8.1. Patient reports

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

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

Fig 28

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

6.8.2. Print reports

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

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

To print a patient report

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

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

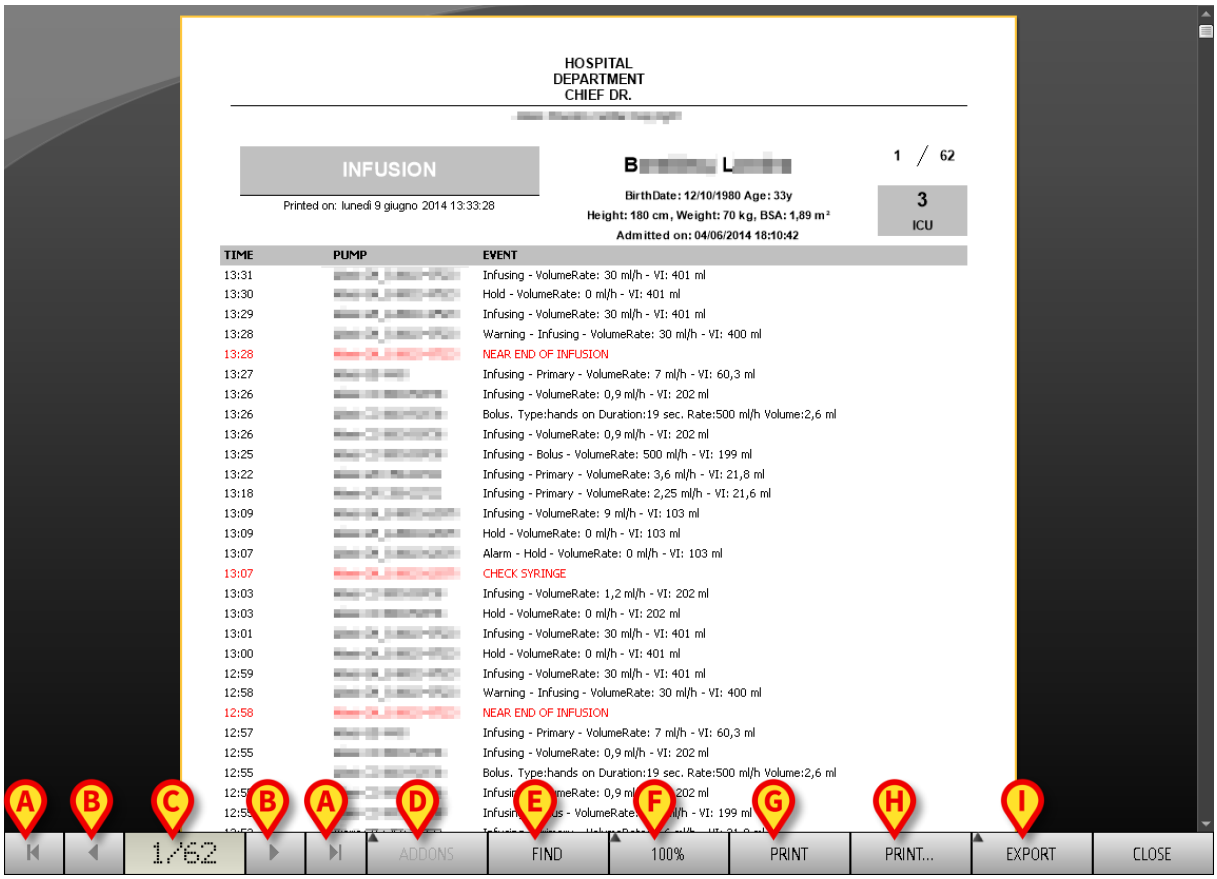


Fig 29

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

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

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

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

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

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

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

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

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

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

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

6.8.2.1. Addons

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

To display the available options,

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

Addons - Watermark

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

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

The following window is displayed (Fig 30).

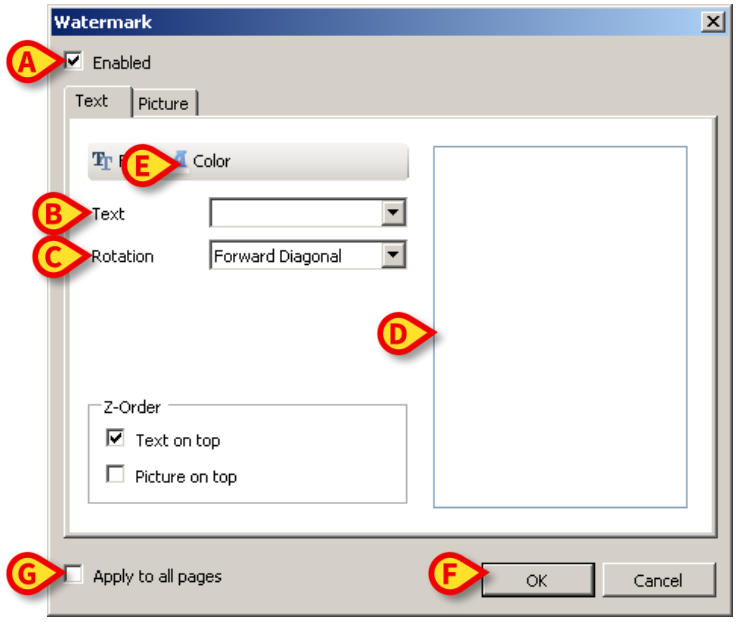


Fig 30

To add a textual watermark,

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

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

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

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

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

The text is this way inserted as watermark.

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

To insert a picture as watermark

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

The following window is displayed (Fig 31).

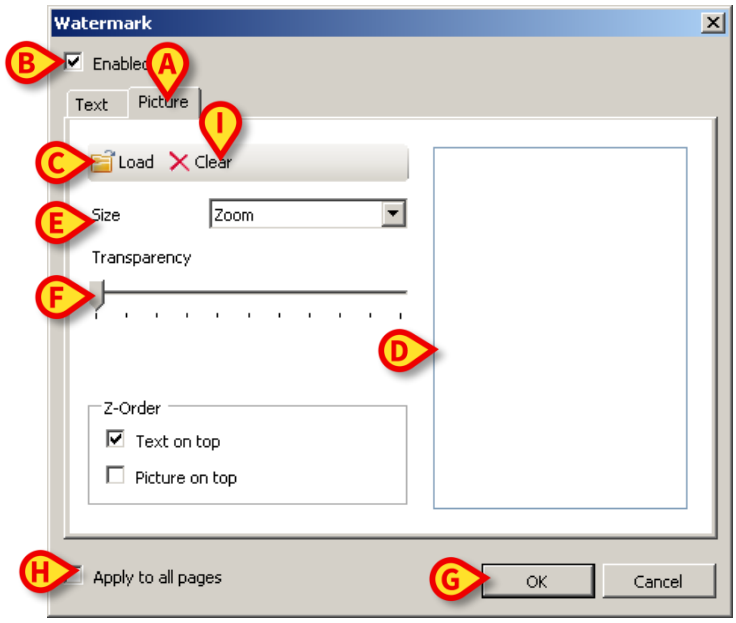


Fig 31

Follow these steps to insert an image as watermark,

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

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

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

- Search and select the image to be uploaded.

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

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

The watermark image is this way inserted.

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

To delete an already selected image,

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

6.8.2.2. Find

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

To search the print report,

- Click the **Find** button.

The following window opens (Fig 32).

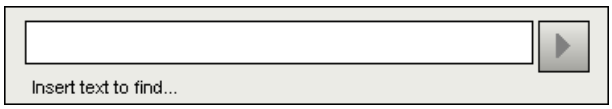


Fig 32

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

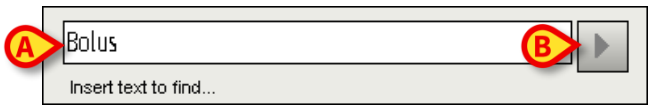


Fig 33

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

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

- Click the  button again to search for the other instances in the text.

6.8.2.3. Zoom

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

To change the display mode,

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

Fig 34

- Click the wanted option on the menu.

The page is displayed anccordingly. The mode currently selected is indicated on the button.

The following options are available:

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

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

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

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

the 

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

6.8.2.4. Print

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

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

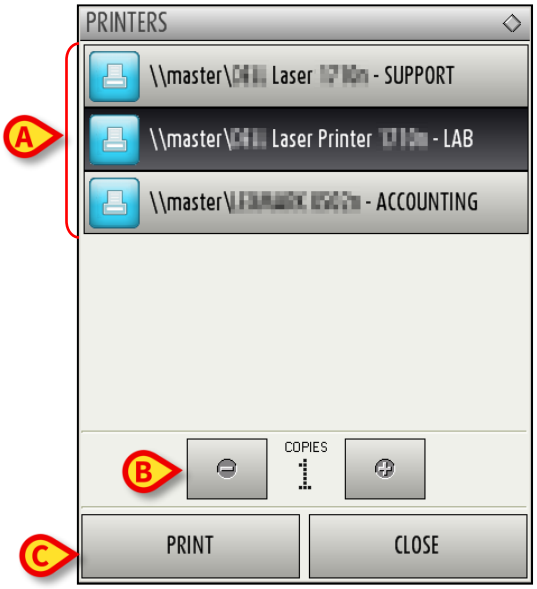


Fig 35

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

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

6.8.2.5. Export

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

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

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

- Click the option corresponding to the wanted extension.

The document is this way exported to the corresponding extension.

6.8.3. Statistics

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

Fig 36

The button opens another menu (Fig 37) that enables to access various distinct tools.
The type and number of accessible tools depend on the configuration in use and the specific modules installed.

These tools are mainly reserved to the system administrators. Please see the specific technical documentation for a description.

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

Fig 37

6.8.3.1. Query Assistant

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

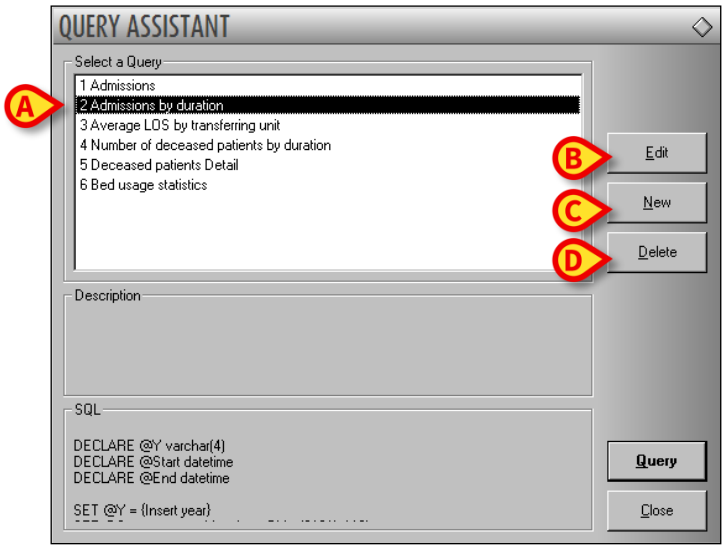


Fig 38

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

To run a query

- click the corresponding name on the list,

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

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

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

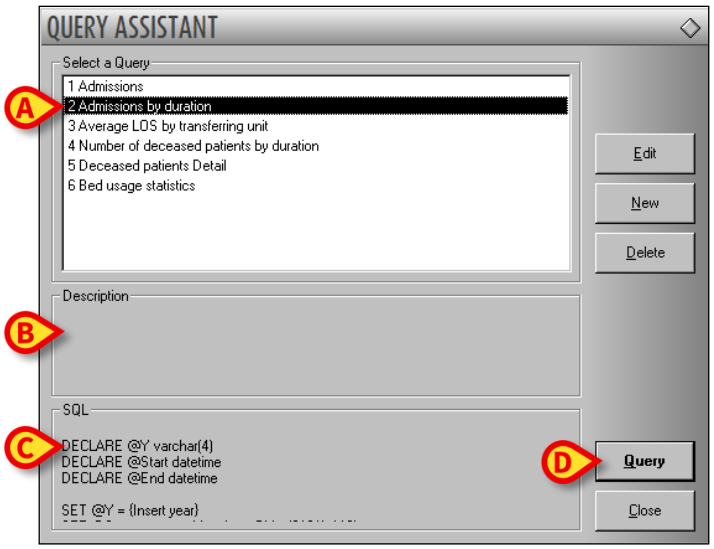


Fig 39

To run the query

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

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

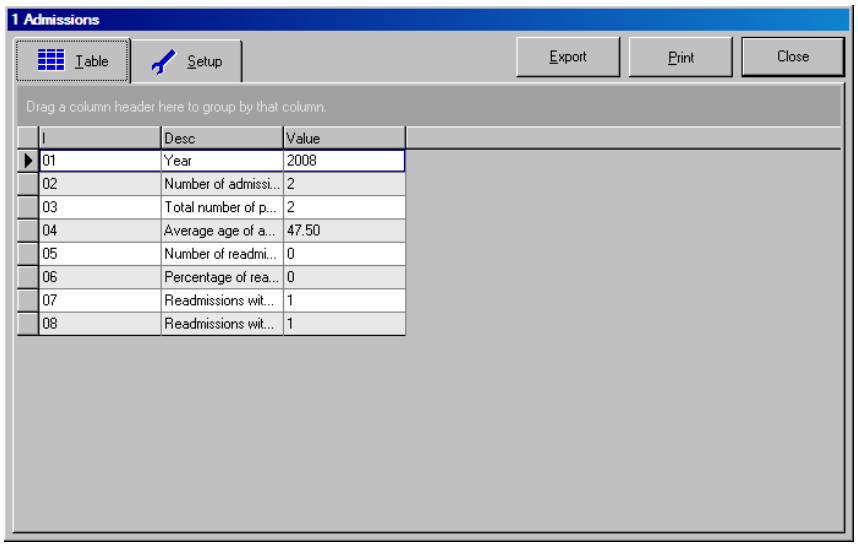


Fig 40

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

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

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

6.8.4. Change password

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

Fig 41

To change the user password

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

The "Change password" window will open.

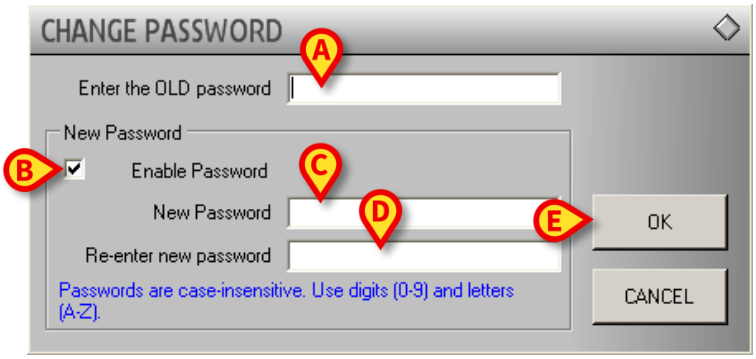


Fig 42

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

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

6.8.5. About DIGISTAT®

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

Fig 43

6.8.6. Quit DIGISTAT®

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

To quit DIGISTAT®

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

Fig 44

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

Fig 45

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

Another menu is displayed (Fig 46).

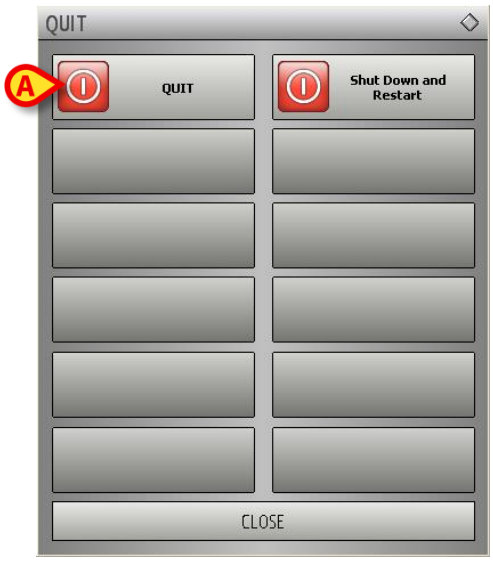


Fig 46

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

User confirmation is required (Fig 47).

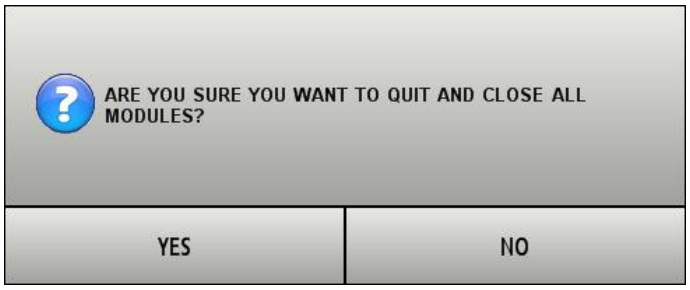


Fig 47

- Click **Yes** to exit DIGISTAT®.

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

7. Scoring Calculator

7.1. Introduction

The DIGISTAT® "Scoring Calculator" module makes it possible to collect and classify clinical information according to the "Standard Severity Scores".

DIGISTAT® "Scoring Calculator" performs all the necessary scoring calculations, importing data both from the DIGISTAT® Database and from most Network-Accessible, shared remote databases.

Scores and parameters are clearly displayed on charts and tables. Detailed information about the various Severity Scores is available.

This system, after patient selection, makes it possible to:

- navigate the available score algorithms and display, for each of them, the score calculations performed for a patient (either by score or by parameters values);
- display, via html, a descrption of the selected score algorithms;
- display in a chart a visual representation of the various scores values;
- configure a subset of parameters for each score parameter (chart, query, limits etc...);
- calculate a new score.

7.2. Module selection

To select the "Scoring Calculator" module,

- click the corresponding icon on the lateral bar (Fig 48).

Fig 48

The screen displayed in Fig 49 appears. In Fig 49 no patient is selected. The buttons on the Control Bar are therefore disabled and no data is displayed on screen.

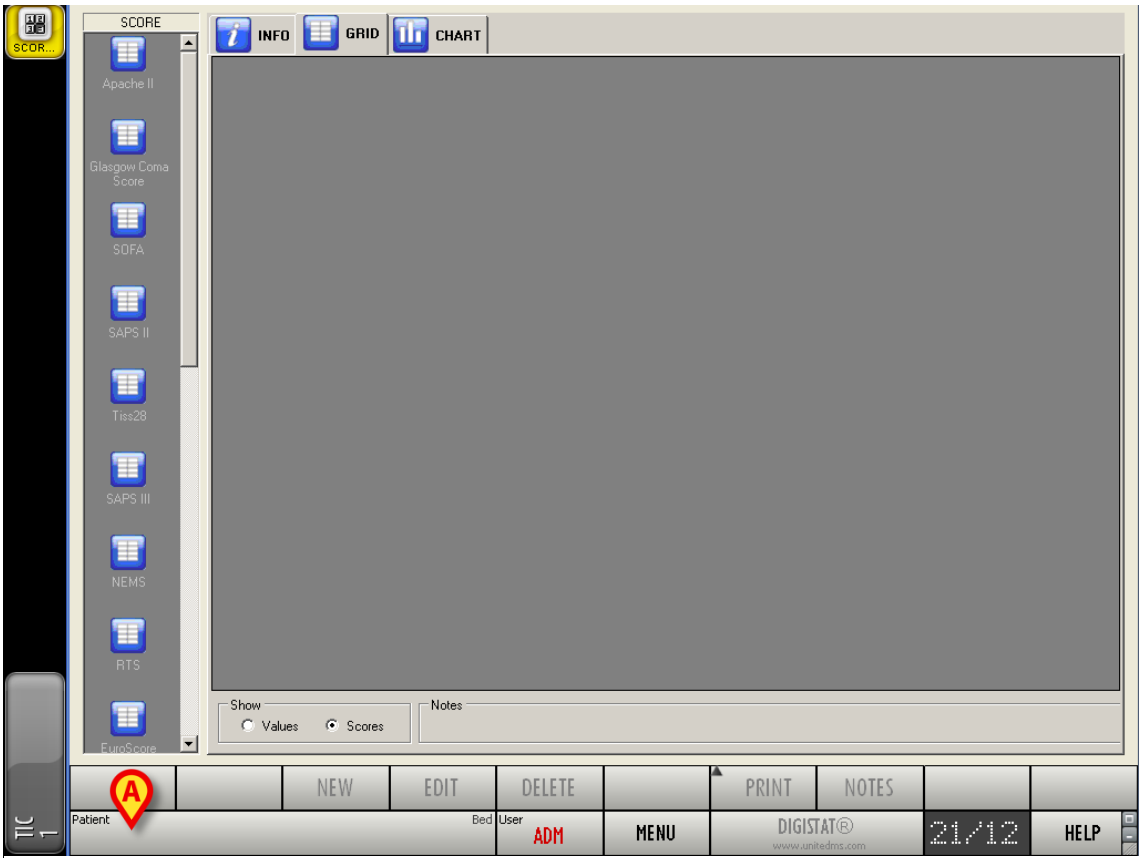


Fig 49 - Scoring table: no patient selected

7.3. Patient search and selection

To select a patient, if the patient search and selection tool is a DIGISTAT® software,

- click the **Patient** button on the Control Bar (Fig 49 **A**).

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

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

If your Healthcare Structure does not use a DIGISTAT® software for the patient search and selection procedures, please refer to the specific related documentation.

When a patient is selected the patient data (if any) are displayed. In Fig 50 patient "Cedar Hill Tarcento" is selected.

7.4. Screen structure

The screen shown in Fig 50 makes it possible to display in charts and tables the various data.

The screen is formed of three main areas:

1) the list of available “Scores” (Fig 50 **A**);
2) the data area (this area displays charts, tables and scores instructions Fig 50 **B**);
3) the command bar (Fig 50 **C**).

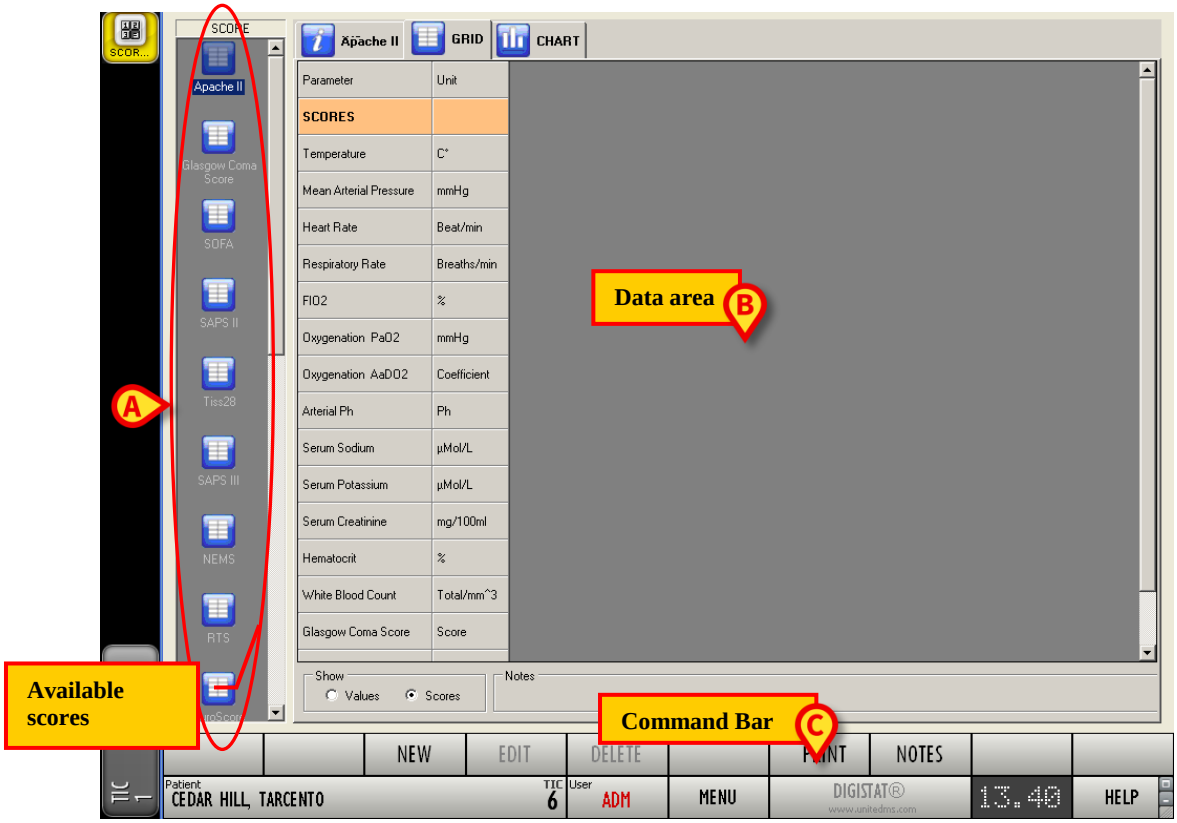


Fig 50 - Scoring table - Patient selected

7.5. The list of available scores

The vertical area on the left (Fig 50 **A**, Fig 51) displays the list of all the available scores.

These are some of the scores currently available (only the scores explicitely enabled by configuration are displayed):

- APACHE II - Acute Physiologic and Chronic Health Evaluation
- APS - Acute Physiologic Score
- SAPS II - Simplified Acute Physiology Score
- TISS 28 - Therapeutic Intervention Score System
- GCS - Glasgow Coma Score

- NEMS - Nine equivalent of nursing manpower
- RTS - Revised Trauma Score
- MPM Admission - Mortality Probability Model
- MPM 24h Model - Mortality Probability Model every 24 hours of ICU stay
- SOFA - Sepsis-Related Organ Failure Assessment
- EUROSCORE - European System for Cardiac Operative Risk Evaluation
- HIGGINS CABG - ICU admission risk based on preoperative conditions and intraoperative events.

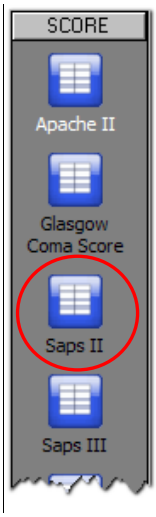


Fig 51 - Selectable scores

An icon and a name indicate each available score (for example “Apache II”, “Saps II” etc…).

The icon corresponding to the score currently in use is highlighted - 

.

To select a score,

- click the corresponding icon.

The central part of the screen (“Data area” - Fig 50 **B**) displays the available data for the selcted score and patient.

7.6. Data area

The “data area” is the central part of each screen. In this area either charts, tables or score information are displayed. (Fig 52, Fig 50 **B**).

Fig 52 - Data area

This area always displays the data referring to the score selected on the bar on the left (Fig 51).

Three tabs are on the top left corner of the data area (Fig 52 **A**).

- The “Table” tab (selected in the figure) displays the table containing the score values.

- The tab containing the name of the selected score (“Apache II” in the figure) displays the score’s on-line guide.

- The third tab “Chart” displays in a chart the trends of the acquired score parameters values.

The area indicated in Fig 52 **C** dispalys the possible notes associated to a single score calculation. The note is displayed only if the column relating to the specific calculation is selected. See paragraph 7.8.

7.7. Table

The table in the data area (Fig 53) displays the different scores associated to the parameters relating to the selected score calculation.

Parameter	Unit	16/12/2011 09.34 ADM	16/12/2011 11.52 ADM	16/12/2011 13.11 ADM	16/12/2011 13.14 ADM	21/12/2011 13.23 ADM
SCORES		**50**	**46**	**56**	**52**	**58**
Temperature	C°	1	2	2	1	1
Mean Arterial Pressure	mmHg	2	3	2	2	2
Heart Rate	Beat/min	0	0	0	0	2
Respiratory Rate	Breaths/min	3	0	1	3	1
FIO2	%	21	21	21	21	21
Oxygenation PaO2	mmHg	1	1	1	3	4
Oxygenation AaDO2	Coefficient					
Arterial Ph	Ph	4	2	3	4	2
Serum Sodium	µMol/L	1	2	1	2	3
Serum Potassium	µMol/L	2	3	3	3	4
Serum Creatinine	mg/100ml	2	2	2	3	2
Hematocrit	%	2	2	0	2	2
White Blood Count	Total/mm^3	2	0	4	1	2
Glasgow Coma Score	Score	9	4	11	7	9

Fig 53 - Scores table - “Apache II”

The first column displays the names of all the parameters (Fig 54).

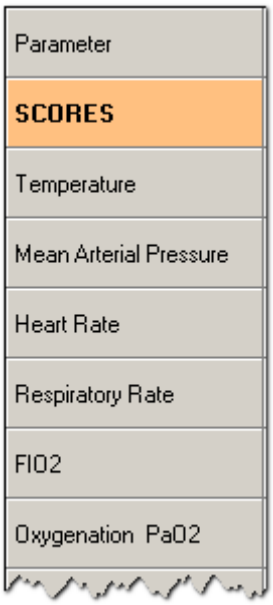


Fig 54 - Parameters

The second column indicates the unit of measure of the values displayed on the table (Fig 55).

Fig 55 - Unit of measure

The other columns refer to a score calculation. Each cell displays the score calculated for the corresponding parameter (Fig 56).

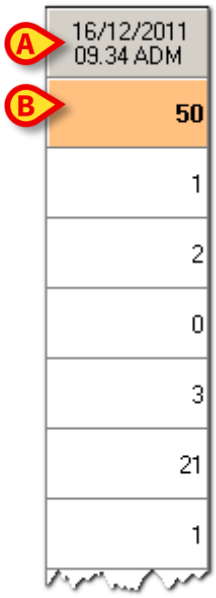


Fig 56 - Scores

The first cell of each column indicates the date, the time and the acronym of the user who recorded the information (Fig 56 **A**).

The second cell indicates the score total value (Fig 56 **B**).

For some parameters it is possible to display the parameter value instead of the corresponding points.

To do that

- select the “Values” option on the bottom left corner (Fig 57, Fig 52 **B**).

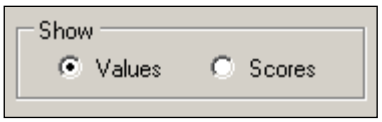
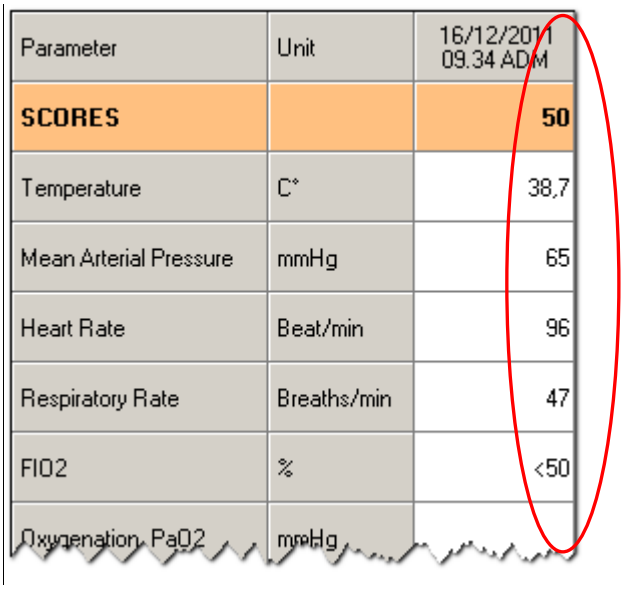


Fig 57 - Display values

The values are this way displayed in the table (Fig 58).



Parameter	Unit	16/12/2011 09.34 ADM
SCORES		**50**
Temperature	C°	38,7
Mean Arterial Pressure	mmHg	65
Heart Rate	Beat/min	96
Respiratory Rate	Breaths/min	47
FIO2	%	<50
Oxygenation PaO2	mmHg	

Fig 58 - Values

7.7.1. Notes

The "Notes" area, indicated in Fig 52 **C** and Fig 59 **B**, displays the possible notes associated to a single score calculation. The note is displayed only when the column corresponding to the specific score calculation is selected.

To select a column,

- Click the column itself.

The column is highlighted (Fig 59 **A**).

If there is a note associated to that score calculation, the note is displayed in the "Notes" area (Fig 59 **B**).

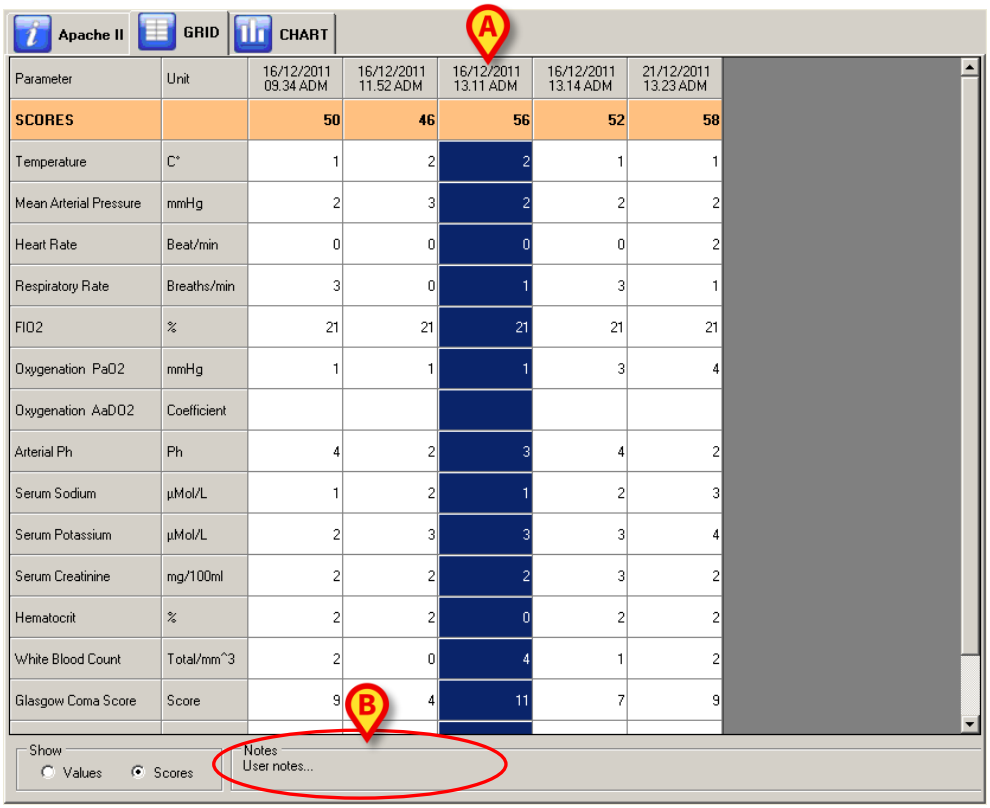


Fig 59

7.8. How to calculate a new score

To calculate a new score and to insert the corresponding values in the table

- select, on the list on the left, the Standard Severity Score to be used (Fig 51).
- Click the **New** button on the command bar (Fig 60).

Fig 60 - Command bar

A window opens, making it possible to specify the values of all the parameters that are relevant for the selected score.

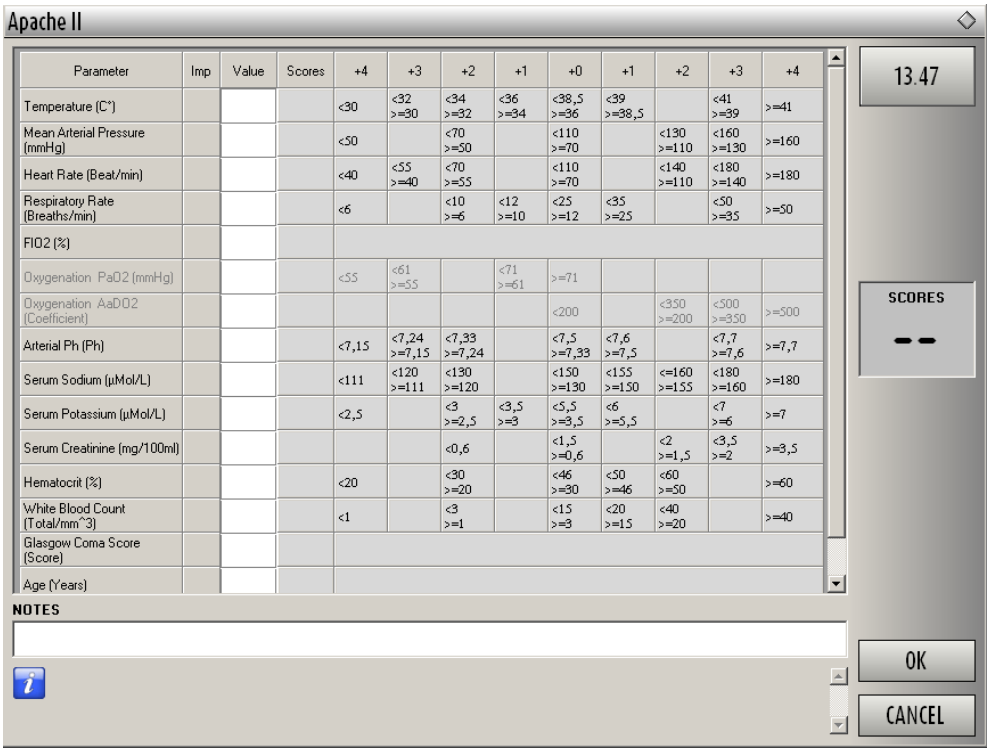


Fig 61 - Data entry window ("Apache II" system)

Each score has its own parameters and points attribution criteria. Therefore the data entry window changes according to the selected scoring system. This paragraph describes, as example, the window relating to the "Apache II" system.
The data entry procedures remain the same for all the available scores.

- Insert the values and /or the points in the window (Fig 62 **A**).

When all the parameters are specified the total value is displayed in the box indicated in

The total value is calculated only if all the parameters are specified.

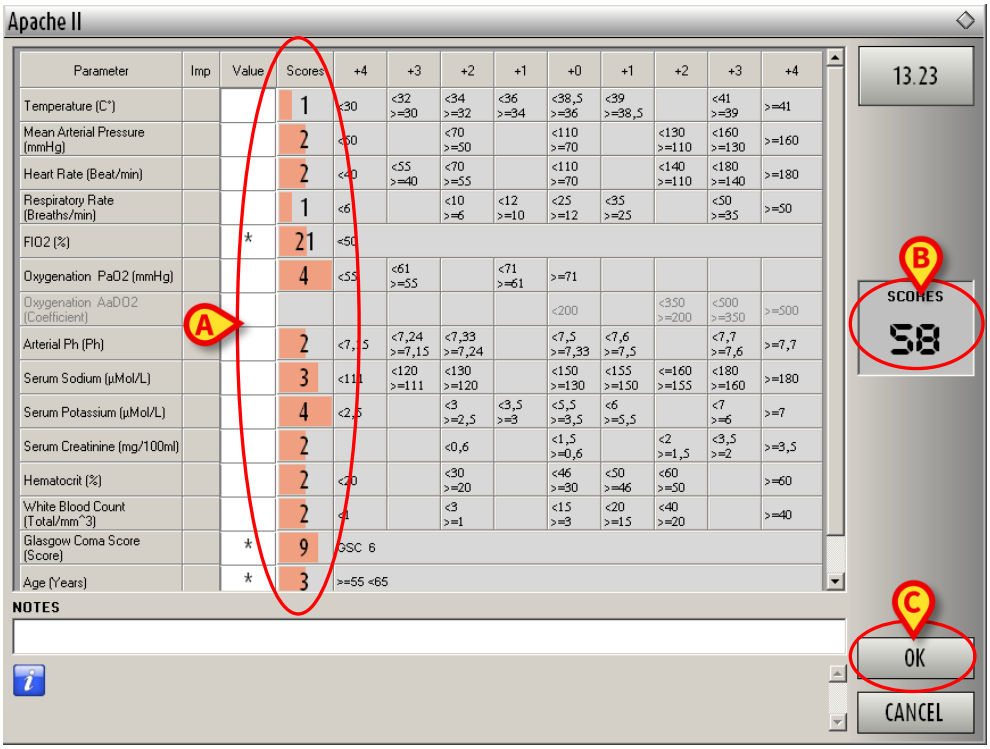
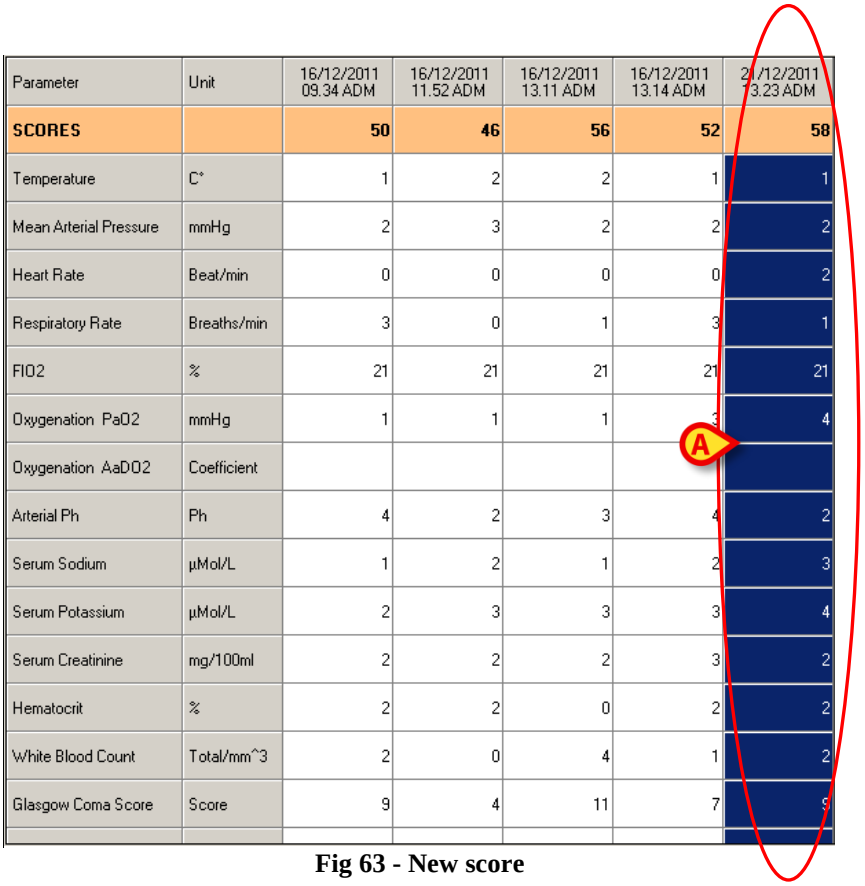


Fig 62 - Specified scores and values

- Click the **Ok** button (Fig 62 **B**).

A new column is this way added to the score's table. The new column displays the new set of values (Fig 63).

The data entry window and the data entry procedures are described in paragrpahs 7.8.1 and 7.8.2.



Parameter	Unit	16/12/2011 09.34 ADM	16/12/2011 11.52 ADM	16/12/2011 13.11 ADM	16/12/2011 13.14 ADM	21/12/2011 13.23 ADM
SCORES		**50**	**46**	**56**	**52**	**58**
Temperature	C°	1	2	2	1	1
Mean Arterial Pressure	mmHg	2	3	2	2	2
Heart Rate	Beat/min	0	0	0	0	2
Respiratory Rate	Breaths/min	3	0	1	3	1
FIO2	%	21	21	21	21	21
Oxygenation PaO2	mmHg	1	1	1	3	4
Oxygenation AaDO2	Coefficient					
Arterial Ph	Ph	4	2	3	4	2
Serum Sodium	µMol/L	1	2	1	2	3
Serum Potassium	µMol/L	2	3	3	3	4
Serum Creatinine	mg/100ml	2	2	2	3	2
Hematocrit	%	2	2	0	2	2
White Blood Count	Total/mm^3	2	0	4	1	2
Glasgow Coma Score	Score	9	4	11	7	9

Fig 63 - New score

Select the “Values” option on the bottom-left corner to display on the table the actual values of the parameters (Fig 64, Fig 52 **B**) instead of the score’s points.

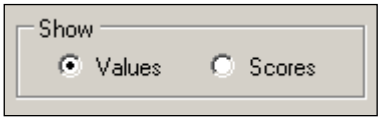


Fig 64 - Display values

7.8.1. Data entry window description

The data entry window (an example is shown in Fig 65), offers several tools to specify the relevant values and to calculate the corresponding scores.

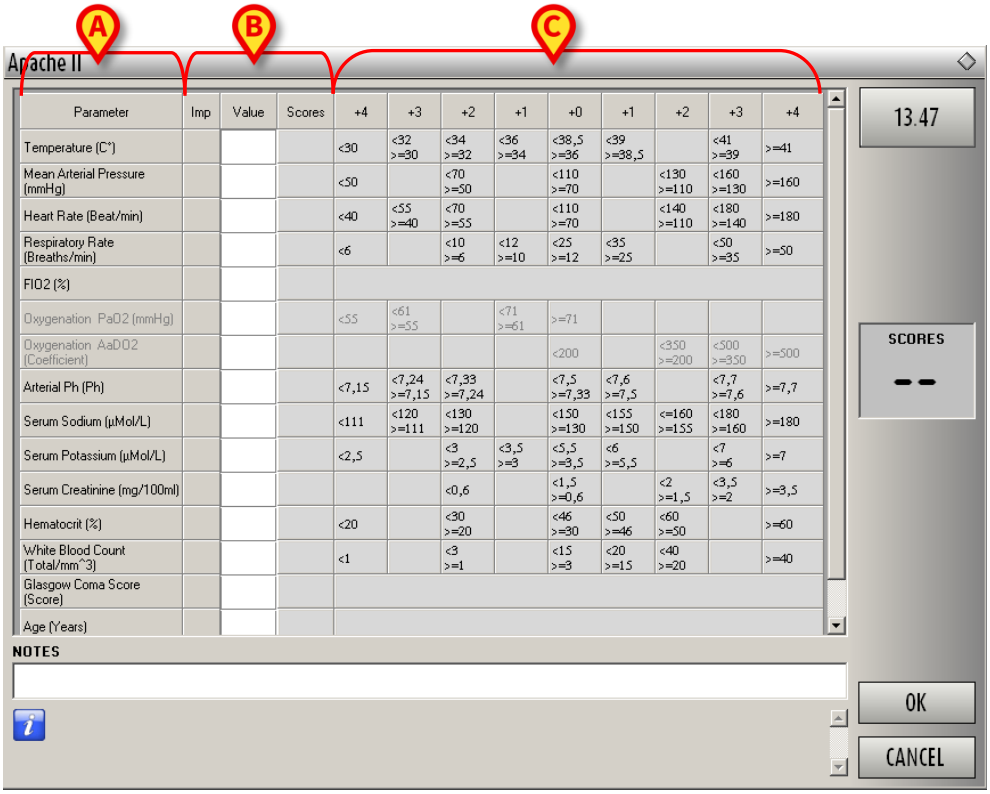


Fig 65 - Data entry window ("Apache II" system)

All the parameters, with their unit of measure, are listed on the left (Fig 65 **A**, Fig 66).

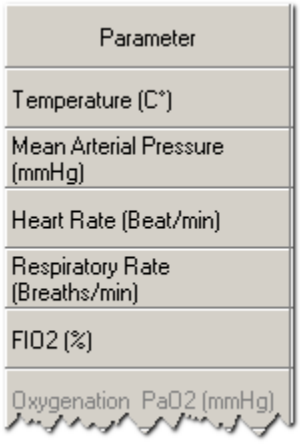


Fig 66 - Parameters list

The three successive columns (Fig 65 **B**, Fig 67),

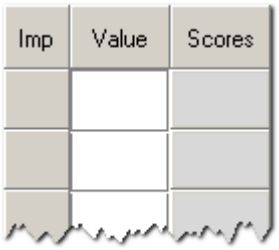


Fig 67 - Import, value and scores

display the following information:

1) the "Imp" column can display, if enabled by configuration, a button making it possible to automatically import the results of a query associated to the parameter. When this is the case a button is displayed inside the cell, as in Fig 68. Click the button to specify the score.

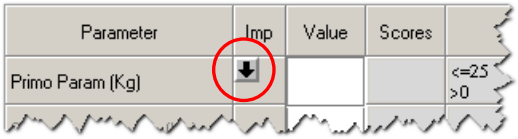


Fig 68

2) the "Value" column makes it possible to specify the parameter's value;
3) the "Scores" column displays the score (points) relating to the value specified for the corresponding parameter.

The rectangles on the central part of the window (Fig 65 **C**, Fig 69) are both scores specification buttons and reference guides indicating the value-points relationship.

+4	+3	+2	+1	+0	+1	+2	+3	+4
<30	<32 >=30	<34 >=32	<36 >=34	<38,5 >=36	<39 >=38,5		<41 >=39	>=41
<50		<70 >=50		<110 >=70		<130 >=110	<160 >=130	>=160
<40	<55 >=40	<70 >=55		<110 >=70		<140 >=110	<180 >=140	>=180
<6		<10 >=6	<12 >=10	<25 >=12	<35 >=25		<50 >=35	>=50

Fig 69 - Values and scores table

Each rectangle is in fact a button. Click the rectangle to insert the score corresponding to the interval specified in the rectangle itself. The first rectangle on the top left corner, for instance, indicates a temperature that is below 30 degrees and corresponds to a score of +4 points. Click the rectangle to add 4 points to the "Scores" column (Fig 70).

Fig 70

7.8.2. Data entry procedures

To specify a value on the data entry window

- click the “Value” column on the row corresponding to the wanted parameter (Fig 71 **A**).

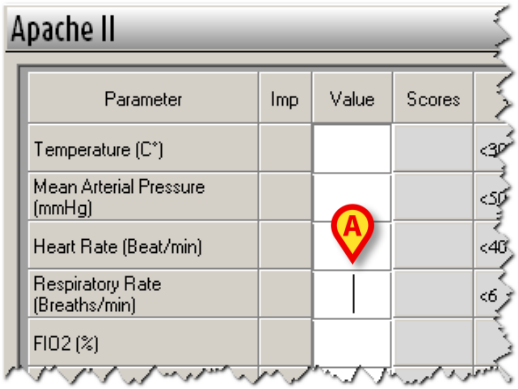


Fig 71

A cursor appears in the cell (as in Fig 71).

- Type the wanted value.

The corresponding score is automatically displayed on the adjacent “Score” cell (Fig 72).

Parameter	Imp	Value	Scores	+4	+3	+2	+1	+0	+1	+2	+3	+4
Temperature (C°)				<30	<32 >=30	<34 >=32	<36 >=34	<38,5 >=36	<39 >=38,5		<41 >=39	>=41
Mean Arterial Pressure (mmHg)				<50		<70 >=50		<110 >=70		<130 >=110	<160 >=130	>=160
Heart Rate (Beat/min)		65	2	<40	<55 >=40	<70 >=55		<110 >=70		<140 >=110	<180 >=140	>=180
Respiratory Rate (Breaths/min)				<6		<10 >=6	<12 >=10	<25 >=12	<35 >=25		<50 >=35	>=50

A

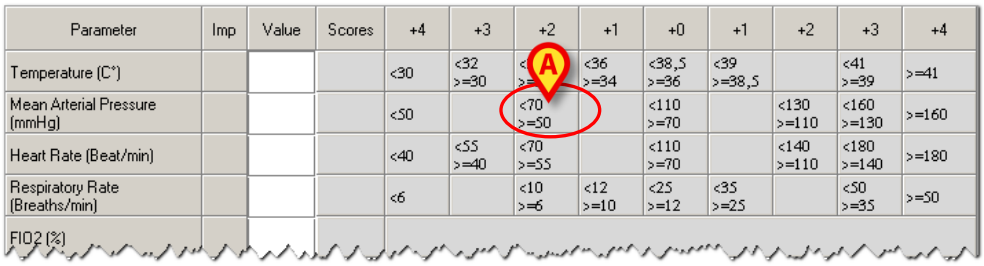
Fig 72 - Value specified

It is also possible to specify the score directly, without entering the exact parameter value. There are two methods to do that:

First method

- Click the button indicating the interval corresponding to wanted score.

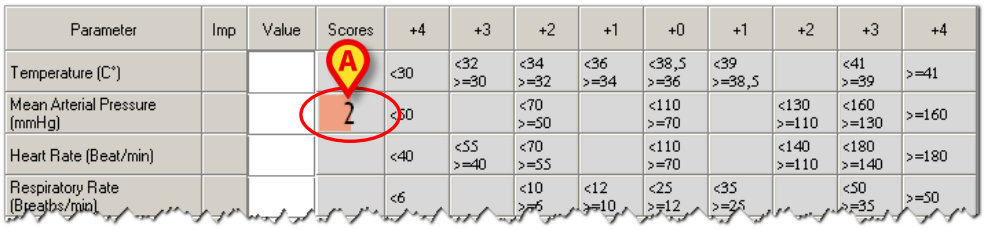
If, for instance, the button shown in Fig 73, indicating a Mean Arterial Pressure comprised between 50 and 70 mmHg, and corresponding to a +2 value is clicked,



Parameter	Imp	Value	Scores	+4	+3	+2	+1	+0	+1	+2	+3	+4
Temperature (C°)				<30	<32 >=30	<34 >=32	<36 >=34	<38,5 >=36	<39 >=38,5		<41 >=39	>=41
Mean Arterial Pressure (mmHg)				<50		<70 >=50		<110 >=70		<130 >=110	<160 >=130	>=160
Heart Rate (Beat/min)				<40	<55 >=40	<70 >=55		<110 >=70		<140 >=110	<180 >=140	>=180
Respiratory Rate (Breaths/min)				<6		<10 >=6	<12 >=10	<25 >=12	<35 >=25		<50 >=35	>=50
FIO2 (%)												

Fig 73

the score 2 for the Mean Arterial Pressure is automatically inserted in the "Scores" column (Fig 74).

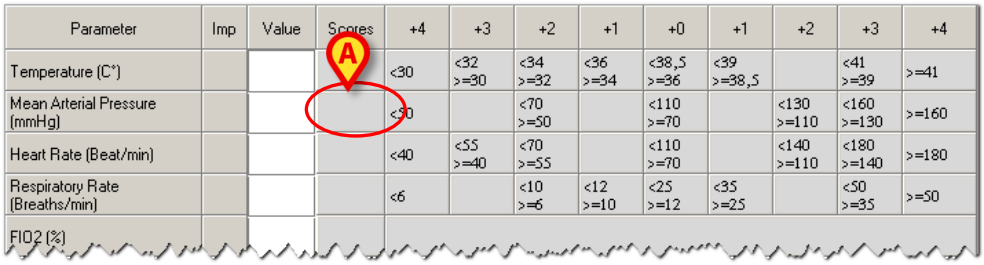


Parameter	Imp	Value	Scores	+4	+3	+2	+1	+0	+1	+2	+3	+4
Temperature (C°)				<30	<32 >=30	<34 >=32	<36 >=34	<38,5 >=36	<39 >=38,5		<41 >=39	>=41
Mean Arterial Pressure (mmHg)			2	<50		<70 >=50		<110 >=70		<130 >=110	<160 >=130	>=160
Heart Rate (Beat/min)				<40	<55 >=40	<70 >=55		<110 >=70		<140 >=110	<180 >=140	>=180
Respiratory Rate (Breaths/min)				<6		<10 >=6	<12 >=10	<25 >=12	<35 >=25		<50 >=35	>=50

Fig 74

Second method

- Click the "Scores" cell corresponding to the parameter to be specified (Fig 75).



Parameter	Imp	Value	Scores	+4	+3	+2	+1	+0	+1	+2	+3	+4
Temperature (C°)				<30	<32 >=30	<34 >=32	<36 >=34	<38,5 >=36	<39 >=38,5		<41 >=39	>=41
Mean Arterial Pressure (mmHg)				<50		<70 >=50		<110 >=70		<130 >=110	<160 >=130	>=160
Heart Rate (Beat/min)				<40	<55 >=40	<70 >=55		<110 >=70		<140 >=110	<180 >=140	>=180
Respiratory Rate (Breaths/min)				<6		<10 >=6	<12 >=10	<25 >=12	<35 >=25		<50 >=35	>=50
FIO2 (%)												

Fig 75

A window referring to the parameter to be specified appears, displaying the possible scores and their corresponding values (Fig 76).

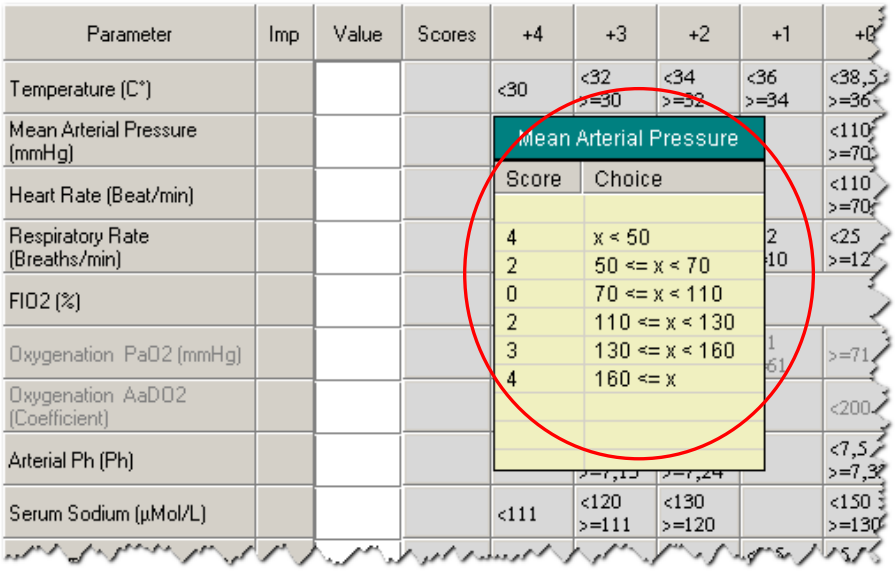


Fig 76

- Click the line corresponding to the wanted score. For instance: the line indicated in Fig 77 (Mean Arterial Pressure between 50 and 70 mmHg) corresponds to a +2 score.

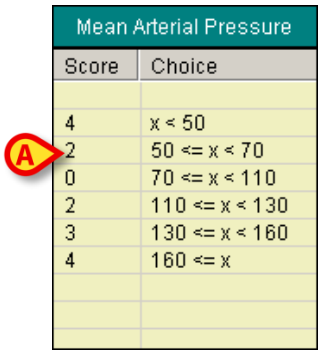


Fig 77

The score “2” is this way inserted in the appropriate cell (Fig 78).

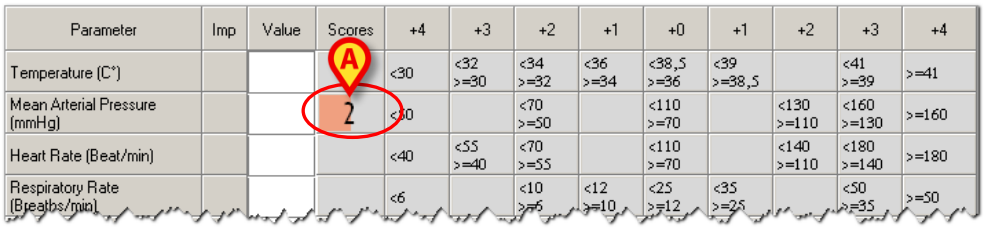


Fig 78

The box indicated in Fig 79 displays the total score.

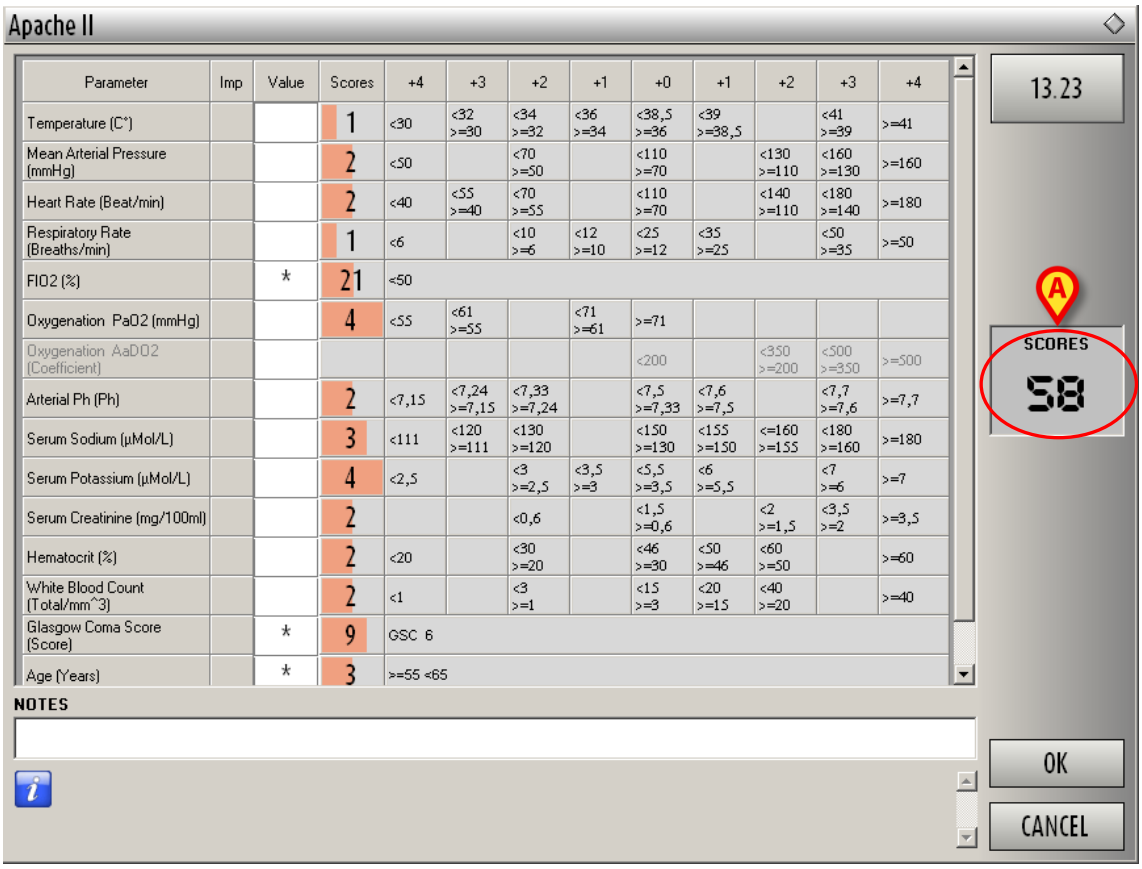


Fig 79

Totals are only displayed when <u>all</u> the parameters are specified.

7.9. Second score formula

A configuration option makes it possible to specify two formulas for the same score. For example: a "main" formula can be specified to calculate the score total value while a "second" formula can be specified to calculate another meaningful value (a value indicating the "mortality rate", for instance).

In these cases the module's interface slightly changes to display both values at the same time. See for an instance Fig 80, displaying the data entry window referring to a sample configuration.

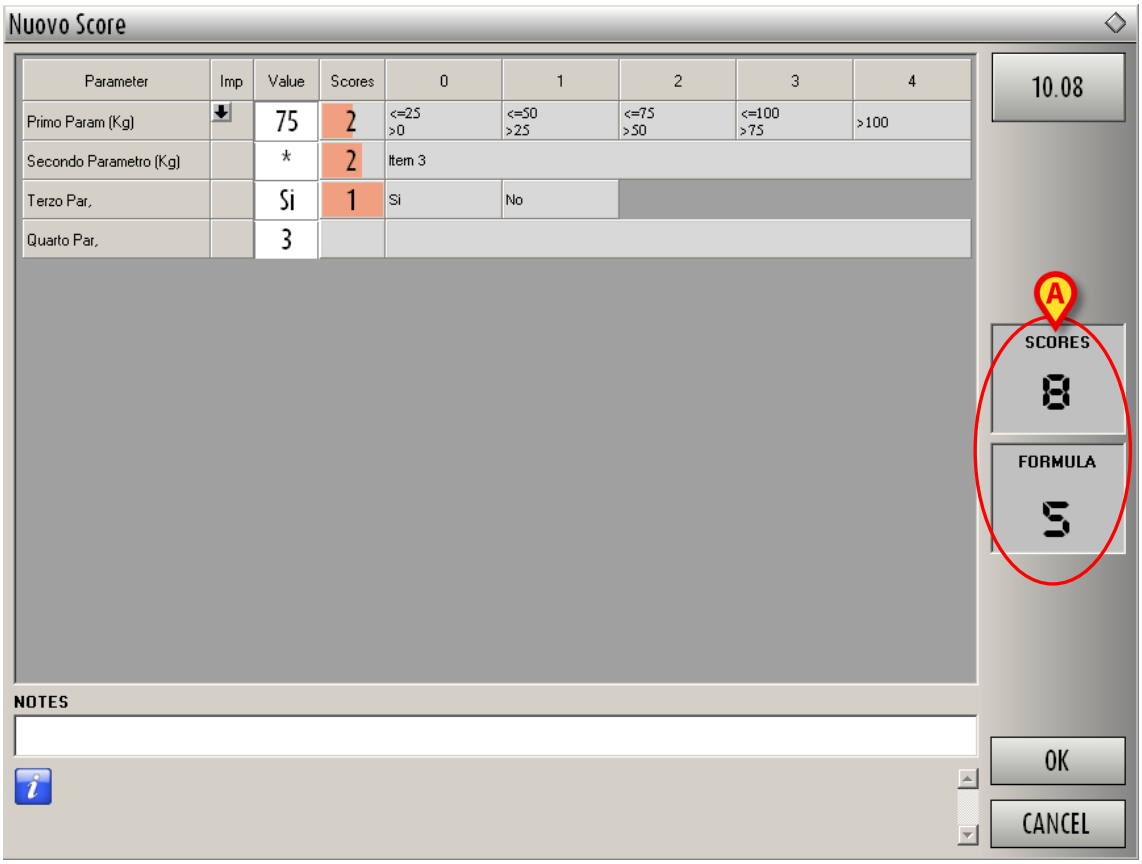


Fig 80

In Fig 80 **A** both scores are indicated: the one calculated by the "main" formula (value = 8) and the one calculated by the "secondary" formula (value = 5).

Both values are then displayed on the "Scores" grid on the module's main screen (Fig 81 **A**).

Parameter	Unit	21/12/2011 09.55 ADM	23/12/2011 10.08 ADM
SCORES		**7 [5]**	**8 [5]**
Primo Param	Kg	1	2
Secondo Parametro	Kg		2
Terzo Par,		1	1
Quarto Par,		5	3

Fig 81

7.9.1. Contextual information on the parameters

The data entry window (Fig 82) can provide information on the relevant parameters.

The existing information (specified by configuration) is displayed on the bottom of the window every time the user clicks the cell displaying the parameter name. See for an instance Fig 82, in which the FIO2 parameter was clicked.

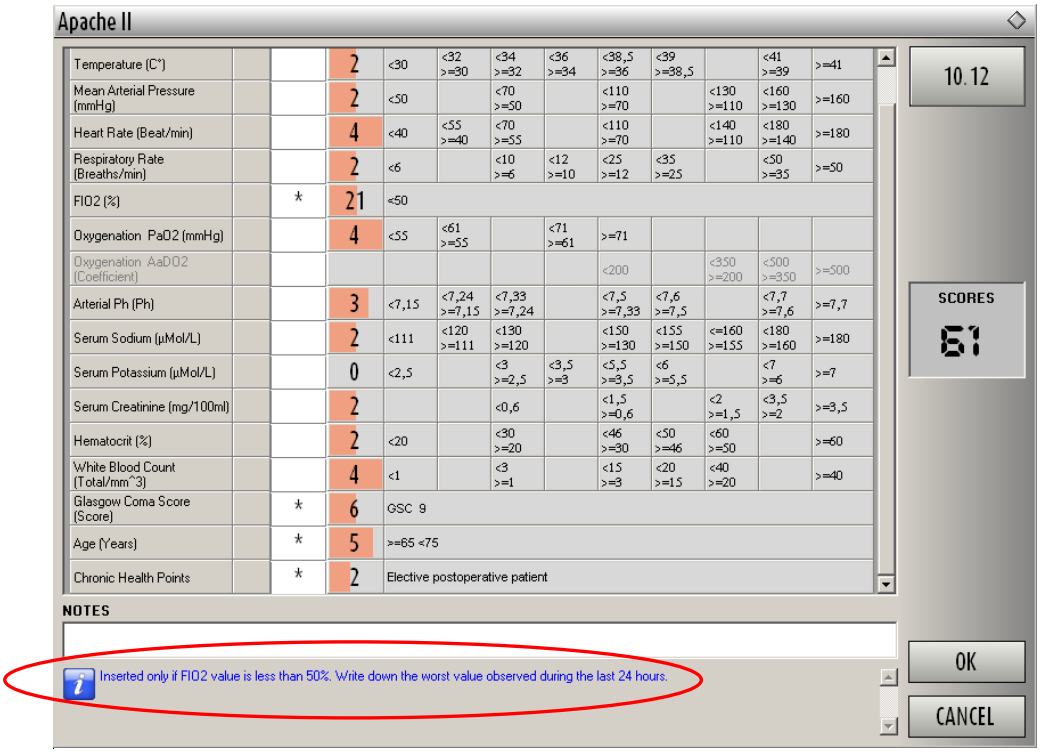
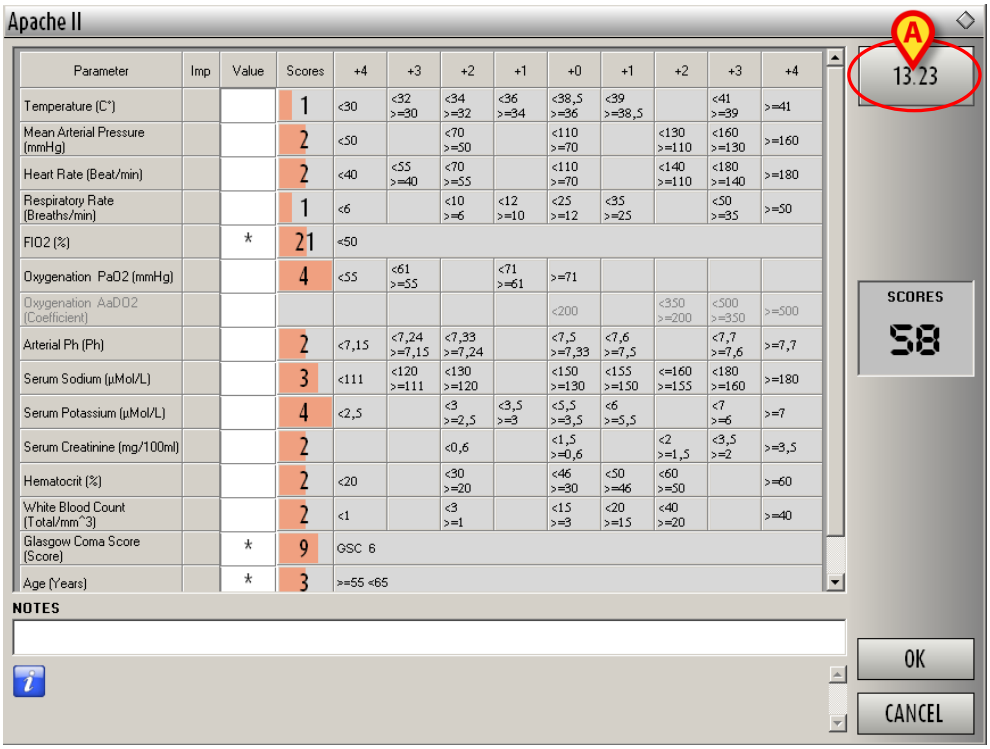


Fig 82 - Parameter information

7.9.2. Time settings

The box indicated in Fig 83 displays the time associated to the score specification. Also the date is displayed if it is different from the current date.



Parameter	Imp	Value	Scores	+4	+3	+2	+1	+0	+1	+2	+3	+4
Temperature (C°)			1	<30	<32 >=30	<34 >=32	<36 >=34	<38,5 >=36	<39 >=38,5		<41 >=39	>=41
Mean Arterial Pressure (mmHg)			2	<50		<70 >=50		<110 >=70		<130 >=110	<160 >=130	>=160
Heart Rate (Beat/min)			2	<40	<55 >=40	<70 >=55		<110 >=70		<140 >=110	<180 >=140	>=180
Respiratory Rate (Breaths/min)			1	<6		<10 >=6	<12 >=10	<25 >=12	<35 >=25		<50 >=35	>=50
FIO2 (%)		*	21	<50								
Oxygenation PaO2 (mmHg)			4	<55	<61 >=55		<71 >=61	>=71				
Oxygenation AaDO2 (Coefficient)								<200		<350 >=200	<500 >=350	>=500
Arterial Ph (Ph)			2	<7,15	<7,24 >=7,15	<7,33 >=7,24		<7,5 >=7,33	<7,6 >=7,5		<7,7 >=7,6	>=7,7
Serum Sodium (µMol/L)			3	<111	<120 >=111	<130 >=120		<150 >=130	<155 >=150	<=160 >=155	<180 >=160	>=180
Serum Potassium (µMol/L)			4	<2,5		<3 >=2,5	<3,5 >=3	<5,5 >=3,5	<6 >=5,5		<7 >=6	>=7
Serum Creatinine (mg/100ml)			2			<0,6		<1,5 >=0,6		<2 >=1,5	<3,5 >=2	>=3,5
Hematocrit (%)			2	<20		<30 >=20		<46 >=30	<50 >=46	<60 >=50		>=60
White Blood Count (Total/mm^3)			2	<1		<3 >=1		<15 >=3	<20 >=15	<40 >=20		>=40
Glasgow Coma Score (Score)		*	9	GSC 6								
Age (Years)		*	3	>=55 <65								

Fig 83 - Time specification

The time displayed in this box is the time displayed on the scores table in the first cell of the specific column (Fig 84).

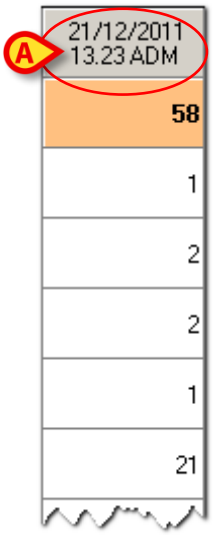


Fig 84

Current time is set by default. The user can set a different time, preceding current time.

To set the time

- click the box displaying the time (Fig 83). The following buttons are displayed (Fig 85).

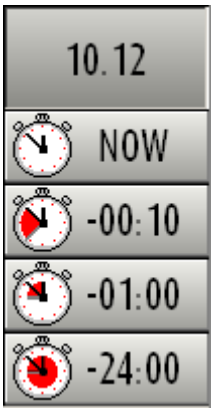


Fig 85

Use the **-00:10** button to set the time ten minutes back (ten minutes per click).
Use the **-01:00** button to set the time one hour back (one hour per click).
Use the **-24:00** button to set the time twenty-four hours back (twenty-four hours per click).
Use the **Now** button to set the current time again.

7.10. The command bar

The command bar contains various buttons (Fig 86, Fig 50 **C**). Each button makes it possible to perform a specific procedure. The different functions are here listed and briefly described. They are explained in detail in the paragraphs indicated.

Fig 86 - Command Bar

Use this button to add a new score. The button opens a data entry window. The data entry window is described in paragraph 7.8.1, the related procedures are described in paragraph 7.8.2.

Use this button to modify the values of a selected score. See paragraph 7.10.1 for the detailed procedure.

Use this button to delete a selected score. See paragraph 7.10.2 for the detailed procedure.

Use this button to create a print report. See paragraph 7.10.3 for the module's print functionalities.

Use this button to add a patient note. See paragraph 7.10.4 for the procedure.

7.10.1. How to edit an existing score

To edit the values of an existing score

- click the corresponding column on the scores table.

The column is this way highlighted (Fig 87 **A**).

Parameter	Unit	16/12/2011 09.34 ADM	16/12/2011 11.52 ADM	16/12/2011 13.11 ADM	16/12/2011 13.14 ADM	21/12/2011 13.23 ADM
SCORES		**50**	**46**	**56**	**52**	**58**
Temperature	C°	1	2	2	1	1
Mean Arterial Pressure	mmHg	2	3	2	2	2
Heart Rate	Beat/min	0	0	0	0	2
Respiratory Rate	Breaths/min	3	0	1	3	1
FIO2	%	21	21	21	21	21
Oxygenation PaO2	mmHg	1	1	1	3	4
Oxygenation AaDO2	Coefficient					
Arterial Ph	Ph	4	2	3	4	2
Serum Sodium	µMol/L	1	2	1	2	3
Serum Potassium	µMol/L	2	3	3	3	4
Serum Creatinine	mg/100ml	2	2	2	3	2
Hematocrit	%	2	2	0	2	2
White Blood Count	Total/mm^3	2	0	4	1	2
Glasgow Coma Score	Score	9	4	11	7	9

Fig 87 - Scores table

- Click the **Edit** button on the command bar (Fig 88).

Fig 88 - Command bar

The corresponding data entry window is displayed (Fig 89).

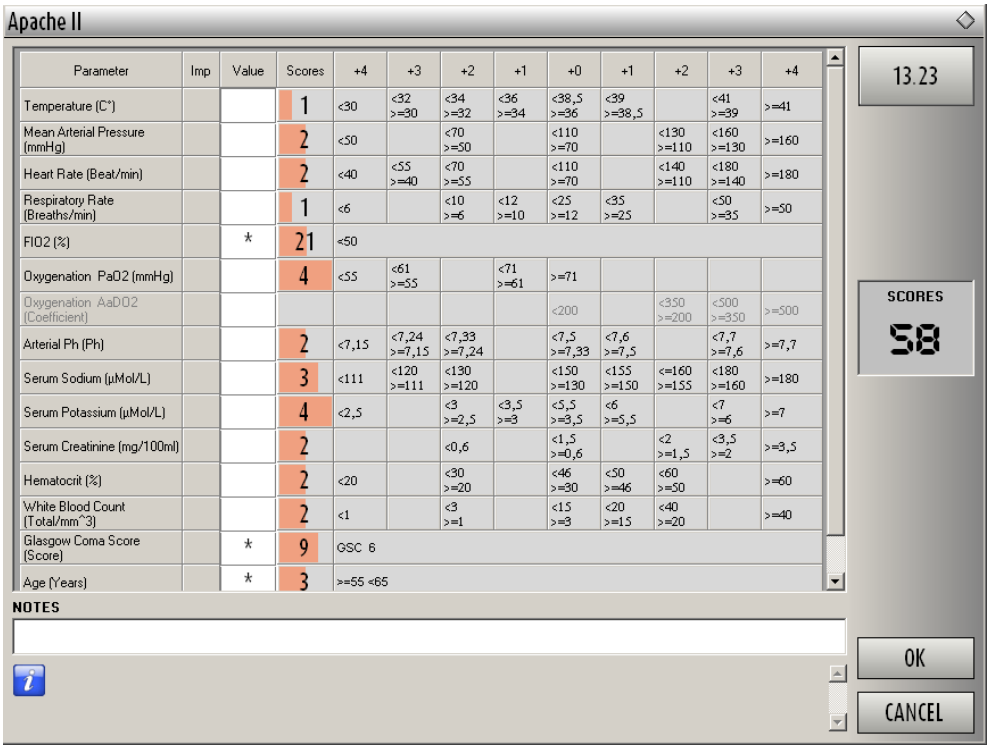


Fig 89 - Data entry window

- Edit the values on the window (see paragraphs 7.8.1 and 7.8.2 for the specific procedure).
- Click the **Ok** button.

The score values are this way changed.

The data entry window can also be displayed by double-clicking the corresponding column.

7.10.2. How to delete a score

To delete one of the scores on the table

- click the corresponding column on the scores table.

The column is highlighted (Fig 90).

Parameter	Unit	16/12/2011 09.34 ADM	16/12/2011 11.52 ADM	16/12/2011 13.11 ADM	16/12/2011 13.14 ADM	21/12/2011 13.23 ADM
SCORES		**50**	**46**	**56**	**52**	**58**
Temperature	C°	1	2	2	1	1
Mean Arterial Pressure	mmHg	2	3	2	2	2
Heart Rate	Beat/min	0	0	0	0	2
Respiratory Rate	Breaths/min	3	0	1	3	1
FIO2	%	21	21	21	21	21
Oxygenation PaO2	mmHg	1	1	1	3	4
Oxygenation AaDO2	Coefficient					
Arterial Ph	Ph	4	2	3	4	2
Serum Sodium	µMol/L	1	2	1	2	3
Serum Potassium	µMol/L	2	3	3	3	4
Serum Creatinine	mg/100ml	2	2	2	3	2
Hematocrit	%	2	2	0	2	2
White Blood Count	Total/mm^3	2	0	4	1	2
Glasgow Coma Score	Score	9	4	11	7	9

Fig 90 - Scores table

- Click the **Delete** button on the command bar (Fig 91).

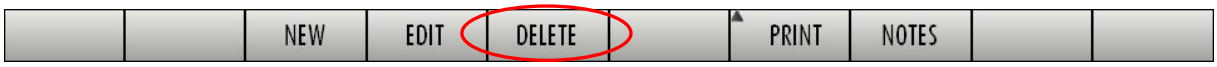


Fig 91 - Command bar

User confirmation is required (Fig 92).

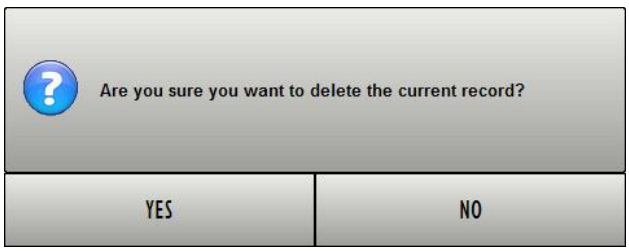


Fig 92

- Click **Yes** to proceed. The selected column disappears from the table.

7.10.3. Print reports

To access the “Scoring Calculator” module print functionalities

- click the **Print** button on the command bar (Fig 93).

Fig 93 - Command bar

Different print options can be configured. In the example shown in Fig 94 a user can print either the values chart or the values grid.

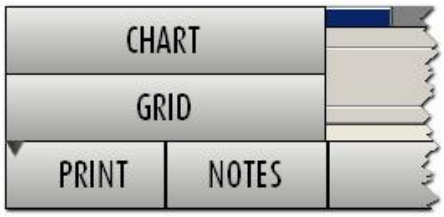


Fig 94

- Click the wanted option.

A print preview is displayed. The system’s print functionalities are described in paragraph 6.8.1.

7.10.4. How to add a patient note

The **Notes** button on the command bar (Fig 95 **A**) makes it possibile to add notes relating to the patient.

Fig 95 - Command bar

To add a patient note

- click the **Notes** button.

The following window opens.

Fig 96 - "Notes" window

- Click the **Edit** button (Fig 96 **A**).

The window changes and turns to "edit" mode.

Fig 97 - "Notes" window (edit mode)

- Type the note. The text is displayed in the window.
- Click the **Save** button to save the note (Fig 97 **A**).

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

Use the **Time Stamp** button on the right (Fig 97 **B**) to display the date, time and the acronym of the user who is adding the note (Fig 98).

Fig 98 - Date and time

Use the **Cut** button (Fig 97 **C**) to cut a selected text portion from the note.

To cut a text portion from a note

- click the **Edit** button (Fig 96 **A**).

- Select the text to be cut using either the mouse device or the workstation keyboard.
- Click the Cut button.

The selected text disappears from the note.

The notes inserted this way are visible - after clicking the **Notes** *button on the command bar - on every DIGISTAT® module currently in use implementing the* **Notes** *button.*

7.11. Charts

The patient scores can be displayed in charts.

To do that

- click the “Chart” tab indicated in Fig 99 **A**.

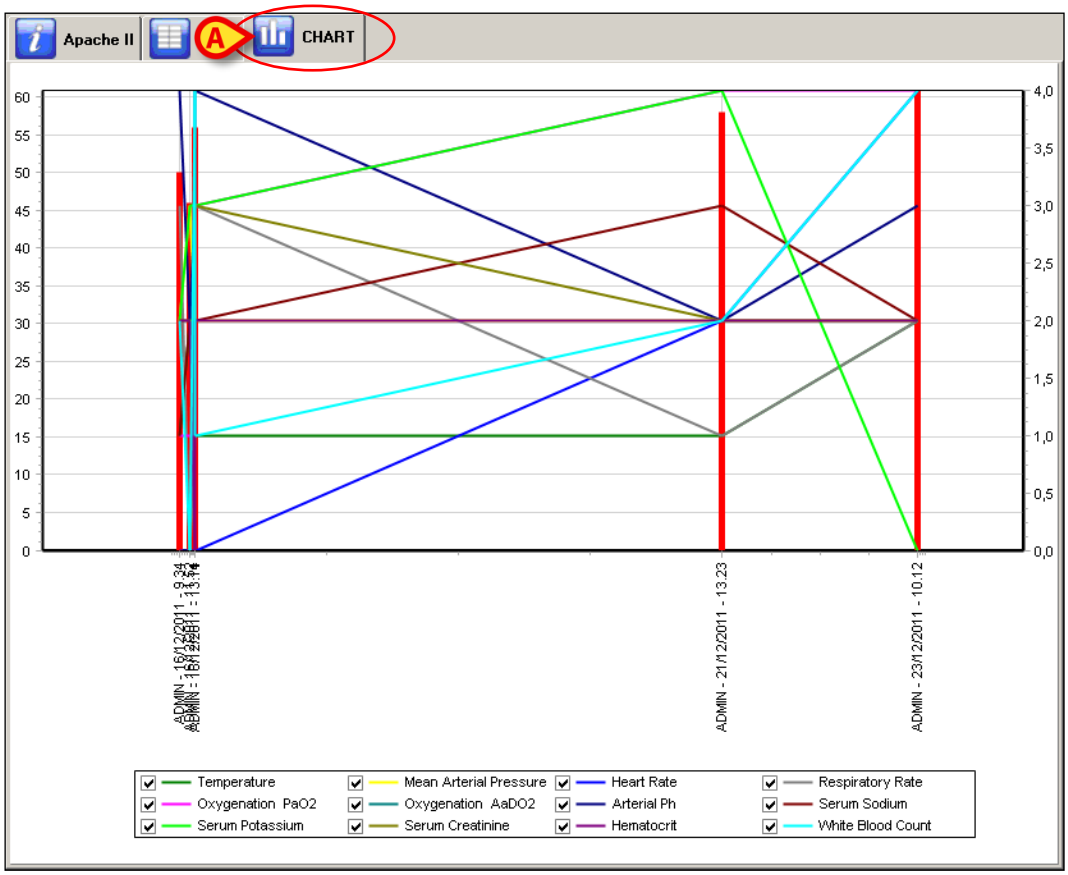


Fig 99 - Grafico

The chart shown in Fig 99 displays the trends of each parameter.

7.12. Scores on-line guide

An on-line user guide is available for each score.

To access the guide

- click the tab indicated in Fig 100 **A**.

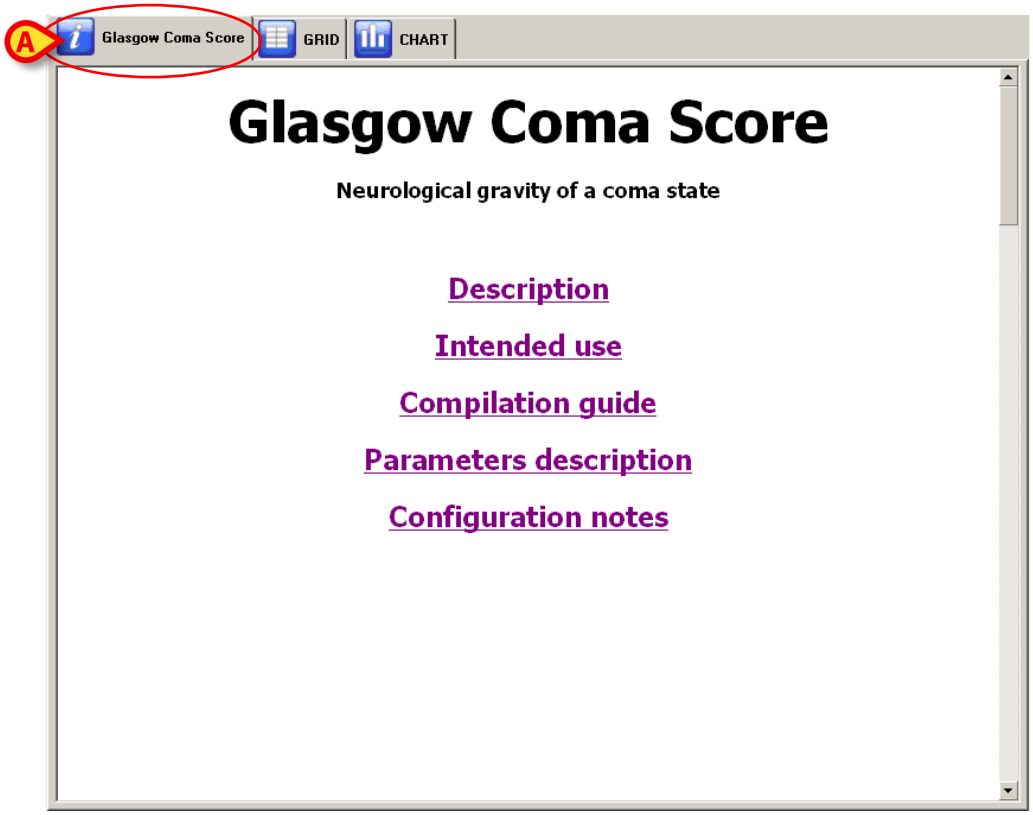


Fig 100 - On line guide

The on line guide of the scoring system currently selected opens (Fig 100).

8. 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

9. 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.

Appendix: end-user license agreement

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

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

IMPORTANT—READ CAREFULLY. This Ascom UMS End-User License Agreement (hereafter "EULA") is a contract between the User (either a natural or corporate person) and the Firm Ascom UMS S.r.l. (hereafter "Ascom UMS") for the "DIGISTAT®" System produced by Ascom UMS.

The product "DIGISTAT®" (also "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 EULA. If the User does not agree to the terms and conditions of this EULA, 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 EULA 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 the licensed number of computers, workstations, terminals, palmtop computers, pagers, smartphones or other electronic digital devices ("COMPUTERS").

   - **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. 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 retains all rights not expressly granted in this EULA.

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, to redistribute or to use them as development components.
     Only exception to this rule is the font UMSCondensed distributed under the Ubuntu Font license agreement (accessible at http://font.ubuntu.com/ufl/).

   - **Trademarks.** This EULA 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.

   - **Export Laws**. The User acknowledges that the license of the PRODUCT is subject to the export control laws, restrictions and regulations and any amendments thereof of Italy, United States of America, Panama and UK, which restrict exports and re-exports of software, technical data, and direct products of technical data, including services and developed software. These restrictions include, but are not limited to: restricted countries, restricted end-users, and restricted end-uses.
     The User agrees that he/she will not export or re-export the PRODUCT, any part thereof, or any process or service that is the direct product of the PRODUCT, to any country, person, entity, or end user subject to export restrictions by one or more of the listed countries.

   - **Technical Assistance Service.** Ascom UMS and/or the distributor 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 and/or distributor 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 EULA. Concerning technical information the User may give to Ascom UMS or to the distributor 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 EULA 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 EULA. 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 beyond the scope of the software license.

4. **COPYRIGHT.** PRODUCT rights and copyright (including, but not limited to, 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 EULA 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 EULA, the User may preserve the original media on which Ascom UMS supplied him the PRODUCT only for backup or storage purposes. If the User needs the original media to use the PRODUCT, he/she may create only one copy of the PRODUCT for backup or storage purposes. Except for this EULA's express specifications, the User may not run copies of the PRODUCT or of the annexed printed material for other purposes.

LIMITED WARRANTY

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

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

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

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

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

Furthermore, due to the ongoing development of intrusion methods and attacks of networks, Ascom UMS does not guarantee that the PRODUCT or other equipment systems, or the network itself on which the PRODUCT is used, will not be vulnerable to intrusions and attacks.

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

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

used in compliance with PRODUCT user manual, (c) has been subjected to abnormal physical or electronic stress, improper or negligent use or accident, or (d) is granted only for pilot testing, evaluation, testing, demonstration purposes or free of charge, for which Ascom UMS receives no payment as license fee.

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

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

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

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

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

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

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

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

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

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

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

* * * * *

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

Date Signature

SPECIFIC ACCEPTANCE OF CERTAIN PROVISIONS IN THIS EULA

IMPORTANT—READ CAREFULLY

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

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

Date Signature