DIGISTAT® Therapy

DIGISTAT® Version 4.1

User Manual

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SOFTWARE LICENSE

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

WARNING

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

LICENSES AND REGISTERED TRADEMARKS

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

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

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

1. Contents

2. Using the manual

2.1. Aims

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

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

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

To be more precise, the differences may concern

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

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

2.2. Charcters used and terminology

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

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

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

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

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

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

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

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

2.3. Symbols

The following symbols are used in this manual.

Useful information

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

Caution!

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

3. Introduction to DIGISTAT®

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

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

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

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

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

3.1. Modular architecture

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

3.2. Intended use

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

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

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

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

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

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

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

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

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

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

DIGISTAT® is not a "Distribuited Alarm System".

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

3.2.1. Intended users

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

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

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

3.2.2. Intended environment

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

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

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

3.2.3. "Off-label" use of the Product

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

3.3. Manufacturer's responsibility

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

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

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

3.4. Product tracking

In order to ensure device tracking and on-going safety and efficiency checks on site, in compliance with ISO 9001 and EN 13485 quality standards and European law on medical devices 93/42/EEC, amended by the directive 2007/47/EC, the former owner is recommended to inform ASCOM UMS/Distributor about any ownership transfer by giving written notice stating the product, former owner and new owner identification data.
Device data can be found in the product labelling (either paper label provided at installation time or "About box" displayed within the product – see paragraph 6.8.5).
In case of doubts/questions about product labelling and/or product identification please contact ASCOM UMS/Distributor technical assistance (for contacts see paragraph 15).

3.5. Post-market surveillance

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

The device details can be found on its labelling.

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

3.6. Product life

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

3.7. CE mark and regulation conformity

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

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

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

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

4. Software/Hardware specifications

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

4.1. Bedside

4.1.1. Hardware

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

Minimum hardware requirements:

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

4.1.2. Operating System

Supported operating systems:

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

4.2. Central

4.2.1. Hardware

Minimum hardware requirements:

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

4.2.2. Operating System

Supported operating systems:

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

4.3. Server

4.3.1. Hardware

Minimum hardware requirements:

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

4.3.2. Operating System

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

4.3.3. System Software

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

4.4. Firewall and Antivirus

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

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

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

WARNING!

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

WARNING!

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

4.5. Local network features

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

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

ATTENTION!

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

ATTENTION!

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

4.5.1. DIGISTAT® impact on the hospital network

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

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

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

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

Average: 0.8 – 6 Mbit/s

Pitch: 5 – 25 Mbit/s

5. Before starting

5.1. Installation and maintenance warnings

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

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

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

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

5.2. Cleaning

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

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

5.3. Precautions and warnings

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

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

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

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

5.3.1. Electrical safety

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

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

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

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

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

5.3.2. Patient Area

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

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

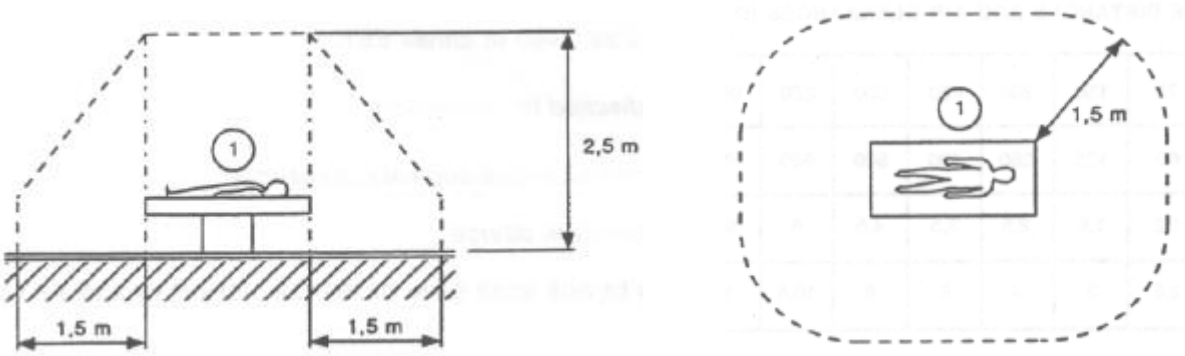


Fig 1

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

WARNING!

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

5.3.3. Electromagnetic compatibility

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

5.3.4. Devices eligibility

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

5.4. Privacy Policy

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

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

Please read the following precautions carefully and strictly observe them.

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

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

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

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

5.4.1. User credentials features and use

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

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

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

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

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

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

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

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

- Password must be at least 8 characters.

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

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

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

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

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

The following information is reserved to system administrators:

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

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

5.4.2. System administrators

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

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

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

5.4.3. System logs

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

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

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

5.5. Back up policy

It is recommended to regularly perform system backups.

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

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

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

5.6. Out-of-order procedure

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

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

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

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

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

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

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

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

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

5.6.1. Reconfiguration/substitution of network equipment

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

5.7. Preventive maintenance

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

This is the maintenence checklist:

Preparatory checks

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

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

- Schedule possible updates with the technical staff

Checks to be performed

Antivirus

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

Database

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

```
USE [DATABASENAME]
GO

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

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

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

EXEC (@INS);

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

DROP TABLE [#SpaceUsed]
```

Server

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

Workstations

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

DIGISTAT®

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

Connection to devices

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

Instruction for use

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

5.8. Compatible devices

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

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

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

Please note that new drivers and new connections are created very often, therefore the list published on the website may sometimes not be complete. It is possibile to make request of the updated list of devices to ASCOM UMS. Please use for this purpose the references (tel, e-mail, fax…) listed in paragraph 15.

5.9. System unavailability

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

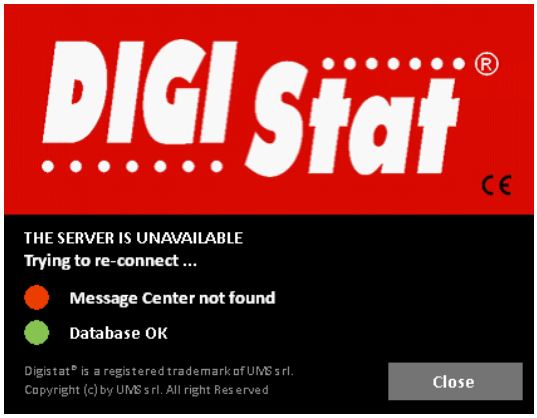


Fig 2

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 15 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 15 for the contacts list.

6. "Control Bar" and DIGISTAT® environment

6.1. Introduction

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

6.2. Touch screen

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

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

6.3. Launching DIGISTAT®

To launch DIGISTAT®,

- double click the desktop icon (Fig 3).

Fig 3

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

Fig 4

6.4. DIGISTAT® Work Area

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

Fig 5 shows Control Bar with no module installed.

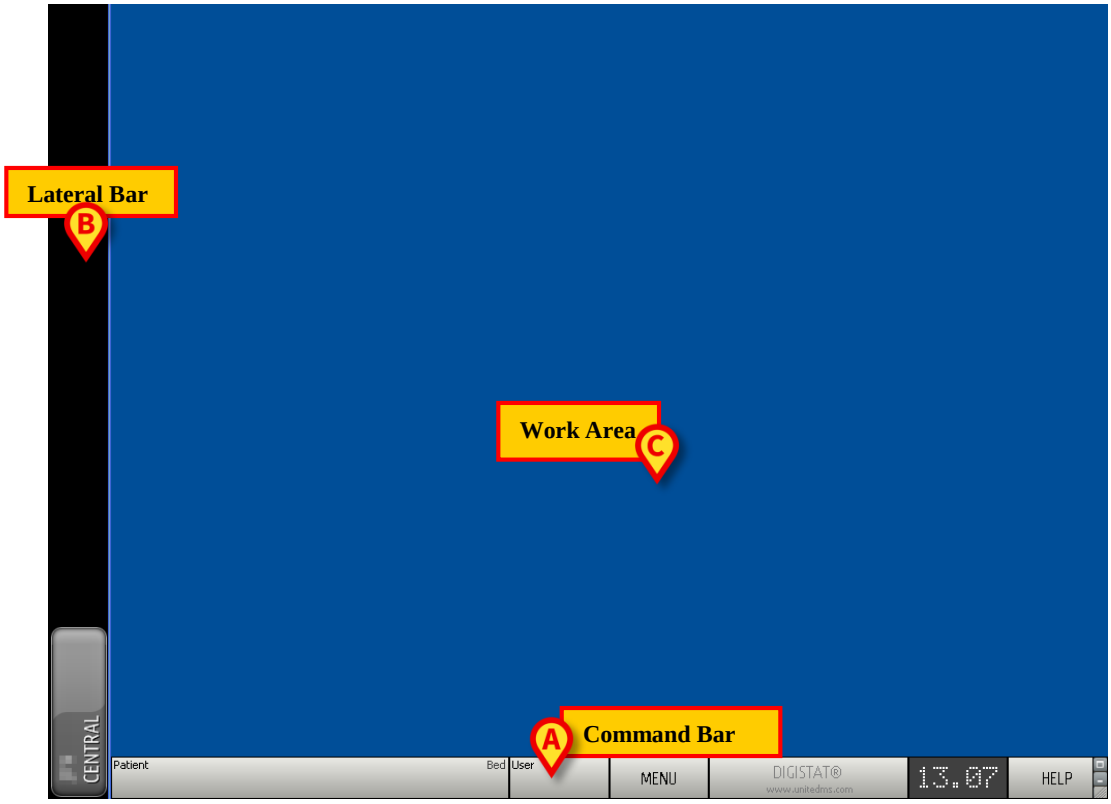


Fig 5

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

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

Fig 6

The module currently selected is highlighted (yellow).

6.4.1. Selecting a module

To select a module

- click the corresponding icon.

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

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

6.5. Accessing the system

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

The following page is displayed.

Fig 7

To access the system,

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

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

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

The username and password are issued by the system administrator. If you do not have a username and a password you are not authorized to use the* DIGISTAT® *system.

You can enter 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 is displayed in red on the control bar (Fig 11).

Fig 11

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

6.5.3. Recent users

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

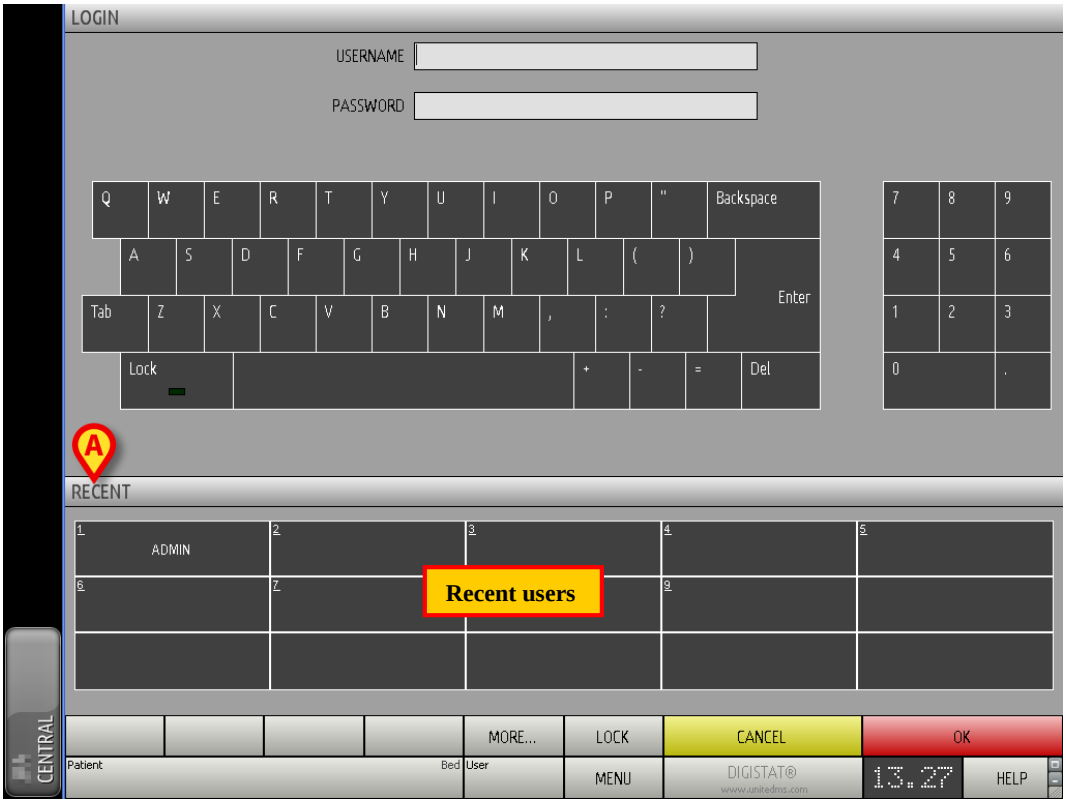


Fig 12

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

6.5.4. How to use the “User List”

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

Fig 13

To display the “User List”,

- click the **More** button.

The following window is displayed (Fig 14).

Fig 14

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

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

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

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

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

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

Otherwise it is possible to

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

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

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

6.6. DIGISTAT® Control Bar

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

Fig 15

- The **Patient** button (Fig 15 **A**) displays, after a patient 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 functionalities accessible from this menu are described later in this manual.

- The button quoting the DIGISTAT® brand name and the ASCOM UMS srl web address (Fig 15 **D**) in some configurations 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 available documentation (user manuals and quick guides).

- The small buttons highlighted in Fig 15 **G** can be used to:

  1. minimize the DIGISTAT® window (button);
  2. select the full screen display mode (button);
  3. select the window display mode (button).

These three buttons are present only if enabled by configuration.

6.6.1. How to read the "Patient" button

Patient selected

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

Fig 17

Patient admitted

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

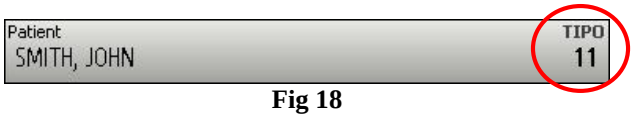


Fig 18

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

Fig 19

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

The signal "Other location" (Fig 20) appears when,

Fig 20

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

Fig 21

See the specific 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.

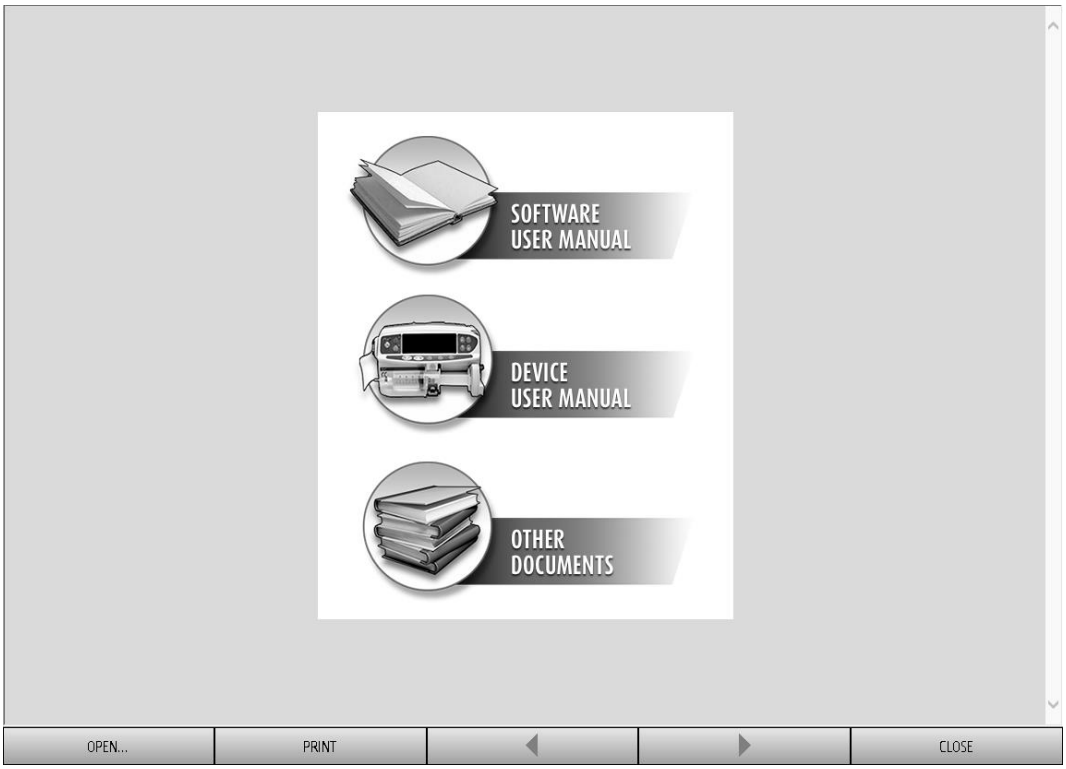


Fig 23

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).

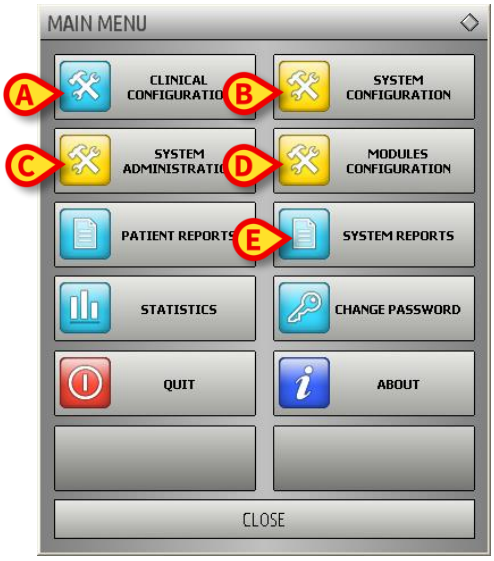


Fig 26

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

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

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

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

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

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

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

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

The other buttons, indicated in Fig 27, make it possible to access functionalities that a user can activate (according to his/her permission level). These are described later on in this manual in the paragraphs indicated below.

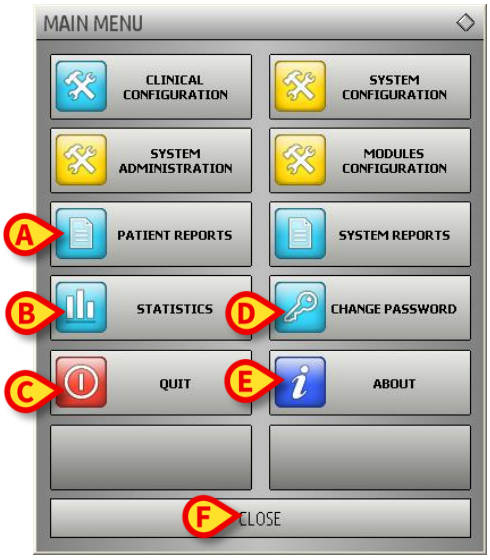


Fig 27

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

To print a patient report

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

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

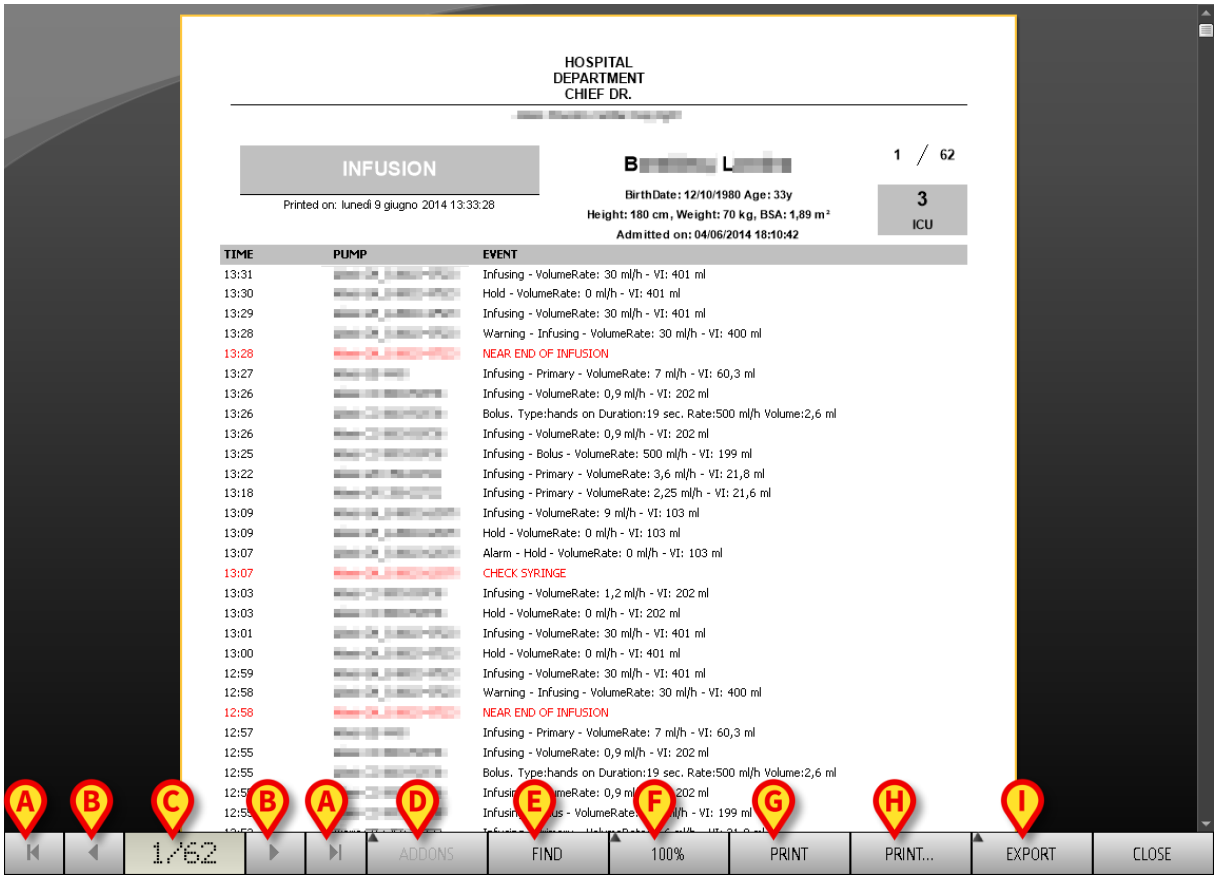


Fig 29

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

A - Use the  and  buttons (Fig 29 **A**) to 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 this option).

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

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

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

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

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

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

6.8.2.1. Addons

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

To display the available options,

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

Addons - Watermark

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

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

The following window is displayed (Fig 30).

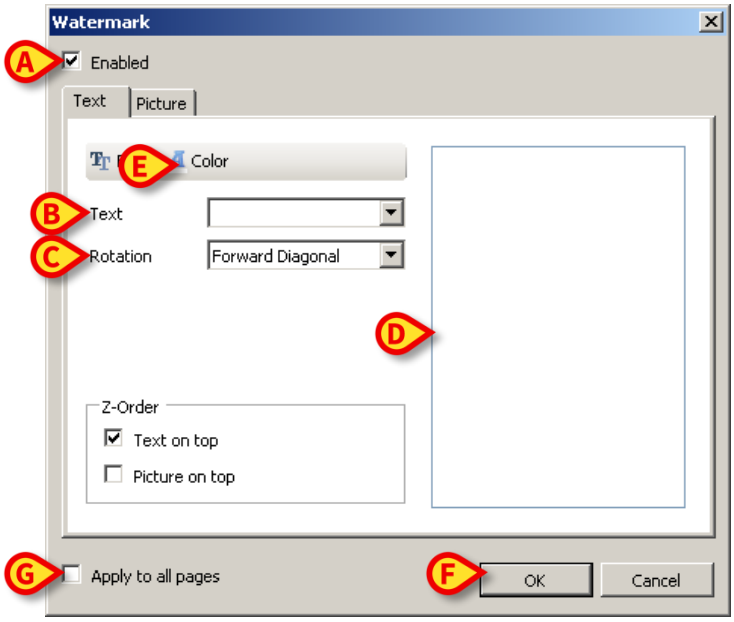


Fig 30

To add a textual watermark,

- Ensure that the "**Enabled**" checkbox is checked (Fig 30 **A**). If not, the 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).

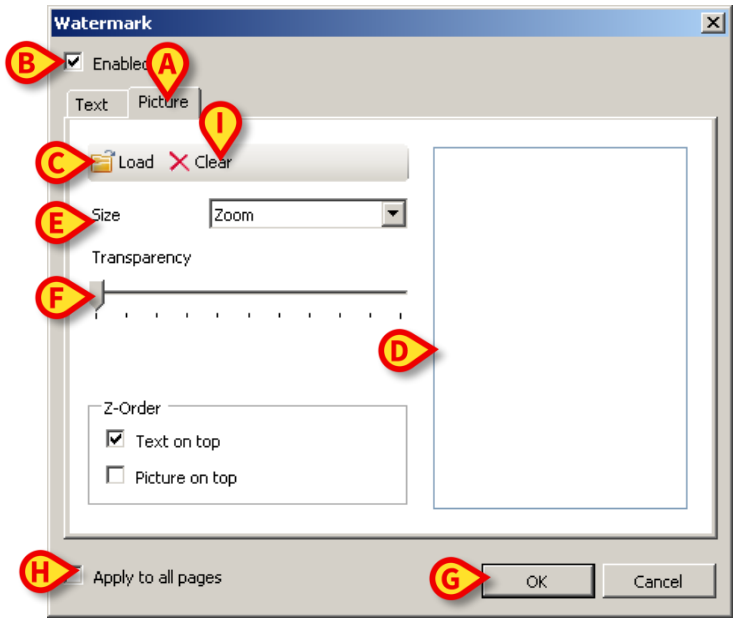


Fig 31

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).

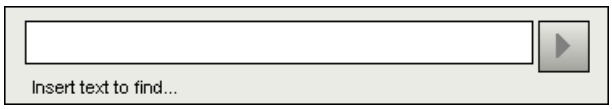


Fig 32

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

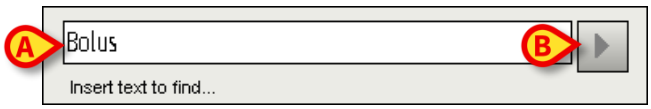


Fig 33

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

The text specified, when found, is 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 will be displayed accordingly. The mode currently selected is indicated on the button.

The following options are available:

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

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

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

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

the 

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

6.8.2.4. Print

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

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

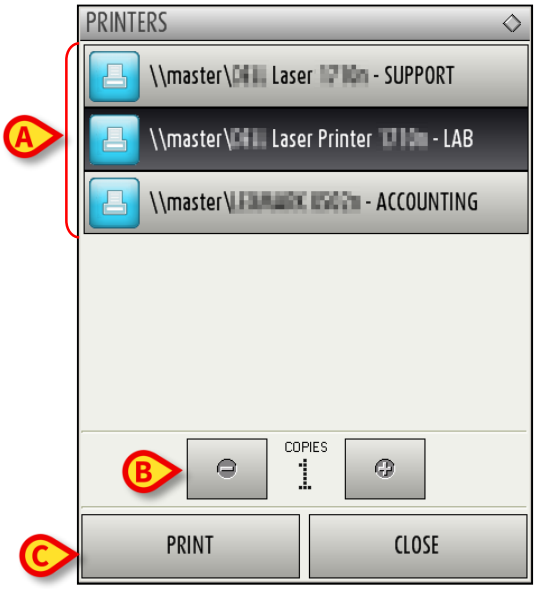


Fig 35

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

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

6.8.2.5. Export

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

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

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

- Click the option corresponding to the wanted extension.

The document is this way exported to the corresponding extension.

6.8.3. Statistics

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

Fig 36

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

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

Fig 37

6.8.3.1. Query Assistant

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

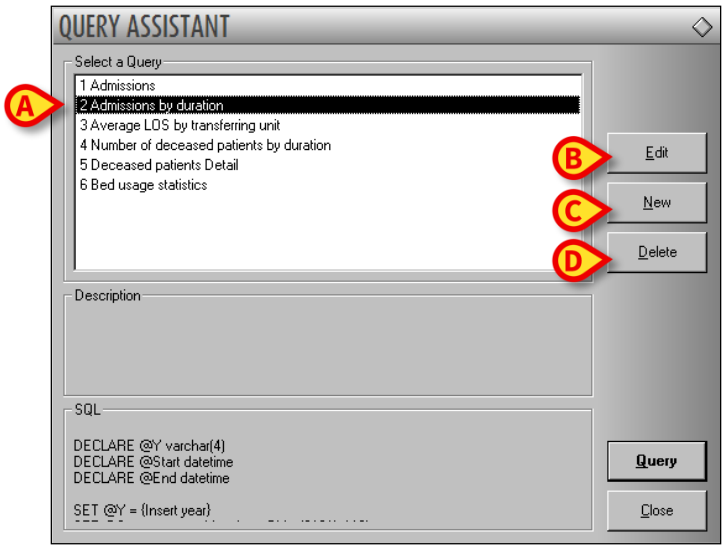


Fig 38

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

To run a query

- click the corresponding name on the list,

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

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

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

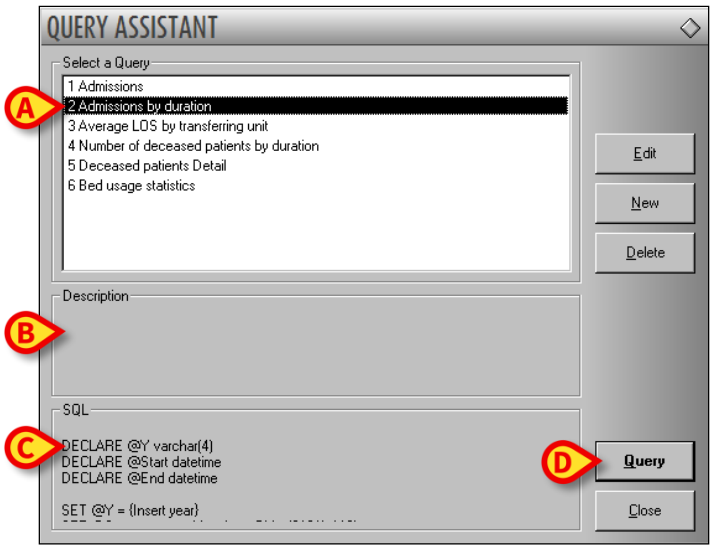


Fig 39

To run the query

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

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

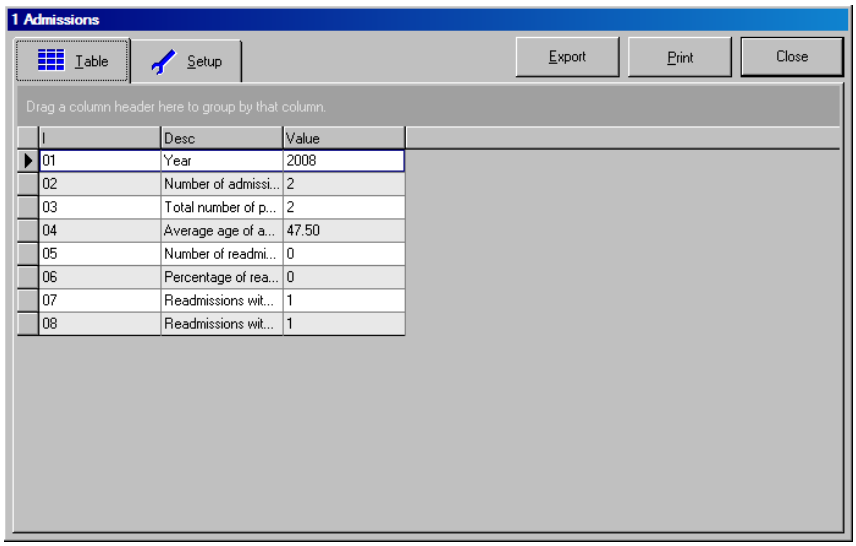


Fig 40

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

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

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

6.8.4. Change password

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

Fig 41

To change the user password

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

The "Change password" window opens.

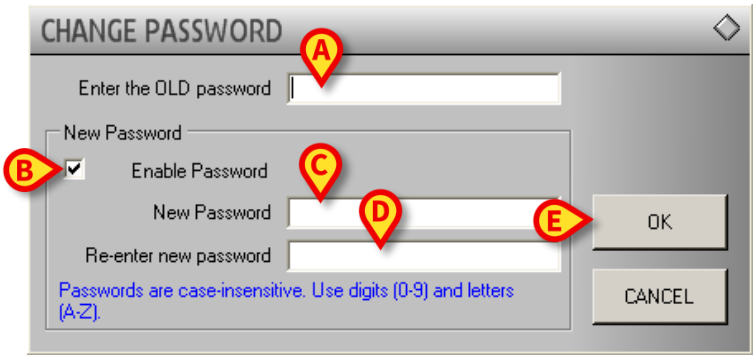


Fig 42

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

The passwords are not sensibile to uppercase and lowercase. 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 opens (Fig 45).

Fig 45

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

Another menu is displayed (Fig 46).

Fig 46

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

User confirmation is required (Fig 47).

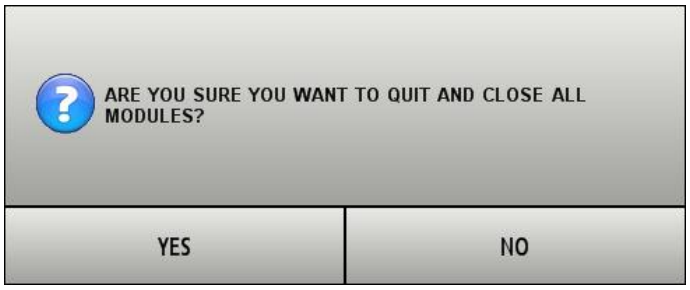


Fig 47

- Click **Yes** to exit DIGISTAT®.

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

6.9. Warning messages

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

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

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

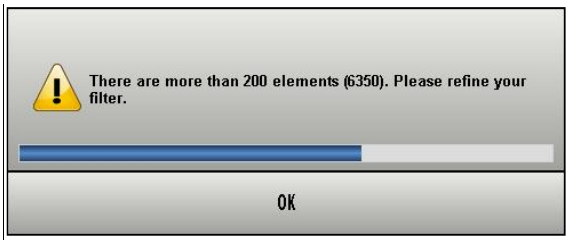


Fig 48

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

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

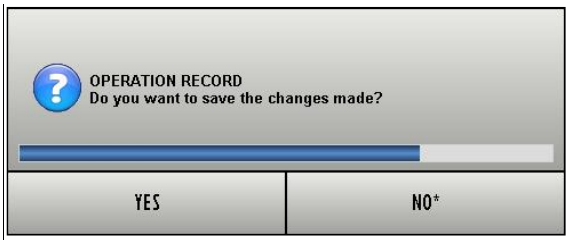


Fig 49

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

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

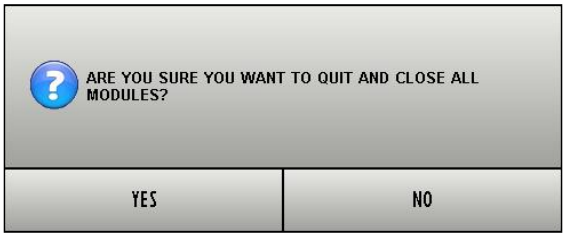


Fig 50

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

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

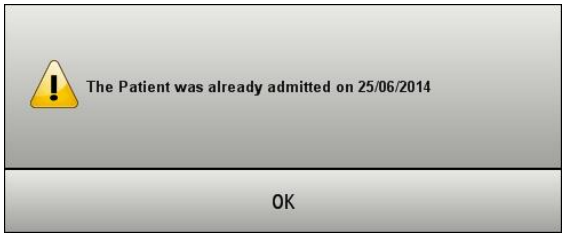


Fig 51

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

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

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

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

7. The DIGISTAT® "Therapy" system

7.1. Introduction

The DIGISTAT® "Therapy" system is a help for the clinical staff for the patient's treatment plan prescription, administration and documentation tasks.

DIGISTAT® "Therapy" specifically aims to help the clinical staff in

- keeping the treatment plan under constant control;
- executing all the needed actions safely and in time;
- accurately and quickly documenting every action performed and every change in the treatment plan.

DIGISTAT® "Therapy" is widely customizable; it can be adapted to the needs of any healthcare structure. It is in fact possible to customize the features of every possible action in the treatment plan to accurately mirror the specific procedures of the department. Refer to your system administrators for the configuration options.

The "Therapy" suite comprises three modules: "Therapy Prescription", "Therapy Execution" and "Central Station".

- The "Therapy Prescription" module is used by doctors to plan, prescrive and document the patient's treatment plan.

- The "Therapy Execution" module is used by nurses in the treatment administration tasks to document the performance of all diagnostic and therapeutic activities.

- The "Central Station" module makes it possible to monitor all the beds in the department, providing real time information on the state and the needs of each patient.

When a doctor prescribes an action (using the "Therapy Prescription" module, described in paragraph 8) the system automatically generates the orders and notifies them to the nursing staff on the "Therapy Execution" module (paragraph 12).
Every action performed is recorded on the same "Therapy Execution" module and inserted in the patient clinical record.

7.2. Patient selection

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

- click the **Patient** button on the Control Bar (Fig 52)

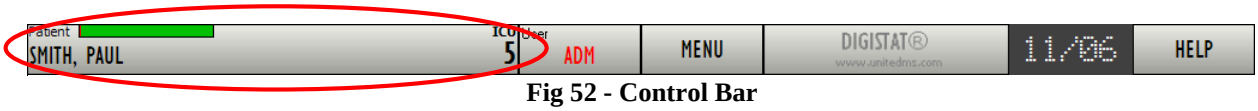


Fig 52 - Control Bar

The DIGISTAT® "Patient Explorer" module will open (if the module is available, otherwise the patient search and selection functions are accomplished by DIGISTAT® "Control Bar").
See either the "Patient Explorer" module or the "Control Bar" 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 name is displayed on the **Patient** button on Control Bar (Fig 53 **A**).

Fig 53 - Patient selected

The "Therapy Prescription" and "Therapy Execution" modules display the data of the selected patient.

The patient can be selected on the "Central Station" module as well, clicking the box corresponding to his/her bed. See paragraph 13.2.

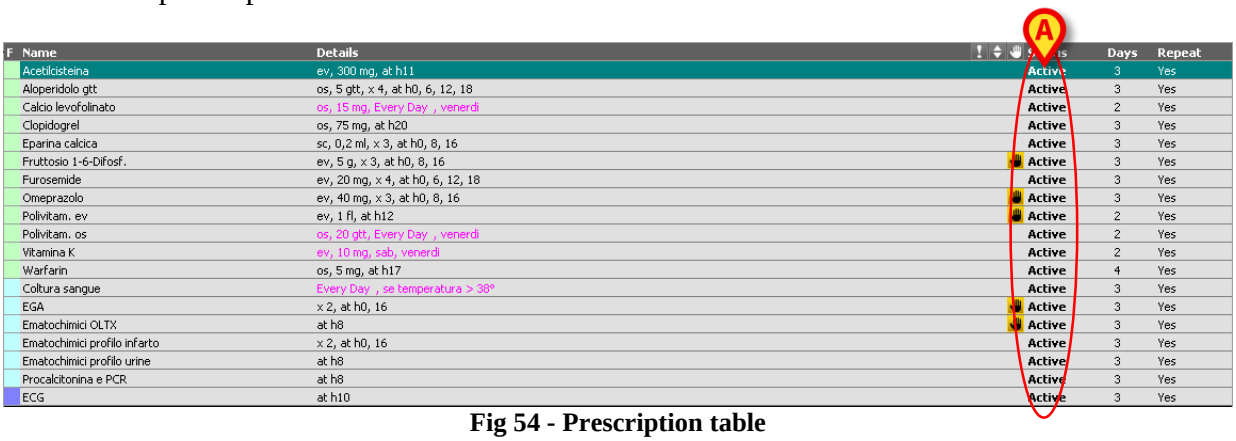
7.3. Basic concepts

This paragraph explains some fundamental notions whose preliminar understanding is essential to the appropriate use of the DIGISTAT® Therapy system.

7.3.1. Prescription status

The "Therapy Prescription" module (described in paragraph 8) makes it possible to create a treatment plan and keep it active in time after scheduled validations. Possible variations are easily and quickly recorded while the general plan remains the same.

The patient's treatment plan is summarized and displayed in a table (Fig 54). Each row corresponds to a treatment prescription.



F	Name	Details	Status	Days	Repeat
	Acetilcisteina	ev, 300 mg, at h11	Active	3	Yes
	Aloperidolo gtt	os, 5 gtt, x 4, at h0, 6, 12, 18	Active	3	Yes
	Calcio levofolinato	os, 15 mg, Every Day , venerdi	Active	2	Yes
	Clopidogrel	os, 75 mg, at h20	Active	3	Yes
	Eparina calcica	sc, 0,2 ml, x 3, at h0, 8, 16	Active	3	Yes
	Fruttosio 1-6-Difosf.	ev, 5 g, x 3, at h0, 8, 16	Active	3	Yes
	Furosemide	ev, 20 mg, x 4, at h0, 6, 12, 18	Active	3	Yes
	Omeprazolo	ev, 40 mg, x 3, at h0, 8, 16	Active	3	Yes
	Polivitam. ev	ev, 1 fl, at h12	Active	2	Yes
	Polivitam. os	os, 20 gtt, Every Day , venerdi	Active	2	Yes
	Vitamina K	ev, 10 mg, sab, venerdi	Active	2	Yes
	Warfarin	os, 5 mg, at h17	Active	4	Yes
	Coltura sangue	Every Day , se temperatura > 38°	Active	3	Yes
	EGA	x 2, at h0, 16	Active	3	Yes
	Ematochimici OLTX	at h8	Active	3	Yes
	Ematochimici profilo infarto	x 2, at h0, 16	Active	3	Yes
	Ematochimici profilo urine	at h8	Active	3	Yes
	Procalcitonina e PCR	at h8	Active	3	Yes
	ECG	at h10	Active	3	Yes

Fig 54 - Prescription table

Each prescription generates a certain number of orders. The orders correspond to the single administrations of the treatment.

A prescription is completed when all the orders that it generated have been executed and no other order will be generated by it in the future.

Completed prescriptions appear in strike-through characters on the prescriptions table (Fig 55).

~~Midazolam~~	~~0,053 mg/kg/h, 3 ml/h, @60 mg/60 ml, h15.10~~		~~Active~~	7

Fig 55 - Completed prescription

The completed prescriptions are still in "Active" status because it is this way possible to prescribe them again quickly, without having to specify the prescription details again (Fig 55 **A**). It is in fact possible to restore a completed prescription by double-clicking the corresponding row. The prescription specification window will appear, displaying the values of the original prescription. See paragraph 10 for the description of the prescription specification window and the related procedures.

The prescription status is displayed, on the table, in the column indicated in Fig 54 **A**.

There are four possible prescription statuses:

1. “Active” - when a prescription is in “Active” status the prescription values can be displayed and edited. Double-click the corresponding row to open the related “prescription specification” window (described in paragraph 10).

2. “Active and completed” - a prescription is completed when all the orders that it generated are executed and no other order will be generated by it in the future. Completed prescriptions are still active, that means that the prescription values can be diplayed and edited. Double-click the row corresponding to the prescription to display the related “prescription details” window. Completed prescriptions appear in strike-through characters on the prescriptions table.
   The **Remove Completed** button on the command bar cancels all the completed prescriptions from the prescriptions table and turns them to “Terminated” status.

3. “Suspended” - the prescription suspension, performed using the **Suspend** button on the command bar, deletes all the existing orders generated by the prescription. Moreover, when a prescription is in “Suspended” status, it does not generate further administration orders. A suspended prescription can be resumed using the **Resume** button on the command bar. See paragraphs 11.4 (precription suspension) and 11.4.1 (how to resume a suspended prescription) for the related procedures.

4. “Terminated” - the prescription is “Terminated” either using the **Remove** or the **Remove Completed** button on the command bar. When a prescription is terminated all the orders generated by it are deleted. Moreover, the “Terminated” prescription does not generate further administration orders. It is **NOT** possible to resume a “Terminated” prescription. See paragraphs 11.3 (prescriptions removal) and 11.8 (completed prescriptions removal) for the related procedures.

The prescriptions table is described in paragraph 8.3.

7.3.2. Repeatable vs. Non Repeatable Prescriptions

Repeatable prescriptions

A prescription is “***Repeatable***” if it generates orders that must be administered at given intervals. For example: a prescription can state that a drug must be administered every day at a certain time. In this case the prescription is repeatable; it generates the corresponding orders placing each of them in the required days at the required time/s.
The orders are generated for seven days in the future starting from the date indicated as treatment start date. The next orders are generated when the next treatment validations are performed (see paragraph 11.1 for the treatment plan validation procedure).

Non-repeatable prescriptions

Non-repeatable prescriptions generate only the administration orders explicitely specified in the prescription. When all the orders are executed the prescription is "Completed" and appears in strike-through characters on the prescriptions table. Then the prescription turns to "Active and completed" status.
The repeatability of a prescription is set by a specific checkbox on the prescription specification window (see Fig 56 **B** for an example).
The repeatability of a prescription is indicated in the last column on the right on the prescriptions table ("Repeat" column, see Fig 61, paragraph *8.3*).

7.3.3. Punctual vs. Durative administrations

Punctual administrations start and end in one moment (a tablet, for instance).

Durative administrations last a certain amount of time (a drip, for instance).

These two types of administrations are characterized by different graphic features and different management procedures on the Therapy Execution module. See paragraph 12.3 for a detailed description of the possible administration types on Therapy Execution.

7.3.4. The Therapy Cycle - treatment plan re-confirmation procedure

The validity of the treatment plan created on DIGISTAT® Therapy is limited in time and needs to be re-confirmed by the medical staff.

The treatment plan validity period is called "Therapy Cycle". The "Therapy Cycle" duration is configurable by the system administrators. See the information box at the end of this paragraph for more information on the "Therapy Cycle" duration.

The "Therapy Cycle" re-confirmation procedure, described in paragraph 11.1, has the following outcomes:

a) it generates the possible not-still-generated orders within the next "Therapy cycle" (see paragraph 7.3.5 for a description of the way orders are generated from prescription);

b) it validates the orders that are within the next "Therapy cycle" (see paragraph 11.1 for the validation procedures).

The "Therapy Cycle" re-confirmation is a safety procedure that forces to check and verify the treatment plan at specified intervals.

When the treatment plan validity is expired the system does not generate any other order from the existing prescriptions.

The treatment plan expiration time is signalled on screen by specific indicators. These indicators are described in paragraph 8.5.

The treatment plan re-confirmation procedure is described in paragraph 11.1.

The "Therapy Cycle" duration is set by configuration.

The "Therapy Cycle" update procedure can have, depending on the configuration in use, the following outcomes:

- *the validity period is updated for the next N hours;*
- *the validity period is updated until NN:NN o'clock of the following day;*
- *the validity period is updated until the midnight of tomorrow;*
- *the validity period is updated until the midnight of day after tomorrow.*

System configuration is reserved to the system administrator. Refer to the system administrator for more information.

7.3.5. Orders generation

This paragraph explains how the system generates the orders from a prescription specified in the treatment plan.

At prescription time, i.e. when the Prescribe button on the "prescription specification" window is clicked (Fig 82 **A**, see paragraph 9.2), the system generates the orders corresponding to the prescription specifications.
When the treatment prescribed is non-repeatable (see paragraph 7.3.2 for an explanation of "treatment repeatability"), the system generates all the corresponding orders.
When the treatment prescribed is repeatable the system generates the orders for a maximum period of seven days in the future starting from the day indicated in the field "starting from" on the prescription detail window (see for example Fig 56 **A**).

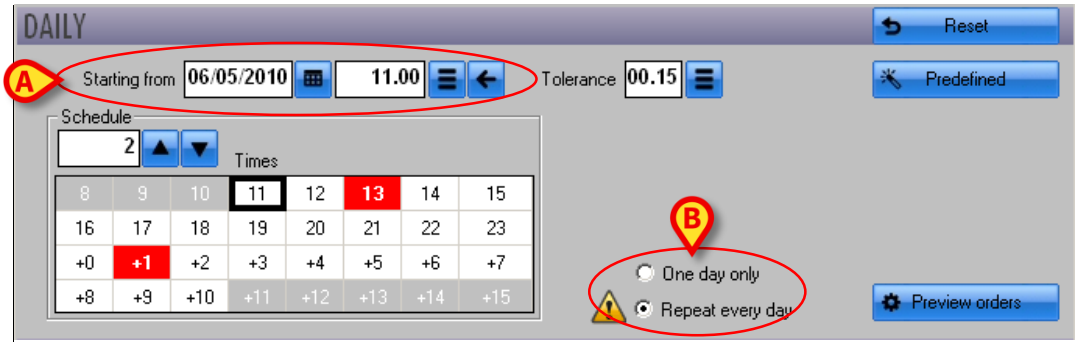


Fig 56 - Daily treatment prescription

For exmple: if a repatable treatment is prescribed "starting from" the 6th of May 2010, the system generates the orders going from the 6th to the 12th of May.

Conditional prescriptions (paragraph 10.2.2) do not generate orders. These prescriptions are executed only when certain specific conditions occur.

7.3.6. Orders validation

The order execution standard procedure requires the order validation before the execution.

The orders that, when generated, are within the “Therapy cycle” are automatically validated.

The other orders are validated every time the “Therapy cycle” is updated when they are within this period (paragraph 11.1).

Non-validated orders are signalled by a specific icon on the Therapy Execution module (Fig 57). They can be executed only after a special procedure, described in paragraph 12.5.2.

Fig 57 - Non-validated order on Therapy Execution

See paragraph 7.3.4 for the explanation of the “Therapy Cycle” (or “treatment plan validity period”).
See paragraph 11.1 for the treatment plan update procedure.
See paragraph 11.1.1 for a description of the “Orders confirmation window”.

7.3.7. Order validity expiration

The validity of an order expires after a certain amount of time after the scheduled administration time has passed. That is: if a validated order is not administered at the scheduled time it remains validated for a certain period. After this period the order goes back to non-validated state (it is named “expired” to differentiate it from future not-yet-validated orders).

Expired orders cannot be validated again.

Expired orders can be deleted from the treatment plan through the “Therapy cycle” update procedure. See paragraph 11.1.

Expired orders can be executed only using a specific procedure. The procedure is described in paragraph 12.5.2.

The orders validity duration is defined by a specific configuration parameter. Refer to the system administrator for more information.

The validity of a conditional prescription expires when the “Therapy Cycle” expires. Thus conditional prescriptions are automatically validated every time the “Therapy Cycle” is updated. See paragraph 10.2.2 for the explanation of “Conditional prescriptions”.

8. The “Therapy Prescription” module

8.1. Module selection

To select the “Therapy Prescription” module

- click the corresponding icon on the lateral bar (Fig 58 **A**).

Fig 58

When a module is selected the icon 

appears highlighted.

The “Therapy Prescription” module’s main screen opens. Fig 59 shows the main screen when no patient is selected.

Fig 59 - Electronic prescription: no patient selected

8.2. “Therapy prescription” module’s main screen

After patient selection the “Therapy prescription” module’s main screen displays the treatment plan of the selected patient. Fig 60 shows an example.

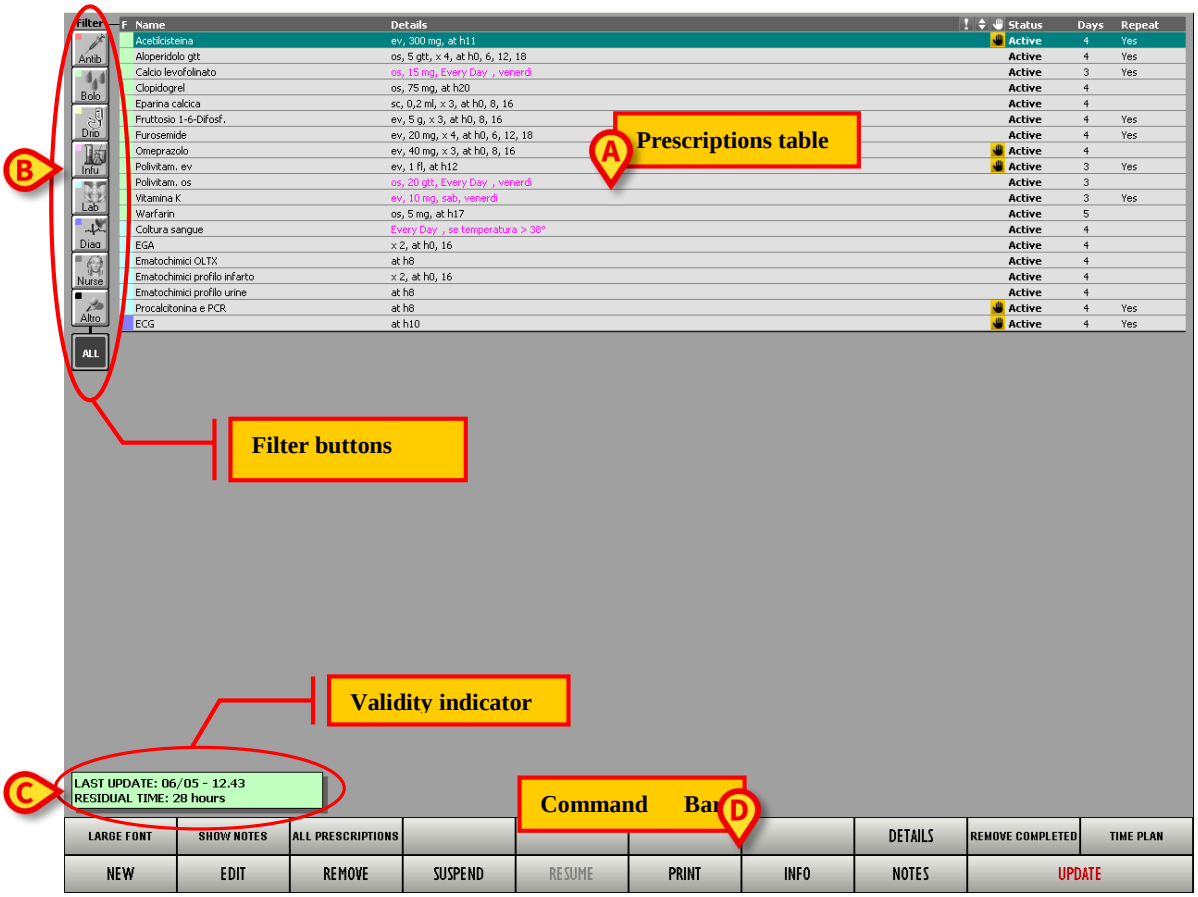


Fig 60 - Treatment plan

The figure highlights the main items on screen:

- the prescriptions table (Fig 60 **A** - described in paragraph 8.3);
- the filter buttons (Fig 60 **B** - paragraph 8.4);
- the validity indicator (Fig 60 **C** - paragraph 8.5);
- the command bar (Fig 60 **D** - paragraph 8.6).

8.3. Prescriptions table description

The various prescriptions of the treatment plan are displayed in a table (Fig 60 **A**, Fig 61).

F	Name	Details	!	⇕	✋	Status	Days	Repeat
	Acetilcisteina	ev, 300 mg, at h11			✋	Active	4	Yes
	Aloperidolo gtt	os, 5 gtt, x 4, at h0, 6, 12, 18				Active	4	Yes
	Calcio levofolinato	os, 15 mg, Every Day , venerdi				Active	3	Yes
	Clopidogrel	os, 75 mg, at h20				Active	4	
	Eparina calcica	sc, 0,2 ml, x 3, at h0, 8, 16				Active	4	
	Fruttosio 1-6-Difosf.	ev, 5 g, x 3, at h0, 8, 16				Active	4	Yes
	Furosemide	ev, 20 mg, x 4, at h0, 6, 12, 18				Active	4	Yes
	Omeprazolo	ev, 40 mg, x 3, at h0, 8, 16			✋	Active	4	
	Polivitam. ev	ev, 1 fl, at h12			✋	Active	3	Yes
	Polivitam. os	os, 20 gtt, Every Day , venerdi				Active	3	
	Vitamina K	ev, 10 mg, sab, venerdi				Active	3	Yes
	Warfarin	os, 5 mg, at h17				Active	5	
	Coltura sangue	Every Day , se temperatura > 38°				Active	4	
	EGA	x 2, at h0, 16				Active	4	
	Ematochimici OLTX	at h8				Active	4	
	Ematochimici profilo infarto	x 2, at h0, 16				Active	4	
	Ematochimici profilo urine	at h8				Active	4	
	Procalcitonina e PCR	at h8			✋	Active	4	Yes
	ECG	at h10			✋	Active	4	Yes

Fig 61 - Prescriptions table

Each row in the table corresponds to a prescription. The prescriptions are grouped into classes. Each class is characterized by a specific colour (see paragraph 8.4 for a description of the different classes). The items belonging to the same class are in alphabetical order.

The columns in the table contain the following information (from left to right):

- "**F**" column ("F" means "Filter") - Indicates the class of the prescription. Each class is associated to a color. See paragraph 8.4.
- "**Name**" column - Indicates the name of the prescribed treatment.
- "**Details**" column - Indicates the deatils of the prescription as, for example, the date and time of the different orders, the doses etc…
- ! column - If the ! icon appears in this column it means that either the actions indicated on this row were executed differently from the way they were prescribed or they were executed without prescription. It is the case, for example, of a treatment executed with doses that are different from those prescribed.
- ⇕ column - The ⇕ icon appears in this column when the values of a durative prescription (a drip, for example) are changed on the "Therapy Execution" module while the administration is in progress. If this is the case the values specified on the "prescription detail" window differ from those recorded on the "Execution" module. The icon disappears when the values on the prescription window are realigned to those specified on "Execution". See paragraph 11.2 for the prescription values change procedures.
- ✋ column - The ✋ icon appears when there is at least a non-validated order approaching administration time. This "proximity to administration time" is a time period set by configuration; in the configuration here described it is a three-hours period.
- "**Status**" column - Indicates the prescription status. See paragraph 7.3.1 for a list of the possible statuses of a prescription.

- "**Days**" column - Indicates the number of days from the first prescription of the treatment. When referred to a prescription in "Terminated" status (see paragraph 7.3.1 for an explanation of this concept) the "Days" column displays the termination date.

- "**Repeat**" column - Indicates whether the treatment is repeatable or not. See paragraph 7.3.2 for an explanation of "repeatable prescriptions".

The prescription is written in strike-through characters when all the corresponding orders are already executed and no other order will be generated by it (completed prescription).

The prescriptions written in purple characters are conditional prescriptions. Conditional prescriptions correspond to the treatments that must be administered only if certain conditions occur (no administration time is specified for these prescriptions). See paragraph 10.2.2 for an explanation of "conditional prescription".

8.4. Prescription filter buttons

Each treatment is associated to a class. The treatment-class association is defined by configuration. The names of the different classes are defined by configuration. The treatments can be grouped in 8 different classes.

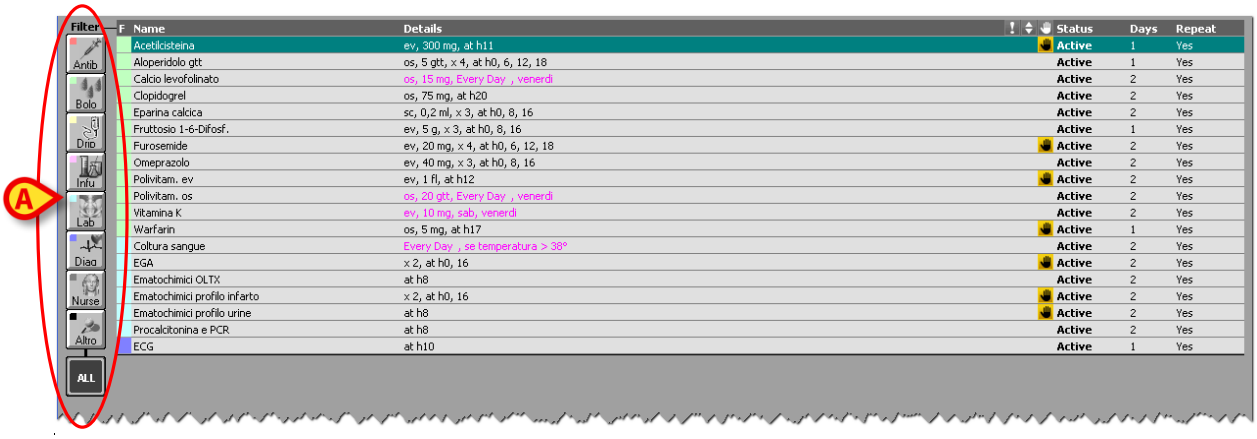


Fig 62 - Prescriptions filters

Each class is characterized by a color. A specific button corresponds to the class (Fig 62 **A**). The classes in use in the configuration here described are:

- Nursing

- Monitoring

- Diagnostic

- Exams

- Infusions

- Drip

- Bolus

- Other.

The class of a treatment is indicated by the color displayed in the "**F**" column (Fig 63).

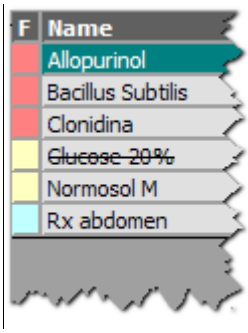


Fig 63 - The class is indicated by the color

In the example shown in Fig 63, the first items in the list, characterized by the color, belong to the "Bolus" class, while the two following items (colour) belong to the "Infusions" class.

The buttons indicated in Fig 62 **A** make it possible to filter the items in the table. When one of the buttons is clicked, only the items belonging to the corresponding class are displayed.

For example, the 

button makes it possible to display only the items belonging to the "Bolus" class (Fig 64).

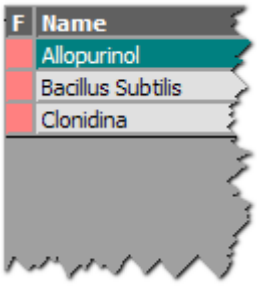


Fig 64

When two buttons are selected at the same time the system displays the items belonging to the two corresponding classes. To display the list shown in Fig 65 ("Infusions" and "Bolus"), for instance, the buttons 

and 

were selected together.

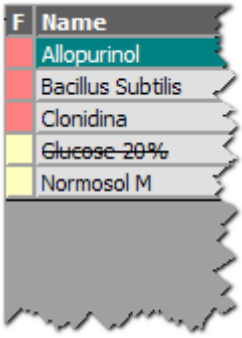


Fig 65

The filter-buttons are on/off switches. Click the button again to remove the filter.

The 

button makes it possible to display the prescriptions full list (Fig 66 **A**).

8.4.1. How to use the filter-buttons

8.4.1.1. How to apply a filter to the prescriptions list

To apply a filter to the prescription list,

- click one of the filter-buttons (Fig 66).

Fig 66

The button is this way selected (Fig 67).

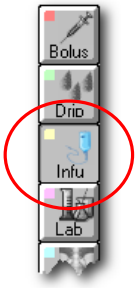


Fig 67 - Selected button

The prescription table displays the list of the items belonging to the class corresponding to the selected button.

8.4.1.2. How to remove a filter

To remove a filter,

- click the selected button again.

The button is this way deselected, the filter is removed.

8.4.1.3. How to display the full prescriptions list again

To display the full prescriptions list,

- click the 

button (Fig 66 **A**).

All the buttons possibly selected are this way deselected.

8.5. Validity indicator

The validity of the treatment plan created on DIGISTAT® Therapy is limited in time. A periodical validation is required. See paragraph 7.3.4 for an explanation of the treatment plan validity.

The box shown in Fig 60 **C** and (in detail) in Fig 68 indicates the treatment plan validity.
The validity indicator is a tool making it possible to constantly monitor the time remaining to the end of the treatment plan validity.

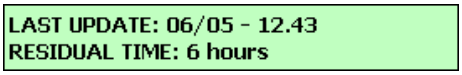


Fig 68 – Validity indicator

The first row of the box specifies the date and time of the last update (Fig 68).

The second row indicates the time remaining to the end of the treatment plan validity.

When the treatment plan expires the box turns to red and specifies that the treatment plan is expired (Fig 69).

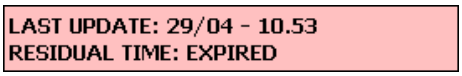


Fig 69 – Expired validity

Also, the treatment plan validity is indicated by a specific indicator on the PATIENT button on Control Bar (Fig 70). This button, which remains always visible, enables the clinical staff to keep the treatment plan validity under control when the "Prescription" module is not selected.

See Fig 70 for an instance.

Fig 70 - Patient button

The red portion of the time bar indicates the time passed from the last update, the green portion represents the time remaining to the expiration of the treatment plan validity.

WARNING!

<u>Updating the treatment plan is extremely important.</u>

The person in charge should check and update the treatment plan validity before it expires.

Treatment plan update procedures are described in paragraph 11.1

8.5.1. The "Notes" area

The area placed on the right of the "Validity indicator" displays the possible patient notes. See paragraph 11.11 for the notes specification procedure.

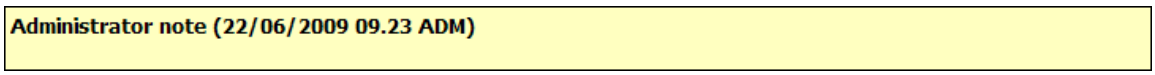


Fig 71 - Notes Area

If relevant, the "notes" area can display the note specification date and time and the acronym of the user who added the note.

8.6. The command bar

The command bar of the “Prescription” module (Fig 60 **D**, Fig 72) contains various buttons that can be used to perform different actions.

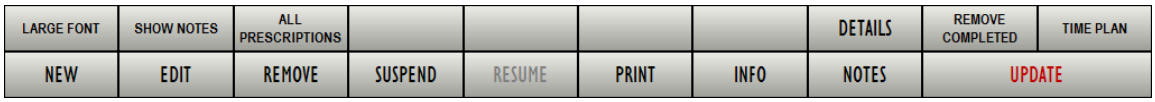
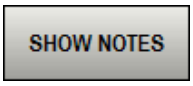


Fig 72 - Command bar

This paragraph summarizes the functions of each button. The detailed procedures are explained in the paragraphs indicated.

This button enlarges the characters displayed on screen to make them easier to be read. See paragraph 11.5.

This button makes it possible to add a new prescription to the treatment plan. See paragraph 9.1.

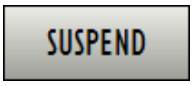


This button displays the notes possibly related to every prescribed action. See paragraph 11.6.

This button makes it possible to display and edit the details of a selected prescription. See paragraph 11.2.

This button displays the patient prescriptions full list, including those suspended and removed. See paragraph 11.7.

This button makes it possible to remove a selected treatment from the treatment plan. See paragraph 11.3.



This button makes it possible to suspend a selected treatment on the treatment plan. See paragraph 11.4.

This button makes it possible to resume one of the treaments previously suspended. See paragraph 11.4.1.

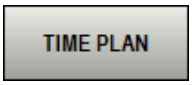
This button makes it possible to create a print report containing the details of the treatment plan. See paragraph 11.12.

This button displays a document containing information about a selected treatment. See paragraph 11.13.

This button makes it possible to display and edit the patient's general notes. See paragraph 11.11.

This button displays the details of a selected prescription. See paragraph 11.9.

This button removes the completed prescriptions from the prescription table. See paragraph 11.8.



This button displays a summary of all the active prescriptions. See paragraph 11.10.

This button makes it possible to update the treatment plan. See paragraph 11.1.

9. How to prescribe a treatment

The following paragraphs describe the procedures that must be performed to specify a prescription and insert it into the patient's treatment plan.

9.1. How to search for a specific treatment

The **New** button on the command bar (Fig 73) displays a window that can be used to search for the treatment (or "standard action") that must be added to the patient's treatment plan (Fig 74). The header of this window is "Select a standard action".

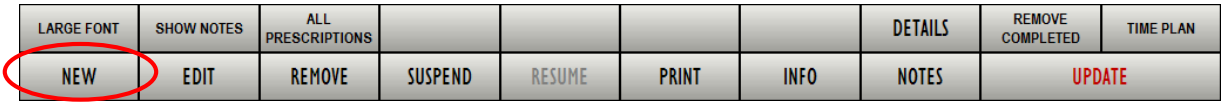


Fig 73 - Command bar

The full treatment selection procedure is summarized in paragraph 9.2. This paragraph describes the window shown in Fig 74.

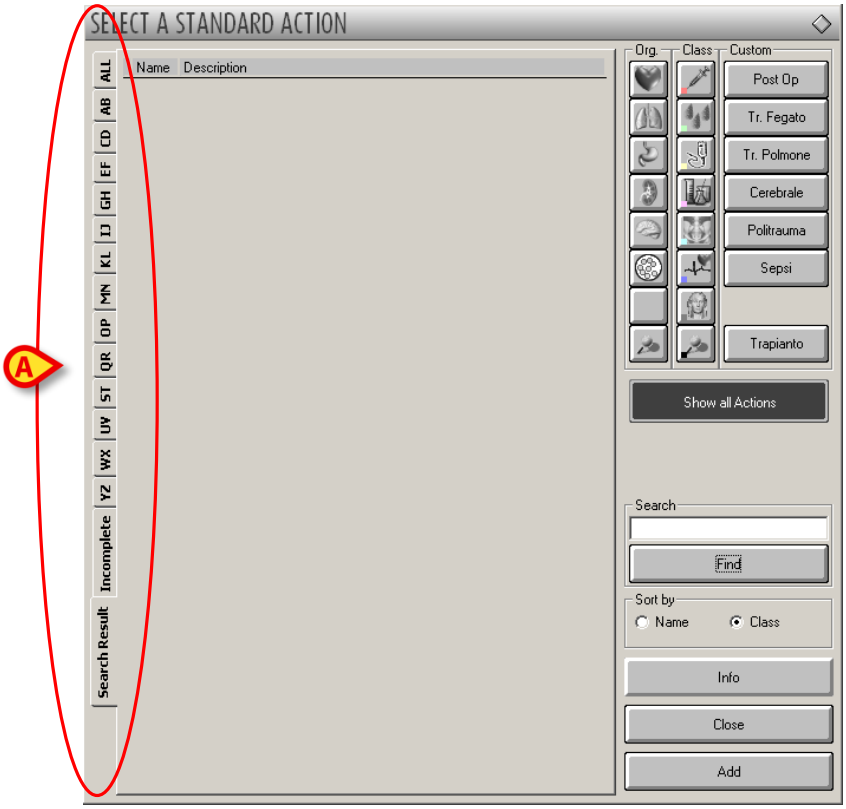


Fig 74 - Select a standard action

This window makes it possible to search and select a treatment (or "standard action") that must be added to the treatment plan.

Various tools, described below, are available for this purpose.

9.1.1. Alphabetic labels

The labels on the left (Fig 74 **A**) make it possible to display the treatments whose names begin with a specific letter. Click the **AB** button, for instance, to display the treatments whose names begin with “A” and “B” (an example is shown in Fig 75).

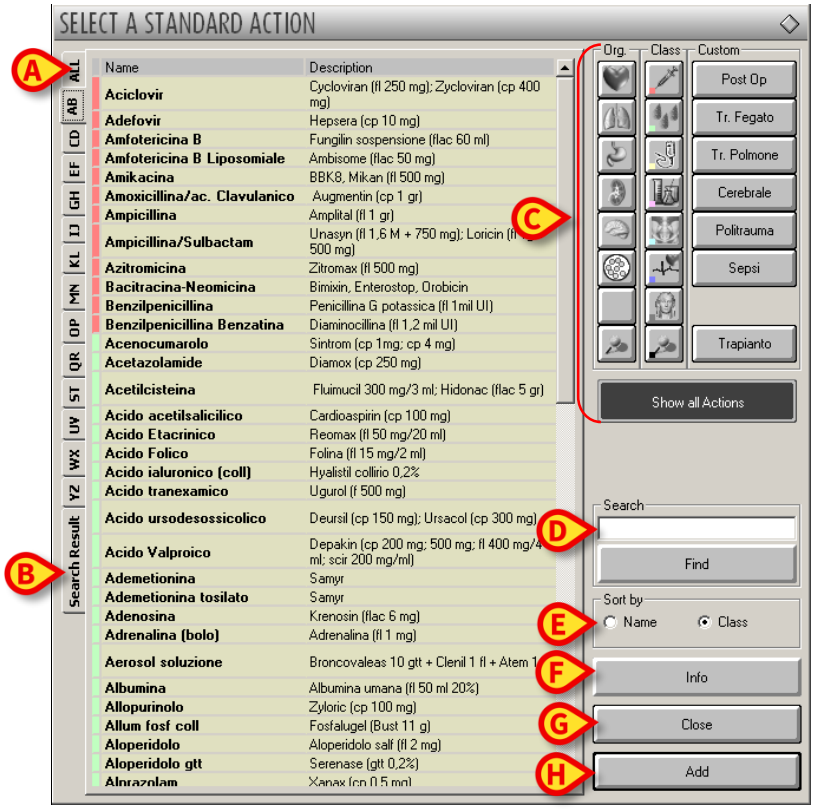


Fig 75 - Treatments whose names begin with “A” and “B”

The **All** label (Fig 75 **A**) displays the treatments full list again.

The **Search Result** label (Fig 75 **C**) displays the results list of the last search performed.

If the name of a treatment appears in blue characters it means that the treatment is related to an external drug management system (for instance: a cabinet or a stockroom). Please contact the technical assistance for more information.

9.1.2. Filter buttons

The filter buttons shown in Fig 76 and Fig 75 **C** make it possible to display a selected subset of treatments.

Fig 76 - Filter buttons

There are three different kinds of filters:

1. The “Organs” filters make it possible to display the subset of treatments that are related to a specific organ (heart, lungs etc...);

2. The “Class” filters reflect the treatment classes explained in paragraph 8.4;

3. The “Custom” filters can be defined by the system administrators according to the needs of the clinical staff.

The list of treatment displayed on the window can be reduced selecting more than one filter at the same time.

The **Show All Actions** button (Fig 76 **A**) displays the treatments full list again.

9.1.3. Search strings

A specific search tool (Fig 75 **D** and Fig 77) makes it possible to find the wanted treatment typing a string of characters that are part of the treatment’s name or description.

Fig 77 - Treatment search

To perform a search

- type the treatment name in the search field.
- Click the **Find** button.

The system will display the list of all the treatments whose name (or description) contains the specified string.

9.1.4. Sort results

The "radiobuttons" placed below the search field (Fig 75 **E**, Fig 78) make it possible to change the treatments display mode.

Fig 78 - Sort results by

When the list is sorted "by name" the treatments are displayed in alphabetical order. When the list is sorted "by class" the treatments belonging to the same class are grouped together. The items within the same class are displayed in alphabetical order.

9.1.5. Treatment Information

The **Info** button (Fig 75 **F**) opens a page containing information on the selected treatment. The contents of the page must be configured by the system administrator.

9.1.6. Close window

The **Close** button (Fig 75 **G**) closes the treatment selection window.

9.1.7. Add treatment to the patient plan

The **Add** button (Fig 75 **H**) makes it possible, once a treatment on the window is selected, to add the treatment to the patient treatment plan. See paragraph 9.2 for a summary of the complete procedure.

9.2. How to add a treatment to the patient plan

To add a new treatment to the patient treatment plan:

- Click the **New** button on the command bar (Fig 79).

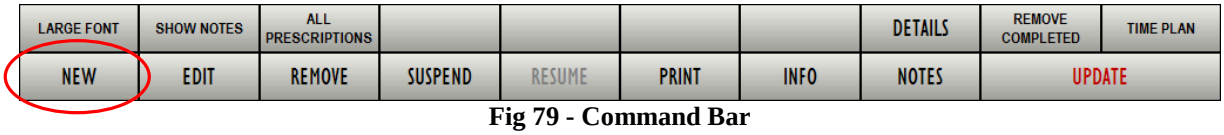


Fig 79 - Command Bar

The window shown in Fig 80 will open.

- Search the wanted treatment using the tools described in the previous paragraphs (9.1).
- Click the treatment to be prescribed.

The corresponding row will be highlighted (Fig 80 **A**).

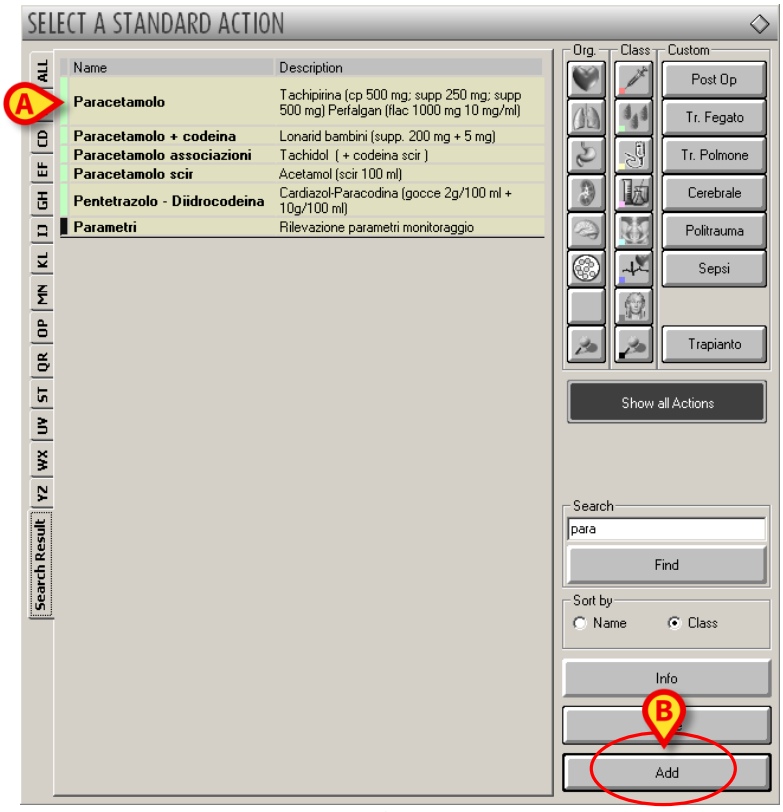


Fig 80

- Click the **Add** button (Fig 80 **B**).

A window making it possible to specify the wanted kind of prescription will open (Fig 81).

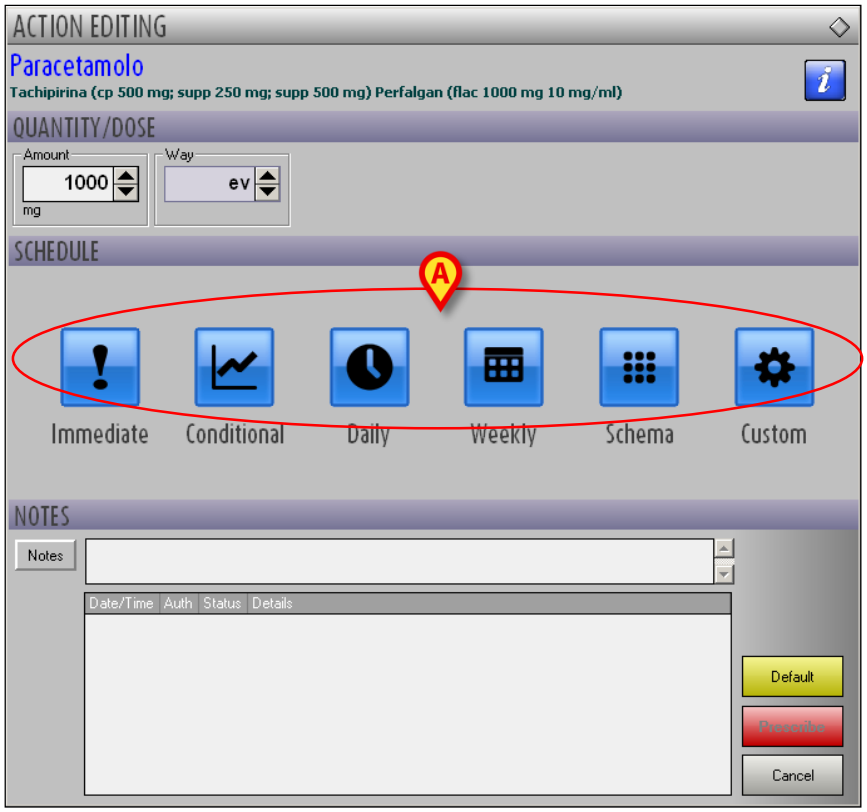


Fig 81

- Select the kind of prescription using the buttons indicated in Fig 81 **A**.

A window enabling to specify all the prescription details will open (Fig 82 shows an example of "Daily" prescription).

*The treatment can be configured to enable only one possible kind of prescription. If this is the case the selection buttons shown in Fig 81 **A** are not displayed and the specification window (see Fig 82 for an example) is instead directly displayed.*

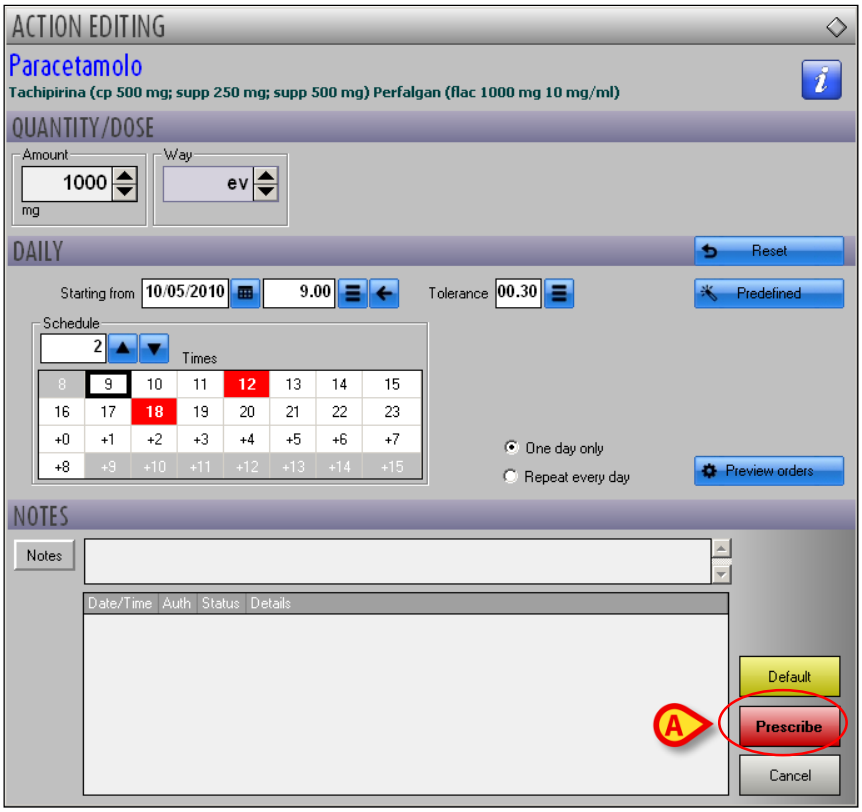


Fig 82 - Daily prescription

- Specify the prescription details.
- Click the **Prescribe** button (Fig 82 **A**).

The treatment is this way added to the patient treatment plan. A row corresponding to the new prescribed treatment appears on the prescription table.

The window shown in Fig 80 is described in detail in paragraph 9.1.

The window shown in Fig 81 and the detailed prescription specification procedures are described in paragraph 10.

10. The treatment specification window

This paragraph describes the treatment specification window shown in Fig 81 and Fig 83.

After treatment selection (Add button - Fig 80 **B**), a window making it possible to specify the details of the selected treatment appears (Fig 83).

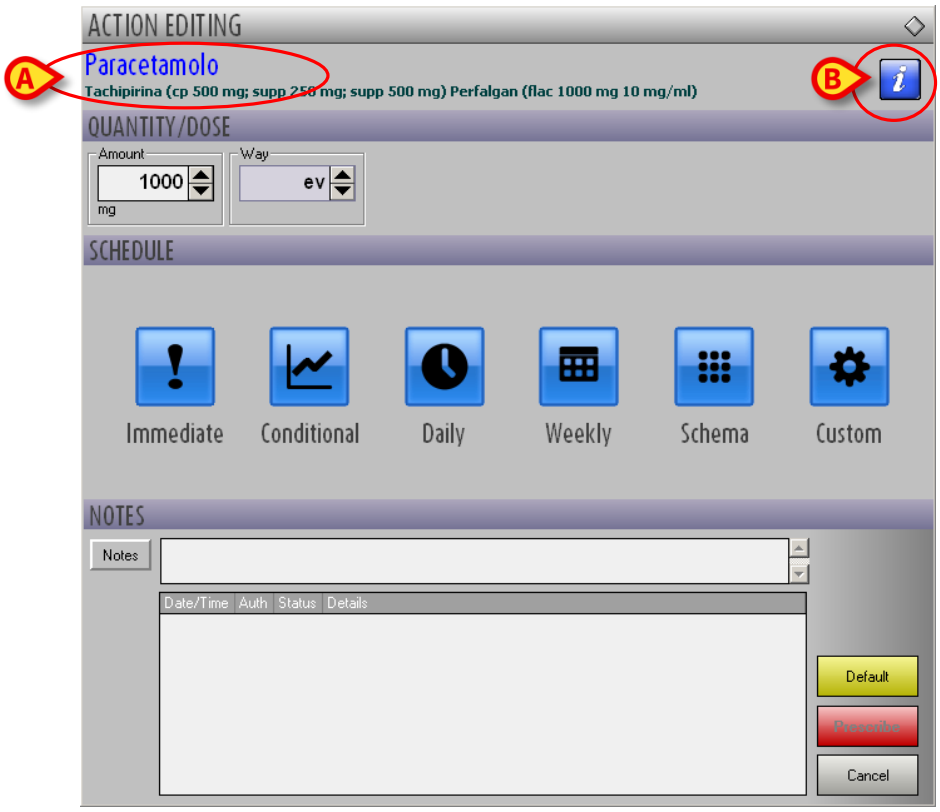


Fig 83 - Prescription

The treatment name is displayed on the upper-left corner of the window (Fig 83 **A**). Under the treatment name additional information can be displayed (specific name, possible dosages etc.).

The  button on the right (Fig 83 **B**) opens a page containing detailed information on the treatment.

The window is divided in several areas, each one dedicated to a specific sub-set of features of the prescription.

Please remember that every treatment is configured to enable the specification of its relevant values and is characterized by specific default values. Thus the specification window changes according to the kind of treatment selected.
It is also possible to set by configuration the automatic selection of the treatment's administration plan (conditional, weekly, daily, schema etc…). In those case the relevant window is automatically displayed (i.e. there is no need to select the kind of administration using the buttons described in paragraph 10.2

Any relevant action can be configured as prescribable treatment. Every configured action is characterized by its relevant parameters and default values.
Therefore the aspect and features of the treatment specification window depend on the treatment prescribed.

10.1. The "Quantity/Dose" area

Use the "Quantity/Dose" area (Fig 84) to specify the dosages and the administration way.

The number and nature of the parameters displayed in this area depend on the specific treatment selected. For example, for an infusion it is possible to specify the drug speed, the solution speed and the concentration (it is the case shown in Fig 84).

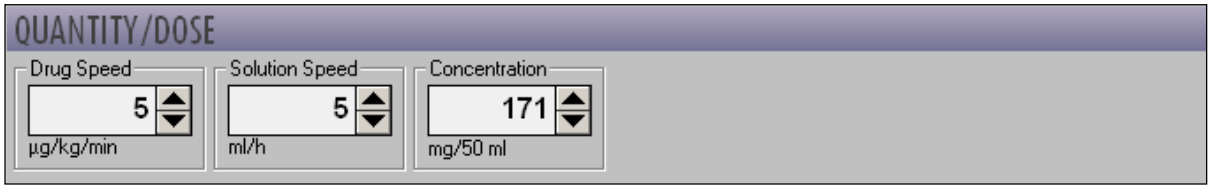


Fig 84 - Quantity/Dose

Standard default values are usually automatically set. Default values can anyway be easily changed.

To edit these values

- click the arrow buttons placed alongside each field -  -.

The value will progressively increase (up arrow) or diminish (down arrow).

Otherwise

- clik on the field that must be edited.

The corresponding value will be highlighted (Fig 85 **A**).

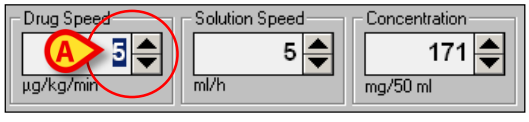


Fig 85

- Type the new value using the workstation keyboard.

The values in the different fields can be related one to the other by a proportionality that is set by configuration. When this is the case, after specifying one value, the system automatically calculates all the related values.

10.2. The “Schedule” area

Use the “Schedule” area (Fig 86) to specify “when” and “how many times” a treatment must be administered.

Six “schedule” types are available. A type can be selected by the buttons indicated in Fig 86 **A**.

Once the type is selected it is possible to specify the treatment schedule details.

It is possible to set by configuration the automatic plan type selection (conditional, weekly, daily, schema etc…). In those cases the relevant window is automatically displayed (i.e. there is no need to select the kind of administration using the buttons described in this paragraph).

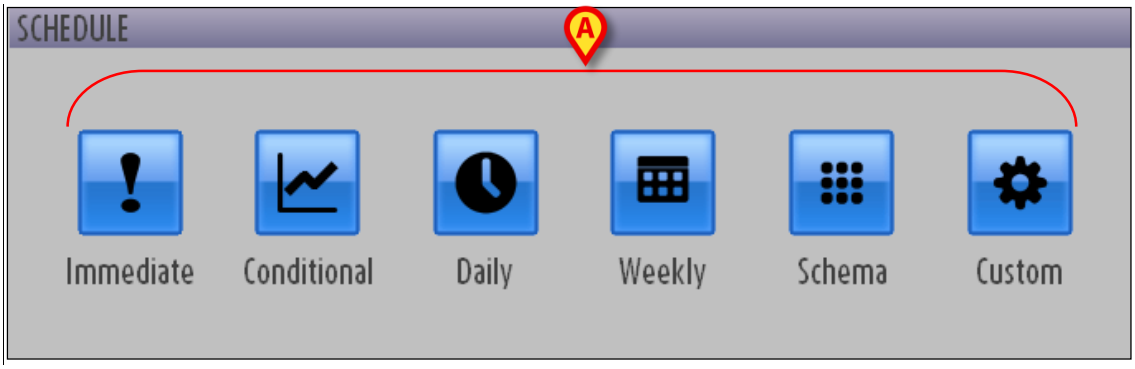


Fig 86 - “Schedule” area

These are the possible plan types:

	IMMEDIATE	The treatment prescribed must be administered immediately. See paragraph 10.2.1.
	CONDITIONAL	The treatment prescribed must be administered only under certain conditions. See paragraph 10.2.2.
	DAILY	The treatment prescribed refers to one day. See paragraph 10.2.3.

	WEEKLY	The treatment prescribed refers to one week. See paragraph 10.2.4.
	SCHEMA	Use this kind of prescription to define a schema like (for example) “administer this treatment 4 times in 3 days”. See paragraph 10.2.5.
	CUSTOM	The treatment plan is completely customized. The orders that must be generated are all explicitely stated. See paragraph 10.2.6.

10.2.1. Immediate administration prescription

“Immediate administration” means that the treatment prescribed must be administered immediately.

To prescribe an immediate administration

- click the  icon on the prescription window.

The “Schedule” area on the window will change in the way shown in Fig 87.

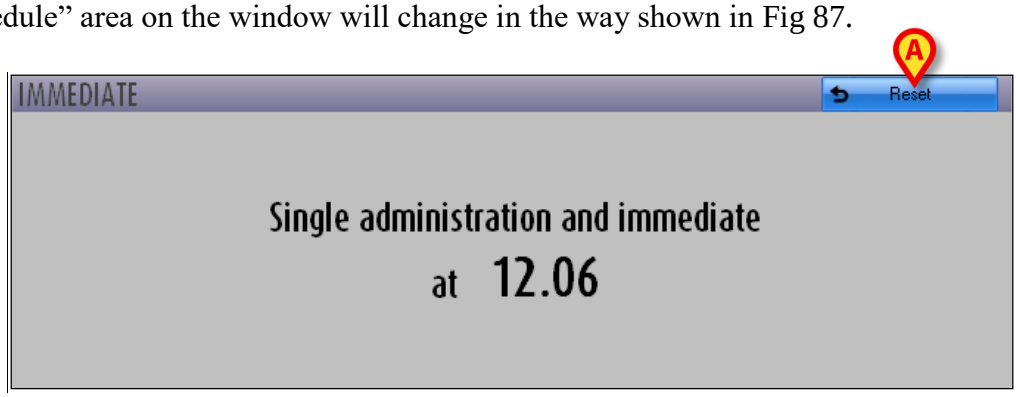


Fig 87

The window states that a single immediate administration is being ordered. The administration time (that is present time) is specified as well.

The **Reset** button on the top-right corner (Fig 87 **A**) makes it possible to go back to the selection window shown in Fig 86.

10.2.2. Conditional administration prescription

“Conditional administration” means that the treatment prescribed must be administered only under certain conditions.

To add a conditional prescription

- click the  icon on the prescription window.

The window will change in the following way

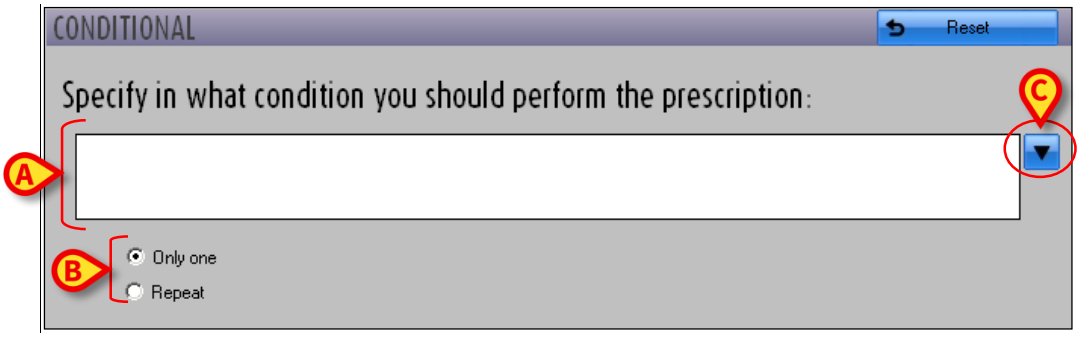


Fig 88 - Conditional prescription

- Specify in the area indicated in Fig 88 **A**, the administration condition, i.e. the condition that "triggers" the treatment administration.

Use the "radiobuttons" indicated in Fig 88 **B** to specify whether the treatment will be administered only once or it will be kept in the treatment plan to be repeated in the future.

Conditional prescriptions are characterized by "purple" color on the prescriptions table (Fig 89, paragraph 8.3).

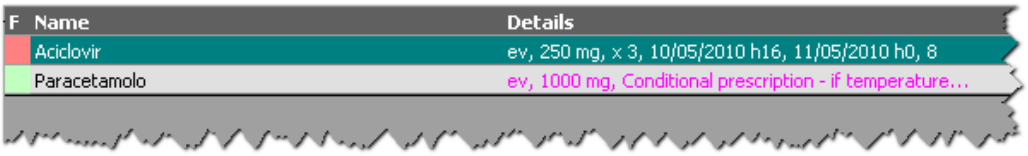


Fig 89

Conditional prescriptions are characterized by "purple" color in the corresponding boxes on the "Therapy Execution" module (Fig 90, paragraph 12.3).

Fig 90

In case you want to go back to the selection window shown in Fig 86, use the **Reset** button on the top-right corner.

10.2.2.1. Standard phrases for the condition specification

It is possible to use pre-defined “Standard phrases” to rapidly indicate the administration conditions.

To insert a “Standard phrase”

- click the  button indicated in Fig 88 **C**.

The following window opens

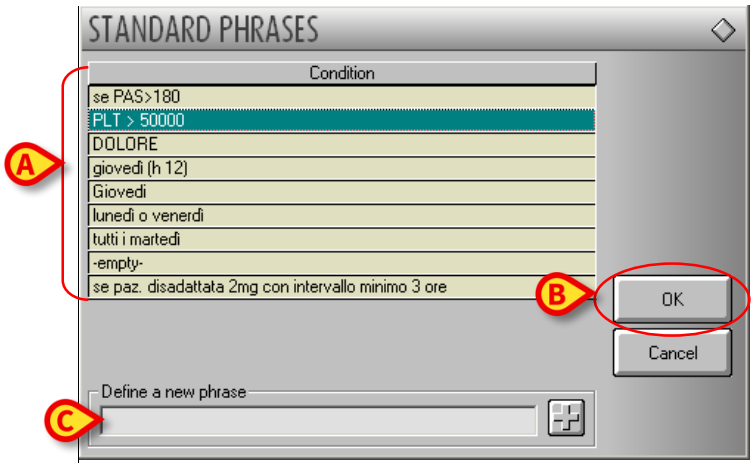


Fig 91 - Standard phrase selection

- Click the relevant phrase. The phrase is this way highlighted (Fig 91 **A**).
- Click the **Ok** button (Fig 91 **B**).

The selected phrase is inserted as condition in the prescription window (Fig 92). If necessary, the phrase can be now edited by the user.

Fig 92 - Inserted standard phrase

10.2.2.2. New standard phrase

To define a new standard phrase

- click the field indicated in Fig 91 **C**.

A cursor appears in the field.

- Type the new standard phrase (Fig 93).

Fig 93 - New standard phrase

- Click the button placed alongside the field (Fig 93 **A**).

The new phrase is this way added to those already existing (Fig 94 **A**).

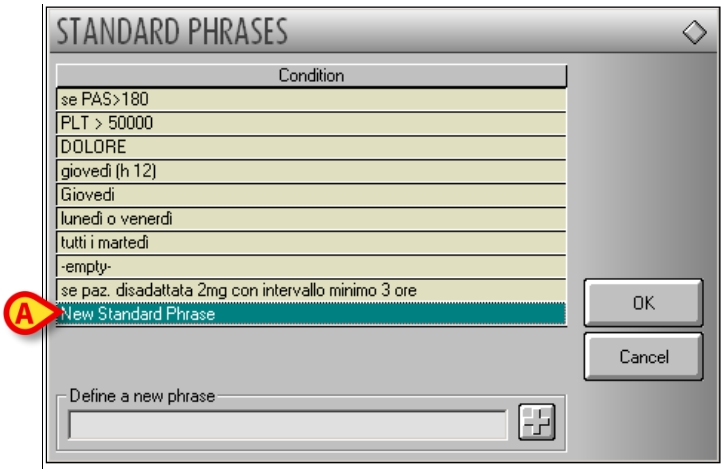


Fig 94

10.2.3. Daily treatment prescription

The prescription of a daily treatment makes it possible to generate the administration orders for one day.

To prescribe a daily treatment

- click the icon on the prescription window.

The window changes in the following way.

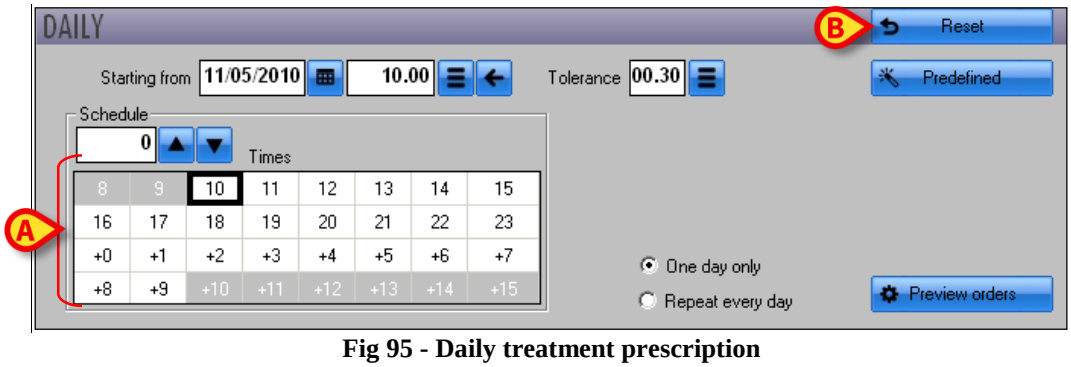


Fig 95 - Daily treatment prescription

The window shown in Fig 95 contains several tools making it possible to specify the prescription details. The next paragraphs describe these tools.
In case you need to go back to the selection window shown in Fig 86, click the **Reset** button on the top-right corner (Fig 95 **B**).

10.2.3.1. Administration time specification

Use the “plan” area (indicated in Fig 95 **A**) to specify the treatment administration times.

The table shown in Fig 96 displays the full hours of the day. Each cell corresponds to a specific hour. The first selectable cell corresponds by default to the closest full hour preceding the current time (for example, if it is 12:30 the first selectable cell is 12:00). 24 cells are selectable (corresponding to 24 hours).

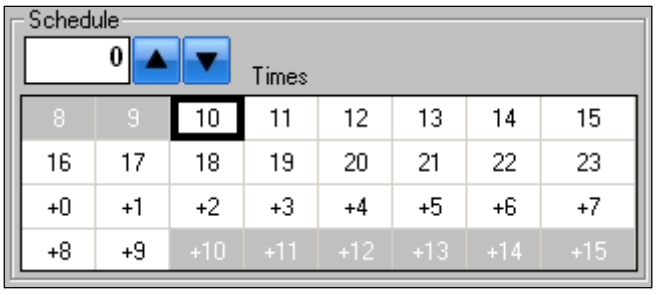


Fig 96

To select a time

- click the corresponding cell.

The selected cell is highlighted red (Fig 97).

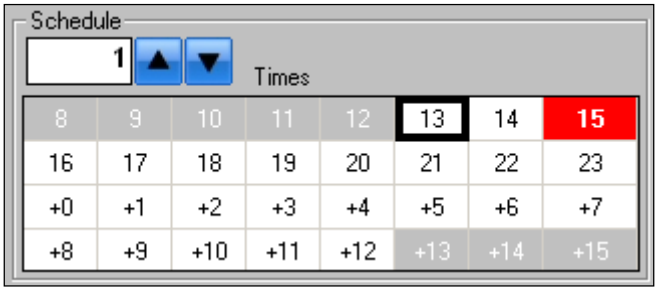


Fig 97 - One administration at 15:00

To deselect a time, click again the corresponding cell. The red cell goes back to white.

It is also possible to specify the number of daily administrations of the treatment.

To do that

- type the number of administrations in the field indicated in Fig 98 **A**.

The system automatically places the administrations at proper times.

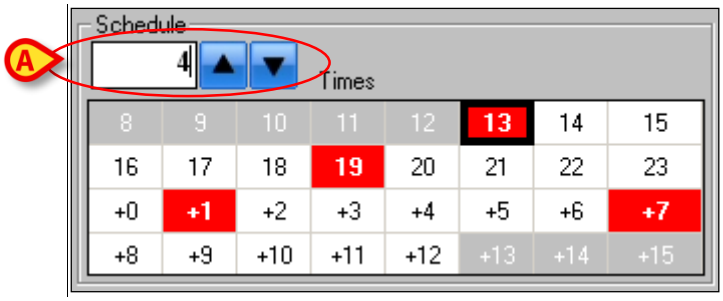


Fig 98

In Fig 98, for example, the user specified that the treatment must be administered 4 times in 24 hours. The system automatically placed the administration orders at 6 hours intervals, with the first administration set at the next selectable time (13:00 o'clock). This scheme can be edited by the user either selecting or deselecting the relevant times (click the corresponding cell to operate).

*If the user sets a time manually and, after that, makes use of the above-described functionality (i.e. he/she indicates the number of administration orders as in Fig 98 **A**), the system places the administration orders at regular intervals starting from the time specified by the user.*

*If the user sets two or more times manually and, after that, makes use of the above-described functionality (i.e. he/she indicates the number of administration orders as in Fig 98 **A**), the system places the administration orders at regular intervals starting from the first time specified by the user and ignoring the other times indicated.*

10.2.3.2. Treatment start time specification

Current day is, by default, the relevant day for the treatment specification. Current time is, by default, the treatment start time (i.e. if it is 12:30 the time indicated by default is "12:00").
It is possible to indicate a different date/time as treatment start time. Namely, it is possible to specify a treatment beginning in a future day and/or at a future time. The values indicated in Fig 99 **A** specify the treatment start time.
Dedicated tools are available to set these values.

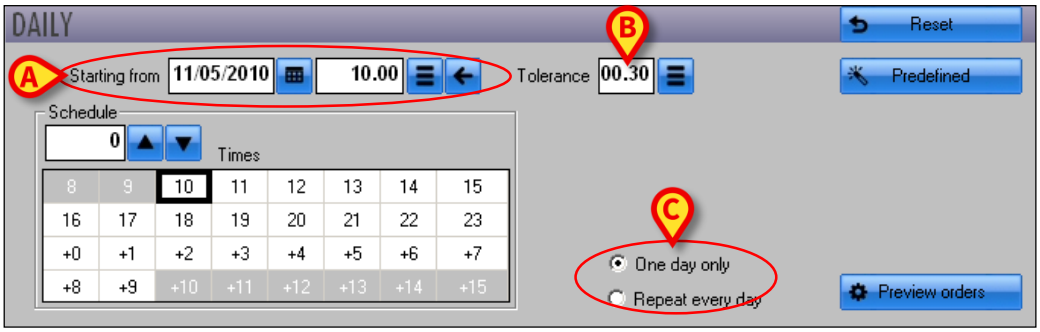


Fig 99 - Daily treatment prescription

To change the start date

- click the button placed alongside the date.

A calendar-window opens (Fig 100).

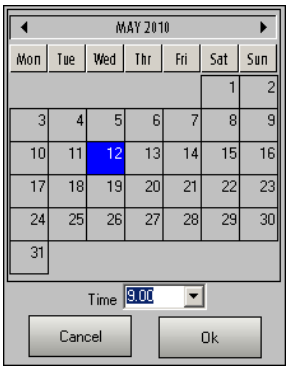


Fig 100 - Calendar

- Select the start date
- Click the **Ok** button on the calendar.

The new start date is displayed, highlighted yellow, on the prescription window.

To change the start time

- click the button placed alongside the time currently selected.

A menu containing several options appears (Fig 101).

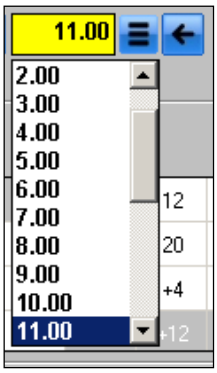


Fig 101

- Click the option corresponding to the wanted start time.

The selected start time remains, highlighted yellow, on the prescription window. The table described in paragraph 10.2.3.1 changes accordingly.

The button can be clicked to set the current time/date back.

10.2.3.3. Tolerance time specification

The "Tolerance" box highlighted in Fig 99 **B** makes it possible to set the tolerance period for the administration.

"Tolerance" is the time interval preceding and following the specified administration time within which the administration is considered "on time".

If a tolerance of 15 minutes is indicated for an administratioon prescribed for 11:00 o'clock, the administration is on time if performed from 10:45 to 11:15.

10.2.3.4. Treatment plan repeatability

The "Radiobuttons" indicated in Fig 99 **C** specify whether the administration must be administered once ("One day only" button) or it must be kept on the treatment plan for further administrations ("Repeat every day" option). See paragraph 7.3.2 for the explanation of "Prescription repeatability".

10.2.3.5. Predefined plan

The **Predefined** button indicated in Fig 102 **A**, opens a window making it possible to select a treatment plan from a list of pre-defined options.

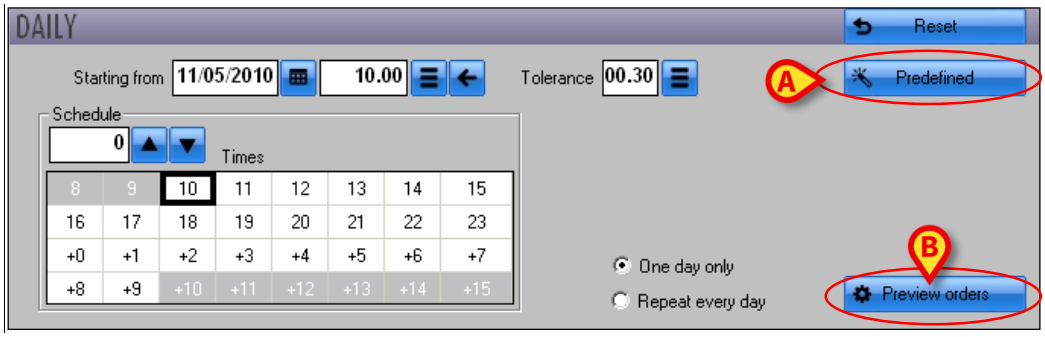


Fig 102 - Daily treatment prescription

To select a pre-defined plan

- click the **Predefined** button.

The following window opens (Fig 103).

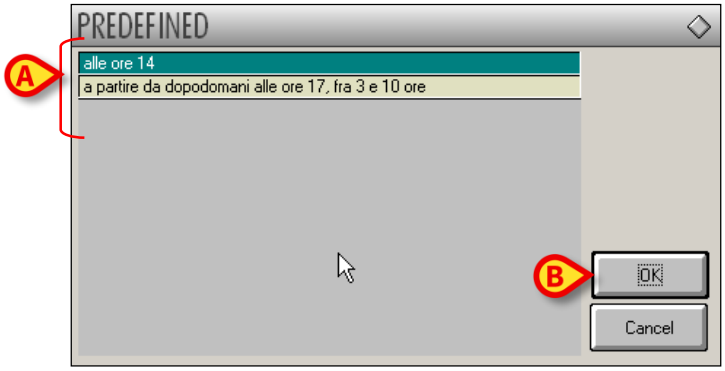


Fig 103 - Pre-defined treatment plans

- Click the option corresponding to the wanted plan (Fig 103 **A**).

The option will be highlighted.

- Click **Ok** (Fig 103 **B**).

The values on the prescription window will change accordingly.

The pre-defined treatment plans are created during configuration by the system aministrators.

10.2.3.6. Orders preview

The **Preview Orders** button indicated in Fig 102 **B** opens a window that summarizes in a list all the orders that will be generated by the treatment plan currently specified (Fig 104).

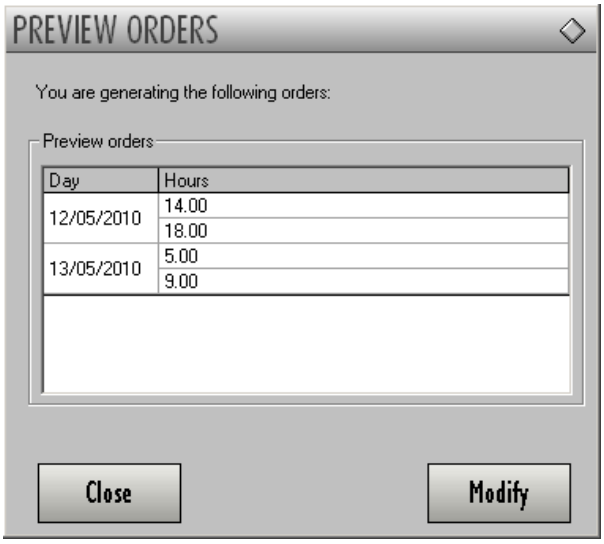


Fig 104 - Orders preview

The "Orders preview" window displays in a table all the orders that will be generated. The scheduled administration date and time are specified for each order.

In case of repeatable prescriptions the "Orders preview" window displays the orders that will be generated in the first seven days. See paragraph 7.3.2 for an explanation of the "prescription repeatability".

Use the **Close** button to close the "Orders preview" window.

Use the **Modify** button to modify the treatment plan, i.e. to add or remove orders and to change their times.

To do that

- click the **Modify** button.

A message box will be displayed, indicating that it will not be possible, after the changes, to go back to the original values (Fig 105).

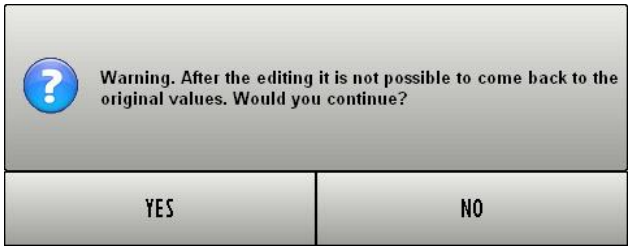


Fig 105

- Click **Yes** to proceed.

The custom prescription functionalities are this way enabled (Fig 106). These functionalities are described in paragraph 10.2.6.

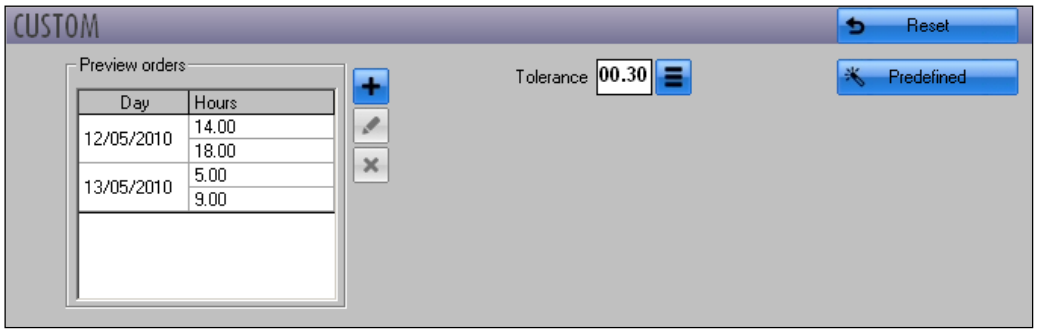


Fig 106 - Custom prescription functionalities

10.2.4. Weekly treatment prescription

Use the "weekly treatment prescription" option to specify the treatment's administration orders for one week.

To prescribe a weekly treatment

- click the  icon on the prescription window.

The window changes in the following way (Fig 107).

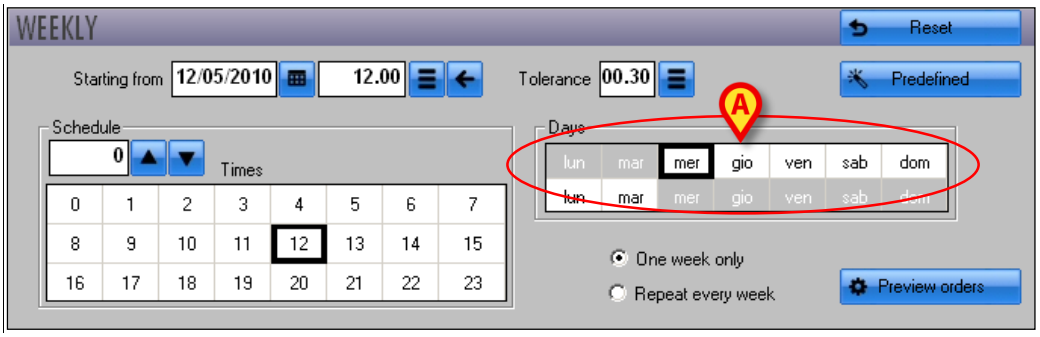


Fig 107 - Weekly plan prescription

This window contains all the options and functionalities already described for the daily prescription plan. These functionalities are explained in the following paragraphs:

- 10.2.3.1 - Prescription times specification;
- 10.2.3.2 - Treatment start time/date specification;
- 10.2.3.3 - Tolerance specification;
- 10.2.3.4 - Treatment plan repeatability (repeatability is reffered in this case to the weekly plan);
- 10.2.3.5 - Pre-defined plan selection;
- 10.2.3.6 - Orders preview.

The above-described functionalities are integrated by a window making it possible to select the administration weekdays (Fig 107 **A**).

To select a day

- click the corresponding cell.

The cell turns red (Fig 108). Click the cell again to deselect it.

Fig 108 - Days selection

When prescribing a weekly treatment plan it is necessary to specify both the administration times and the administration days.

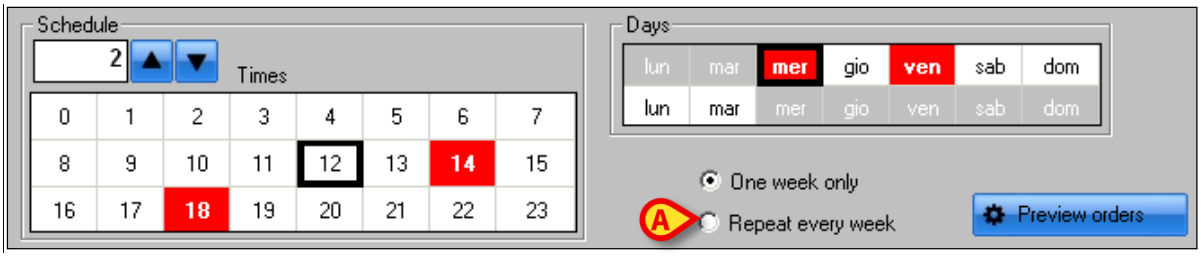


Fig 109

In Fig 109, for example, the treatment must be administered at 14:00 and at 18:00 on Wednesday and Friday. Thus 4 administration orders will be generated.

If the treatment is repeatable (by selecting the "radiobutton" indicated in Fig 109 **A** - "Repeat every week") the system generates every week 4 administration orders at 14:00 and 18:00 on Wednesdays and Fridays.

10.2.5. Treatment prescription schema

Use the "Treatment prescription schema" option to specify a prescription like the following: "Administer this treatment N times in N days (4 times in 3 days, for instance)". The system

calculates the appropriate time intervals and places the administration orders starting from the time indicated in the “Starting from” field.

To use this option

- click the  icon on the prescription window.

The window changes in the following way (Fig 110).

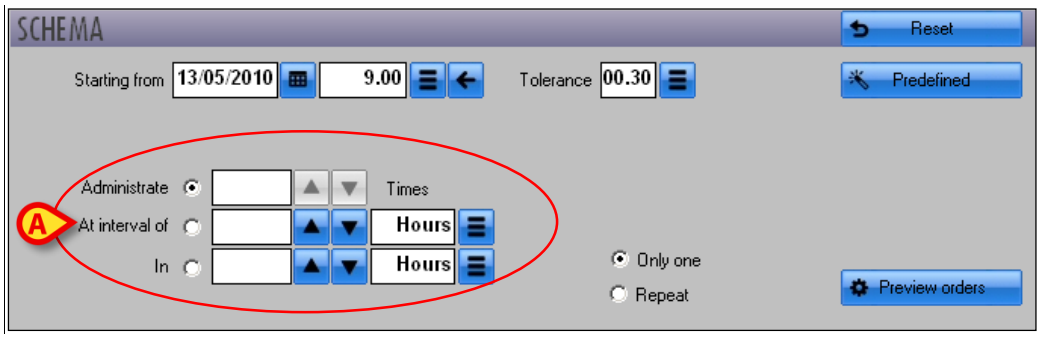


Fig 110 - Dictionary

Some of the functionalities described regarding the daily and weekly treatment plan prescriptions are here maintained. See the paragraphs indicated below for these functionalities:

- 10.2.3.2 - Treatment start time/date specification;
- 10.2.3.3 - Tolerance specification;
- 10.2.3.4 - Treatment plan repeatability (repeatability is referred in this case to the specified schema);
- 10.2.3.5 - Pre-defined plan selection;
- 10.2.3.6 - Orders preview.

Use the tools highlighted in Fig 110 **A** and Fig 111 to define the schema.

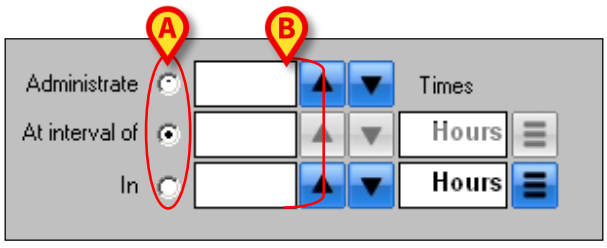


Fig 111

To define a schema,

- use the “radiobuttons” indicated in Fig 111 **A** to select the appropriate option for the wanted schema.

The “Administer” option makes it possible to specify the treatment’s period (every how much time) and duration (in how much time). The system automatically calculates the number of administrations. For example: if the user indicates that a treatment must be administered every 3

hours in 8 hours the system calculates 3 administrations (one now, one after 3 hours, one after 6 hours).

The “Intervals” option makes it possible to specify the number of administrations and the treatment’s duration (in how much time). The system automatically calculates the treatment’s period (every how much time the orders must be administered). For example: if the user indicates that a treatment must be administered 3 times in 8 hours the system calculates a 2,7 hours period.

The “In” option makes it possible to specify the number of administrations and the treatment’s period (every how much time). The system automatically calculates the treatment’s duration (in how much time the orders must be administered). For example: if the user indicates that a treatment must be administered 3 times every 2 hours the system calculates a 6 hours duration.

- Specify the relevant values in the fields indicated in Fig 111 **B**.

Use the  button indicated in Fig 112 **A** to specify the schema’s unit of measure (hours, days, minutes). The system automatically turns the specified value into the appropriate unit of measure (more than 119 minutes is turned to hours, more than 47 hours is turned to days).

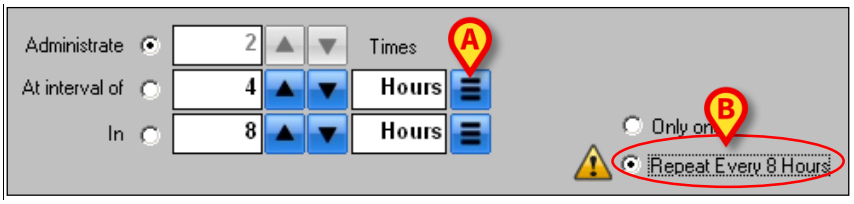


Fig 112

Select the option indicated in Fig 112 **B** to specify a repeatable schema. The repeatability period is the schema duration. In the example shown in the figure the schema is repeated every 8 hours. See paragraph 7.3.2 for a description of repeatable treatments.

10.2.6. Custom treatment plan prescription

It is possible to prescribe a treatment plan that is completely decided by the user. In these cases the orders are all explicitely specified, one by one.

To prescribe a custom treatment plan

- click the  icon on the prescription window.

The window changes in the following way (Fig 113).

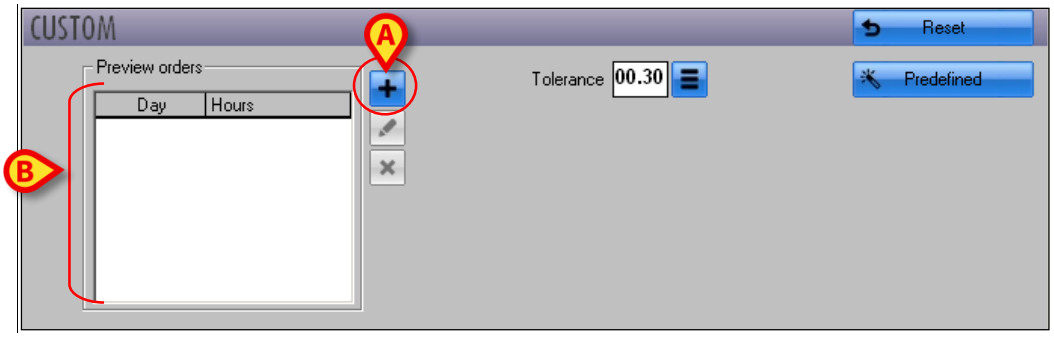


Fig 113 - Custom treatment plan specification

- Click the  button indicated Fig 113 **A**.

A window making it possible to specify the treatment date and time opens (Fig 114). Current date and time are set by default.

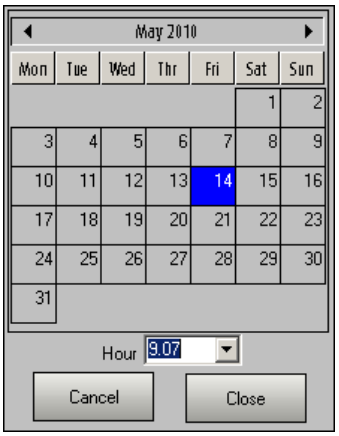


Fig 114

- Specify the order's date and time.
- Click the **Close** button.

A row will be added to the "Orders preview" table (Fig 115, Fig 113 **B**). The row indicates the treatment's date and time.

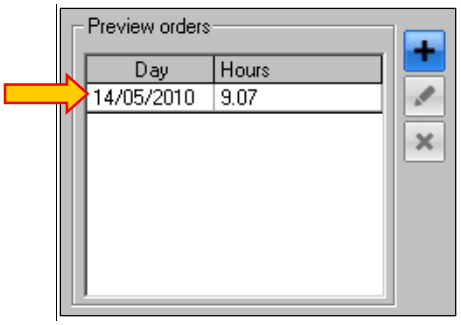


Fig 115

10.2.6.1. Editing the order values

To edit the values of an order

- click the row corresponding to the order that must be edited (click it on the cell displaying the time).

The row is highlighted (Fig 116 **A**). The buttons indicated in Fig 116 **B** are active.

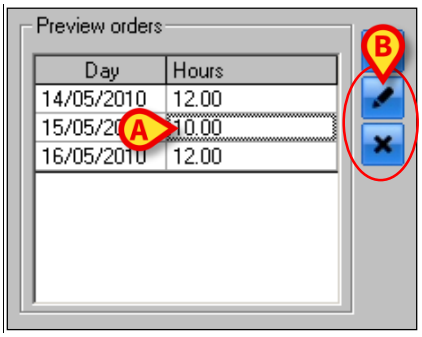


Fig 116

- Click the  button.

A calendar window appears, displaying the values of the selected order (date and time).

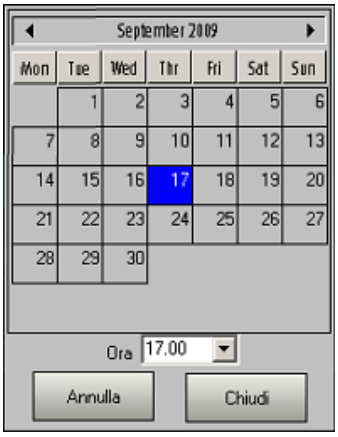


Fig 117

- Edit the order values.
- Click the **Close** button.

The order's values are this way changed.

10.2.6.2. How to delete an order

To delete one of the specified orders,

- click the row corresponding to the order that must be deleted (click the cell displaying the time).

The row is highlighted (Fig 116 **A**). The buttons indicated in Fig 116 **B** are active.

- Click the  button. The order is this way deleted.

10.2.6.3. Other options on the custom prescription window

Some of the functionalities that have been described before relating the daily and weekly treatment plan prescriptions are here maintained. See the paragraphs indicated below for these functionalities:

- 10.2.3.3 - Tolerance specification;
- 10.2.3.5 - Pre-defined plan selection;

10.3. The “Notes” area

The “Notes” area on the prescription specification window (Fig 118 **A**) makes it possible to:

1) add a note to the prescription;
2) read about the past prescriptios of the same treatment.

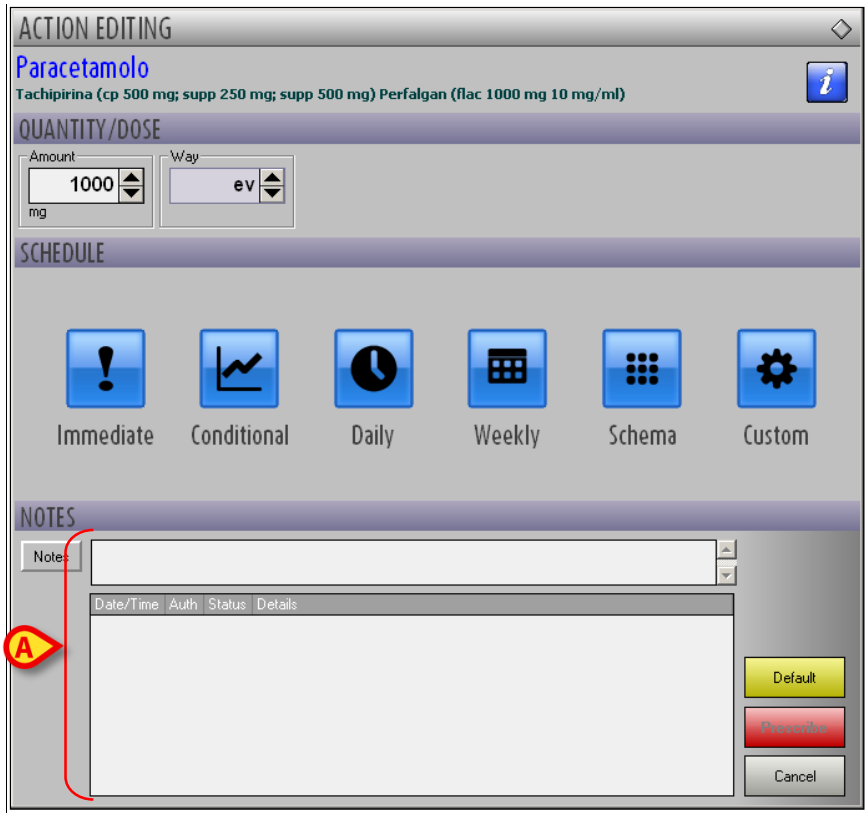


Fig 118 - Notes area

10.3.1. How to add a note

To add a note

- click the “Notes” field (Fig 119 **A**).

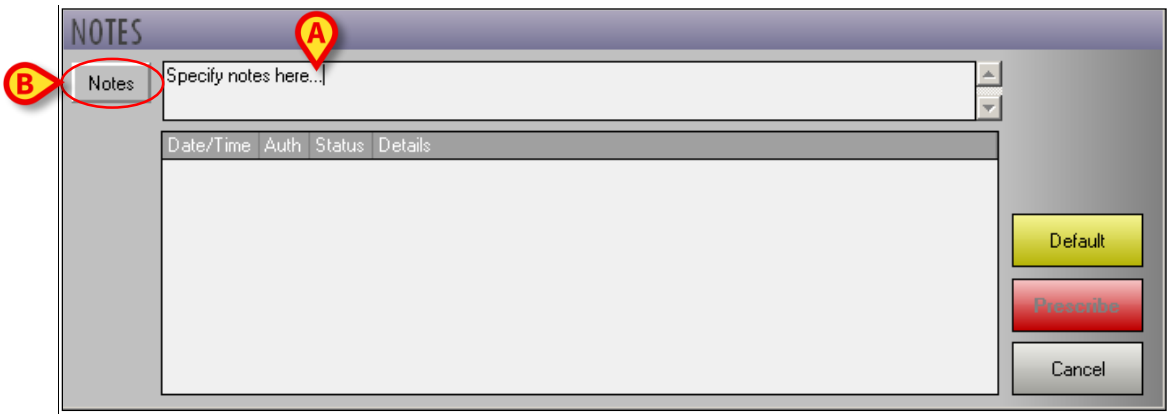


Fig 119

- Specify the note.

The notes are visible on the prescribed treatments table when the **Show Notes** button is selected on the command bar (see Fig 153, paragraph 11.6).

The notes added using these functionalities are referred to the treatment prescription, not to the patient. The patient notes are specified through the procedure described in paragraph 11.11.

10.3.1.1. Standard phrases for notes specification

Pre-defined “Standard phrases” can be used to speed-up the notes specification.

To add a standard phrase

- click the **Notes** button (Fig 119 **B**).

The following window opens (Fig 120).

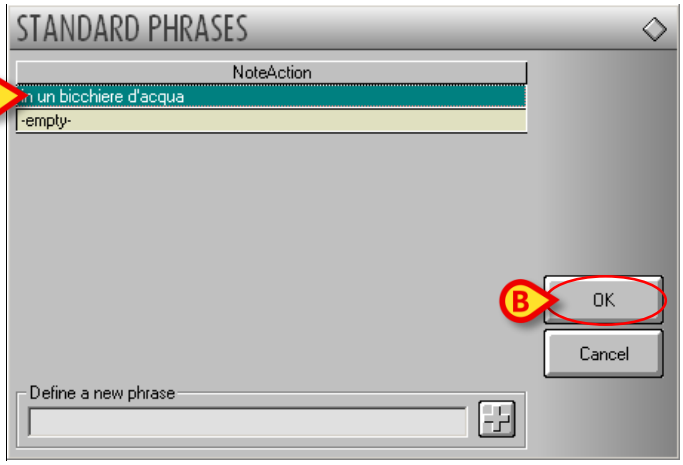


Fig 120 - Standard Phrases

The window shown in the figure contains the list of all the pre-defined phrases.

- Click the wanted phrase.

The phrase is highlighted (Fig 120 **A**).

- Click the **Ok** button (Fig 120 **B**).

The phrase is displayed in the "Notes" field.

It is possible for an authorized user to add a new standard phrase to the existing list.

To define a new phrase

- click the **Notes** button (Fig 119 **B**).

The "Standard phrases" window opens (Fig 121).

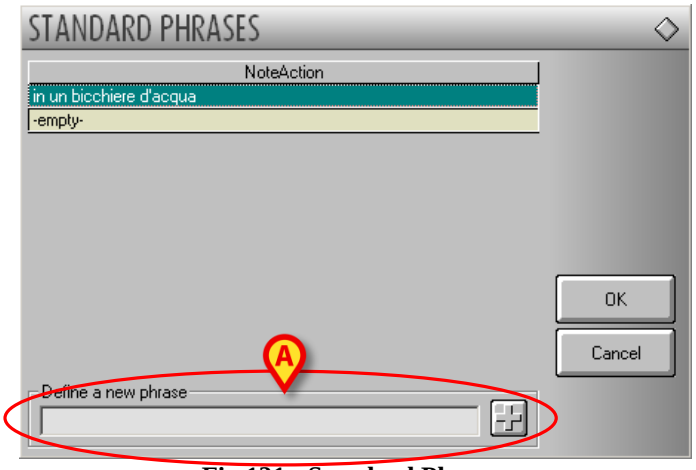


Fig 121 - Standard Phrases

- Click the "Define a new phrase" field (Fig 121 **A**).
- Type the new standard phrase (Fig 122 **A**).

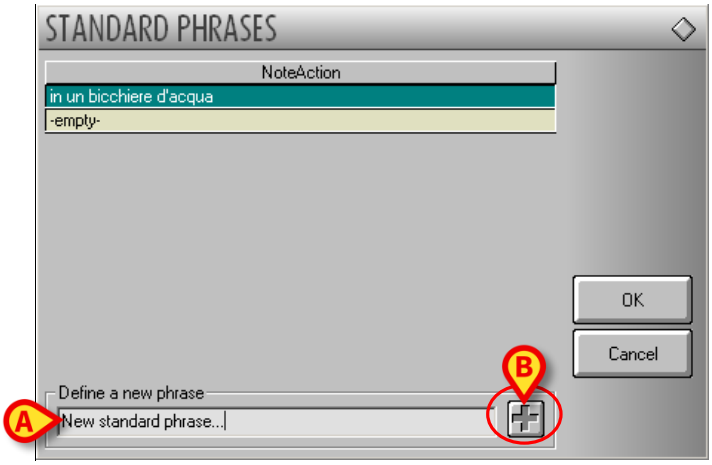


Fig 122 - New standard phrase

- Click the  button placed alongside the field (Fig 122 **B**).

The new phrase is this way added to the standard phrases list (Fig 123) and will be available in the future.

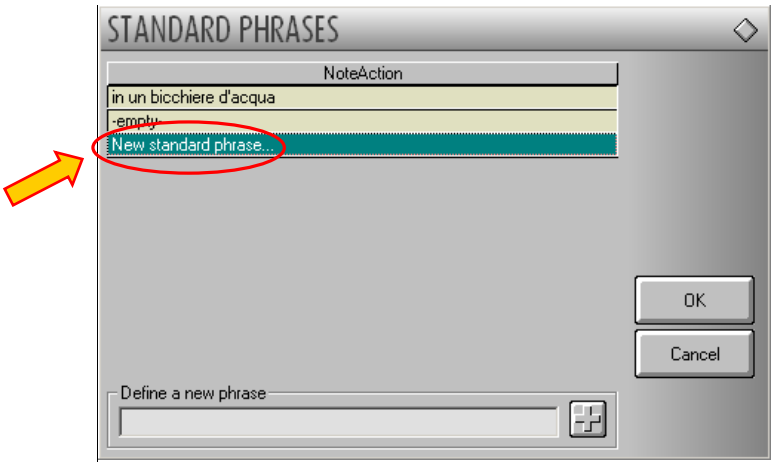


Fig 123

The phrase can be inserted in the "Notes" field (Fig 124) using the procedure described in paragraph 10.3.1.

Fig 124

10.3.2. Treatment history

The history area (Fig 125 **A**) displays a table containing the main information on the previous orders that were generated for that treatment.

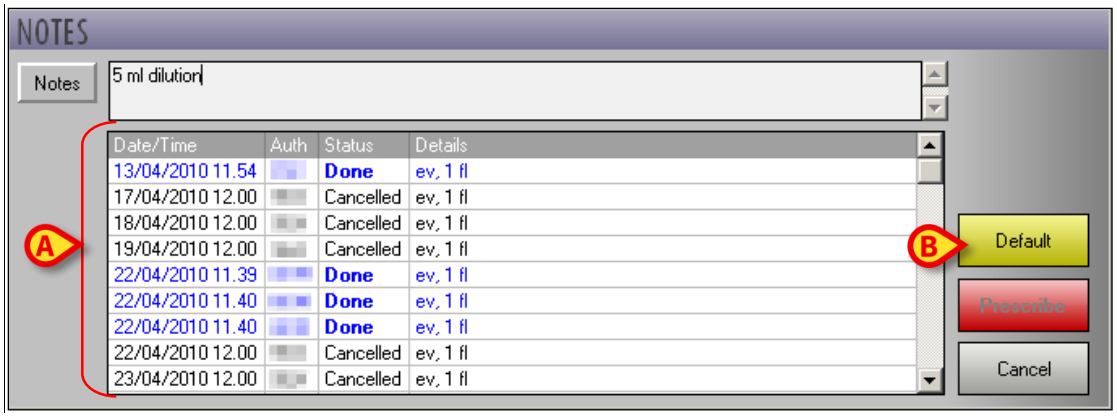


Fig 125 - Treatment history

In the table each row corresponds to an action referred to a certain order.

For each action the following information is provided:

- action date and time;
- acronym of the user who prformed the action;
- kind of action performed;
- action details.

10.3.2.1. How to restore the prescription default values

If, after editing the prescription values, it is necessary to restore the prescription default values,

- click the **Predefinito** button on the "Notes" area, indicated in Fig 125 **B**.

All the changes will be lost; the prescription default values will be restored.

10.3.3. Prescription window configurability

Virtually any kind of action can be added to the actions list, with its specific features (values, parameters, default values etc…).

The treatment specification window changes accordingly. Thus changes the way the treatment specification window looks like.

The look and functionalities of the prescription specification window depend on the kind of treatment specified.

Refer to the system administrators for the treatments configuration.

11. The command bar

The command bar of the "Therapy Prescription" module (Fig 60 **D**, Fig 126) is formed by several function-buttons.

Fig 126 - Command bar

Each button gives access to a specific functionality. This paragraph describes the functionalities activated by each button.

11.1. Treatment plan update

To understand this paragraph - 11.1 - and the following one - 11.1.1 - it is necessary a good understanding of the basic concepts explained in paragraph 7.3.

The treatment plan update procedure makes it possible to

a) validate the orders that are within the "Therapy cycle" that have not yet been validated (the "Therapy cycle" is explained in paragraph 7.3.4);
b) generate the not-yet-generated orders within 7 days after validation;
c) delete the orders that must be deleted.

To update the treatment plan

- click the UPDATE button on the command bar (Fig 127).

Fig 127 - Command bar

The following window opens (Fig 128).

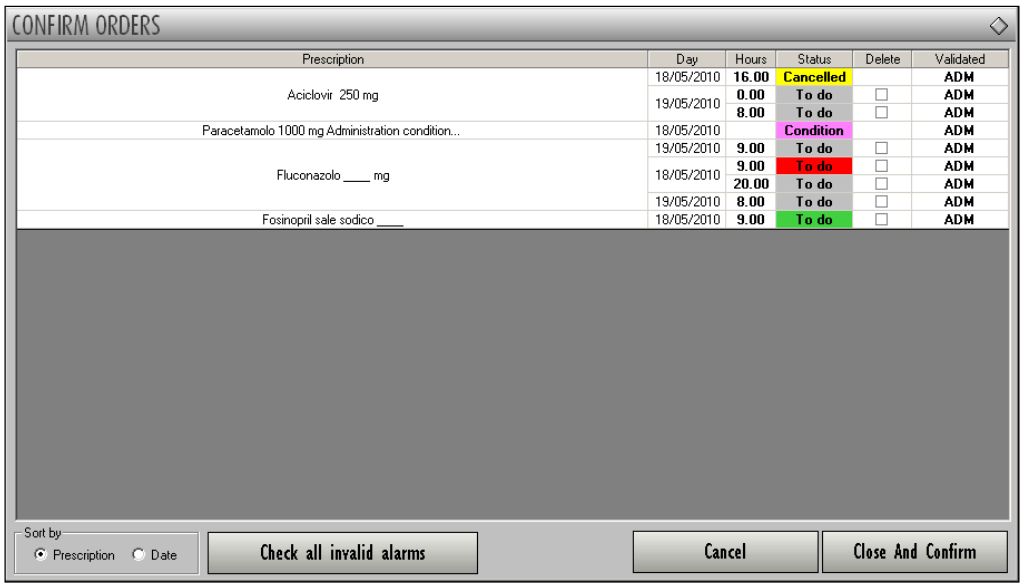


Fig 128 - Orders confirmation

The "Orders confirmation" window displays in a table all the orders that are within the "Therapy cycle" and the past orders that have not been administered yet. This window is described in paragraph 11.1.1.

- Click the **Chiudi e Conferma** button.

The window closes. A print report is created, containing the list of the orders to be administered. The printed list contains all the not-yet-administered orders that are within the Therapy Cycle. The print preview is displayed (Fig 129).

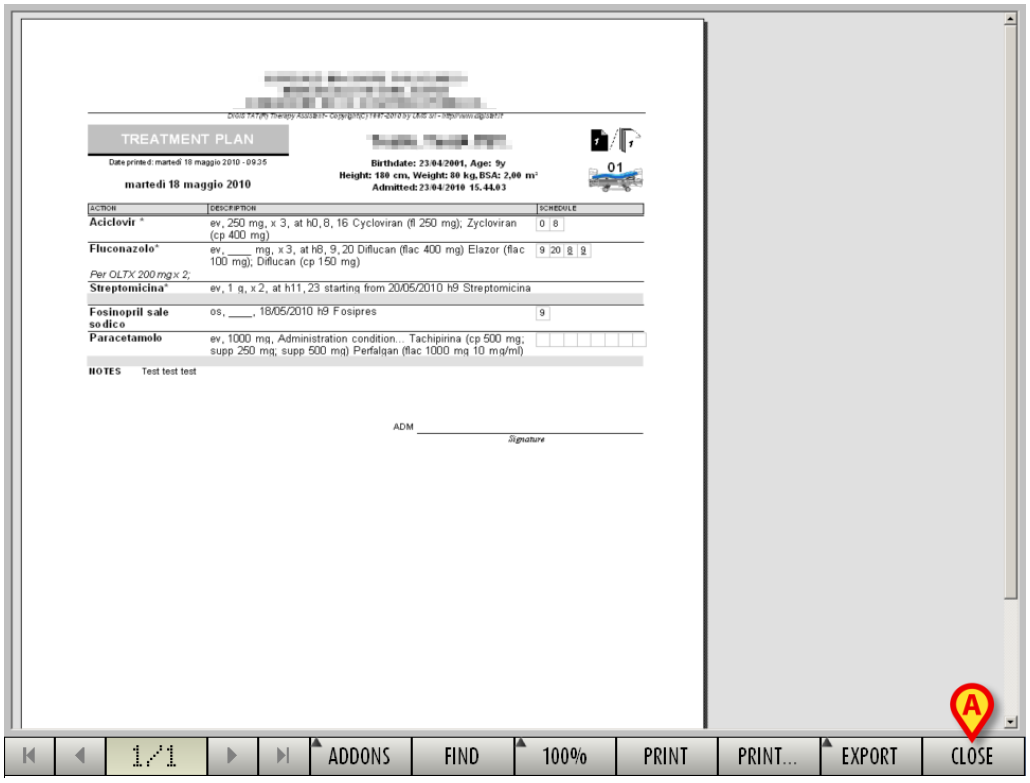


Fig 129 - Orders list print preview

See paragraph 6.8.1 for the system's print functionalities.

➢ Click **Close** to close the preview (Fig 129 **A**).

The treatment plan is this way updated. The time counter is reset to zero on the treatment plan validity indicators.

11.1.1. Orders confirmation window description

The "Orders confirmation" window (Fig 130) is displayed when the **Update** button on the command bar is clicked.
The window displays in a table all the orders that are within the "Therapy cycle" and the past orders that have not been administered yet.

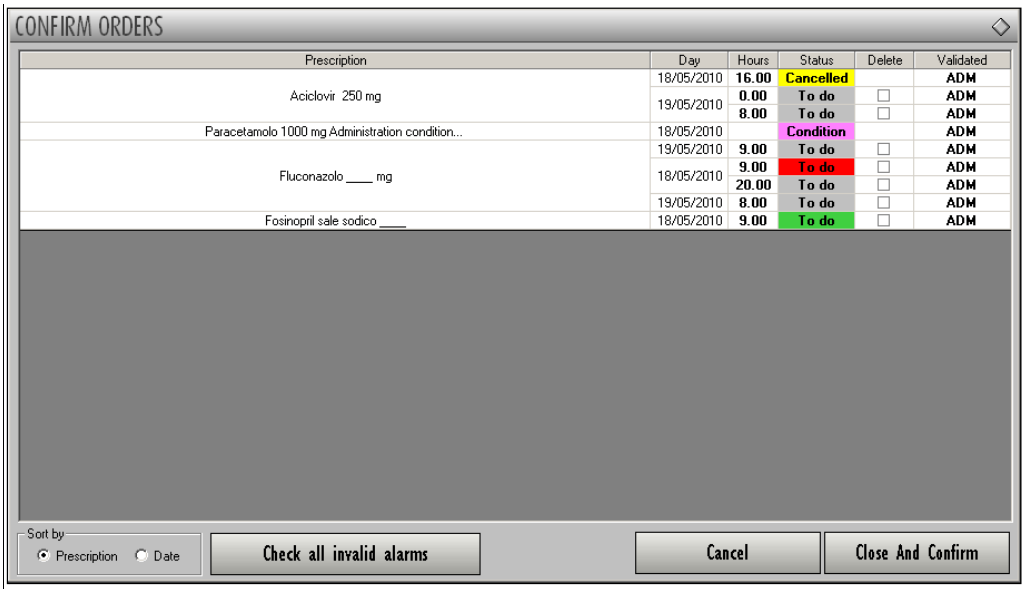


Fig 130 - Orders confirmation

Each row on the table corresponds to an order. For each order the following information is provided:

- prescribed treatment name (Fig 131 **A**);
- prescribed administration date (Fig 131 **B**);
- prescribed administration time (Fig 131 **C**);
- order status (Fig 131 **D**);
- order deletion checkbox (Fig 131 **E**);
- validation indication (Fig 131 **F**).

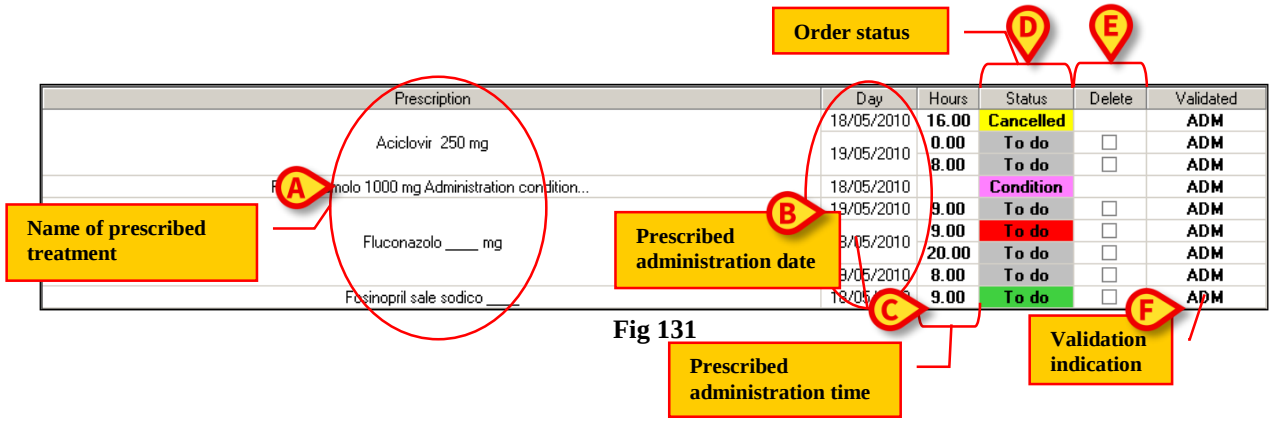


Fig 131

Treatment name (Fig 131 B)

The name indicated in this area can refer to several adjacent rows on the table. Each row corresponds to a single administration order.

Date (Fig 131 C)

The planned administration date of the correponding order is specified on each row.

Times (Fig 131 D)

The planned administration time of the correponding order is specified on each row.

Checkbox (Fig 131 E)

On the second last column there is a deletion checkbox. If the box is selected (Fig 132) it means that the corresponding order will be deleted.

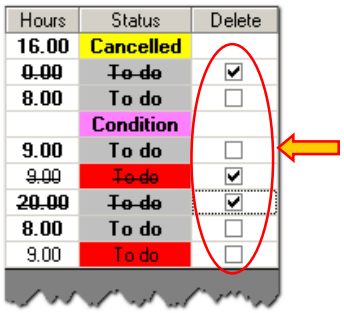


Fig 132 - Deletion checkboxes

The order selected for deletion is written in strike-through characters on the “Hours” and “Status” columns.

Status (Fig 131 F)

The order status is specified on each row. The status of an order can be:

- To do
- Done
- Cancelled
- Condition

The “status” cell is highlighted in specific colours. The colour provides additional information on the order.

- Grey - future orders
- Green - ready for the administration
- Red - the administration is late (alarm)
- Blue - durative administration is in progress
- Purple - conditional order
- Yellow - deleted

See Fig 133 for an example.

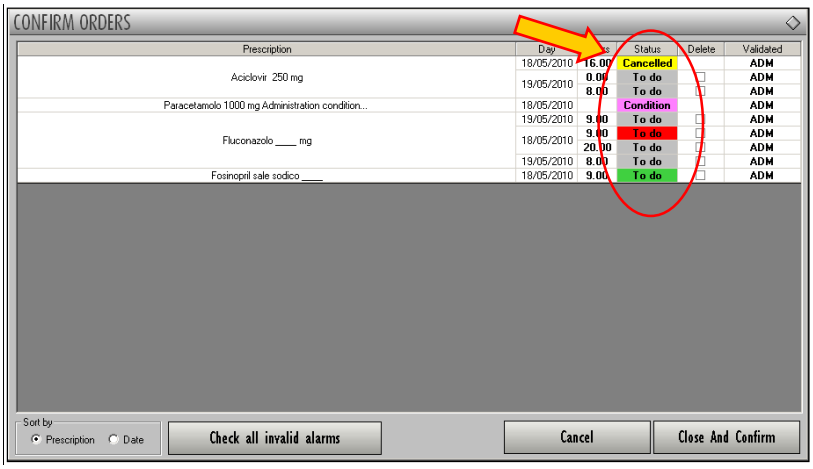


Fig 133

Further information is provided by the characters used:

- strike-through characters mean that the corresponding order is selected for deletion;
- bold character means that the order is within the "Therapy cycle";
- plain character means that the order is outside the "Therapy cycle" in the past.

Validation indications (Fig 131 F)

The last column on the right ("Validated" column) displays information relating to the order validation.

When the cell contains the user acronym (ADM in Fig 133) it means that the order has been validated. If the user acronym is in bold characters it means that the currently logged user is validating the order with the current validation procedure. If the user acronym is not in bold characters it means that the order was validated in the past by the user whose acronym is specified in the cell.

If the cell does not display the user acronym it means that the order is not valid anymore (validation expired) and it cannot be validated again.

Orders list display mode

The orders can be listed either by date or by prescription.

To change the display mode

- click the wanted option on the bottom-left corner of the window (Fig 134).

Fig 134

The "Prescription" option groups the orders of the same prescription all together. The various prescriptions are displayed in alphabetical order (Fig 135a)

The “Date” option groups together, in chronological order, all the orders that must be executed on the same day (Fig 135b).

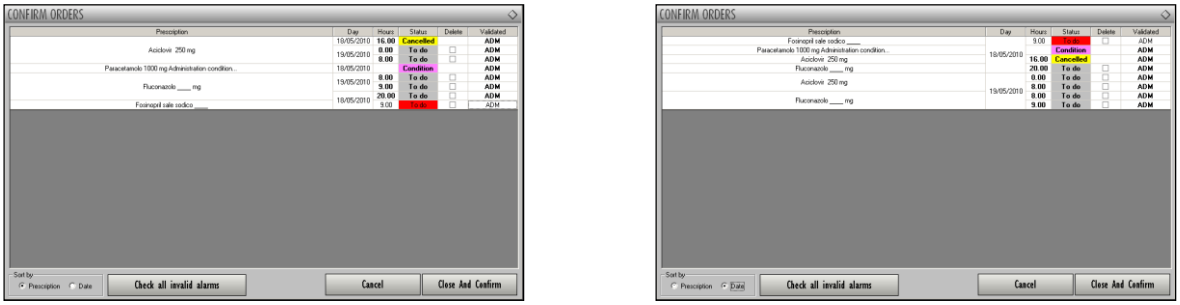


Fig 135 a/b - By prescription (left)/By date (right)

Quick selection of the alarmed non-valid orders

The **Check all invalid alarms** button on the window selects for deletion all the orders that are not valid and are alarmed (i.e. they should have been administered in the past). It is this way possible to quickly delete these orders. The orders are deleted, after “delete” checkbox selection, when the **Close and Confirm** button is clicked.

11.2. Editing the values of an existing prescription

To edit the values of an existing prescription

- click, on the prescriptions table, the name of the prescription whose values must be edited.

The corresponding row is highlighted (Fig 136 **A**).

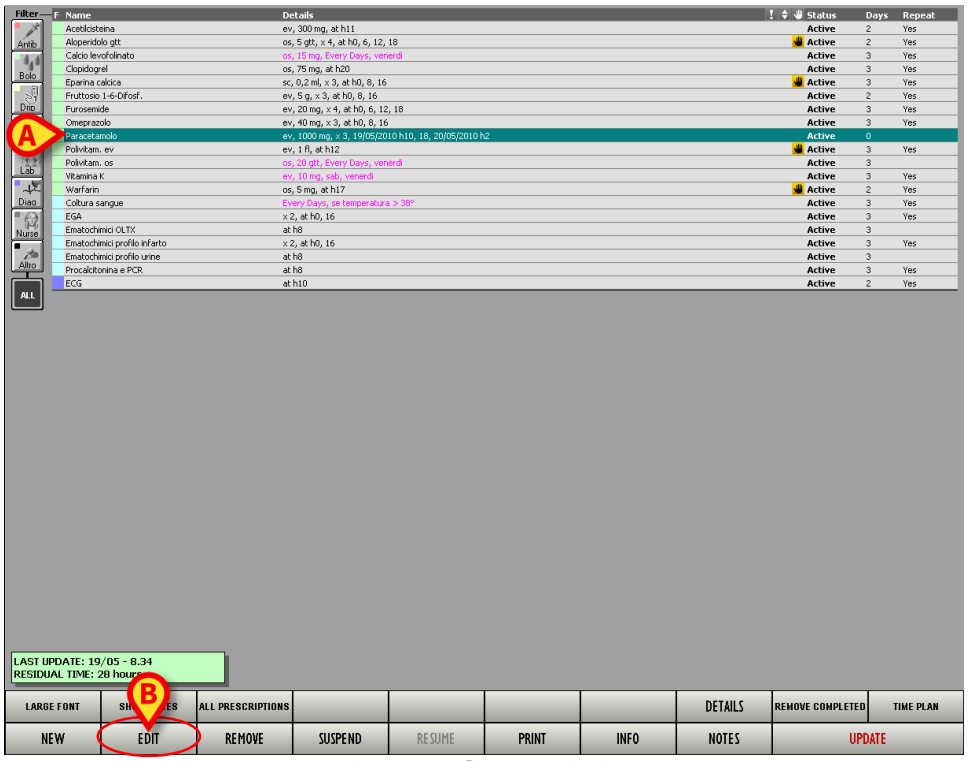


Fig 136 - Edit prescription

- Click the **Edit** button on the command bar (Fig 136 **B**).

The "Treatment specification" window, described in paragraph 10, opens. The window refers to the selected prescription.

The window also appears double-clicking the prescription row.

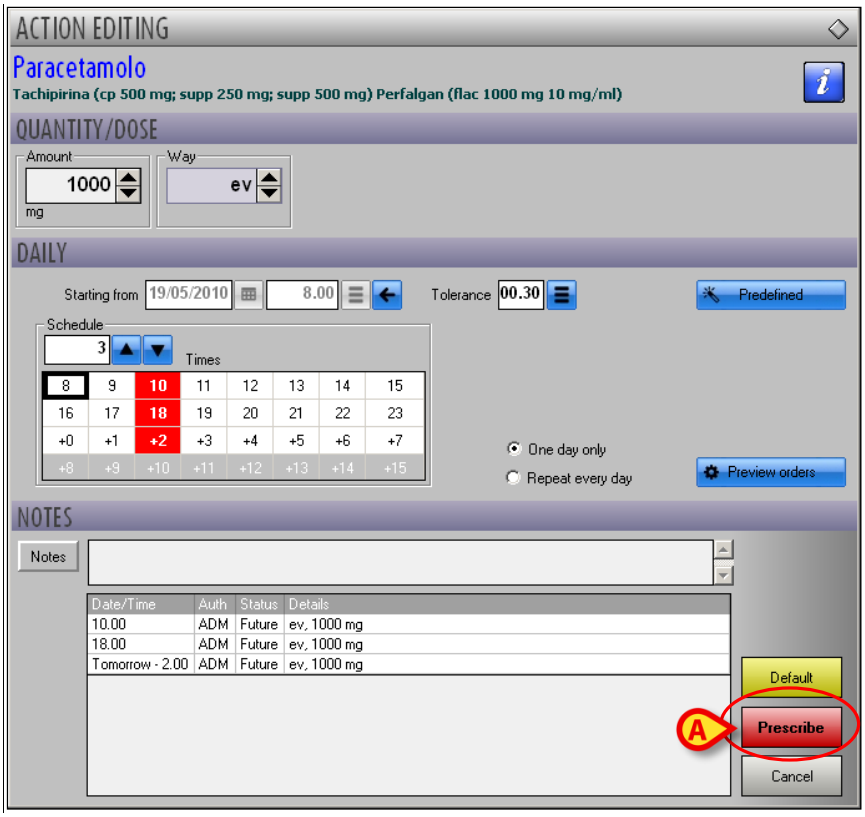


Fig 137 - Action editing

- Edit the prescription values.
- Click the **Prescribe** button (Fig 137 **A**).

A specific pop-up message (Fig 138) asks the user to double-check that the possible active orders in "ready" status (green colour on the "Execution" module) have not been already administered.

WARNING!

The prescription editing implies the deletion of all the orders possibly generated before the editing and the generation of a set of new orders according the new values.

Double check that the "former" orders have not been already administered.

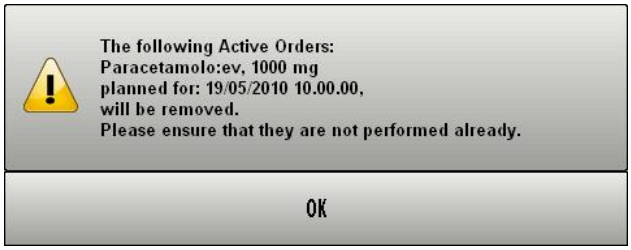


Fig 138

- Click **Ok** to complete the procedure.

11.3. Remove prescription

To remove a prescription from the patient treatment plan

- click, on the prescription table, the row corresponding to the precription that must be removed.

The row is highlighted (Fig 139 **A**).

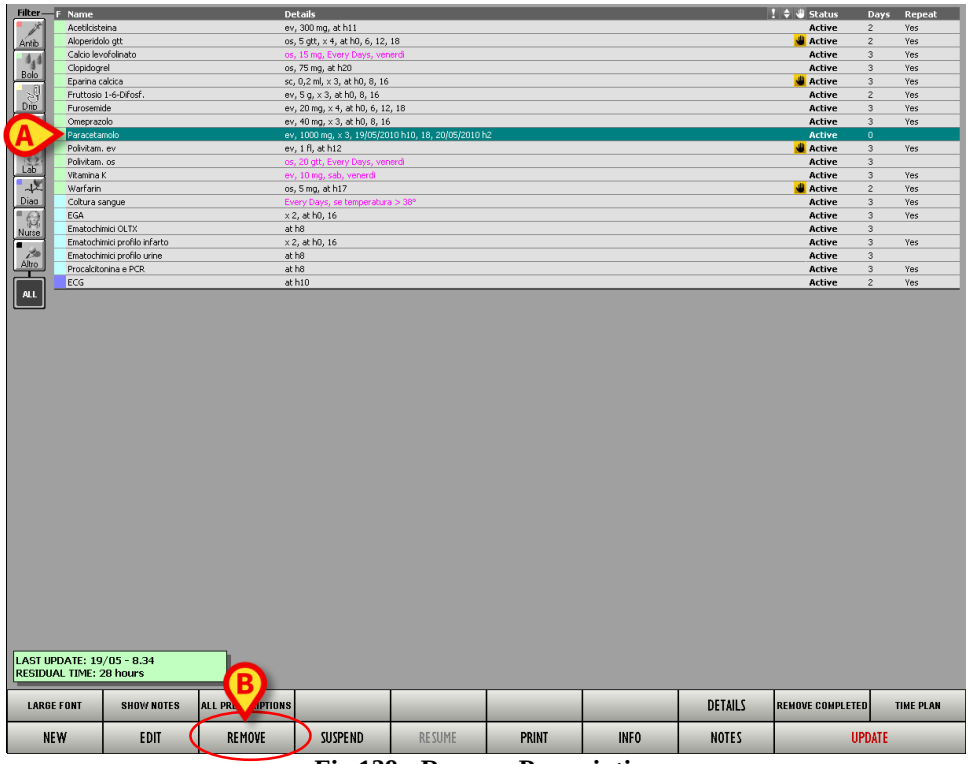


Fig 139 - Remove Prescription

- Click the **Remove** button on the command bar (Fig 139 **B**).

A confirmation is required by the following pop up window.

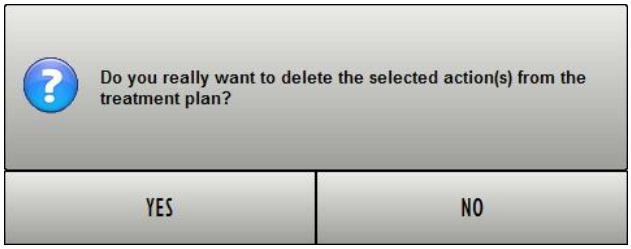


Fig 140 - Confirm removal

- Click **Yes** to confirm.

The selected row disappears from the prescriptions table.

A specific pop up message (Fig 141) asks the user to double-check that the possible active orders in "ready" status (green colour on the "Execution" module) have not been already administered.

WARNING!

The removal of a prescription causes the removal of all the orders generated by the prescription itself.

Double check that these orders have not been already administered.

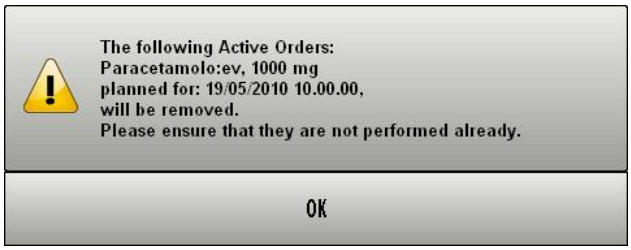


Fig 141

- Click **Ok** to complete the procedure.

The removed prescriptions turn to "Terminated" status. They are still visibile in "All prescriptions" mode (see paragraph 11.7). When the prescription table is displayed in "All prescriptions" mode the removed prescriptions are labelled by the - Terminated - flag appearing in the "Status" cell (Fig 142 **A**).

Fig 142 - Terminated prescription

A removed prescription cannot be resumed.

The deletion of a prescription corresponding to a durative action which is currently running does not automatically stop the corresponding action. It instead generates a new order whose corresponding action must be manually performed on the "Execution" module.

For example: if a prescription corresponding to an infusion currently running is stopped, the corresponding box on the "Execution" module turns back to green colour. This happens to let the nursing staff know that there is a new order to be executed (the action "Removal", in this case). See chapter 12 for a description of the procedures related to the "Therapy Execution" module.

11.4. Suspend prescription

To suspend a prescription

- click, on the prescriptions table, the row corresponding to the prescription to be suspended.

The clicked row is highlighted (Fig 143 **A**).

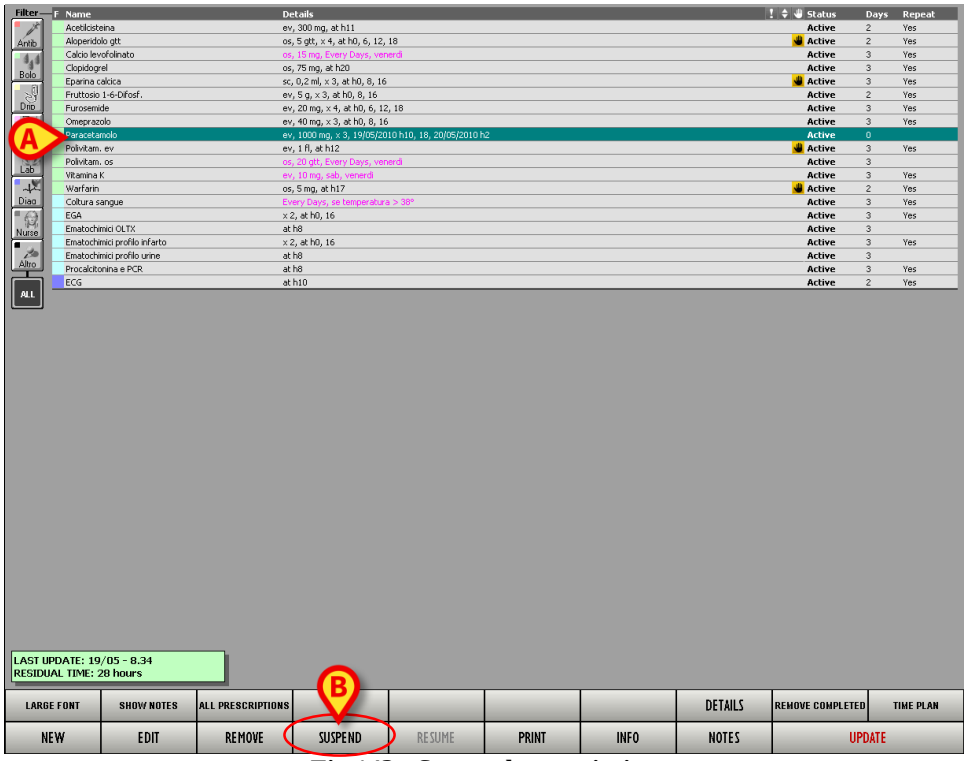


Fig 143 - Suspend prescription

- Click the **Suspend** button on the command bar (Fig 143 **B**).

The system requests a confirmation with the following pop up window.

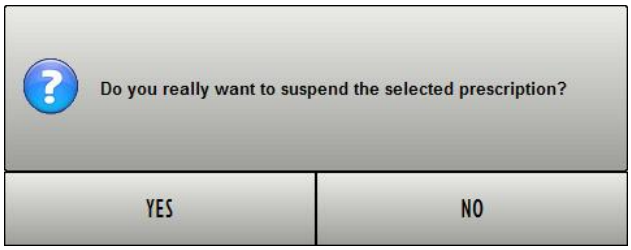


Fig 144 - Confirm suspension

- Click **Yes** to confirm.

The selected row disappears from the prescriptions table.

A specific pop up message (Fig 145) asks the user to double-check that the possible active orders in "ready" status (green colour on the "Execution" module) have not been already administered.

WARNING!

The suspension of a prescription causes the removal of all the orders generated by the prescription itself.

Double check that these orders have not been already administered.

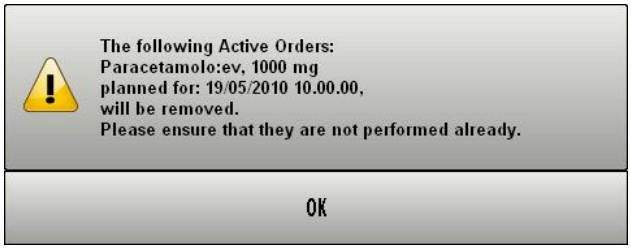


Fig 145

- Click **Ok** to complete the procedure.

The suspended prescriptions turn to "Suspended" status are still visibile in "All prescriptions" mode (see paragraph 11.7). When the prescription table is displayed in "All prescriptions" mode the suspended prescriptions are labelled by the - Suspended - flag appearing in the "Status" cell (Fig 146 **A**).

Fig 146 - Suspended prescription

The suspension of a prescription corresponding to a durative action which is currently running does not automatically stop the corresponding action. It instead generates a new order whose corresponding action must be manually performed on the "Execution" module.

For example: if a prescription corresponding to an infusion currently running is suspended, the corresponding box on the "Execution" module turns back to green colour. This happens to let the nursing staff know that there is a new order to be executed (the action "Removal", in this case). See chapter 12 for a description of the procedures related to the "Therapy Execution" module.

11.4.1. How to resume a suspended prescription

The suspended prescriptions are visibile when the prescription table is displayed in "All prescriptions" mode (see paragraph 11.7).

To display the prescriptions table in "All prescriptions" mode

- click the **All Prescriptions** button on the command bar (Fig 147 **A**). The button is this way selected.

The prescriptions table displays all the prescriptions: the active, the suspended and the removed ones.

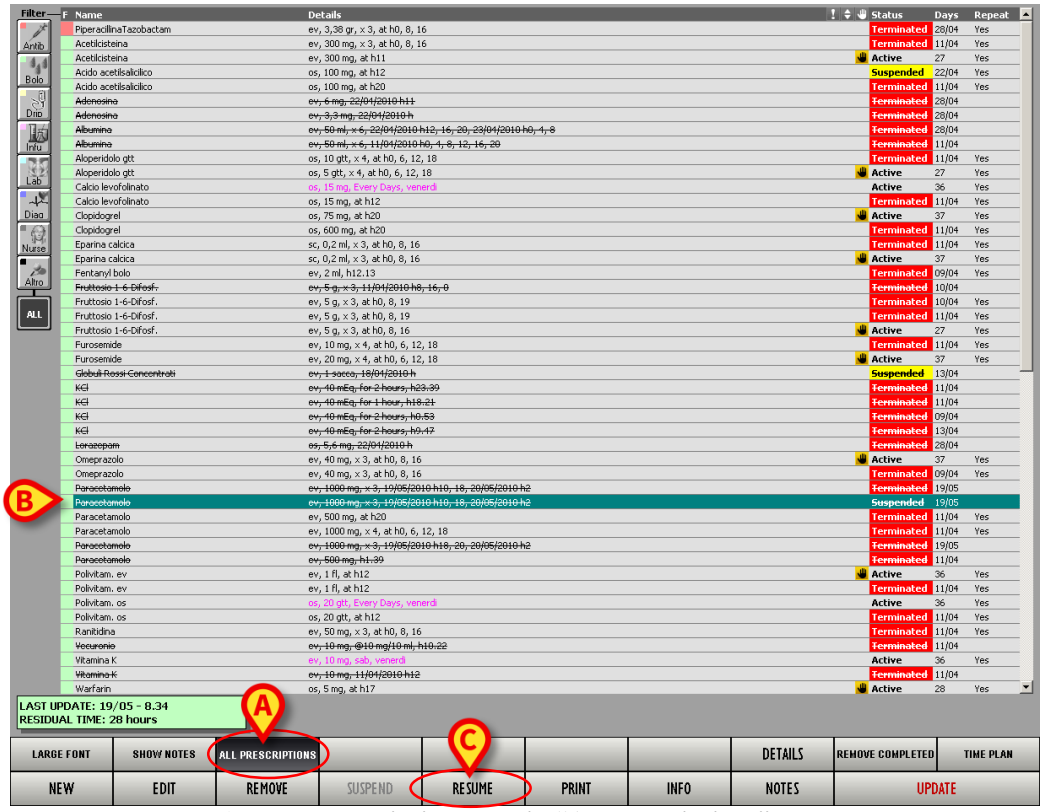


Fig 147 - Prescription table in "All prescriptions" mode

- Click the row corresponding to the suspended prescription that must be resumed.

The clicked row is highlighted (Fig 147 **B**).

Only the prescriptions in "Suspended" status can be resumed.

The **Resume** button is active on the command bar (Fig 147 **C**).

- Click the **Resume** button.

A user confirmation is required (Fig 148).

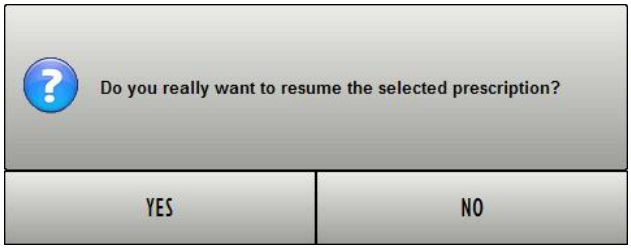


Fig 148 - Confirm suspension

- Click **Yes** to confirm.

The selected prescription becomes active again. The yellow label Suspended disappears; the prescription is again part of the patient treatment plan.

11.5. Large font display

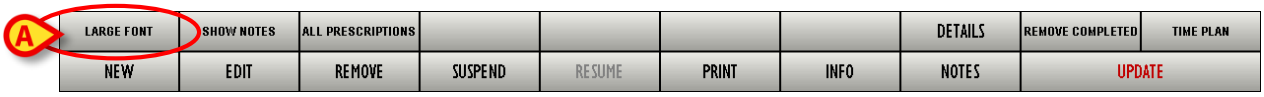


Fig 149 - Command bar

The **Large Font** button (Fig 149 **A**) makes it possible to display the information on screen in larger fonts that are easier to read.

Fig 150 shows the prescriptions table when normally displayed.

F	Name	Details	Status	Days	Repeat
	Acetilcisteina	ev, 300 mg, at h11	Active	2	Yes
	Aloperidolo gtt	os, 5 gtt, x 4, at h0, 6, 12, 18	Active	2	Yes
	Calcio levofolinato	os, 15 mg, Every Days, venerdi	Active	3	
	Clopidogrel	os, 75 mg, at h20	Active	3	
	Eparina calcica	sc, 0,2 ml, x 3, at h0, 8, 16	Active	3	Yes
	Fruttosio 1-6-Difosf.	ev, 5 g, x 3, at h0, 8, 16	Active	2	
	Furosemide	ev, 20 mg, x 4, at h0, 6, 12, 18	Active	3	Yes

Fig 150 - Normal display

Fig 151 shows the prescriptions table when displayed in “large fonts”.

F	Name	Details	Status	Days	Repeat
	Acetilcisteina	ev, 300 mg, at h11	Active	2	Yes
	Aloperidolo gtt	os, 5 gtt, x 4, at h0, 6, 12, 18	Active	2	Yes
	Calcio levofolinato	os, 15 mg, Every Days, venerdi	Active	3	
	Clopidogrel	os, 75 mg, at h20	Active	3	
	Eparina calcica	sc, 0,2 ml, x 3, at h0, 8, 16	Active	3	Yes
	Fruttosio 1-6-Difosf.	ev, 5 g, x 3, at h0, 8, 16	Active	2	
	Furosemide	ev, 20 mg, x 4, at h0, 6, 12, 18	Active	3	Yes

Fig 151 - Large fonts display

11.6. Show notes

Fig 152 - Command Bar

The **Show Notes** button (Fig 152 **A**) displays in the prescriptions table all the notes associated to the various prescriptions.

See the table shown in Fig 153 for an example.

Vitamina K	ev, 10 mg, sab, venerdi Vitamina K salf (fl 10 mg/2 ml)	Active	3	Yes
Warfarin	os, 5 mg, at h17 Coumadin (cp 5 mg)	Active	2	Yes
Coltura sangue	Every Days, se temperatura > 38° emocoltura	Active	3	Yes
EGA	x 2, at h0, 16 Emogasanalisi arteriosa	Active	3	Yes
Ematochimici OLTX	at h8 + troponina	Active	3	Yes
Ematochimici profilo infarto	x 2, at h0, 16	Active	3	Yes
Ematochimici profilo urine	at h8	Active	3	Yes
Procalcitonina e PCR	at h8 attenzione, mandare in laboratorio prima delle ore 11.00	Active	3	Yes
ECG	at h10 pro test	Active	2	Yes

Fig 153 - Notes displayed

The notes displayed by the **Show Notes** *button are inserted on the "Prescription specification" window (see paragraph 10.3 for the procedure).*

11.7. Display all prescriptions

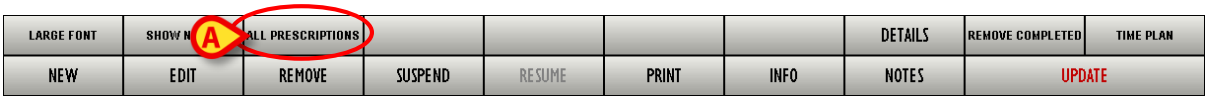


Fig 154 - Command Bar

The **All Prescriptions** button (Fig 154 **A**) makes it possible to display, on the prescriptions table:

- the active prescriptions,

Fig 155 - Active prescription

- the suspended prescriptions,

Fig 156 - Suspended prescription

- the terminated prescriptions.

Fig 157 - Terminated prescription

Fig 158 shows, as example, a prescriptions table displaying "all prescriptions".

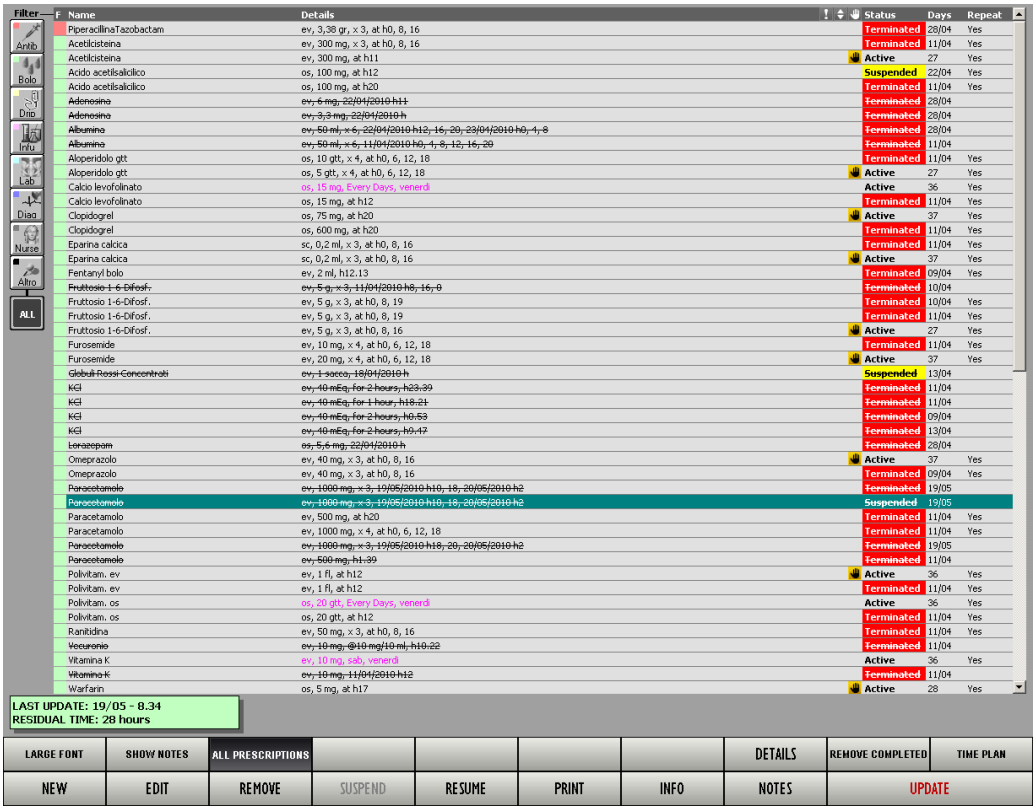


Fig 158 - Prescription table displayed in "All prescriptions" mode

11.8. Remove completed prescriptions

A prescription is completed when all the orders that it generated have been executed and no other order will be generated by it in the future. These prescriptions are still in "Active" status.
The rows corresponding to these prescriptions are still visible on the prescription table. Completed prescriptions are displayed in strikethrough characters (Fig 159).

Fig 159 - Completed prescription

These rows can be removed from the table using the **Remove Completed** button on the command bar (Fig 160 **A**).

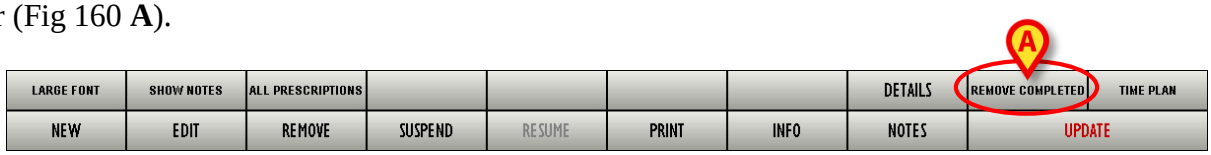


Fig 160 - Command bar

A user confirmation is required (Fig 161).

Fig 161

- Click **Yes** to remove from the prescriptions table the rows corresponding to the completed prescriptions.

The removed prescriptions turn to "Terminated" status. Thay can be displayed again when the prescriptions table is in "All prescriptions" mode (see paragraph 11.7).

The "Terminated" prescription cannot be resumed.

11.9. Show the prescription details

The **Details** button (Fig 162) opens a window containing all the details of a single prescription. This window displays all the available information on the prescriptions of a treatment and the orders generated by it.

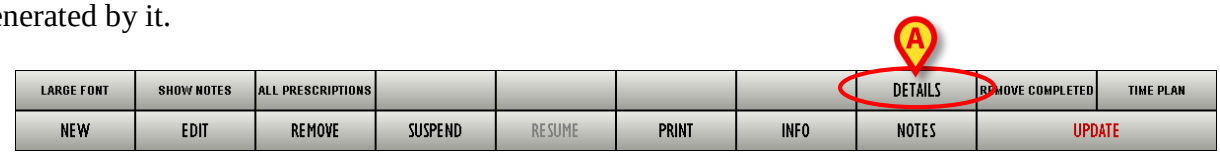


Fig 162

To display the prescription details window,

- click, on the prescriptions table, the row corresponding to the relevant prescription.

The row is highlighted.

- Click the **Details** buttons.

The window shown in Fig 163 opens.

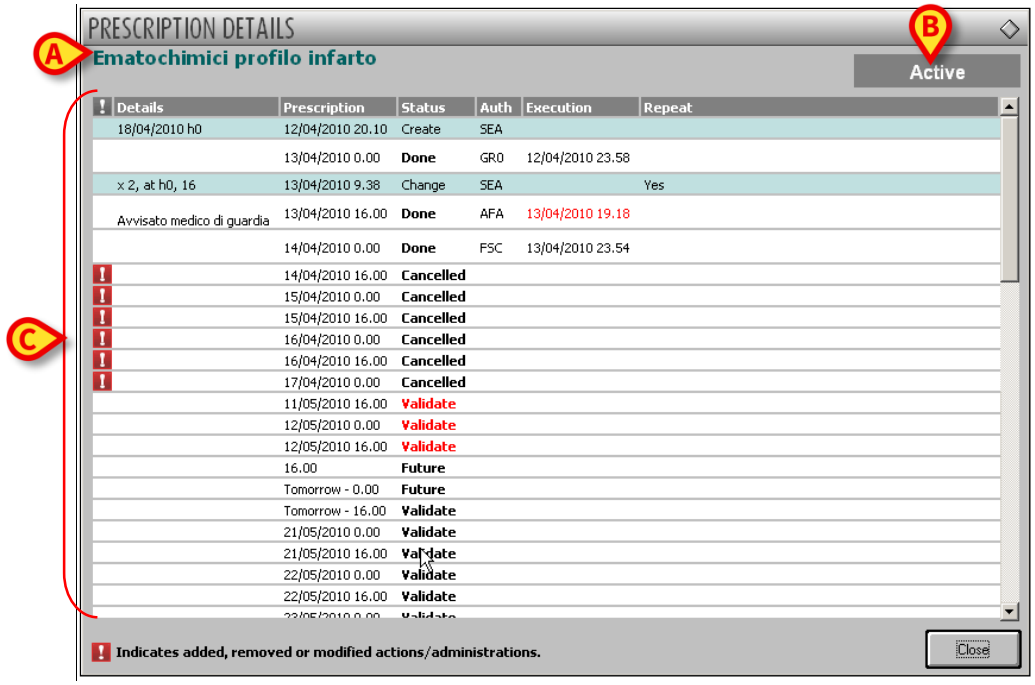


Fig 163 - Prescription details

The name of the treatment is indicated on the top-left corner of the window (Fig 163 **A**).

The prescription status is indicated on the top-right corner of the window (Fig 163 **B**).

All the meaningful events and all the actions performed that are related to the prescription are listed in a table (Fig 163 **C**).

The blue rows refer to the prescription. The white rows refer to the orders.

The information provided on the table is:

- the prescription/administration details;
- date and time in which the event/action displayed was recorded;
- prescription/order status;
- acronym of the user who performed the specific action;
- date and time of administration (if the line corresponds to an administration). When date and time are red it means that they are quite different from those prescribed;
- prescription repeatability.

The  symbol appears at the beginning of a row to indicate that the corresponding action was performed without an explicit prescription.

The "Status" cell indicates an action performed by the user or an event occurred. The information in this cell refers to an order if it is on a white row; it refers to a prescription if it is on a blue row.

The possible indications displayed on the "Status" cell are:

if referred to a prescription (blue lines)

- **Create** - indicates the prescription creation;
- **Change** - indicates any change to the prescription values;
- **Suspend** - indicates the prescription suspension;
- **Resume** - indicates the retrieval of the suspended prescription;
- **Terminate** - indicates the prescription removal.

If referred to an order (white lines)

- **Done** - indicates the execution of an order;
- **Alarm** - indicates an alarm on one of the orders (administration is late);
- **Future** - indicates that the order must be executed in the future;
- **Validate** - indicates that the order must be validated;
- **Cancelled** - indicates the deletion of the order;
- **Start** - indicates when a durative administration was started;
- **Stop** - indicates when a durative administration was stopped.

11.10. Prescriptions time plan

The **Time Plan** button (Fig 164 **A**) opens a window containing a summary of all the active prescriptions and the statuses of the corresponding orders.

Fig 164 - Command bar

To display the time plan

- click the **Time Plan** button on the command bar.

The following window opens.

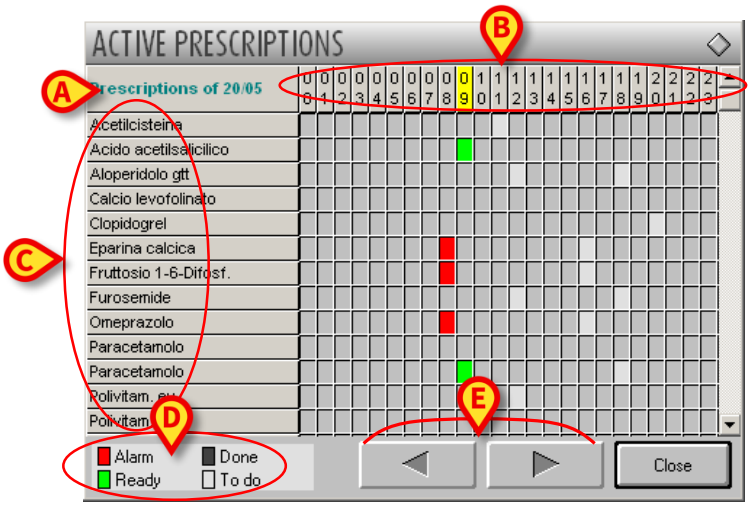


Fig 165 - Scheda oraria

The current day is indicated on the top left corner of the window (Fig 165 **A**).

The line highlighted in Fig 165 **B** indicates the time. The current time is highlighted yellow (it is 09.00 o'clock in the figure).

All the active prescription are listed on the left (Fig 165 **C**). For each prescription there are 24 cells available, one for each full hour. If a cell is highlighted it means that there is an administration scheduled at the corresponding time.

The cell colour provides information on the order status.

- To do - it means that the administration must be performed in the future.

- Done - it means that the order was executed.

- Ready - it means that the order should be executed now, i.e. we are within the time span configured as "range of tolerance" - see paragraph 10.2.3.3 for more details).

- Alarm - it means that the treatment administration is late.

On the bottom-left corner of the window there are indications on how to read the information provided by the window itself (Fig 165 **D**).

Use the arrow-buttons indicated in Fig 165 **E** to display the days either preceding - - or following - - the current day.

11.11. Add\Display notes

Use the **Notes** button on the command bar (Fig 166 **A**) to add a note that will be displayed on the "Therapy Execution" module main screen.

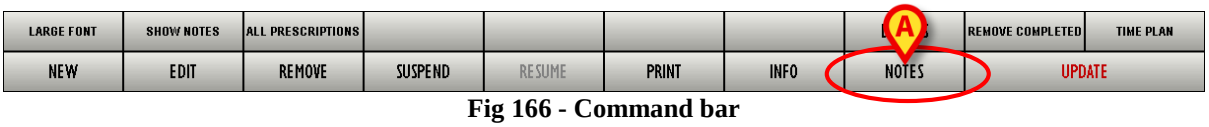


Fig 166 - Command bar

The notes inserted using the procedure described here are general notes referring either to the patient or to the whole therapy. They are not referred to the single treatment prescription. They are not to be confused with the notes specified using the procedure described in paragraph 10.3.1, referring to the treatment prescription.

To add a note

- click the **Notes** button.

The following window opens.

Fig 167 - "Notes" window

- Click the **Edit** button (Fig 167 **A**).

The window changes in the following way

Fig 168 - "Notes" window (edit mode)

- Type the note. The text is displayed inside the window.
- Click the **Save** button to save the note (Fig 168 **A**).

The window closes automatically; the presence of a note is indicated by the color of the button on the command bar (yellow). Click the button again to display the notes-window again.
The note is displayed on the “Electronic Prescription” screen, in a specific box (Fig 169 **A**).

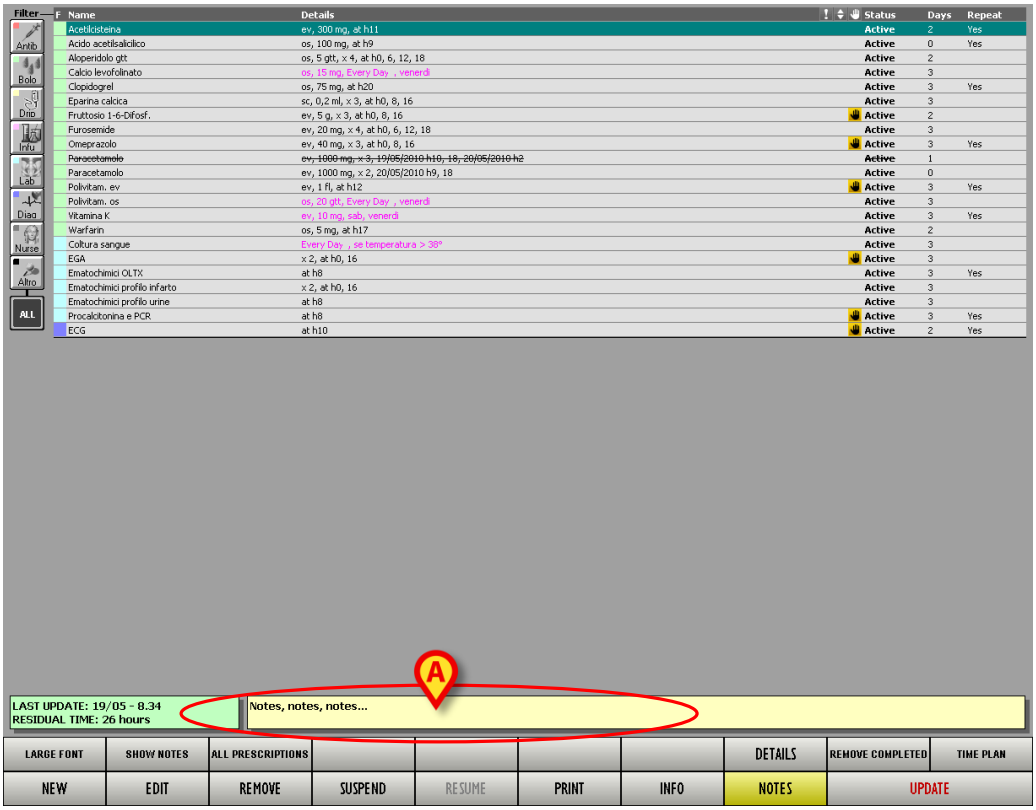


Fig 169 - Nota inserita

Use the **Time Stamp** button (Fig 168 **B**) to display the date, time and the acronym of the user who is adding the note (Fig 170).

Fig 170 - Date and time

Use the **Cut** button (Fig 171 **A**) to cut a selected text portion.

Fig 171

To cut a text portion

- click the **Edit** button (Fig 167 **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 "Notes" window.

The notes specified using the **Notes** *button can be displayed by other DIGISTAT® modules as well, if the* **Notes** *button is present on the command bar.*

11.12. Print reports

The **Print** button on the command bar (Fig 172 **A**) creates a print report of the patient treatment plan.

Fig 172 - Command bar

- Click the **Print** button to display a print preview.

The system's print functionalities are described in paragraph 6.8.1.

11.13. Drug Info

The **Info** button on the command bar (Fig 173 **A**) displays a page containing information on a selected treatment.

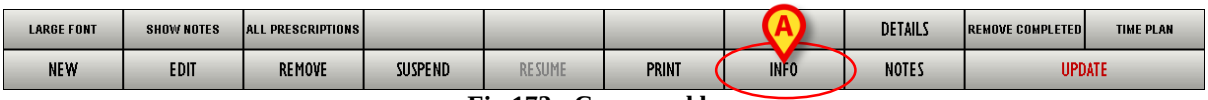


Fig 173 - Command bar

To display the treatment information, on the prescriptions table,

- click the row corresponding to the relevant treatment.

The row is highlighted.

- Click the **Info** button on the command bar.

The information page opens.

The contents of the information page are configured by the clinical supervisor. Please refer to your system administrators for information regarding the treatment info pages.

12. The “Therapy Execution” module

The DIGISTAT® “Therapy Execution” module is designed to be a help for the nursing staff in performing the tasks related to the administration of the prescribed treatments.
When a physician prescribes a treatment, the corresponding administration orders are created and added to the “to do” list for the nursing staff.
The orders are automatically generated by the system on the base of the treatment plan specified by the physician on the DIGISTAT® “Therapy Prescription” module (chapter 8). They are displayed in graphic form on the “Therapy Execution” module’s main screen, on an easily readable “treatment schedule” table.
The “Therapy Administration” module is also used to document each action performed: every relevant event is automatically added to the patient clinical record.

12.1. “Therapy Execution” module selection

To select the “Therapy Execution” module

- click the corresponding icon on the lateral bar (Fig 174).

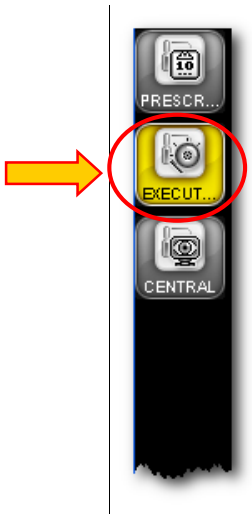


Fig 174

When the module is selected the 

icon is highlighted yellow.

The “Administration” module can be also selected on the “Central Station” module clicking the boxes corresponding to the different patients. See paragraph 13.2 for more details.

12.2. Main screen

The module's main screen appears as in Fig 175.

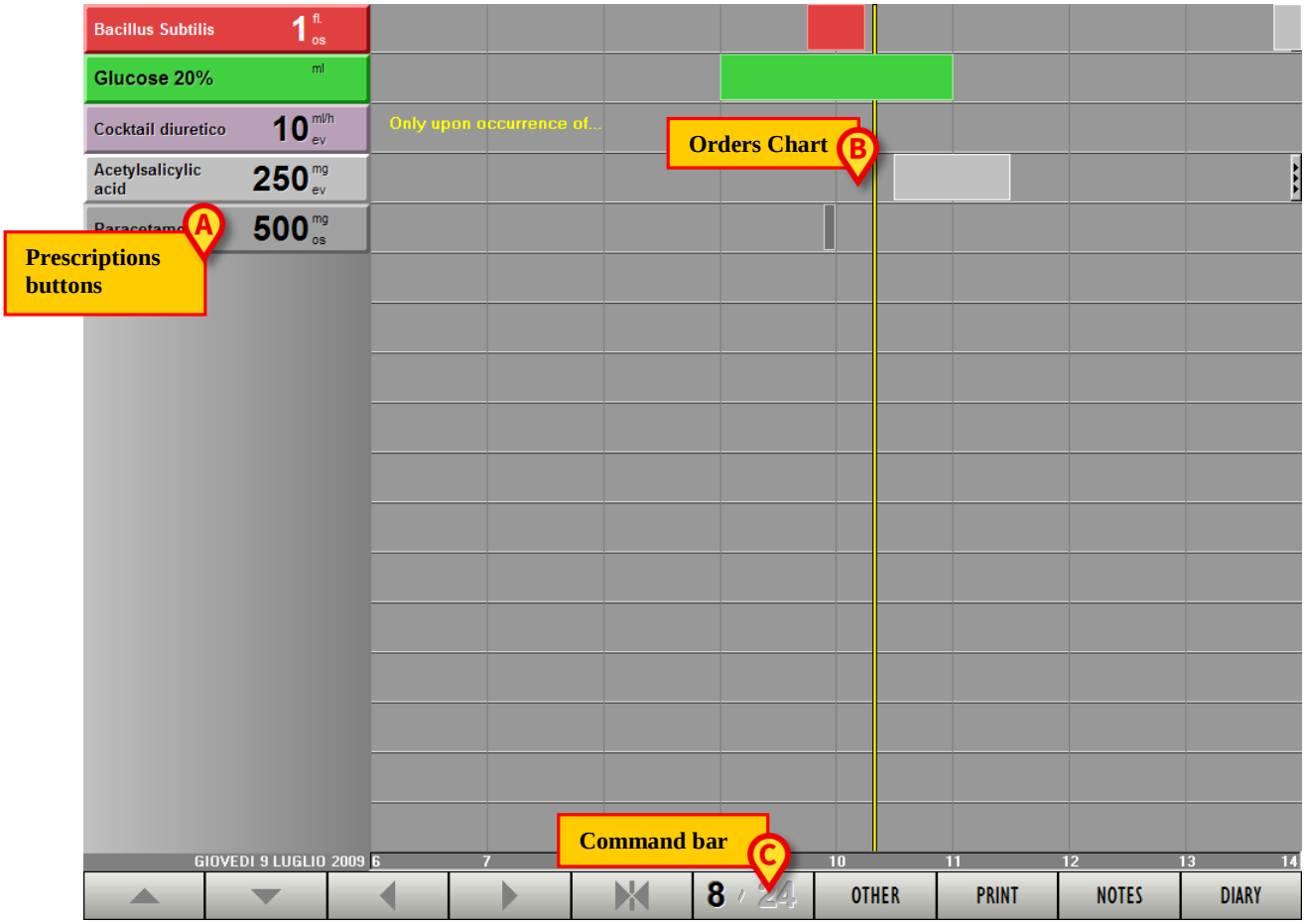


Fig 175 - Administration module (example)

There are three main areas:

1) the column on the left contains the buttons corresponding to the prescribed treatments (Fig 175 **A**);

2) the central area shows in a chart the orders generated by the prescriptions (Fig 175 **B**);

3) the command bar contains the function-buttons making it possible to perform different actions (Fig 175 **C**).

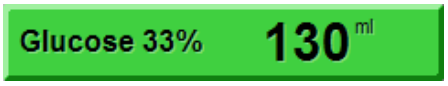
12.3. Prescribed orders representation

The treatments prescribed on the "Prescription" module are displayed on the left as colored boxes (Fig 175 **A**).
These boxes are buttons that, when clicked, make it possible to record the administration of a specific order. See paragraph 12.5 for the administration recording procedure.
The different colors provide information on the status and the kind of the corresponding treatment.

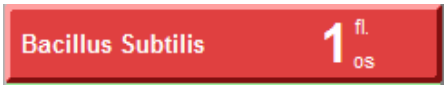
There are 6 possible colors:

Light grey characterizes active prescriptions whose orders must be administered in the future.

Dark grey characterizes completed prescriptions.



Green characterizes prescriptions having an order "ready to be administered".



Red characterizes prescriptions having at least one "late" order.

Cyan characterizes durative prescriptions having one order in progress (see paragraph 7.3.3 for a description of durative prescriptions).

Purple characterizes conditional prescriptions; these are treatments to be administered only if specific conditions occur.

The boxes are displayed by urgency on the "Administration" screen. The "late" orders are on top, then the "ready" ones, then the "durative" orders in progress, then the "conditional" ones, then those to be executed in the future. In the end are the boxes corresponding to completed prescriptions.

I.e. the colors appear in this order:

1. *red*
2. *green*
3. *cyan*
4. *purple*
5. *light grey*
6. *dark grey*

12.4. The orders chart

The central area of the administration screen displays on a chart all the orders generated (the already executed ones, the future ones, the “in progress” ones - Fig 176).

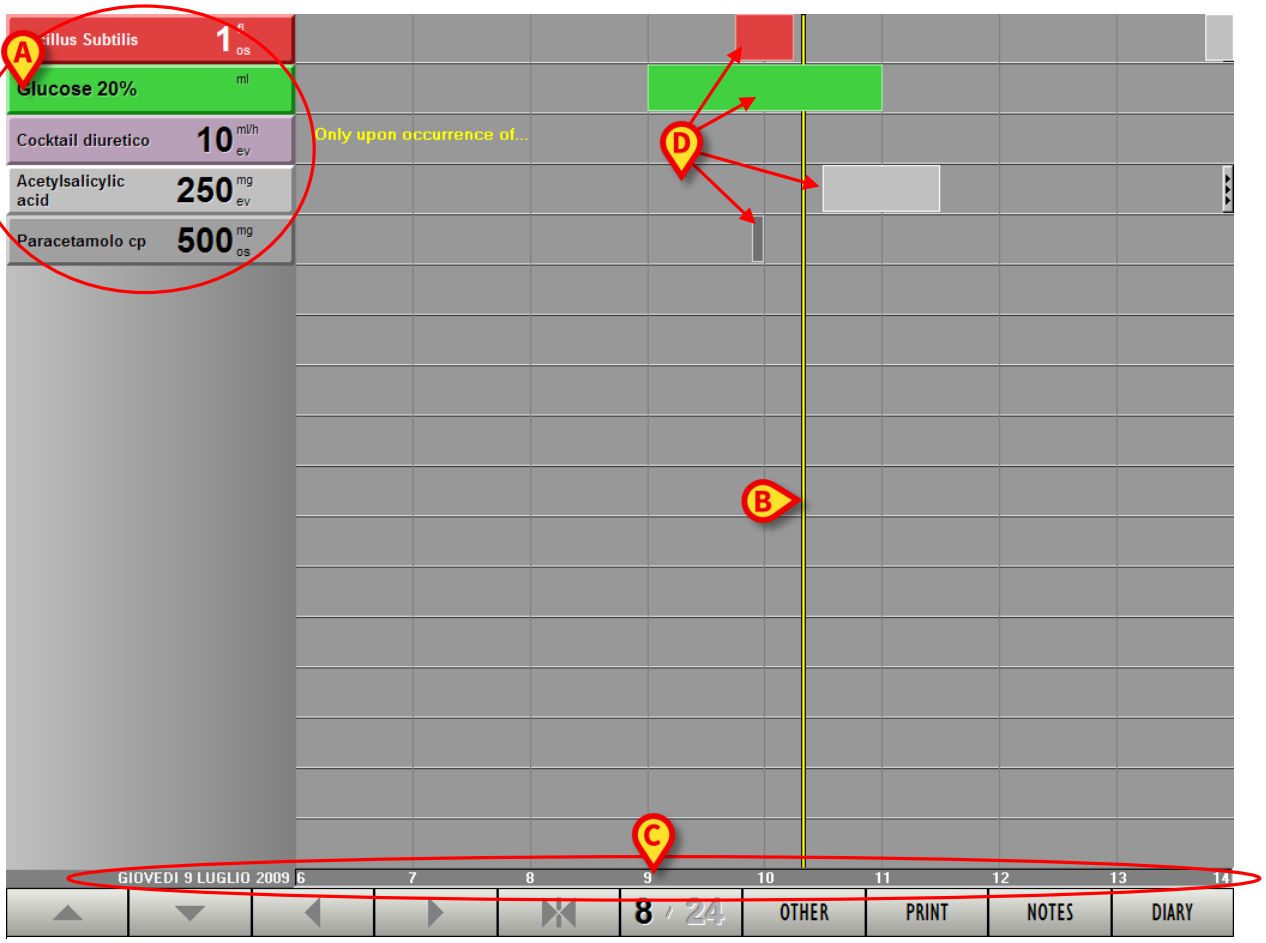


Fig 176 - Orders chart

The chart is a grid, made of rows and columns. The orders corresponding to the same treatment are on the same row (in Fig 176 there are five prescribed treatments on the left - Fig 176 **A**); the columns correspond to the different hours of the day.

The yellow bar shown in Fig 176 **B** indicates the present time. The bar scrolls forward as time goes by. In Fig 176 it is 10:20 a.m. approximately. Time can be read below, on the bar indicated in Fig 176 **C**. The date is displayed on the bar as well.

12.4.1. Graphic representation of the orders

The boxes indicated in Fig 176 **D** correspond to the different orders. The boxes are in the place corresponding to their prescribed administration time (or execution time if already executed).

12.4.1.1. Administration tolerance period

The lenght of the boxes is proportional to the time period that was indicated as “tolerance period for the administration” when the order was prescribed (see paragraph 10.2.3.3).

For instance: if the treatment is prescribed at 10:00 and the administration tolerance period is set to 15 minutes, the administration time indicated on the chart is a period going from 9:45 to 10:15 (it is the case highlighted in Fig 177 **A**).
If the treatment is prescribed at 10:00 and the administration tolerance period is set to 1 hour, the administration time indicated on the administration chart is a period going from 9:00 to 11:00 (it is the case highlighted in Fig 177 **B**).
The position of the boxes corresponds to the prescribed administration times. The boxes length is proportional to the tolerance period.

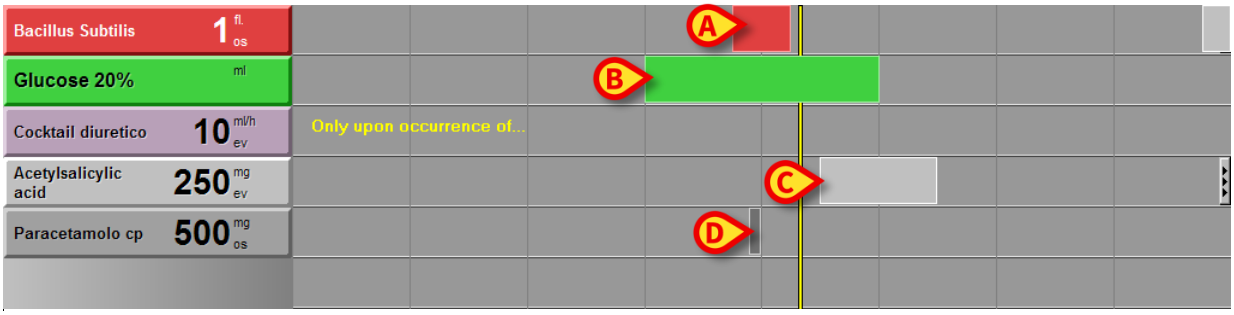


Fig 177

12.4.1.2. Order status

The box color indicates the status of the order.

Green means that the order is to be administered immediately, i.e. it means that it is within the administration tolerance period. When the box is green the vertical time bar intersects the box (Fig 177 **B**).

Light grey means that the order is to be executed in the future. When the box is light grey the vertical time bar is on the left of the box (Fig 177 **C**).

Dark grey means that the order was executed (i.e. the treatment was administered). When the box is dark grey the vertical time bar is on the right of the box (Fig 177 **D**).

The lenght of the boxes corresponding to an executed order is reduced to indicate the exact administration time. The tolerance period is not displayed anymore. When the prescription is durative (a drip, for instance) the administration duration is fully displayed in grey. See paragraph 12.5.1 for the durative orders administration procedure.

Red means that the administration of the order is late; i.e. the tolerance period is over (Fig 178 **A**). When the box is red the vertical time bar is on the right of the box.

Cyan characterizes durative prescriptions having one order in progress (Fig 178 **B**). The vertical time bar in these cases coincides with the box’s right border.

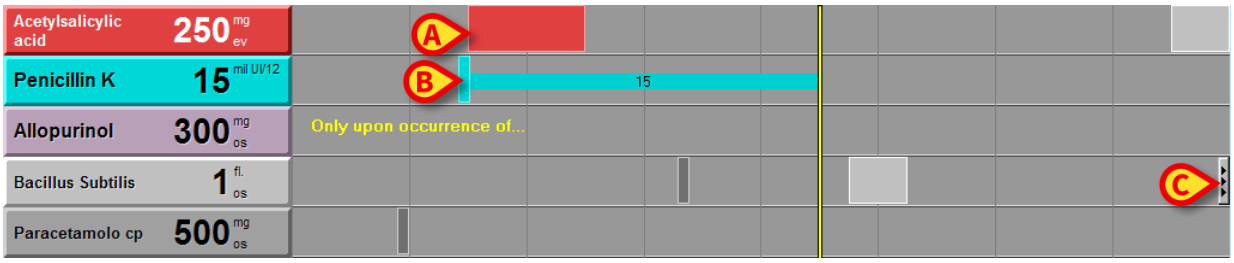


Fig 178

The duration of an administration is displayed in cyan (Fig 179).

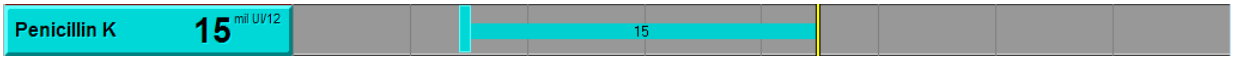


Fig 179 - Durative administration

When the administration is stopped the duration becomes grey (Fig 180).

Fig 180 - Durative administration stopped

Two different shades of cyan - ■ and ■ - can be used for the durative prescriptions to increase the chart readibility. The choice depends on a configuration parameter.

On the chart, three small arrows appear at the end of a row (Fig 178 **C***) if there are (on the right) orders for that prescription that are not currently displayed. When the three arrows are on the left it means that the undisplayed items are on the left.*

The  icon appearing on the top-left corner on a box means that the order has not been validated yet. See paragraph 7.3.6 for the explanation of the "order validation" concept. The not validated orders can be administered using a specific procedure. This procedure is described in paragraph 12.5.2.

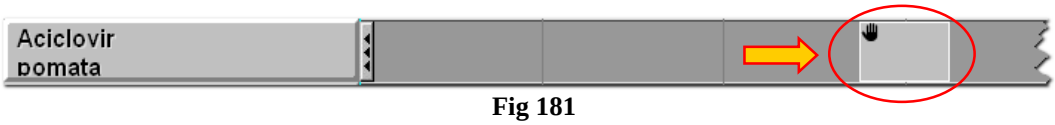


Fig 181

When the administration time for a non validated order approaches, a specific icon -  - appears on the "Therapy prescription" module on the prescriptions table on the row corresponding to the prescription that generated the order (Fig 182 **A**).

Fig 182

The value indicating that the administration time is approaching is set by configuration. In the configuration here described the specified period is three hours.
A dark vertical line indicates the limit of this period on the chart (Fig 183).

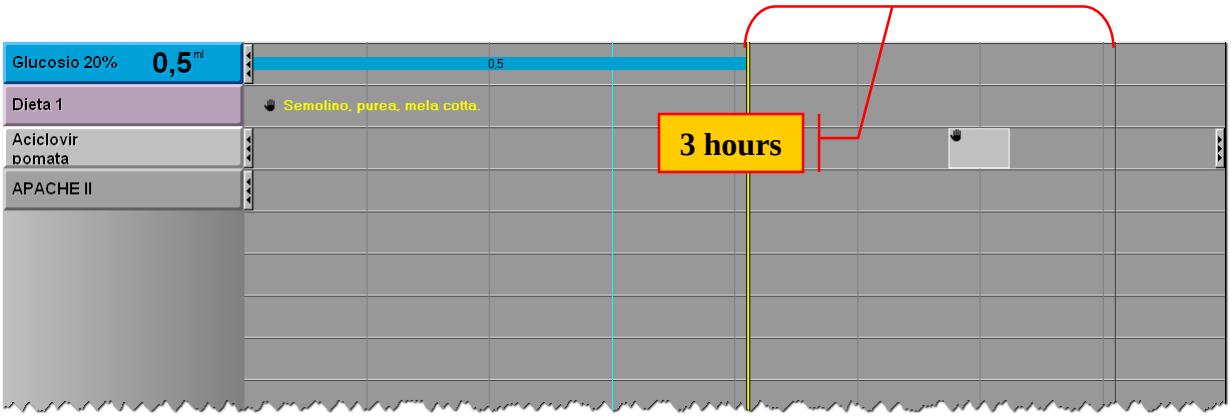


Fig 183

The  icon appears for the conditional prescriptions as well if they are not yet validated. The validity of a prescriptional prescription expires when the "Therapy Cycle" expires. Thus conditional prescriptions are automatically validated every time the "Therapy Cycle" is updated. See paragraph 10.2.2 for the explanation of "conditional treatment". See paragraph 7.3.4 for the explanation of "Therapy Cycle".

12.4.1.3. Additional information on the executed administrations

The executed orders are represented by grey vertical bars. See Fig 184 for an example.

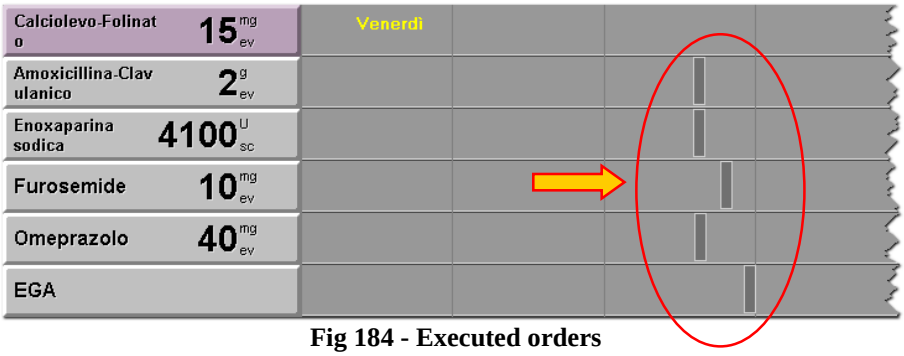


Fig 184 - Executed orders

The graphic design of the vertical bars provides additional information on the kind of administration executed.

These are:

 - it means that the order has been cancelled.

 - it means that the order causes the  icon on the "Therapy Prescription" module. The  icon appears if there is not a prescription originating the executed action.

- it corresponds either to the administration of an extemporaneous order (i.e. an administration recorded using the procedure described in paragraph 12.6.3) or to the durative prescription stop time.

- it corresponds to any other case, to indicate an executed order.

12.5. How to record the treatment administration

To record the administration of a treatment, on the "treatments column" on the left,

- click the button corresponding to the relevant treatment (Fig 185 **A**).

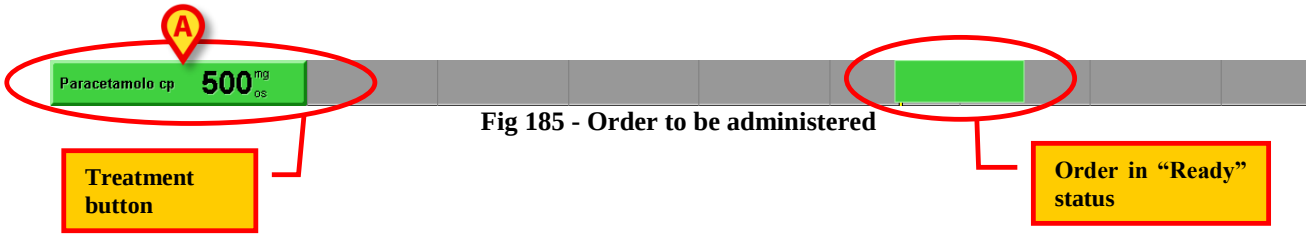


Fig 185 - Order to be administered

An administration window opens (Fig 186).

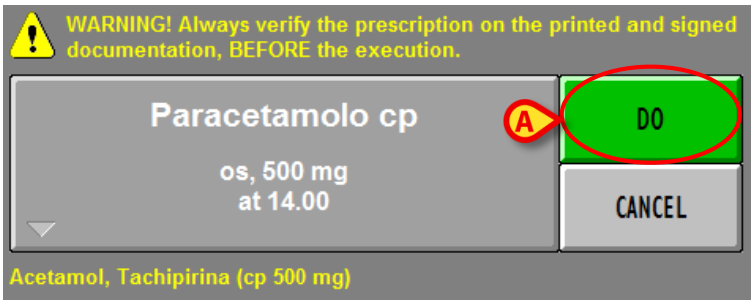


Fig 186 -Order administration window

- Click the **Do** button (Fig 186 **A**).

The chart changes in the following way

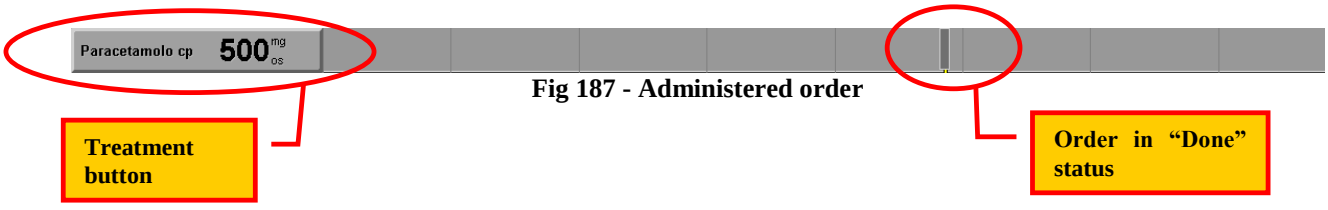


Fig 187 - Administered order

The treatment administration is this way recorded.

The order does not need to be in "Ready" status to be administered. The administration can be recorded before the scheduled prescription time. In this case a user confirmation is required.

12.5.1. Durative treatment administration

The administration recording procedure is slightly different for durative treatments. In these cases it is in fact necessary to record the beginning and the end of the administration.

To record the administration of a durative treatment

- click the treatment button (Fig 188 **A**).

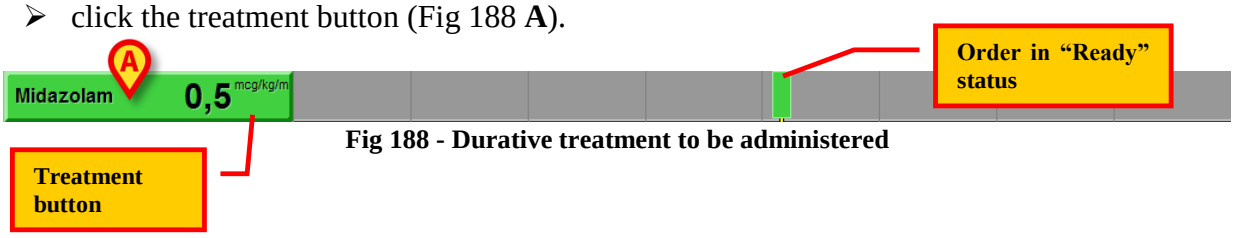


Fig 188 - Durative treatment to be administered

An administration window opens (Fig 189 **A**).

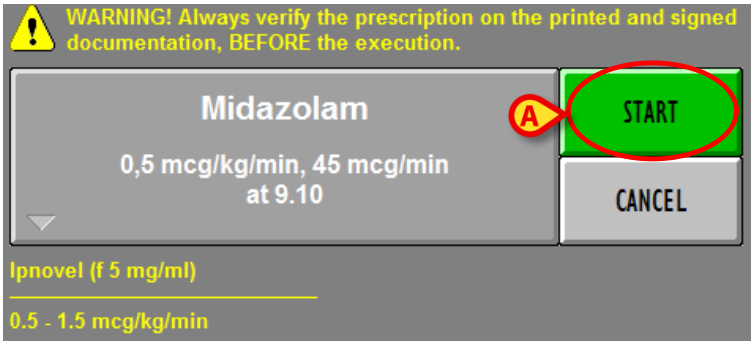


Fig 189 - Durative administration "start"

- Click the **Start** button (Fig 189).

The beginning of the durative treatment administration is this way recorded. The corresponding button becomes cyan (Fig 190 **A**). A cyan bar is traced on the chart while the administration goes on (Fig 190 **B**).

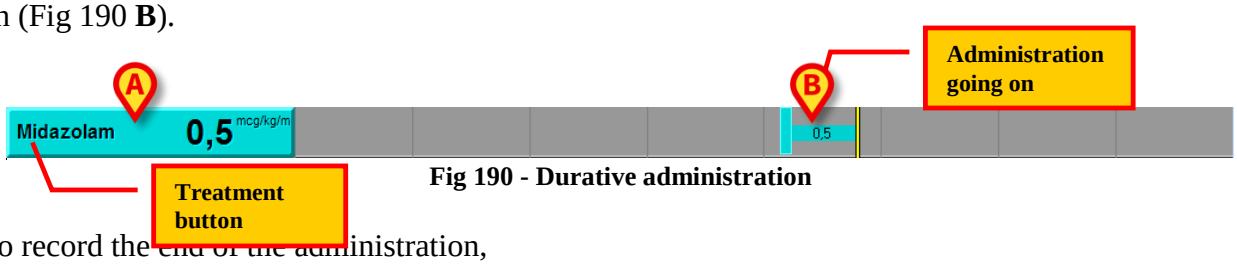


Fig 190 - Durative administration

To record the end of the administration,

- click the treatment button again (Fig 190 **A**).

A specific window appears (Fig 191).

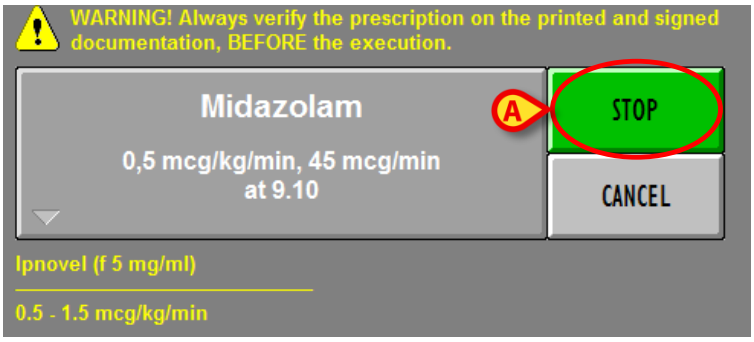


Fig 191 - Durative administration "stop"

- Click the **Stop** button (Fig 191).

The chart changes in the following way.

Fig 192 - Durative administration stopped

The duration of the administration is this way represented on the chart.

12.5.2. Administration of an order either expired or not-yet-validated

The order validity expires after a certain time. See paragraph 7.3.7 for the related procedures. These orders are "Expired". An expired order can be administered anyway but, to do that, a specific procedure must be performed.

Here is the procedure.

- Click, on the left, the button corresponding to the treatment that must be administered.

In the example shown in Fig 193 it is "Acetilcisteina".

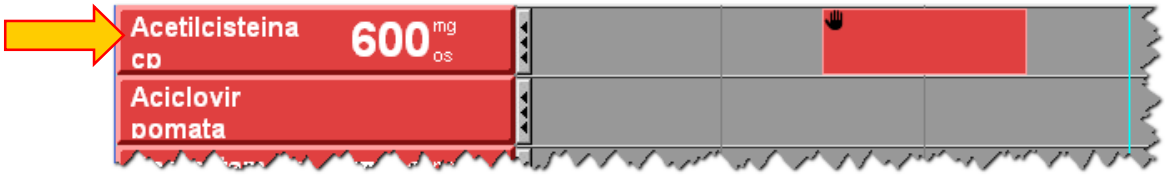


Fig 193

A user confirmation is required (Fig 194).

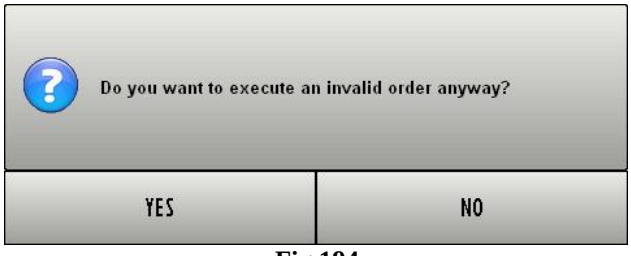


Fig 194

- Click **Yes** to proceed.

The following window is displayed (Fig 195), highlighting the fact that the order is not valid.

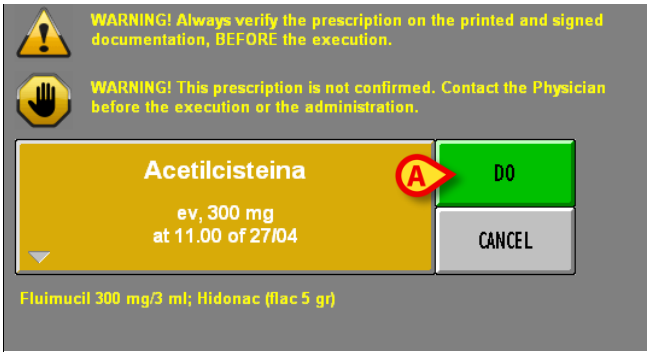


Fig 195

- Click the **Do** button to administer the treatment (Fig 195 **A**).

A note explaining the reasons of the execution must be now inserted.

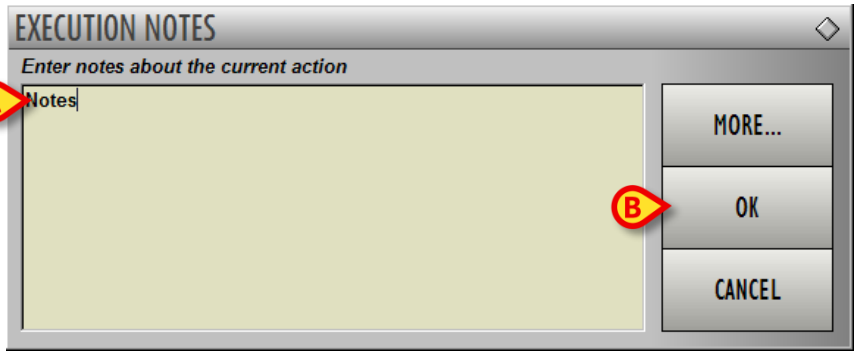


Fig 196

- Insert the note (Fig 196 **A**).
- Click **Ok** (Fig 196 **B**).

The execution is this way recorded.

The same procedure can be used to record the administration of a future not-yet-validated order.

12.5.3. Changes in the administration values

It is possible to record the changes in the values of the durative administration while it is still in progress.

To do that

- click the prescription button corresponding to the treatment whose values must be changed (Fig 197 **A**).

Fig 197

The following window appears (Fig 198).

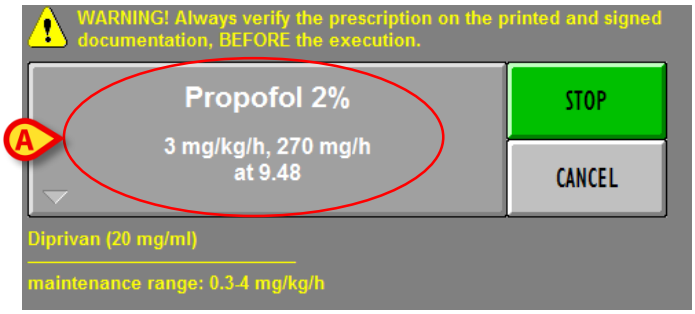


Fig 198

- Click the large button containing the treatment name (Fig 198 **A**).

The window enlarges, as in Fig 199.

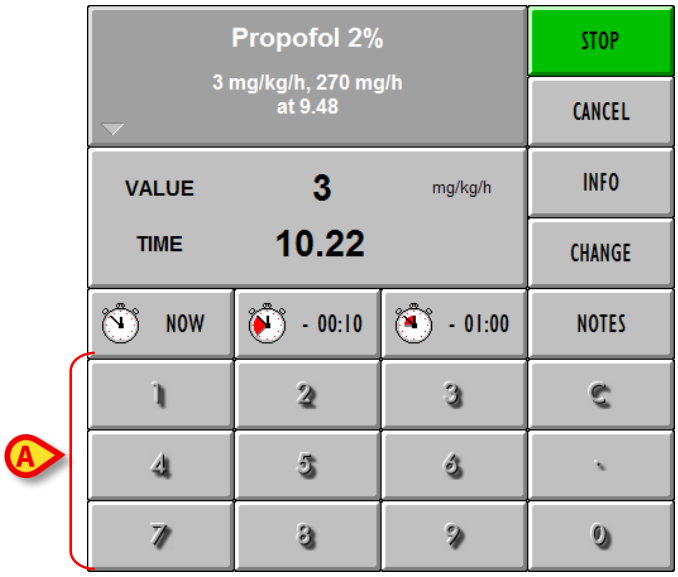


Fig 199

- Use the numeric keyboard (Fig 199 **A**) to set the new administration values (Fig 200 **A**).

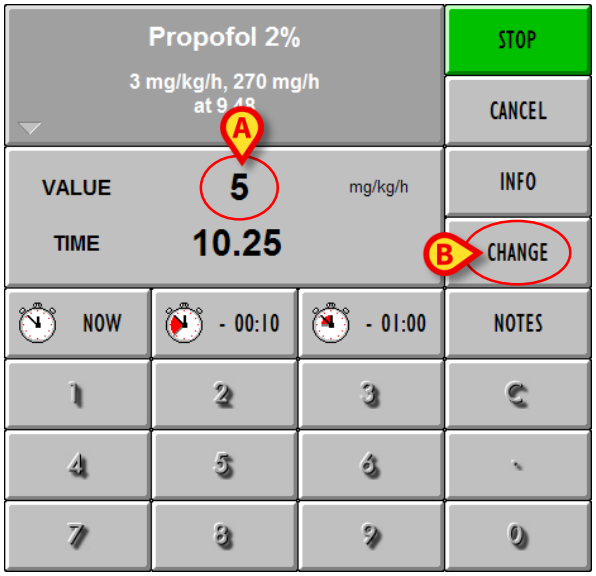


Fig 200

- Click the **Change** button (Fig 200 **B**)

The following window appears, requesting to add a textual note (Fig 201).

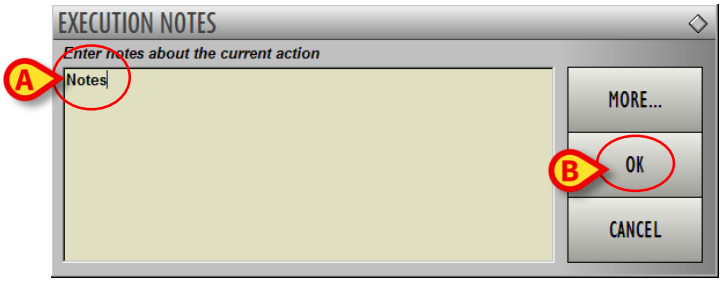


Fig 201

- Type the note (Fig 201 **A**).
- Click the **Ok** button (Fig 201 **B**).

The chart changes in the following way (Fig 202).

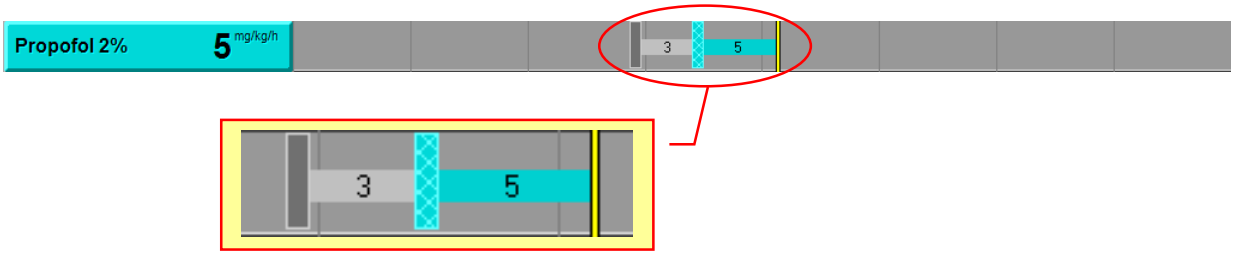


Fig 202

The moment in which the change is recorded is highlighted on the chart by the cyan vertical bar . The old value is specified on the left of the bar ("3" in the figure), the new value is specified on the right ("5" in the figure).

The change is signalled on the "Prescription" module by a specific icon  *on the prescription table (Fig 203). The icon means that the values recorded on the "Execution" module are now different from those specified by "Prescription".*

Fig 203

12.5.4. The administration window

Some of the administration values (quantities and dosages, for instance) can be edited during the treatment administration phase.
The treatment administration window (Fig 206) makes it possible to set or edit these values on the "Therapy Execution" module.

To open the administration window,

- click the prescription button (see Fig 204 for an instance).

Fig 204 - Prescription button

The administration window opens (Fig 205).

Fig 205 - Administration window

- Click the area containing the administration data (Fig 205 **A**).

Additional buttons are displayed on the administration window (Fig 206).

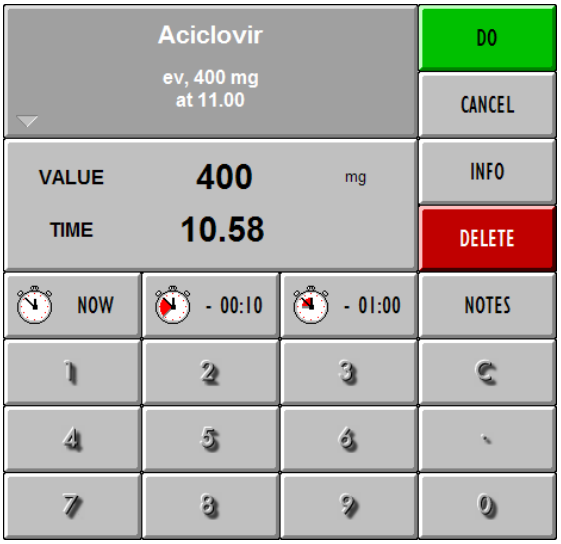


Fig 206

These are the functions of the buttons on the window:

The **Do** button records the treatment administration.
The **Cancel** button closes the window without recording the treatment administration.
The **Info** button opens an information page about the specific treatment.
The **Delete** button deletes the specific order. The orders cancelled this way appear on the chart in the following way -  - see Fig 207.

Fig 207

The **-00:10** button changes the administration recording time (10 minutes back per click).
The **-01:00** button changes the administration recording time (1 hour back per click).
The **Now** button sets the current time again.
The numeric keyboard makes it possible to set the administration values.
The **Notes** button makes it possible to add a textual note.

To add a note

- click the **Notes** button.

The following window opens.

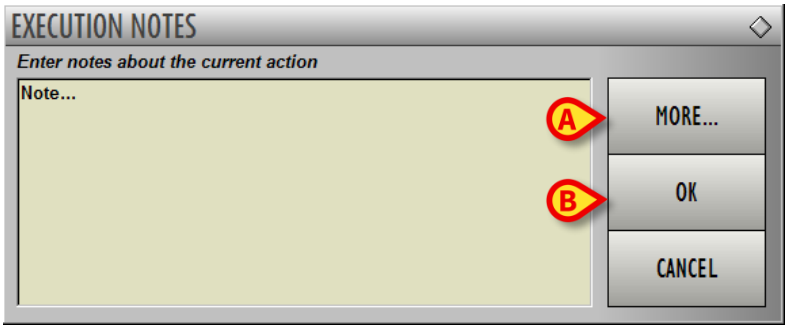


Fig 208 - Execution notes

A textual note can be either inserted manually or using the **More…** button on the window (Fig 208 **A**). This button opens a list of pre-defined standard phrases (Fig 209).

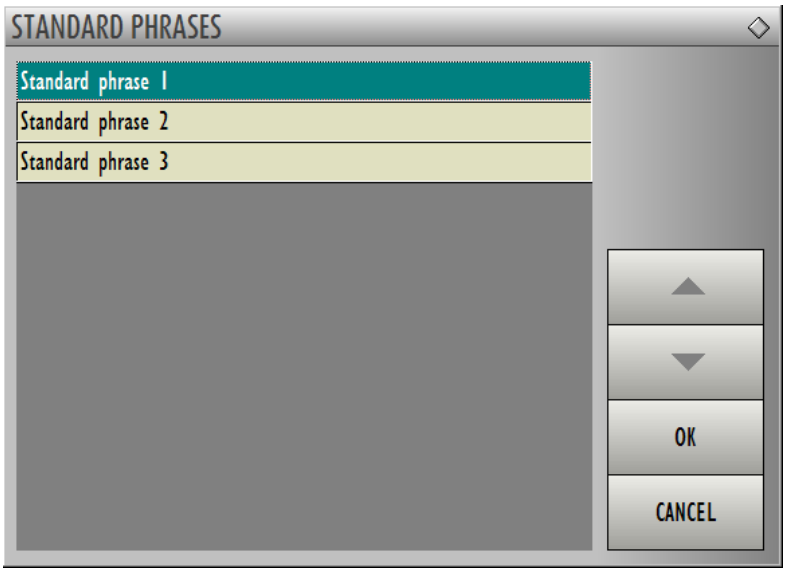


Fig 209 - Standard phrases

The standard phrases can be quickly added to the note. To do that

- click the phrase you want to add.

The phrase is highlighted.

- Click the **Ok** button.

The selected phrase is displayed on the window shown in Fig 208. The standard phrase added this way can be completed or edited by the user.

To complete the procedure

- click the **Ok** button on the "Execution notes" window (Fig 208 **B**).

This note is visible on the "Prescription details" window on the "Prescription" module (see paragraph 11.9).

The administration window, when referred to durative treatments, is different.

Fig 210 shows an example.

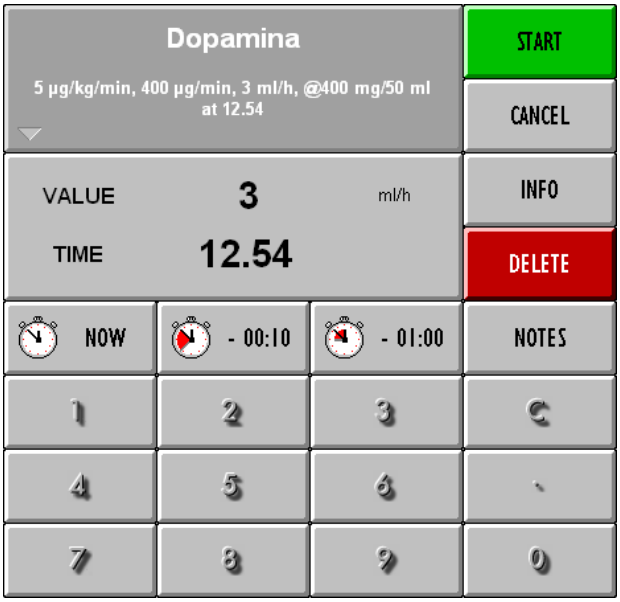


Fig 210

The **Start** button is on the window instead of the **Do** button before the administration is started.
After the administration is started the **Stop** button takes the place of the **Start** button.
The **Change** button is on the window while the administration is in progress.

The procedures related to the administration of durative prescriptions are descibed in paragraph 12.5.1.

12.6. “Execution” module command bar

The various buttons on the “Administration” module command bar (Fig 175 **C**, Fig 211) make it possible to perform specific actions.

Fig 211 - Command bar

The first 6 buttons from the left (Fig 211 **A**) make it possible to change the way the different items are displayed on the window.

The  and  buttons make it possible to scroll up and down the screen contents.

The  and  buttons make it possible to scroll left and right the screen contents.

The  button brings back to the original display mode. When a time different from present time is displayed the button turns red and starts flashing  .

The  button makes it possible to switch from 8 hours to 24 hours display mode (and vice versa). The 8 hours display mode is shown in the previous figures. The 24 hours display mode is shown in Fig 212. When the 24 hours display mode is activated the button on the command bar changes in the following way -  .

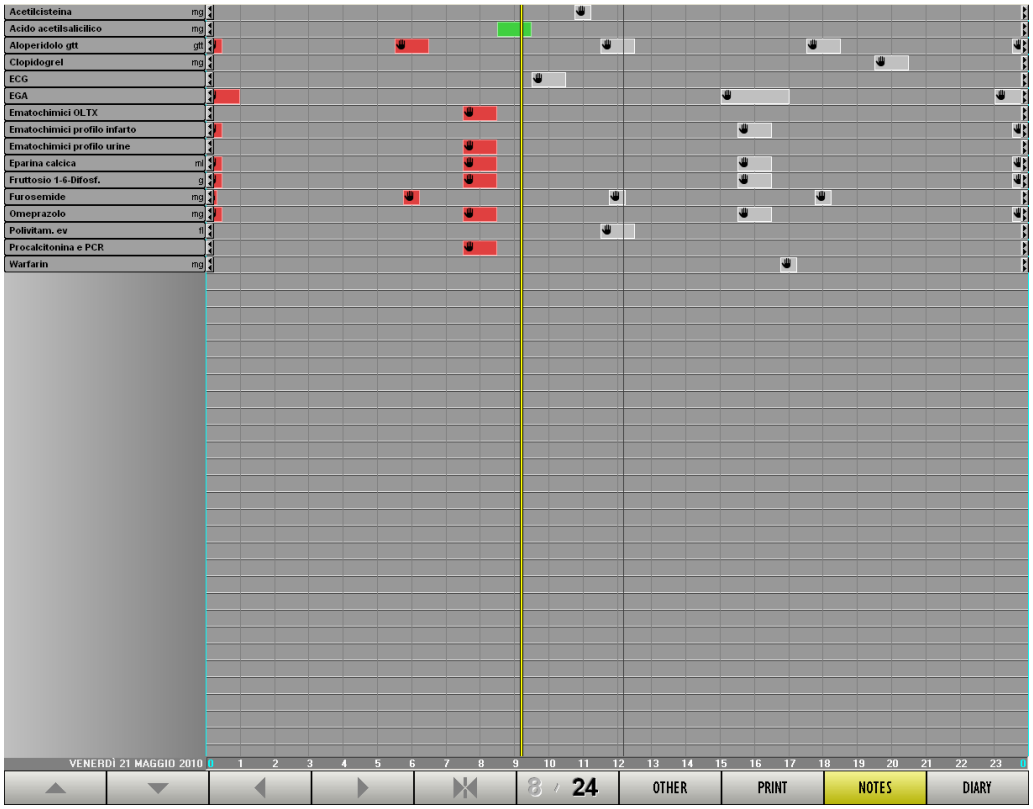


Fig 212 - 24 hours display mode

Fig 213 shows, as example, a detail of a 24 hours display screen.

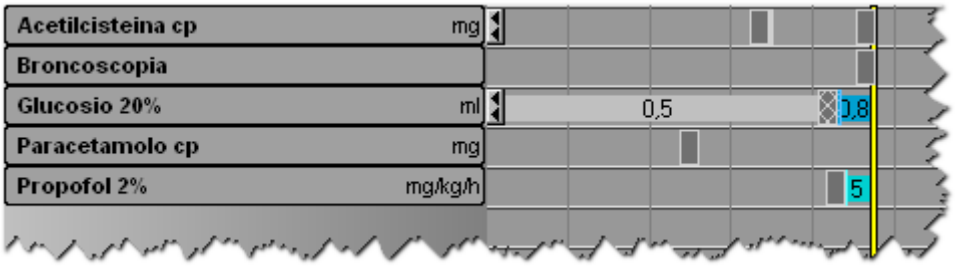


Fig 213 - 24 hours display (detail)

This is a read-only display. I.e. it is not possible to operate on the screen contents when the 24 hours display is activated.
The time span displayed goes from 0:00 to 24:00 of the current day.
Only the prescriptions having at least one order in the time span considered are displayed.
This display mode offers an immediate and complete view of the patient's treatment plan in the 24 hours.

To go back to normal display mode (8 hours) click the 

button again.

12.6.1. Quick chart navigation tool

A quick chart navigation tool (Fig 214) is displayed when any point on the chart area is clicked.

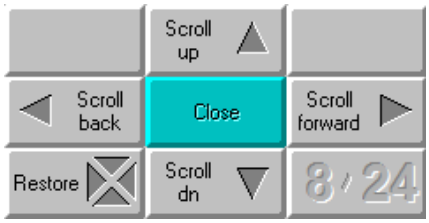


Fig 214

These are the functions of the various buttons:

the **Scroll Up** and **Scroll Dn** buttons scroll up and down the chart contents;

the **Scroll Back** and **Scroll Forward** buttons scroll back and forward the chart contents;

the **Restore** button brings back to the original display mode;

the **8/24** button makes it possible to switch from 8 hours to 24 hours display mode (and vice versa).

The **Close** button makes the quick chart navigation tool disappear.

12.6.2. The "Other" function: extemporaneous orders

The **Other** button on the command bar (Fig 215 **A**) makes it possible to record the administration of a treatment that was not previously prescribed on the "Therapy Prescription" module.

Fig 215

This function can be used when the clinical staff must administer a treatment that is not on the patient treatment plan.

This is the procedure:

- click the **Other** button.

The following window opens:

Fig 216 - Other treatment

The boxes on the window are buttons. Each button is associated to a treatment. The treatments are grouped into classes. The labels placed on top of the window display the names of the various classes.

To display the items of a specific class

- click the corresponding label.

Click the **Drip** label, for instance (Fig 217 **A**), to display the treatments belonging to the corresponding class (Fig 217).

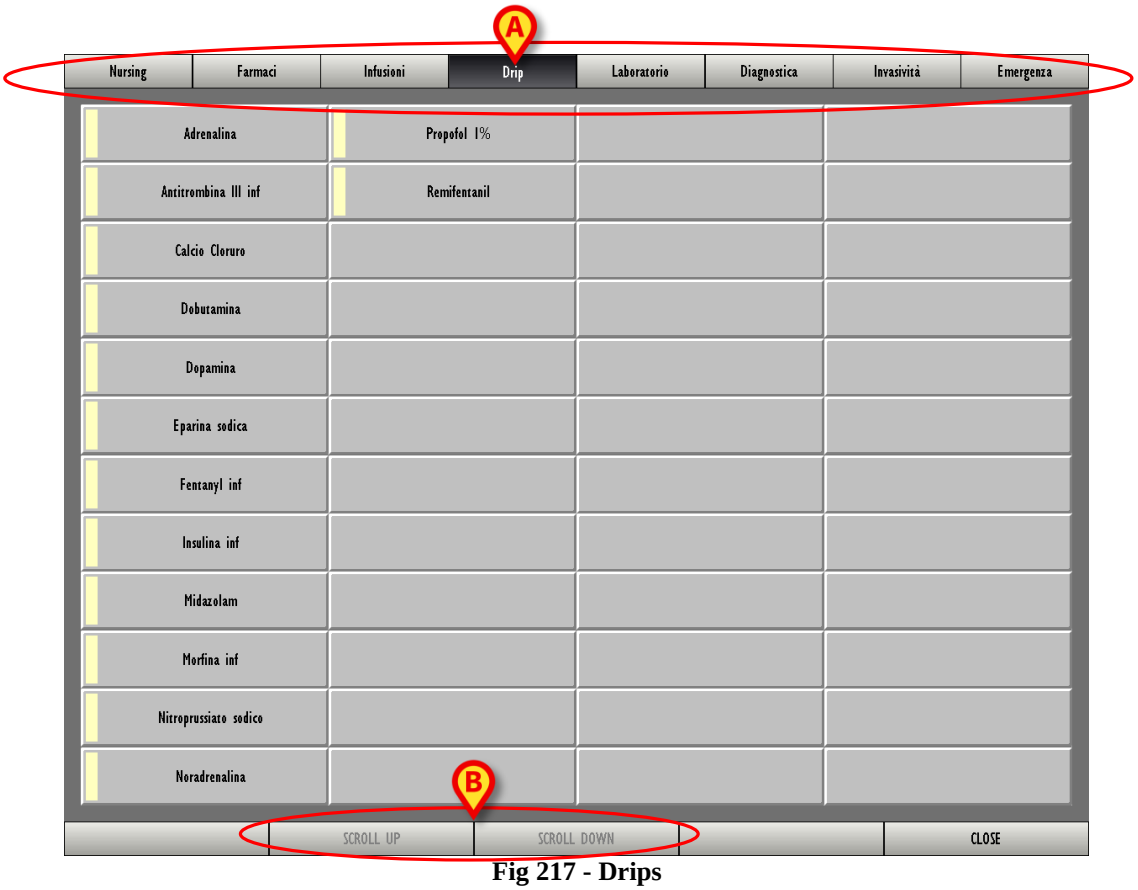


Fig 217 - Drips

When the number of available treatments of a class exceeds the number of available cells the buttons **Scroll Up** and **Scroll Down** (Fig 217 **B**) activate, making it possible to scroll the treatments list.

The various treatments are characterized by a color indicating the class to which they belong. The classes and their related colors are listed in paragraph 8.4.

12.6.3. Extemporaneous orders administration

To record the administration of a treatment that is not part of the patient's treatment plan

- click the **Other** button.

The window shown in Fig 216 and Fig 217 opens.

- Click the label corresponding to the class to which the relevant treatment belongs (Fig 217 **B**).

Only the treatment-buttons belonging to that specific class are this way displayed on the window.

- Click the button corresponding to the wanted treatment (the name of the treatment is displayed on the button).

Another window appears, making it possible to set the values of the specific administration (see Fig 218 for an instance).

- Use the numeric keyboard to set the administration values.
- Click the **Do** button (Fig 218 **A**) to record the treatment administration

Fig 218 - Administration window

The administration is now displayed on the chart as "Executed" (Fig 219).

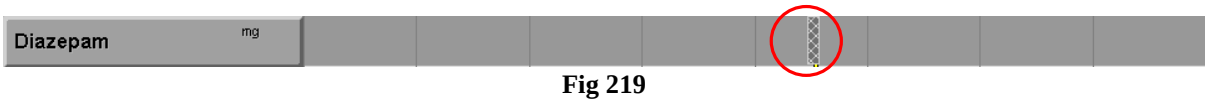


Fig 219

The administration is also displayed on the treatment plan on the "Prescription" module as "Executed" (Fig 220).

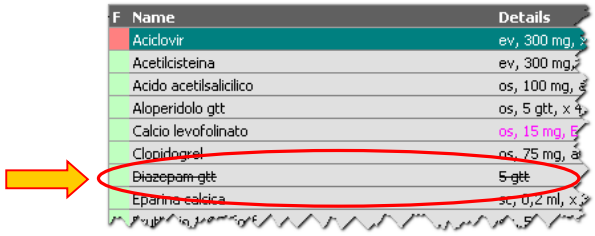


Fig 220

The administration window shown in Fig 218 is described in detail in paragraph 12.5.4.

12.6.4. “Execution” module print functionalities

The **Print** button on the “Administration” module’s command bar (Fig 221) makes it possible to create different kinds of documents.

Fig 221 - Command bar

Click the **Print** button to open a window making it possible to define the features of the document to be printed (Fig 218).

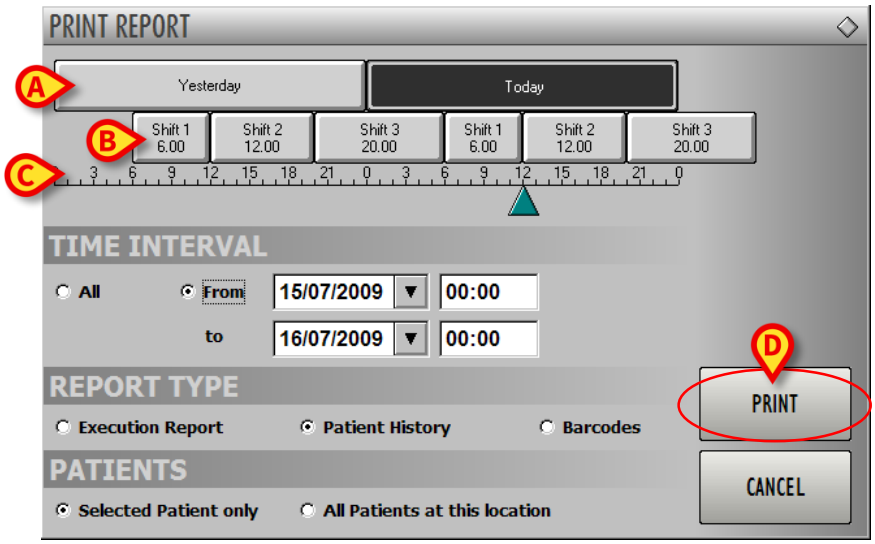


Fig 222 - Print options

The “Print report” window contains several tools making it possible to define the print report features.

These are the tools available:

The **Yesterday** and **Today** buttons (Fig 222 **A**) make it possible to print either the data referring to the current day or the data referring to the day before. The selected option is highlighted.

The “Shifts” buttons (**Shift 1**, **Shift 2** etc. Fig 222 **B**) limit the printed data to those referring to a specific shift. The selected shift is highlighted.

The time bar (Fig 222 **C**) indicates the current time. Current time is between 11:00 and 12:00 o’clock in the figure.

The “Time Interval” area (Fig 223) makes it possible to specify the beginning and the end of the time interval of the data to be printed. The “All” checkbox selection (Fig 223 **A**) prints all the available data, not depending on the time interval.

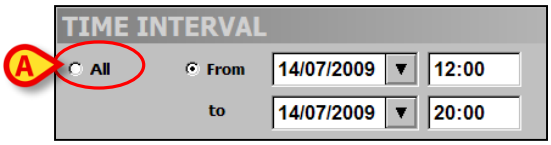


Fig 223 - Print options - Time Interval

The "Report type" area (Fig 224) makes it possible to select the kind of print report. Several options are available. The example here described offers the following options:

- execution report;
- patient history;
- administered treatments barcodes.

Click the corresponding checkbox to select a report type.

Fig 224 - Print options - Report Type

The "Patients" area (Fig 225) makes it possible to print either the single selected patient data or the data of all the patients in the selected location. Click the corresponding checkbox to select an option.

Fig 225 - Print Options - Patients

- When all the report features are set click the **Print** button (Fig 222 **D**) to display a print preview of the report. The "Print preview" screen is described in paragraph 6.8.1.

12.6.5. Patient notes

The Notes button (Fig 226 **A**) makes it possible to add and display the patient's notes.

Fig 226 - Command bar

The procedures related to this button are described in paragraph 11.11.

12.6.6. Patient clinical diary

The **Diary** button (Fig 226 **B**) makes it possible to access and use the DIGISTAT® "Clinical Diary" module if the module is installed. This module makes it possible to create and manage the patient's clinical diary.

See the specific documentation to know the DIGISTAT® "Clinical Diary" module functions and features.

13. The “Central Station” module

The “Central Station” module displays on the same screen the state and the needs of all the patients in the ward, providing real time information on each patient’s treatment plan and on the related schedule.

13.1. Module selection

To access the module

- click the 

icon on the lateral bar (Fig 227).

Fig 227 - Lateral bar

The “Central Station” screen opens (Fig 228).

13.2. “Central Station”

Fig 228 shows the Therapy “Central Station”.

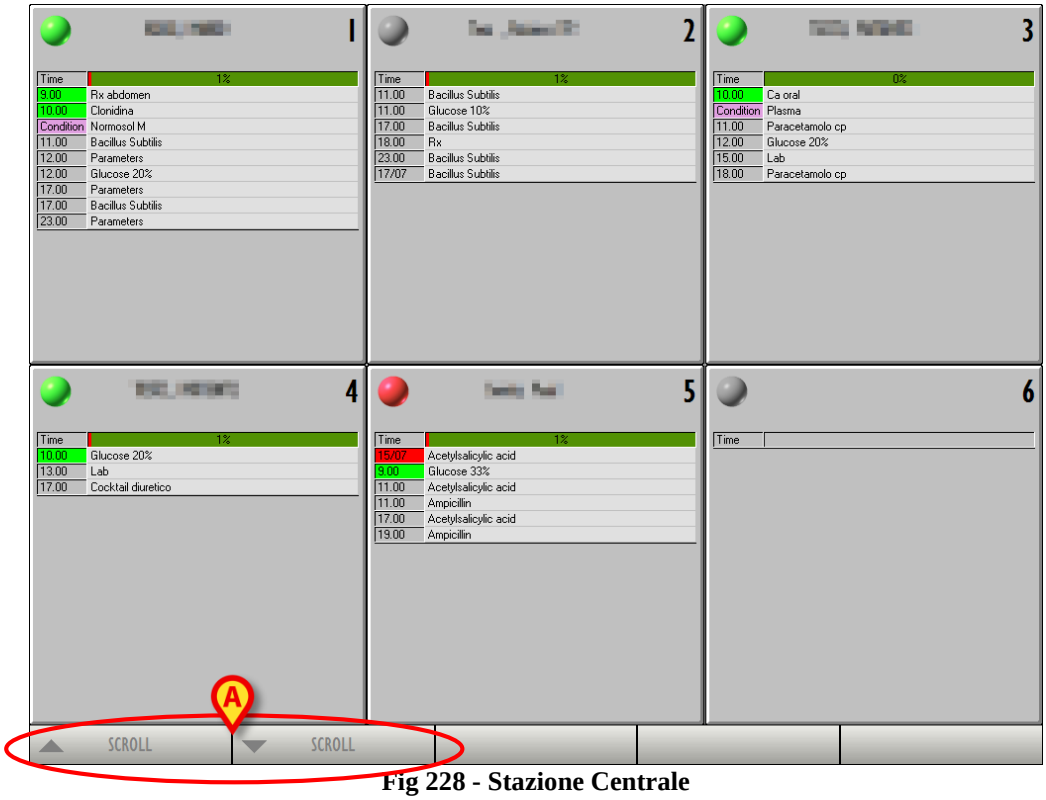


Fig 228 - Stazione Centrale

The screen contains several boxes; each box corresponds to a bed in the ward (Fig 229).
In case the configured beds are more than those displayed on screen the scroll buttons indicated in Fig 228 **A** activate; click these button to display the beds that are not currently displayed.

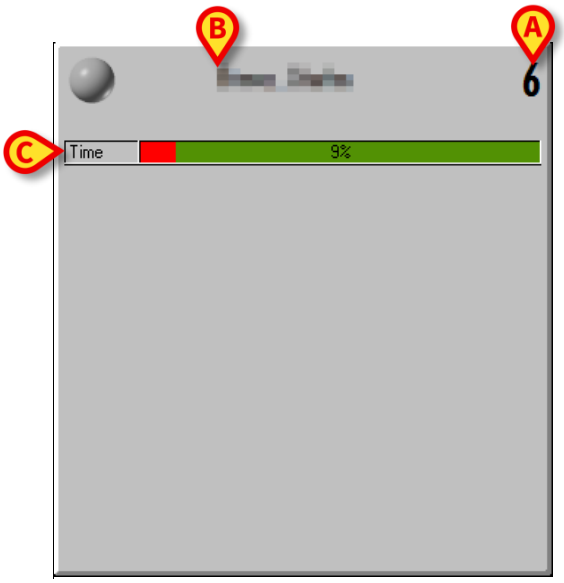


Fig 229 - Bed

The bed number is displayed on the top-right corner of the box (Fig 229 **A**).

When a patient is admitted to the bed the patient name appears on top of the box (Fig 229 **B**). Below the patient's name a temporal bar indicates the time that passed from the last therapy plan update.

The time bar has the same function and displays the same values of the tools described in paragraph 8.5.

In Fig 229 **C** the time bar indicates that the 9% of the total duration of the treatment plan validity passed.

The list of the patient's active orders is displayed in the central area of the patient-box (Fig 230). The orders are displayed by urgency: on top the alarmed ones, then the "ready" ones, then the conditional ones, then the orders to be executed in the future.

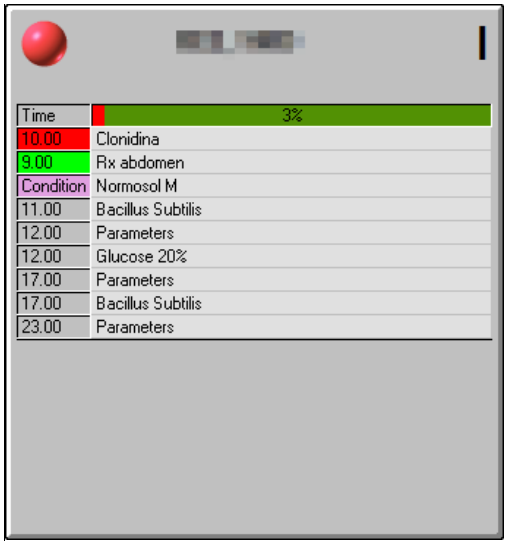


Fig 230 - Orders

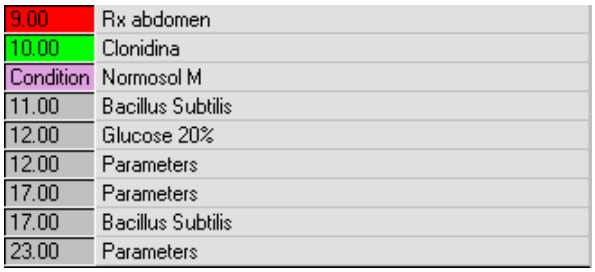


Fig 231 - Orders (detail)

The treatment name and the planned administration time are displayed for each order.

The planned administration time can be highlighted in different ways to provide information on the order state.

- Red means that the administration is late.

- Green means that the order should be administered now.
- Grey means that the administration is planned in the future.
- Purple indicates a conditional prescription (see paragraph 10.2.2 for an explanation of the meaning of "conditional prescription").

When the  icon appears beside an order it means that the order is not validated (there are two possibilities: either the order is not yet validated or the order validity expired).

Fig 232 - Order not validated

If there is at least one late order the round button on the top left corner of the box turns red (Fig 233)

Fig 233

If there is at least one order to be administered "now" the round button on the top left corner of the box turns green (Fig 234).

Fig 234

For the orders planned for the current day the scheduled administration time is indicated; for the orders planned for a different day the administration date is indicated (Fig 235).

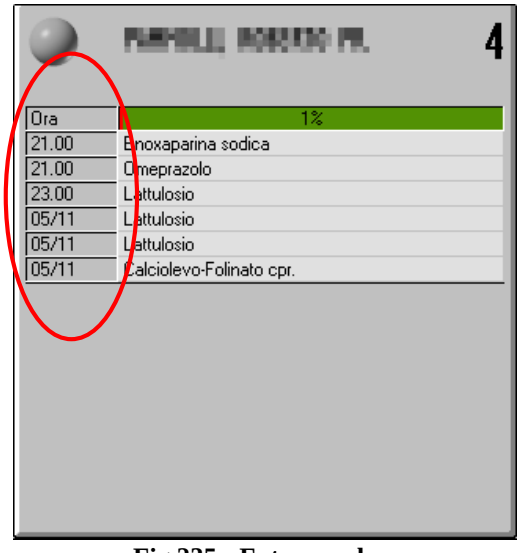


Fig 235 - Future orders

- Click the patient boxes to access the corresponding treatment administration screen ("Therapy Administration" module - Fig 175).

14. Enclosed Documentation

The following documents are enclosed

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

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

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

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

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Only these signed documents are a valid source of information for diagnostic or therapeutic processes and/or procedures.

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

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

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

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

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

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

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

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

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

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

* * * * *

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

Date Signature

SPECIFIC ACCEPTANCE OF CERTAIN PROVISIONS IN THIS CONTRACT

IMPORTANT—READ CAREFULLY

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

- COPYRIGHT

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

Date Signature

15. Contacts

- **ASCOM UMS srl unipersonale**

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

- **Technical assistance**

support@unitedms.com

800999715 (toll free, Italy only)

- **Sales and products information**

sales@unitedms.com

- **General info**

info@unitedms.com

Appendix A: glossary

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

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

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

ALARM MESSAGE

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

BUTTONS

- **Function buttons**

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

- **Active button**

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

- **Inactive button**

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

- **Make button active**

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

CHECKBOX

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

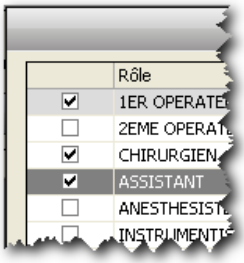

Figure 1 - Checkbox

- **Selection box**

  See “Checkbox”.

CLICK

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

- **Double Click**

  Click twice in rapid succession.

CLIENT

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

COMMAND BAR

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

Figure 2

CONFIGURATION

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

CONTROL BAR

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

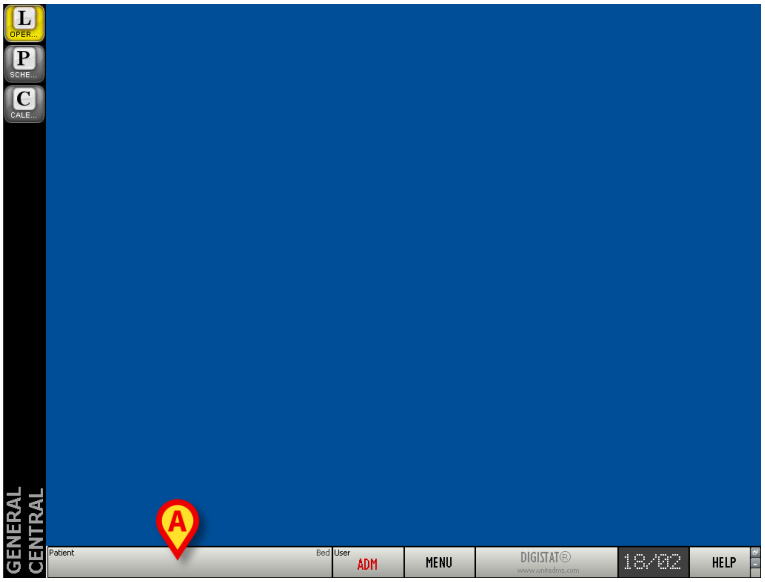

Figure 3

CURSOR

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

DATABASE

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

DEFAULT

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

DIGISTAT®

- **DIGISTAT® Module**

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

- **DIGISTAT® System**

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

- **DIGISTAT® Environment**

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

DRAG

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

DRAG AND DROP

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

EDIT

Modify the data on a screen.

- **Edit Mode**

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

- **Edit state**

  See “Edit Mode”.

EVENTS

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

FIELD

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

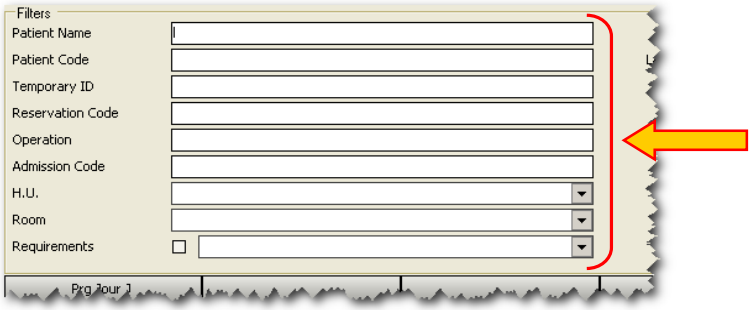

Figure 4 - Fields

❖ **Free field**

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

LOCATION

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

LOG

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

LOGIN (procedure)

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

❖ **Logout**

The act of exiting the system.

MARKER

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

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

MESSAGE CENTER

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

PAGE

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

PASSWORD

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

PATIENT

- **Admitted Patient**

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

- **Patient registered in the database**

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

- **Patient Selected**

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

POP-UP

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

QUERY

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

RADIOBUTTON

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

Figure 5

READ-ONLY

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

RECORD

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

RESERVE

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

SCREEN

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

SERVER

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

SLOT

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

Figure 6 - slot

STATE (of the operation)

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

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

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

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

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

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

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

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

SYSTEM ADMINISTRATOR

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

TAB

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

Figure 7 - Tab

TOOLTIP

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

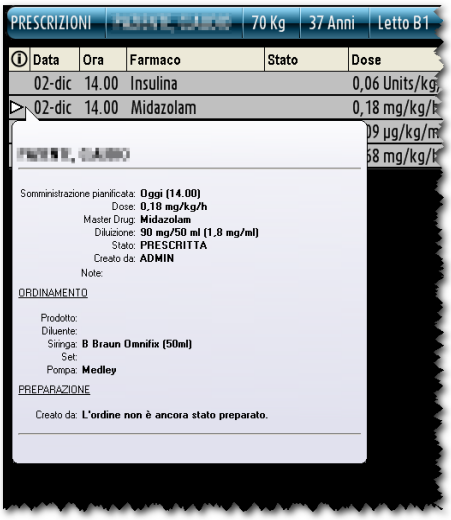

Figure 8 - Tooltip

TOUCH SCREEN

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

USER

The person using the system.

- **User Connected**

  See “User Logged In”.

- **User Logged In**

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

- **User Logged-out**

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

USERNAME

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

WARNING MESSAGE

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

WORKSTATION

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

Appendix B – Residual risks

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

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

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

RISKS RELATING TO THE HARDWARE PLATFORM IN USE

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