DIGISTAT® OranJ

DIGISTAT® Version 4.0

User Manual

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SOFTWARE LICENSE

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

WARNING

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

LICENSES AND REGISTERED TRADEMARKS

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

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

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

1. Contents

2. Using the manual

2.1. Aims

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

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

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

To be more precise, the differences may concern

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

Care has been taken to highlight and emphasize this concept every time the configuration possibilities are such as to prevent a univocal description of the system operation.
Should you require more details regarding a specific configuration, please contact your system administrator or the UMS technical support service.
Remember that, by specific request, UMS is able to provide custom-made documentation for every specific type of procedure and/or configuration.
Please remember that DIGISTAT® must only be used by authorized and trained users, as specified in the "Intended users" paragraph.

2.2. Charcters used and terminology

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

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

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

Every time reference is made to a button, this is written in upper case and highlighted in grey. For example, in expressions like.

- Click the XYZ button,

XYZ is a button featured on the page being described.

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

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

2.3. Symbols

The following symbols are used in this manual.

Useful information

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

Caution!

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

3. Introduction to DIGISTAT®

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

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

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

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

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

3.1. Modular architecture

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

3.2. Intended use

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

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

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

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

Always check that the information supplied is correct. It is complete and exclusive responsibility of the user to make correct use of the information supplied and check every time that they are correct.

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

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

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

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

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

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

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

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

"DIGISTAT®" does not substitute a "Nurse Call" system and it is not a "Distributed Alarm System" (as defined by the regulation EN 60601-1-8). Therefore, it must not be used in place of the direct monitoring of the alarms generated by the medical devices.

DIGISTAT® is not a "Distribuited Alarm System".

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

3.2.1. Intended users

"DIGISTAT®**"** must be used by properly trained physicians, nurses, administrative staff and technicians.
Use of the system must be granted, by means of specific configuration of the passwords and active surveillance, only to trained personnel in possession of the professional qualifications to correctly interpret the information supplied and to implement the appropriate safety procedures.

Use of the system must be granted only to professionally qualified and properly trained personnel.

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

3.2.2. Intended environment

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

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

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

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

In using the Product, the user declares to have understood and accepted the characteristics, limits and responsibilities described in this user manual. Should the user consider any of these clauses to be unacceptable, he must stop using "DIGISTAT®" immediately and inform promptly the system administrator.

3.3. Manufacturer's responsibility

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

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

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

3.4. Product tracking

In order to ensure device tracking and on-going safety and efficiency checks on site,

in compliance with ISO 9001 and EN 13485 quality standards and European law on medical devices 93/42/EEC, amended by the directive 2007/47/EC,

the former owner is recommended to inform UMS, one of its branches or the nearest authorised dealer about any ownership transfer either by duly filling in the "Product Tracking Form" published in the final pages of the present document or by giving written notice with the same data requested in the abovementioned form.

Device data can be found in the product labelling (either paper label provided at installation time or "About box" displayed within the product – see paragraph 7.5.5).
In case of doubts/questions about product labelling and/or product identification please contact UMS technical assistance (for contacts see paragraph 6)

3.5. CE mark and regulation conformity

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

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

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

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

3.6. Post-market surveillance

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

The device details can be found on its labelling.

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

3.7. Product life

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

4. Software and hardware specifications

4.1. Bedside

4.1.1. Hardware

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

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

4.1.2. Operating System

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

4.2. Central

4.2.1. Hardware

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

Hardware requirements:

- Intel® Celeron® processor with Intel® dual-core technology (or faster)
- Memory: 2 GB RAM (4 GB recommended)
- Hard Disk: at least 20 GB of available space
- Monitor: 1024 x 768 or higher (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- Windows 7/XP compatible printer (optional)
- Ethernet interface 10/100 Mb/s (or higher)
- CD/DVD Drive (optional)

4.2.2. Operating System

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

4.3. Server

4.3.1. Hardware

Minimum hardware requirements:

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

RECOMMENDED SERVER IN A CLUSTER ENVIRONMENT:

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

4.3.2. Operating System

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

4.3.3. System Software

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

4.4. Local network features

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

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

ATTENTION!

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

4.4.1. DIGISTAT® impact on the hospital network

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

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

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

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

Average: 0.8 – 6 Mbit/s

Pitch: 5 – 25 Mbit/s

5. Before starting

5.1. Installation and maintenance warnings

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

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

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

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

5.2. Cleaning

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

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

5.3. Precautions and warnings

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

5.3.1. Precautions

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

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

5.3.2. Warnings

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

- **Electrical safety**

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

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

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

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

- **Patient Area**

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

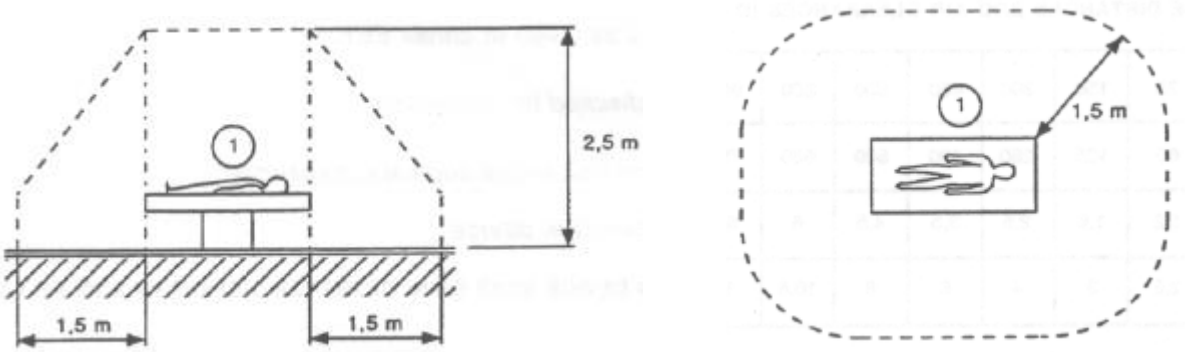


Fig 1 – Patient Area

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

WARNING!

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

- **Electromagnetic compatibility**

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

- **Devices eligibility**

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

5.4. Privacy Policy

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

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

Please read the following precautions carefully and strictly observe them.

- The workstations must not be left unattended and accessible during work sessions. It is recommended to log out when leaving a workstation. See paragraph 7.2 for log out procedure.

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

- The user is advised against the frequent use of the lock function (paragraph 6). Automatic log out allows to protect the system from unauthorized accesses.

5.4.1. User credentials features and use

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

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

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

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

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

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

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

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

- Password must be at least 8 characters.

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

- The password is given by the system administrator at user account creation time. It must be changed by the user at first access (see paragraph 7.5.4 for the password modification procedure).

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

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

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

The following information is reserved to system administrators:

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

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

5.4.2. System administrators

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

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

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

5.4.3. System logs

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

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

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

5.5. Back up policy

It is recommended to regularly perform system backups.

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

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

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

5.6. Out-of-order procedure

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

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

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

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

In order to speed up replacement times, we suggest to have at disposal one or more substitution equipment with all the necessary apllications already installed (OS, firewall, antivirus, RDP, ...) and with DIGISTAT® already installed, but disabled (i.e. not executable by a user without the assistance of an UMS technician).
In case of out of order of a DIGISTAT® workstation, the substitution equipment availability assures the minimization of restoration times (hardware substitution) an limits at the same time the risk of patient exchange.

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

1) The hospital staff replaces the out of order PC with the "substitution equipment"
2) The hospital staff calls UMS and requests the "substitution equipment" activation

3) The UMS staff disables the out of order workstation and correctly configure the "substitution equipment"
4) The out of order PC is repaired and prepare d as "sustitution equipment"

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

5.6.1. Reconfiguration/substitution of network equipment

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

5.7. Preventive maintenance

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

This is the maintenence checklist:

Preparatory checks

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

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

- Schedule possible updates with the technical staff

Checks to be performed

Antivirus

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

Database

- Check that an effective DIGISTAT® database clean-up and back-up policy is configuraed.

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

```
USE [DATABASENAME]
GO

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

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

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

EXEC (@INS);

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

DROP TABLE [#SpaceUsed]
```

Server

- Check the Windows™ server event log.
- Check the permissions on the shared folders (es: Backup folder).
- Useless files and directories clean up to free up space on server disk.
- Check the displays (if any) on the server rack and verify that there are neither visual nor sound alarms.
- Check that on the different disk units there is enough space available.

- Disk check with dedicated tools (checkdisk, defrag, etc.).
- In case there are disks in RAID, check the health conditions of the RAID unit on the RAID management software.
- Check the leds of the non-alarmed RAID units.
- If an UPS is connected, check its health conditions with its management software.
- In case of UPS schedule an electric interruption (an electric failure simulation) and check thet the server is configured ti perform a CLEAN shutdown.

Workstations

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

DIGISTAT®

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

Connection to devices

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

Instruction for use

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

5.8. Compatible devices

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

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

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

It is possibile to make request of the updated list of those devices to UMS. Please use for this purpose the references (tel, e-mail, fax…) printed on the cover of this manual.

5.9. System unavailability

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

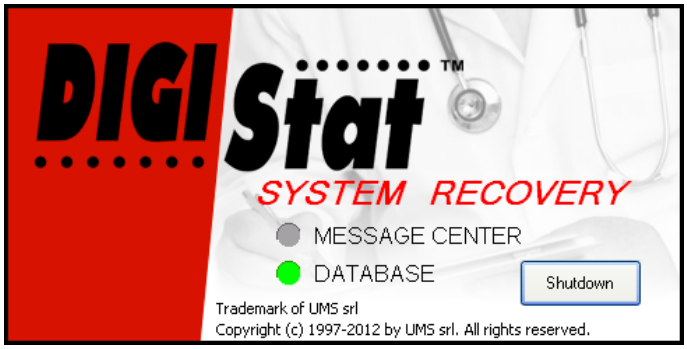


Fig 2

The connection problem is often automatically solved in a short time. If it does not happen it is necessary to contact the technical assistance (see paragraph 6 for the contacts list).

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

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

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

WARNING!

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

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

See paragraph 6 for the contacts list.

6. Contacts

- **UMS srl - United Medical Software**

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

- **Technical assistance**

support@unitedms.com

800999715 (toll free, Italy only)

- **Sales and products information**

sales@unitedms.com

- **General info**

info@unitedms.com

7. “Control Bar” and DIGISTAT® environment

7.1. Introduction

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

7.1.1. Launching DIGISTAT®

To launch DIGISTAT®,

- double click the desktop icon (Fig 3).

Fig 3

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

Fig 4

7.1.2. DIGISTAT® Work Area

The DIGISTAT® Work Area is defined and delimited by Control Bar, a tool that is common to all and every possible DIGISTAT® installation (Fig 5).
Control Bar manages the installed modules and systems, the patients and their data, the users and their permissions etc.

DIGISTAT® Control Bar is formed by a horizontal command bar (Fig 5 **A**), by a vertical selection bar on the left (Fig 5 **B**) and by a central Work Area. The different screens of the installed modules are displayed within the Work Area (Fig 5 **C**).

Fig 5 shows Control Bar with no module installed.

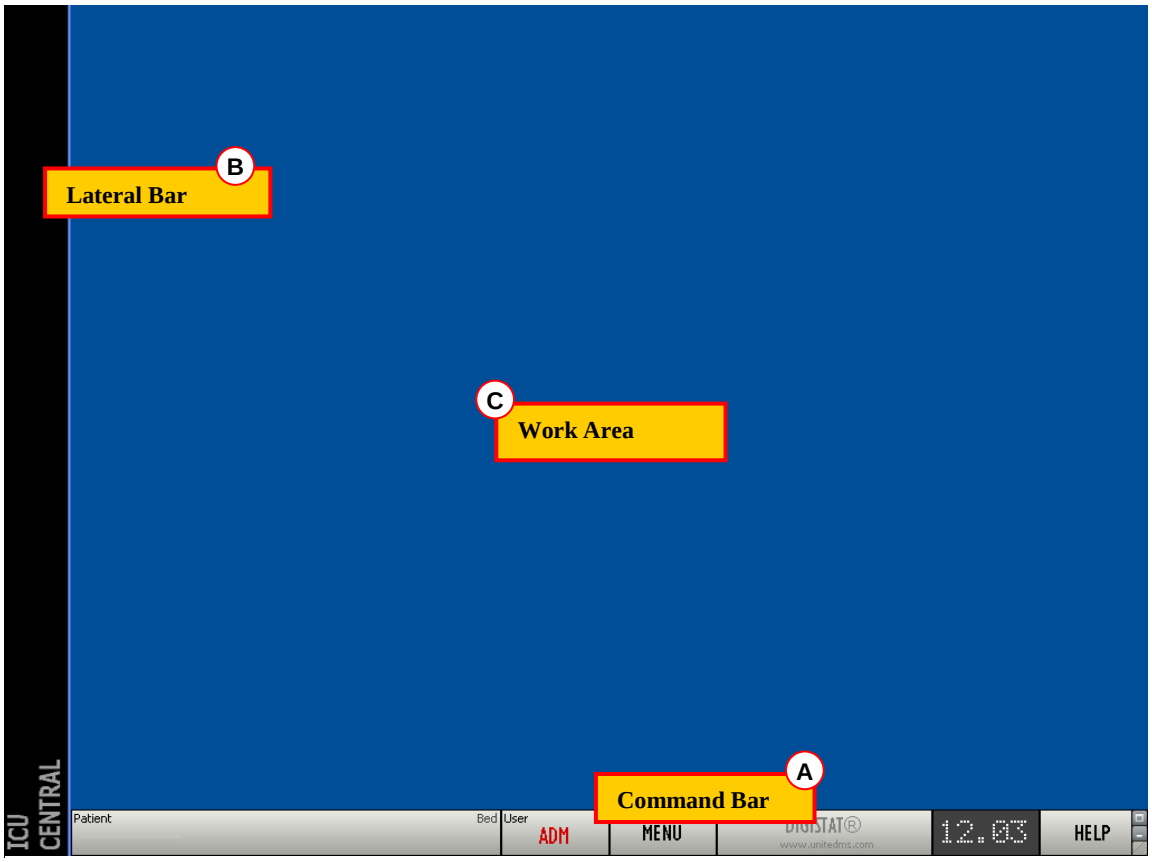


Fig 5 - Control Bar

The command bar (Fig 5 **A**) will be described in paragraph 7.1.3 (and subsequent).

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

Fig 6 - Two available modules

The module currently selected is highlighted (yellow).

7.1.3. Selecting a module

To select a module

- click the corresponding icon.

The icon will be highlighted and the module's functionalities will be displayed within the Work Area.

It is possibile to select a specific module only after the user log in (paragraph 7.2).

7.2. Accessing the system

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

The following page appears.

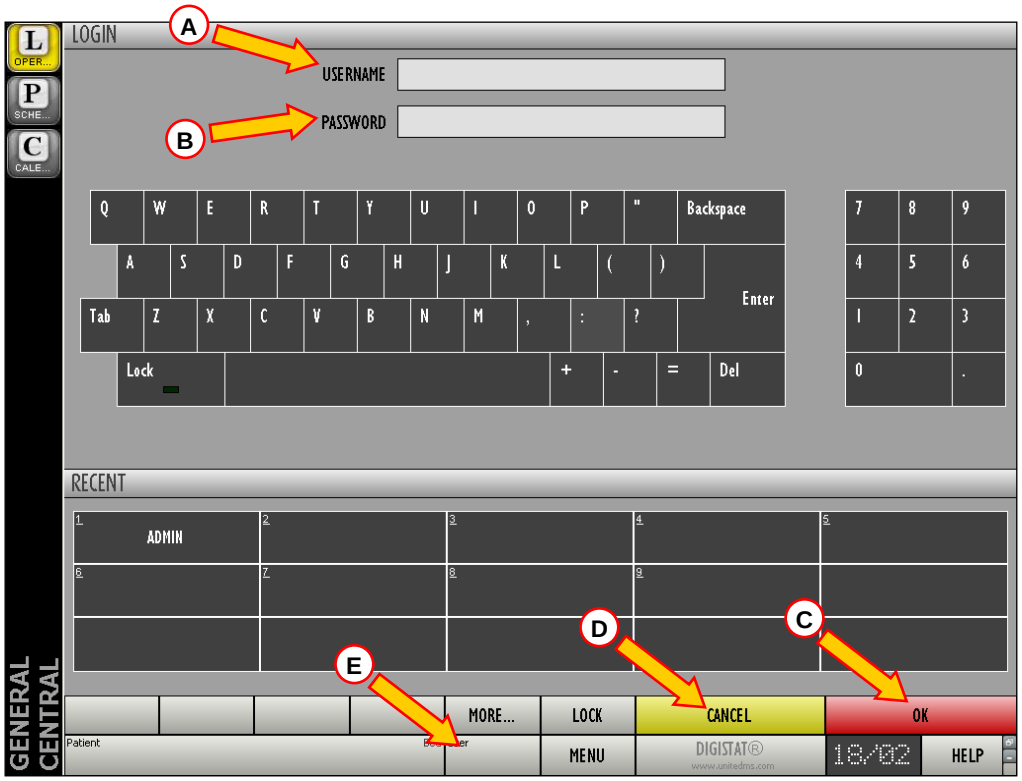


Fig 7 – Access to the system

To access the system,

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

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

- click the CANCEL button (Fig 7 **D**).

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

You can enter your username and password either using the virtual keyboard displayed on screen (clicking the letters with the mouse or touching them if you are using a touch screen) or the workstation keyboard.

After accessing the system, an acronym corresponding to the logged user appears on the USER button on the control bar (the acronym is ADM in Fig 8 **A**).

Fig 8 – User connected

WARNING!

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

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

To log in again, click the USER button again. The page shown in Fig 7 will appear again.

WARNING!

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

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

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

7.2.1. Barcode log in

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

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

- scan the user's personal barcode.

Fig 9 - Barcode reader (example)

The user is immediately logged in.

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

7.2.2. Disabling the automatic log out

If the system remains idle for a certain length of time, the user is automatically disconnected (automatic log out). This length of time depends on a configuration parameter.

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

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

Fig 10 – Control Bar

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

Fig 11 – User Locked

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

7.2.3. Recent users

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

Fig 12

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

7.2.4. How to use the “User List”

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

Fig 13 – Opening the “User List”

To display the “User List”,

- click the MORE button.

The following window appears (Fig 14).

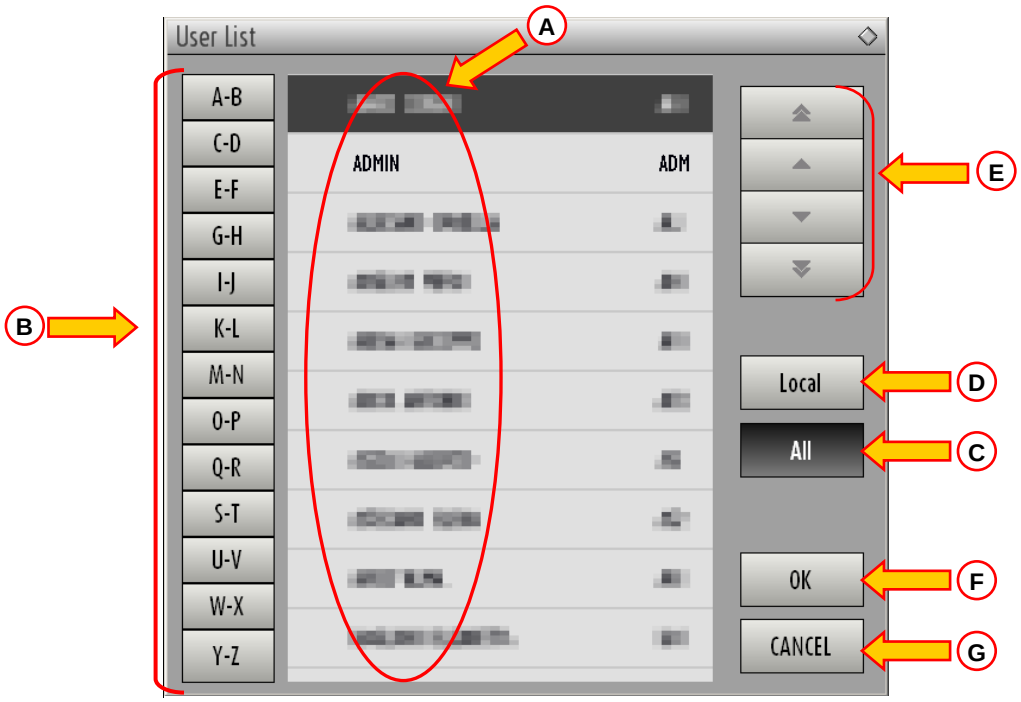


Fig 14 – User List

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

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

The letters on the left side of the window (Fig 14 **B**) work like an index and make it possible to see only the users whose names begin with a specific letter.

For example: click the C-D button to see the list of patients whose names begin with the letters C or D.

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

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

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

To select a user

- click the name of the user.

The name will be highlighted, then

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

Otherwise you can

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

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

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

7.3. DIGISTAT® Control Bar

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

Fig 15 - Control Bar

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

Fig 16 – Main Menu

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

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

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

These three buttons are present only if enabled by configuration.

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

7.3.1. How to read the "Patient" button

Patient selected

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

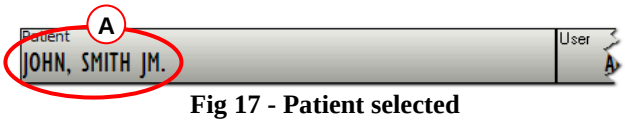


Fig 17 - Patient selected

Patient admitted

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

Fig 18 - Patient Admitted

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

Fig 19

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

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

Fig 20

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

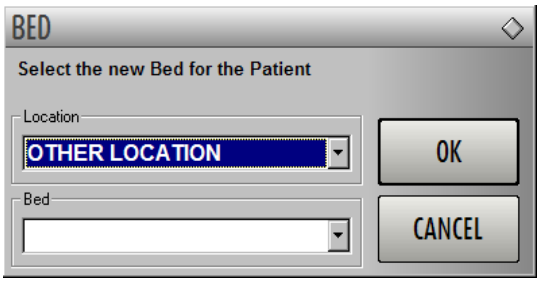


Fig 21 - Bed selection window

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

Workstation locked to bed

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

Fig 22

Patient management.

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

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

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

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

WARNING!

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

7.4. Help

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

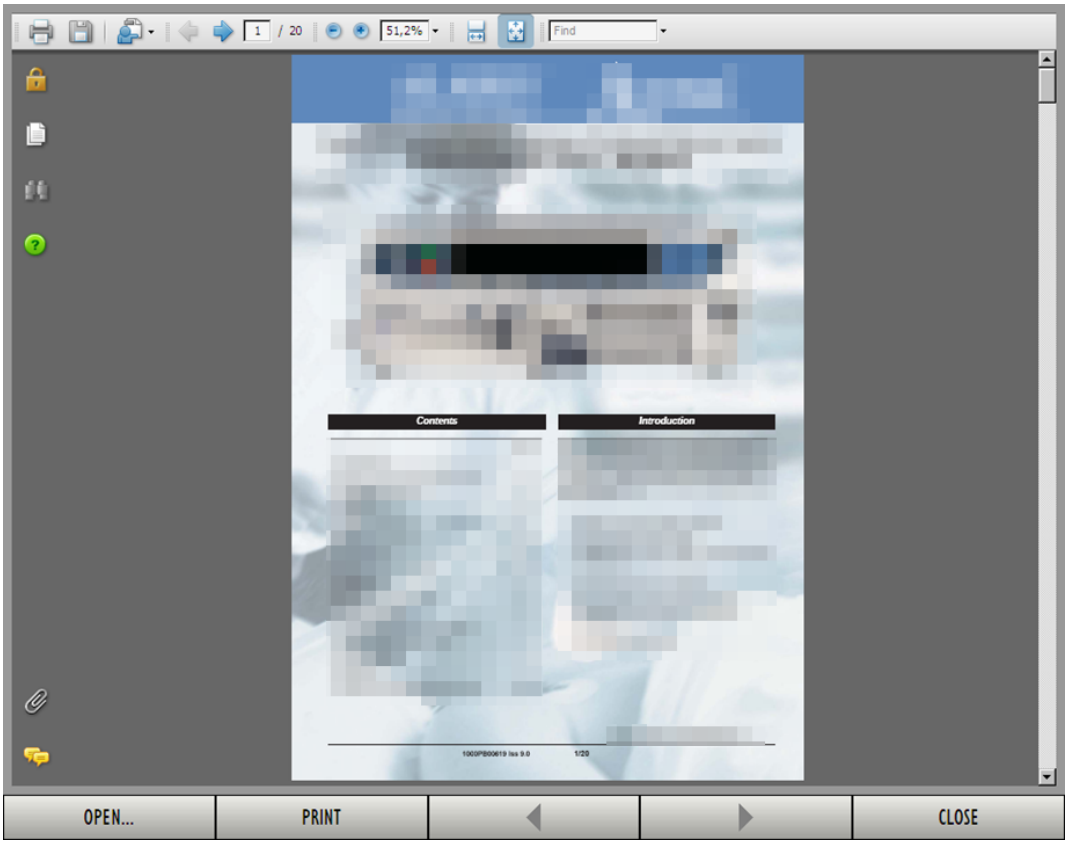


Fig 23

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

Fig 24

- the OPEN... button makes it possible to open other documents (if the user has the required permissions);
- the PRINT button prints the currently displayed document;

- the  and  buttons display either the previous or the next page of the document;
- the  button closes the on-line help.

7.5. DIGISTAT® Main Menu

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

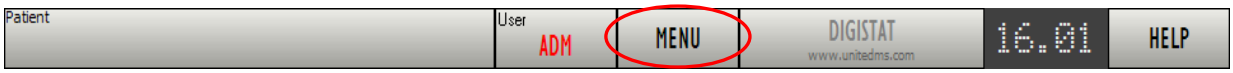


Fig 25

opens a menu containing several options (Fig 26).

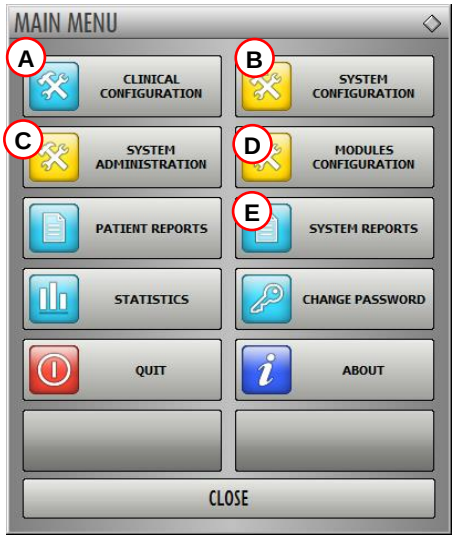
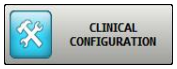
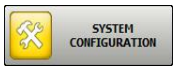


Fig 26 - Configuration functions

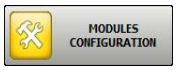
Each button on the menu accesses a specific set of functions.

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

 - (Fig 26 **A**)

 - (Fig 26 **B**)

 - (Fig 26 **C**)

 - (Fig 26 **D**)

- (Fig 26 **E**)

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

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

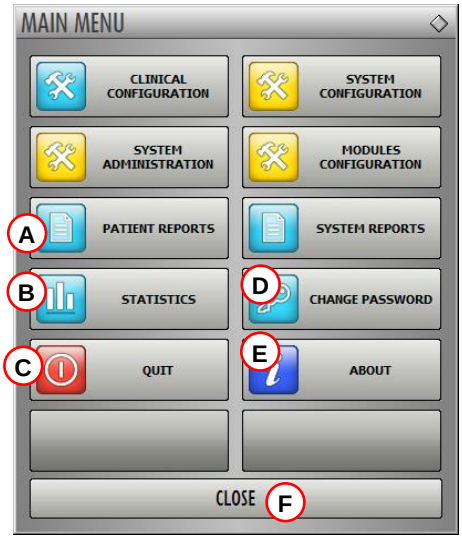


Fig 27 - Functions for the user

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

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

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

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

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

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

7.5.1. Patient reports

The “Patient reports” button - 

(Fig 27 **A**) - accesses a set of options enabling the user to print reports of different kinds for the selected patient.

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

Fig 28 - Patient reports

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

7.5.2. Print reports

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

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

To print a patient report

- click one of the buttons on the menu (for example 

).

A print preview will open (Fig 29).

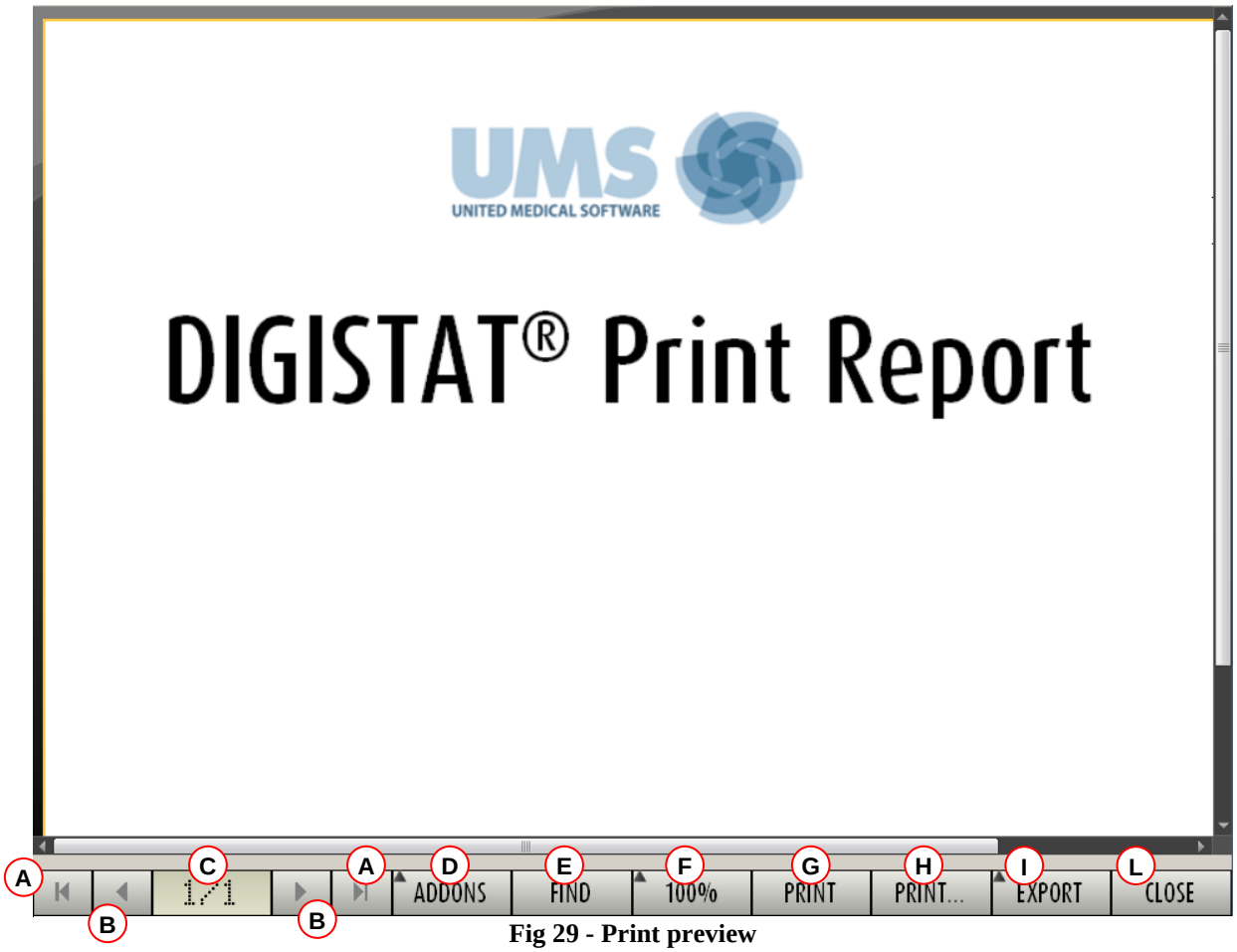


Fig 29 - Print preview

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

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

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

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

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

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

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

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

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

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

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

7.5.2.1. Addons

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

To display the available options,

- Click the ADDONS button.

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

Fig 30

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

Addons - Watermark

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

- Click the MARK button.

The following window is displayed (Fig 31).

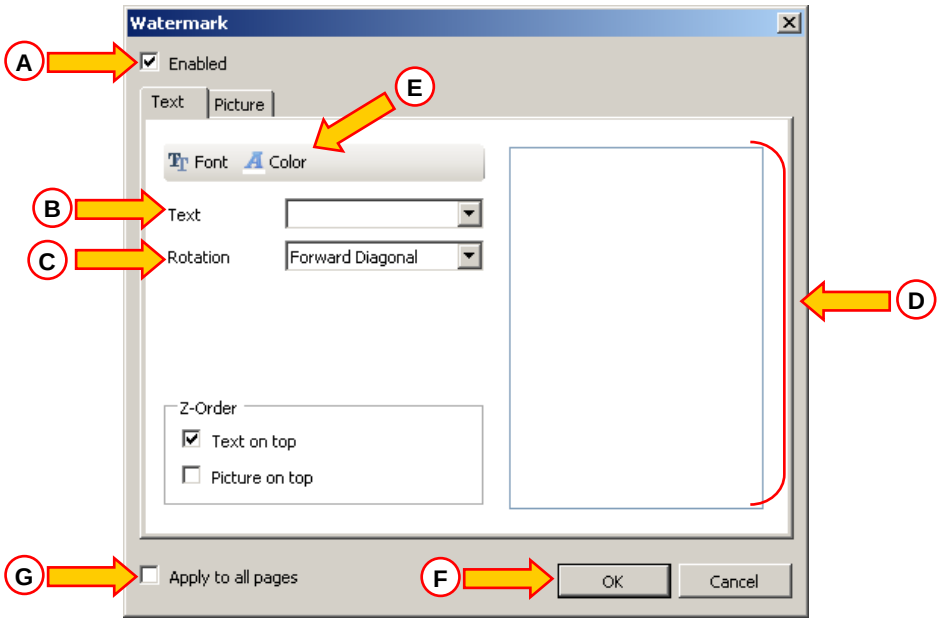


Fig 31

To add a textual watermark,

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

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

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

The text is this way inserted as watermark.

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

To insert a picture as watermark

- Click the "Picture" tab indicated in Fig 32 **A**.

The following window is displayed (Fig 32).

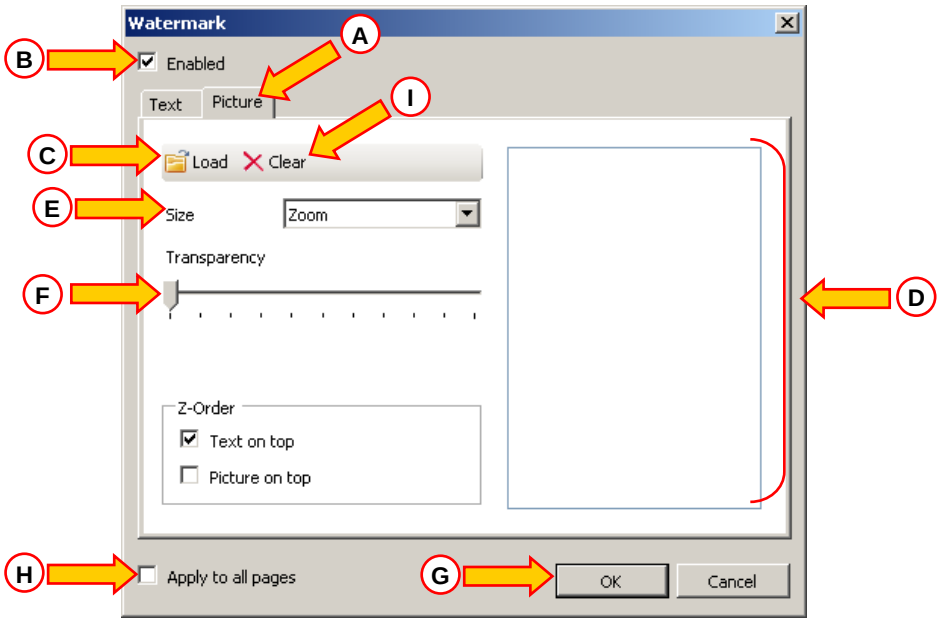


Fig 32

Follow these steps to insert an image as watermark,

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

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

- Search and select the image to be uploaded.

The image is displayed in the area indicated in Fig 32 **D**.

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

The watermark image is this way inserted.

If the "Apply to all pages" checkbox is selected (Fig 32 **H**) the watermark is applied to each page in the document, otherwise it is applied only to the current page.

To delete an already selected image,

- Click the "Clear" button indicated in Fig 32 **I**.

7.5.2.2. Find

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

To search the print report,

- Click the FIND button.

The following window opens (Fig 33).

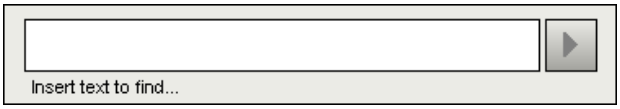


Fig 33

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

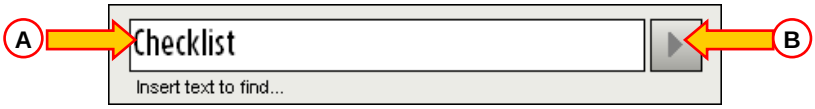


Fig 34

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

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

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

7.5.2.3. Zoom

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

To change the display mode,

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

Fig 35

- Click the wanted option on the menu.

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

The following options are available:

the WIDTH button makes it possible to display the page using the full screen width;

the PAGE button displays the whole page;

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

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

the 

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

7.5.2.4. Print

The PRINT... button opens a window offering several print options.

- Click the PRINT... button (Fig 29 **H**) to display the print options window (Fig 36)

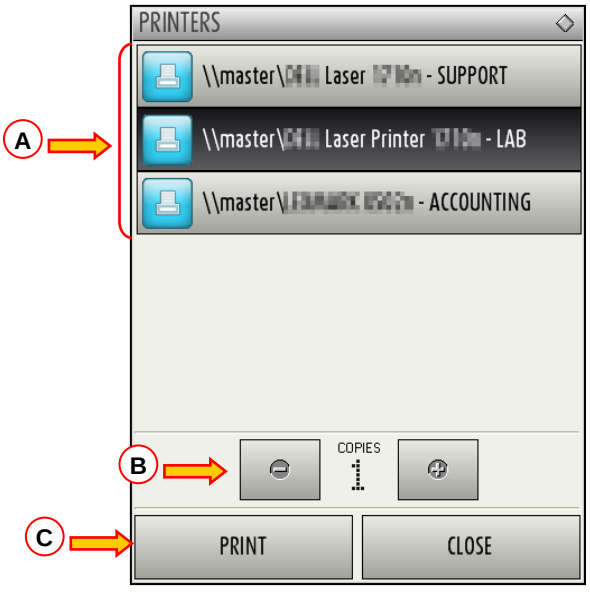


Fig 36

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

- Click the wanted option on the menu to select the printer (Fig 36 **A**).

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

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

7.5.2.5. Export

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

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

Fig 37

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

- Click the option corresponding to the wanted extension.

The document is this way exported to the corresponding extension.

7.5.3. Statistics

The 

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

Fig 38

The button opens another menu (Fig 39) that enables to access various distinct tools.
The type and number of accessible tools depend on the configuration in use and the specific modules installed.

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

The "Query assistant" tool, which is accessible for users having specific permissions, is described in paragraph 7.5.3.1.

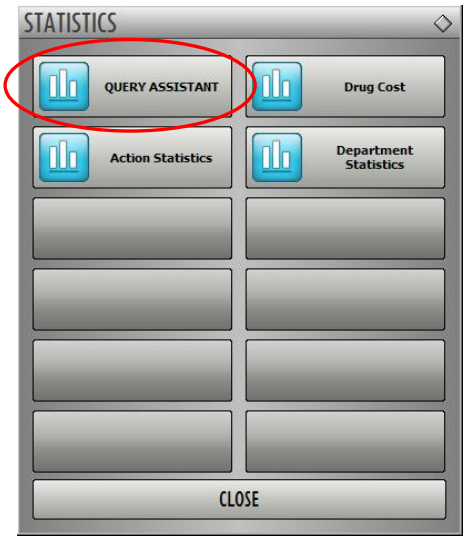


Fig 39

7.5.3.1. Query Assistant

The 

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

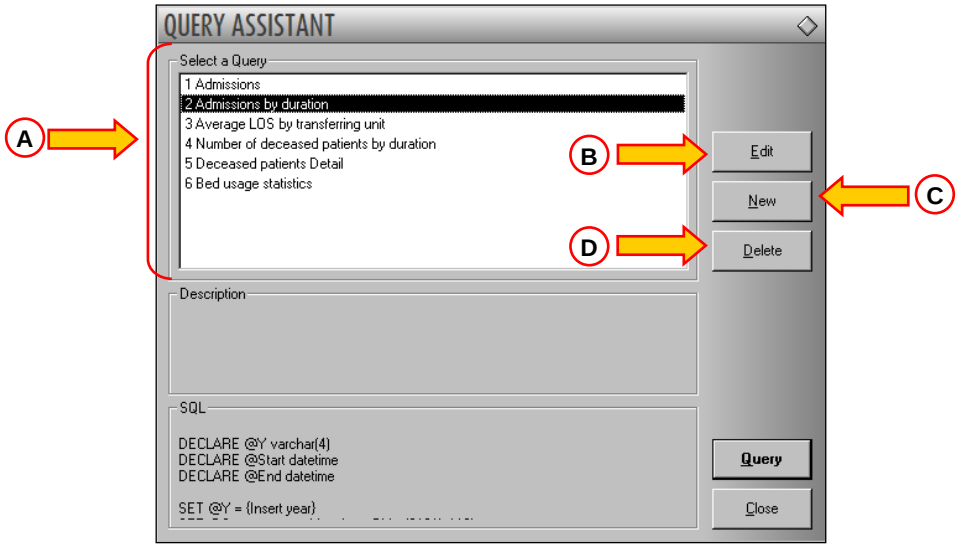


Fig 40 - Query Assistant

The user can select a query from a list of pre-defined queries, to execute it and display the results in a specific window.
The "Select a Query" area displays the list of all the pre-defined queries (Fig 40 **A**).

To run a query

- click the corresponding name on the list,

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

A textual description of the query is displayed in the "Description" area (Fig 41 **B**).
The "SQL" area (indicated in Fig 41 **C**) displays the content of the query in SQL language (Structured Query Language).

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

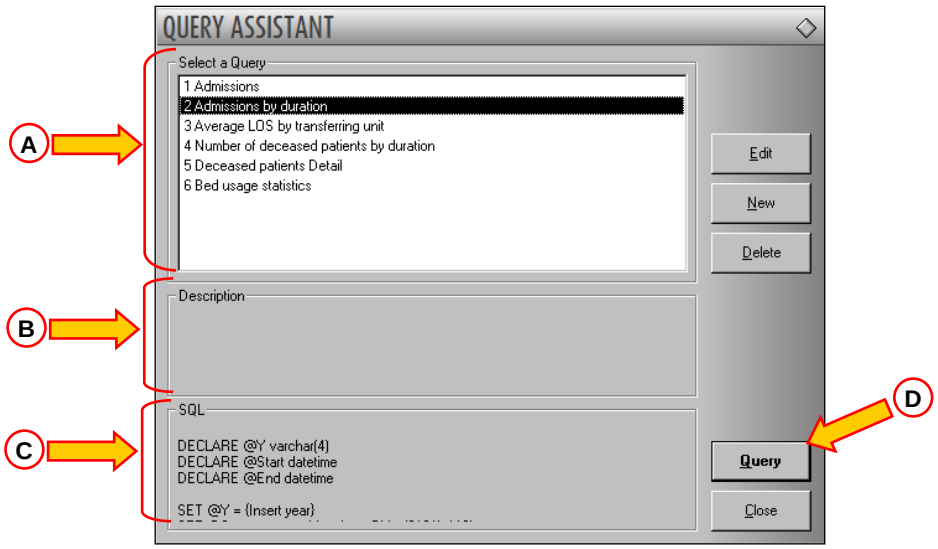


Fig 41 - Selected query

To run the query

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

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

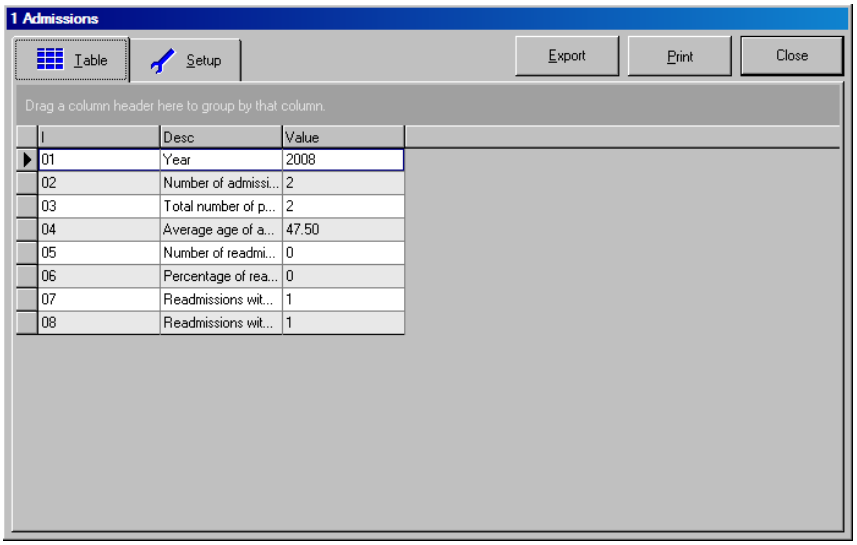


Fig 42 - Results

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

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

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

7.5.4. Change password

The 

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

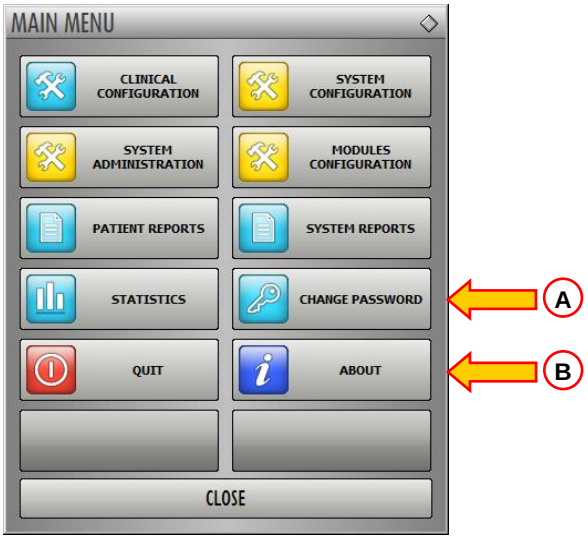


Fig 43

To change the user password

- click the 

button (Fig 43 A).

The "Change password" window will open.

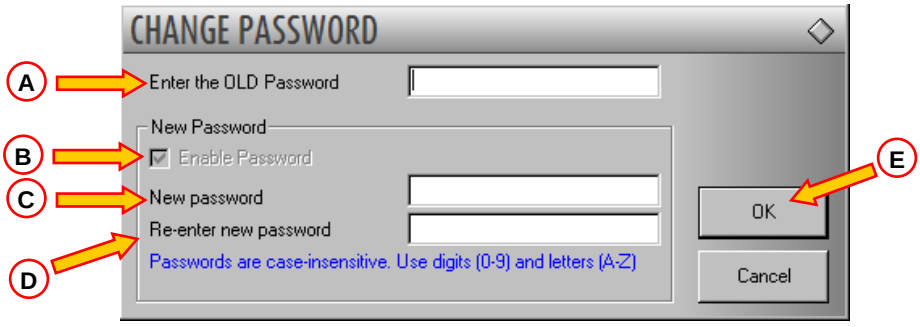


Fig 44 - Change password

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

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

7.5.5. About DIGISTAT®

The 

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

Fig 45

7.5.6. Quit DIGISTAT®

The 

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

To quit DIGISTAT®

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

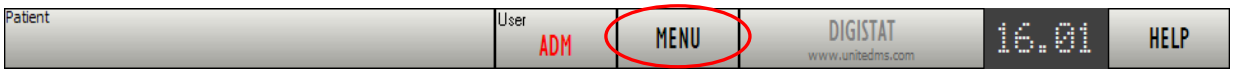


Fig 46

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

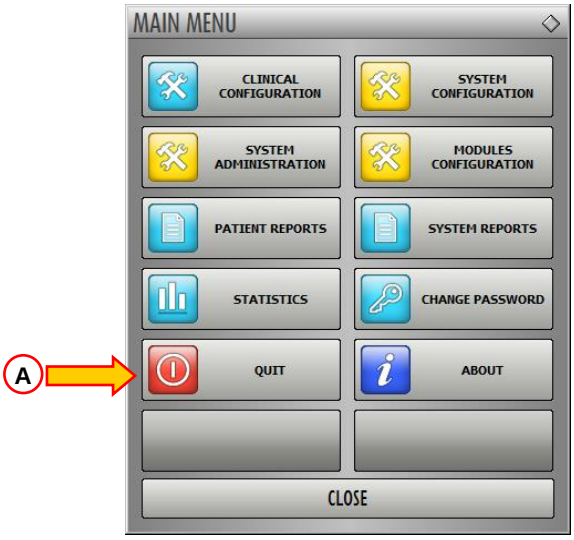


Fig 47 - Main menu

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

Another menu is displayed (Fig 48).

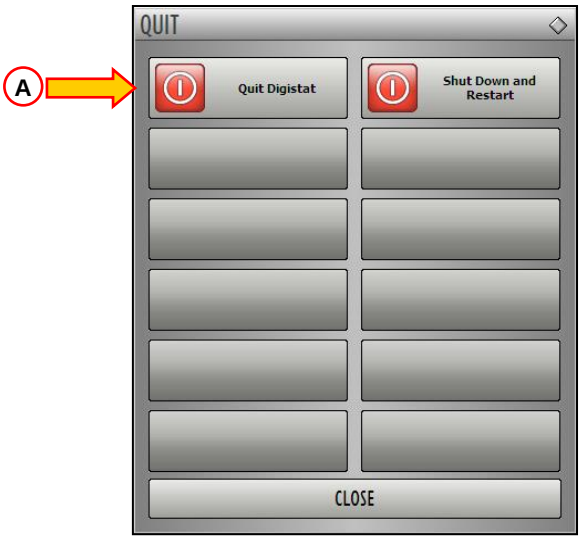


Fig 48

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

A confirmation is requested (Fig 49).

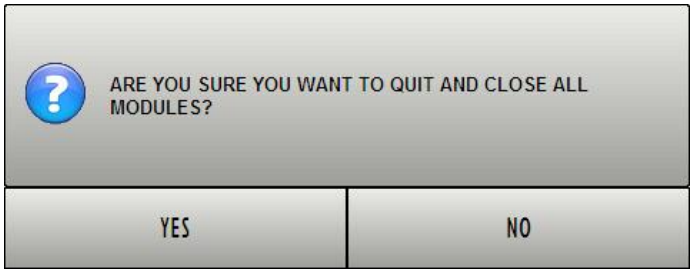


Fig 49

- Click YES to exit DIGISTAT®.

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

7.6. Side toolbar

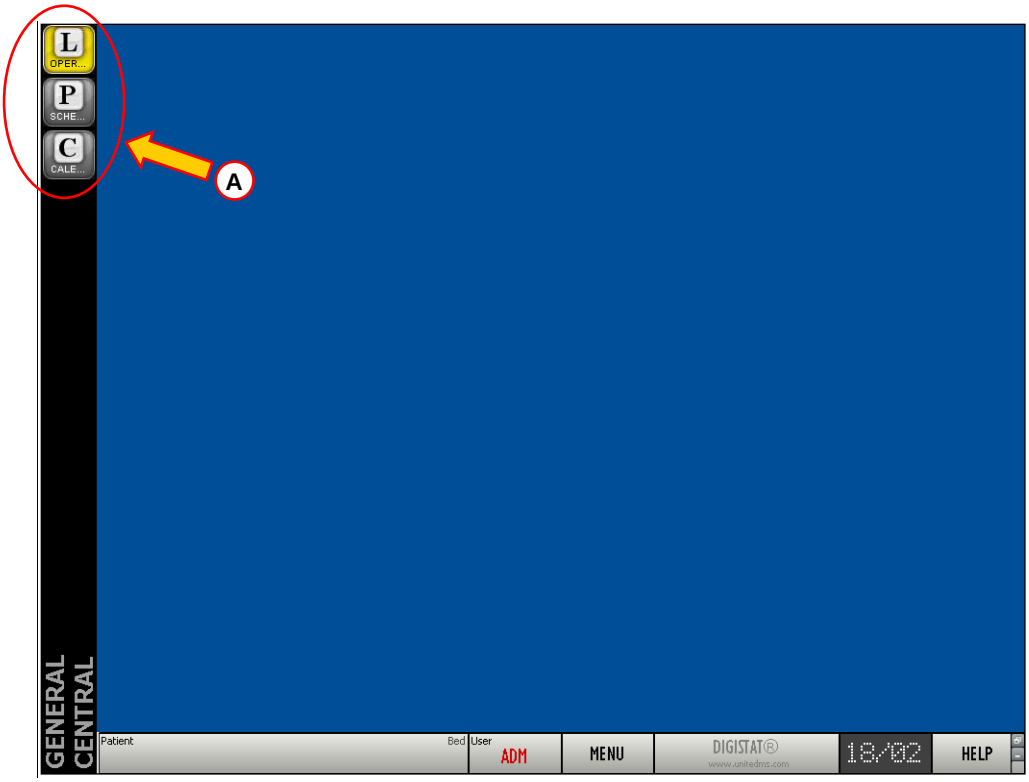


Fig 50- Side Toolbar

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

Fig 51 – Module icons

The icons on the side toolbar represent the available modules.

To activate one of the system modules

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

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

7.7. Warning messages

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

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

1) Timer window with single option (Fig 52).

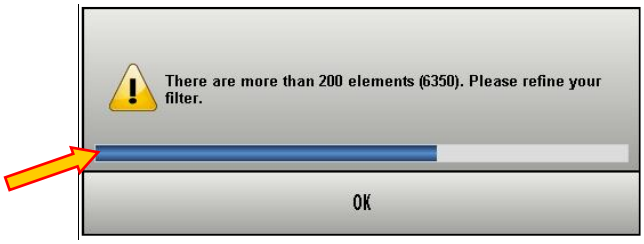


Fig 52 – Timer window with single option

This type of window is generally used to issue warnings or error messages to the user. The bar indicated in Fig 52 is a timer indicating how much time the window remains on screen. The blue part of the bar gets shorter as time goes by.
When the blue part reaches the left side of the bar the window disappears.
To make the window disappear immediately, click the OK button.

2) Timer window with double choice (YES or NO - Fig 53).

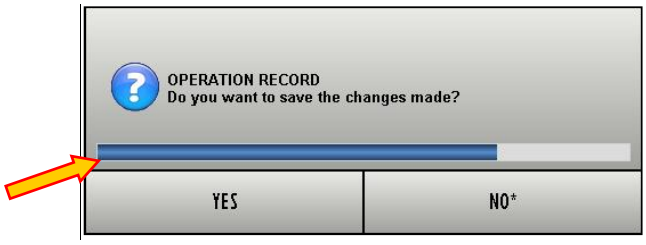


Fig 53 – Timer window with Yes/No choice

This window offers two options, usually related to an action which has just been performed. Click the YES button to perform the action, click the NO button to cancel the action.
The bar indicated in Fig 53 is a timer. The blue part of the bar gets shorter as time goes by.
When the blue part reaches the left side of the bar the window disappears. When this happens the system automatically makes a choice depending on the type of question and the context in which the message appears.

3) Window without timer with double choice (YES or NO - Fig 54).

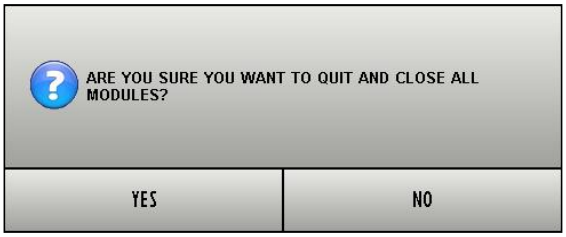


Fig 54 – Window without timer with double choice

The window shown in Fig 54, as the previous one, requires a choice between the options YES and NO in relation to an operation which has just been performed. Click the YES button to perform the action, click the NO button to cancel the action. This type of window has no timer and remains on screen until a choice is made.

4) Window without timer with single option (Fig 55)

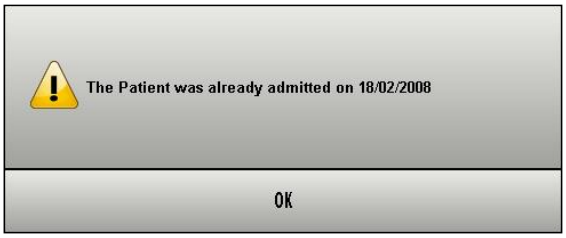


Fig 55 – Window without timer with single option

The window shown in Fig 55 provides information regarding a procedure error. No timer here, the kind of information provided requires a reading confirmation from the user (click OK).

The presence or absence of the timer in a window depends on the context it appears in. Certain messages only make sense momentarily and with reference to the operation the user is performing. These messages have a timer and disappear after a certain time.
Other messages must be received by anyone using the system, even after some time, and require a reading confirmation. These messages have no timer.

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

8. The OranJ system

8.1. Introduction

The set of modules belonging to the OranJ (Operating Room and Anesthesia Journal) system, which is part of the DIGISTAT® environment, provides a complete documentation of operations in the operating room at surgical block or individual room level.

Using OranJ, it is possible to record every significant event, manage room staff, plan time schedules, spaces and operating resources.

The information gathered is for documentation use. This system is not intended for the replacement or alteration of the management and control practices usually implemented in the structure where it is used.

We also recommend that you keep accurate paper records of every activity performed, making reference to it when necessary.

8.2. System goals

OranJ is a modular software product which provides a series of useful instruments to assist physicians, nurses and administrative personnel in the performance of their duties.

The aim of the system is to provide:

- A tool for monitoring the activities of the various operating rooms.
- Electronic documentation of the activity in the location.
- Information on the use of human resources and materials.
- Deferred statistics for quality control.

The producer has dedicated extreme care to making the system highly reliable. However, due to the intrinsic complexity of the mechanisms involved, it is not possible to provide any guarantee of the reliability or correct nature of the data supplied by the Product.

In no case must the user rely solely on the information supplied by the Product, on the display, in the database or in the printouts, when performing therapeutic or diagnostic actions or procedures, formulating diagnoses, making any decision or taking any consequent clinical/therapeutical action, without having verified the correct nature of the information.

Always check that the information supplied is correct. It is the complete and exclusive responsibility of the user to make correct use of the information supplied and check, from time to time, that it is correct.

Depending on the configuration and the method of use preferred by the User, he must implement adequate procedures to guarantee that any errors made by OranJ are detected and canceled and cannot pose a risk to the Patient and the operator.

Use of the system must only be granted, by means of specific configuration of the passwords and active surveillance, to personnel in possession of the professional qualifications to correctly interpret the information supplied and implement the appropriate safety procedures.

Only printouts signed by the head physician and medical operators shall be classed as valid clinical documents. In signing the aforementioned printouts, the user certifies that he/she has checked the precision and completeness of the data printed in the document. Only these signed documents may be considered as a valid source of information for every diagnostic or therapeutic process or procedure.

The typical user is a physician, nurse or member of the administrative staff of the structure where the system is used. Every user must be properly trained before using the OranJ system.

Use of the system must only be granted to professionally qualified and properly trained personnel.

8.3. General structure

OranJ is structured to supply a constantly up-to-date picture of the situation in the surgical block or individual room. The workstations are configured in such a way as to provide all and only the information relevant to the user concerned.
This means that every workstation enables the use of the program functions concerning the specific user.
There are four types of standard configuration:

1) GENERAL CENTRAL STATION: destined for use inside the surgical block. This makes it possible to display the situation of every single block and to operate on it. From this type of workstation you can access the operation check-in and check-out functions, the planned operation time in the various blocks and the management of resources and the operating staff.
2) BLOCK CENTRAL STATION: destined for use inside a specific surgical block. It has the same functions as the GENERAL CENTRAL STATION, but limited to block level.
3) OPERATING ROOM: destined for use inside the operating room. It enables the management of all the activities relating to the individual room.

4) CHECK IN: destined for procedures relating to the admission of the patient to the surgical block.

8.4. Colors and operation state in OranJ

The term "operation state" indicates a meaningful moment in the patient's operating process.

Four different operation states are possible.

1) Scheduled – the operation has been scheduled;
2) Ready – the patient has undergone block check-in;
3) In progress – the patient has entered the operating room;
4) Completed – the operation has been completed.

On the pages of OranJ, each of these four states is identified by a color.

1) Light gray: indicates that the operation is scheduled (Scheduled).
2) Green: indicates that the patient has undergone block check-in (Ready).
3) Cyan: indicates that the patient has entered the operating room (In progress).
4) Dark gray: indicates that the operation has been completed (Completed).

The DIGISTAT® Smart Scheduler/OranJ combined system envisages six different operation states. The first two (in logical and chronological order) are "foreseen" and "requested". These two states are managed by the DIGISTAT® Smart Scheduler system and are not displayed by the OranJ system.

It is moreover possible (in ways depending on the specific configuration) to activate on "OranJ" an ulterior state which makes an operation impossible to edit. The operations, when in this state, are "Read only". A darker shade of grey characterizes this state.

8.5. The "List of operations" page

To access the "List of Operations" page (Fig 57)

- Click the PATIENT button on the DIGISTAT® Controlbar (Fig 56 **A**).

Fig 56 - Control Bar

A page similar to that shown in Fig 57 will open.

The “List of Operations” screen is formed of three main areas:

1) the lists of operations (grouped by state - Fig 57 **A**);
2) the filter buttons (Fig 57 **B**);
3) the command bar (Fig 57 **C**).

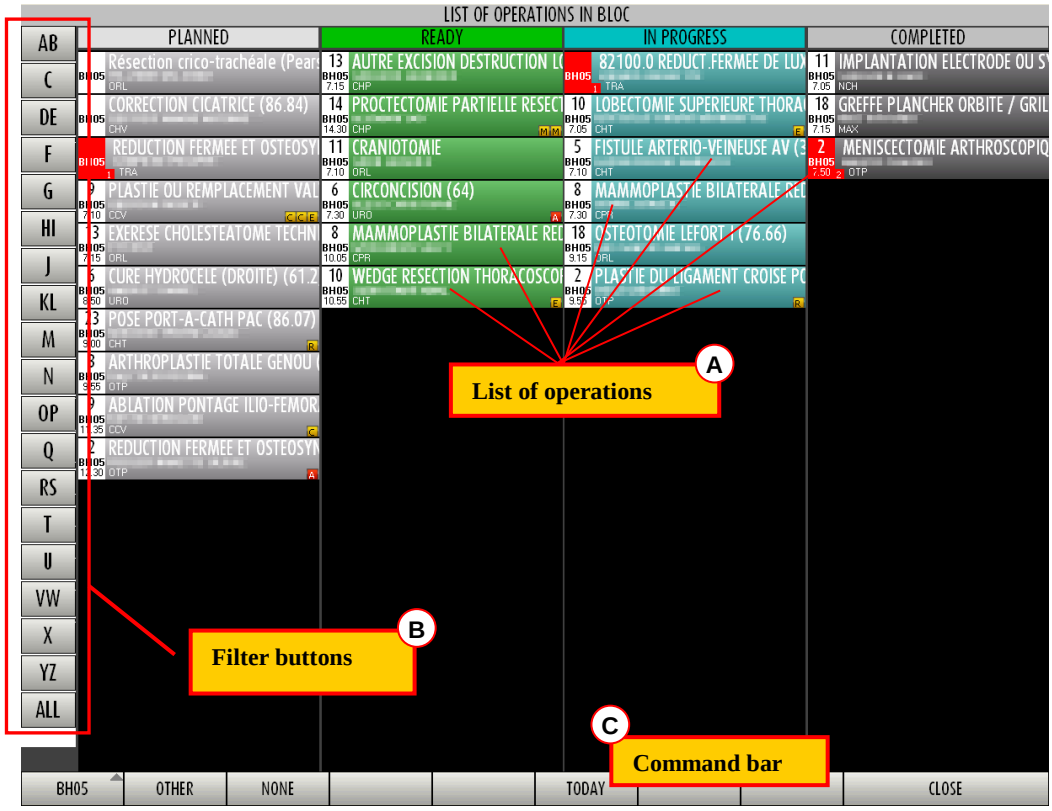


Fig 57 – List of operations

8.5.1. The list of operations

The operations appear on this screen in the form of colored boxes (Fig 57 **A**, Fig 58).

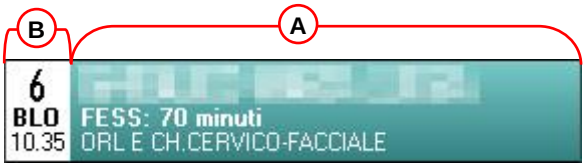


Fig 58 – Operation

Boxes are arranged into four columns. Every column is related to an “operation state” and includes all the operations which have that state and are scheduled for the day and the operating block displayed (see paragraph 8.4 for a description of the possible states)
The page shows all the operations scheduled for the current day, plus any operations begun on previous days and still in progress.

The color of the operation boxes indicates the "state" of the relative operation (See paragraph 8.4 for an explanation of the association between color and operation state).

Information on the corresponding operation is displayed within the box.

On the right (Fig 58 **A**) the following information can be displayed:

- the patient's name;
- the type of operation;
- the hospital unit requesting the operation.

On the left (Fig 58 **B**) the following information can be displayed:

- the planned room (room 6 in Fig 58);
- the planned surgical block (BLO in Fig 58);
- the time scheduled to start the operation (10:35 in Fig 58).

The kind and position of the information displayed within a box depend on the configuration in use.Thus the information can be different from that displayed in the examples here explained.

If an operation is assigned to a different block and a different room from those specified in the scheduling phase at the last moment, the corresponding operation box (Fig 58) shows the actual block and room and no longer those scheduled. The block and room originally scheduled, however, remain indicated on the record shown on the "Patient and Operation Details" page (described in paragraph 10).

The box may contain small yellow or red letters (Fig 59).

Fig 59 – Allergies and devices

The yellow letters indicate any devices required for the operation. The letter is the initial of the name of the device.

The red letters indicate the presence of infections, allergies or transmissible diseases.

One or more requirements can be configured to be displayed on the "Operation box". For instance: to indicate that an ICU bed is required after an operation, or to indicate that an operation requires no anesthesia. The requirement is displayed on the operation box as a small square, having customizable colour and indicating the first letter of the name of the requirement.

When the left part of a box is red (as in Fig 60) it means that the operation is an “Emergency” (“Emergencies” are defined either on the “Patient and Operation Detail” screen - Fig 148, paragraph 10 - or using the DIGISTAT® “Smart Scheduler” system, if present).
“Emergencies” are displayed not only on the current day, but also on the pages referring to future days (see paragraph 8.5.3 for the procedure required to change the day displayed).
The small number indicated in Fig 60 **A** indicates the emergency level (level 1 in the figure - the configuration here described envisages three emergency levels).

Fig 60 - Emergency

If the ! icon (Fig 61 **A**) appears alongside the patient’s name this means that the patient’s data is temporary. The “Temporary patient” related procedures are described in the DIGISTAT® “Smart Scheduler” system user manual.

The red triangle indicated in Fig 61 **B** means that the operation is a reserve planned for a day that is not the current day. See paragraph 11.3 for the explanation of the term “Reserve” in the “OranJ” context.

Fig 61 – Temporary patient

If a red cross appears before the operation name (Fig 62) it means that the patient is checked-in and, for any reason, not operated and checked-out immediately after.

Fig 62

<u>The operation boxes are clickable</u>. Click one of the boxes to access the corresponding “Home OranJ” screen. The “Home OranJ” screen makes it possible to display and manage all the information available for a specific operation. The “Home OranJ” screen, shown in Fig 146, is described in paragraph 9.1.

The boxes characterized by the ! icon (temporary patient data) cannot be clicked

8.5.2. The filter buttons

On the left side of the screen there is a vertical bar comprising all the letters of the alphabet (Fig 57 **B**). This bar works like an index and makes it possible to display the patients whose names begin with a specific letter.

- For example, click the AB button on the bar once and only patients whose names begin with the letter A appear (the button changes to Ab).
- Double click the same button and only patients whose names begin with the letter B appear (the button changes to aB).
- Click the ALL button to see the complete list of patients.

8.5.3. "List of operations" screen command bar

The command bar of the "List of operations" screen (Fig 57 **C**, Fig 63) contains several buttons making it possible to perform specific operations.

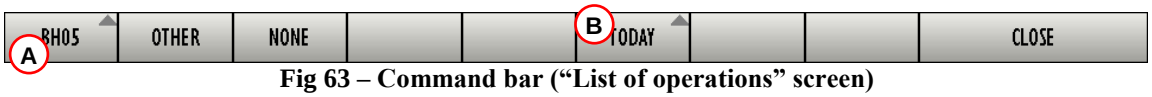


Fig 63 – Command bar ("List of operations" screen)

The specific function of each button is described in the following paragraphs.

The command bar may appear differently depending on the type of workstation you are using. Some buttons are not enabled if the related functionality is not relevant for the specific workstation goals.

8.5.3.1. Block selection

The first button on the left - BH05 - shows the name of the operating block currently displayed.

The button can be used, if the workstation is a General Central Station, to display the data relating to another surgical block. To do that

- click the BH05 button.

A list of all the blocks configured in the OranJ system opens (Fig 64).

Fig 64 – Block selection

- Click the button corresponding to the relevant block.

The data relating to the selected surgical block will be displayed.

8.5.3.2. Selection of another patient

To select a patient that is not currently displayed on screen

- click the OTHER button on the command bar.

The patient search and selection tool will open. See the specific relatd documentation for descriptions and procedures.

8.5.3.3. Patient deselection

The NONE button makes it possible to deselect the patient currently selected.

The name of the selected patient is displayed on the PATIENT button on Control Bar.

To deselect the patient currently selected.

- Click the NONE button.

The patient's name disappears from the PATIENT button.

8.5.3.4. Displayed day selection

The TODAY button makes it possible to display the data relating to a different day.

To change the day displayed on screen

- click the TODAY button.

A calendar window opens (Fig 65).

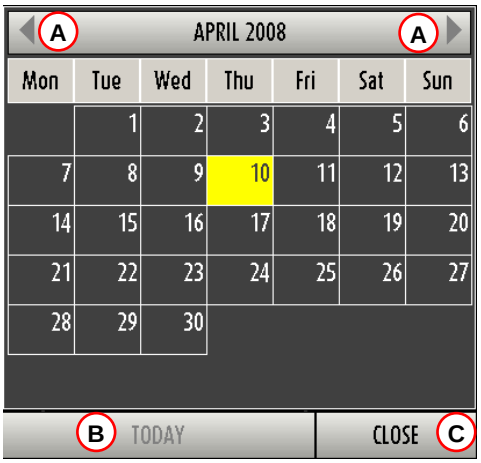


Fig 65 – Calendar

The selected day is highlighted in yellow.

You can use the arrows indicated in Fig 65 **A** to change month. If it is April, for example, click the right arrow to display the calendar for May and the left arrow to display the calendar for March.

After selecting the month

- Click the day you wish to display.

The day selected on the calendar will become yellow.

The page relating to the day selected will be automatically displayed.

If the reference day has passed, the page is divided into two columns (planned operations and completed operations).

If the reference day is in the future, the only operations displayed will be those planned (there will be a single light gray column).

If you select a different day from the current one, the TODAY button will show the date of the day displayed.

To return to the current day

- click, on the calendar, the button indicated in Fig 65 **B**.

To close the calendar

- click the CLOSE button indicated in Fig 65 **C**.

8.5.3.5. Closing the "List of operations" screen

To close the "List of operations" screen

- click the CLOSE button on the command bar.

9. The “OranJ” module

The DIGISTAT® OranJ module makes it possible to manage and document all the activities relating to an operation.

The OranJ module is installed on GENERAL CENTRAL STATION, BLOCK CENTRAL STATION and OPERATING ROOM Workstations.

9.1. “OranJ Home” screen

When accessing the “OranJ” module, the “OranJ Home” screen is displayed (Fig 67).

This page is accessed when

a) you select the OranJ module icon on the side bar - 

;

b) you select a patient and/or an operation wherever this is possible.

The screen is formed of three main areas that will be described in the following paragraphs. These are:

1. the operation data (Fig 66 **A**);
2. the command bar (Fig 66 **B**);
3. the chronology of the operation (markers list - Fig 66 **C**).

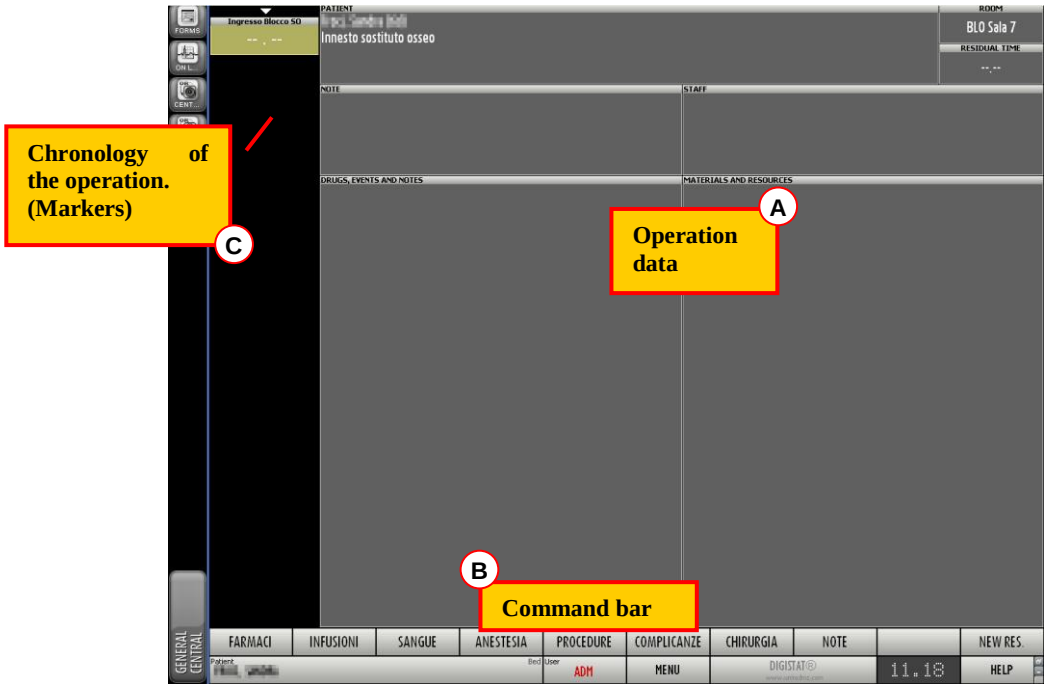


Fig 66 - OranJ Home

9.2. Operation data

The area shown in Fig 67 makes it possible to record and display all the operation's relevant data.

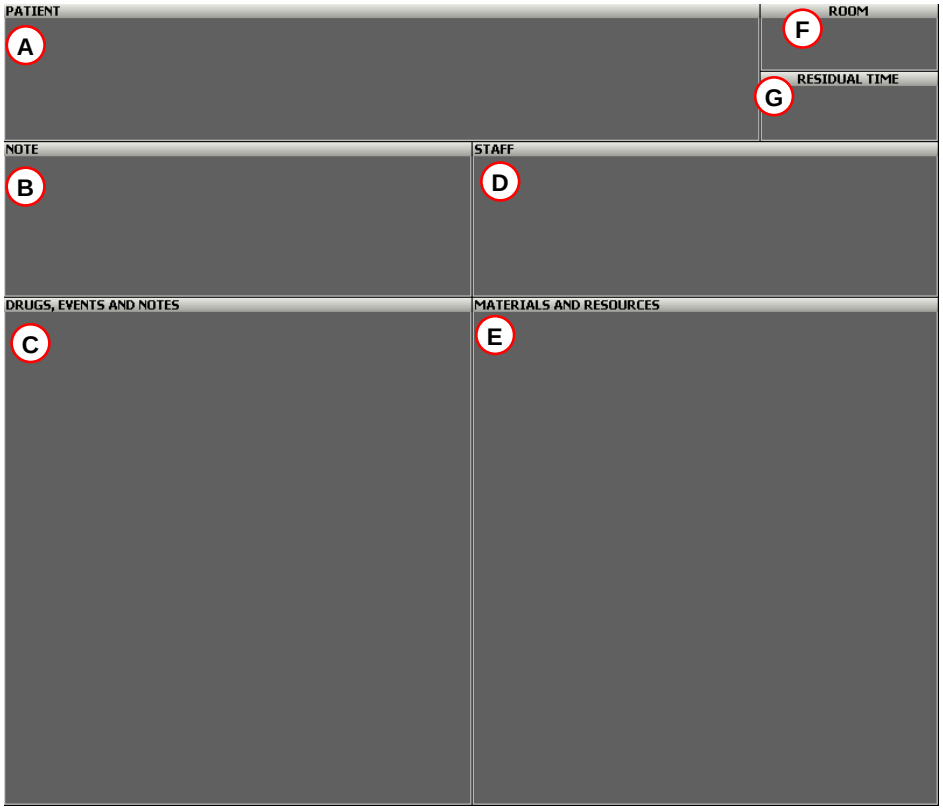


Fig 67 – Operation data

The "Operation data" area is itself divided in further different sections, each of which is related to a set of features of the operation.

These sections are here listed and briefly described. A detailed description is provided in the paragraphs indicated.

- **"Patient"** area (Fig 67 **A**). Summarizes the data of the patient and the operation. Click it to access the "Patient and Operation Details" page (paragraph 10).

- **"Note"** area (Fig 67 **B**). Shows any notes concerning the operation or the patient. Click it to open a keyboard window and add a note (see paragraph 9.6 for the related procedures).

- "**Drugs, events and notes**" area (Fig 67 **C**). Shows the complete list of events recorded during the operation, the drugs administered and the notes added, in chronological order. Click it to access the "Events" page and enter, delete or edit these events (paragraph 9.5).

- "**Staff**" area (Fig 67 **D**). Shows the list of names and roles of staff involved in the operation. Click it to access a page to edit this list and manage changes in room staff in real time (paragraph 9.10).

- "**Materials and resources**" area (Fig 67 **E**). Shows the list of materials and instruments used during the operation. Click it to access a page to manage the resources scheduled and to add or eliminate them if necessary during the operation (paragraph 9.11).

- "**Room**" area (Fig 67 **F**). Indicates the surgical block and operating room. This section cannot be clicked. In the event of a change in the room scheduled for the operation, this must be recorded using the OranJ Plan module (paragraph 11) or the "Patient and Operation Details" page (paragraph 10).

- "**Residual time**" area (Fig 67 **G**). Indicates the time remaining until the end of the operation according to the scheduled duration. This quadrant works like a countdown which starts when the patient enters the room (paragraph 9.9).

9.3. Command bar

The command bar of the main page of the OranJ module contains a series of buttons which make it possible to directly access some of the pages and functions described in this chapter.
These are shortcut buttons to facilitate access to those operations performed more frequently.
This bar is configurable: i.e., the number and function of the buttons change to suit the specific user's needs. The figure below should only therefore be considered as an example.

Fig 68 – OranJ module command bar

In the example shown here, the NOTE button (Fig 68 **A**) makes it possible to directly access the page used to add a note. Use the NEW RES. Button (Fig 68 **B**) to directly access the page to manage the operation room resources. Each of these pages is described in detail during this chapter.

Similarly, the other buttons, when so configured, offer direct access to those pages and functions which, depending on the user's needs, are used most frequently.

9.4. Operation chronology: the "Markers"

The left side of the screen (Fig 67 **C**) shows the sequence of events that make up an operation, in chronological order.
It is assumed that certain events are repeated for all operations and that they occur in a specific order. These are known as "**Markers**".

A marker follows the other, both chronologically and logically.

The OranJ system envisages 6 markers as standard:

- Block in (the patient has undergone block check-in)
- Room in (the patient has undergone room check-in)
- Skin incision
- Suture
- Room out (Operation done)
- Block exit

The number and nature of Markers, as well as their sequential logic, can be configured to suit the specific healthcare structure's needs. The example here refers to a configuration which comprises the events most commonly used.

9.4.1. Markers sequence

The markers appear as a sequence of boxes (Fig 69). The boxes are arranged in chronological and logical order.

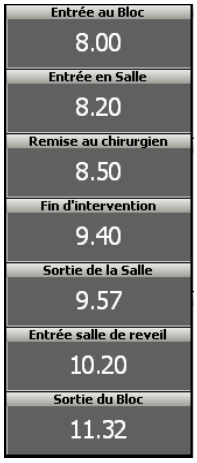


Fig 69 – Markers sequence

The first box, relating to entrance into the surgical block, appears when an operation is scheduled. The box is yellow and contains no information on the moment (date and time) in which the event occurred (Fig 70). This means that the event has not occurred (the patient has not yet entered the block).

Fig 70 – First marker

When the patient physically enters the surgical block, to record the event, the user has to simply click the box.
At this point, if specified by configuration, patient identification is necessary. Patient identification procedure is described in paragraph 9.4.2.

If an OranJ "Check In" workstation is active it is used to manage the patient's block entrance. OranJ "Check In" is described in paragraph 14.

After patient identification the box becomes gray and records the time at which it is clicked. A new ochre yellow box (or several boxes, depending on the configuration) indicating no time appears below it. New boxes refer to subsequent events (Fig 71).

The system can be configured to show the date of entry as well as the time.

Fig 71 – Second marker

The events this way recorded appear at the same time in the "drugs, events and notes" area of the page (Fig 72).

Fig 72 – Markers sequence

In general, to record a marker

- click the box corresponding to the event.

When the patient enters the operating room (the corresponding marker is called "room in") the system, if so configured, requests renewed confirmation of the patient's identity by means of a page similar to that shown in Fig 76. The identification procedure is the same as that described in paragraph 9.4.2, apart from the fact that identification can occur by means of barcode, patient code and also reservation number or the admission code (Fig 73).
This form enables to specify the actual room and block of the operation.

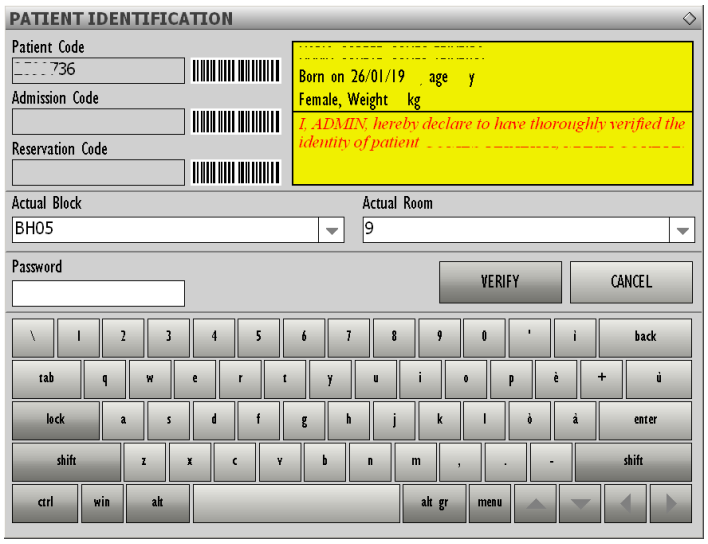


Fig 73 – Patient Identification

After identification, the "room in" box becomes gray and showns the room entrance time.
The event just recorded appears at the same time in the "drugs, events and notes" area of the page (Fig 74 **A**).
The patient's entrance into the operating room corresponds to the actual operation start time. Consequently, when the "room in" event is recorded, the length of time envisaged for the operation appears in the "residual time" area (Fig 74 **B**). This area works like a clock which performs a countdown (see paragraph 9.9 for a detailed description of this area).
The recording of the "room in" event sets off the countdown.

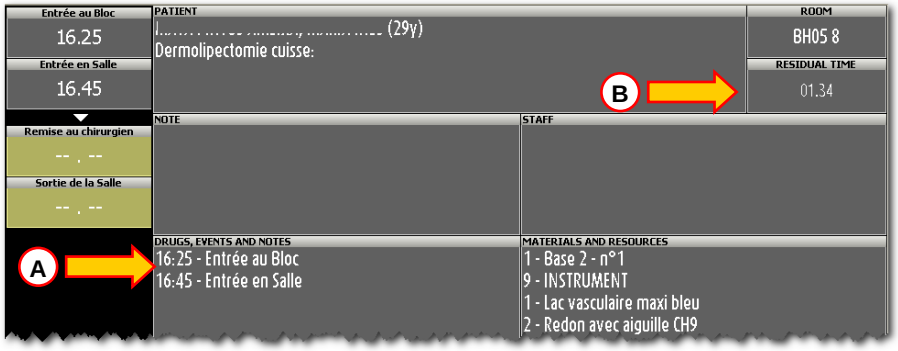


Fig 74 – Markers sequence

Every time an event is recorded, it appears in the "drugs, events and notes" area.

When the "room out" event occurs, the operation is over. The countdown of the "residual time" area stops and this area shows the actual duration time of the operation (in the form "Completed in hh:mm").

9.4.2. Patient identification

The possibility of entrance to the block and room is subject to identification of the patient if so specified by configuration.
When the entrance of the patient into the block is recorded the system opens a specific window requesting confirmation of the patient's identity (Fig 75).

Fig 75 – Patient identification

To identify the patient

- Enter the patient code in the "Patient Code" field (Fig 75 **A**).
- Click the IDENTIFY button (Fig 75 **B**)

or, if the function is available

- Scan the patient's barcode.
- Click the IDENTIFY button (Fig 75 **B**)

A window containing the patient's data and a declaration of acceptance of responsibility by the user appears on the screen (Fig 76).

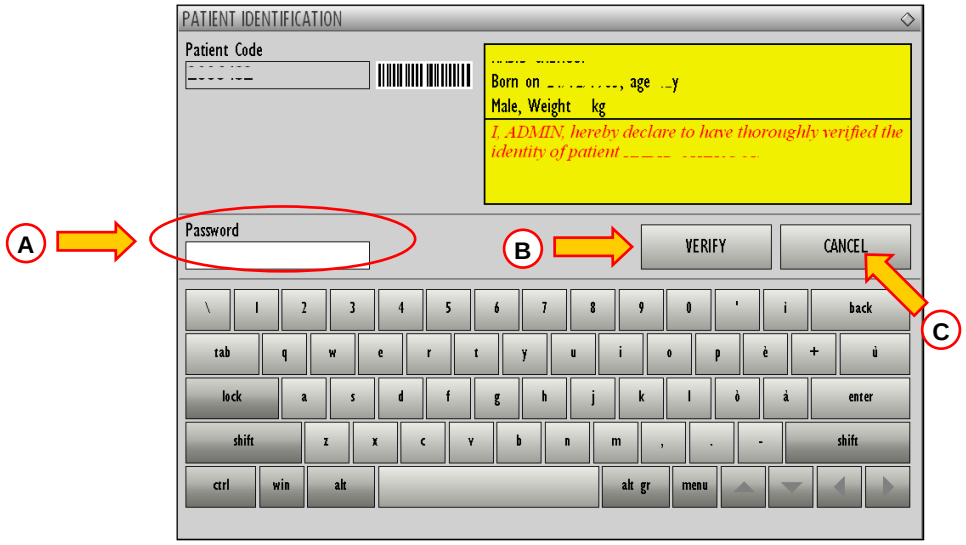


Fig 76 –Identification window

To complete the procedure the user has to

- Enter his/her password in the “Password” field (Fig 76 **A**).
- Click the VERIFY button (Fig 76 **B**).

The first event (entrance to the block) will be this way recorded.

You may abandon the procedure at any time by clicking the CANCEL button (Fig 76 **C**).

9.4.3. Markers and operation state changes

The changes in the operation state are linked to some of the markers recorded on the “OranJ Home” screen. The recording of the marker determines a change in the operation state.

- The “Block entrance” marker implies passage from “Planned” state to “Ready” state.
- The “Room in” marker implies passage from “Ready” state to “In progress” state.
- The “Cut” marker implies the end of pre surgical time and the beginning of surgical time.
- The “Suture” marker implies the end of surgical time and the beginning of post surgical time.
- The “Room out” marker implies passage from “In progress” state to “Completed” state.

9.4.4. Markers management

9.4.4.1. How to change the time of a marker after it has been recorded

To change the time of a marker after it has been recorded

- Click the box corresponding to the marker (Fig 77 **A**).

A numeric keyboard appears (Fig 77 **B**).

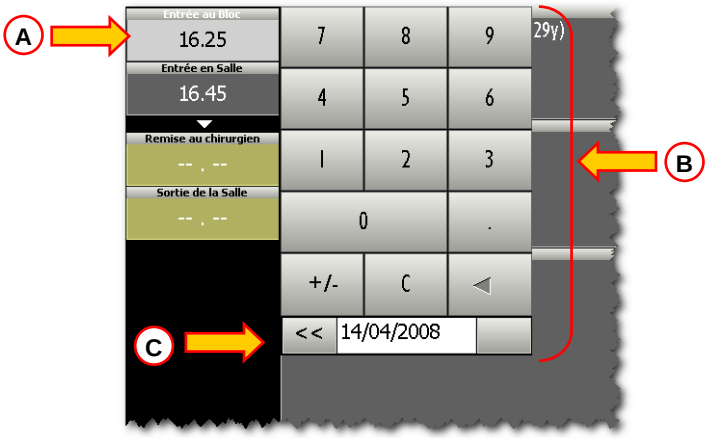


Fig 77 – Markers time change

- Enter the time required using the keyboard.

- Click again the box corresponding to the marker to record the new time.

The numeric keyboard disappears and the new time is displayed.

To hide the numeric keyboard, click the box corresponding to the event.

If the time entered is not coherent, the following error message appears (Fig 78).

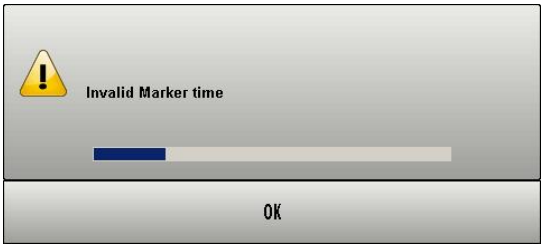


Fig 78 – Error: invalid time

9.4.4.2. Deleting a marker

To delete a recorded marker

- Click the (gray) box corresponding to the marker (Fig 77 **A**).

A numeric keyboard appears (Fig 77 **B**).

- Click the C button on the keyboard.

A message requesting confirmation of the operation appears.

Fig 79 – Marker cancellation confirmation window

- Click YES to delete the marker.

Considering that one marker follows the other, not only chronologically but also logically (for example, a patient cannot be operated before entering the operating room), then

the deleting of a marker implicates the deleting of all subsequent markers.

The box corresponding to the marker deleted becomes ochre yellow again and indicates no time, meaning that the related event has not yet occurred. This box is now the last on the markers sequence list; the event related to the deleted marker is the next event to happen.

9.4.4.3. How to change the date of a marker

To change the date of a marker

- Click the box corresponding to a marker (Fig 77 **A**).

A numeric keyboard appears (Fig 77 **B**). The keyboard displays the date on which the marker was recorded. Alongside the date there are two arrow-buttons (Fig 77 **C**).

- Click the left arrow 

to bring the date of the event forward by one day.

- Click the right arrow 

to postpone the date of the event by one day.

You can only change the date within the range of specific values.
It is possible to bring the date of the first event forward by one day; the date of subsequent events on the other hand can be changed between the current date and the date on which the first event is recorded.

9.5. “Drugs, events and notes” area

Several kinds of events can be associated to an operation. The OranJ system makes it possible to configure a series of events which make it possible to describe the chronology of an operation in detail. The nature and number of these events are decided during configuration. In general, these are data relating to drugs administered (type, quantity, boluses), operating procedures implemented or possible complications which might occur during or after the operation is indicated.

These events are recorded on the “Events” page (Fig 81).

To access the “Events” page, on the “OranJ Home” page (Fig 80),

- Click the “drugs, events and notes” area of the screen (Fig 80 **A**).

Fig 80 - OranJ Home

The “Events” page will open (Fig 81).

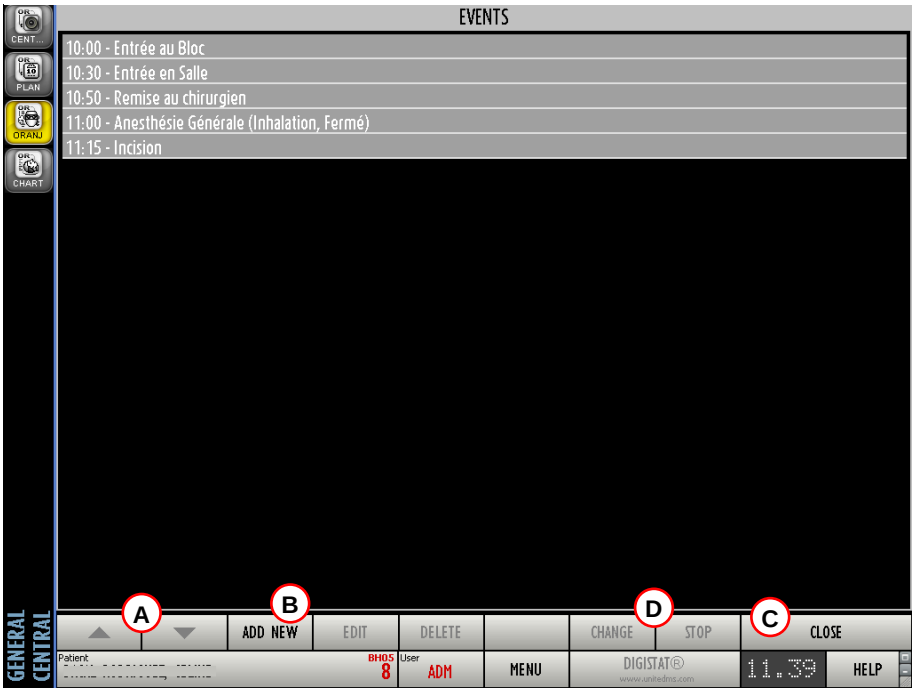


Fig 81 – "Events" page

The "Events" page shows all the events associated with the operation in chronological order, together with the markers and any notes added.

Markers cannot be edited on this page. To edit a marker, you have to use the procedure described in paragraph 9.4.

If the whole list of events cannot be displayed on the screen, you can use the arrows on the control bar to scroll the list (Fig 81 **A**).

To close the "Events" page, on the control bar

- Click the CLOSE button (Fig 81 **C**).

The system returns to the "OranJ Home" page (Fig 67).

The CHANGE and STOP buttons (Fig 81 **D**) are used to manage those events that continue over time and which, while occurring, may be subject to changes. This is true, for example, for certain infusions for which it might be necessary to change the infusion speed while they are in progress.

- Click the CHANGE button to access the page that makes it possible to manage the data related to the event (an example is shown in Fig 85; remember, however, that the page in question can be configured in numerous ways and changes according to the event selected).

- Click the STOP button to record the end of the event in progress.

9.5.1. How to record an event

To record an event

- Click the ADD NEW button on the command bar (Fig 81 **B**).

A page similar to that shown in Fig 82 appears.

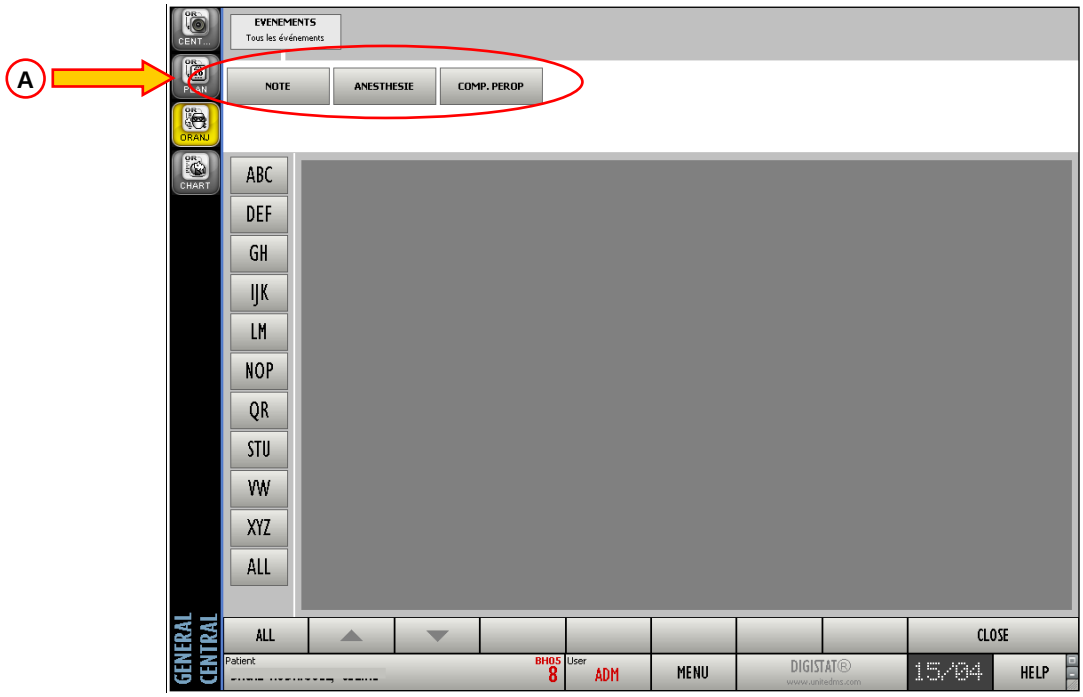


Fig 82 – Adding an event

Every type of event is represented by a gray rectangle (Fig 83).

Fig 83 – Type of event

In this example 3 types of events are configured: notes, type of anesthesia and operating procedures (Fig 82 **A**).

Remember that the number and kind of events are customizable. The configuration described here is an example.

At this point it is necessary to select one of the types (rectangles) available.

- Click the type of event required.

Every “type” of event can offer access to various sub-types. In the example shown in Fig 84, the “anesthesia” event gives access to four specific types of anesthesia. Likewise, the “drugs” event can give access to a list of types of drug (sleep inducers, anesthetics, painkillers, etc.), and every type of drug gives access to a list of specific drugs (Propofol, Midazolam, etc.).

To display the list of all the elements of a specific type (e.g., all drugs or all types of anesthesia)

- click the ALL button (Fig 84 **C**).

The elements on the list can be filtered using the index buttons on the left of the screen (Fig 84 A - See paragraph 8.5 for the explanation of how these buttons work).

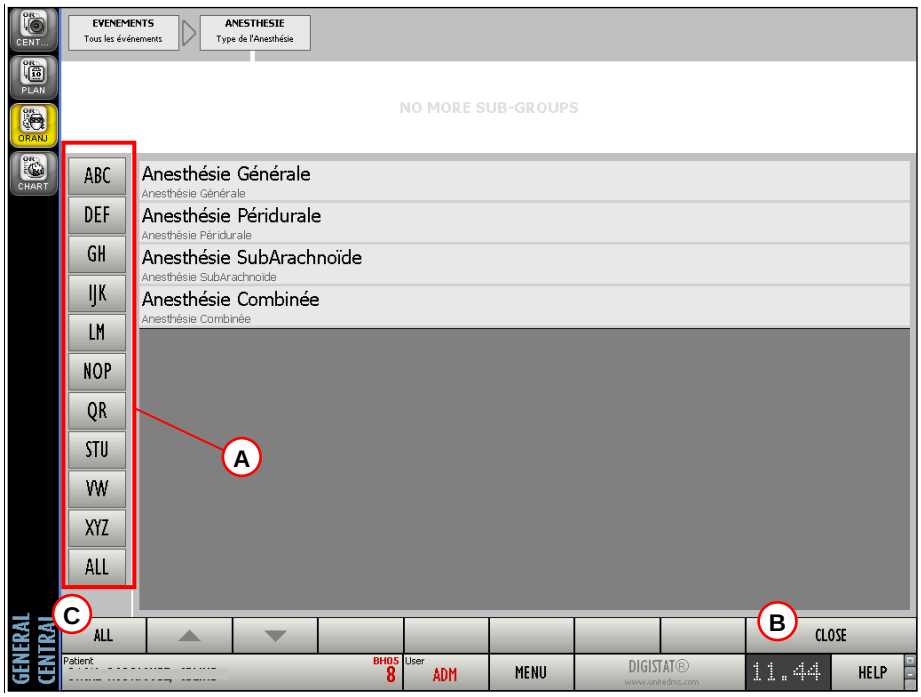


Fig 84 – Types of anesthesia

To add the event, you have to select one of the items from the list.

- Click the name of the event required.

By way of example, we have selected “Subarachnoid Anesthesia”. This selection gives access to the page shown in Fig 85.

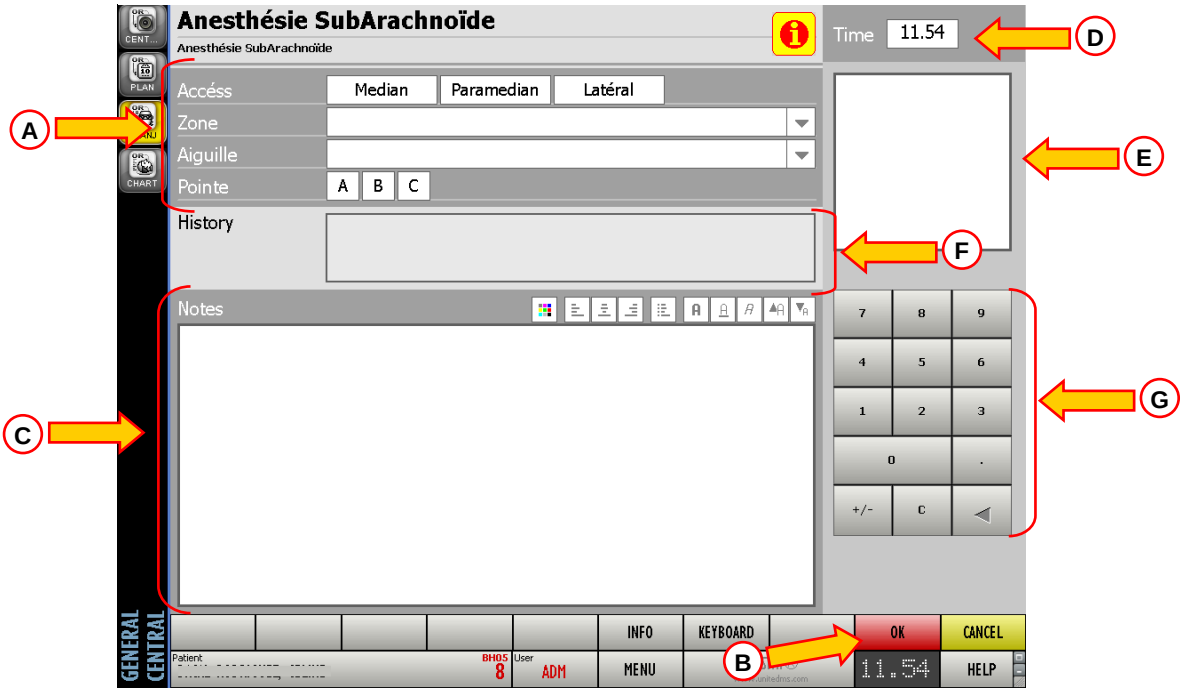


Fig 85 – Event: subarachnoid anesthesia

The page makes it possible to specify, in detail, the type of anesthesia administered (Fig 85 **A**).

After entering the specific values, to record the new event

- Click the OK button (Fig 85 **B**).

The new event recorded appears on the "events" page (Fig 81) and in the "drugs, events and notes" area of the "OranJ Form" page (Fig 80 **A**).

To cancel the operation

- Click the CANCEL button (Fig 85 **B**).

The system returns to the page shown in Fig 84 without making any changes.

To close this page and return to the "Events" page

- click the CLOSE button on the page (Fig 84 **B**).

You can also record an event using the shortcut buttons described in paragraph 9.3 (Fig 68). Click the buttons on the control bar to directly access the relative page for the addition of events.

The page which makes it possible to enter data relating to an event (Fig 85) changes depending on the type of event selected. While, for example, for an anesthesia you can specify the approach, location, needle, etc., for a drug to be administered, you can specify the dose, dilution, etc.

These parameters are decided during configuration and depend on the user's requirements.

Here is a description of the characteristics of the page which are common to all events.

9.5.1.1. The "notes" area

The "notes" area (Fig 85 **C**) makes it possible to add a note.

To enter a note

- Click the "notes" area.

A cursor appears inside the area.

- Enter the note using your workstation keyboard.

or

- Click the KEYBOARD button (Fig 86 **D**) to display a virtual keyboard on the screen (Fig 86).

Fig 86 – Virtual keyboard

When the keyboard is displayed, the KEYBOARD button is black.

To hide the keyboard on the screen

- Click the KEYBOARD button again.

The buttons at the top of the notes area make it possible to use some of the most common text formatting functions (Fig 86 **A**).

The  button makes it possible to change the color of the text.

The  button makes it possible to align the text to the left.

The  button makes it possible to center the text.

The  button makes it possible to align the text to the right.

The  button makes it possible to create bulleted lists.

The  button makes it possible to write in bold type.

The  button makes it possible to write underlined.

The  button makes it possible to write in italics.

The  button makes it possible to enlarge the character used.

The  makes it possible to shrink the character used.

9.5.1.2. Information

The  button (Fig 86 **B**), like the INFO button (Fig 86 **C**), makes it possible to access a page containing information on the event being added (Fig 87).

Fig 87 – Event information

The page can contain notes, bibliographic references, pictures, etc…

To exit the information page

- Click the  button again or click the INFO button.

9.5.1.3. Time

The "Time" field (Fig 85 **D**) shows the current time if you are entering a new event and shows the time at which the event was entered when displaying an event entered previously.
The time can be changed using the numeric keyboard shown in Fig 85 **G**.

9.5.1.4. Picture

The white box on the right of the page (Fig 85 **E**) can contain a picture relating to the event being recorded; if it is a drug, for example, the box may contain the photo of the drug in question.

9.5.1.5. History

The history area (Fig 85 **F**) displays information on all the past recordings of the same event.

9.5.1.6. Numeric keyboard

The numeric keyboard (Fig 85 **G**) makes it possible to enter numeric values in the fields on the page. To do this, it is necessary to click the field in which you wish to write and then use the keyboard number buttons.

9.5.2. How to edit an existing event

To edit data relating to an existing event, to enter a note relating to the event or to display all the details relating to that event,

on the "Events" page (Fig 81).

- Click the event to be edited.

The line corresponding to the event appears highlighted (Fig 88).

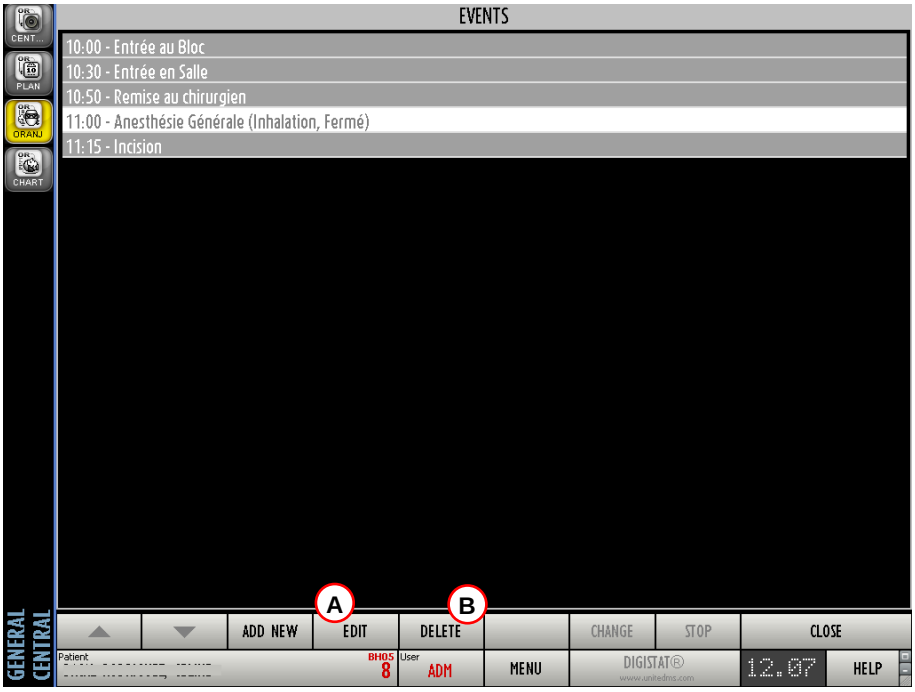


Fig 88 – Event selected

On the control bar

- Click the EDIT button (Fig 88 **A**).

This directly accesses the page that shows the details of the event selected (Fig 89).

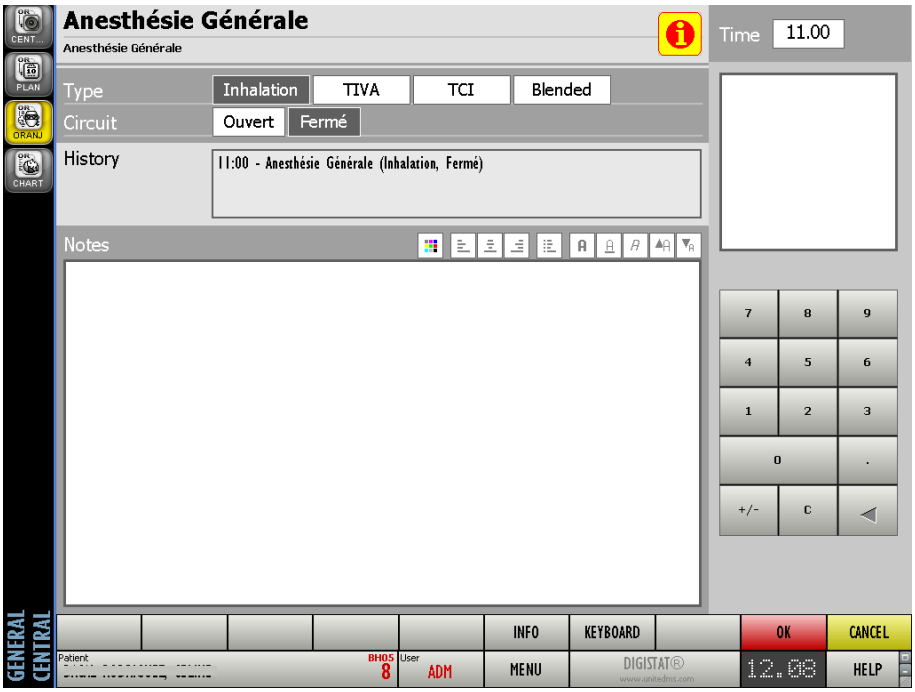


Fig 89 – Event details

The characteristics and functions of this page are described in paragraph 9.5.1.

You can now edit the data relating to the event.

To save the changes made

- click the OK button.

Remember that the markers cannot be edited or deleted from the "events" page. To edit markers it is necessary to use the procedure described in paragraph 9.4.4 .

9.5.3. How to delete an existing event

To delete an event,

on the "Events" page (Fig 81)

- Click the event to be deleted

The line corresponding to the event appears highlighted (Fig 88).

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

A window requesting confirmation of the operation appears (Fig 90).

Fig 90 – Event deletion confirmation

- Click YES to delete the event.

The deleted event disappears from the "Events" page (Fig 88) and from the "Drugs, events and notes" area of the "OranJ Home" page (Fig 80 **A**).

Remember that the markers cannot be edited or deleted from the "events" page. To edit markers it is necessary to use the procedure described in paragraph 9.4.4 .

9.6. The "Notes" area

To add a note to the operation selected

- Click the "Notes" area of the "OranJ Home" page (Fig 92 **A**).

Fig 91 - OranJ Home

A virtual keyboard appears on the screen (Fig 92).

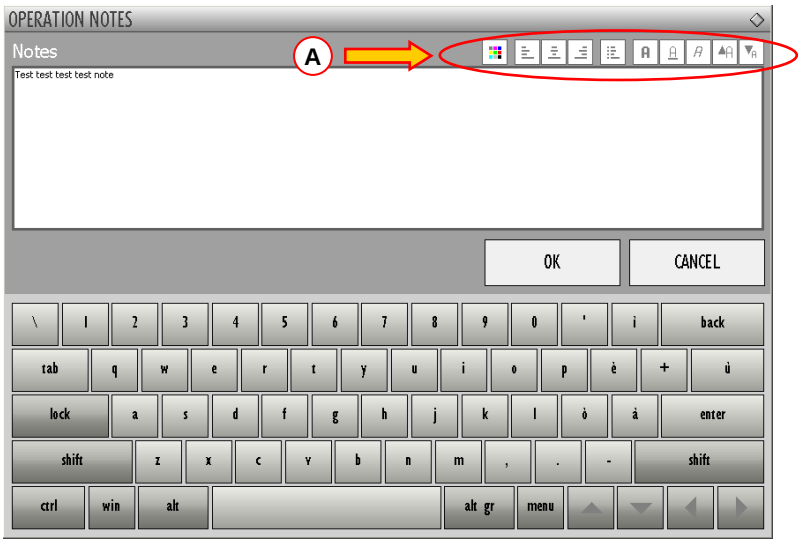


Fig 92 – Virtual keyboard

- Use the keyboard to enter the note.
- Click OK to record the note.

or

- Click CANCEL to cancel the operation.

The buttons at the top of the keyboard (Fig 92 **A**) make it possible to use some of the most common text formatting functions.

The  button makes it possible to change the color of the text.

The  button makes it possible to align the text to the left.

The  button makes it possible to center the text.

The  button makes it possible to align the text to the right.

The  button makes it possible to create bulleted lists.

The  button makes it possible to write in bold type.

The  button makes it possible to write underlined.

The  button makes it possible to write in italics.

The  button makes it possible to enlarge the character used.

The  makes it possible to shrink the character used.

The note is displayed in the “notes” area of the “OranJ Form” page (Fig 93).

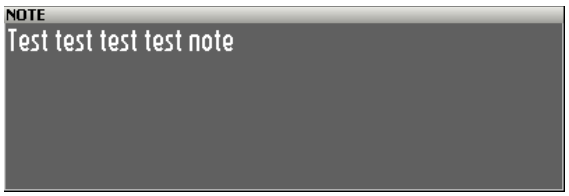


Fig 93 - Note

9.7. The “patient” area

The “patient” area of the “OranJ Form” page (Fig 94 **A**) shows the name of the patient for whom the operation is scheduled.

Fig 94 - OranJ Home

This area may also contain, depending on the configuration, the operation reservation code, the type of operation envisaged and, where specified, the location which has requested the operation.

Fig 95 – “Patient” Area

The “patient” area makes it possible to access the “Patient and Operation Details” page (Fig 135).

To access the “Patient and Operation Details” page

- click the patient area.

The “Patient and Operation Details” page containing the data of the patient and the operation selected opens. See paragraph 10 for a detailed description of this page.

9.8. The “room” area

The “room” area (Fig 96 **A**) shows the block and the operating room scheduled for the operation.

Fig 96 - OranJ Home

In the example shown in the figure “BH05” is the surgical block, “8” is the room number.

Fig 97 – “Room” area

The “room” area cannot be clicked. If there are changes concerning to the block or the room scheduled for an operation, these must be recorded on the “Patient and Operation Details” page (paragraph 10).

9.9. The “residual time” area

The “residual time” area (Fig 98 **A**) indicates the time remaining until the end of the operation with respect to the scheduled duration. The residual time is the sum of the pre-surgical, surgical and post-surgical times specified either on the “Patient and Operation Details” (Fig 139) or, if in use, on the DIGISTAT® “Smart Scheduler” system.

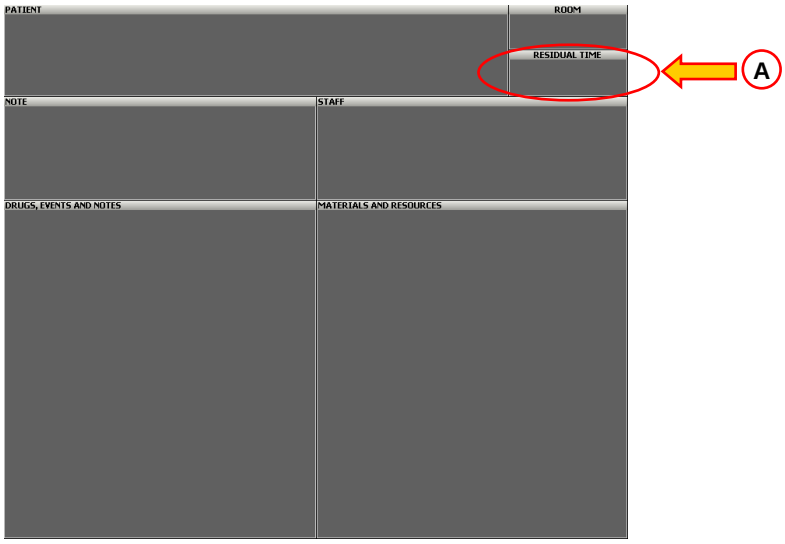


Fig 98 - OranJ Home

This quadrant works like a countdown. The example shown in Fig 99 indicates that there is 1 hour and 27 minutes left until the end of the operation (according to the planned duration).

Fig 99 – “Residual time” Area

The countdown starts when the “Room in” marker is recorded (see paragraph 9.4 for a description of the markers).

Before the patient enters the room, the area appears as shown in Fig 100.

Fig 100

When the countdown approaches zero (in the configuration used in the example, when the remaining time is less than thirty minutes) the residual time area turns yellow and starts flashing (Fig 101).

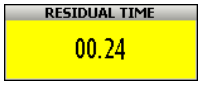


Fig 101

When the actual operation time exceeds the time scheduled, the “residual time” area continues flashing and turns red. The value shown on it becomes negative and starts indicating how much of a delay is being accumulated (Fig 102).

Fig 102

It is possible to signal, while the operation is in progress, that the operation is requiring more time than scheduled.

To do that

- click the “Residual time area”.

A quadrant containing four buttons opens (Fig 103).

Fig 103

- Click one of the buttons.

This first click brings the counter back to zero.

- Click the buttons to indicate the time remaining.

The 

button adds 10 minutes to the scheduled duration.

The 

button deducts 10 minutes from the scheduled duration.

The 

button adds an hour to the scheduled duration.

The 

button deducts an hour from the scheduled duration.

The “residual time” area indicates the new duration. Length of the operation-box on the OranJ planning screens changes accordingly (see paragraph 11 for more information about this feature).

To hide the four buttons, simply click the “residual time” area again.

9.10. The “staff” area

The “staff” area (Fig 104 **A**) indicates the names and relative roles of the room staff assigned to the operation.

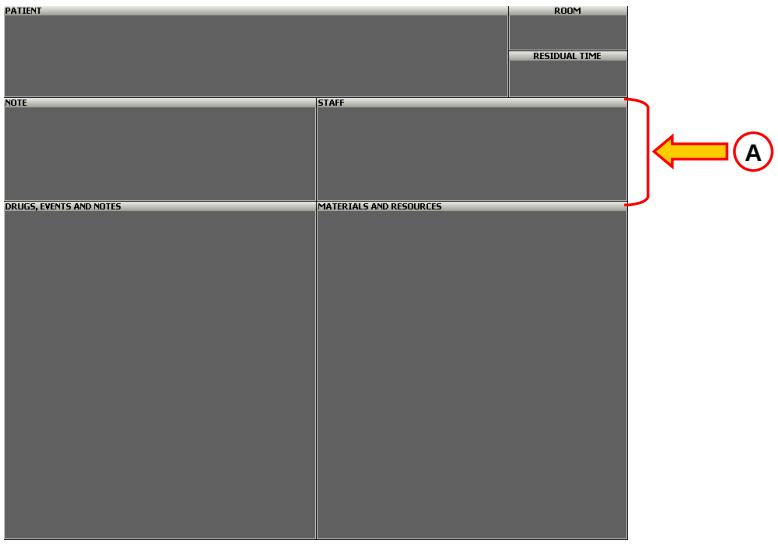


Fig 104 - OranJ Home

You can record any changes in the room staff while the operation is in progress.

To record a change in the room staff

- click the “staff” area (Fig 104 **A**).

The page shown in Fig 105 opens.

9.10.1. Description of the “Room Staff” page

The “Room Staff” page (Fig 105) is split into four columns.

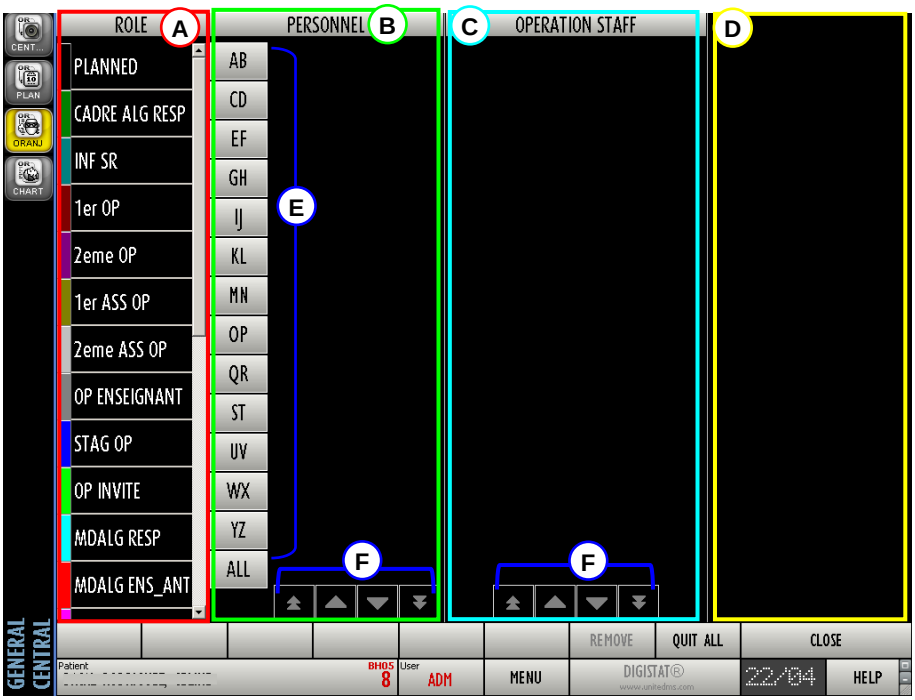


Fig 105 – Room staff

The “role” column (Fig 105 **A**) contains a list of the possible roles of the staff involved in the operation.
Every role is characterized by a color.

The number and nature of the roles can be configured to reflect the real organization of the structure using the software.

After the role has been selected, the “personnel” column (Fig 105 **B**) contains the list of persons who are able to cover the required role (see the following paragraph for the selection procedure).

After the person has been selected the “Operation staff” column (Fig 105 **C**) contains the names of the personnel actually involved in the operation (see the following paragraph for the selection procedure).

When the staff is selected, the fourth column (Fig 105 **D**) contains a numeric keyboard which makes it possible to specify the room entrance and exit times of every member of staff.

The buttons containing the letters of the alphabet (Fig 105 **E**) make it possible to filter the list of names displayed. Click one of the letters to display the names that begin with that letter only. Click the ALL button to display the list of all the names.

The arrows at the bottom of the two central columns (Fig 105 **F**) make it possible to scroll up and down the list of names displayed.

The control bar of the page contains three buttons

Fig 106 – Command bar of the "Room Staff" page

The CLOSE button (Fig 106 **C**) closes the page. Click CLOSE to return to the "OranJ Form" page (Fig 104).

The QUIT ALL button (Fig 106 **B**) makes it possible to assign the whole staff the current time as the room exit time. For example, if an operation ends at 15.00, and the QUIT ALL button is then clicked, 15.00 o'clock is indicated as the room exit time for the whole staff.

The REMOVE button (Fig 106 **A**) makes it possible to remove a member of the operation staff (see the following paragraph for the selection procedure).

9.10.2. Operating staff management

9.10.2.1. How to select a staff member

To select a member of the room staff

- click one of the roles indicated in the "role" column (Fig 105 **A**)

In the "staff" column, the list of all the people who can perform that function appears. For example, if I click "1er OP", the list of all the "first operators" appears in the second column (Fig 107).

Fig 107 – List of operators

- Click the name of the person who will be part of the room staff.

The box corresponding to the person disappears from the "staff" column and appears in the "operation staff" column (Fig 108). The name of the person selected is marked by the color that characterizes his/her function.

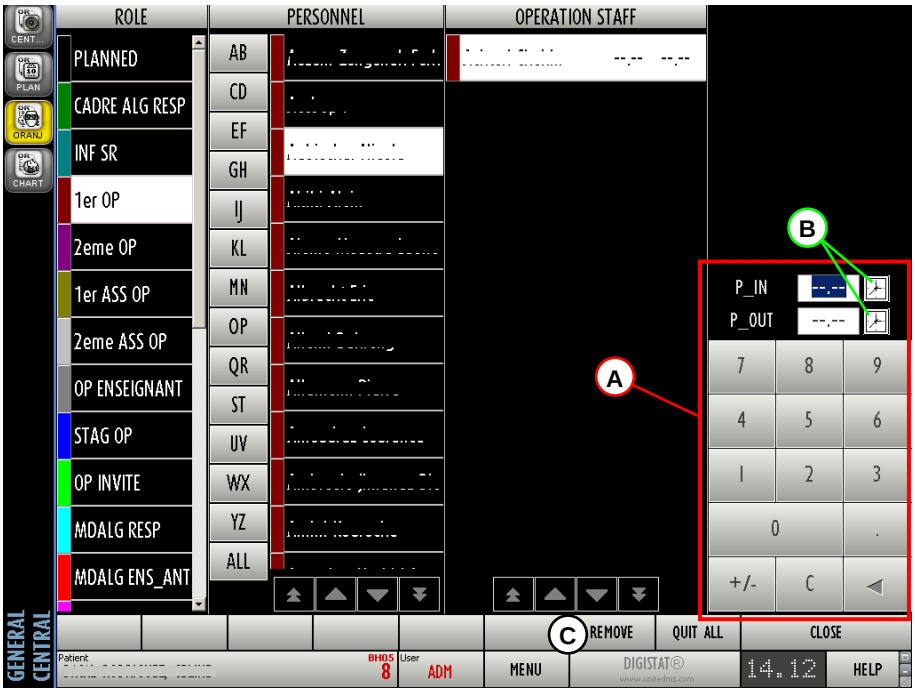


Fig 108 – Staff Selection

At the same time, a numeric keyboard appears in the column on the right, making it possible to specify the room entrance and exit time for the person specified (Fig 108 **A**).

The entrance and exit time should be entered when every member of staff actually enters or exits the room.

The small clocks  highlighted in Fig 108 **B** make it possible to automatically assign the person selected the current time as the entrance or exit time.

The staff selected appears in the "staff" area of the "OranJ Form" page (Fig 109).

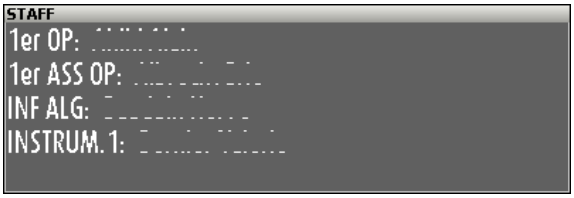


Fig 109 – Operation Staff

9.10.2.2. Recording the entrance and exit time of a member of staff

To record the entrance and exit time of a member of staff

- Click the person's name.

The name is highlighted and the numeric keyboard appears on the screen.

- Enter the entrance or exit time using the buttons on the keyboard
- Click the field which is not being edited (i.e., if you have entered the entrance time, click the "exit" field; vice versa, if you have entered the exit time, click the "entrance" field).

In both cases the entrance/exit time will be recorded and appear alongside the name of the member of staff selected (Fig 110).

Fig 110 – Time Recording

In alternative, to record the current time as the room entrance/exit time for a member of staff, simply click the little clock alongside the corresponding field (Fig 108 **B**).

- Repeat the operation for every member of the operation staff to be entered.

9.10.2.3. Removing a member of the operating staff

To remove a member of the operating staff

- Click the member of staff you wish to remove.

The box containing his/her name is selected and will appear as highlighted.

The REMOVE button on the command bar becomes active (Fig 108 **C**).

- Click the REMOVE button.

A window requesting confirmation of the operation appears (Fig 111).

Fig 111

- Click YES to confirm.

9.11. The “materials and resources” area

The “materials and resources” area (Fig 112 **A**) contains the list of all the resources and materials used during an operation

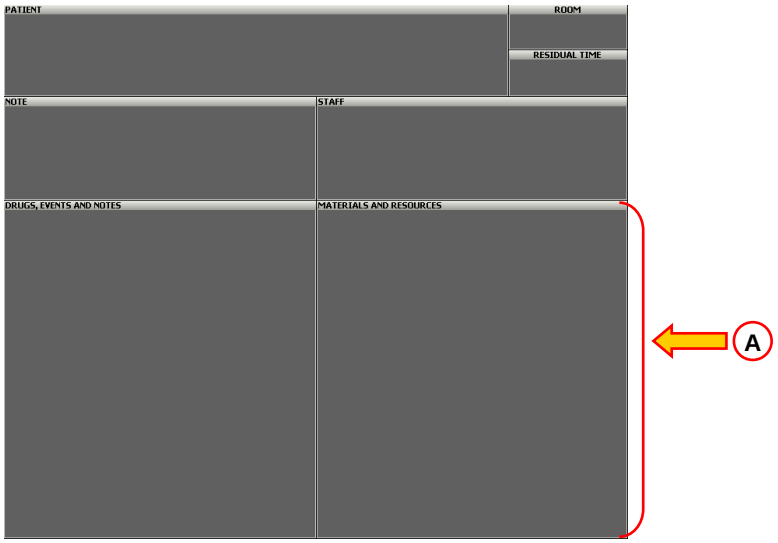


Fig 112 - OranJ Home

You can edit the quantities indicated and, if necessary, add new resources to the list of resources used at any time.

To add a new resource

- Click the materials and resources area.

The “Resources Used” page opens (Fig 114).

The procedure here described requires, where possible, scanning the barcode of the different resources to select them.

If barcode reading is not possible a manual procedure can be used. Manual procedure is described in paragraph 9.11.1.

Fig 113 – “Resources Used” page

- Scan the resource’s barcode

The single resource can be configured to require, after barcode is scanned, to specify the resource’s serial number for further verification.

In this case, after barcode is scanned, the following window appears.

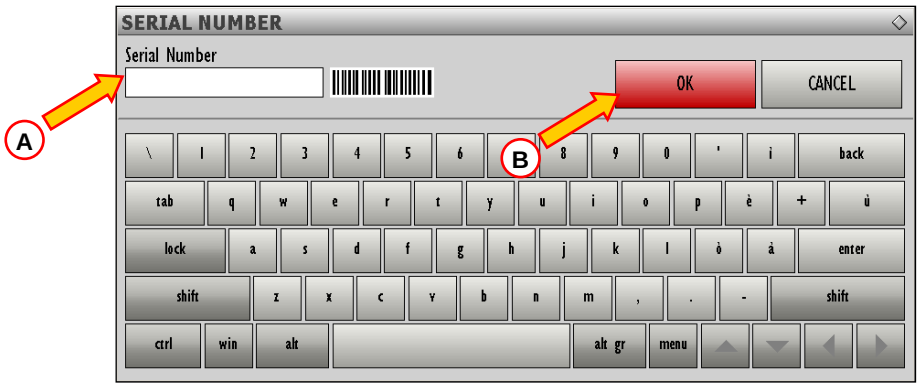


Fig 114

- Scan the barcode corresponding to the resource's "Serial number".

or

- Enter the resource's "Serial Number" (Fig 114 **A**), then click the OK button (Fig 114 **B**).

The window shown in Fig 114 does not show up if the resource is not configured to require "Serial number" specification.

The system adds the chosen resource to the "Resources used" list (Fig 115 **A**).

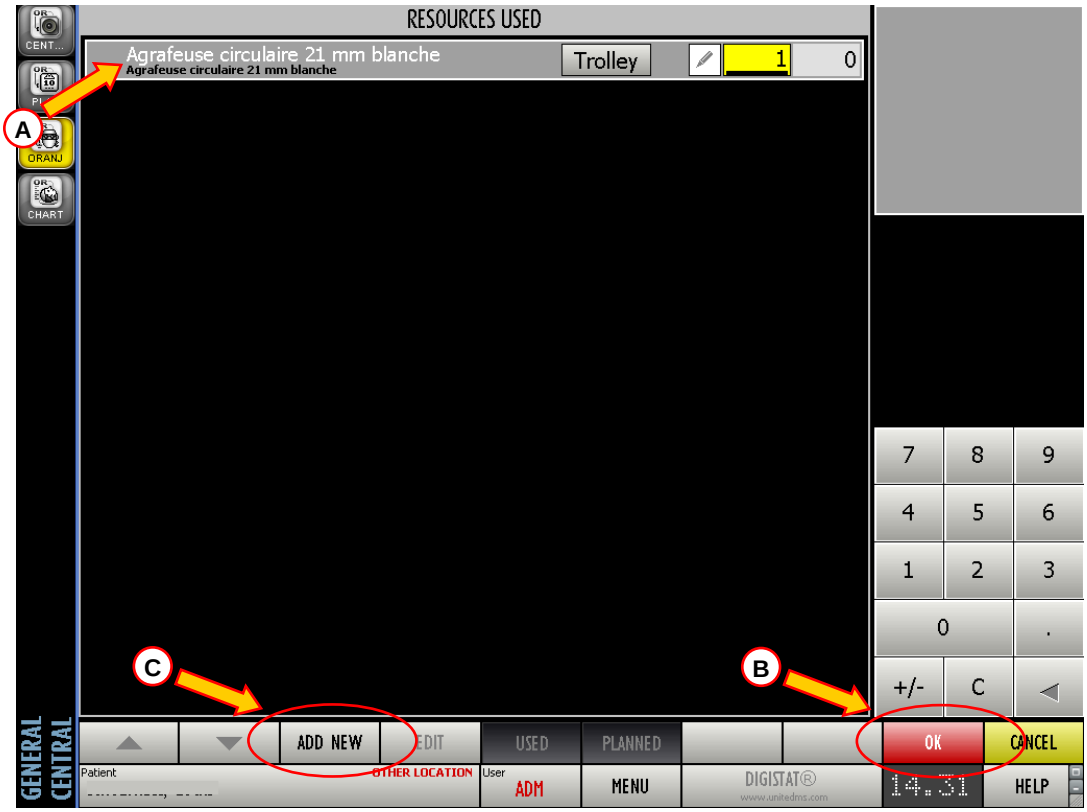


Fig 115 – Resource used

One item is recorded (as quantity). To edit quantity scan the barcodes of the additional resources.

To complete the procedure

- click the OK button on the command bar (Fig 115 **B**).

The recorded resource's name and quantity appear in the "materials and resources" area of the "OranJ Form" page (Fig 116 **A**).

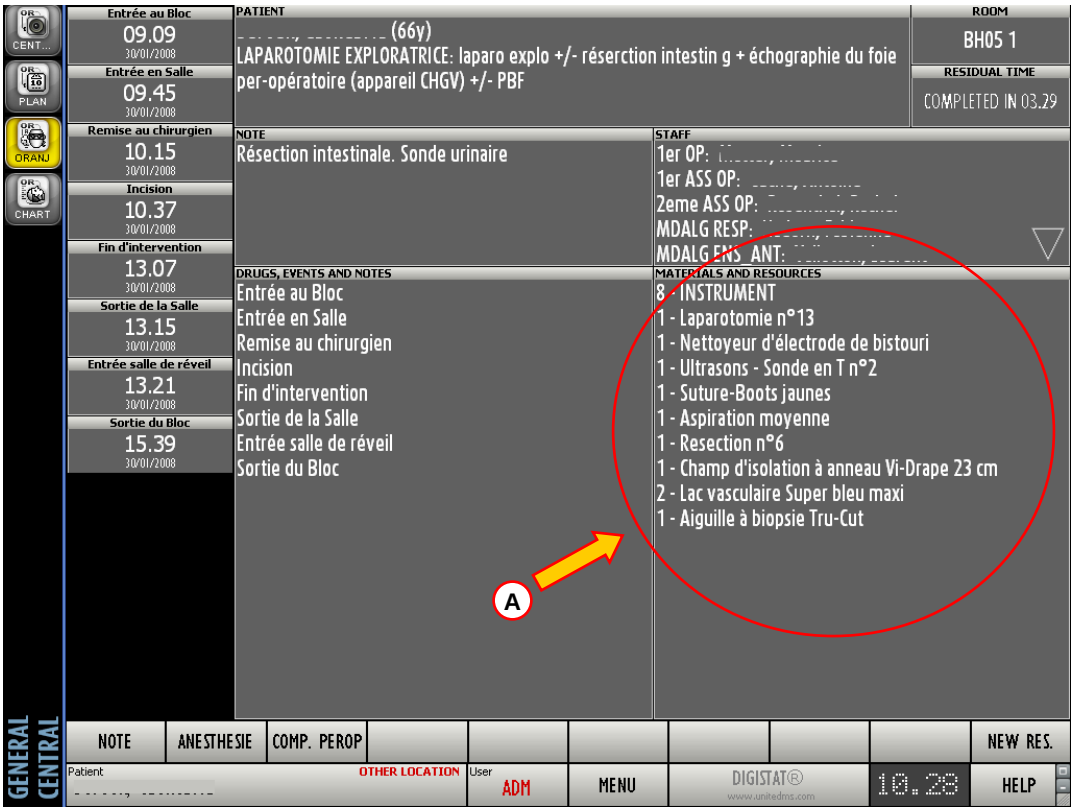


Fig 116

9.11.1. Manual procedure

To manually record a resource

- click the "Materials and Resources" area.

The "Resources Used Screen" opens (Fig 115).

- Click the ADD NEW button on the command bar (Fig 115 **C**).

A page listing the available resources opens (Fig 117).

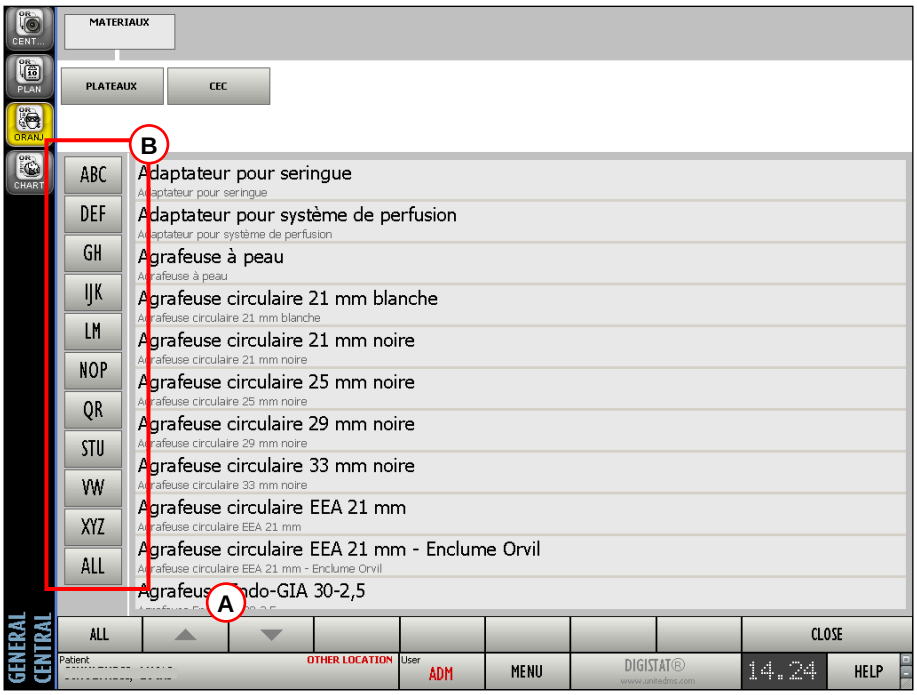


Fig 117 – List of Resources

In the example shown in Fig 117 the resources are grouped by type ("plateaux", "CEC"). Click one of the boxes representing the type of resource to display all the resources of that type.

You can scroll the list using the arrows shown in Fig 117 **A**.
The buttons containing the letters of the alphabet (Fig 117 **B**) make it possible to filter the list displayed. Click one of the letters to display the resources whose names begin with that letter only. Click the ALL button to display the whole list.

To add a new resource

- Click the name of the resource you wish to add.

The system will open a specific window requesting specification of the resource's "Serial Number" (if required by configuration - Fig 118).

"Serial Number" request depends on a configuration parameter.

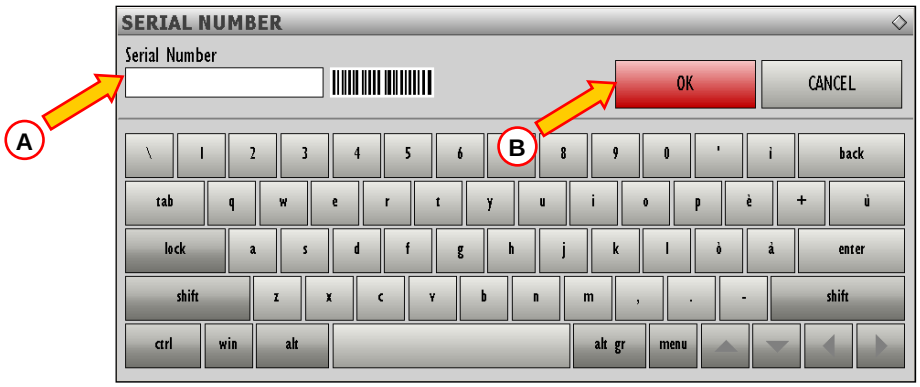


Fig 118

- Enter the resource's "Serial Number" manually (Fig 118 **A**) and then click the OK button (Fig 118 **B**).

The system automatically adds the resource selected to the list of resources used (Fig 119).

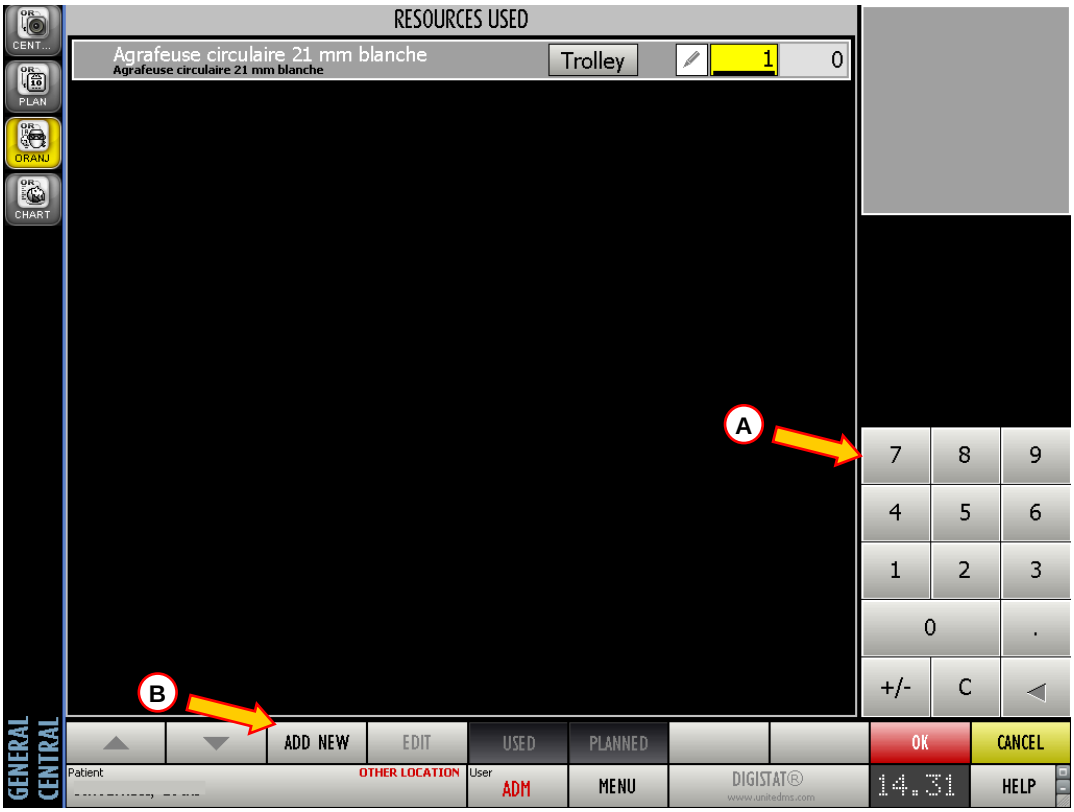


Fig 119 – Resource added

9.12. "Resources Used" screen description

On the "Resources used" screen (Fig 119) the resource is displayed on one line (Fig 120). Every line contains a variety of information.

Fig 120 – Information on the Resource

- The name of the resource is indicated on the left side (Fig 120 **A**).
- The TROLLEY button (Fig 120 **B**) makes it possible to indicate whether or not the resource can be fitted onto a trolley. Clicking and highlighting the button (Trolley) indicates that the resource can be fitted onto a cart.
- The button (Fig 120 **C**) makes it possible to add a note to the resource selected.

Click it to open a virtual keyboard which makes it possible to add possible notes (Fig 121). The operation of the virtual keyboard is described in detail in paragraph 9.6.

Fig 121 – Add note to the resource

To save the notes added

- ➢ Click the OK button (Fig 121) on the command bar.

When there is a note referring to one of the resources entered in the list of "resources used", the button (Fig 120 **C**) appears highlighted in yellow.

- Box 1 (Fig 120 **D**) indicates the quantity of resources to be added or removed.

This quantity is entered using the numeric keyboard in the bottom right corner of the "Resources Used" page (Fig 119 **A**, Fig 122).

Fig 122 – Numeric Keyboard

To specify the quantity of resources

- Click the EDIT button (Fig 119 **B)**.
- Click box 1 .

The cursor appears inside it.

- Click the numbers on the keyboard to enter the quantity.

The ◄ button makes it possible to delete the digits in the box.

The +/- button makes it possible to specify whether or not you intend to add or subtract the quantity of resources indicated. Click this button to make the number inside the box positive or negative.

- Box 0 (Fig 120 **E**) indicates the quantity of resources previously programmed and from which you are subtracting (or to which you are adding) a specific number.

When you have programmed the quantity required

- Click OK to record the new resource.

The resource selected appears, together with the relative quantity, in the "materials and resources" area of the "OranJ Home" page (Fig 123).

The information contained in the "materials and resources" area depends on the configuration chosen. Besides to the name and quantity, it is possible, for example, to show the date and time of addition or the serial number of the resource added.

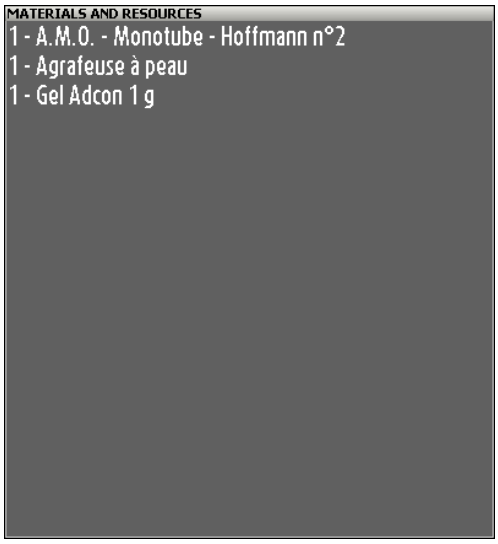


Fig 123 – Resource Added

9.12.1. Editing the "Resources used" screen

To display the list of resources added in detail, or to edit this list

- Click the "materials and resources" area (Fig 123).

The page shown in Fig 119 ("Resources Used") opens.

The names of resources entered previously are flanked by the square (Fig 124).

If there are notes, the square is yellow (Fig 124).

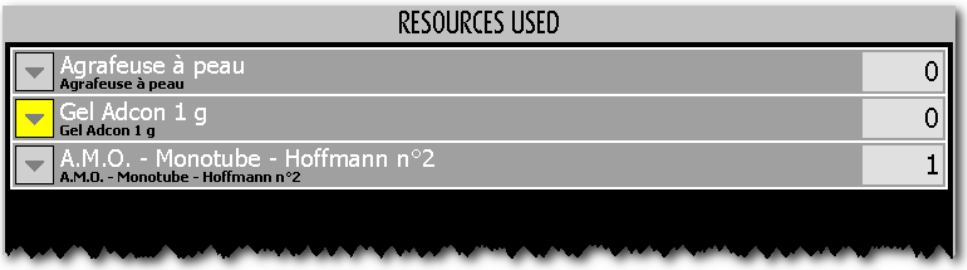


Fig 124

The square can be clicked. Click it to display the details of every editing (time of editing, notes added, name of the user who edited the resource - Fig 125).

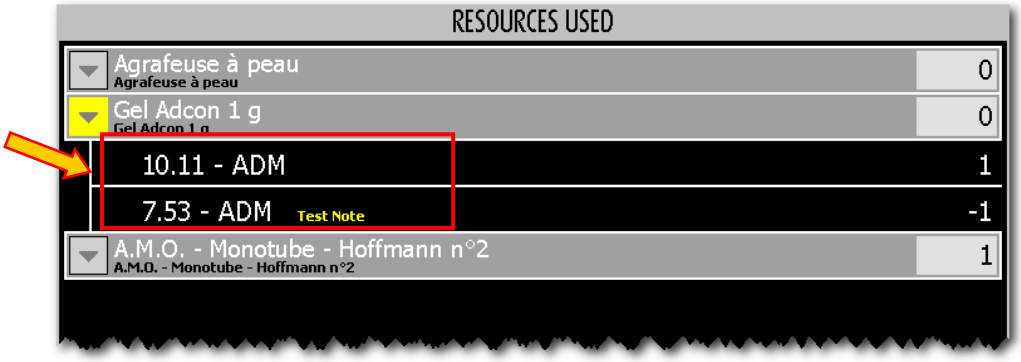


Fig 125 – Display Notes

It is possible to rapidly remove a resource using a specific button.

To rapidly remove a resource

- Access the "Resources Used" screen (Fig 119)
- Click the EDIT button (Fig 119 **B**)
- Click the button placed near the resource you want to remove.

The corresponding line will change as in Fig 126.

- Click the button (Fig 126 **A**).
- Click OK.

The resource will disappear from the "Materials and Resources" area, the corresponding line will still be present on the resources screen, but the quantity will be changed.

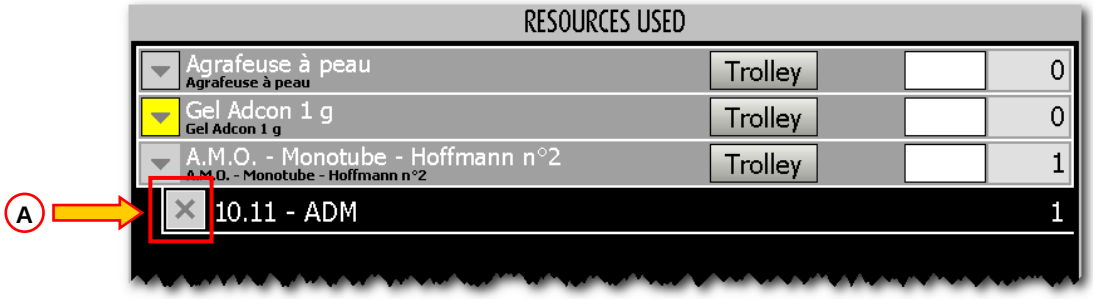


Fig 126

To change the quantity of an added resource ,

The following procedure depends on the configuration in use. Some configurations require the identification of every resource by serial number. In these cases, to modify the quantity of a specific resource it is necessary to repeat the procedure described at the beginning of paragraph 9.11. Contact your system administrator to know the details of the configuration in use.

- Click the "Materials and Resources" area (Fig 123).

The page shown in Fig 127 opens. The EDIT button will be active.

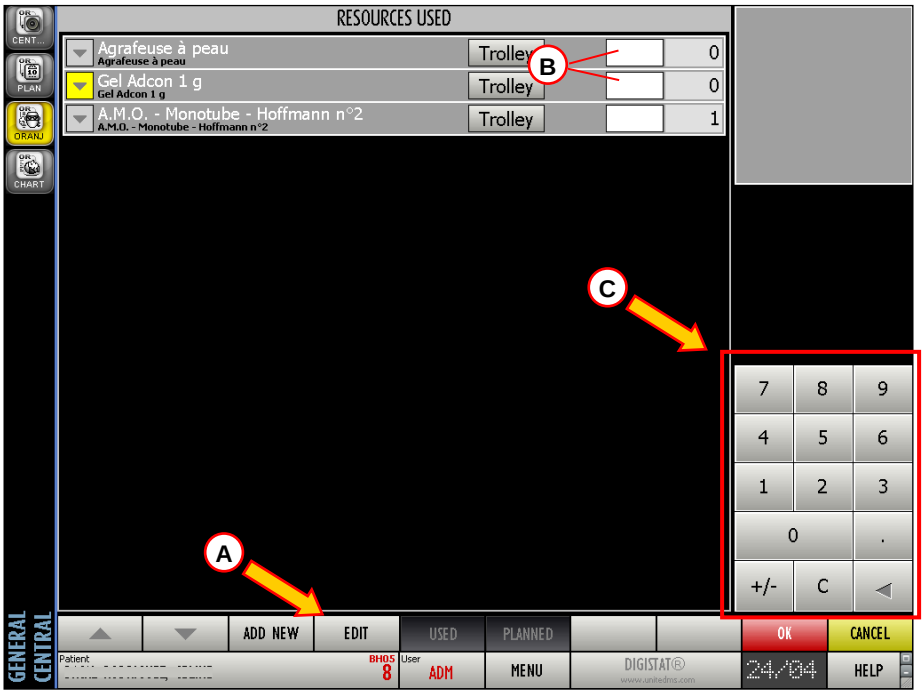


Fig 127 – Change Quantity

- Click the EDIT button on the command bar (Fig 127 **A**).

Boxes which make it possible to program the quantity appear alongside every resource (Fig 127 **B**).

- Click the box corresponding to the resource you want to edit.

- Use the numeric keyboard (Fig 127 **C**) to enter the quantity of resources to be added to or deducted from the number previously programmed.

- Use the +/- button of the numeric keyboard to specify weather the inserted number is positive or negative.

- Click the OK button.

The new quantity will be calculated by the system and shown in the “materials and resources” area of the “OranJ Home” page (Fig 123).

9.12.2. How to move a specified resource set to another operation

It is possible to move the whole set of resources specified for an operation and directly associate it to another operation.

To do that

- click the “Materials and Resources” area (Fig 128).

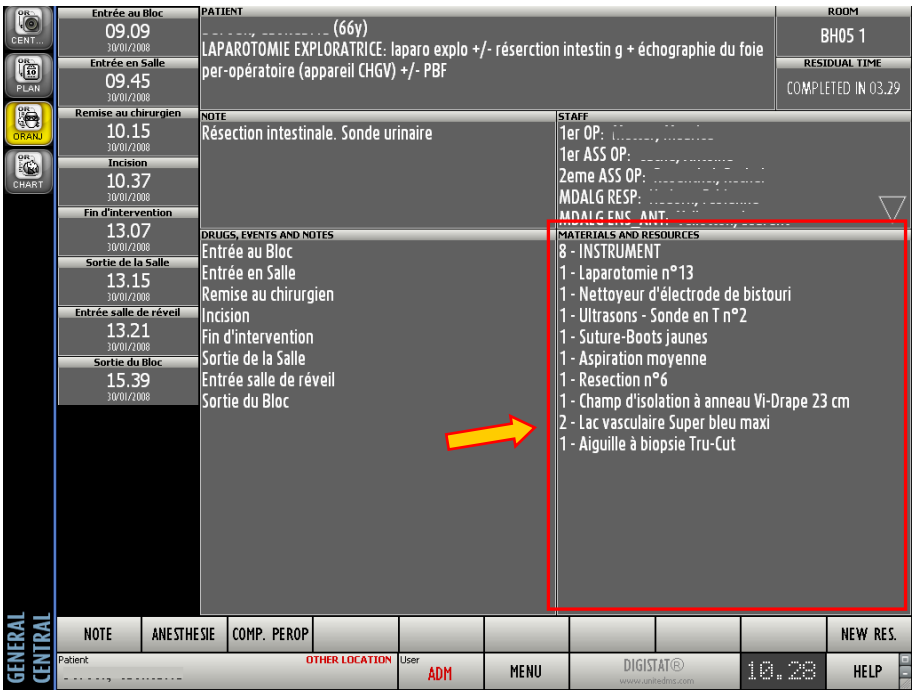


Fig 128

The “Resources Used” screen will open (Fig 129).

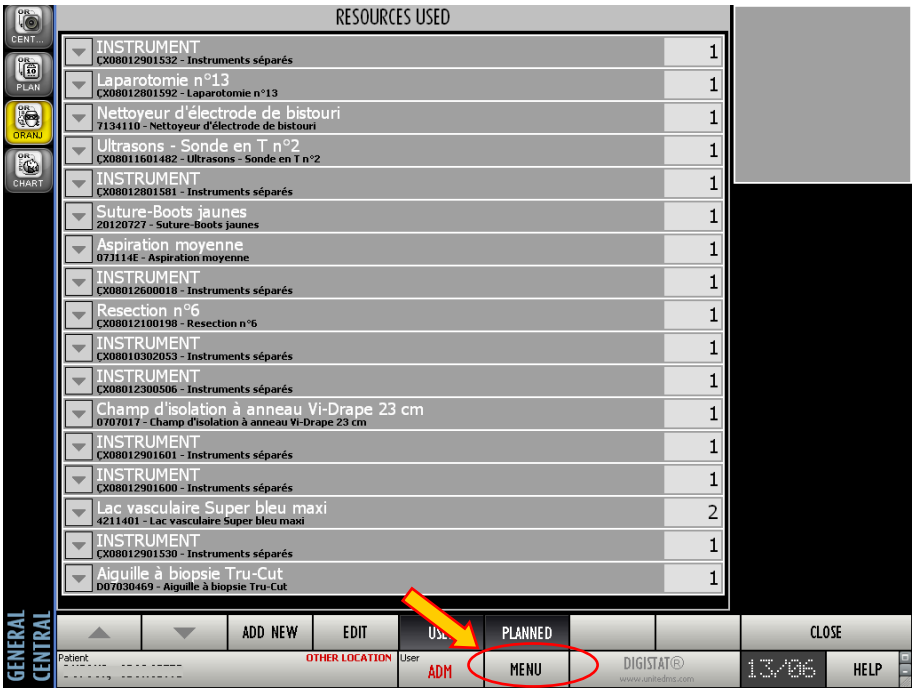


Fig 129

- Click the MENU button on the Control Bar (Fig 129).

The following menu will open (Fig 130).

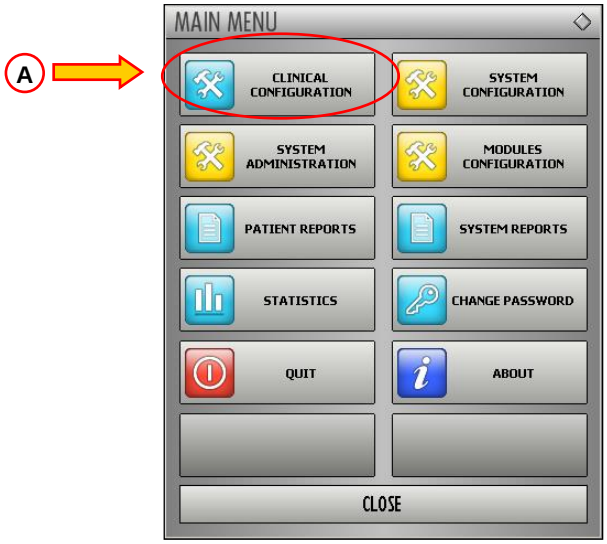


Fig 130

- Click the CLINICAL CONFIGURATION button (Fig 130 **A**).

The following menu will open (Fig 131).

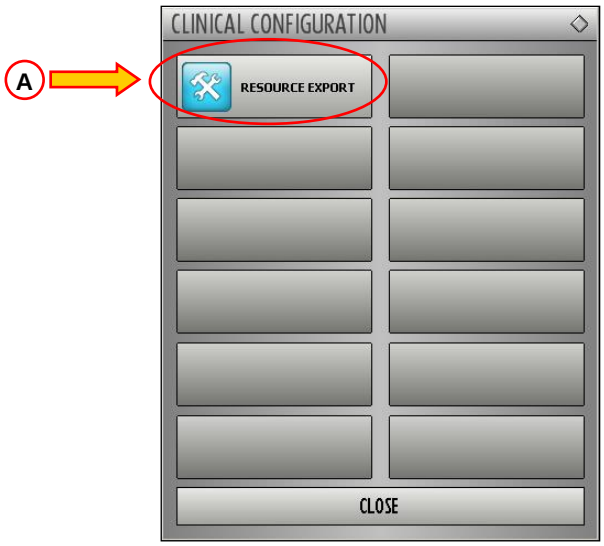


Fig 131

- Click the RESOURCE EXPORT button (Fig 131 **A**).

A pop-up message is displayed, requesting confirmation (Fig 132).

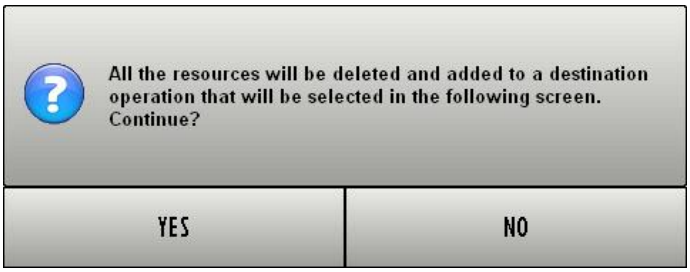


Fig 132

- Click YES

The "Operation list" screen will open. The selection of the destination operation is now required (Fig 133 **A**).

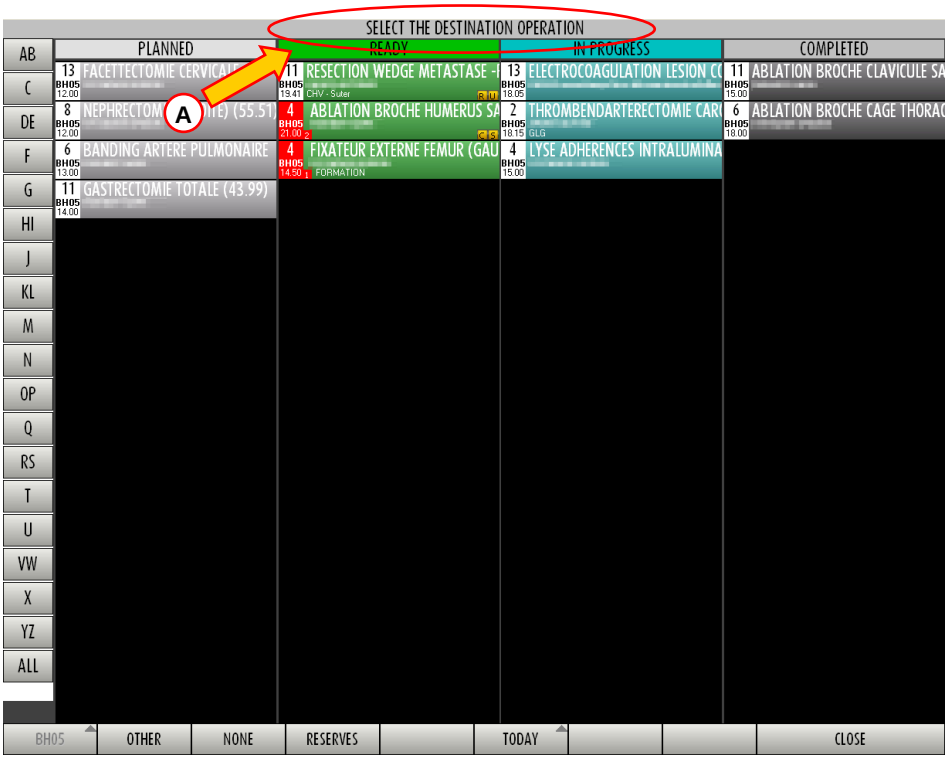


Fig 133

- Click the operation box corresponding to the destination operation.

The set of resources specified for the original operation will be this way automatically associated to the destination operation.

10. Operation and patient management

The OranJ system makes it possible to manage the opartion and patient data. This chapter describes the related screens and procedures.

Specifically, within the OranJ context, it is possible to

1) schedule a new operation for a patient (paragraph 10.1.2);
2) display and possibly edit the data relating to an operation (paragraph 10.1.3);
3) display and possibly edit the patient's personal data (paragraph 10.1.1).

When OranJ is used together with the DIGISTAT® Smart Scheduler system the scheduling procedure is usually performed through Smart Scheduler. The actual workflow depends on the specific hospital procedures in use.

To access these functionalities

- click the "Patient" area on the "OranJ Home" screen (Fig 134 **A**).

Fig 134 - OranJ Home

The "Patient and Operation Details" screen opens (Fig 135).

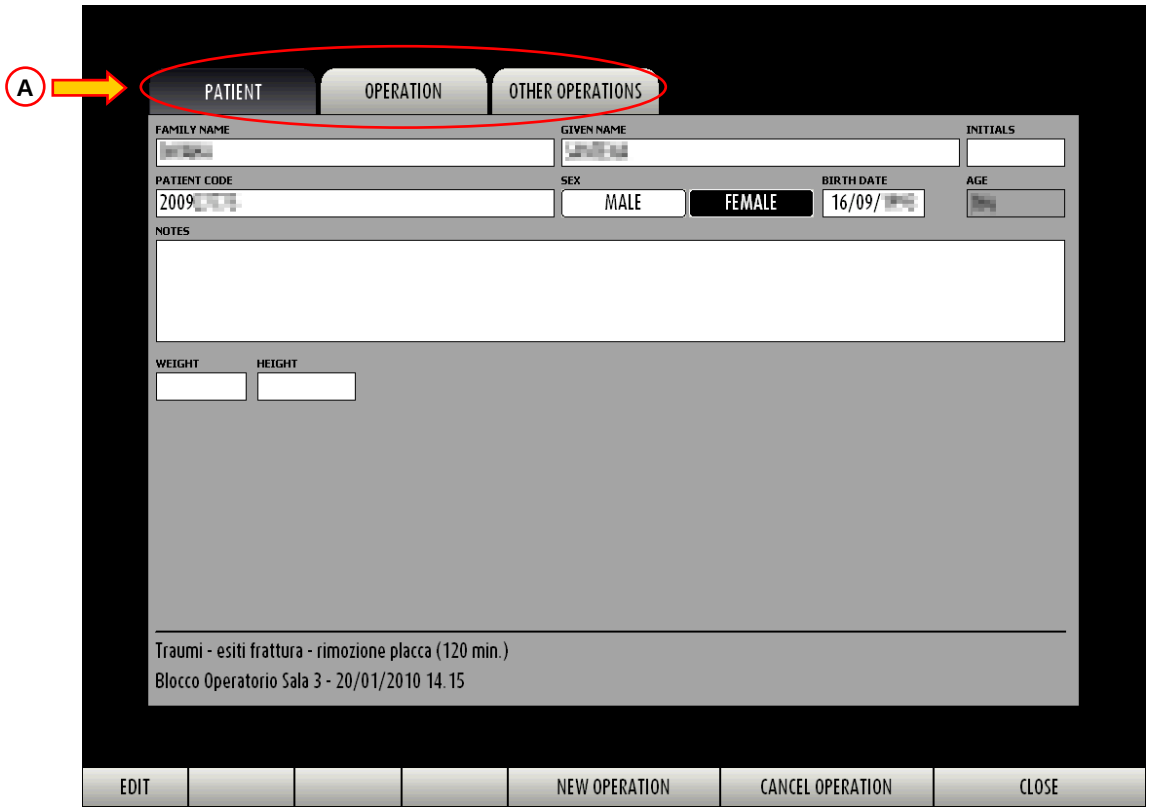


Fig 135 - Patient and operation details

This screen includes three “tabs” (Fig 135 **A**). Each “tab” makes it possible to access a specific subset of information and functionalities.

The “Patient” tab contains the selected patient data (see paragraph 10.1.1).
The “Operation” tab contains the selected operation data (paragraph 10.1.2).
The “Other operations” tab contains the data regarding the possible other operation of the selected patient (paragraph 10.1.3).

10.1.1. Patient

The “Patient” screen (Fig 136) contains the patient’s main data.

To access this screen,

- click the “Patient” tab (Fig 136 **A**).

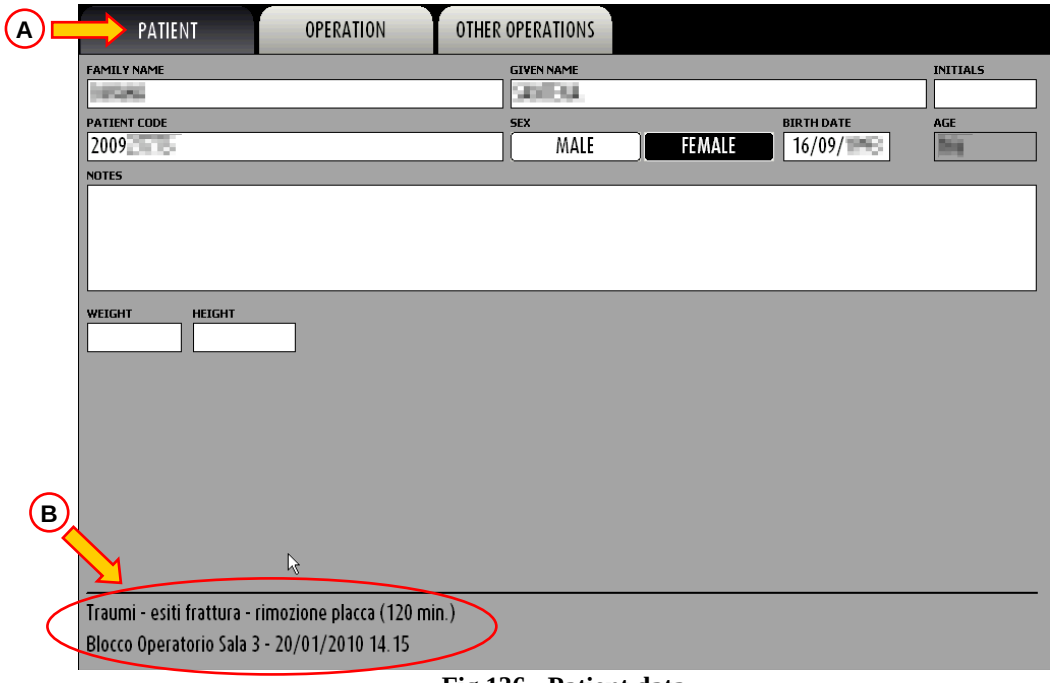


Fig 136 - Patient data

Information that can be here specified is:

- Family name
- Given name
- Initials
- Patient code
- Sex
- Birthdate
- Age
- Notes
- Weight
- Height

If there’s an operation planned for the selected patient the main operation data (type of operation, planned duration, planned block, room and time) appear at the bottom-left corner of the screen (Fig 136 **B**).

To specify new data or to modify the existing ones

- click the EDIT button on the command bar (Fig 137).

Fig 137

The screen will turn to "Edit mode". It will be now possible to modify the patient data.
The CANCEL and UPDATE buttons appear on the command bar (Fig 138).

Fig 138

After editing, click the UPDATE buttin to save the changes made.

10.1.2. Operation

The "Operation" screen makes it possible to display all the data related to the main operation. It also displays the list of the possible related operations.

To access this screen

- click the "Operation" tab (Fig 139 **A**).

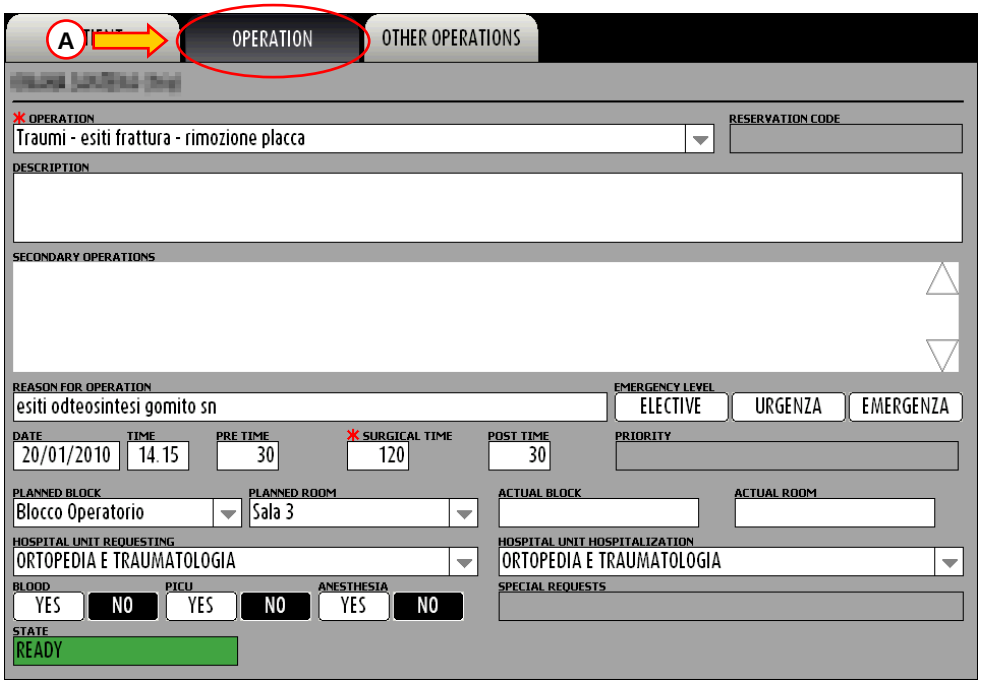


Fig 139 - Operation data

The information required is signaled by the * symbol. The other information is optional, i.e. it is not possible to schedule an operation without specifying the operation name and the planned duration.

The information that can be specified on this page is

- Name of the operation
- Reservation code
- A brief description of the operation
- A list of the possible related operations
- The reason for operating
- The urgency level
- Planned date
- Planned time
- Planned pre-surgical time
- Planned surgical time
- Planned post surgical time
- Planned block
- Planned room
- Actual block
- Actual room
- Hospital unit requesting the operation
- Hospital unit of hospitalization
- Possible necessity of blood
- PICU (Pediatric Intensive Care Unit)
- Possible necessity of anesthesia
- Special requests
- Reason for cancellation (if the operation is canceled)
- State - The "State" box specifies whether the operation is scheduled - SCHEDULED, ready - READY, in progress - IN PROGRESS or completed COMPLETED IN 06.09.

To specify new data or to modify the existing ones

- click the EDIT button on the command bar (Fig 140).

Fig 140

The screen will turn to "Edit mode". It will be now possible to modify the patient data.
The CANCEL and UPDATE buttons appear on the command bar (Fig 141).

Fig 141

After editing, click the UPDATE button to save the changes made.

When editing the screen, some fields can be filled through specific pre-defined menus. These menus can be opened by the button.

For example, the button alongside the “operation” field opens a list of possible operations from which to choose.

To select one of the items on the list click on the item’s name. The clicked item will be displayed on screen in the appropriatre field. This procedure is possible every time the button appears.

10.1.3. Other operations

The “Other operations” screen provides a list of all the past, present and future operations of a patient.

To access this page

- click the “Other operations” tab (Fig 142 **A**).

The following screen opens.

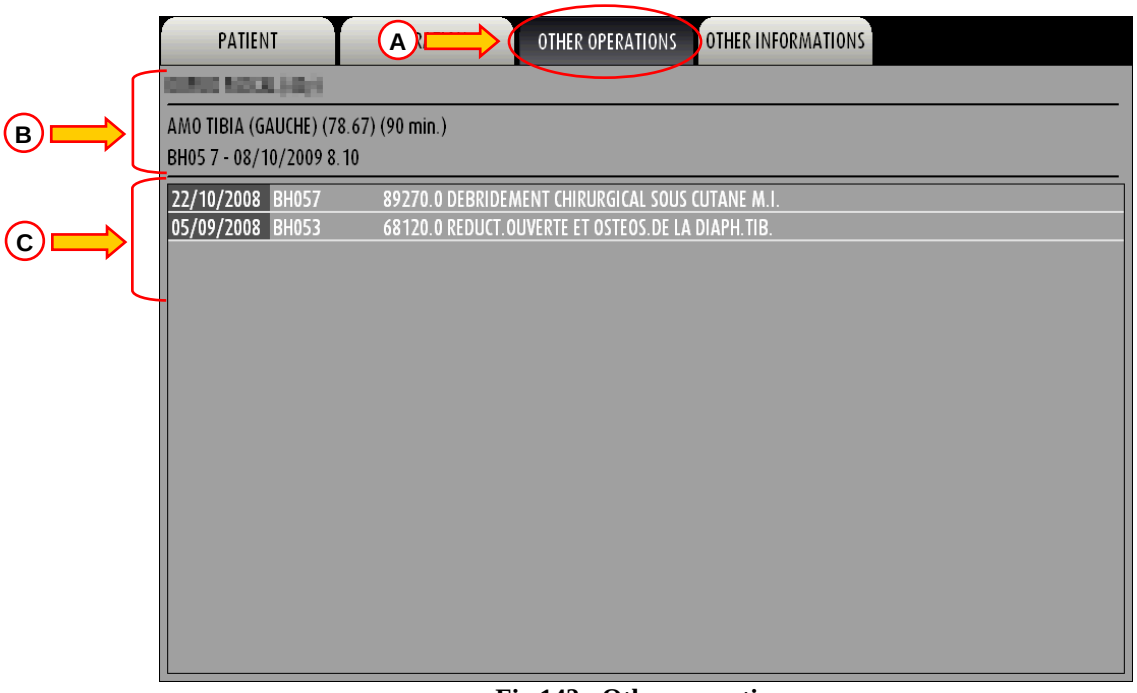


Fig 142 - Other operations

The name of the patient and the selected operation main data are an the top-left corner of the screen (Fig 142 **B**).

The different operations are displayed in chronological order, most recent on top (Fig 142 **C**).

Fig 143

Each line corresponds to an operation (Fig 143).

The information provided for each operation is:

- Date (05/11/2007 in the example)
- Block (BH05)
- Room (2)
- Type of operation (Fermeture de…).

Additional information is provided by the colour of the cell containing the date of the operation. The color of this cell depends on the state of the operation, and follows the color coding used throughout the whole OranJ system. Thus the cell is dark grey if the operation is "completed", it is cyan when the operation is "in progress", green when it is "ready" and light grey when it is "scheduled".

Each line can be clicked to display a window containing a summary of all the operation data.

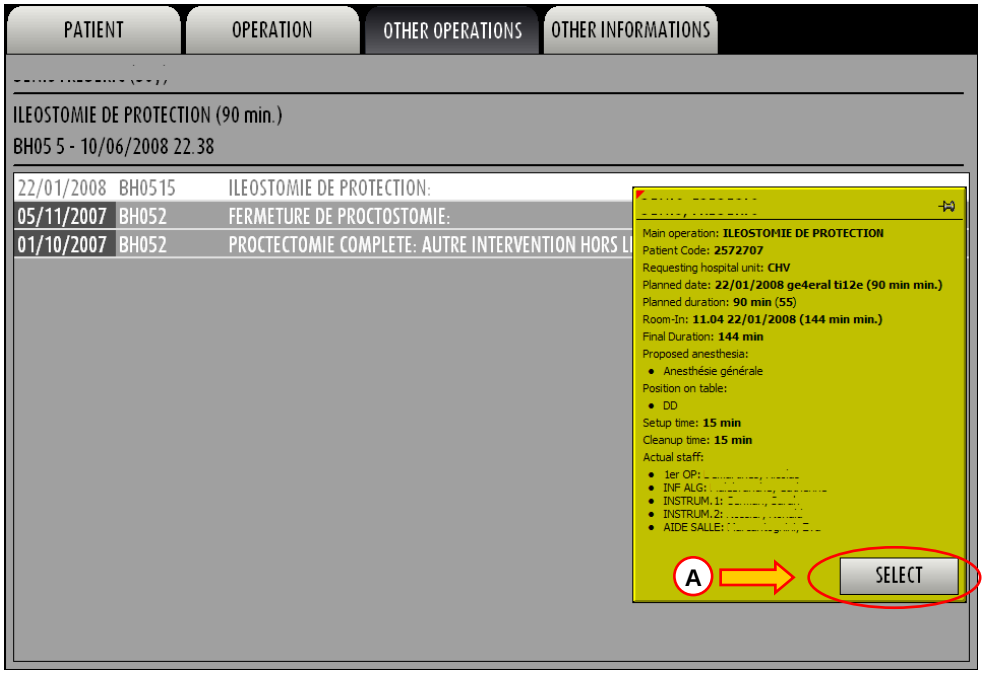


Fig 144

The SELECT button (Fig 144 **A**) on the information window can be clicked to access the "OranJ Home" page for the specific operation. See paragraph 9.1 for a description of the "OranJ Home" screen,

The info window shown in Fig 144 can be customized by the system administrator, i.e. the type and amount of information contained in the window is decided by the user. Therefore, it varies with every single configuration.

10.1.4. Other information

Some configurations use an additional tab to display more relevant data. The “Other informations” page contains a set of additional information regarding a selected patient/operation that are considered useful (Fig 145).

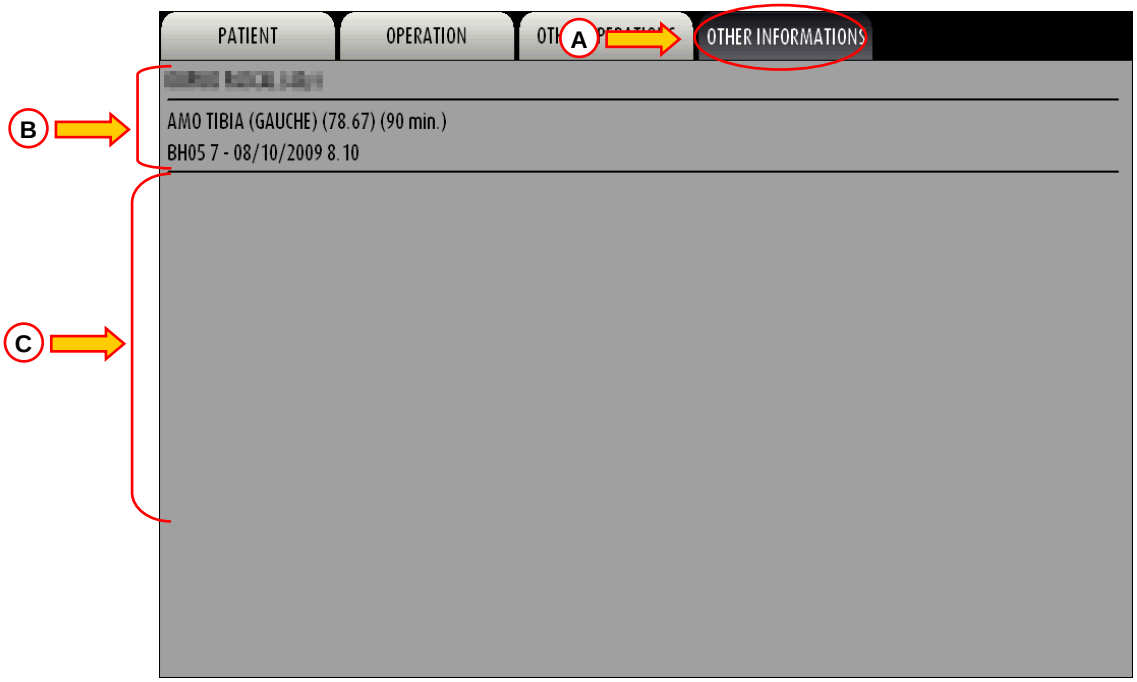


Fig 145

To access this screen

- click the “Other informations” tab indicated in Fig 145 **A**.

The patient and operation main data are displayed on the top left corner of the page (Fig 145 **B**).

The additional information is displayed in the area indicated in Fig 145 **C**.

The nature and kind of information displayed depends on a specific query created by the system administrators. The information displayed therefore varies with the specific query. Please refer to the system administrator to know exactly what kind of information is displayed on this page on the specific system you are using.

10.2. How to schedule a new operation

The “OranJ” system makes it possible to schedule a new operation for a selected patient.

To schedule a new operation

- Select the patient for whom the operation will be scheduled.

The“OranJ Home” screen relating to the selected patient will open (Fig 146 - See paragraph 9.1 for a detailed description of this screen).

Fig 146 – OranJ Home

- Click the “patient” area (Fig 146 **A**).

The “Patient and Operation detail” screen will open (Fig 147).

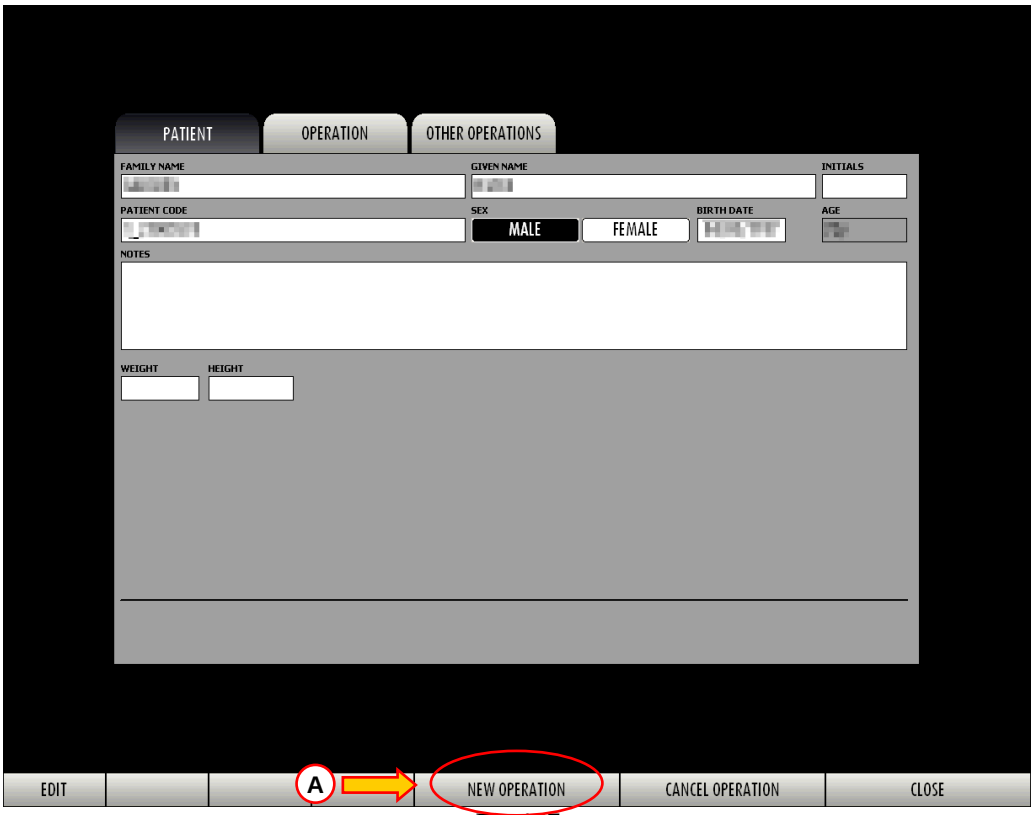


Fig 147

The "Operation" tab will be automatically selected, that will be in "edit" mode. It will be here possible to specify the new operation data (Fig 148).

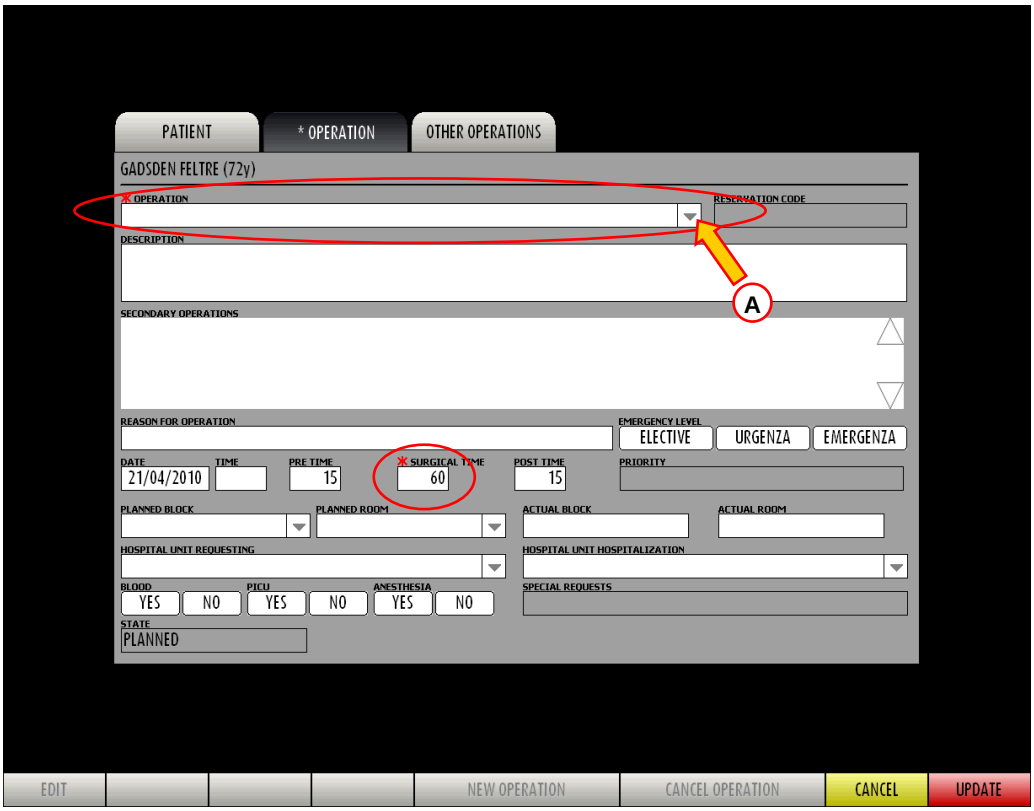


Fig 148 – New operation data specification

- Specify the operation details (operation name and planned duration - indicated in Fig 148 - are required)

Where the button is present, a list of options from which to choose can be opened (by clicking this button).

For example, the button alongside the "operation" field (Fig 148 **A**) opens a list of possible operations from which to choose (Fig 149).

- Use the arrows on the right of the list (Fig 149 **A**) to scroll the list, or type the initial letter of the wanted operation to jump to the list of operations beginning with that letter.

- Click the name of the wanted operation to select it.

The operation name will appear in the "Operation" field.

The pre surgical, surgical and post surgical time can be associeted to the selected operation by configuration. When this is the case these values are automatically inserted when the operation is selected.

The same procedure can be used wherever the button is present.

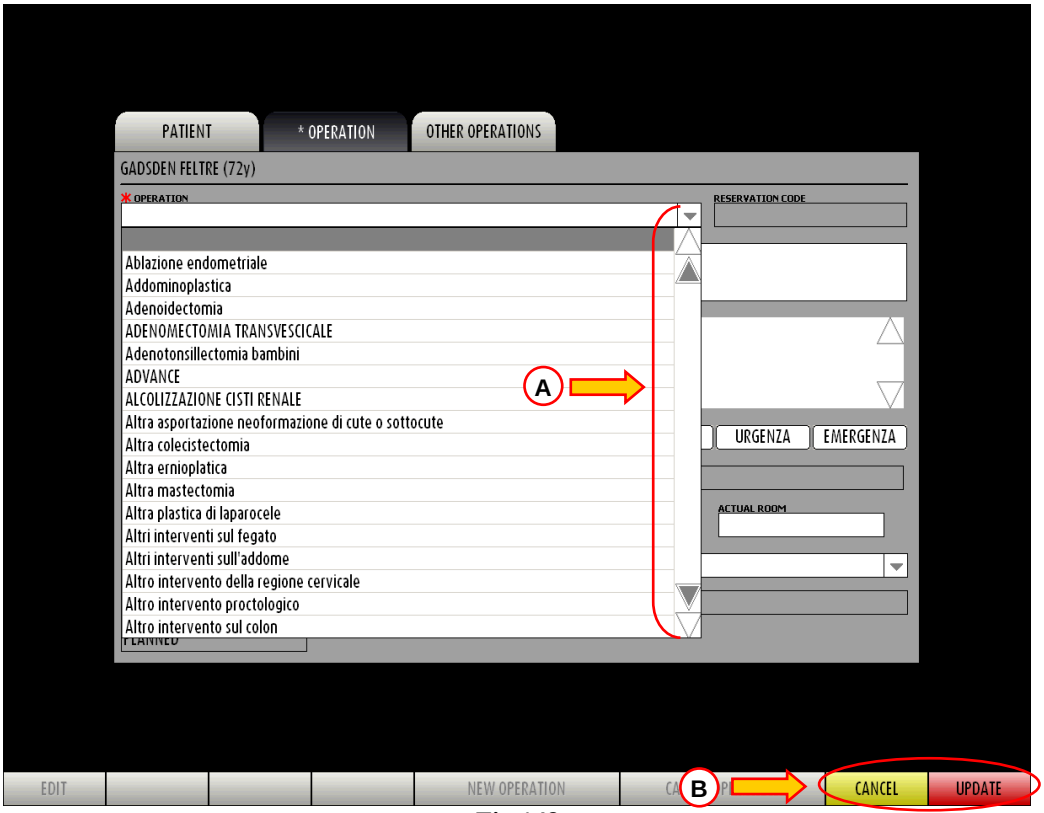


Fig 149

After entering all the data

- Click the UPDATE button to save the data entered (Fig 149 **B**, Fig 150).

This schedules the operation.
The operation will also be present in the other pages and modules of the OranJ system.

Otherwise, if you wish to cancel the data entered

- Click the CANCEL button (Fig 149 **B**, Fig 150).

Fig 150

10.2.1. How to cancel a scheduled operation

To cancel a scheduled operation

- Select the operation that must be cancelled.

The "OranJ Home" screen relating to the selected operation will open (Fig 151).

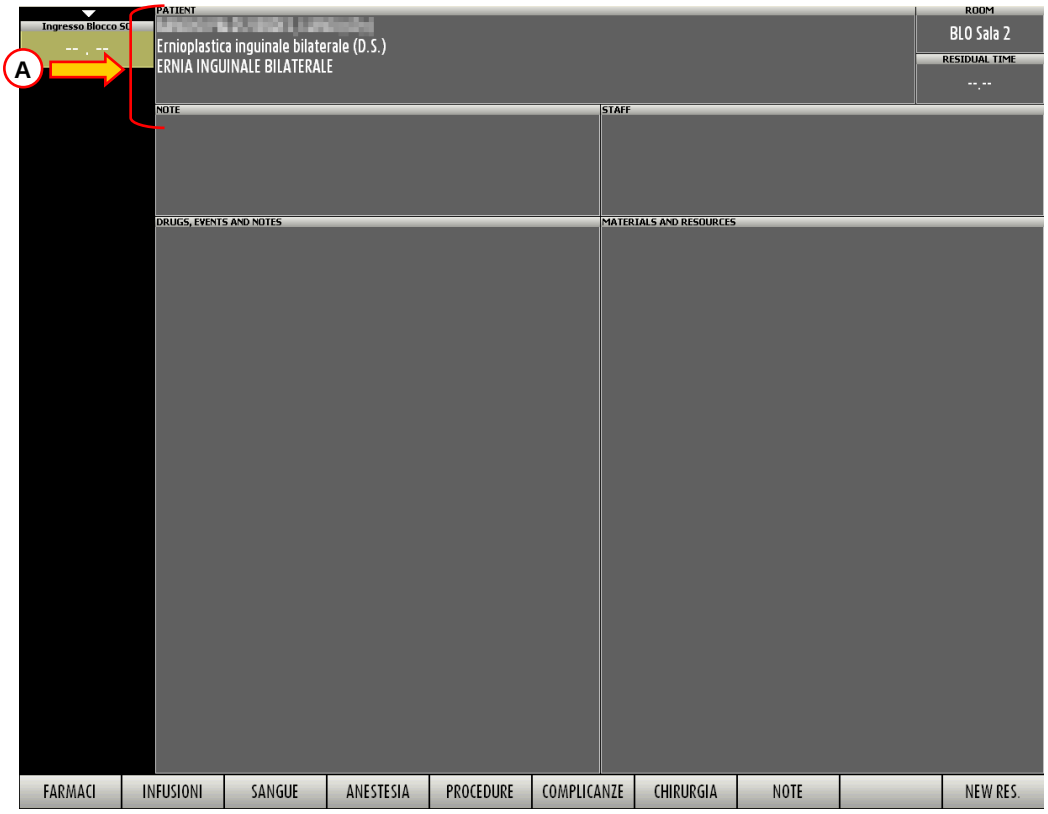


Fig 151 - OranJ Home

- Click the "Patient" area (Fig 151 **A**).

The "Patient and Operation details" screen will open (Fig 152).

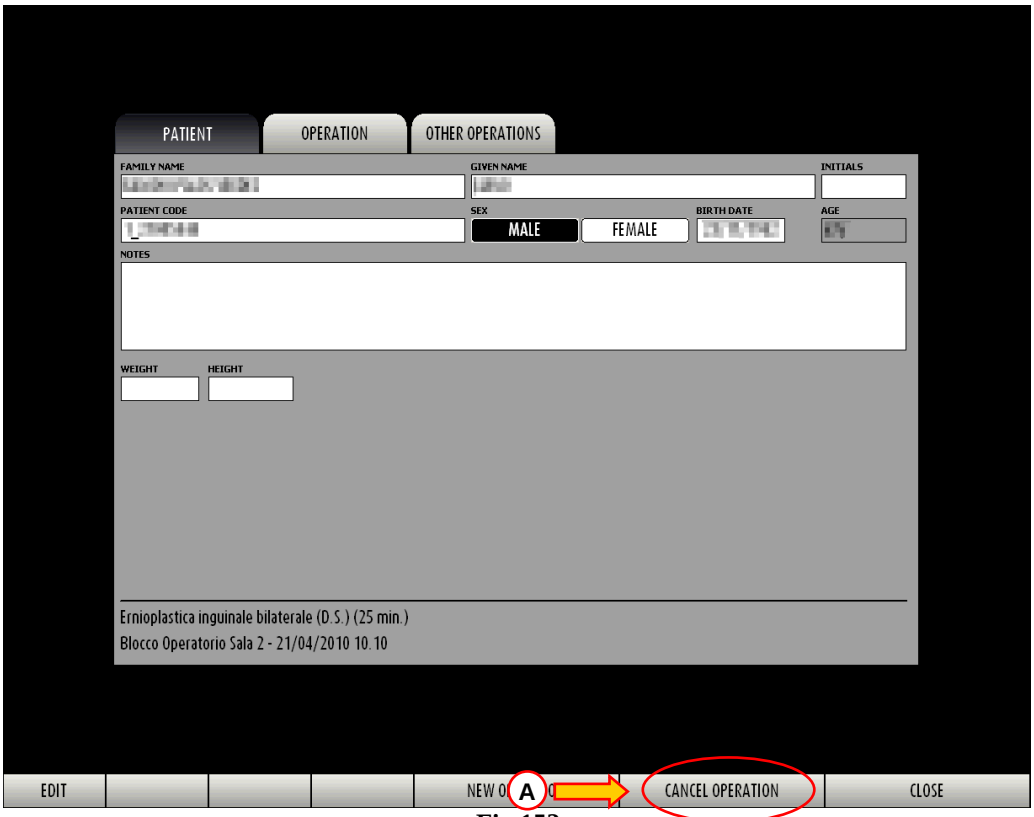


Fig 152

- click the CANCEL OPERATION button on the command bar (Fig 152 **B**)

A window requesting confirmation will open (Fig 153).

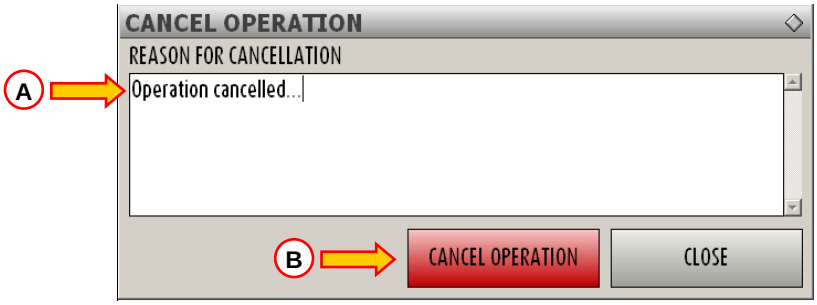


Fig 153 – Operation cancellation

You can type the reason for cancellation of the operation in this window.

- Specify the reason fof cancellation (Fig 153 **A**)

- Click the red CANCEL OPERATION button (Fig 153 **B**)

Once the reason has been entered, it appears on the record relating to the cancelled operation in the "Reason for cancellation" field.

The operation state is now “Cancelled” (Fig 154 **A**).

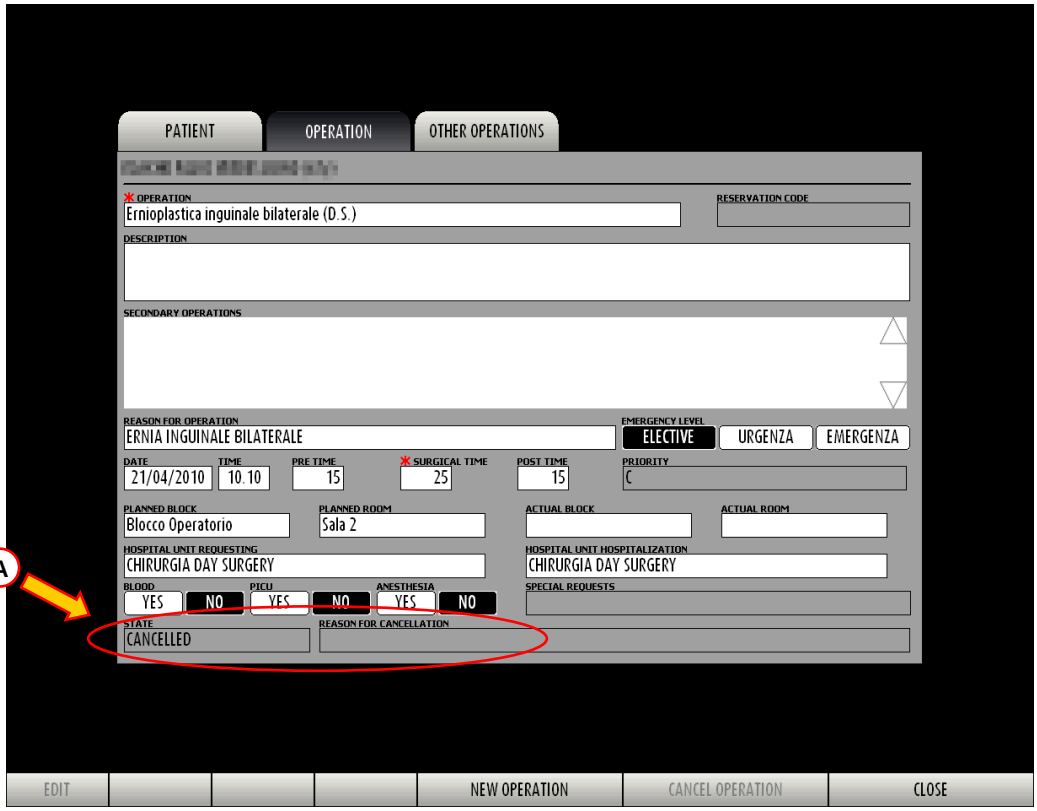


Fig 154 - Cancelled operation

Once cancelled, the operation disappears from all the pages of the OranJ system modules.

11. The OranJ “Plan” module

The “OranJ Plan” module makes it possible to monitor the activities in one or more operating block(s).
To select the “OranJ Plan” module

- Click the corresponding icon 

on the DIGISTAT® lateral bar (Fig 155).

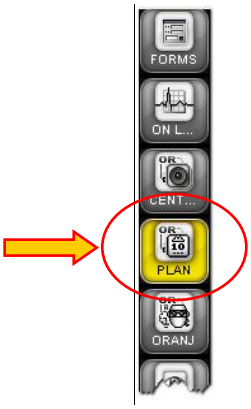


Fig 155

The “OranJ Plan” module screen will open. Fig 156 shows an example. The screen shows the state and the trends of the actual operations on a block in the current day.

Fig 156 - Operating day (example)

11.1. Screen description

Every numbered line represents an operating room. The box at the beginning of the line contains the number of the room. In Fig 157 **A** rooms 1 e 2 are indicated.

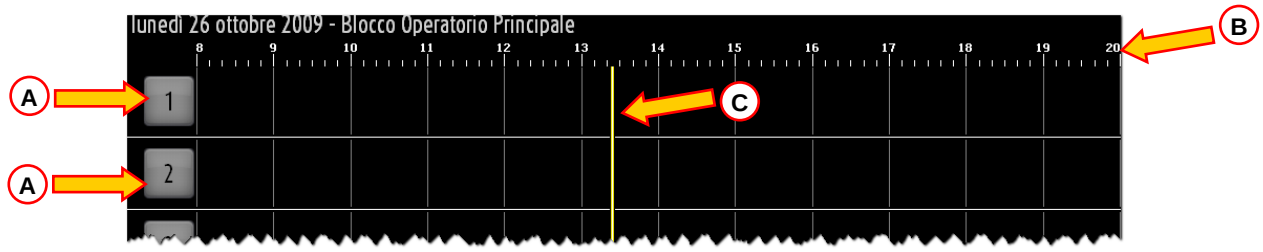


Fig 157

If enabled by configuration, the colour of that box provides information on the state of the operation that is more relevant at present time.

There are four possible configuration options regarding the room number box colour:

- room numbers are always grey;
- only operation states are highlighted;
- only late and close to end operations are highlighted;
- both operation states and late/close to end operations are highlighted .

In this last case the room number colour changes according to the following priorities:

- if an operation is late the box turns red;
- if an operation is close to the end (30 minutes or less in the configuration here described) the box turns yellow;
- if an operation is in progress the box turns cyan;
- if an operation is ready (and no operation is in one of the above mentioned states) the box turns green;
- if an operation is planned (and no operation is in one of the above mentioned states) the box turns light grey;
- if there are no operations or all the operations in the room are completed the box turns dark grey.

Fig 156 and Fig 158 show some examples.

Fig 158

The hours are indicated on top and bottom of the screen (Fig 157 **B**).

The yellow bar shown in Fig 157 **C** indicates the current time. In Fig 157 it is about 13:20. The bar runs as time goes by.

Possible yellow letters placed near the room box (Fig 159) indicate the devices that are in the room. The relation between a letter and a device is set by configuration.

Fig 159

The rectangles displayed on screen represent the various operations (Fig 160).

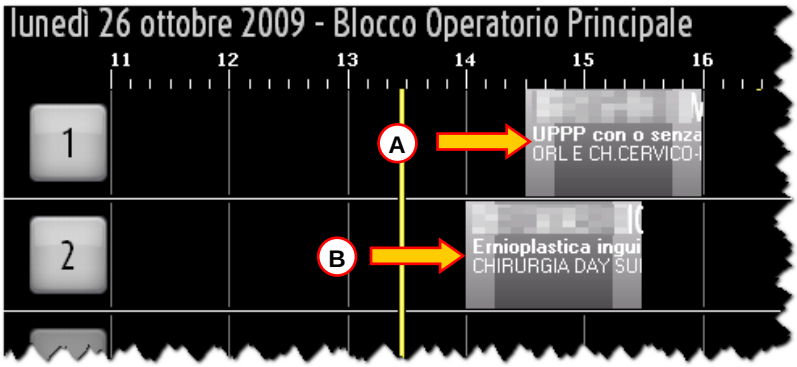


Fig 160

The rectangles on the right of the yellow time-bar represent scheduled operations (they are placed on a future time); their values (duration, room, time etc…) are planned values. The rectangles on the left of the yellow time-bar represent completed operations (they are placed on a past time); their values are actual values. The rectangles intersecting the yellow bar represent operations in progress. In Fig 156 some examples of all kinds are visible.

The position of every rectangle indicates the scheduled time and the room where the operation will be performed (or was performed if completed). In Fig 160, for example, an operation is planned at 14:30 in room 1 and an operation is planned at 14:00 in room 2.

The dimensions of every rectangle are proportional to the scheduled duration of the corresponding operation (actual duration if the operation is completed). For example: the planned duration of the operation indicated in Fig 160 **A** is 90 minutes (from 14:30 to 15:00). the planned duration of the operation indicated in Fig 160 **B** is 90 minuti as well (from 14:00 to 15:30). The duration represented this way includes pre-surgical, surgical and post-surgical times.

These times are indicated by different shades of color (Fig 161).

Fig 161

The lighter part on the left (Fig 161 **A**) represents pre-surgical time; the darker part in the middle (Fig 161 **B**) represents surgical time; the lighter part on the right represents post-surgical time (Fig 161 **C**).

Each rectangle displays certain information on the operation, depending on the configuration in use. In the configuration here described the patient name, the operation and the hospital unit requesting the operation are displayed in the rectangle (see Fig 162 for an instance).

The rectangle colour indicates the operation state.

Four different operation states are possible in the OranJ system.

- Planned – the operation has been scheduled; at least the operation day was specified. Light grey indicates the "Planned" state (Fig 162).

Fig 162 - "Planned" operation

- Ready – the patient has undergone block check-in. Green colour indicates the "Ready" state (Fig 163).

Fig 163 - "Ready" operation

- In Progress – the patient has entered the operating room. Cyan indicates the “In progress” state (Fig 164).

Fig 164 - “In progress” operation

- Completed – the operation has been completed; the patient is out of the operating room. Dark grey indicates the “Completed” state (Fig 165).

Fig 165 - “Completed” operation

When an operation changes state the color of the corresponding rectangle changes.

The changes in the operation state is linked to the recording of certain markers on the “OranJ Home” screen (see paragraph 9.4 for a description of the “Markers”).

- The “Block In” marker recording implies passage from “Planned” state to “Ready” state.
- The “Room In” marker recording implies passage from “Ready” state to “In progress” state.
- The “Cut” marker recording implies the end of the pre-surgical time and the beginning of the surgical time. When this marker is recorded the operation rectangle looks like the one shown in Fig 164; here the different shading differentiate pre surgical and surgical times.
- The “Suture” marker implies the end of surgical time and the beginning of post surgical time. When this marker is recorded the operation rectangle looks like the one shown in Fig 166, the different shading here differentiate pre surgical, surgical and post surgical times.

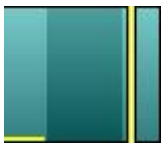


Fig 166

- The “Room out” marker implies passage from “In progress” state to “Completed” state.

The kind of information displayed on the operation-rectangles depends on the configuration in use and can be changed and/or translated. Therefore they can appear different from those shown in the figures.

If enabled by configuration, the possible operation delay is visible on a yellow bar placed at the bottom of the operation-rectangle (Fig 167).

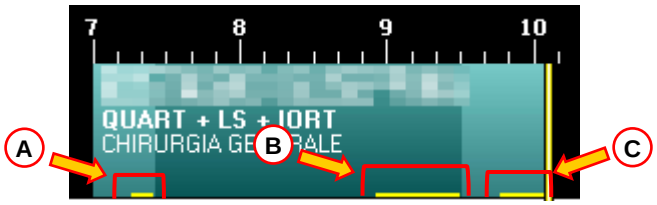


Fig 167

A configuration parameter makes it possible to display separately the possible delays in pre surgical, surgical and post surgical durations. That is the case shown in Fig 167. In the figure here displayed the three yellow bars indicate

1) a 12 minutes delay in the pre surgical planned duration (Fig 167 **A**);
2) a 40 minutes delay in the surgical planned duration (Fig 167 **B**);
3) a 21 minutes delay in the post surgical planned duration (Fig 167 **C**).

The operation shown in the figure is still in progress. Total delay is 73 minutes so far. This value is indicated in the "residual time" area on the "OranJ Home" screen (see paragraph 9.9).

The operations scheduled after the delayed ones are, if necessary, automatically postponed.

The operations indicated as "Emergencies" on the "Patient and operation detail" screen (Fig 139 - or, if installed, on the DIGISTAT® "Smart Scheduler" system) are characterized by a red stripe on the left (Fig 168). The small box indicated in Fig 168 **A** specifies the emergency level. In the configuration here described there are three possible emergency levels.

Fig 168 - Emergency

Every operation box can be clicked, whether on the page or the "not assigned" column (see paragraph 11.3).
Click one of the boxes to open a window (Fig 169) containing the main data of the operation.

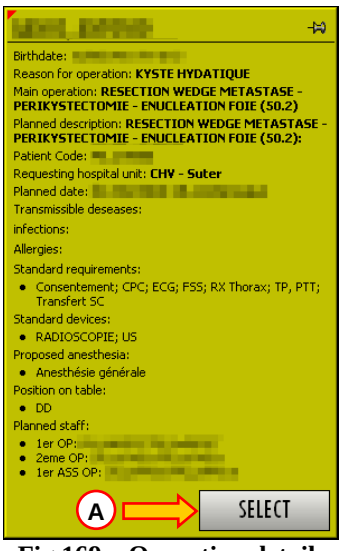


Fig 169 – Operation details

Click the SELECT button in the window (Fig 169 **A**) to access the "OranJ Form" page relating to the operation clicked (Fig 66).

11.2. The "OranJ Plan" command bar

The command bar on the bottom of the OranJ Plan screen is formed by function-buttons making it possible to perform different procedures. These buttons are listed and shortly described in this paragraph. The procedures are described in detail in the paragraphs here indicated.

Fig 170

This button makes it possible to edit the operation plan. The button must be selected before any editing procedure. See paragraph 11.2.1.

This button makes it possible to display the plan of a different block. This button is only active if working on a "General Central" station. See paragraph 11.2.2.

This button makes it possible to display a different time span. See paragraph 11.2.3.

This button makes it possible to display the plan of a different day. See paragraph 11.2.4.

Scroll buttons - They make it possible to display a plan either preceding or following that currently displayed. If, for example, a time span going from 12:00 to 24:00 is displayed, one click on the right arrow displays a time span going from 15:00 to 3:00 (next day). Similarly, one click on the left arrow displays a time span going from 9:00 to 21:00.

This button is a filter for the operations in the "not assigned" area. If selected only the operations of the currently selected block are displayed in this area, if not selected allthe not assigned operations of all the blocks configured in the system are displayed. See paragraph 11.3.

11.2.1. How to edit the operation plan

The operation plan can be edited directly on the "OranJ Plan" module main screen.

Before any editing it is necessary to click the EDIT button (Fig 171).

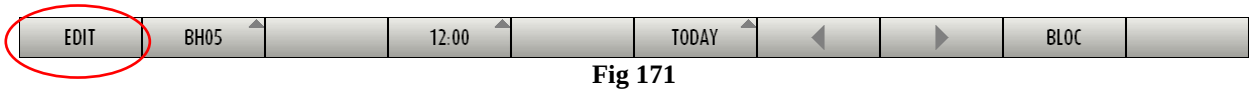


Fig 171

When the button is selected the screen is in “edit” mode.

The selected button appears like this - 

.

Once the editing is performed the button automatically deselects. It is necessary to click it again to edit the screen again.

To edit the plan

- click the 

button,

The “drag and drop” functionalities will be this way enabled.

- Drag the operation rectangle to the point required on the plan (or in the “not assigned” area).

The rectangle will remain there, whereas the 

button will deselect. The changes (operation time and room) will be recorded on the other OranJ modules.

The term “drag and drop” indicates the possibility to physically take one of the rectangles corresponding to an operation, drag it to the point required and release it. Remember that the position of a box on the page indicates the room and the time scheduled for the corresponding operation, so moving a box from one position to another means assigning or changing time and/or operating room.

If working on a “touch screen” the same operation can be performed using the fingers.

The 

button makes it possible to:

- change the time and/or room scheduled for an operation,
- add one of the operations from the “not assigned” area to the daily schedule,
- remove one of the operations from the daily schedule and add it to the “not assigned” area.

11.2.2. How to change the block displayed

This button is only active if the workstation on which you are working is configured to display more than one surgical block (i.e., if it is a GENERAL CENTRAL STATION).

To display the page relating to another surgical block

- click the BH05 button on the command bar (Fig 172 - the button is characterized by an abbreviation corresponding to the block currently displayed).

Fig 172

A list of all the blocks configured in the OranJ system will open (Fig 173).

Fig 173 – Block selection

- Click one of the names on the list.

The situation relating to the surgical block selected will appear on the screen.

11.2.3. How to change the time range displayed

To change the time range displayed

- click the 

on the command bar (Fig 174 - the button displays the timer ange currently selected).

Fig 174

A drop-down menu offering three different options (6:00 – 12:00 – 24:00) will open (Fig 175).

Fig 175 – Time interval options

- Click the option required.

The screen changes accordingly. Click 

, for instance, to display a 6 hours time range.

11.2.4. How to change the day displayed

The 

button (Fig 176) on the command bar makes it possible to display the situation of the surgical block on a different date from the current one.

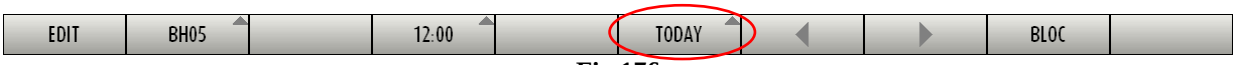


Fig 176

- Click the 

button.

A calendar window relating to the current month will open (Fig 177).

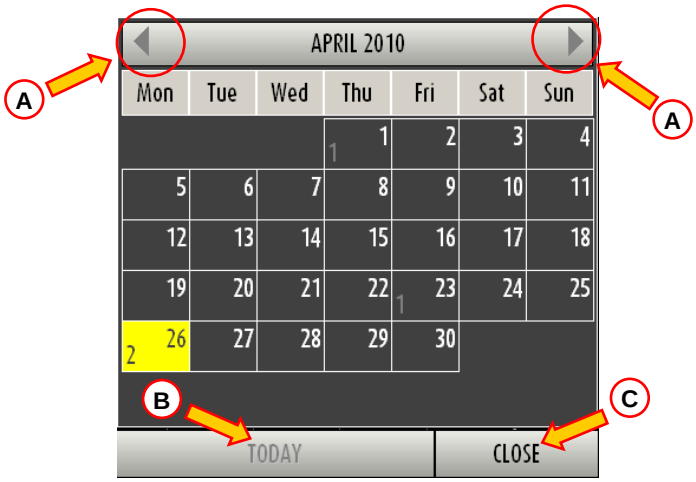


Fig 177 – Calendar

The current day is highlighted in yellow. Inside every day the number of operations completed during that day is shown in dark gray.
You can use the arrows (Fig 177 **A**) to change month. If it is April, for example, click the right arrow to display the calendar for May and the left arrow to display the calendar for March.

After selecting the month

- Click the day you wish to display.

The day selected on the calendar will become yellow.

The page relating to the day selected will be displayed.
If you select a different day from the current one, the TODAY button will show the date of the day displayed - for example: 08/09/2009 -.

To return to the current day

- Click the TODAY button on the calendar (Fig 177 **B**).

To close the calendar window

- Click the CLOSE button on the calendar (Fig 177 **C**).

11.3. The “not assigned” area

The “Not assigned” area on the right of the “OranJ Plan” screen (Fig 178 **A**, Fig 179), contains operations which have not been assigned a block, room or time.

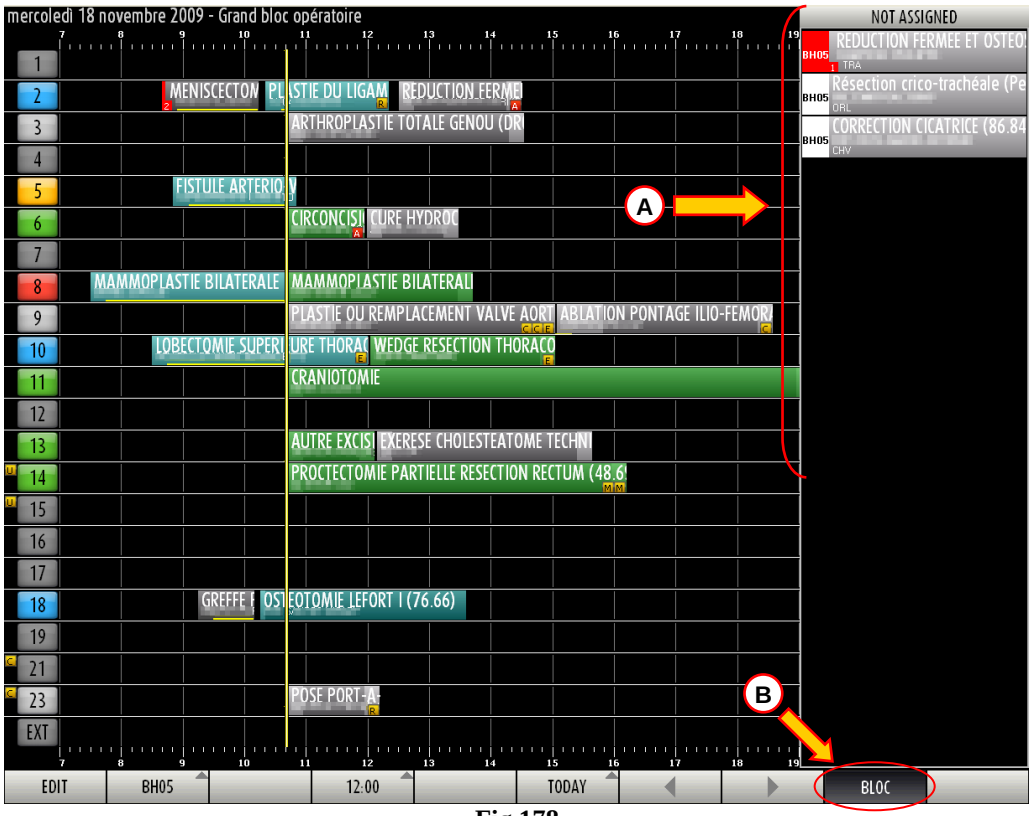


Fig 178

This area is used to add particularly urgent operations, which become necessary from one minute to the next, to the daily schedule. The criterion observed for these urgent cases is “as soon as a place is free, the operation goes ahead”; the “not assigned” area makes it possible to display the operations waiting to be added to the daily schedule.

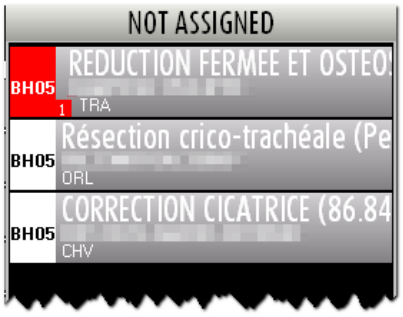


Fig 179 – “Not assigned” area

A scheduled operation appears in the “not assigned” column when

- the block is not specified;

- the room is not specified;
- the time is not specified;
- the block and room are not specified;
- the time and room are not specified;
- the time, block and room are not specified.

In the DIGISTAT® systems, these operations are called Reserves.

The "not assigned" area also displays operations which are indicated as "emergencies". These operations, regardless of the time, block and room specifications, are highlighted in red and are not only displayed on the day for which they are scheduled, but also on the days to come (so that the emergency is always visible. All the emergencies are grouped together on top of the list.
The small box indicated in Fig 180 **A** specifies the emergency level.

Fig 180

On the control bar, to the right, there is the BLOC button (Fig 178 **B**). This button makes it possible to filter the operations of the "not assigned" group. If it is pressed, only the operations relating to the block selected are displayed. If it is not pressed, all the "not assigned" operations of the surgical block are displayed. When you access the page, the BLOC button is pressed by default.

The emergencies, when inserted in the plan, are characterized by a red stripe on the left (Fig 181).

Fig 181 - Emergency

When the EDIT button on the command bar is selected it is possible to set up the order of the "reserves" in the area by dragging and dropping the single boxes in different positions.

When a day in the past is displayed on the plan the "not assigned" area contains the list of the operations that were planned for that day but were not performed. Fig 182, for instance, shows the

area referred to a day in the past. Note the title “planned” on top of the list instead of “not assigned”.

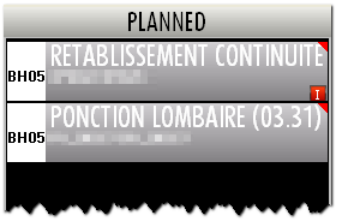


Fig 182

The operation boxes that appear in the not assigned area in the way indicated in Fig 183 **A** are reserves that were planned for a day that is different from the current day.

Fig 183

11.4. Room Plan

You can display details of the schedule of every single operating room by clicking the box containing the room number (Fig 184).

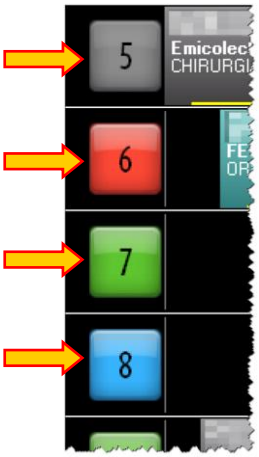


Fig 184

11.4.1. Scheduling the single room

Click one of the boxes indicated in Fig 184 **A** to access a page showing details of the information available on the daily schedule of the single room (Fig 185).

Fig 185 – Room Plan

The figure shows the details of room 4.

11.4.2. Room schedule

There is a time line in the upper part of the page, schematically representing the schedule of the operating day (Fig 185 **A**, Fig 186).

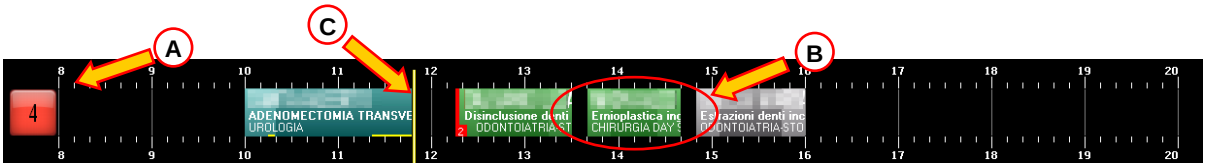


Fig 186

The box on the left (Fig 186 **A**) contains the room number. If enabled by configuration, the colour of that box provides information on the state of the operation that is more relevant at present time.

There are four possible configuration options regarding the room number box colour:

- room numbers are always grey;
- only operation states are highlighted;
- only late and close to end operations are highlighted;
- both operation states and late/close to end operations are highlighted .

In this last case the room number colour changes according to the following priorities:

- if an operation is late the box turns red;
- if an operation is close to the end (30 minutes or less in the configuration here described) the box turns yellow;
- if an operation is in progress the box turns cyan;
- if an operation is ready (and no operation is in one of the above mentioned states) the box turns green;
- if an operation is planned (and no operation is in one of the above mentioned states) the box turns light grey;
- if there are no operations or all the operations in the room are completed the box turns dark grey.

Possible letters placed beside the room number (Fig 187) indicate the room devices. The relationship between a letter and a device is defined by configuration.

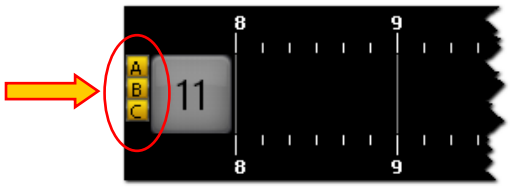


Fig 187

The numbers along the line represent the hours of the day.

The boxes inside the line represent the operations scheduled, in progress or completed in that room. The color of the boxes corresponds to the operation state. The association between color and operation state is explained in paragraph 11.2

The dimensions of every box are proportional to the scheduled duration of the corresponding operation. The longer the box, the longer the scheduled duration of the operation.

The position of every box indicates the scheduled time for the operation. The left side of the box is positioned in line with the start time scheduled for the operation.
For example, the box indicated in Fig 186 **B** corresponds to an operation which should start at 13:40 and should last an hour.

If the data relating to an operation is changed, i.e., if the scheduled time or duration is changed, the system automatically moves the corresponding box on the page and/or changes its dimensions.
See paragraph 10 to find out how to change the data of a scheduled operation.

The vertical yellow cursor indicates the current time (Fig 186 **C**). In the example shown in the figure, the yellow cursor is in line with 11:50.
The cursor runs across the page as time goes by.
If the cursor meets the start time established for an operation (i.e., the left side of a box) and the operation does not start at the established time, the box moves in time together with the cursor.

In general

- completed operations (dark gray) are all to the left of the time cursor,
- scheduled operations (light gray) and those that have only undergone block check-in (green) are all to the right of the time cursor,
- in progress operations (cyan) are across the time cursor.

Data relating to completed operations (duration, start time, end time etc…) are actual data; data relating to scheduled operations are planned data.

If enabled by configuration, the possible operation delay is visible on a yellow bar placed at the bottom of the operation-rectangle (Fig 188).

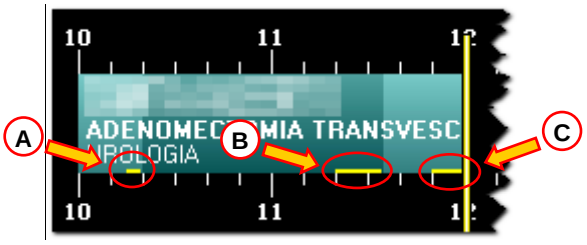


Fig 188

A configuration parameter makes it possible to display separately the possible delays in pre surgical, surgical and post surgical durations. That is the case shown in Fig 188. In the figure here displayed the three yellow bars indicate

1) a 5 minutes delay in the pre surgical planned duration (Fig 188 **A**);
2) a 15 minutes delay in the surgical planned duration (Fig 188 **B**);
3) a 10 minutes delay in the post surgical planned duration (Fig 188 **C**).

The operation shown in the figure is still in progress. Total delay is 30 minutes so far. This value is indicated in the "residual time" area on the "OranJ Home" screen (see paragraph 9.9).

The operations envisaged after the overrunning operation will be automatically postponed by the system.
The operations scheduled after the delayed ones are, if necessary, automatically postponed.

The operations indicated as "Emergencies" on the "Patient and operation detail" screen (Fig 139 - or, if installed, on the DIGISTAT® "Smart Scheduler" system) are characterized by a red stripe on the left (Fig 189). The small box indicated in Fig 189 **A** specifies the emergency level. In the configuration here described there are three possible emergency levels.

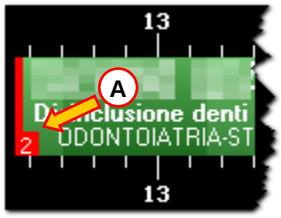


Fig 189 - Emergency

Every operation box can be clicked, whether on the page or the "not assigned" column (see paragraph 11.3).

Click one of the boxes to open a window (Fig 190) containing the main data of the operation.

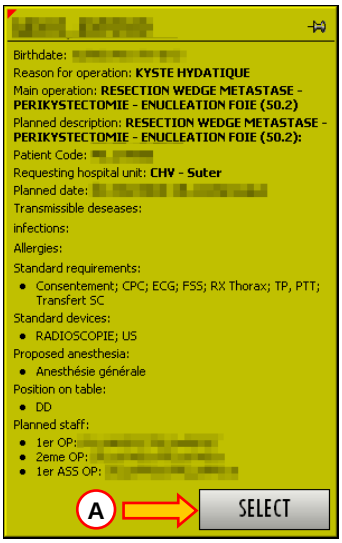


Fig 190 – Operation details

Click the SELECT button in the window (Fig 190 **A**) to access the "OranJ Form" page relating to the operation clicked (Fig 66).

11.4.3. The command bar

Fig 191 – Room Plan module command bar

On the control bar, the three buttons 6 HOURS, 12 HOURS, 24 HOURS (Fig 191 **A**) make it possible to change the time range displayed. By clicking the 6 HOURS button, for example, the time range of 6 hours is displayed, while clicking the 12 HOURS button displays the time range of 12 hours.

The arrow buttons (Fig 191 **B**) make it possible to scroll backwards and forwards in the time range displayed. If, for example, you are displaying the time range from 12:00 to 24:00, click the right arrow once to display the time range from 15:00 to 3:00 of the following day. Likewise, click the left arrow once to display the time range from 9:00 to 21:00.

The EDIT button (Fig 191 **C**) makes it possible to intervene on the page to edit the data. See paragraph 11.4.6 for a detailed description of this function.

The NOT ASSIGNED button (Fig 191 **D**) makes it possible to select a scheduled operation and bring it to the "Not assigned" area. The related procedure is described in paragraph 11.4.6.

11.4.4. The “daily program” area

The “daily program” area (Fig 192 **A**) indicates in textual form information on the schedule of the selected operating room.

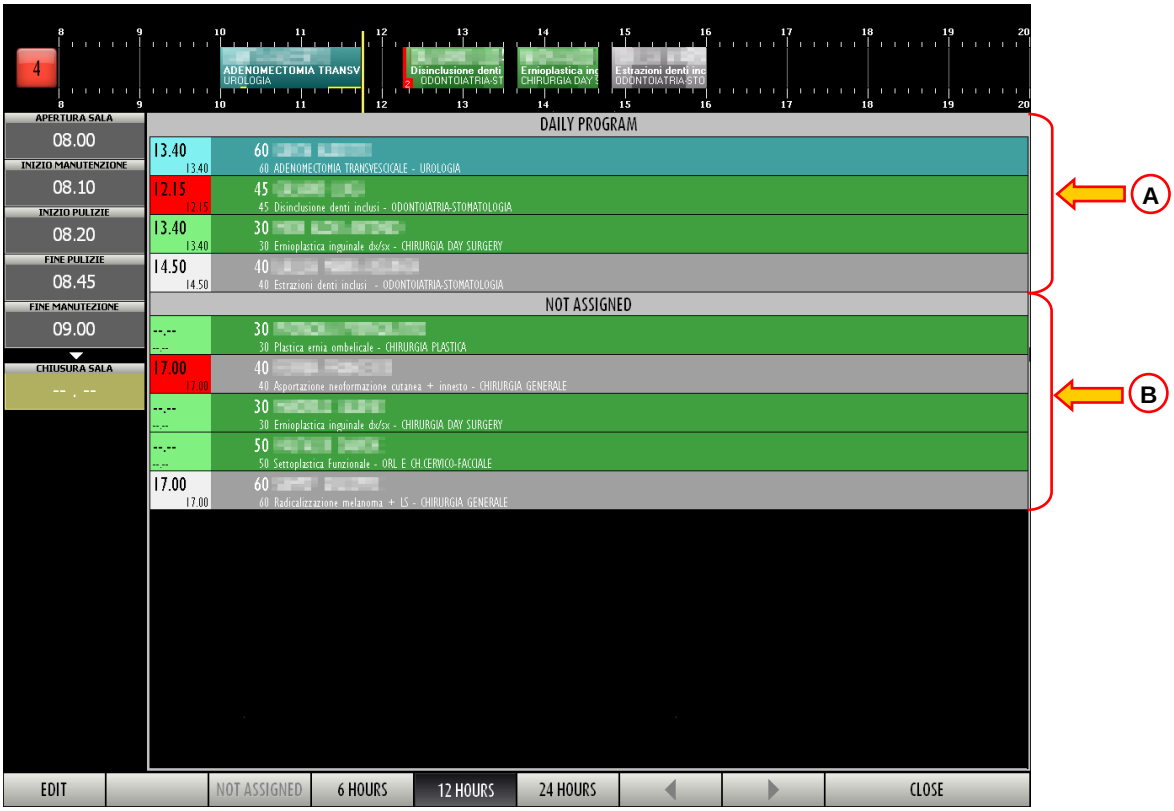


Fig 192

Every line corresponds to an operation (Fig 193).

Fig 193

The color of the line indicates the operation state and follows the color-coding used by all OranJ system modules (see paragraph 11.2 for the association between colors and operation state in OranJ).

The left part of every line contains the start time scheduled for the operation (Fig 193 **A**).

The remainder of the line shows:

- the planned duration of the operation (Fig 193 **B**);
- the patient’s name (Fig 193 **C**);

- the type of operation scheduled (Fig 193 **D**).

If specified, the hospital unit which requested the operation is also indicated.

If the left part is highlighted red (Fig 194) it means that the operation was indicated as "Emergency" on the "Patient and operation screen" (Fig 139 - or, if installed, on the DIGISTAT® "Smart Scheduler" system).

Fig 194 - Emergency

11.4.5. The "not assigned" area

The module makes it possible to display the operations not assigned at any time. Those operations for which no start time, room or block have been scheduled (these operations are known as "reserves", see paragraph 11.3 for a description of these operations and the procedures connected to them).

The "not assigned" area of this page shows the same operations shown in the "not assigned" area of the general scheduling page (Fig 179).

Every line of this section shows the scheduled duration for the operation, the name of the patient, the type of operation scheduled and, if specified, the location which requested the operation (Fig 192 **B**).

All the lines of the "daily program" and "not assigned" pages can be clicked. Click a box to open the window shown in Fig 190 which contains the main data of the operation.

11.4.6. How to edit the operations schedule

You can intervene on the main page of the Room Plan module to edit the operations schedule

Fig 195 – Room Plan module command bar

To make any change it is necessary, first, to click the EDIT button (Fig 195 **A**).

When this button is pressed it appears as selected - EDIT.

To edit the page, you have to

- click the EDIT button.
- make the change required.

Once the change has been made the EDIT button is automatically deselected. To allow intervention on the page you have to press it again.

When the EDIT button is pressed, the "drag and drop" functions are enabled.
The term "drag and drop" indicates the possibility to physically take one of the boxes corresponding to an operation, drag it to the point required on the time line and release it. Remember that the position of a box indicates the time scheduled for the corresponding operation, so moving a box from one position to another on the time line means changing the time of the corresponding operation.

The changes will be automatically displayed on the other OranJ modules.

If you are working with a touch screen and there is no mouse, you can perform the same operation using your fingers.

Likewise, you can add an operation from the "not assigned" list to the daily schedule by dragging the corresponding box.

You can also remove an operation from the daily schedule and add it to the "not assigned" list. To do so you have to

- click the EDIT button.
- On the list of scheduled operations (Fig 192 **A**), click the line corresponding to the operation you wish to remove.

The rectangle that contains the time becomes yellow (Fig 196)

Fig 196

The NOT ASSIGNED button on the command bar becomes active.

- Click the NOT ASSIGNED button (Fig 195 **B**).

The operation is this way moved to the "not assigned" list.

Hence, use the EDIT button on the on the main page of the Room Plan module to

- change the time scheduled for an operation.
- add one of the operations from the “not assigned” list to the daily schedule.
- remove one of the operations from the daily schedule and add it to the “not assigned” list.

11.4.7. Room markers

The markers relating to the room events (Fig 197) are displayed and recorded in the column on the left side of the page (Fig 185 **B**).

Fig 197 – Room markers

These markers make it possible to record any occurrence which is considered significant and of which a record is required.

The system makes it possible to record the event and the time at which it occurred.

The number and nature of room events change according to the needs of the specific user and depend on the particular configuration of the system used. Remember that the procedures explained in this paragraph are only an example of configuration.

The room markers in this configuration are

- Room opens
- Start of maintenance
- Start of cleaning
- End of cleaning
- End of maintenance
- Room closes

The markers appear on the left side of the screen as a sequence of boxes. The boxes are arranged in chronological order.

The box relating to the marker initially appears in ochre yellow and does not contain any information on the moment (the time and day) in which the event took place. This means that the marker has not yet been recorded, the corresponding event has not yet occurred (Fig 198).

Fig 198 – First room marker

To record a markert, simply click the corresponding box. The box becomes gray and records the time at which it was clicked. A new ochre yellow box (or several boxes, depending on the configuration) indicating no time appears below it. New boxes refer to subsequent markers (Fig 199).

Fig 199 – Second room marker

In general, to record a marker you have to

- click the corresponding box.

The system automatically records the time at which the operation is performed.

11.4.8. How to edit the room markers

To change the time of a marker after it has been recorded

- Click the box corresponding to the marker for which the time has to be changed.

A numeric keyboard appears (Fig 200).

Fig 200 – Numeric keyboard

- Enter the time required using the keyboard.

To record the new time.

- Click the box corresponding to the event again.

The numeric keyboard disappears and the new time is displayed in the box.

If the time entered is impossible, the following error message appears (Fig 201).

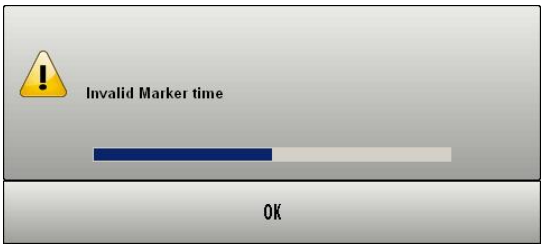


Fig 201

To delete a marker recorded

- Click the box corresponding to the marker to be deleted.

A numeric keyboard appears (Fig 200).

- Click the  button on the keyboard (Fig 200 **A**).

A message requiring confirmation of the operation appears (Fig 202).

Fig 202

- Click YES to delete the marker.

The deleting of an event implicates the deleting of all subsequent events.

The box corresponding to the event deleted becomes ochre yellow again and will indicate no time, meaning that the event has not yet occurred.

12. The OranJ Central module

The OranJ Central module provides a general summary of the situation of the whole surgical block. OranJ Central is destined to be used by those responsible for monitoring the state and availability of the operating structures in real time.

The OranJ Central module is installed on the BLOCK CENTRAL STATION and GENERAL CENTRAL STATION workstations.

12.1. The main page

The main page of this module (Fig 203) represents the detail of a surgical block.

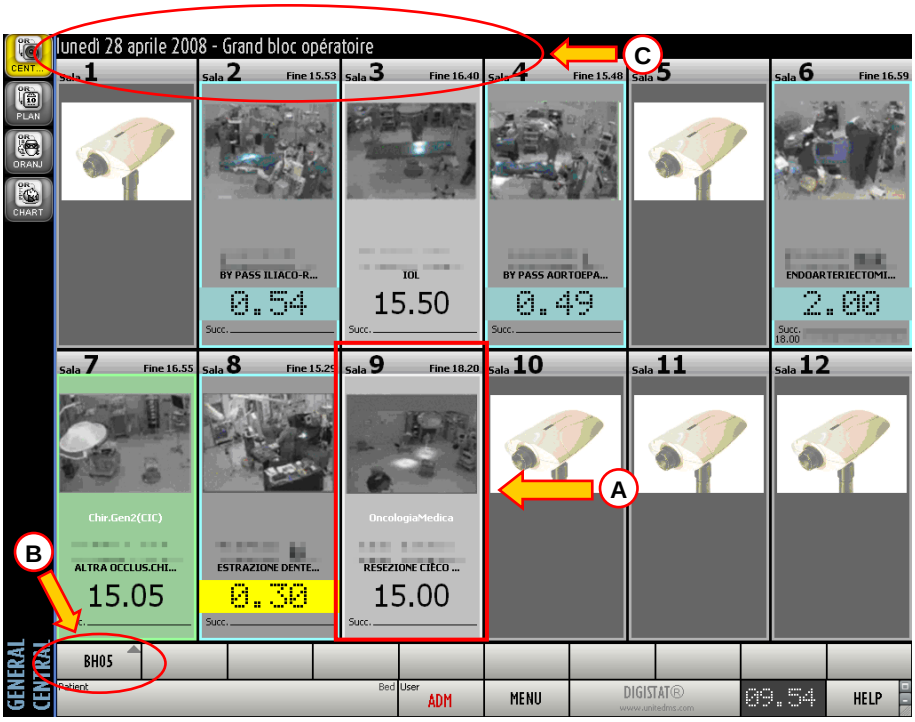


Fig 203 – OranJ Central

The  button on the command bar (Fig 203 **B**) makes it possible to display the situation of the other blocks. It is only enabled when working with a General Central Station workstation, covering several surgical blocks. The name of the block displayed appears on the button (Fig 203 **C**).
If you are working on a Block Central Station workstation, which covers only one surgical block, this button is not enabled.

Every cell (Fig 203 **A**, Fig 204) represents an operating room.

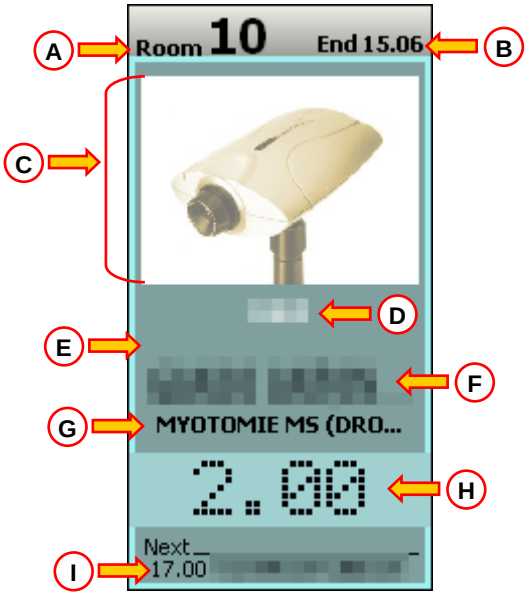


Fig 204 – Operating room detail

Every cell can contain the following information (Fig 204).

- The room number (Fig 204 **A**).
- The time envisaged for the end of the operation in progress (Fig 204 **B**).
- The picture of the operating table. This is only possible if a webcam is installed in the room. If there is no webcam installed, or if the webcam is not working, the box contains the picture of a webcam (Fig 204 **C**).
- The name of the hospitalization unit requesting the operation (if specified - Fig 204 **D**).
- The name of the operating surgeon (if already assigned - Fig 204 **E**).
- The patient's name (Fig 204 **F**).
- The type of operation (Fig 204 **G**).
- The time remaining until the end of the operation in progress according to the planned duration (if the operation is in progress, this is the case shown in Fig 204 **H**).
- The scheduled operation start time (if the operation has not yet started, this is the case shown in Fig 203 **A**)
- The patient's name and the type of operation, if any, which will follow the one in progress (Fig 204 **I**).

When there is less than half an hour until the envisaged end of the operation (in the example configuration) the corresponding part of the cell becomes yellow and starts flashing.

When an operation exceeds the time envisaged, the corresponding part of the cell continues flashing and becomes red, indicating, with a negative number, the delay accumulated.
The color of the cell indicates the current “state” of the operation.

The term “operation state” means the current moment during the patient’s operating process.

Four different operation states are possible.

- Scheduled – the operation has been scheduled; i.e., an operation has been associated to a patient.
- Ready – the patient has undergone block check-in
- In progress – the patient has entered the operating room
- Completed – the operation has been completed.

On the pages of OranJ, each of these four states is identified by a color.

- Light gray: indicates that the operation is scheduled (Scheduled)
- Green: indicates that the patient has undergone block check-in (Ready)
- Blue: indicates that the patient has entered the operating room (In progress)
- Dark gray: indicates that the operation has been completed (Completed)

Completed operations are not displayed on the main page of the OranJ Central module. Therefore, there will be no dark gray cells.

Click the box containing the picture of the room (or the picture of the webcam) to access a page containing details of all the information concerning the operating room selected (Fig 206).

Click any other part of the cell to open a window (Fig 205) containing the main data of the operation.

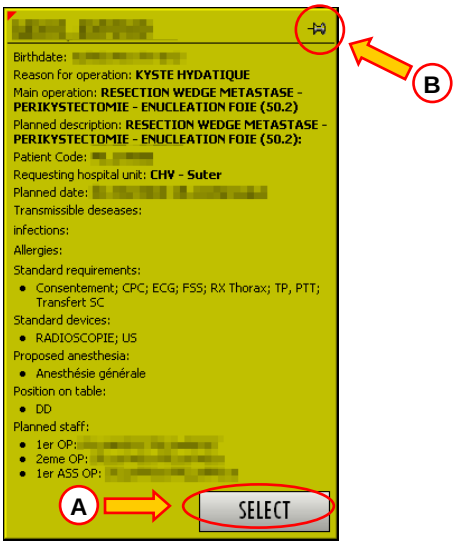


Fig 205 – Operation details

Click the SELECT button in the window (Fig 205 **A**) to access the "OranJ Form" page relating to the operation clicked (Fig 66).

The window shown in Fig 205 disappears after a few seconds.
Click on it to make it disappear immediately.
Click the "thumbtack" indicated in Fig 205 **B** to "pin" it to the page.

12.2. Operating Room detail

The page shown in Fig 206 displays all the details of the operating room selected.

Fig 206 – Operating room monitor

To access this page it is necessary to

- Click the area of the cell showing the picture of the room or the picture of the webcam (Fig 204 **C**).

The line at the top shows the name of the surgical block, the room number, the patient's name and the type of operation (Fig 206 **A**).

Beneath it there is a time line which makes it possible to display the whole daily schedule of the room (Fig 206 **B**).

12.3. Room schedule

There is a time line in the upper part of the page, schematically representing the schedule of the operating day (Fig 206 **B,** Fig 207).

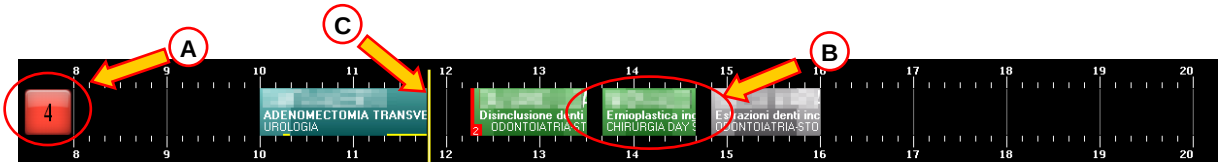


Fig 207

the box on the left (Fig 207 **A**) contains the room number. If enabled by configuration, the colour of that box provides information on the state of the operation that is more relevant at present time.

There are four possible configuration options regarding the room number box colour:

- room numbers are always grey;
- only operation states are highlighted;
- only late and close to end operations are highlighted;
- both operation states and late/close to end operations are highlighted .

In this last case the room number colour changes according to the following priorities:

- if an operation is late the box turns red;
- if an operation is close to the end (30 minutes or less in the configuration here described) the box turns yellow;
- if an operation is in progress the box turns cyan;
- if an operation is ready (and no operation is in one of the above mentioned states) the box turns green;
- if an operation is planned (and no operation is in one of the above mentioned states) the box turns light grey;
- if there are no operations or all the operations in the room are completed the box turns dark grey.

Possible letters placed beside the room number (Fig 208) indicate the room devices. The relationship between a letter and a device is defined by configuration.

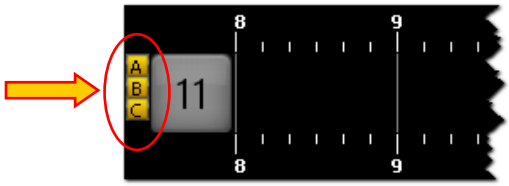


Fig 208

The numbers along the line represent the hours of the day.

The boxes inside the line represent the operations scheduled, in progress or completed in that room. The color of the boxes corresponds to the operation state. The association between color and operation state is explained in paragraph 11.2

The dimensions of every box are proportional to the scheduled duration of the corresponding operation. The longer the box, the longer the scheduled duration of the operation.

The position of every box indicates the scheduled time for the operation. The left side of the box is positioned in line with the start time scheduled for the operation.

For example, the box indicated in Fig 207 **B** corresponds to an operation which should start at 13:40 and should last an hour.

If the data relating to an operation is changed, i.e., if the scheduled time or duration is changed, the system automatically moves the corresponding box on the page and/or changes its dimensions.
See paragraph 10 to find out how to change the data of a scheduled operation.

The vertical yellow cursor indicates the current time (Fig 207 **C**). In the example shown in the figure, the yellow cursor is in line with 11:50.

The cursor runs across the page as time goes by.

If the cursor meets the start time established for an operation (i.e., the left side of a box) and the operation does not start at the established time, the box moves in time together with the cursor.

In general

- completed operations (dark gray) are all to the left of the time cursor,
- scheduled operations (light gray) and those that have only undergone block check-in (green) are all to the right of the time cursor,
- in progress operations (cyan) are across the time cursor.

Data relating to completed operations (duration, start time, end time etc…) are actual data; data relating to scheduled operations are planned data.

If enabled by configuration, the possible operation delay is visible on a yellow bar placed at the bottom of the operation-rectangle (Fig 209).

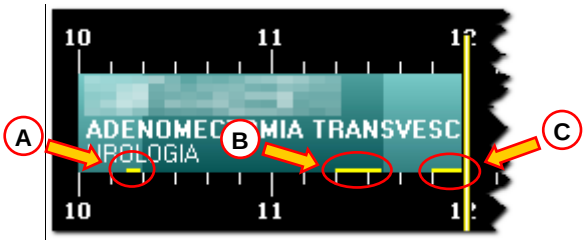


Fig 209

A configuration parameter makes it possible to display separately the possible delays in pre surgical, surgical and post surgical durations. That is the case shown in Fig 209. In the figure here displayed the three yellow bars indicate

1) a 5 minutes delay in the pre surgical planned duration (Fig 209 **A**);
2) a 15 minutes delay in the surgical planned duration (Fig 209 **B**);
3) a 10 minutes delay in the post surgical planned duration (Fig 209 **C**).

The operation shown in the figure is still in progress. Total delay is 30 minutes so far. This value is indicated in the “residual time” area on the “OranJ Home” screen (see paragraph 9.9).

The operations envisaged after the overrunning operation will be automatically postponed by the system.
The operations scheduled after the delayed ones are, if necessary, automatically postponed.

The operations indicated as “Emergencies” on the “Patient and operation detail” screen (Fig 139 - or, if installed, on the DIGISTAT® “Smart Scheduler” system) are characterized by a red stripe on the left (Fig 210). The small box indicated in Fig 210 **A** specifies the emergency level. In the configuration here described there are three possible emergency levels.

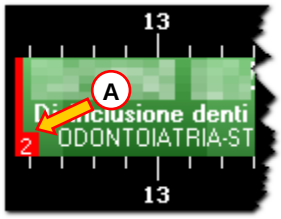


Fig 210 - Emergency

Every operation box can be clicked, whether on the page or the “not assigned” column (see paragraph 11.3).

Click one of the boxes to open a window (Fig 211) containing the main data of the operation.

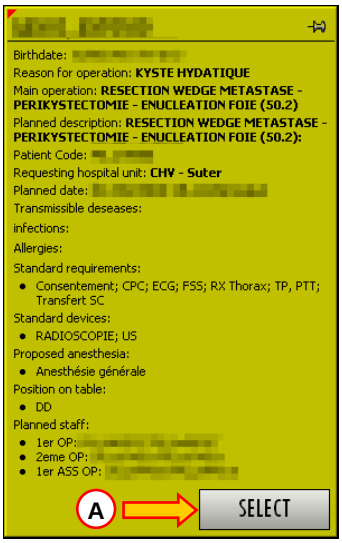


Fig 211 – Operation details

Click the SELECT button in the window (Fig 211 **A**) to access the “OranJ Form” page relating to the operation clicked (Fig 66).

12.4. The command bar

Fig 212 – Room monitor screen command bar

On the control bar, the three buttons 6 HOURS, 12 HOURS, 24 HOURS (Fig 212 **A**) make it possible to change the time range displayed. By clicking the 6 HOURS button, for example, the time range of 6 hours is displayed, while clicking the 12 HOURS button displays the time range of 12 hours.

The arrow buttons (Fig 212 **B**) make it possible to scroll backwards and forwards in the time range displayed. If, for example, you are displaying the time range from 12:00 to 24:00, click the right arrow once to display the time range from 15:00 to 3:00 of the following day. Likewise, click the left arrow once to display the time range from 9:00 to 21:00.

The CLOSE button closes the window.

12.5. "Room monitor" page contents

The central part of the page (Fig 206 **C**) shows, on the left, the enlarged picture of the operating table taken by the webcam, if installed. The details relating to the operation in progress are shown on the right. In particular, in this section of the screen you can read the start time scheduled for the operation, the patient's name and the type of operation.
The time specified is that at which the operation should have started and not that at which it actually starts.

The lower part of the page (Fig 206 **D**, Fig 213)) shows a series of data relating to the operation in progress.

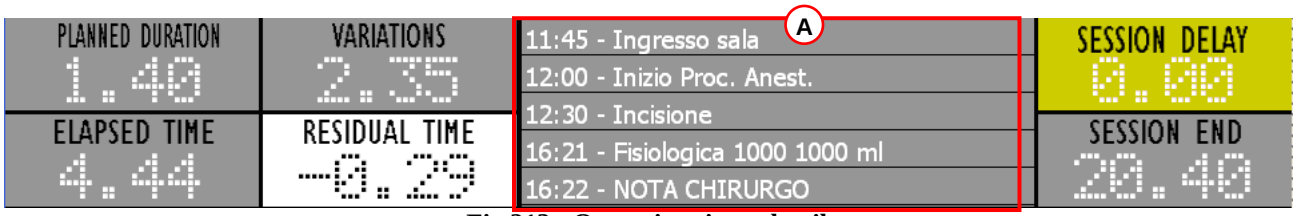


Fig 213 - Operating times detail

The area shown in Fig 213 is described in the following paragraphs.

12.6. Operating times detail

The area indicated in Fig 206 **A** and Fig 214 provides detailed information on both the room times and the current operation progresses.

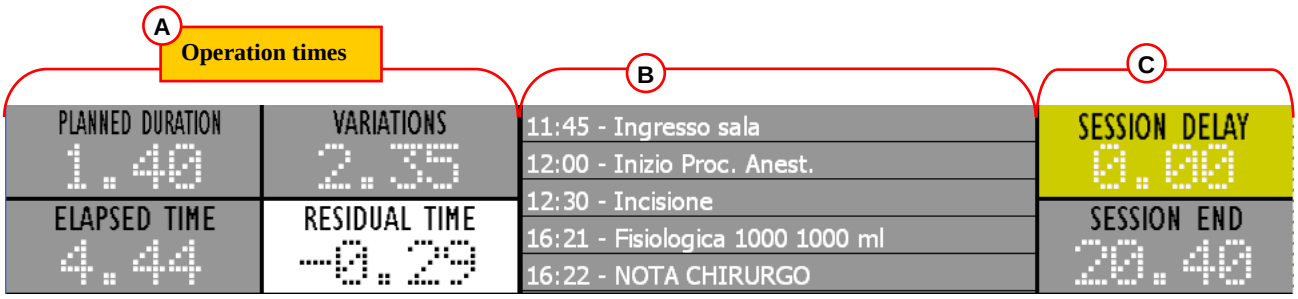


Fig 214

There are three sections in the area:

1) the section indicated in Fig 214 **A** is formed by four timers displaying the currently selected operation times. These timers are described in paragraph 12.6.1;
2) the section indicated in Fig 214 **B** shows the chronologic list of all the markers and the events recorded for the currently selected operation;
3) the section indicated in Fig 214 **C** is formed by two timers displaying the overall operating room times. These timers are described in paragraph 12.6.2.

12.6.1. Operation times

Operation times indicated on the bottom-left corner of the screen (Fig 214 **A**, Fig 216) refer to the operation that is either in progress in the operating room or is the next planned operation. Relevant operation main data are displayed near the screen header (Fig 215).

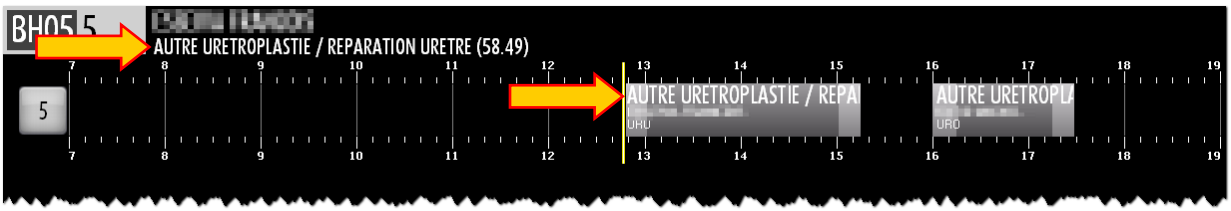


Fig 215

There are four timers indicating the operation times (Fig 214 **A**, Fig 216).

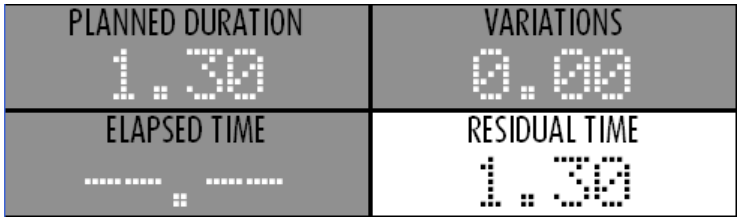


Fig 216

1) The "PLANNED DURATION" timer displays the planned duration of the selected operation and indicates the sum of the pre-surgical, surgical and post-surgical times. The value displayed on this timer only changes when the the successive operation is selected.

2) The "ELAPSED TIME" timer displays the time actually elapsed since the beginning of the operation. This timer starts when the operation switches to the "In progress" state, i.e. when the "Room-in" ("*Entrée en Salle*" in the CHUV configuration) marker is recorded on the "OranJ Home" screen.

3) The “VARIATIONS” marker displays the additional time possibly requested by the operating room staff on the “OranJ Home” screen through the relevant buttons on the “Residual time” area.

4) The “RESIDUAL TIME” timer displays the time remaining to the end of the operation (calculated both on the planned times and on the possible variations requested by the operating staff, those displayed on the “VARIATIONS” timers).
This timer displays the same time displayed on the “OranJ Home” screen, on the “Residual time” area.

Please note that the sum of the times displayed on the “PLANNED DURATION” and “VARIATIONS” timers is equal to the sum of the times displayed on the “ELAPSED TIME” and “RESIDUAL TIME” timers.

Times shown in Fig 216 correspond to an operation that is either in “Planned” or “Ready” state (i.e. the operation hasn’t started yet).

Next paragraphs explain the behaviour of the “Operating room monitor” screen timers and show the relation with the relevant markers recording on the “OranJ Home” screen.

12.6.1.1. Operation beginning - “Room in” marker

The operation switches to the “In progress” state when the “Room in” marker is recorded on the “OranJ Home” screen.
The “Room in” marker implies the beginning of the pre-surgical time.
When the pre-surgical time begins the “ELAPSED TIME” and “RESIDUAL TIME” timers start displaying their values (Fig 217).

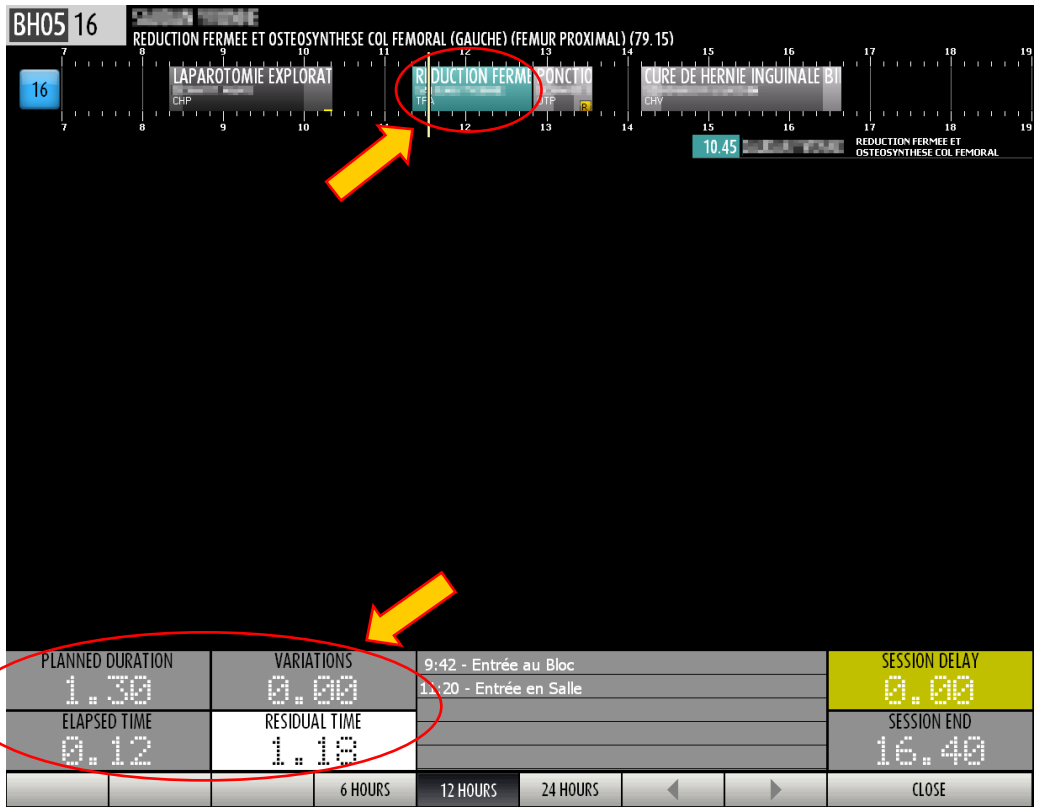


Fig 217

12.6.1.2. Surgical time beginning - "Cut" marker

Pre-surgical time ends when the "Cut" marker is recorded on the "OranJ Home" screen ("*Remise au chirurgien*" in the CHUV configuration). If enabled by configuration, a yellow bar at the bottom of the operation-rectangle indicates the possible delay on the pre-surgical time (Fig 218). The yellow bar length is proportional to the delay amount.

Fig 218 - Pre-surgical time delay

The "Cut" marker implies the beginning of the surgical time. This change is highlighted on the operation-rectangle by a change in the colour shade (Fig 219 **A**).

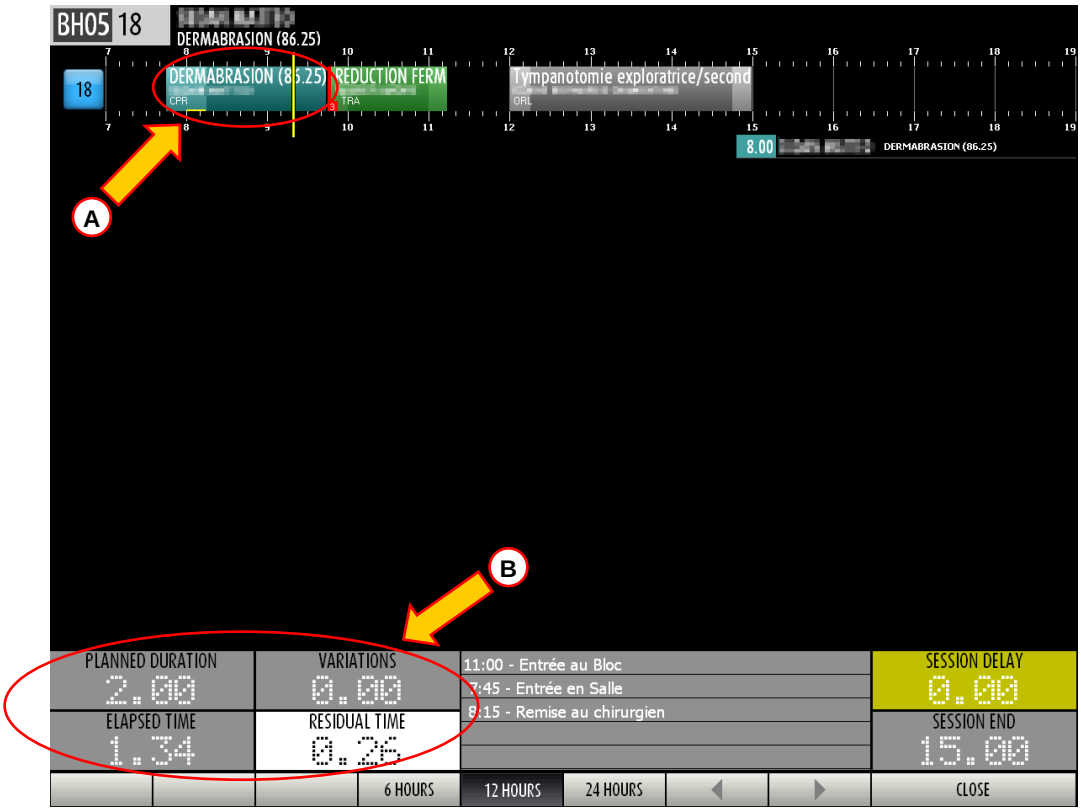


Fig 219

In Fig 219 **B** timers indicate that:

- 1 hour and 34 minutes passed since the operation began (ELAPSED TIME);
- planned residual operation duration is 26 minutes (RESIDUAL TIME);
- no additional time was requested by the operating staff (VARIATIONS);
- operation planned duration ***was*** 2 hours (PLANNED DURATION).

The “PLANNED DURATION” timer does not change until the current operation is completed. It displays in fact the duration that was planned before the operation started and does not depend on the possible variations recorded during the operation.

The time actually elapsed is displayed on the “ELAPSED TIME” timer.

If enabled by configuration, when the planned surgical time ends, the system starts indicating the delay through a yellow bar at the bottom of the operation-rectangle. The yellow bar length is proportional to the delay amount (Fig 220).

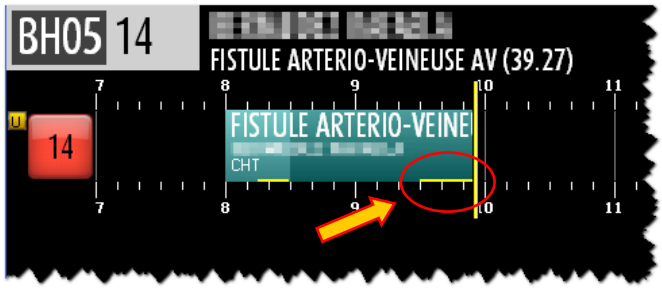


Fig 220 - Surgical time delay

12.6.1.3. Post-surgical time beginning - “Suture” marker

Surgical time ends when the “Suture” marker is recorded on the “OranJ Home” screen. A different shade of the operation-rectangle colour indicates this switch (Fig 221 **A**).
The “Suture” marker implies the beginning of the post-surgical time.

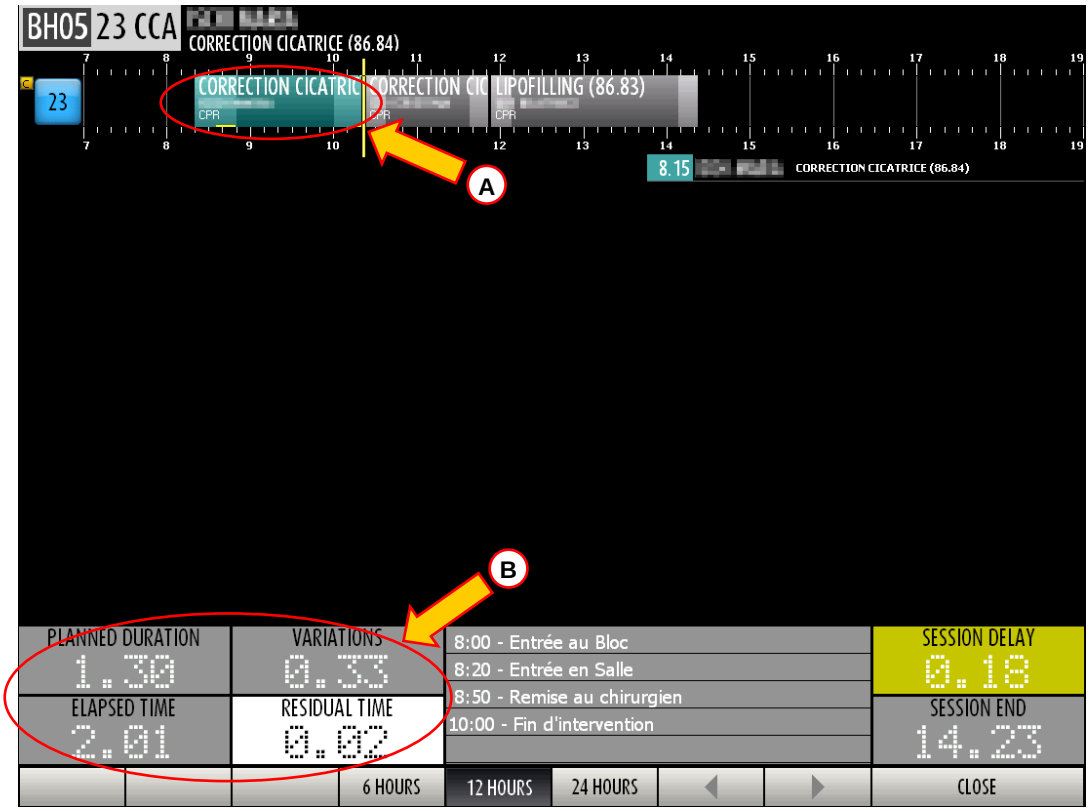


Fig 221

In Fig 221 **B** timers indicate that

- 2 hours and 01 minutes passed since the operation began (ELAPSED TIME);
- RESIDUAL TIME is 2 minutes. Residual time is calculated on the sum of the PLANNED DURATION value plus the VARIATIONS value (01:30h plus 00:33h in the example shown in Fig 221 **B**), less the ELAPSED TIME value (elapsed time is 02:01h, therefore residual time is 2 minutes).
  A negative value displayed on this timer indicates the possible delay amount. See for instance Fig 222 **A**.

- 33 additional minutes were requested by the operating staff (VARIATIONS);
- operation planned duration ***was*** 1 hour and 30 minutes (PLANNED DURATION).

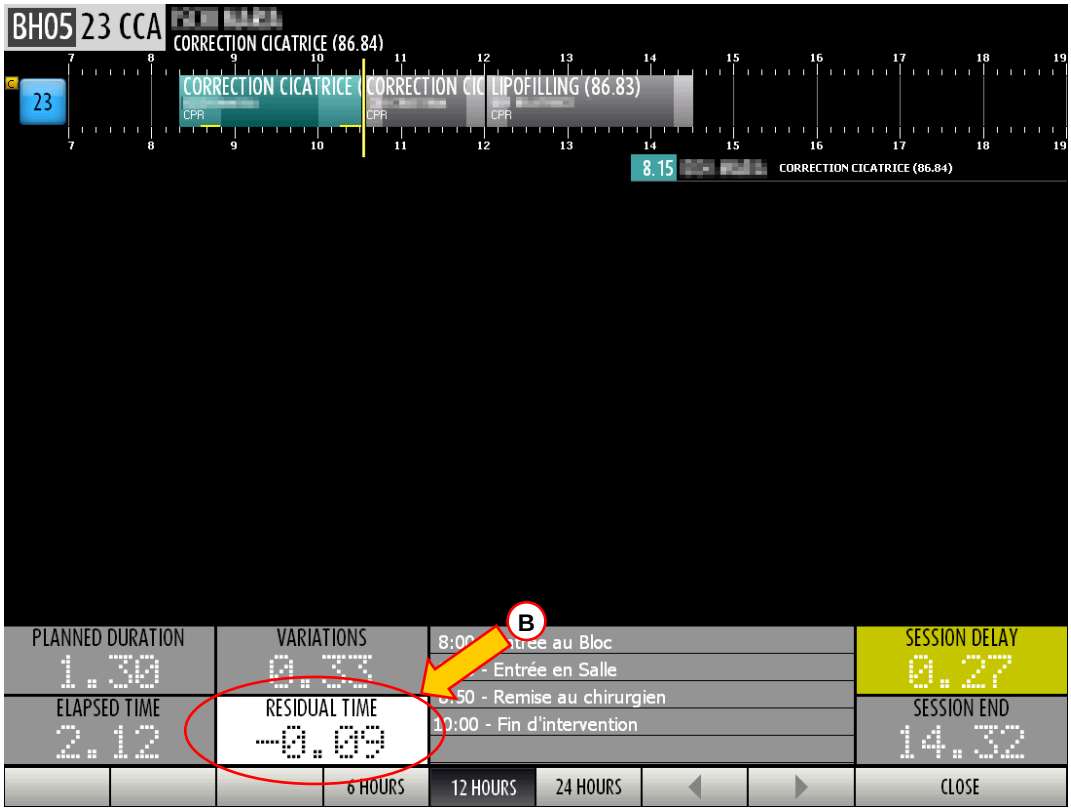


Fig 222 - Operation delay

If enabled by configuration, a yellow bar at the bottom of the operation-rectangle indicates the possible delay on the post-surgical time. The yellow bar length is proportional to the delay amount (Fig 223 **A**).

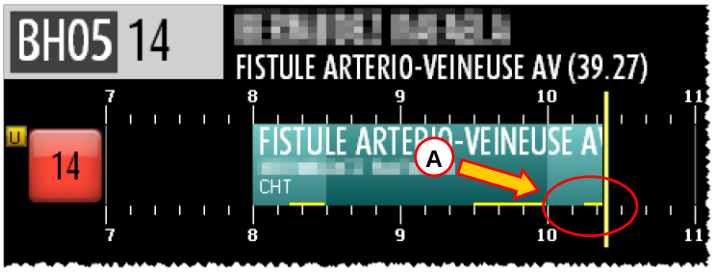


Fig 223 - Post-surgical time delay

The overall operation delay does not depend on the specific delays on the pre-surgical, surgical and post-surgical times indicated by the yellow bars at the bottom of the operation-rectangle.
In Fig 222, for instance, the overall operation delay is 9 minutes, but the post-surgical time delay is 17 minutes (planned post-surgical time was 15 minutes and it is in progress since 32 minutes).

12.6.1.4. Operation end - “Room out” marker

Operation ends when the “Room out” marker is recorded on the “OranJ Home” screen. The operation switches to “Completed” state. The operation-rectangle represents now the actual operation times and indicates both the overall duration and the specific durations and the delays (if enabled by configuration) of the pre-surgical, surgical and post surgical times (Fig 224 **A**)

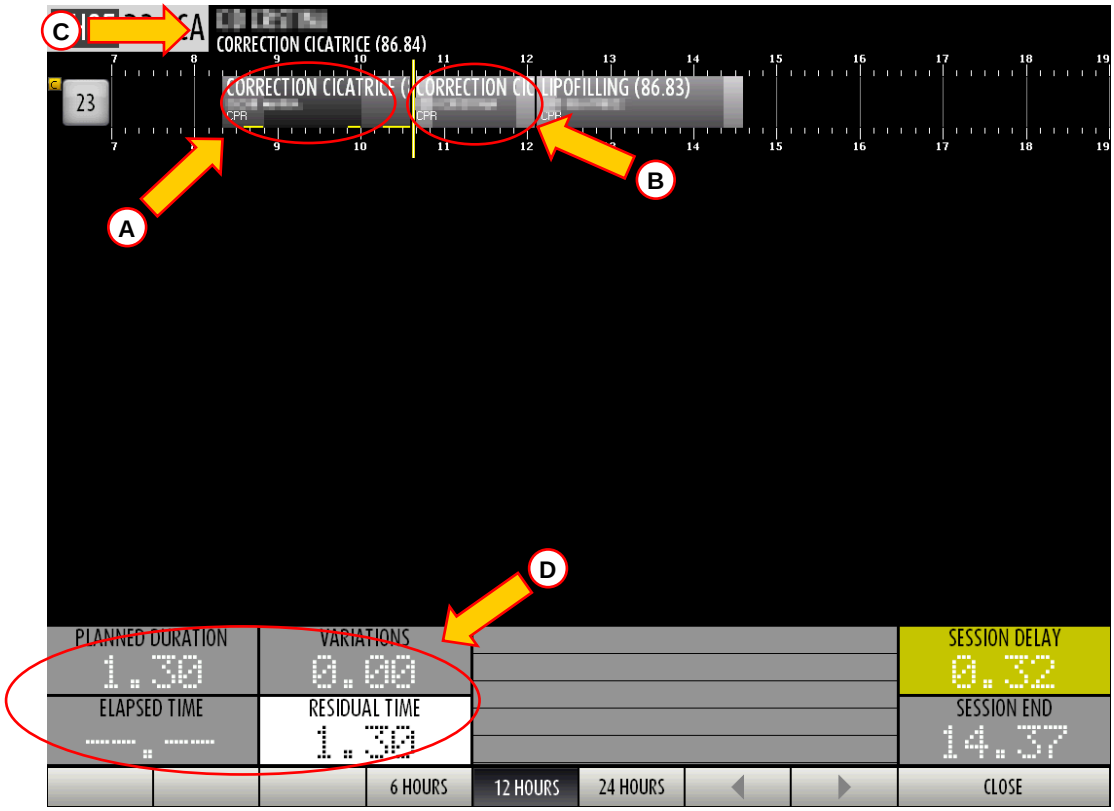


Fig 224

The successive operation is automatically selected (Fig 224 **B**), its main data appear near the screen header (Fig 224 **C**). Timers display the times of the selected operation (Fig 224 **D**).

12.6.1.5. Variations requests

The operating staff, when the operation is in progress, can request any moment additional time.

Duration variation requests are managed on the “OranJ Home” screen (paragraph 9.1).

The next two figures (Fig 225 and Fig 226) illustrate the changes on the operating room timers following a time variation request.

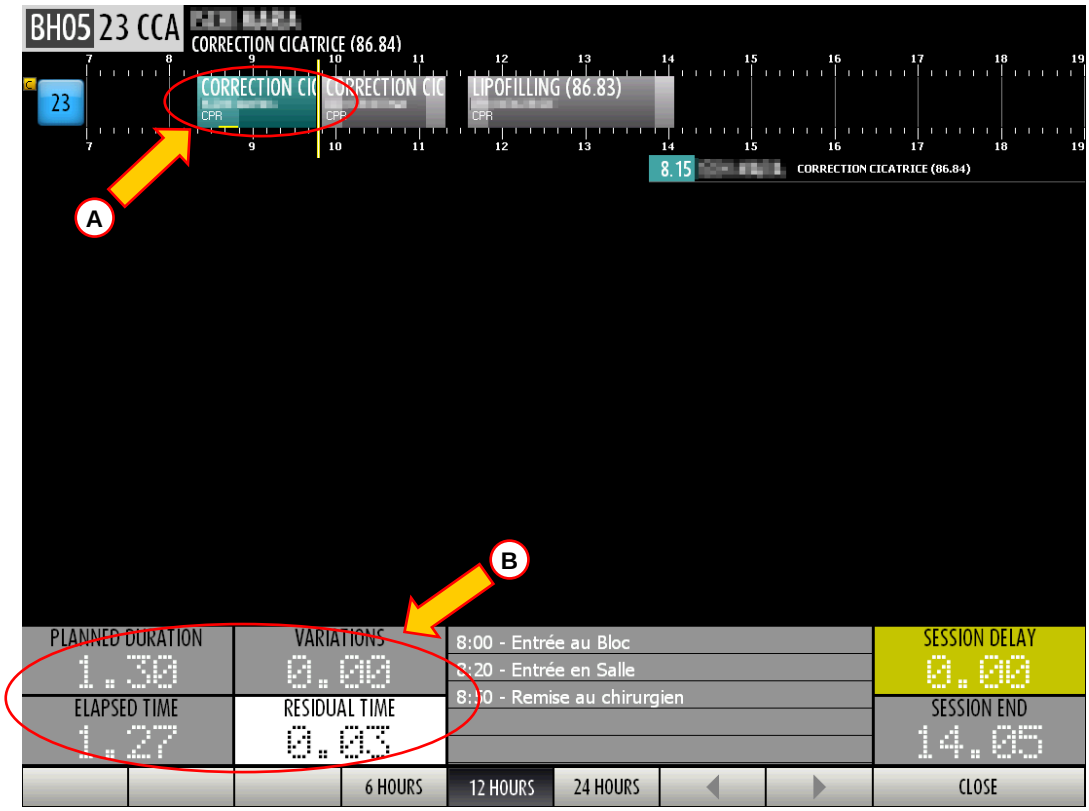


Fig 225 - Times before variation request

Before requesting additional time the "Operating room details" screen timers display the following values (Fig 225 **B**):

- 1 hour and 27 minutes passed since the operation began (ELAPSED TIME);
- planned residual operation duration is 3 minutes (RESIDUAL TIME);
- no additional time was requested by the operating staff (VARIATIONS);
- operation planned duration ***was*** 1 hour and 30 minutes (PLANNED DURATION).

The operating staff requests 33 additional minutes. The "Room monitor" screen displays this change in the following way (Fig 226).

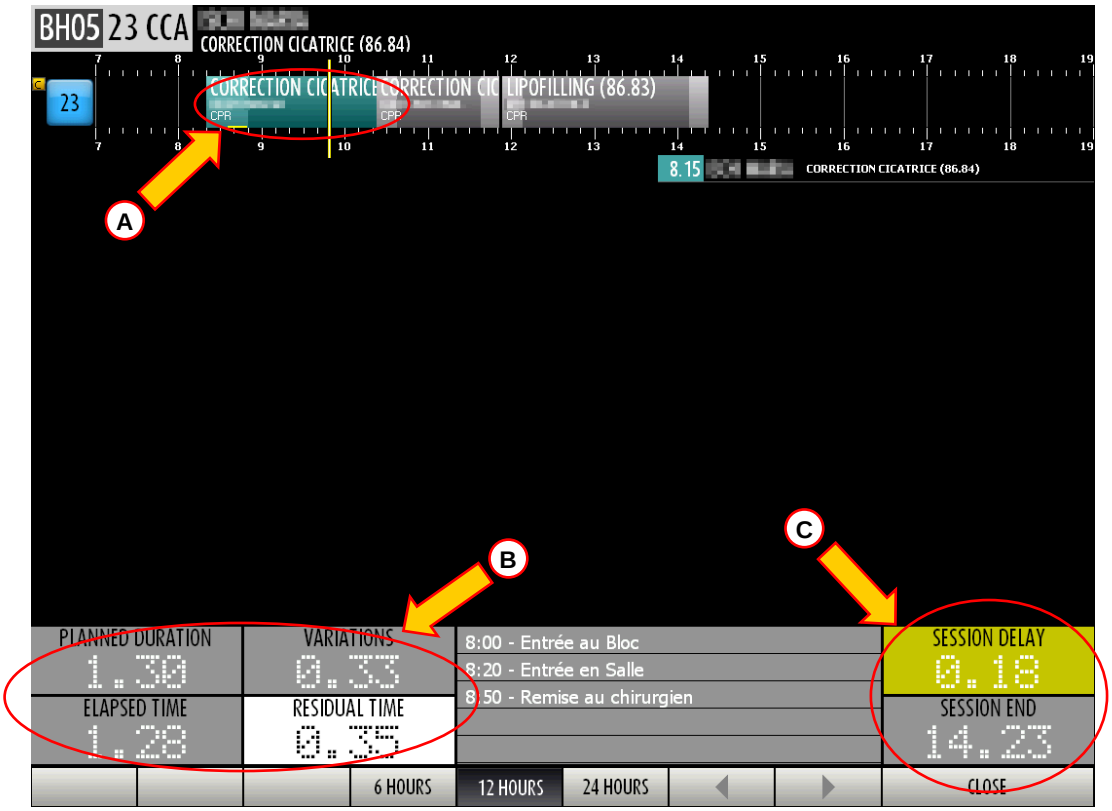


Fig 226 - 30 minutes variation

After requesting additional time the "Operating room monitor" screen timers display the following values (Fig 226 **B**):

- 1 hour and 28 minutes passed since the operation began (ELAPSED TIME);
- planned residual operation duration is 35 minutes (RESIDUAL TIME);
- 33 additional minutes were requested by the operating staff (VARIATIONS);
- operation planned duration ***was*** 1 hour and 30 minutes (PLANNED DURATION).

The corresponding operation-rectangle length indicates the overall duration (2 hours and 3 minutes, Fig 226 **A**).

Please note that the variation causes a delay in the planned session end time (it was 14:05 before the variation). The new planned session end time and the session delay amount are now displayed on the timers on the right (Fig 226 **C** - see next paragraph 12.6.2 for the "Room times" timers description).

12.6.2. Room times

Room times refer to the overall timing of the operative session. Two timers display the relevant times: session delay and session end (Fig 214 **C**, Fig 227).

Fig 227

12.6.2.1. Session end

The SESSION END timer displays the planned end time of the last operation in the room. The time indicated by the SESSION END timer always corresponds to the right limit of the last operation-rectangle shown on the time bar (Fig 228)

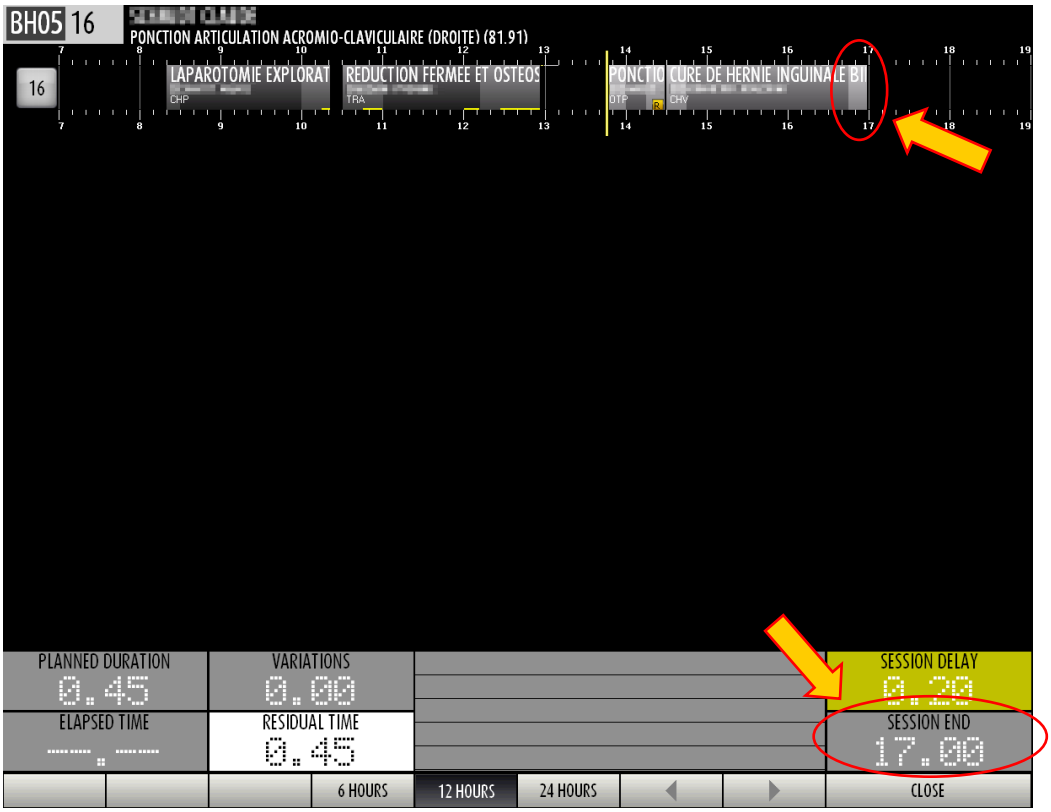


Fig 228 - Session end

12.6.2.2. Session delay

The SESSION DELAY timer indicates if the operations planned in the room are likely to cause a delay in the operative session and, in case, displays the possible delay amount.

See for instance Fig 229.

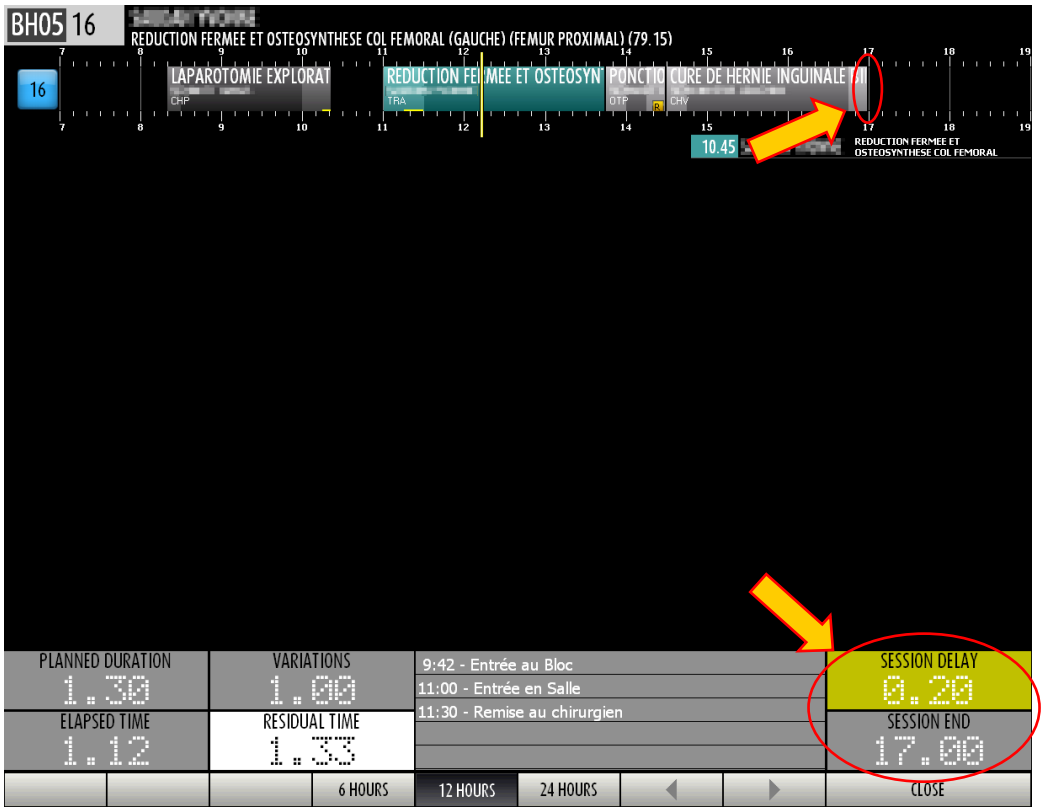


Fig 229 - Session delay

In Fig 229 the planned session end was 16:40 at the room opening. The delay caused by the operation times variations made the planned end of the last operation become 17:00.
The SESSION DELAY timer displays therefore 20 minutes delay.
As long as the room is open and the operative session goes on it is a ***planned*** time, not an actual one. In case the operations in the room last longer than planned, this time increases, in case they last less, this time decreases.
When the last planned operation is completed the SESSION DELAY time becomes an actual value.

When the SESSION DELAY time is negative it means that the planned end of the last operation is anticipated.

13. OranJ Chart module

The OranJ Chart module provides a graphic representation in real time of some of the data collected during the operation; at the same time, this module makes it possible to display the events recorded on a time line.

The module is present on GENERAL CENTRAL STATION and OPERATING ROOM workstations.

The main page of the module can change considerably depending on the configuration chosen. That shown in Fig 230 is an example of configuration.

13.1. Characteristics of the page

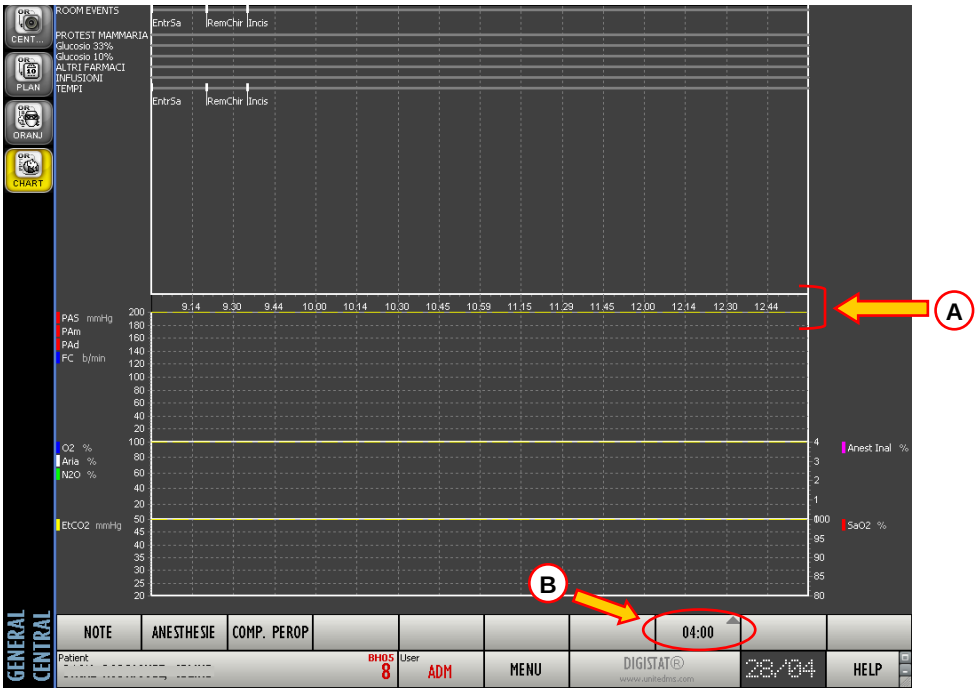


Fig 230 – OranJ Chart

The series of numbers highlighted in Fig 230 **A** indicates the time of day. If the operation for which the data is displayed is still in progress, a vertical yellow cursor indicates the current time (Fig 230 **A**).

You can change the time range displayed using the button on the command bar highlighted in Fig 230 **B**.
Click the button to open a pull down menu that makes it possible to choose between a range of 2, 4, 8, 12 or 24 hours (Fig 231).

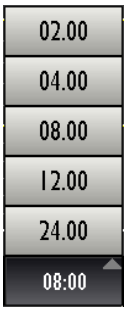


Fig 231 – Time range selection

The option selected appears written on the button. In Fig 230, for example, an 8-hour time range is displayed.

You can display time ranges subsequent or prior to the current range using the mouse. To do so, simply move the mouse to the area of the chart for which you wish to change the display, left click it and, keeping the button pressed, move left/right as needed. The page moves together with the cursor of the mouse.

If you are working with a touch screen, you can perform the same operation using your fingers.

The page is split into two areas.

13.1.1. The "Events" area

The upper part of the screen (Fig 232) shows the events recorded on different time lines.

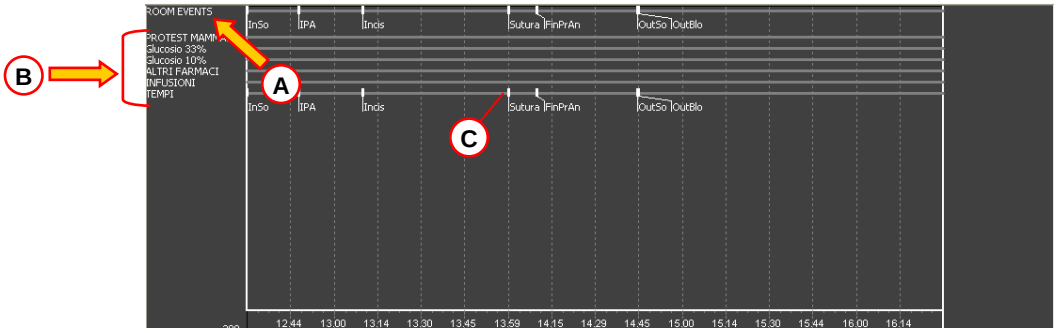


Fig 232 – Events Chronology

Both the markers (Fig 232 **A**), and other room events such as the drugs administered, any infusions, anesthesiological and surgical procedures implemented, etc. are shown (Fig 232 **B**). The number and nature of the events displayed depend on the configuration selected and the user's requirements. See paragraph 9.4 for details of the various types of event.
An event is marked on the time bar in correspondence with the moment in which it is recorded. In the figure, for example, the "Suture" event was recorded at 13:59 (Fig 232 **C**).

In the example chart, the markers are abbreviated in this way:

- Block entrance - InBlo
- Room in - InSo
- Start of Anesthesiology Procedure - IPA
- Skin incision - Incis
- Suture - Sutura
- End of Anesthesiology Procedure - FinPrAn
- Room out - OutSo
- Block exit - OutBlo

Remember that the number and nature of the markers change according to the configuration chosen.

13.1.2. The "Chart" area

The lower part of the screen (Fig 233) contains the charts showing the trend of the parameters acquired by the room instruments.

Fig 233 - Charts

The charts are created in real time and updated every minute.
The number and nature of the parameters acquired change according to contingent requirements.

The side areas of the screen show the data which can be displayed in the charts according to the current configuration (Fig 233 **A**). Alongside every type of data there is the color used to trace the line of the chart for that particular data item.

You can display different quantity ranges using the mouse. To do so, simply move the mouse to the area of the chart for which you wish to change the display, left click it and, keeping the button pressed, move up or down as needed. The page moves together with the cursor of the mouse.

If you are working with a touch screen, you can perform the same operation using your fingers.

13.1.3. The command bar

Fig 234 – OranJ Chart screen command bar

The buttons on the command bar (Fig 234) make it possible to record the configured room events directly on the OranJ Chart module.

The number and nature of the buttons depend on the configuration chosen. The procedure required to add a specific event is the same as that described for the addition of the room events described in paragraph 9.5.1.

14. Check-In configuration

The Check-In configuration of the DIGISTAT® OranJ system is used to identify the patient during block check in and check out.

Identification is usually performed by scanning the patient's barcode. If barcode reading function is not enabled a manual procedure is available.

"Barcode" procedure is described in paragraph 14.2.1, manual procedure is described in paragraph 14.2.2.

Barcode technology is recommended when identifying a patient. Scanning the patient's barcode, instead of selecting it manually, helps the user to diminish selection errors.

14.1. Modules in use

The check-in configuration usually includes two modules: the OranJ Plan module, making it possible to monitor the state of the operating block and the OranJ Check-in module, making it possible to identify the patient when entering the operating block.

14.1.1. OranJ Plan

The OranJ Plan module offers a birds-eye view of the state of the operations in the operating block.

To select the module

- click the corresponding icon 

on the DIGISTAT® lateral bar (Fig 235).

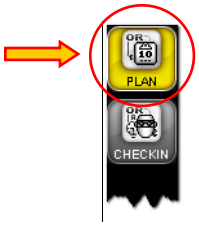


Fig 235

The following screen will open (Fig 236).

Fig 236 - OranJ Plan

The OranJ Plan module is described in chapter 11 in this manual. See chapter 11 for a description of the module's functionalities.

Some buttons on the command bar are disabled because this configuration only enables monitoring on one block for the current day. Thus it is not possible to use the "Edit" functionalities to change the operating plan; it is not possible to change the day displayed; it is not possible to display a different block.

The time span display functionalities are still active (i.e. it is possible to use the 

button on the command bar to display either 6, or 12 or 24 hours on the same screen).

14.1.2. OranJ Check-In

The OranJ Check module is used to identify the patient when checking in the operating block and when cracking out from the block.

To select the module

- click the corresponding icon 

on the DIGISTAT® lateral bar (Fig 237).

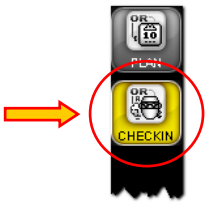


Fig 237

The following screen will open (Fig 238).

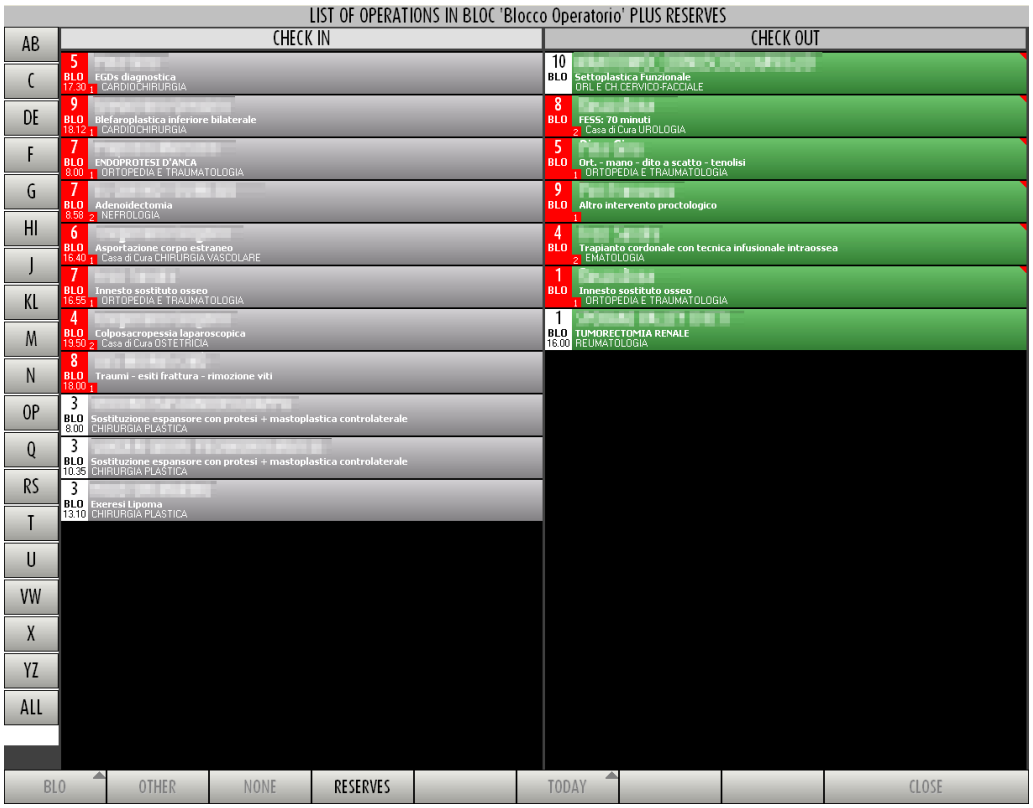


Fig 238 - OranJ Check-in

The screen is divided in two columns. The operations for which the block check-in has not yet been performed are listed on the left column (Check-In). These operations are all in “Planned” state. The column on the right contains the operations for which the block check-out has not yet been performed.

In the OranJ system an operation is completed when the "Room out" marker is recorded. See paragraph 9.4 for the explanation of the "markers" in the DIGISTAT® OranJ system.

The RESERVES button on the command bar displays on the left column the "Reserves" operations as well, for which the check-in procedure has not been completed.

See paragraph 11.3 for an explanation of the "Reserve" concept.

14.2. How to perform the patient check-in

14.2.1. Check-in procedure by barcode reading

If barcode selection functionalities are enabled, to perform the patient check-in

- access the "Check-in" screen (Fig 238).
- scan the barcode of the patient who is entering the operating block.

A patient identification window appears (Fig 239).

Fig 239 - Patient identification

The patient code is visible in the field indicated in Fig 239 **A**.

- Click the IDENTIFY button (Fig 239 **B**).

The window changes in the following way (Fig 240).

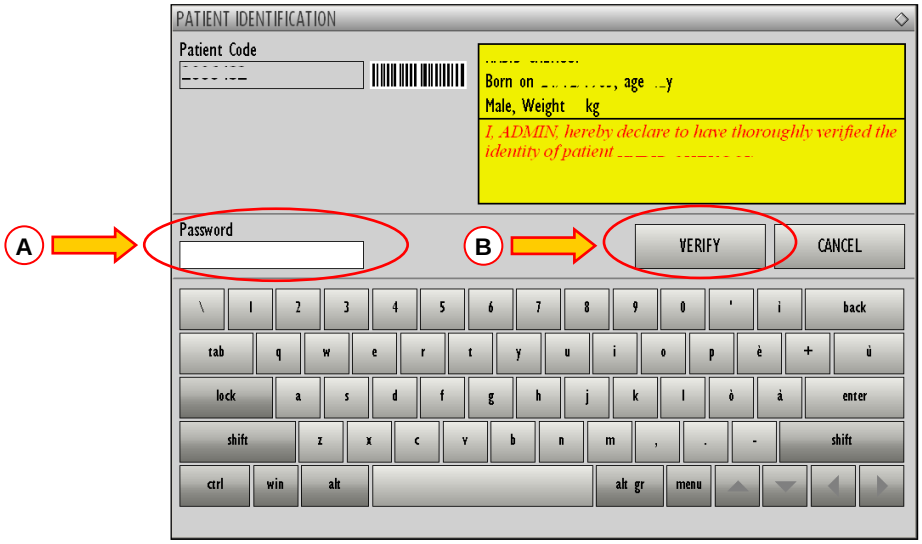


Fig 240 - User identification

The window shown in Fig 240 requires user identification. The logged user declares this way that he/she personally verified the patient identity.

- Insert user password in the field indicated in Fig 240 **A**.
- Click the VERIFY button (Fig 240 **B**).

The block check-in is this way completed.

The corresponding operation-rectangle disappears from the "Check in" column on the screen.

On the "OranJ Home" screen (Fig 66) the "Block-in" marker is this way recorded.

The operation passes to "Ready" state; the corresponding rectangle is now characterized by green colour (Fig 241).

Fig 241

See paragraph 8.4 for a description of the possible operation states and the associated colours.

See paragraph 9.1 for a detailed description of the "OranJ Home" screen.

14.2.2. Manual check-in procedure

Manual check-in is possible if barcode selection is not available.

To do that

- click the  icon on the lateral bar to access the OranJ “Check in” module (Fig 242).

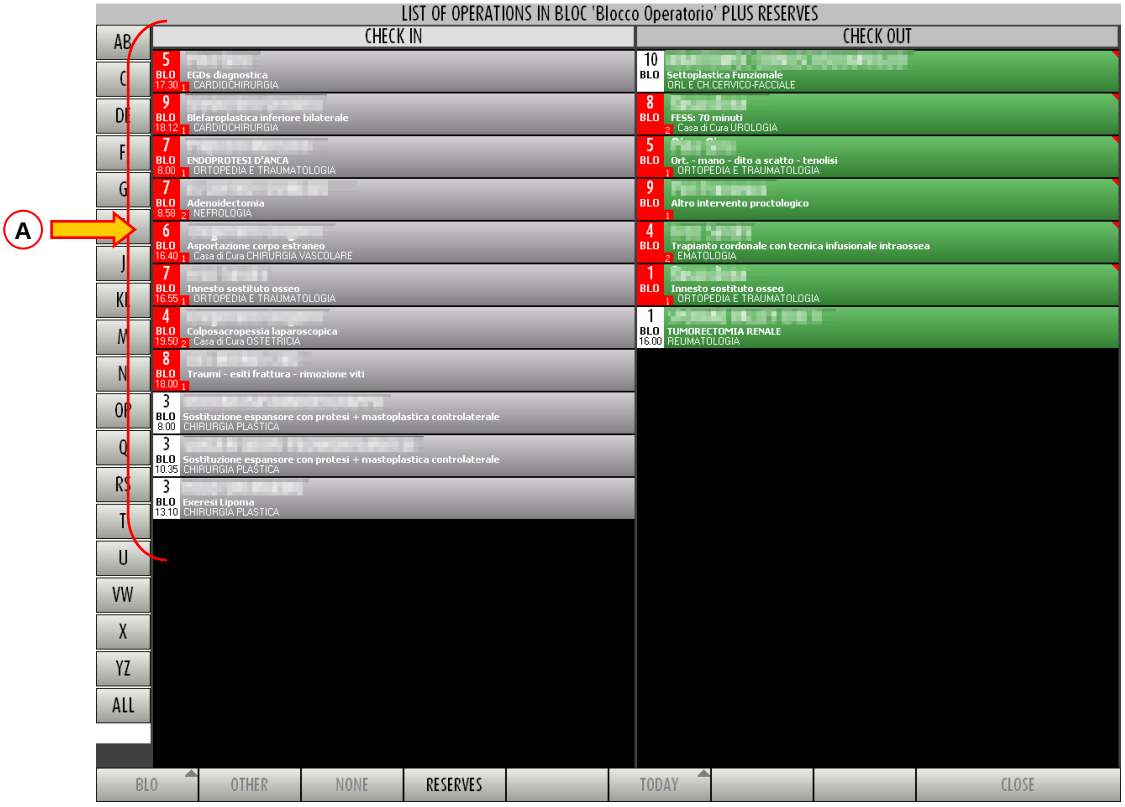


Fig 242 - OranJ “Check in”

On the left column (“Check in”),

- click the rectangle corresponding to the patient/operation that is checking-in (Fig 242 **A**).

A patient identification window opens (Fig 243).

Fig 243 - Patient identification

- Type the patient code in the field indicated in Fig 243 **A**.
- Click the IDENTIFY button (Fig 243 **B**).

The window changes in the following way (Fig 244).

Fig 244 - User identification

The window shown in Fig 244 requires user identification. The logged user declares this way that he/she personally verified the patient identity.

- Insert user password in the field indicated in Fig 244 **A**.
- Click the VERIFY button (Fig 244 **B**).

The block check-in is this way completed.

The corresponding operation-rectangle disappears from the “Check in” column on the screen shown in Fig 242.

On the “OranJ Home” screen (Fig 66) the “Block-in” marker is this way recorded.

The operation passes to “Ready” state; the corresponding rectangle is now characterized by green colour (Fig 245).

Fig 245

See paragraph 8.4 for a description of the possible operation states and the associated colours.

See paragraph 9.1 for a detailed description of the “OranJ Home” screen.

14.3. How to perform the patient check-out

The “Check-in” module makes it possible to record the patient check-out from the operating block.

To do that

- click the  icon on the lateral bar to access the OranJ “Check in” module (Fig 246).

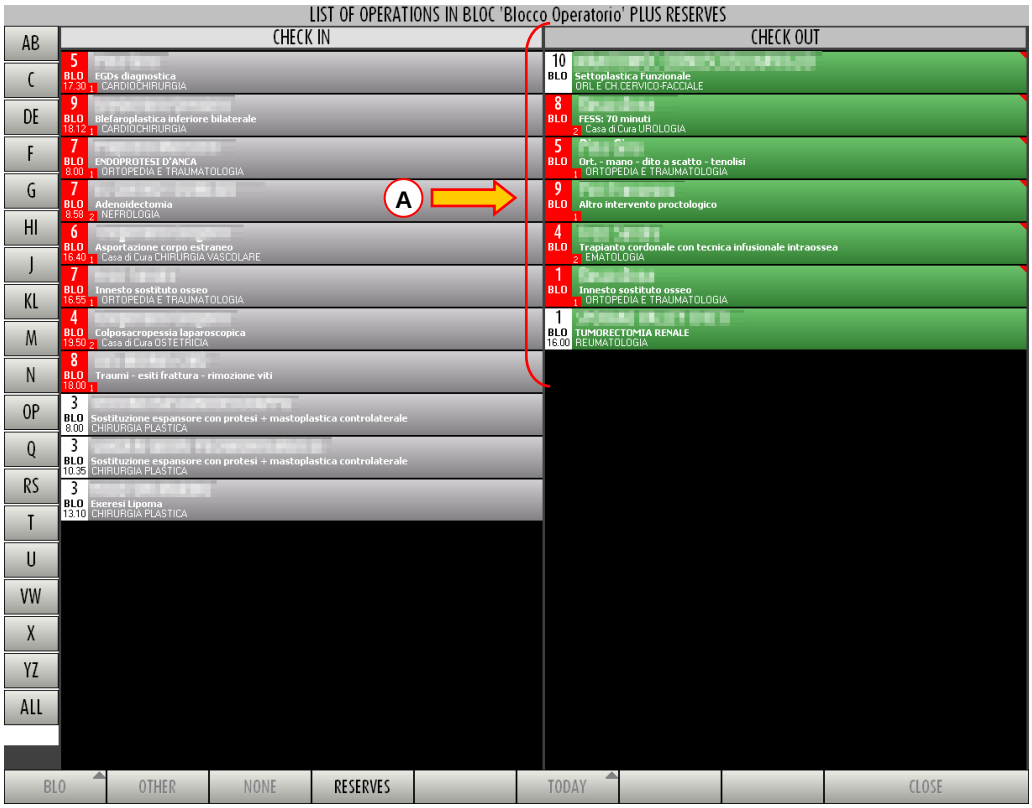


Fig 246 - OranJ “Check in”

On the column on the right (“Check out”),

- click the rectangle corresponding to the patient/operation that is checking-out (Fig 246 **A**).

The system requests confirmation with the following pop-up window (Fig 247).

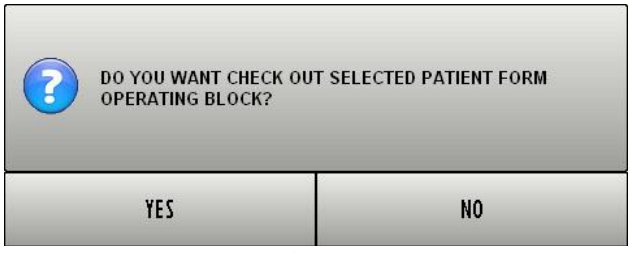


Fig 247

- Click YES to record the patient’s check-out.

On the “OranJ Home” screen (Fig 66) the “Block Out” marker is this way recorded.

See paragraph 9.1 for a detailed description of the “OranJ Home” screen.

15. OranJ - “Bedside”Configuration

The OranJ system can be configured to be used in the operating room in such a way as to be dedicated entirely to the management of the single room.
Considering its position, in these cases the system has specific characteristics and functionalities. This type of configuration is called “bedside”.
The bedside configuration of the OranJ system is made up of three modules:

- OranJ
- Charts
- Room Plan

The Room Plan module is peculiar to this configuration and, despite working in a way very similar to that of the scheduling page of a single room seen in paragraph 11.4, for ease, we shall provide a detailed description.
In this case, given that we are working with a “bedside” workstation, the substantial different is that all the information is related to the room configured, meaning that the reserves of the “not assigned” area will only be room reserves (see the following paragraph 15.1.3).

15.1. The Room Plan module

The main page of the Room Plan module (Fig 248) shows a combination of information on the daily schedule of the room for which the workstation is configured.

Fig 248 – Room Plan

The figure shows the details of room 4.

15.1.1. Room schedule

There is a time line in the upper part of the page, schematically representing the schedule of the operating day (Fig 248 **A**, Fig 249).

Fig 249

The box on the left (Fig 249 **A**) contains the room number. If enabled by configuration, the colour of that box provides information on the state of the operation that is more relevant at present time.

There are four possible configuration options regarding the room number box colour:

- room numbers are always grey;
- only operation states are highlighted;
- only late and close to end operations are highlighted;
- both operation states and late/close to end operations are highlighted .

In this last case the room number colour changes according to the following priorities:

- if an operation is late the box turns red;

- if an operation is close to the end (30 minutes or less in the configuration here described) the box turns yellow;
- if an operation is in progress the box turns cyan;
- if an operation is ready (and no operation is in one of the above mentioned states) the box turns green;
- if an operation is planned (and no operation is in one of the above mentioned states) the box turns light grey;
- if there are no operations or all the operations in the room are completed the box turns dark grey.

Possible letters placed beside the room number (Fig 250) indicate the room devices. The relationship between a letter and a device is defined by configuration.

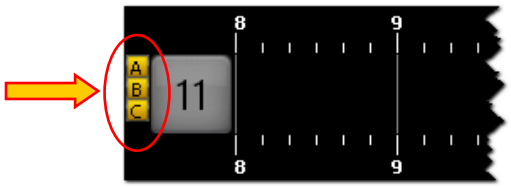


Fig 250

The numbers along the line represent the hours of the day.

The boxes inside the line represent the operations scheduled, in progress or completed in that room. The color of the boxes corresponds to the operation state. The association between color and operation state is explained in paragraph 11.2

The dimensions of every box are proportional to the scheduled duration of the corresponding operation. The longer the box, the longer the scheduled duration of the operation.

The position of every box indicates the scheduled time for the operation. The left side of the box is positioned in line with the start time scheduled for the operation.
For example, the rectangle indicated in Fig 249 **B** corresponds to an operation that should start at 13:40 and should last one hour.

If the data relating to an operation is changed, i.e., if the scheduled time or duration is changed, the system automatically moves the corresponding box on the page and/or changes its dimensions.
See paragraph 10 to find out how to change the data of a scheduled operation.

The vertical yellow cursor indicates the current time (Fig 249 **C**). In the example shown in the figure, the yellow cursor is in line with 11:50.
The cursor runs across the page as time goes by.
If the cursor meets the start time established for an operation (i.e., the left side of a box) and the operation does not start at the established time, the box moves in time together with the cursor.

In general

- completed operations (dark gray) are all to the left of the time cursor,

- scheduled operations (light gray) and those that have only undergone block check-in (green) are all to the right of the time cursor,

- in progress operations (cyan) are across the time cursor.

Data relating to completed operations (duration, start time, end time etc…) are actual data; data relating to scheduled operations are planned data.

If enabled by configuration, the possible operation delay is visible on a yellow bar placed at the bottom of the operation-rectangle (Fig 251).

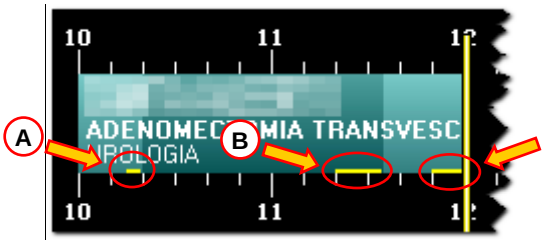


Fig 251

A configuration parameter makes it possible to display separately the possible delays in pre surgical, surgical and post surgical durations. That is the case shown in Fig 251. In the figure here displayed the three yellow bars indicate

1) a 5 minutes delay in the pre surgical planned duration (Fig 251 **A**);
2) a 15 minutes delay in the surgical planned duration (Fig 251 **B**);
3) a 10 minutes delay in the post surgical planned duration (Fig 251 **C**).

The operation shown in the figure is still in progress. Total delay is 30 minutes so far. This value is indicated in the "residual time" area on the "OranJ Home" screen (see paragraph 9.9).

The operations envisaged after the overrunning operation will be automatically postponed by the system.
The operations scheduled after the delayed ones are, if necessary, automatically postponed.

The operations indicated as "Emergencies" on the "Patient and operation detail" screen (Fig 252 - or, if installed, on the DIGISTAT® "Smart Scheduler" system) are characterized by a red stripe on the left (Fig 189). The small box indicated in Fig 252 **A** specifies the emergency level. In the configuration here described there are three possible emergency levels.

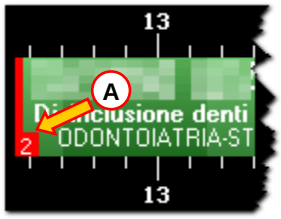


Fig 252 - Emergency

Every operation box can be clicked, whether on the page or the “not assigned” column (see paragraph 11.3).

Click one of the boxes to open a window containing the main data of the operation (Fig 253).

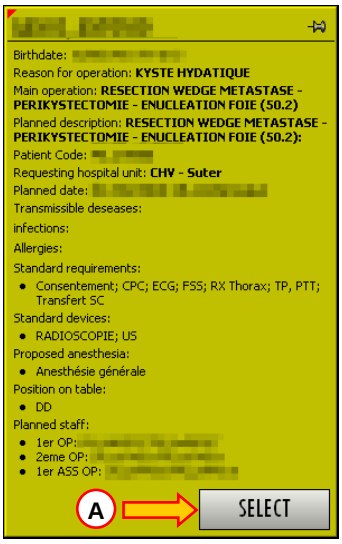


Fig 253 – Operation details

Click the SELECT button in the window (Fig 253 **A**) to access the “OranJ Form” page relating to the operation clicked (Fig 66).

15.1.2. The command bar

Fig 254 – Room Plan module command bar

On the control bar, the three buttons 6 HOURS, 12 HOURS, 24 HOURS (Fig 254 **A**) make it possible to change the time range displayed. By clicking the 6 HOURS button, for example, the time range of 6 hours is displayed, while clicking the 12 HOURS button displays the time range of 12 hours.

The arrow buttons (Fig 254 **B**) make it possible to scroll backwards and forwards in the time range displayed. If, for example, you are displaying the time range from 12:00 to 24:00, click the right arrow once to display the time range from 15:00 to 3:00 of the following day. Likewise, click the left arrow once to display the time range from 9:00 to 21:00.

The EDIT button (Fig 254 **C**) makes it possible to intervene on the page to edit the data. See paragraph 15.1.5 for a detailed description of this function.

The NOT ASSIGNED button (Fig 254 **D**) makes it possible to select a scheduled operation and bring it to the “Not assigned” area. The related procedure is described in paragraph 15.1.5.

15.1.3. The “daily program” area

The “daily program” area (Fig 255 **A**) indicates in textual form information on the schedule of the selected operating room.

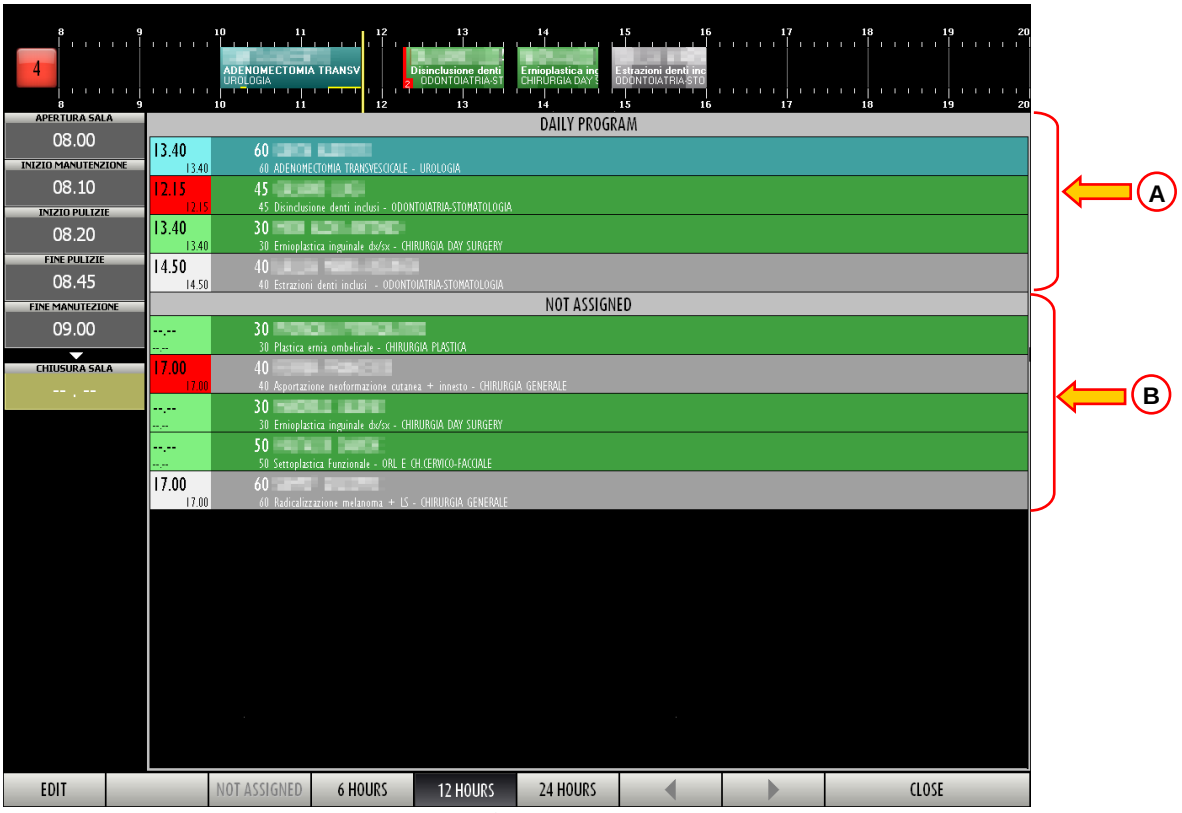


Fig 255

Every line corresponds to an operation (Fig 256).

Fig 256

The color of the line indicates the operation state and follows the color-coding used by all OranJ system modules (see paragraph 11.2 for the association between colors and operation state in OranJ).

The left part of every line contains the start time scheduled for the operation (Fig 256 **A**).

The remainder of the line shows:

- the planned duration of the operation (Fig 256 **B**);
- the patient’s name (Fig 256 **C**);
- the type of operation scheduled (Fig 256 **D**).

If specified, the hospital unit which requested the operation is also indicated.

If the left part is highlighted red (Fig 257) it means that the operation was indicated as "Emergency" on the "Patient and operation screen" (Fig 139 - or, if installed, on the DIGISTAT® "Smart Scheduler" system).

Fig 257 - Emergency

15.1.4. The "not assigned" area

This configuration makes it possible to display the operations not assigned at any time. Those operations for which no start time, room or block have been scheduled (these operations are known as "reserves", see paragraph 11.3 for a description of these operations and the procedures connected to them).

Since we are working on a "Bedside" workstation, only the operations that could be scheduled for the current room will be displayed (that is: the emergencies, the room reserves, the block reserves and the general reserves - the reserves assigned to other blocks are not displayed).

Every line of this section shows the scheduled duration for the operation, the name of the patient, the type of operation scheduled and, if specified, the location which requested the operation (Fig 255 **B**).

All the lines of the "daily program" and "not assigned" pages can be clicked. Click a box to open the window shown in Fig 253 which contains the main data of the operation.

15.1.5. How to edit the operation plan

You can intervene on the main page to edit the operations schedule

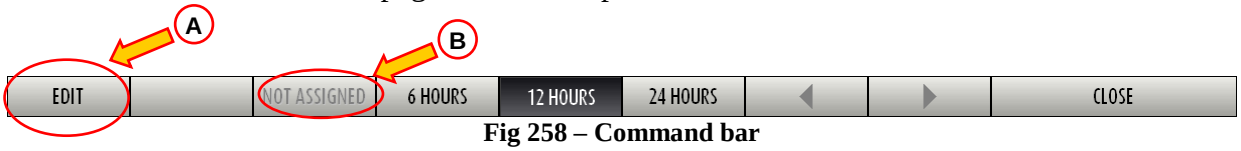


Fig 258 – Command bar

To make any change it is necessary, first, to click the EDIT button (Fig 258 **A**).

When this button is pressed it appears as selected - EDIT.

To edit the page, you have to

- click the EDIT button.

- make the change required.

Once the change has been made the EDIT button is automatically deselected. To allow intervention on the page you have to press it again.

When the EDIT button is pressed, the "drag and drop" functions are enabled.
The term "drag and drop" indicates the possibility to physically take one of the boxes corresponding to an operation, drag it to the point required on the time line and release it. Remember that the position of a box indicates the time scheduled for the corresponding operation, so moving a box from one position to another on the time line means changing the time of the corresponding operation.

The changes will be automatically displayed on the other OranJ modules.

If you are working with a touch screen and there is no mouse, you can perform the same operation using your fingers.

Likewise, you can add an operation from the "not assigned" list to the daily schedule by dragging the corresponding box.

You can also remove an operation from the daily schedule and add it to the "not assigned" list. To do so you have to

- click the EDIT button.
- On the list of scheduled operations (Fig 258 **A**), click the line corresponding to the operation you wish to remove.

The rectangle that contains the time becomes yellow (Fig 259)

Fig 259

The NOT ASSIGNED button on the command bar becomes active.

- Click the NOT ASSIGNED button (Fig 258 **B**).

The operation is this way moved to the "not assigned" list.

Hence, use the EDIT button on the on the main page of the Room Plan module to

- change the time scheduled for an operation.
- add one of the operations from the “not assigned” list to the daily schedule.
- remove one of the operations from the daily schedule and add it to the “not assigned” list.

15.1.6. Room markers

The markers relating to the room events (Fig 260) are displayed and recorded in the column on the left side of the page (Fig 248 **B**).

Fig 260 – Room markers

These markers make it possible to record any occurrence which is considered significant and of which a record is required.

The system makes it possible to record the event and the time at which it occurred.

The number and nature of room events change according to the needs of the specific user and depend on the particular configuration of the system used. Remember that the procedures explained in this paragraph are only an example of configuration.

The room markers in this configuration are

- Room opens
- Start of maintenance
- Start of cleaning
- End of cleaning
- End of maintenance
- Room closes

The markers appear on the left side of the screen as a sequence of boxes. The boxes are arranged in chronological order.

The box relating to the marker initially appears in ochre yellow and does not contain any information on the moment (the time and day) in which the event took place. This means that the marker has not yet been recorded, the corresponding event has not yet occurred (Fig 261).

Fig 261 – First room marker

To record a markert, simply click the corresponding box. The box becomes gray and records the time at which it was clicked. A new ochre yellow box (or several boxes, depending on the configuration) indicating no time appears below it. New boxes refer to subsequent markers (Fig 262).

Fig 262 – Second room marker

In general, to record a marker you have to

- click the corresponding box.

The system automatically records the time at which the operation is performed.

15.1.7. How to edit the room markers

To change the time of a marker after it has been recorded

- Click the box corresponding to the marker for which the time has to be changed.

A numeric keyboard appears (Fig 263).

Fig 263 – Numeric keyboard

- Enter the time required using the keyboard.

To record the new time.

- Click the box corresponding to the event again.

The numeric keyboard disappears and the new time is displayed in the box.

If the time entered is impossible, the following error message appears (Fig 264).

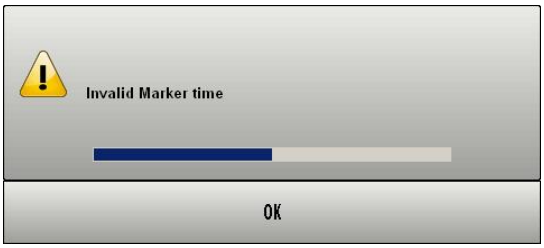


Fig 264

To delete a marker recorded

- Click the box corresponding to the marker to be deleted.

A numeric keyboard appears (Fig 263).

- Click the  button on the keyboard (Fig 263 **A**).

A message requiring confirmation of the operation appears (Fig 265).

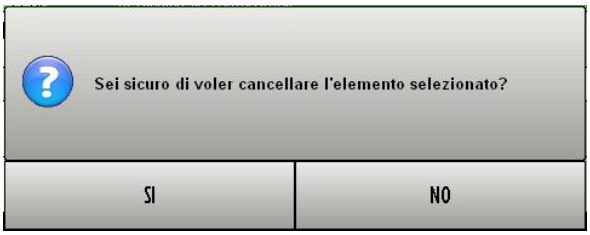


Fig 265

- Click YES to delete the marker.

The deleting of an event implicates the deleting of all subsequent events.

16. Enclosed Documentation

The following documents are enclosed

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

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

PRODUCT TRACKING FORM

Return to:

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

Italy

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

Name of product/system _____

Code (REF) _____

Serial Number (SN) _____

Name and address of the former owner:

Name and address of the new owner:

Date: _____ Signature and Stamp

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

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

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This License Contract grants the User the following rights:

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

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

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

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

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

Technical Assistance Service. UMS may provide the User with a Technical Assistance Service for the PRODUCT ("Technical Assistance Service"). Use of the Technical Assistance Service is governed by UMS policies and programs, which are provided on request. Any additional software code provided to the User as part of the Technical Assistance Service shall be considered as part of the PRODUCT and subject to the terms and conditions of this Contract. Concerning technical information the User may give UMS during the Technical Assistance Service, UMS may use such information for its business purposes, including product support and development. UMS will not utilize such technical information in a form that personally identifies the User.

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

UPGRADES

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

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

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

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

Limitation of Liability. IN NO CASE WILL UMS OR ITS SUPPLIERS BE HELD RESPONSIBLE FOR THE LOSS OF INCOME, PROFIT OR DATA OR FOR SPECIAL, INDIRECT, SUBSEQUENTIAL, INCIDENTAL OR PUNITIVE DAMAGES EITHER CAUSED, TRIGGERED OR RESULTING FROM THE USE OR INABILITY TO USE THE PRODUCT, EVEN IF UMS OR ITS SUPPLIERS WERE INFORMED ABOUT THE POSSIBILITY THAT SUCH DAMAGES COULD OCCUR. Under no circumstance will either UMS or its suppliers' responsibility cover compensation exceeding the price paid by the Client. UNDER NO CIRCUMSTANCE WILL THESE GENERAL CONTRACT CONDITIONS INVOLVE ACKNOWLEDGEMENT OF UMS OR ITS SUPPLIERS' RESPONSIBILITY IN CASE OF DECEASE OR PERSONAL LESIONS RESULTING FROM THE USE OF THE PRODUCT. The said limitations shall apply even if this warranty fails to meet its essential purpose. THE ABOVEMENTIONED LIMITATIONS SHALL NOT APPLY IN THE STATES AND IN THE JURISDICTIONS WHICH DO NOT ALLOW LIMITATION OR EXCLUSION OF INCIDENTAL OR CONSEQUENTIAL DAMAGE.

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

INTENDED USE

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

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

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

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

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

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

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

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

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

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

The PRODUCT does not substitute a “Nurse Call” system and it is not a “Distributed Alarm System” (as defined by the regulation EN 60601-1-8). Therefore, it must not be used in place of the direct monitoring of the alarms generated by the medical devices.

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

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

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

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

In using the PRODUCT, the User declares to have understood and accepted the provisions and the limitations contained herein.

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

* * * * *

Should you have any questions concerning this End-User License Contract, please contact the UMS representative in your area or write to UMS srl, Customer Service, Via di Mucciana 17, 50026 San Casciano in Val di Pesa (Firenze), Italy.

Date Signature

SPECIFIC ACCEPTANCE OF CERTAIN PROVISIONS IN THIS CONTRACT

IMPORTANT—READ CAREFULLY

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

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

Date Signature

Appendix A - Glossary

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

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

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

ALARM MESSAGE

An “Alarm message” coming from any one of the devices in use warns the user about an immediate danger for the patient or the users of the device. Alarm messages are of vital importance and must be managed with the highest priority.

BUTTONS

- **Function buttons**

  Buttons which, when clicked, make it possible to perform different operations or access different functions of the software. In Figure 2 the function buttons are NEW, SHOW, DELETE, CHANGE and REPORTS.

- **Active button**

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

- **Inactive button**

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

- **Make button active**

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

CHECKBOX

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

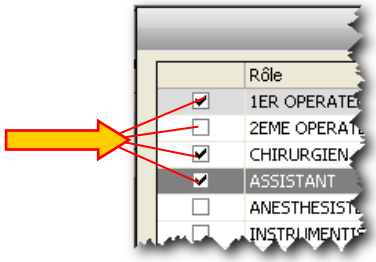

Figure 1 - Checkboxes

- **Selection box**

  See “Checkbox”.

CLICK

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

- **Double Click**

  Click twice in rapid succession.

CLIENT

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

COMMAND BAR

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

Figure 2 – Command Bar

CONFIGURATION

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

CONTROL BAR

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

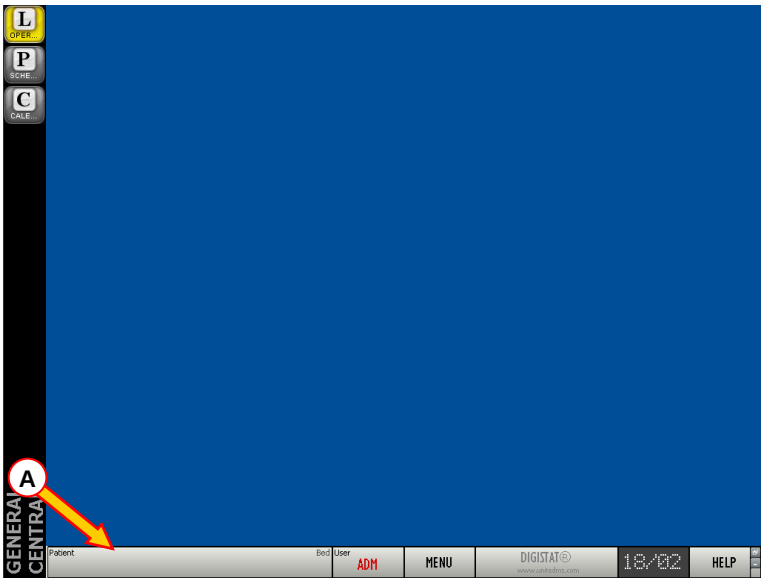

Figure 3 - Control Bar

CURSOR

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

DATABASE

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

DEFAULT

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

DIGISTAT®

- **DIGISTAT® Module**

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

- **DIGISTAT® System**

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

- **DIGISTAT® Environment**

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

DRAG

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

DRAG AND DROP

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

EDIT

Modify the data on a screen.

- **Edit Mode**

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

- **Edit state**

  See “Edit Mode”.

EVENTS

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

FIELD

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

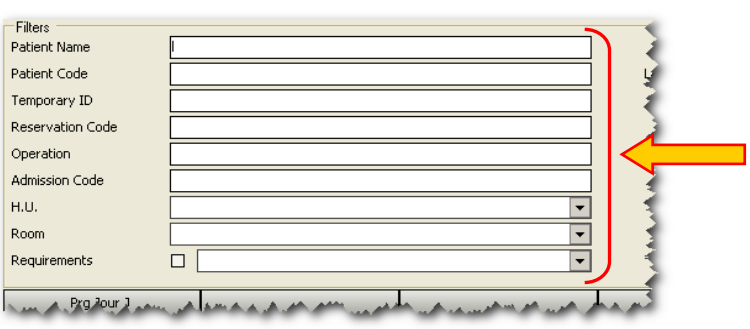

Figure 4 - Fields

❖ **Free field**

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

LOCATION

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

LOG

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

LOGIN (procedure)

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

❖ **Logout**

The act of exiting the system.

MARKER

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

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

MESSAGE CENTER

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

PAGE

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

PASSWORD

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

PATIENT

- **Admitted Patient**

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

- **Patient registered in the database**

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

- **Patient Selected**

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

POP-UP

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

QUERY

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

RADIOBUTTON

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

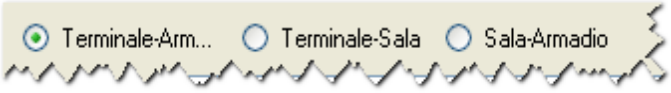

Figure 5

READ-ONLY

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

RECORD

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

RESERVE

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

SCREEN

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

SERVER

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

SLOT

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

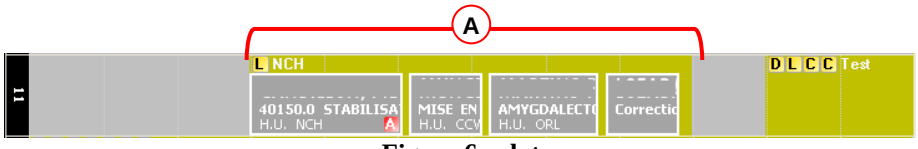

Figure 6 - slot

STATE (of the operation)

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

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

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

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

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

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

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

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

SYSTEM ADMINISTRATOR

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

TAB

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

Figure 7 - Tab

TOOLTIP

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

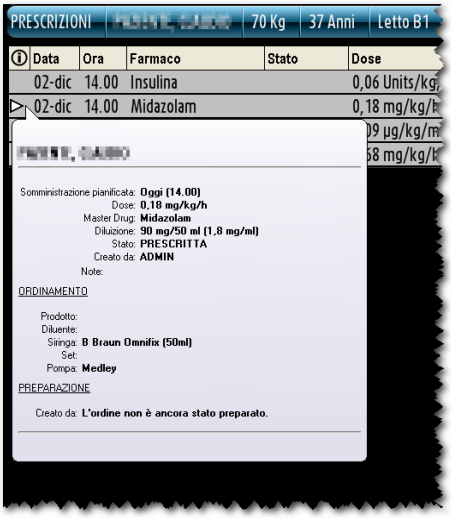

Figure 8 - Tooltip

TOUCH SCREEN

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

USER

The person using the system.

- **User Connected**

  See “User Logged In”.

- **User Logged In**

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

- **User Logged-out**

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

USERNAME

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

WARNING MESSAGE

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

WORKSTATION

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

Appendix B - Residual risks

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

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

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

RISKS RELATING TO THE HARDWARE PLATFORM IN USE

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