

DIGISTAT® Smart Scheduler

DIGISTAT® Version 4.2

User Manual

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DIGISTAT® version 4.2

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WARNING

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

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

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

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2. Using the manual

2.1. Aims

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

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

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

To be more precise, the differences may concern

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

Care has been taken to highlight and emphasize this concept every time the configuration possibilities are such as to prevent a univocal description of the system operation.

Should you require more details regarding a specific configuration, please contact your system administrator or the ASCOM UMS technical support service.

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

2.2. Charcters used and terminology

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

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

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

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

➤ Click the "**Update**" button,

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

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

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

2.3. Symbols

The following symbols are used in this manual.

Useful information



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

Caution!



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

3. Introduction to DIGISTAT®

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

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

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

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

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

3.1. Modular architecture

"Modular Architecture" means that different products (or modules) having particular goals can be implemented within the same software environment (DIGISTAT® in the present case) that is characterized by a determined graphic design, general goals and terms of use.

Different modules can be added in different times, and in a way that is agreed with the user. The resultant software suite fits to the specific user needs and can change in time, according to the possible changes in the user needs.

3.2. Intended use

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

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

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

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

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

The Product is intended for use by trained healthcare professionals within a hospital/clinical environment and relies on proper use and operation of the IT and communication infrastructure in place at the healthcare facility, the display devices used and the connected clinical devices and systems.

Additionally, the Product provides specific functions and interfaces intended to be used by non-professional users in remote locations for non-clinical purposes for display of information, reports, charts and statistics, without any possibility to add, change or delete any information or data.

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

3.2.1. Safety Advisories

The Product, even if designed to provide very high accuracy, cannot guarantee the perfect correspondence of the acquired data, nor can it substitute the direct verification of the same by the User.

The User shall base therapeutic or diagnostic decisions and interventions solely on the direct examination of the original source of information. It is exclusive responsibility of the User to check that the information displayed by the Product is correct and to make appropriate use of it.

In any case, the Product must be used in compliance with the safety procedures reported in the user documentation accompanying the Product.

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

Only these signed documents are a valid source of information for diagnostic or therapeutic processes and/or procedures.

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

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

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

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

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

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

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

The Product is a stand-alone software that can run on standard computers and/or standard mobile devices connected to the hospital local network. The computers, devices and the local network shall be adequately protected against cyber-attacks.

The Product shall be installed only on computers and devices fulfilling the minimum hardware requirements and on supported operating systems.

PATIENT POPULATION

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

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

3.2.2. "Off-label" use of the Product

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

3.3. Manufacturer's responsibility

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

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

WARNING!



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

3.4. Product tracking

In order to ensure device tracking and on-going safety and efficiency checks on site, in compliance with ISO 9001 and EN 13485 quality standards and European law on medical devices 93/42/EEC, amended by the directive 2007/47/EC, the former owner is recommended to inform ASCOM UMS/Distributor about any ownership transfer by giving written notice stating the product, former owner and new owner identification data.

Device data can be found in the product labelling (either paper label provided at installation time or "About box" displayed within the product – see paragraph 6.8.5).

In case of doubts/questions about product labelling and/or product identification please contact ASCOM UMS/Distributor technical assistance (for contacts see paragraph 15).

3.5. Post-market surveillance

The **C** marked device is subject to a post-market surveillance - which ASCOM UMS, its distributors and dealers must provide for each marketed copy - concerning actual and potential risks, either for the patient or the User, during the Product's life cycle.

In case of deterioration of the device characteristics, poor performance or inadequate user instructions that have been or could be a hazard to either the patient or User' health or to environmental safety, the User must immediately give notice to either ASCOM UMS, one of its branches or nearest authorised dealer.

The device details can be found on its labelling.

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

3.6. Product life

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

3.7. CE mark and regulation conformity

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

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

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

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

4. Software/Hardware specifications

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

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

4.1. Bedside

4.1.1. Hardware

Minimum hardware requirements:

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

4.1.2. Operating System

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

4.2. Central

4.2.1. Hardware

Minimum hardware requirements:

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

4.2.2. Operating System

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

4.3. Server

4.3.1. Hardware

Minimum hardware requirements:

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

4.3.2. Operating System

Microsoft Corporation Windows Server 2012 R2

4.3.3. System Software

Microsoft SQL Server 2012/2014

4.4. Handheld device

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

WARNING!



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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

4.5. Firewall and Antivirus

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

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

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

WARNING!



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

WARNING!



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

4.6. Local network features

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

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

ATTENTION!



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

ATTENTION!



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

4.6.1. DIGISTAT® impact on the hospital network

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

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

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

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

Average: 0.8 - 6 Mbit/s

Pitch: 5 - 25 Mbit/s

5. Before starting

5.1. Installation and maintenance warnings

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

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



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

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

5.2. Cleaning

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



Check the suggested cleaning procedures in the manuals of the hardware products that accompany DIGISTAT $^{\otimes}$.

5.3. Precautions and warnings



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



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



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



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

5.3.1. Electrical safety

The hardware devices used together with DIGISTAT® (PC, display, barcode reader, etc...) must comply with therelevant $\mathbf{C}\mathbf{E}$ 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 \mathbf{C} \mathbf{E} marking in accordance with directive 2006/95/EC and subsequent amendments.



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

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



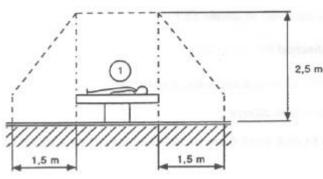
The hospital structure is responsible for all the required measurements on the electrical safety of the electro-medical system in use (PC, display and other possible connected devices) taking into consideration the actual environment in which the system is used.

5.3.2. Patient Area

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



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



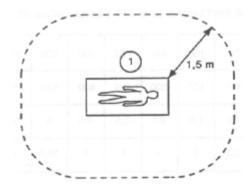


Fig 1

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

WARNING!



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

5.3.3. Electromagnetic compatibility

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

5.3.4. Devices eligibility

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

5.4. Privacy Policy

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



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



Please read the following precautions carefully and strictly observe them.

- The workstations must not be left unattended and accessible during work sessions. It is recommended to log out when leaving a workstation. See paragraph 6.5 for log out procedure.
- Sensible data saved in the system, as passwords or users' and patients' personal data, must be protected from possible unauthorized access attempts through adequate protection software (antivirus and firewall). It is the hospital structure responsibility to implement this software and keep them updated.
- The user is advised against the frequent use of the lock function (paragraph 6.5.2). Automatic log out allows to protect the system from unauthorized accesses.



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

5.4.1. User credentials features and use

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

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

- Username and password must be kept private. Do not let anybody know your username and password.
- Each user can own one or more credentials to access the system (username and password). The same username and password must not be used by more than one user.
- Authorization profiles must be checked and renewed at least once a year.
- It is possible to group different authorization profiles considering the homogeneity of the users' tasks.
- When user accounts are created, it is recommended to always use a nominal identification. Generic users as, for instance, "ADMIN" or "NURSE" must be avoided. Every account must be used by one and only one user.
- Each user is characterized by a profile enabling him/her to access only the functionalities that are relevant for his/her working tasks. The system administrator must assign an appropriate user profile when creating the user account. The profile must be reviewed at least once a year. This revision can also be performed for classes of users. The user profile definition procedures are described in the DIGISTAT® configuration manual.
- Password must be at least 8 characters.
- The password must not refer directly to the user (containing, for instance, user's first name, family name, birthdate etc.).
- The password is given by the system administrator at user account creation time. It must be changed by the user at first access in case this procedure is defined by configuration (see paragraph 6.8.4 for the password modification procedure).
- After that, the password must be changed at least every three months.
- If username and password are left unused for more than 6 months they must be disabled. Specific credentials, used for technical maintenance purposes, are an exception. See technical manual for the configuration of this feature.
- User credentials must also be disabled if the user is not qualified anymore for those credentials (it is the case, for instance, of a user who is transferred to another department or structure). A system administrator can manually enable/disable a user. The procedure is described in the DIGISTAT® configuration manual.

The following information is reserved to system administrators:

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

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

5.4.2. System administrators

ASCOM UMS/Distributor technical staff, when performing installation, updates and/or technical assistance may have access to and deal with personal sensible data stored in the DIGISTAT® database.

ASCOM UMS srl or Distributor, for issues relating to management of personal sensible data, adopts procedures and working instructions complying with the current privacy regulation (D.Lgs 196/2003 of the 30th of June 2003).

In performing the abovementioned activities the ASCOM UMS/Distributor technical staff is configured as "System Administrator" for the DIGISTAT® system (see regulation of 25/11/2008 of the Privacy Guarantor on "System Administrators"). ASCOM UMS/Distributor staff performing this kind of procedures is appropriately trained on privacy issues and, in particular, in sensible data treatment issues.

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

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

5.4.3. System logs

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

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

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

5.5. Back up policy



It is recommended to regularly perform system backups.

The responsible healthcare structure using DIGISTAT® system must define a backup policy that best suits its data safety requirements.

ASCOM UMS/Distributor is available to help and support in implementing the chosen policy.

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

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

5.6. Out-of-order procedure

This paragraph describes the policy suggested by ASCOM UMS in case a DIGISTAT® workstation gets out of order. The goal of the procedure here described is to minimize the time required to replace the out-of-order workstation with one properly working.

ASCOM UMS suggests for this purpose to have at disposal, as substitute equipment, an additional PC on which DIGISTAT® is already installed.

In case of a DIGISTAT® workstation is out-of order, the substitute equipment can promptly replace the DIGISTAT® workstation.

Always remember that DIGISTAT® must only be installed by trained authorized personnel. This includes ASCOM UMS/Distributors staff and any other person specifically trained and explicitly authorized by ASCOM UMS/Distributor. Missing an explicit, direct authorization from ASCOM UMS/Distributor, the hospital staff is not authorized to perform installation procedures and/or to modify DIGISTAT® configuration.

The risk related to the DIGISTAT® workstation deactivation and substitution is that of associating the workstation with a wrong bed or room. This could lead to a "patient switch", which is an extremely hazardous condition.

The risk related to the substituion and/or reconfiguration of network equipment involved in the DIGISTAT® data acquisition (i.e port server, docking station, etc...) is that of assigning the acquired data to a wrong patient. The patient-acquired data relation is based on the IP address. Changing it could lead either to data flow interruption or, in severe cases, to assigning data to the wrong patient.



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

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

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

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

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

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

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

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

5.6.1. Reconfiguration/substitution of network equipment

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

5.7. Preventive maintenance

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

This is the maintenence checklist:

Preparatory checks

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

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

• Schedule possible updates with the technical staff

Checks to be performed

Antivirus

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

Database

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

Workstations

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

DIGISTAT®

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

Connection to devices

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

Instruction for use

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

5.8. Compatible devices

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

5.9. System unavailability

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



Fig 2

The connection problem is often automatically solved in a short time. If it does not happen it is necessary to contact the technical assistance (see paragraph 15 for the contacts list).

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

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

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





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

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

See paragraph 15 for the contacts list.

6. "Control Bar" and DIGISTAT® environment

6.1. Introduction

This section of the manual describes the features and functionalities of the DIGISTAT® environment. Namely, here are described the functionalities of the system that are common to all the DIGISTAT® configurations.

Please remember that DIGISTAT® is a software environment that, depending on the modules that are actually implemented, can be used in different kinds of locations (as, for instance, intensive care, operating rooms, outpatients departments etc...) and for different goals.

6.2. Touch screen

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

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

6.3. Launching DIGISTAT®

To launch DIGISTAT®,

be double click the desktop icon (Fig 3).



Fig 3

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



Fig 4

6.4. DIGISTAT® Work Area

The DIGISTAT® Work Area is defined and delimited by Control Bar, a tool that is common to all and every possible DIGISTAT® installation (Fig 5).

Control Bar manages the installed modules, the patients and their data, the users and their permissions etc.

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

Fig 5 shows Control Bar with no module installed.



Fig 5

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

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



Fig 6

The module currently selected is highlighted (yellow).

6.4.1. Selecting a module

To select a module

> click the corresponding icon.

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

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

6.5. Accessing the system

The DIGISTAT® system can only be accessed by entering the personal username and password ("Log in" procedure).

For this reason, at the beginning of every work session, it is necessary to click the **User** button (Fig 7 A).

The following page is displayed.



Fig 7

To access the system,

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

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

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



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

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

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



Fig 8

WARNING!



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

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

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

WARNING!

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

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

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

6.5.1. Barcode log in

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

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

> scan the user's personal barcode.



The user is immediately logged in.



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

6.5.2. Disabling the automatic log out

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

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

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



Fig 10

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





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

6.5.3. Recent users

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



Fig 12

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

6.5.4. How to use the "User List"

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



Fig 13

To display the "User List",

> click the **More** button.

The following window is displayed (Fig 14).



Fig 14

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

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

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

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

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

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

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

To select a user

> click the name of the user.

The name will be highlighted, then

 \triangleright click the **Ok** button (Fig 14 **F**).

Otherwise you can

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

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

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

6.6. DIGISTAT® Control Bar

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



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



Fig 16

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

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

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



These three buttons are present only if enabled by configuration.

6.6.1. How to read the "Patient" button

Patient selected

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



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).



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).





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

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



Fig 20

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



Fig 21

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

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

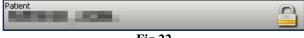


Fig 22

Patient management.



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

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

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

If the patient archives management tool in use is not part of the DIGISTAT $^{\text{(8)}}$ environment please refer the relevant technical documentation.

WARNING!



When entering patient-relating data it is necessary to double-check that the patient identity, hospitalization department and bed displayed in DIGISTAT® match with the actual ones.

This is utterly important in case of critical actions as, for instance, drug administration.

6.7. Help

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



Fig 23

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



Fig 24

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

6.8. DIGISTAT® Main Menu

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



opens a menu containing several options (Fig 26).

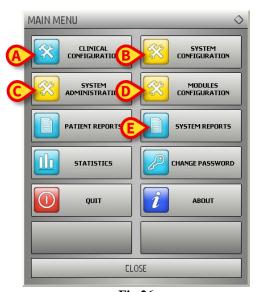


Fig 26

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

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

Clinical configuration - (Fig 26 A)

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

System administration - (Fig 26 C)

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

System reports - (Fig 26 E)

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

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

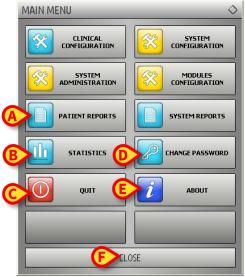


Fig 27

Patient reports - (Fig 27 A, paragraph 6.8.1)

Statistics - (Fig 27 B, paragraph 6.8.3)

Quit - (Fig 27 C, paragraph 6.8.6)

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

About - (Fig 27 E, paragraph 6.8.5)

The Close button (Fig 27 F) closes the "Main menu" window (Fig 27).

6.8.1. Patient reports

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

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



Fig 28



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

6.8.2. Print reports

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



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

To print a patient report

> click one of the buttons on the menu.

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

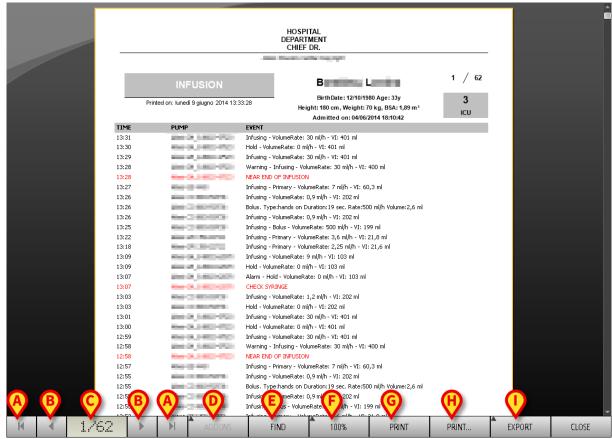


Fig 29

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

- **A** Use the and buttons (Fig 29 **A**) to reach the beginning and the end of the document.
- **B** Use the and buttons (Fig 29 **B**) to go to the previous or the next page.
- C The display (Fig 29 C) indicates the current page number.
- **D** The **Addons** button (Fig 29 **D**) activates the possible additional print management options (in this configuration the "Watermarks" option is available see paragraph 6.8.2.1 for a description of these options).
- **E** The **Find** button (Fig 29 **E**) makes it possible to search the displayed document. See paragraph 6.8.2.2 for more instructions.
- \mathbf{F} The button indicating the $\mathbf{100\%}$ percentage (Fig 29 \mathbf{F}) is a zoom, making it possible to change the display mode. See paragraph 6.8.2.3 for more instructions.
- **G** Use the **Print** button (Fig 29 **G**) to print the report.
- **H** Use the **Print...** button (Fig 29 **H**) to display the print options window (Fig 35). See paragraph 6.8.2.4 for a description of this window and the related procedures.

- **I** Use the **Export** button (Fig 29 **I**) to export the document contents to different file extensions. See paragraph 6.8.2.5 for more instructions.
- L Use the Close button to close the "Print preview" screen.

6.8.2.1. Addons

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

To display the available options,

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

Addons - Watermark

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

Click Addons and then Mark.

The following window is displayed (Fig 30).

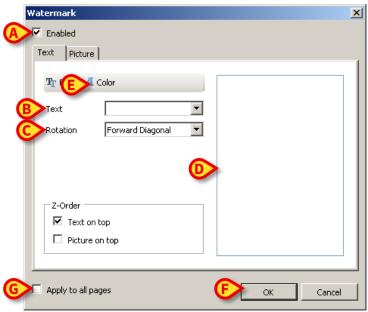


Fig 30

To add a textual watermark,

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

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

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

- ➤ Use the buttons indicated in Fig 30 E to select the watermark font and color.
- Click the Ok button (Fig 30 F).

The text is this way inserted as watermark.

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

To insert a picture as watermark

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

The following window is displayed (Fig 31).

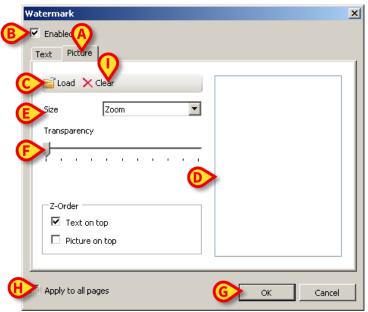


Fig 31

Follow these steps to insert an image as watermark,

- Ensure that the "Enabled" checkbox is checked (Fig 31 B). If not, the window's contents cannot be edited.
- Click the "Load" button indicated in Fig 31 C.

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

Search and select the image to be uploaded.

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

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

The watermark image is this way inserted.

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

To delete an already selected image,

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

6.8.2.2. Find

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

To search the print report,

Click the Find button.

The following window opens (Fig 32).



Fig 32

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



Fig 33

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

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

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

6.8.2.3. Zoom

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

To change the display mode,

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



Fig 34

> Click the wanted option on the menu.

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

The following options are available:

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

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

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

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

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

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

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

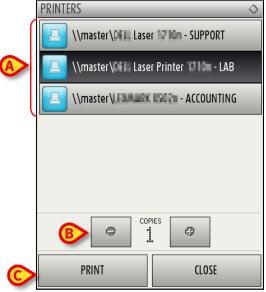


Fig 35

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

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

6.8.2.5. Export

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

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

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

Click the option corresponding to the wanted extension.

The document is this way exported to the corresponding extension.

6.8.3. Statistics

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



Fig 36

The button opens another menu (Fig 37) that enables to access various distinct tools.

The type and number of accessible tools depend on the configuration in use and the specific modules installed.

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

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



Fig 37

6.8.3.1. Query Assistant

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

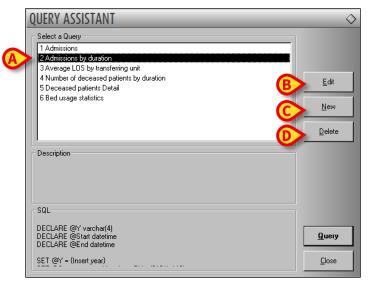


Fig 38

The user can select a query from a list of pre-defined queries, to execute it and display the results in a specific window.

The "Select a Query" area displays the list of all the pre-defined queries (Fig 38 A).

To run a query

> click the corresponding name on the list,

The name will be highlighted (Fig 39 A).

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



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

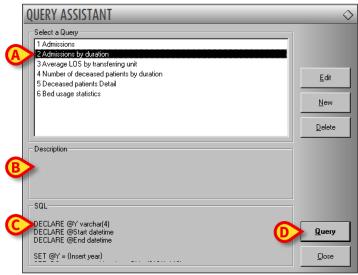


Fig 39

To run the query

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

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

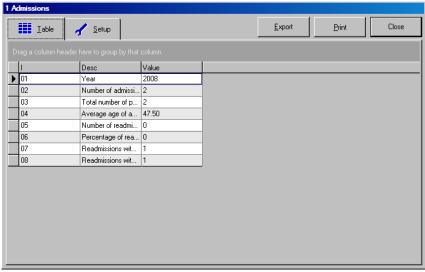


Fig 40

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

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

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

6.8.4. Change password

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



Fig 41

To change the user password

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

The "Change password" window will open.



Fig 42

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



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

6.8.5. About DIGISTAT®

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



Fig 43

6.8.6. Quit DIGISTAT®

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

To quit DIGISTAT®

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



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



Fig 45

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

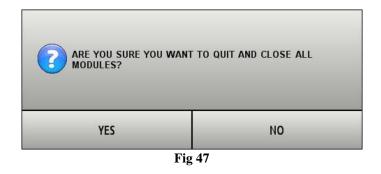
Another menu is displayed (Fig 46).



Fig 46

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

User confirmation is required (Fig 47).



➤ Click **Yes** to exit DIGISTAT[®].



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

7. DIGISTAT® "Smart Scheduler"

7.1. Introduction

The DIGISTAT® "Smart Scheduler" system is an instrument for planning operations in the operating room at surgical block or individual room level.

Using "Smart Scheduler", it is possible to record every significant detail concerning the patient and the surgical, manage room staff, plan time schedules, spaces and operating resources.

The information gathered is for documentation use. The "Smart Scheduler" 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.

7.2. Operation state

The "Operation State" concept characterizes work inside the whole "Smart Scheduler" system, so it is necessary to explain it before looking at the different pages and procedures.

The term "Operation state" means the "stage" of the "path" that every surgical operation has to go through from the initial meeting with the patient until completion of the operation.

The Smart Scheduler system envisages three different operation states.

- Foreseen The operation is "foreseen" when the decision has been made to operate on a specific patient. Therefore the procedure for the operation in question is opened.
- Requested The operation is usually "requested" when all the bureaucratic or medical requirements in relation to the operation in question have been met. In practical terms, to facilitate the inclusion of emergency operations, an operation can be "requested" by simply indicating the type of operation and its planned duration (see paragraph 12.2).
- Scheduled The operation is "scheduled" when it has been included in the general schedule of operations. A surgical block, room, date and time are usually assigned in "scheduled" state. It is possible, in order to quickly schedule emergency operations, to "plan" an operation lacking the above characteristics (either all or some of them). These operations are known as "reserves" and are described in paragraph 13.5.5.

i

The Smart Scheduler-OranJ combined system envisages six different "operation states". The three states described above are followed by the "Ready" state (the patient has undergone the surgical block check-in), by the "In progress" state (the operation is in progress) and by the "Completed" state (the patient is out of the operating room). The last three states, while shown on Smart Scheduler, are managed by the DIGISTAT® OranJ (Operating Room and Anesthesia Journal) system.

It is also possible, according to the needs and the procedures in use, to activate on "OranJ" an ulterior state making the "Completed" operations impossible to edit. The data of these operations are "Read-only" data. These operations are characterized by a dark grey colur when displayed both in "OranJ" and in "Smart Scheduler".

7.3. Lock/Unlock operation

This chapter explains the principles and the goals of the operation lock/unlock functionalities.



The lock/unlock operation procedure is available on different screens. The specific lock/unlock procedures will be explained in this manual contextually with the specific screen.

The operation planning can be locked to increase the reliability and the accuracy of the plan.

When an operation is locked none of the values regarding the operation planning can be edited unless the user has adequate explicit permissions.

When an operation is locked the following data cannot be edited:

- patient name;
- main operation and secondary operations;
- infections and transmissible diseases;
- surgical times;
- date and time;
- room.

There are three possible lock/unlock levels. Each hospital decides - by configuration - how many lock/unlock levels (none, one, two, three) to use.

The different levels can be used to create different user types, characterized by specific lock/unlock permissions.

An operation locked by a certain kind of user can be this way unlocked only by users having the explicit permission to do that. The hospital procedures are this way fixed in a way that increases their reliability.

Three specific icons appearing in the appropriate contexts identify the lock levels:



- First level lock.



- Second level lock.



- Third level lock.

Only certain "lock actions" are enabled for the logged user, depending on the context and his/her permission level.

Fig 48, for instance, shows a situation in which, after a level 1 lock (Fig 48 A), the following options are enabled:

lock level 2;

lock level 3;

unlock level 1 (Fig 48 B).

The other options are disabled.

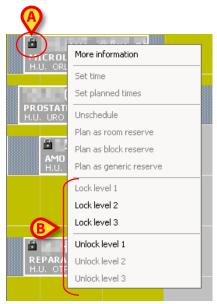


Fig 48 - Lock/Unlock operation options



Only the operations scheduled for either the current day or the future days can be locked/unlocked. The operations scheduled for a past day and not done yet cannot be locked/unlocked.

8. System structure

The DIGISTAT® "Smart Scheduler" system is formed of four modules:

These are:

- **Operation list** makes it possible to search an operation/patient among those recorded by the system. This module is described in paragraph 9.
- **Schedule** makes it possible to actually schedule the operations and to display the rooms schedule and availability. This module is described in paragraph 13.
- Calendar provides a global view of the rooms availability in time. This module is described in paragraph 13.6.
- **Staff Management** makes it possible to manage the operating staff. This module is described in paragraph 14.

9. Operation list

To access the "Operation List" module

Click the corresponding icon on the lateral bar.



Fig 49

The following screen will open (Fig 50)

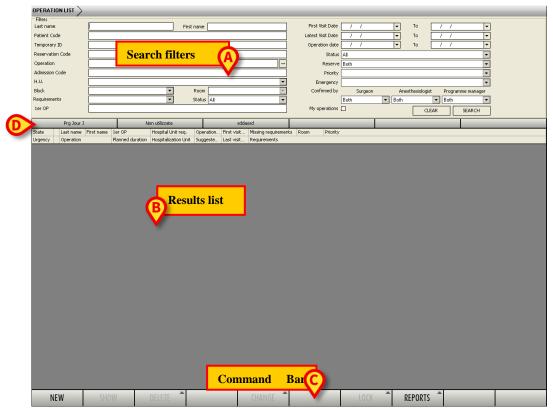


Fig 50 - Operation list

The screen is formed by four main areas:

1) The search filters - The area indicated in Fig 50 A contains the search fields that can be used to filter the list of operations. This area is described in paragraph 9.1.1.

- 2) The results area The area indicated in Fig 50 **B** displays the search results after the search is performed. This area is described in paragraph 9.2. Each result refers to one of the operations recorded in the system.
- 3) The command bar The command bar (Fig 50 C) contains a series of buttons making it possible to perform specific procedures. See paragraph 9.3 for a description of these procedures.
- 4) Pre-defined searches The buttons indicated in Fig 50 **D** can be used to launch pre-defined searches that were previously recorded by the user. This functionality is described in paragraph 9.1.3.

Each result on this screen refers to an operation record containing all the detailed operation data (patient, date, requirements etc...).

9.1. How to search for an operation

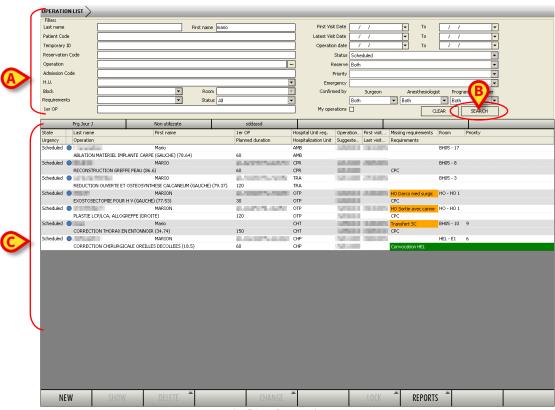


Fig 51 - Operation search

To search for an operation

- ➤ Insert the available operation data in the search field (In Fig 51 A we are searching for an operation in "Scheduled" state with "Mario" as patient's name).
- Click the Search button indicated in Fig 51 B.

The list of operations corresponding to the specified values will appear (Fig 51 C).

If the results are more than a given number specified by configuration (more than 200 in the configuration we are describing) a specific pop-up message asks for a further specification of the search parameters (Fig 52).

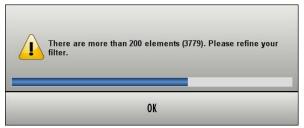


Fig 52

9.1.1. Search parameters

The following parameters can be entered in the search fields.

- Patient name
- Patient surname
- Patient code
- Temporary ID.

This value is a temporary code which can be assigned to the patient who is not present in the hospital database, when it is necessary to create an operation-entry immediately (see paragraph 9.3.1.1 for the detailed procedure).

- Reservation code.
- Operation.

Specifies the type of operation to be scheduled.

A configuration parameter defines the way this field is specified. It can be either through a textual field in which the name of the operation is typed, or through a popup search tool.

In this case the button appears near the field. Click it to open a window making it possible to search and select the operation from a pre-defined list (Fig 53).



Fig 53 - Operation selection

To use this window

- insert the operation name (or part of it), in the field indicated in Fig 53 A.
- ➤ Click the **Search** button indicated in Fig 53 **B**.
- ➤ The list of operations whose names contain the inserted characters will appear (Fig 53 C).
- > Select the wanted operation/s.

The name of the operation/s will appear in the "Operation" field. Multiple selection is possible. The result of a search performed with multiple entries in the "Operation" field returns the list of operation records corresponding to any one of the operations specified.

- Admission code.
- H.U.

Specifies the hospital unit of the wanted operation.

The button placed near the field (Fig 54 A) opens a drop down menu listing all the possible hospital units.

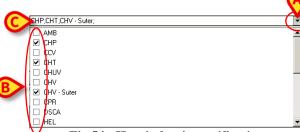


Fig 54 - Hospital unit specification

Click the box/es placed near the name of the relevant hospital unit/s (Fig 54 B).

The box will be selected.

The names of the selected units will appear in the field (Fig 54 C).

Block

Specifies the block of the wanted operation. Multiple specification is here as well available.

Room

Specifies the room scheduled for the operation. Multiple specification is here as well available.

• Requirements.

This field enables to display the list of the operations for which information on the operation requirements are available (a requirement may be a document, a medical examination, a certain type of test, etc. - see paragraph 12.3 for a detailed explanation of the possible requirements).

The "Status" field placed nearby enables to specify whether the requirements for the operation are either missing, or obtained, or not obtained, or there is no information available on the operation requirements.

First Operator

Specifies the name of the first operator associated to the wanted operation

First visit date

It is here possible to specify two dates indicating the time span within which the search is performed.

• Latest visit date

It is here possible to specify two dates indicating the time span within which the search is performed.

Operation date

It is here possible to specify two dates indicating the time span within which the search is performed.

Status

Specifies the state of the operation you are searching for.

Reserve

This field specifies whether the operation for the patient you are searching for is a reserve and, if so, the type of reserve (see paragraph 13.5.5 for details on the concept

of reserve). "Both" means that you are searching among both "reserves" and "non-reserves".

• Priority.

Specifies the type of priority assigned to the wanted operation. The "Priority" and "Emergency" fields are mutually exclusive, i.e. if one is selected the other one is disabled.

Emergency

Specifies the emergency level assigned to the wanted operation. The "Priority" and "Emergency" fields are mutually exclusive, i.e. if one is selected the other one is disabled.

• Confirmed by Surgeon/Anesthesiologist/Program manager.

Specifies whether or not the wanted operation has been confirmed by those specified. Choose "Both" to search among all confirmed and unconfirmed operations.

My operations

Choose this box to limit the search to the operations scheduled by the user connected at that time and inserted in a personal list (See paragraph 12.2.19 for a description of this option).

In fields flanked by the arrow click the arrow to enter the value. This opens a window containing different options to choose from. See, for example, Fig 55 related to the "Status" field.



Fig 55 – State selection window

To choose the preferred option, simply click it. The clicked item will appear in the "Status" field.

9.1.2. Date specification

A dedicated tool is available every time the date must be specified.

To open that tool

> Click the button placed near the "date" field.

A calendar-window will open (Fig 56)



Fig 56

The month is specified on top. The numbers correspond to the days.

To insert a date

> click the number corresponding to the wanted day.

The date will be automatically inserted in the field.

Current day is circled (red - 26th of May in Fig 56).

Use the arrows indicated in Fig 56 A to select another month. Left arrow displays the previous month, right arrow displays the following month.

Use the **Today** button to select to the current day again.

Use the **Clear** button to close the window without selecting a date.

9.1.3. Pre-defined searches

The bar that divides the upper and lower parts of the page Fig 57 is made up of buttons that can be configured to perform pre-defined searches.



To create a pre-defined search

- Enter the search parameters required.
- Move with the mouse to the button you wish to use for the search (Fig 57 A).
- > Right click.

The following window will open.

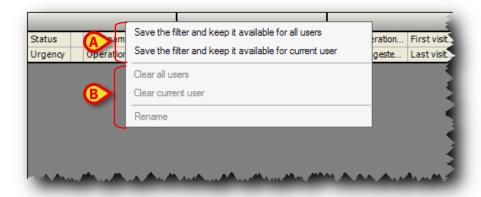


Fig 58 – Setting a pre-defined search

Click the first or second option (Fig 58 A).

The "Save the filter and keep it available for all users" option saves the pre-defined search so that it can be seen by all Smart Scheduler users.

The "Save the filter and keep it available for current user" option saves the pre-defined search so that it can be seen only by the user who created it.

The following window will appear (Fig 59).



- Fig 59 Name search
- Enter the name you wish to assign to the pre-defined search (Fig 59 A).
- Click the Ok button.

The name assigned to the search will appear on the chosen button (Fig 60).



Fig 60 – Search button

From now on, when that button (**User 1** in the example) is clicked, the search parameters saved will be automatically set.

To eliminate the type of search created, simply click either the "clear all users" options (if the button is visible to all users) or the "clear current user" option (if the button is only visible to the current user - Fig 58 **B**).

To change the name of a stored search, simply click "Rename" (Fig 58 B).

9.2. Search results

The results of the search are shown in the lower part of the page Fig 61).



Fig 61 – Search results

In this example, the search has been carried out specifying the patient name ("Mario"). The result is the list of all the operations for patients whose name is "Mario" (or contains these sequence of letters).

Every result is arranged on two lines. The two heading lines provide the key to reading the results, indicating the information available in the list (Fig 61 A, Fig 62).



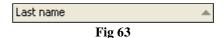
Fig 62 – Results structure

The information contained in every result, starting from the box in the top left corner of Fig 62, comprises:

- The operation state.
- The patient's last name and name.
- The name of the operating surgeon
- The hospital unit which requested the operation.
- The operation date.
- The first visit date.
- Any missing requirements (see paragraph 9.2.1 for details on this item).
- The scheduled room.

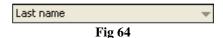
- Any priority assigned to the operation.
- Any degree of urgency specified.
- The type of operation.
- The scheduled duration of the operation.
- The hospitalization unit.
- The suggested date for the operation.
- The last visit date
- Any necessary requirements (see paragraph 9.2.1 for details on this item).

The results can be sorted based on the criteria specified inside the box by simply clicking the box. If, for example, you click the "Last name" box, it will appear like this (Fig 63).



In this case the search results will be arranged by last name in alphabetical order (from A to Z).

If you click the same box again, it will appear like this (Fig 64).



In this case the search results will be arranged, again, by last name in alphabetical order but from Z to A.

Every box on the bar shown in Fig 62 can be clicked to display the results in the preferred order.

Click the 10 icon present on every row (Fig 65),



to open a window containing the main data relating to the operation (Fig 66).



Fig 66 - "Operation data" window

Click the **Select** button in the window (Fig 66 **B**) to access the "Operation Record" relating to the operation (Fig 98, paragraph 10).

The window disappears automatically as soon as the mouse is moved; click the "thumbtack" in the top right corner of the window (Fig 66 A) to fix the window to the screen.

The occupant icon possibly appearing before the patient's name means that the operation was planned for a day in the past but still is not executed.

The three icons and possibly placed before the patient's name indicate that the operation is locked at the level indicated by the icon itself. See paragraph 7.3 for an explanation of the "lock/unlock operation" functionalities in the Smart Scheduler system.

9.2.1. Missing requirements and necessary requirements

A "requirement" may be any document necessary to the progress of the operation procedure (e.g., the result of a medical examination or a patient consent form).



Fig 67

The "Missing requirements" box (Fig 67 A) indicates the documents that have to be obtained while the operation is in its current state and the documents which should have been obtained while the operation was in a previous state. The items indicated in this area are the product of procedures which have not yet been completed.

The "Requirements" box (Fig 67 **B**) indicates correctly obtained documents, documents which have not been obtained because the procurement procedure has failed (these are not classed as "missing" because the procurement procedure has been completed, but has had a negative outcome) and documents which must be obtained in a state subsequent to that currently held.

The information related to the missing requirements and the requirements needed for the operation can appear highlighted in different colors.

The color, if present, provides information on the group of requirements requested. This information will be presented in more detail on the subsequent "Operation Record" page (Fig 168, see paragraph 12.3).

The colors have the following meanings.

If the area is highlighted red (Fig 68), at least one of the requirements is missing because the procurement procedure has failed (e.g. failed exam or consent denied).



Fig 68 - Patient requirements color code -1

If the area is highlighted orange (Fig 69), one of the missing requirements should have been obtained in the previous state (i.e., the operation procedure has progressed even though one of the requirements should have been satisfied earlier).

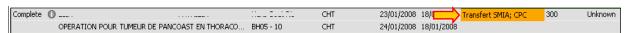


Fig 69 – Patient requirements color code -2

If the area is highlighted green (Fig 70), at least one of the requirements has been obtained successfully (and none of the requirements are missing because the procurement procedure has failed, otherwise the area would be highlighted in red).



Fig 70 - Patient requirements color code -3

If the area is not highlighted (Fig 71), the patient is waiting for the necessary documentation.



Fig 71 - Patient requirements color code - 4

9.2.2. Reserves

Reserves are those operations for which either no time, no block or no room has been assigned, but which are included in the daily schedule.

The Smart Scheduler system envisages three types of reserve:

- Room reserve The operation has been assigned an operating room but not a time.
- Block reserve The operation has been assigned a surgical block but not a room and a time.
- General reserve No time, room or block have been assigned to the operation.

The "Operation List" page uses special icons to indicate whether one of the operations on the list is a reserve.

Room reserves are identified by the icon (Fig 72).

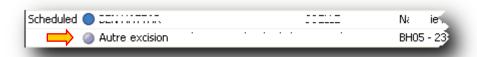


Fig 72 – Room reserve

Block reserves are identified by the icon (Fig 73).



Fig 73 – Block reserve

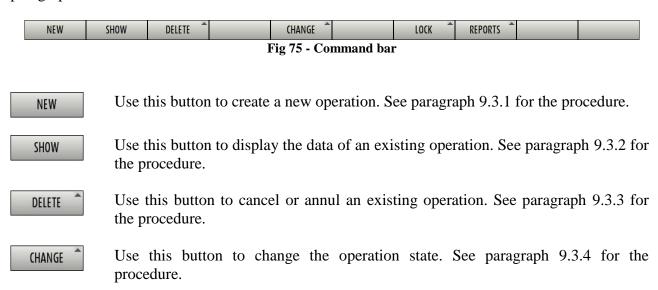
Generic reserves are identified by the icon (Fig 74).



Fig 74 – Generic reserve

9.3. The "Operation list" screen command bar

It is possible to perform various procedures with the items displayed on the "Operation list" screen. These procedures are performed using the buttons on the command bar (Fig 75). This paragraph lists briefly the functions of the different buttons. They will be described in detail in the indicated paragraphs.



LOCK

Use this button to lock/unlock a scheduled operation. See paragraph 9.3.5 for the lock/unlock procedure when used on the "Operation list" screen.



Use this button to create the appropriate print reports. See paragraph 6.8.1 for the procedure.



The buttons on the command bar are enabled or not depending on the screen content (some procedures are not possible in some contexts) and on the logged user permission level (the users can perform only the actions for which they are entitled).

9.3.1. Creating a new operation record

To create a record for a new operation (new operation creation)

> click the **New** button on the command bar (Fig 76).

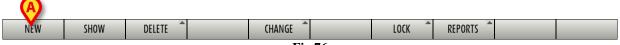


Fig 76

The patient search and selection software currently in use will open.

. 1

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 $DIGISTAT^{\otimes}$ environment please refer the relevant technical documentation.

Select the patient for which the new operation is being created.

The "Operation record" screen will open (Fig 77). The patient data will appear in the relevant fields (Fig 77 **A**).

The "Operation Record" screen is described in paragraph 10.

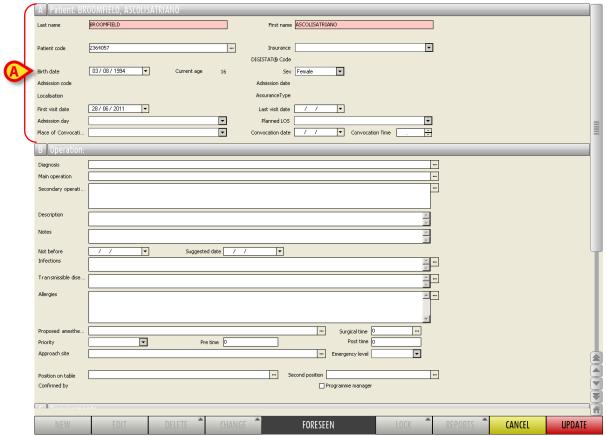


Fig 77 – Operation record

- Fill the operation record with all the relevant data. See paragraph 10 for all the detailed information.
- Click the **Update** button on the command bar.

A new "Operation record" is this way recorded. The operation is in "Foreseen" state.



The "Operation Record" can be recorded with no other data than the patient data. In this case the operation will be in "Foreseen" state. To go further to "Requested" state the name of the main operation and the planned duration at least must be specified.

See paragraph 7.2 for a description of the operation states managed by the "Smart Scheduler" system.

9.3.1.1. Creating a new operation with provisional data

There may be a case in which an operation has to be created for a brand new patient; a patient whose data is not stored in the databases of the structure where you are operating. In these cases, the procedure envisages the recording of the patient's data <u>first of all</u>, and <u>then</u> the creation of the new operation.

For various reasons (the particular urgency of the operation, for example) it may be better to proceed directly with the creation of the operation with DIGISTAT® "Smart Scheduler" and then, later, to record the patient's data.

In this case, it is necessary to open an operation record with provisional data.



This possibility depends on a configuration parameter. The system can be configured in a way that inhibits the creation of interventions with provisional data. Please refer to your system administrator to know the details of the configuration in use.

To create an operation record with provisional data

> click the **New** button on the command bar (Fig 76).

The patient search and selection software will open.

> Close the patient search and selection software.

The <u>completely empty</u> "Operation Record" will open, lacking any data relating to the patient (Fig 78).

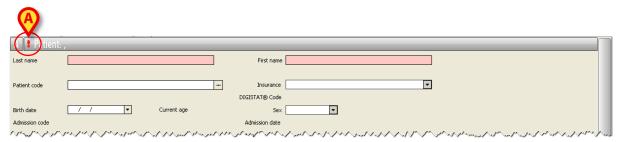


Fig 78 – Operation record with provisional data

Enter all the known data of the patient and the operation.



To save a record with provisional data, the only mandatory data is the patient's name and last name.

Click the Update button on the command bar.

The new record will be saved by the Smart Scheduler system as a provisional record.

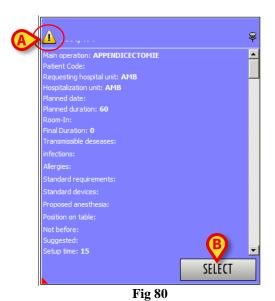
The red exclamation mark towards the top left of the page (Fig 78 A) warns that the patient's data is provisional.

Once the record has been saved, the exclamation mark is also displayed on the "Operation List" page (Fig $79 \, A$).



Fig 79

The exclamation mark on this page can be clicked to display the window containing the main information on the operation (Fig 80).



OO A indicates that the information window maken

The icon highlighted in Fig 80 A indicates that the information window refers to an intervention with provisional data.

Click the **Select** button in the window (Fig 80~B) to access the "Operation Record" screen relating to the operation (Fig 98)

The window disappears if clicked again.

9.3.1.2. How to make the data of a record final

To make the data of a provisional record final

- Access the provisional operation record (to do that double click the corresponding line on the "Operation List" screen Fig 50).
- Click the **Edit** button (Fig 81).



Fig 81 - "Operation record" screen command bar

The screen will turn to "Edit" mode. I.e. data entry will be enabled.

➤ Click the "Patient Code" field (Fig 82 A), or the **Patient** button on Control Bar (Fig 83).

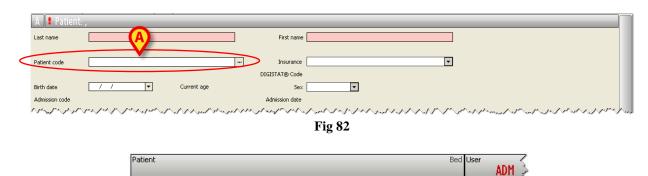


Fig 83

The patient management software in use will open (DIGISTAT® "Patient Explorer", for instance).

Enter the patient's data.

The patient's operation record (see Fig 98 for an example) will open again, containing the final data.

In this way, all the patient's data contained in the database are transferred to the operation record which is no longer provisional (the exclamation mark is no longer present).



If the data contained in the DIGISTAT® registry differ from those present in other systems in use of which DIGISTAT® is "Slave", the red exclamation mark may remain after the data are made final. This feature signals the possible differences between the DIGISTAT® registry and the data of the other systems in use.

9.3.2. How to display an "Operation record"

To display a specific record, on the "Operation list" screen (Fig 84),

> search for the wanted record using the procedures described in paragraph 9.1.

The corresponding row will appear on screen.

Click the row.

The row will be highlighted (Fig 84 A).

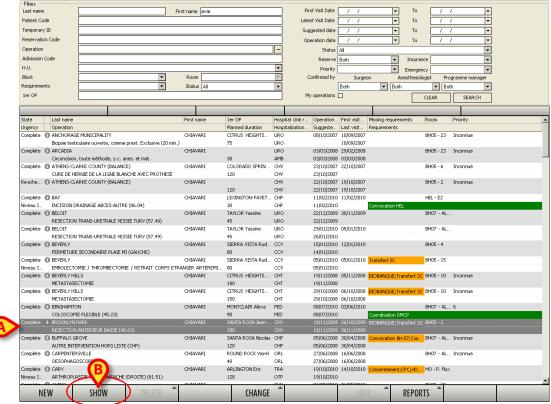


Fig 84 - Operation list

click the **Show** button on the command bar (Fig 84 **B**).

The corresponding "Operation record" will open (Fig 85).

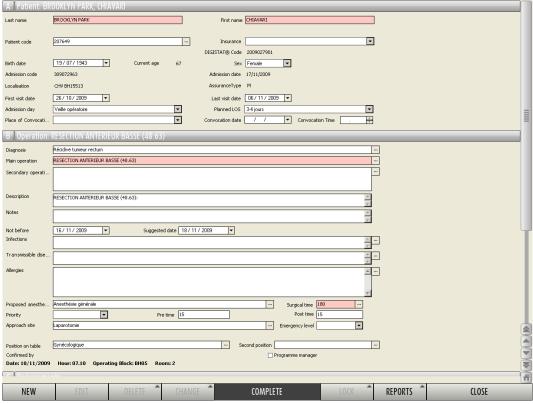


Fig 85 - Operation Record



You can also double-click the relevant row to open the corresponding "Operation record".

9.3.3. How to either delete or annul an operation

To either delete or annul an operation record, on the "Operation list" screen (Fig 86),

> search for the wanted record using the procedures described in paragraph 9.1.

The corresponding row is displayed.

Click the row.

The row is this way highlighted (Fig 86 A).

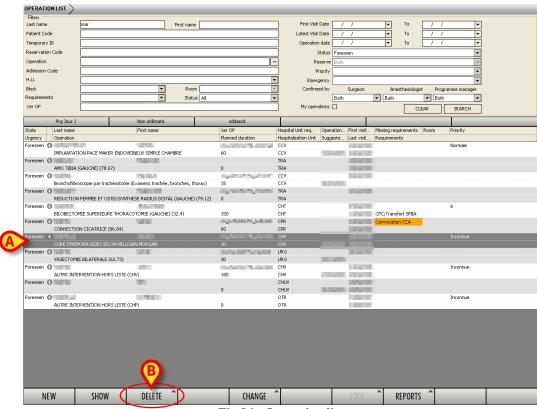


Fig 86 - Operation list

➤ Click the **Delete** button (Fig 86 **B**).

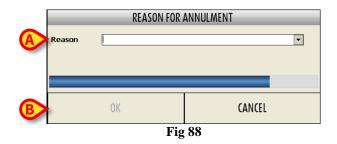
A menu containing two options opens (Fig 87).



Fig 87

Annul - Use the "Annul" option (Fig 87 A) to annul the selected operation.

After clicking on "Annul" the following window opens, requesting to specify the annulment reason (Fig 88).

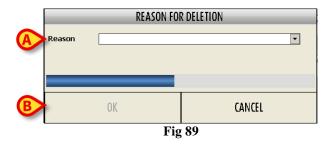


- Enter the reason for annulment in the "Reason" field (Fig 88 A).
- Click **Ok** to annul the operation (Fig 88 **B**).

The selected operation is this way annulled. Annulling an operation is an irreversible administrative procedure indicating that the operation will not be managed in any way by any hospital unit. The operation record will be stll visible in read-only mode as "Annulled operation".

Delete - Use the "Delete" option (Fig 87 B) to delete the operation highlighted.

After clicking on "Delete" the following window opens, requesting to specify the deletion reason (Fig 89).



- Enter the reason for deletion in the "Reason" field (Fig 89 A).
- Click **Ok** to delete the operation (Fig 89 **B**).

Operation deletion permanently deletes the operation data. The "Operation record" disappears from the DIGISTAT® Smart Scheduler system. This procedure can only be used only in case of wrong or double operation records.

9.3.4. Changing the operation state

The **Change** button on the "Operation list" screen command bar makes it possible to change the state of an operation.

To change the operation state

> search for the operation whose state must be changed using the procedures described in paragraph 9.1.

The corresponding row will appear on screen.

Click the row.

The row will be highlighted (Fig 90 A).

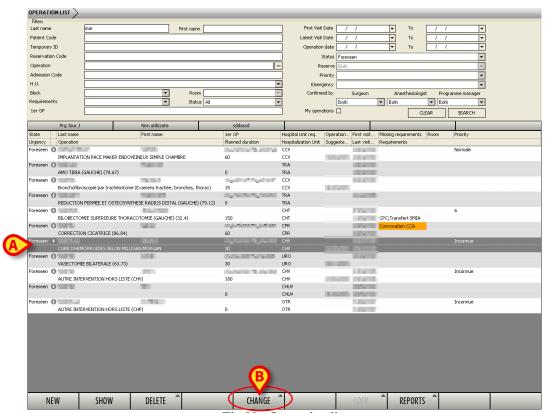


Fig 90 - Operation list

> Click the **Change** button (Fig 90 **B**).

The menu shown in Fig 91 will open.



Fig 91 – "Change" button



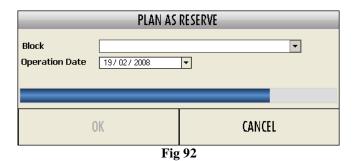
On the menu shown in Fig 91 the buttons can be either enabled or disabled depending on the state and the characteristics of the selected operation. Only the procedures that are coherent with the selected operation will be enabled.

If the **Change** button is not active it is not possible to change the state of the selected operation.

• Plan as reserve (Fig 91 A).

The "Plan as reserve" option enables to quickly manage the urgent operations. The option is enabled only if the highlighted operation is marked as "Emergency level I" and is not already scheduled. The emergency level is specified by the appropriate field on the "Operation record" screen (see Fig 98).

After clicking this option the system requests to specify the date and the block of the operation. The window shown in Fig 92 appears.



- > Specify the block and the date.
- Click Ok.

The operation will be directly scheduled as block reserve for the specified date and block. See paragraph 13.5.5 for an explanation of the meaning of "reserve" in the Smart Scheduler System

• Reschedule (Fig 91 **B**)

The "Reschedule" option enables to change the selected operation schedule. This option is active only if the chosen operation is already planned. The procedure is described in paragraph 13.5.3.

• Schedule with help (Fig 91 C)

The "Schedule with help" option enables to access the "Shedule with help" screen to schedule the selected operation (Fig 279, see paragraph 13.7).

• Schedule (Fig 91 **D**)

The "Schedule" option enables to access the "Schedule" screen to schedule the operation (Fig 220, paragraph 13).

• Request (Fig 91 **E**)

The "Request" option changes the operation state to "Requested". See paragraph 7.2 for the explanation of "Operation state".

• Foreseen (Fig 91 **F**)

The "Foreseen" option changes the operation state to "Foreseen". See paragraph 7.2 for the explanation of "Operation state".



It is possible to select numerous operations at the same time on the "Operation list" screen. In order to do that, click the corresponding row while keeping the Ctrl key pressed on the workstation keyboard. All the clicked rows will be highlighted.

9.3.5. Locking and unlocking an operation

Use the **Lock** button to either lock or unlock a scheduled operation. A locked operation cannot be rescheduled. Only the operation scheduled for the current day and for the future days can be locked/unlocked, not those that were scheduled for a day in the past and have not been executed yet. In these cases the **Lock** button is not active.

To lock/unlock an operation

> search for the operation that must be locked/unlocked using the procedures seen in paragraph 9.1.

The corresponding row will appear on screen.

Click the corresponding row.

The row will be highlighted (Fig 93 **A**).



Fig 93 - Operation list

➤ Click the **Lock** button (Fig 93 **B**).

The following menu will open (Fig 94).

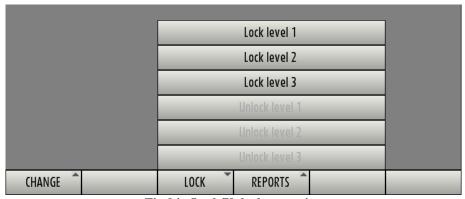


Fig 94 - Lock/Unlock operation

Three lock levels are possible in the configuration here explained (Fig 94).

See paragraph 7.3 for a detailed explanation of the goals and features of the lock/unlock functionalities.

Only certain procedures are enabled for the logged user, depending on his/her permission level and the current context.

In Fig 94, for example, the user has the possibility to lock level 1, 2, 3 an unlocked operation (Fig 93 A).

Click the wanted option on the menu.

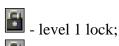
The operation will be locked/unlocked at the specified level.

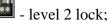
A specific icon is placed on the row corresponding to the operation to indicate that it is locked (Fig 95).



Fig 95 - Operation locked level 1

Three different icons identify three lock levels:









The options triggered by the **Delete**, **Change** and **Lock** buttons can also be activated by right-clicking the row corresponding to the relevant operation. A menu containing the different options described in this chapter will open (Fig 96).



Fig 96

The "More information" option on the menu displays the window seen in Fig 66.

9.3.6. Printing documentation

The **Reports** button on the command bar enables the creation of a document containing the data of the patients and operations in the database.



Fig 97 – Operation list screen command bar

To create the document

> Click the **Reports** button.

Several options are displayed. Their number and their kind depend on the configuration in use.

> Click the wanted option.

A print preview is displayed. See paragraph 6.8.1 for the system's print functionalities.

10. Operation Record: main features

The "Operation Record" (Fig 98) page contains all the available data of an operation.

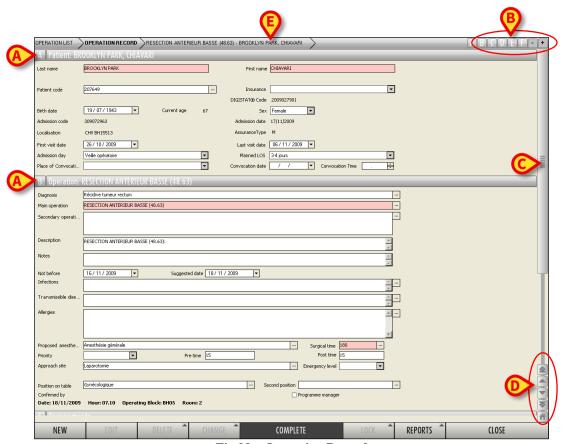


Fig 98 – Operation Record

10.1. Page structure

The page is divided into 5 sections.

Every section is identified by a letter and by a title indicating the type of information contained.

The five sections are:

- A. "Patient" section. This section contains information relating to the patient (name, last name, birthdate etc.).
- B. "Operation" section. This section contains information relating to the operation (type, duration, diagnosis etc.).
- C. "Requirements" section. This section contains information relating to the requirements necessary to the operation (necessary documents, medical examinations to be carried out etc.).

- D. "Planned Staff" section. This section contains information relating to the personnel who will be involved in the operation.
- E. "Special Services" section. This section contains information relating to any specific services or machinery required for the operation.
- F. "Materials". This section makes it possible to schedule the necessary materials required for the operation.

The sections are separated from each other by horizontal gray bars (Fig 98 A).

Click on one of the bars to close or open the section below (Fig 99).

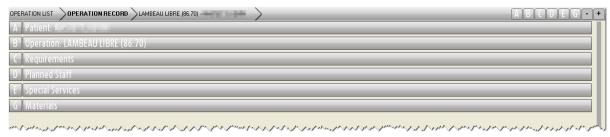


Fig 99 – "Closed" sections

Fig 99 shows a page where all the sections have been closed.

Click the bar again to reopen the section below (Fig 100).

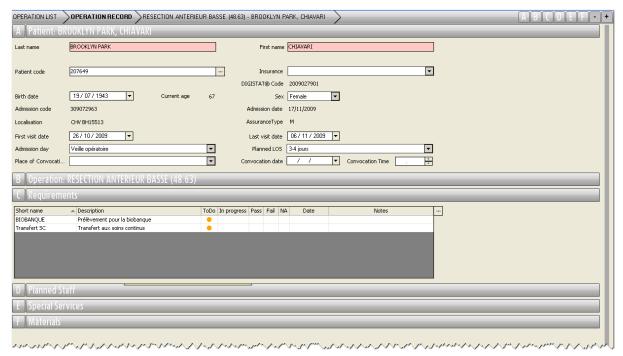
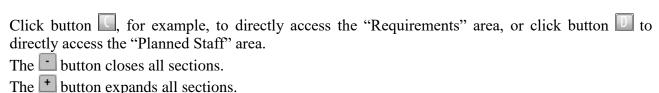


Fig 100 - "Patient" and "Requirements" areas

Fig 100 shows a page where only the "Patient" and "Requirements" sections have been reopened.

The buttons in the top right corner of the page (Fig 98 **B**, Fig 101) make it possible to directly access the different sections.





The bar on the right side of the screen makes it possible to scroll up and down the page (Fig 98 C).

The arrow buttons in the bottom right corner perform the same function (Fig 98 **D**).

The and buttons make it possible to move slowly up and down.

The and buttons make it possible to move quickly up and down.

The button makes it possible to return the beginning of the page.

The navigation bar in the top left corner of the page indicates the path followed to reach the current page, the type of operation envisaged and the patient's name. (Fig 98 E, Fig 102).



Fig 102 - Navigation Bar

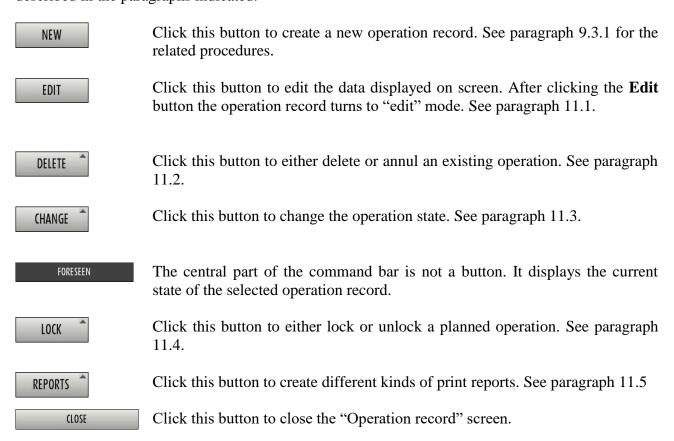
Fig 102 indicates we passed from the "Operation List" page to the "Operation Record" page of the patient and operation specified.

11. Operation Record: procedures and functionalities

The page control bar (Fig 98, Fig 103) contains various buttons which make it possible to perform various operations.



This paragraph lists briefly the main functionalities of each button. The related procedures are described in the paragraphs indicated.



11.1. How to edit the "Operation Record"

The **Edit** button (Fig 104) makes it possible to edit the page.



Fig 104 - Operation record screen command bar

Every time you decide to change something on the "Operation record" page, whether you wish to add information or change information already registered, it is necessary to click the **Edit** button.

When you click the **Edit** button, the control bar changes its appearance (Fig 105).



Fig 105 – Command bar in "Edit" mode

In Fig 105 you can see that:

- The **New** button is no longer active (so in this situation you cannot create a new record).
- The **Edit** button is selected (meaning that the screen is in "edit mode").
- The **Change** button is active (you can change the operation state or scheduling).
- The **Reports** button is no longer active.
- The Close button disappeared and was replaced by the two buttons Cancel and Update.

After making the changes required to the page, it is necessary to

> click the **Update** button to save the changes.

After that, the **Edit** button is deselected and the control bar returns to the appearance shown in Fig 103.

11.2. Deleting/annulling an operation record

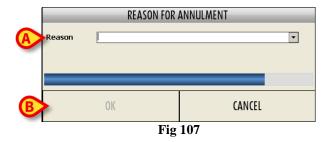
The **Delete** button opens a menu containing two options (Fig 106).



Fig 106

Annul - Use the "Annul" option (Fig 106 A) to annul the operation.

After clicking on "Annul" the following window opens, requesting to specify the annulment reason (Fig 107).



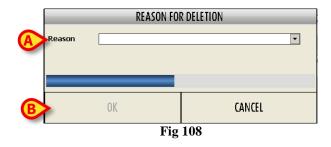
➤ Enter the reason for annulment in the "Reason" field (Fig 107 A).

Click **Ok** to annul the operation (Fig 107 **B**).

The selected operation is this way annulled. Annulling an operation is an irreversible administrative procedure indicating that the operation will not be managed in any way by any hospital Unit. The operation record will be stll visible in read-only mode as "Annulled operation".

Delete - Use the "Delete" option (Fig 106 **B**) to delete the operation.

After clicking on "Delete" the following window opens, requesting to specify the deletion reason (Fig 108).



- Enter the reason for deletion in the "Reason" field (Fig 108 A).
- Click **Ok** to delete the operation (Fig 108 **B**).

The selected operation record is this way deleted. Operation deletion permanently deletes the operation data. The "Operation record" disappears from the DIGISTAT® Smart Scheduler system. This procedure should only be used in case of wrong or double operation records.

11.3. Changing the operation state

The **Change** button makes it possible to change the operation state.

To change the operation state,

click the Edit button on the command bar (Fig 109).



The screen turns to "edit" mode. The command bar changes in the way shown in Fig 110.



Click the Change button

The menu shown in Fig 111 opens.



Fig 111 - "Change" button



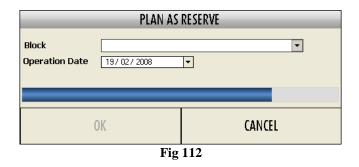
On the menu shown in Fig 111 the buttons can be either enabled or disabled depending on the state and the characteristics of the selected operation. Only the procedures that are coherent with the selected operation are enabled.

If the **Change** button is not active it is not possible to change the state of the selected operation.

• Plan as reserve (Fig 111 **A**).

The "Plan as reserve" option makes it possible to quickly manage the urgent operations. This option is enabled only if the highlighted operation is marked as "Emergency level I" and is not already scheduled. The emergency level is specified by the appropriate field on the "Operation record" screen (see Fig 161).

After clicking this option the system requests to specify the date and the block of the operation. The window shown in Fig 112 appears.



- > Specify the block and the date.
- Click Ok.

The operation will be directly scheduled as block reserve for the specified date and block. See paragraph 13.5.5 for an explanation of the meaning of the term "reserve" in the Smart Scheduler System

• Reschedule (Fig 111 **B**)

The "Reschedule" option makes it possible to change the selected operation schedule. This option is active only if the chosen operation is already planned. The procedure is described in paragraph 13.5.3.

• Schedule with help (Fig 111 C)

The "Schedule with help" option enables to access the "Shedule with help" screen to schedule the selected operation (Fig 279, see paragraph 13.7).

• Schedule (Fig 111 **D**)

The "Schedule" option enables to access the "Schedule" screen, making this way possible to schedule the operation (Fig 220, paragraph 13).

• Request (Fig 111 **E**)

The "Request" option changes the operation state to "Requested". See paragraph 7.2 for the description of the "Operation states".

• Foreseen (Fig 111 **F**)

The "Foreseen" option changes the operation state to "Foreseen". See paragraph 7.2 for the description of the "Operation states".

11.4. Locking/Unlocking the operation

The **Lock** button makes it possible to either lock or unlock a scheduled operation. A locked operation cannot be rescheduled.

Only the operations scheduled for either the current day or the future days can be locked. The operations scheduled for a day in the past and not yet executed cannot be locked. To lock/unlock an operation

click the **Edit** button on the command bar (Fig 113).



The screen turns to "edit" mode. The command bar changes in the way shown in Fig 114.



Click the **Lock** button (Fig 114).

The following menu opens (Fig 115).

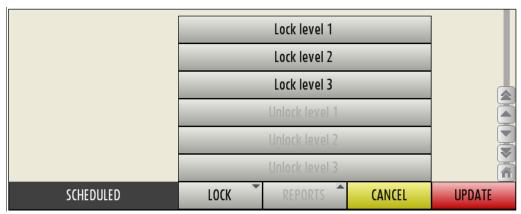


Fig 115 - Lock/Unlock operation

There are three possible lock/unlock levels. Each hospital decides - by configuration - how many lock/unlock levels to use (none, one, two, three). The menu shown in Fig 115 refers to a configuration enabling three lock levels. See paragraph 7.3 for a more detailed description of the lock/unlock functionalities.

Only certain "lock actions" are enabled for the logged user, depending both on the context and on his/her permissions level.

In Fig 115, for example, the user is enabled to lock an unlocked operation level 1,2 or 3.

> Click the wanted option on the menu.

The operation will be locked/unlocked at the corresponding level.

An icon on the top left corner of the "Operation record" signals that the operation is locked (Fig 116).



Fig 116 - Locked operation (Operation record screen)

11.5. Printing documentation

The **Reports** button on the command bar makes it possible to create a document which reports some of the information managed by the "Smart Scheduler" system.



Fig 117 - Operation record command bar

To create the document

> Click the **Reports** button (Fig 117).

Several options are available. Their number and nature depend on the specific configuration.

> Click the wanted option.

A print preview is displayed. See paragraph 6.8.1 for the system's print functionalities.

12. Operation Record: description of the different areas of the page

The "Operation Record" page is divided into five separate areas. We will analyze them one by one in this paragraph.



The fields highlighted in pink are required. It is not possible to proceed without specifying a value in these fields. The number and the kind of required fields changes according both to the configuration and to the specific procedures in use.



The "Operation record" screen is customizable, i.e. some fields can be either hidden or displayed by configuration. Therefore, the screens actually used in your structure can be slightly different from those displayed here.

12.1. The "Patient" area

The "Patient" area contains all the data regarding the selected patient.

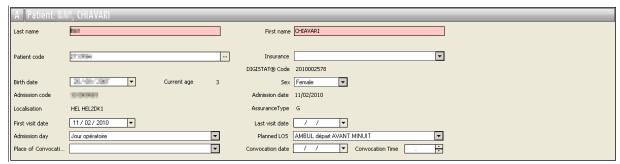


Fig 118 - The "Patient" area

This data is

- The last name and name.
- Temporary ID

The temporary ID is a code assigned to the patient in the absence of a final patient code.

• ID type

This field requests specification of the type of ID used to temporarily identify the patient.

• Patient code

This is the final patient code assigned when the patient is included in the structure's databases.

Insurance

This specifies the patient's type of insurance cover (if any).

• DIGISTAT® code

This is the code assigned by the DIGISTAT® systems when a new operation is created.

- Estimated weight
- Estimated height
- Birthdate
- Current age
- Sex
- Admission code
- Admission date
- Location
- Age when operated
- Room number
- Assurance type
- First visit date
- Last visit date

1

Every time you have to enter a date it is possible, clicking the \square arrow next to the field, to enter it using a digital calendar (Fig 120)



Fig 119 – Digital calendar

To enter the date, simply click the day required. The corresponding date will automatically appear in the field. Paragraph 9.1.2 describes the digital calendar in detail.

- Admission day
- Envisaged duration of hospitalization (Planned LOS).
- Place of convocation
- Convocation date
- Convocation time



Remember that, to make any change, <u>before making the change</u> you must click the **Edit** button on the command bar.

After making the change, either click the **Update** button to save the new data or click the **Cancel** button to return to the data prior to the change.

12.2. The "Operation" area

The "Operation" area displays the information concerning the operation to be performed (Fig 120).

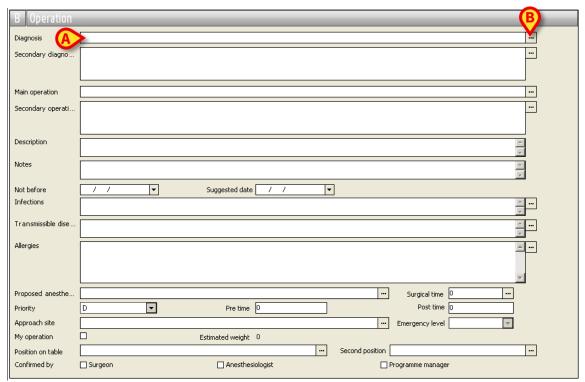


Fig 120 - "Operation" Area

The following paragraphs describe the procedures related to the operation data specification.

12.2.1. Diagnosis

The "Diagnosis" field makes it possible to specify diagnostic codes according to the most common standards. There are three possible ways of selecting the diagnosis. The one actually used depends on the configuration chosen. All these three methods are described in the following paragraphs. Only one is relevant for the system in use in your structure.

A fourth possibility makes use of the "Free field" and "DIGISTAT® Codefinder" options at the same time.

12.2.1.1. Free field

The "Diagnosis" field can be a free field, i. e. an area in which the appropriate text can be freely typed. In this case, to specify the diagnosis, a user can simply click the field and then type the text.

12.2.1.2. DIGISTAT® Codefinder

The DIGISTAT® "Codefinder" software can be used to directly insert the diagnostic codes according to the most common standards. This functionality can be activated by configuration. To use DIGISTAT® "Codefinder":

- > Click the **Edit** button on the command bar.
- Click the button placed alongside the "Diagnosis" field (Fig 120 B).

The following window opens (Fig 121).

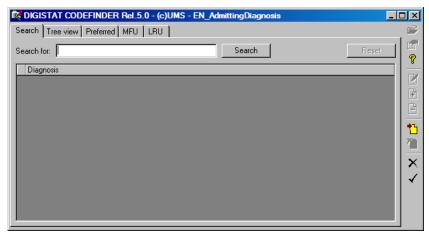


Fig 121 - Codefinder

This tool makes it possible to rapidly search and select the wanted diagnostiuc codes. All procedures and functionalities are described in the user manual, provided with the product. See the DIGISTAT® "Codefinder" user manual to know these procedures and functionalities.

Once the diagnosis is specified, to save the data entered,

> click the **Update** button on the command bar.



By configuration, the "Free field" and DIGISTAT® "Codefinder" procedures can be used together.

12.2.1.3. DIGISTAT® selection window

The diagnosis can be insrted using a specific DIGISTAT® search and selection window.

To activate this tool

> Click the **Edit** button on the command bar.

Data entry is this way enabled.

Enter the first letters of the operation required in the "Diagnosis" field (Fig 120 A).

Otherwise

> click the button placed alongside the "Diagnosis" field (Fig 120 **B**).

In both cases the "Diagnosis" window is displayed (Fig 122).

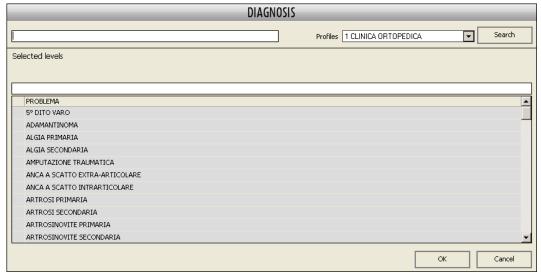


Fig 122

This window makes it possible to search the diagnosis coded according to DIGISTAT® parameters.

12.2.1.4. DIGISTAT® diagnosis search and selection

There are two ways to search for a diagnosis: one requires the specification of the diagnosis name (or part of it), one makes it possible to get to the right diagnosis by selecting the appropriate levels on a tree-structure. Both methods are described in the following paragraphs.

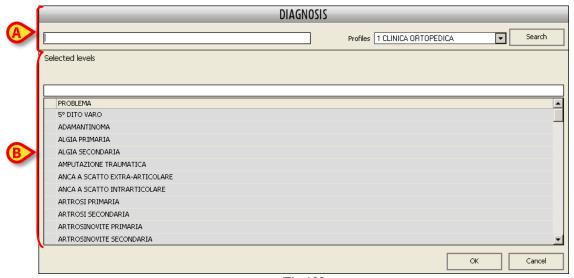


Fig 123

1) Search by name

The upper part of the window (indicated in Fig 123 A and displayed in Fig 124) can be used to search the diagnosis by name.

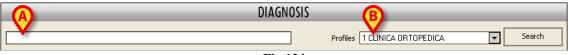


Fig 124

There are two fields in this area. The field on the left (Fig 124 **A**) makes it possible to specify the name (or part of it) of the wanted diagnosis; the field on the right (Fig 124 **B**) is a drop down menu making it possible to specify the relevant hospital area. If no area is selected the search is performed on all areas. Each user is enabled to search only the areas for which he/she is qualified.

To perform the search

- 1. Insert the name (or part of the name) of the diagnosis in the field indicated in Fig 125 A.
- 2. Either wait for the system to automatically search, or click the **Search** button (Fig 125 **B**).

All the diagnosis whose name contains the typed charcters are displayed (Fig 125 C).

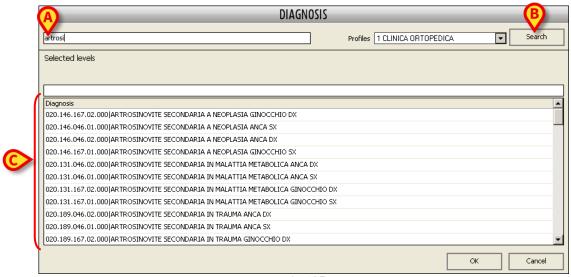


Fig 125

3. Double click the row containing the relevant diagnosis.

The diagnosis is this way inserted in the "Operation record", in the "Operation" area (Fig 126).



Fig 126

4. Click the **Update** button on the command bar.

2) Search by structured levels

The lower part of the window (indicated in Fig 123 **B** and enlarged in Fig 127) can be used to search the diagnosis by selecting successive levels on a tree-structure.

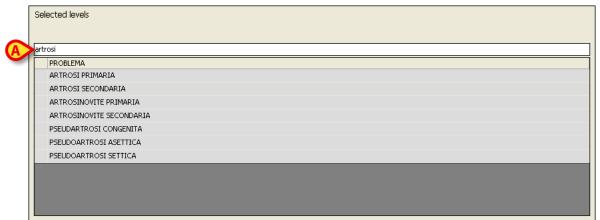


Fig 127

The first level concerns the diagnosis' general area of reference. The filter indicated in Fig 127 A can be used to search for the wanted area of reference. In the figure, as example, the word "artrosi" has been specified in the filter. All the areas containing the specified word are displayed in the lower part of the window.

1. Double click the row corresponding to the wanted area. "Artrosi secondaria" is now selected.

The next level is displayed, making it possible to indicate the cause (Fig 128).

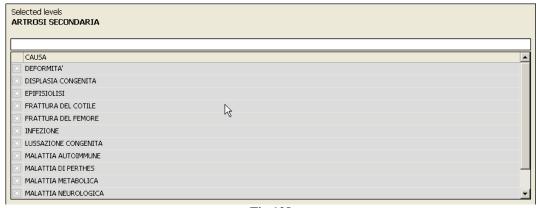


Fig 128

2. Double click the wanted cause. "Malattia metabolica" is now selected.

The next level is displayed, making it possible to indicate the site (Fig 129).

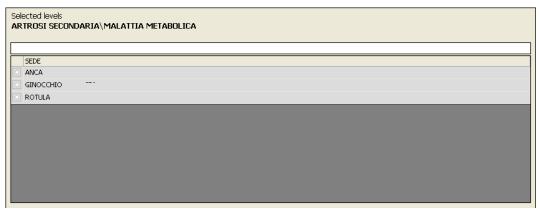


Fig 129

3. Double click the wanted site. "Anca" is now selected.

The next level is displayed, making it possible to indicate the side (Fig 130).



Fig 130

4. Double click the wanted side. The left side "SX" is now selected.

The next level is displayed, making it possible to indicate the level (Fig 131).

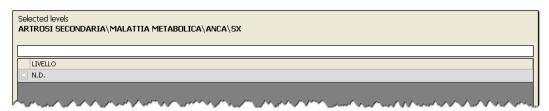


Fig 131

5. Double click the wanted level. In this case the only option is "non-determined" (N.D.).

Information for the user.



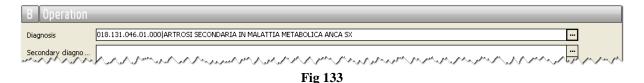
"Non Determined" means that the information is not relevant for the diagnosis specification. In other words: the value of this level is not part of the definition of the diagnosis to be specified.

The diagnosis is now displayed (Fig 132).



Fig 132

6. Double click the diagnosis. The diagnosis is this way inserted in the "Operation record", in the "Operation" area (Fig 133).



7. Click the **Update** button on the command bar.

The button is available on the selection window, on each level and for each row, to make it possible to go back to the previous level (Fig 134 A). The chosen path is indicated in the "Selected levels" area (Fig 134 B).

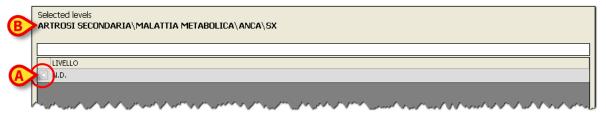


Fig 134

12.2.2. Secondary diagnosis

If the diagnosis selection modality is the one described in paragraph 12.2.1.4 (by DIGISTAT® selection window) another field activates, making it possible to specify the secondary diagnosis.

To specify the secondary diagnosis, after main diagnosis specification,

- 1. Click the **Edit** button on the command bar.
- 2. Click the button placed alongside the "Secondary diagnosis" field (Fig 135 A).

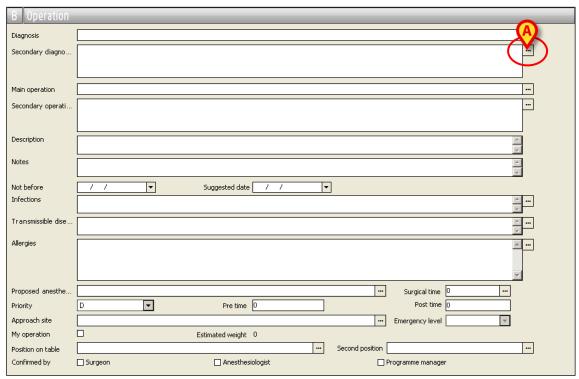


Fig 135

The following window opens (Fig 136).

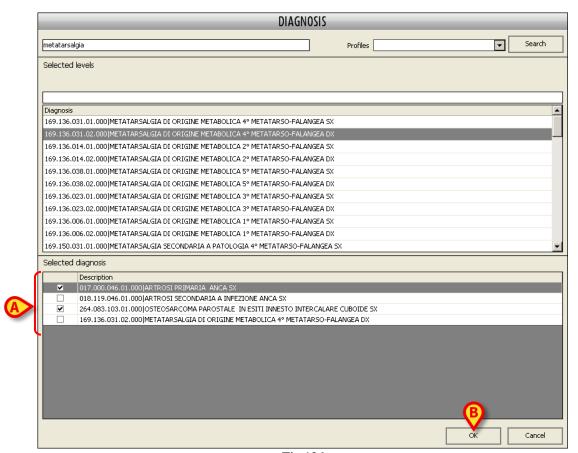


Fig 136

The procedures relating to the secondary diagnosis specification are similar to those relating to the main diagnosis specification. Therefore, see paragraph 12.2.1 for these procedures.

There is a difference: the secondary diagnosis can be more than one, and they can be specified all at the same time. For this reason, when one diagnosis is selected (by double-clicking the corresponding row), the diagnosis is not directly inserted in the "Operation record", but is inserted in a list displayed below the selection window. The list is indicated in Fig $136 \, A$.

On this list, a checkbox is placed at the beginning of each row.

To select the diagnosis that will be inserted as secondary diagnosis

- 1. Click the checkbox corresponding to the diagnosis to be inserted.
- 2. Click the **Ok** button (Fig 136 **B**).

All the "checked" diagnosis are this way inserted on the "Operation record" (Fig 137).



Fig 137

3. Click the **Update** button on the command bar.

12.2.3. Main Operation

The "Main operation" field makes it possible to specify the name of the operation to be performed.



The "Main operation" field, together with the patient's data (name, last name and patient code) and the envisaged duration of the operation, is required to change the operation state from "foreseen" to "requested".

To specify the main operation

> click the **Edit** button on the command bar.

Data entry is this way enabled.

Enter the first letters of the operation required in the "Main operation" field (Fig 120 A).

Otherwise

> click the button next to the field (Fig 120 **B**).

The "Operations" window opens (Fig 138).

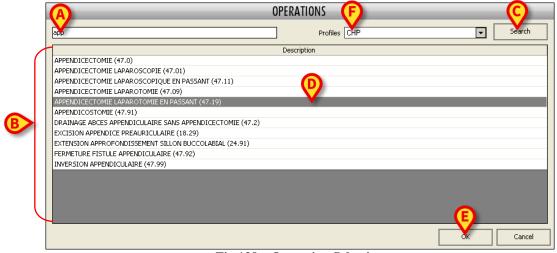


Fig 138 – Operation Selection

The "operations" window makes it possible to search for and select the operation required.

To search for the operation

Enter the name (or part of it) of the operation in the space indicated in Fig 138 A.

From the third letter entered onwards, the system will automatically display in the middle of the window the list of all the operations with names containing the sequence of letters entered. The list appears inside the "description" area (Fig 138 **B**).

If only one or two letters are entered and you wish to proceed with the search, you must click the **Search** button (Fig 138 **C**).

If you click the **Search** button without entering any letters, the list of all possible operations will appear.

After finding the operation to be entered, click it.

The operation will appear as selected (Fig 138 **D**).

> Then click the **Ok** button (Fig 138 **E**).

The operation selected appears inside the "Main operation" field of the "Operation Record" page (Fig 139). This result is also obtained by double clicking the name of the operation to be entered.



If you click the Cancel button, the "Operations" window closes without any changes being made.

The "profiles" field (Fig 138 **F**) in the operation entry window makes it possible to limit the group of operations in which the search is performed.

Click the button alongside the "profiles" field to open a menu containing different options (Fig 140). Each one usually specifies a location or an area of responsibility. Select one of these options to limit the search to the group of operations performed in that location or that area.

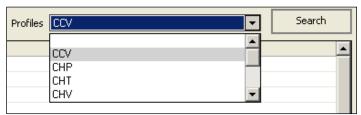


Fig 140 – Profile Selection



The profiles are defined during configuration. You can create a specific profile for the user so that he/she can view only the operations for which he/she is responsible. For further information, contact the system administrator.

In short, the procedure to enter an operation in the "Main operation" field of the "Operation Record" page is the following.

- Click the Edit button on the command bar.
- Enter the first letters of the operation required in the search field (Fig 120 A)

or

Click the button next to the field (Fig 120 B).

The "Operations" window opens (Fig 138).

- > Search for the operation required.
- > Double click the name of the operation found.

The operations window disappears and the name of the operation is displayed inside the "Main operation" field (Fig 139).

Click the **Update** button on the command bar to save the data.

12.2.3.1. Select an operation linked to the diagnosis

A configuration parameter makes it possible to link the operation search to the diagnosis previously selected. If enabled by configuration, a checkbox named "Based on selected diagnosis" is displayed on the operation search and selection window (Fig 141).

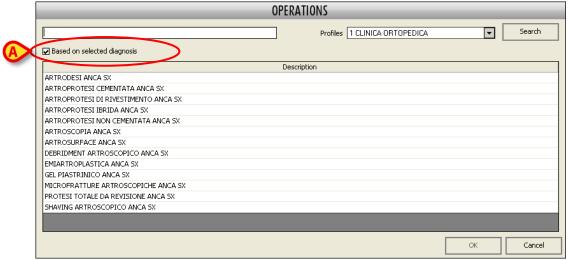


Fig 141

When the box is checked only the operations linked to the selected diagnosis (visible in the "Diagnosis" field) are displayed on the operations search and selection window.



This option is only available if the main diagnosis selection is performed on the DIGISTAT® search and selection window, described in paragraph 12.2.1.4. In this case the main operation selection can be performed only after diagnosis has been selected.

12.2.4. Secondary operations

The "Secondary operations" field (Fig 142) specifies the list of any other operations that the patient has had or will have to have and are considered significant in relation to the current operation.

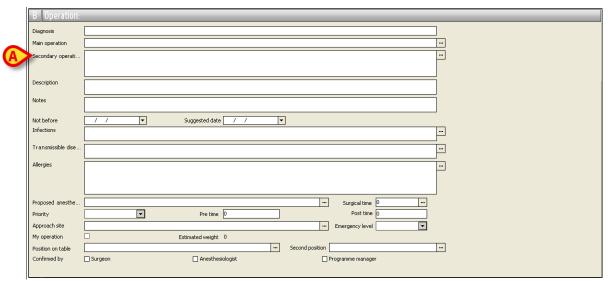


Fig 142 - "Operation" Area

The function of this field is exactly the same as that of the "Main operation" field and described in paragraph 12.2.3.

To specify the possible "Secondary operations",

> click the **Edit** button on the command bar.

Data entry is this way enabled.

Enter the first letters of the operation required in the "Secondary operations" field.

Otherwise

> click the button next to the field.

The "Operations" window opens (Fig 143).

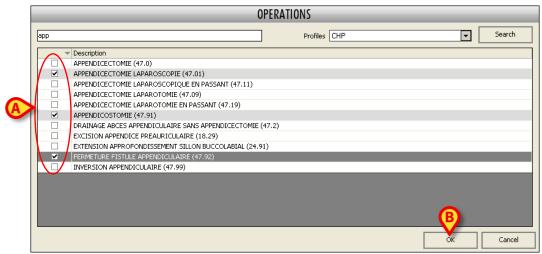


Fig 143 – Other Operations

The window shown in Fig 143 offers the chance to select and enter more than one operation at the same time.

Then click the **Ok** button (Fig 143 **B**) to enter all the operations selected in the "Secondary operations" field of the "Operation Record" page.

12.2.5. Description

This field makes it possible to enter a more detailed description of the operation to be performed. It is a free field, meaning that it is not conditioned by pre-defined selections.

12.2.6. Notes

This field makes it possible to enter any notes relating to the operation to be performed. It is a free field, meaning that it is not conditioned by pre-defined selections.

12.2.7. Not before...

This field makes it possible to enter a date before which it is not possible to perform the operation. This value is binding to the value to be entered into the next field "Suggested date". If the date 20/05/2010 is entered into the "Not before..." field, it is not possible to enter an earlier date in the "Suggested date" field".

The value is not binding in relation to the scheduling of the operation. This means that the operation can be scheduled for a date before that specified here. In this case the system will warn the user that the scheduling contrasts with that specified previously.

12.2.8. Suggested date

This field makes it possible to indicate a date as being the best for performing the operation. The suggestion need not necessarily be observed during scheduling; i.e., the date entered is not binding in relation to the scheduling of the operation. This date is, however, binding in relation to the value to be entered into the "Not before..." field. For instance, if the date 20/05/2010 is entered into the

"Suggested date" field without entering a value into the "Not before..." field, the latter field assumes the date in the "Suggested date" field (20/05/2010 in this case) as default.

i

Every time you have to enter a date it is possible, clicking the \square arrow next to the field, to enter it using a digital calendar.



Fig 144 - Digital calendar

To enter the date simply click the day required. The corresponding date will automatically appear in the field. Paragraph 9.1.2 describes the digital calendar in detail.

12.2.9. Infections

The "Infections" field makes it possible to specify any possible infections.

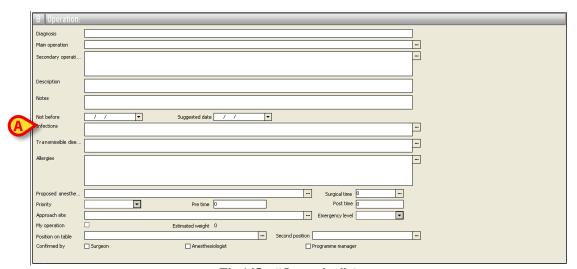


Fig 145 - "Operation" Area

To enter an infection

- > click the **Edit** button on the command bar.
- Enter the first letters of the infection being searched for in the "infections" field.

Otherwise

> click the button next to the field.

The "Infections" window will appear (Fig 146).



Fig 146 – Specify Infections

- > Search, if necessary, the wanted item using the search field on the window (Fig 146 A).
- Click the checkbox corresponding to the infections that must be specified (Fig 146 **B**).

Multiple selection is possible.

Click the **Ok** button (Fig 146 **C**) to display all the selected infections on the "Operation record" screen.

The "Infections" window offers the chance to manually enter an infection not contained in the database.

This is possible using the "other" field (Fig 146 **D**).

To enter an infection not contained in the database, simply write the name of the infection in the field and click Ok.

The name appears inside the "Infections" field of the "Operation Record" page.

When you enter an infection, the system can be configured to automatically add a certain amount of time to the estimated time required to clean the room (Fig 147). The actual duration is specified by configuration.

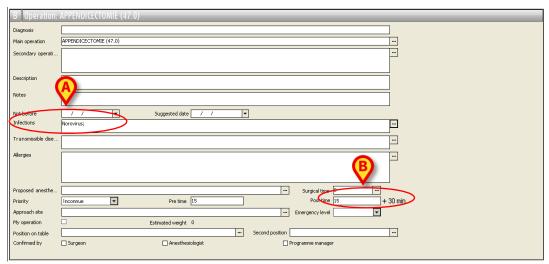


Fig 147 – Infection in progress and cleaning times

12.2.10. Transmissible diseases

The "Transmissible diseases" field makes it possible to specify any transmissible diseases suffered by the patient.

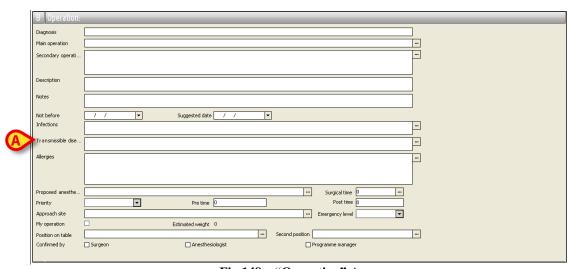


Fig 148 – "Operation" Area

To specify a transmissible disease

- > click the **Edit** button on the command bar.
- ➤ Enter the first letters of the transmissible disease being searched for in the "Transmissible diseases" field.

Otherwise

> click the button next to the field.

The "Transmissible diseases" window appears (Fig 149).

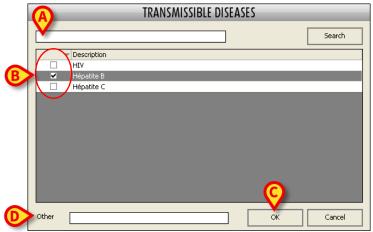


Fig 149 – Specify transmissible diseases

- > Search, if necessary, the wanted item using the search field on the window (Fig 149 A).
- Click the checkbox corresponding to the diseases that must be specified (Fig 149 **B**).

Multiple selection is possible.

Click the **Ok** button (Fig 149 C) to display all the selected diseases on the "Operation record" screen.

The "Transmissible diseases" window offers the chance to manually enter a disease not contained in the database.

This is possible using the "other" field (Fig 149 **D**).

To enter a disease not contained in the database, simply write the name of the disease in the field and click **Ok**.

The name is displayed in the "Transmissible diseases" field of the "Operation Record" page.

When you enter a disease, the system can be configured to automatically add a certain amount of time to the estimated time required to clean the room (Fig 147). The actual duration is specified by configuration.

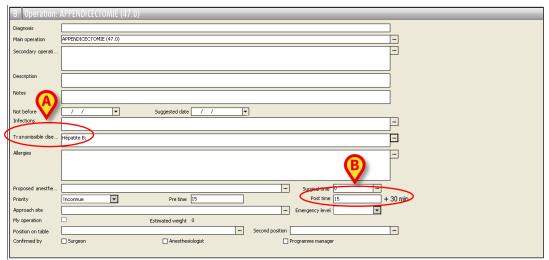


Fig 150 – Transmissible diseases and cleaning times

12.2.11. Allergies

The "Allergies" field (Fig 151 A) makes it possible to specify any allergies suffered by the patient.

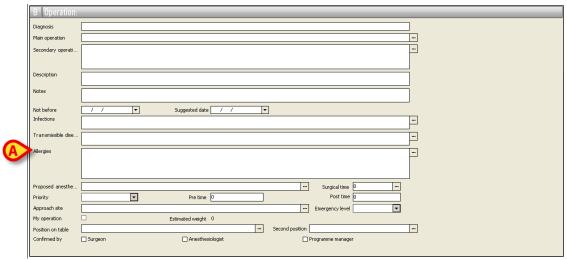


Fig 151 - "Operation" Area

To specify an allergy

- > click the **Edit** button on the command bar.
- Enter the first letters of the allergy being searched for in the "Allergies" field.

Otherwise

> click the button next to the field.

The "Allergies" window opens (Fig 152).



Fig 152 – Specify Allergies

To specify an allergy,

> click the box alongside the name of the allergy selected (Fig 152 A).

Multiple selection is possible. All the selected items are inserted in the "Operation record" screen.

Click the "Reaction" column on the row corresponding to the selected allergy to specify the kind of allergic reaction (if so configured, the kind of allergic reaction can be selected on a list of predefined options - Fig 152 **B**).

Click the "note" column for the allergy selected to enter any notes concerning the allergy selected (Fig $152 \, \mathbb{C}$).

➤ Click the **Ok** button (Fig 152 **D**) to enter all the allergies selected in the "Allergies" field of the "Operation Record" page.

The icon 4, which may appear alongside the field, highlights the presence of notes relating to the allergies entered (Fig 153).



Fig 153 - Allergy Notes

12.2.12. Proposed Anesthesia

The "Proposed Anesthesia" field (Fig 154 A) makes it possible to specify the type of anesthesia proposed for the operation.

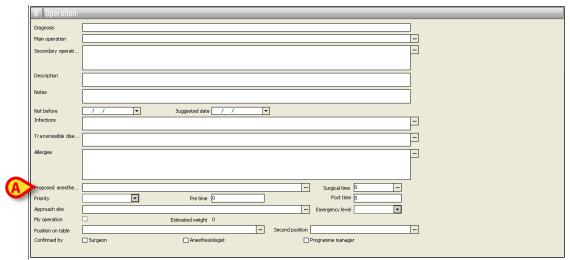


Fig 154 - "Operation" Area

To specify a type of anesthesia

- > click the **Edit** button on the command bar.
- Enter the first letters of the anesthesia being searched for in the "Proposed anesthesia" field.

Otherwise

> click the button placed next to the field.

The "Anesthesia" window opens (Fig 155).



Fig 155 – Specify Anesthesia

> Search, if necessary, the wanted item using the search field on the window (Fig 155 A).

Click the checkbox corresponding to the anesthesia that must be specified (Fig 155 **B**).

Multiple selection is possible.

Click the **Ok** button (Fig 155 **C**) to display all the selected anesthesias on the "Operation record" screen.

The "Anesthesia" window offers the chance to manually enter an anesthesia not contained in the database.

This is possible using the "Other" field (Fig 155 **D**).

To enter an anesthesia not contained in the database, simply write the name of the anesthesia in the field and click Ok.

The name appears inside the "Proposed anesthesia" field of the "Operation Record" page.

12.2.13. Surgical time

The "Surgical time" field (Fig 156 A) makes it possible to specify the envisaged duration of the operation.



The "Surgical time" field, together with the patient's main data (name, last name and patient code) and the type of operation envisaged, is required to change the operation state from "foreseen" to "requested".

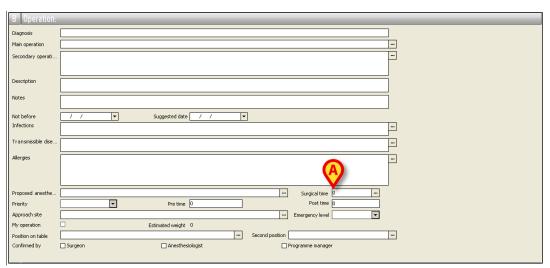


Fig 156 - "Operation" area

To specify the surgical time:

- > click the **Edit** button on the command bar.
- Insert the duration (in minutes) in the "Surgical time" field.

Otherwise

> click the button placed near the field.

In both cases the "Surgical time" window appears (Fig 157).

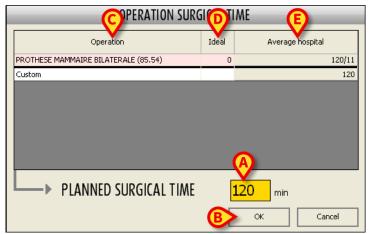


Fig 157 – Expected surgical time specification

- Insert the value (in minutes) in the field indicated in Fig 157 A.
- Click the **Ok** button (Fig 157 **B**).

The specified duration appears in the "Surgical time" field on the "Operation record" screen.

The central part of the window can display, if specified by configuration, three different kinds of information.

The "Operation" column (Fig 157 C) displays the envisaged operation name.

The "Ideal" column (Fig 157 **D**) displays the optimal duration for that kind of operation.

The "Average hospital" column (Fig 157 **E**) displays the average duration for that kind of operation in the form "average/number of operations on which the average is calculated". For example: "45/8" means that hospital average duration is 45 minutes calculated on 8 operations of the same kind.

If there are secondary operations specified the average duration of each of them is displayed separately.

The "Ideal" and "Average" values can be double-clicked to be inserted as surgical time on the "Operation record".

i

The expected duration of the operation influences the operation scheduling possibilities. Every operation can be scheduled in relation to the expected duration. On the "Operation Scheduling" pages, analyzed in detail in paragraph 13, the operations are displayed as boxes (Fig 226) and the length of the boxes is proportional to the duration of the operation.

12.2.14. Priority

The "priority" field makes it possible to specify the level of priority assigned to the operation. The levels of priority are established during configuration according to the user's requirements. The example shown allows for 4 possibilities (Fig 158):

- 1) Unknown priority;
- 2) Normal priority;
- 3) High priority;
- 4) Very high priority.



Fig 158 - Priority



The fields "prority" and "emergency level" are mutually exclusive, i.e. when the the "priority" is specified the "emergency level" field is disabled and vice versa.

12.2.15. Pre - time

The "Pre time" field ("pre surgical time") makes it possible to specify the estimated time required to prepare the room for the operation. To enter this value, simply type it into the field. The time entered is added to the operation duration when it is scheduled. It will be displayed on the "Schedule Operation" screen (paragraph 13) as a gray portion (see Fig 229). In the configuration here described the default pre surgical time is 15 minutes.

12.2.16. Post - time

The "Post time" field ("post surgical time") makes it possible to specify the estimated time required to make the room ready again after the operation. In the configuration shown in the example, the system assigns a default post surgical time of 15 minutes. To enter a different value, simply type it into the field. The time entered is added to the operation duration when it is scheduled. It will be displayed on the "Schedule Operation" screen (paragraph 13) as a grey portion (see Fig 229).

12.2.17. Approach site

The "Approach site" field makes it possible to specify the approach mode to the patient.

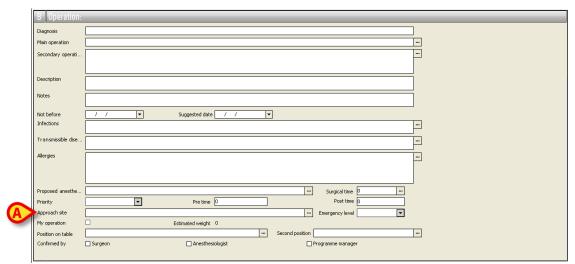


Fig 159 - "Operation" area

To specify an approach mode

- > click the **Edit** button on the command bar.
- Enter the first letters of the kind of approach being searched for in the "Approach site" field.

Otherwise

> click the button placed next to the field.

The "Approach site" window appears (Fig 160).

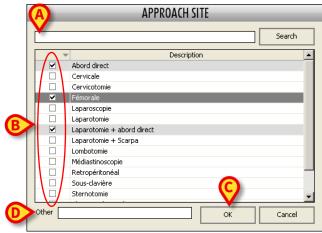


Fig 160 – Approach site

- > Search, if necessary, the wanted item using the search field on the window (Fig 160 A).
- Click the checkbox corresponding to the approach that must be specified (Fig 160 B).

Multiple selection is possible.

➤ Click the **Ok** button (Fig 160 **C**) to display all the selected approaches on the "Operation record" screen.

The "Approach site" window offers the chance to manually enter an approach mode not contained in the database. This is possible using the "Other" field (Fig 160 **D**).

To enter an approach mode not contained in the database, write the name of the approach mode in the field and click Ok.

The name appears inside the "Approach site" field of the "Operation Record" page.

12.2.18. Emergency level

The "Emergency level" field (Fig 162 A) makes it possible to specify the urgency of an operation.

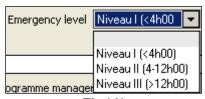


Fig 161

When an emergency level is assigned (any level in the configuration here described) it is possible to directly schedule the operation as a day reserve; i.e. the "Plan as reserve" option in the **Change** menu of the control bar is activated (Fig 162 **B**). See paragraph 13.5.5 for an explanation of the meaning of "reserve" in the Smart Scheduler system.



Fig 162

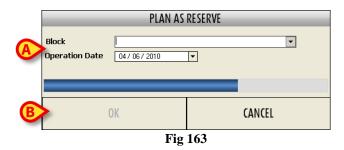
To plan the operation as reserve

Click the **Change** button on the command bar (Fig 162 **B**).

The menu shown in Fig 162 will open

> click the "Plan as reserve" option (Fig 162 C).

The window shown in Fig 163 will open.



- > Specify the operating block and the operation date in the appropriate fields (Fig 163 A).
- Click Ok.

The operation will be scheduled as reserve for the specified date and block. The operation state will change to "Scheduled"

When an operation is indicated as "Emergency" (any level), the corresponding rectangle in the graphic representation of the "Schedule" module is bordered in red (Fig 164). See paragraph 13 for the scheduling procedure.



Fig 164



The fields "priority" and "emergency level" are mutually exclusive, i.e. when the the "priority" is specified the "emergency level" field is disabled and vice versa.

12.2.19. My operation

The "My operation" checkbox makes it possible to enter the operation in the user's personal list of operations. A user having the required permissions level (this option is usually granted to surgeons) can check this box to limit the visibility of the operation. The operation this way checked is (and will be) only visible to the user who is creating or editing it.

This option is only available if the operation is in "Foreseen" state. In the moment it turns to "Requested" state, the operation becomes visible to all users.

This option is linked to the "My operations" field of the "Operation list" page (see paragraph 9.1.1). When performing a search, select this field to display the list of operations that are only visible to the user currently logged, i.e. the list of operations for which the "My operation" checkbox was selected.

12.2.20. Estimated weight

The "Estimated weight" field shows the patient's weight. This field cannot be directly edited. The "estimated weight" value is entered in the "patient" area of the page. See paragraph 12.1

12.2.21. Position on the operating table

The "Position on table" field makes it possible to specify the patient's position on the operating table.

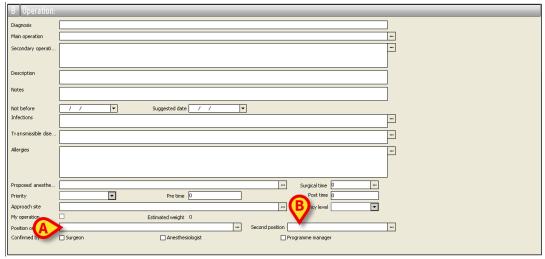


Fig 165 - "Operation" area

To specify a position

- > click the **Edit** button on the command bar.
- Enter the first letters of the position being searched for in the "Position on table" field.

Otherwise

> click the button placed next to the field.

In both cases the "Position on table" window appears (Fig 166).

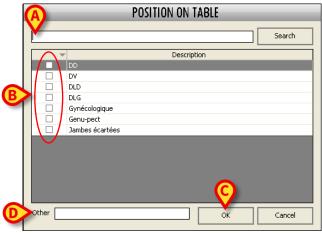


Fig 166 – Position on Table

- > Search, if necessary, the wanted item using the search field on the window (Fig 166 A).
- Click the checkbox corresponding to the position that must be specified (Fig 166 **B**).

Multiple selection is possible.

➤ Click the **Ok** button (Fig 166 **C**) to display all the selected positions on the "Operation record" screen.

The "Position on table" window offers the chance to manually enter a position not contained in the database.

This is possible using the "Other" field (Fig 166 **D**).

To enter an a position not contained in the database, simply write the name of the position in the field and click Ok.

The name appears inside the "Position on table" field of the "Operation Record" page.

12.2.22. Second position

Use the "Second position" field to specify a possible second position for the patient during the operation. The "Second position" specification procedure is identical to that described in paragraph 12.2.21 for the "Position on table" specification.

12.2.23. Confirmed by...

This field makes it possible to specify whether or not confirmation to proceed with the operation has been given by the

- 1) Surgeon
- 2) Anesthesiologist
- 3) Program Manager

To specify that confirmation has been given, select the checkbox corresponding to the person who has given confirmation.

12.2.24. Operation schedule summary

After the operation has been scheduled, the "operation" area shows, at the bottom, the date, time, room and block established (Fig 167).



Fig 167

12.3. The "Requirements" area

The "Requirements" area makes it possible to specify and manage the patient's requirements necessary to the performance of the operation (Fig 168).

A "requirement" is any document necessary to the progress of the operation procedure (e.g.: the result of a medical examination or patient consent form).

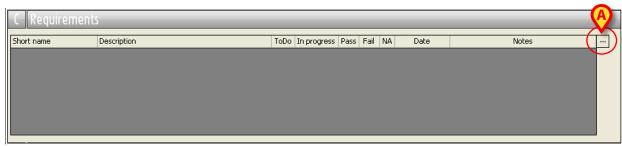


Fig 168 - "Requirements" Area

To enter a new requirement

- Click the **Edit** button on the command bar of the "Operation Record" page.
- ➤ Click the button alongside the "Requirements" table (Fig 168 A).

The following window opens.



Fig 169 – Enter Requirement

The central part of the window contains the list of possible requirements. The area is split into three columns. The first contains the selection boxes (Fig 169 A). Click a box to select the corresponding requirement; you can select more than one requirement at a time. The second column contains the

abbreviated name of the requirement (Fig 169 **B**). The third column contains a more detailed description of the requirement in question (Fig 169 **C**).

Click the button alongside the "type" field to open a menu which makes it possible to indicate the type of requirement being searched for. A "Hospital Unit" filter is also available (Fig 169 **D**). The requirements list displayed is linked to the hospital unit, i.e. the number and kind of requirements displayed depend on the hospital unit selected.

To enter the requirements desired

- > Select the corresponding box (Fig 169 A).
- ➤ Click the **Ok** button (Fig 169 **E**).

The requirements selected appear on the "Operation Record" page (Fig 170).

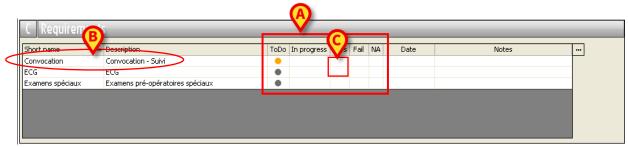


Fig 170 – Requirements Table

The "Requirements" table (Fig 170) makes it possible to display various kinds of information concerning the state of the acquisition process of every requirement.

The first two columns of the table contain the abbreviated name and the description of the requirement.

The columns indicated in Fig 170 A show the position of the requirement in the acquisition process.

The way the icon looks (shape and colour) provides additional information.

The • icon indicates that the requirement should have been obtained in one of the previous states.

The • icon indicates that the requirement should have been obtained in the state preceding current state.

The icon indicates that the requirement must be obtained in the current state.

The option indicates that the requirement will have to be obtained in a subsequent state.

The **o** indicates that the requirement has been properly obtained.

The option indicates that the process for obtaining the requirement has failed (e.g., a test has resulted negative or a patient consent form has not been signed).

The original icon indicates that no information is available for the particular requirement concerned.

i

Remember that the term "state" indicates the state of the operation (see paragraph 7.2 for a description of possible states). So, for example, if the operation has "scheduled" state, the "previous state" is the "requested" state, while if the operation has "requested" state, the previous state is the "foreseen" state.

Every icon is in a specific column of the "Requirements" table

The "To Do" column will contain the •, • or • icons, depending on whether or not the requirement has to be obtained in the current state, should have been obtained in a previous state or must be obtained in a subsequent state.

The "In Progress" column will contain the •, • or • depending on whether or not the requirement has to be obtained in the current state, should have been obtained in a previous state or must be obtained in a subsequent state.

The "Requirement Pass" column will contain the o icon if the requirement has been properly obtained.

The "Requirement Fail" column will contain the of if the process the obtain the requirement has failed.

The "N/A" column will contain the o icon if no data is available for the requirement indicated.

To indicate a change in a requirement acquisition process (e.g., to indicate the acquisition of the requirement in question), simply click the corresponding box.

If, for example, you wish to indicate that the "Convocation" requirement (Fig 170 **B**) has been obtained, simply click the box indicated in Fig 170 **C**.

The table will change as shown below.

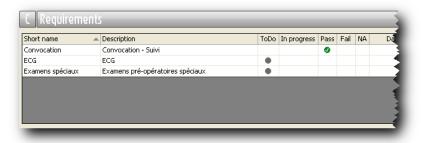


Fig 171 – Requirement Obtained

The "Date" column makes it possible to indicate the date on which a requirement was obtained or the date on which the acquisition process failed.

The "Notes" column makes it possible to enter any notes on the requirement in question.

To enter a note or a date, simply click the corresponding box.

You can add or remove a requirement from the list by right clicking. Right click the "requirements" area to open the menu shown in Fig 172.

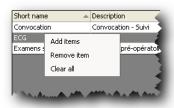


Fig 172

Click "Add items" to open the window shown in Fig 169 and add new requirements.

Click "Remove item" to remove an item selected from the list of requirements

Click "Clear all" to clear all items from the list of requirements.

To display a window providing information on one of the requirements on the list, pass the mouse pointer on the item (Fig 173).

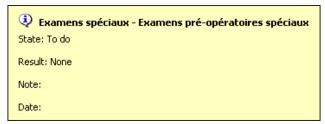


Fig 173 - Requirement information

12.4. The "Planned staff" area

The "Planned Staff" area" (Fig 174) makes it possible to indicate the staff required for the operation, stating both their "roles" (surgeon, anesthesiologist etc.) and their identities (specific names and last names).

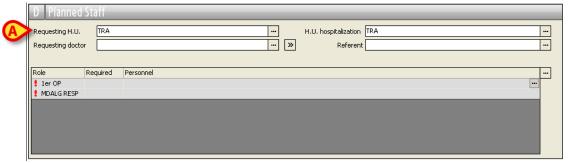


Fig 174 – Planned Staff

To select the staff, you must first specify the hospital unit requesting the operation.

To specify the requesting hospital unit

Click the **Edit** button on the command bar of the "Operation Record" page.

Enter the first letters of the name of the requesting unit in the "Requesting H.U." field (Fig 174 A).

Or

> click the button alongside the "Requesting H.U." field.

The following window opens (Fig 175).

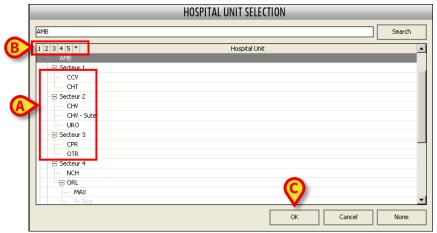


Fig 175 – Hospital unit selection

The central part of the window reflects the organization of the hospital structure where you are operating. This means that the various locations, blocks or areas of the hospital are specified. These are shown as a tree structure which highlights their inclusion relationships. The area shown in Fig 175 A indicates that Sector 2 includes the two locations called CHV and URO and that Sector 3 includes the locations called CPR and OTR; both sectors are included in a structure called AMB. To indicate the position occupied by an item on the list in the tree structure, we say that the specific item is at a specific level. In the figure, for example, level 1 indicates the whole hospital, level 2 indicates the sub-units of the hospital, level 3 indicates the sub-units of these sub-units, and so on. The sectors in the figure shown are at level 4, and the locations included in them are at level 5.

The buttons in the top left corner (Fig 175 \mathbf{B}) make it possible to display only items of the level specified by the button (and those of lower levels).

To select one of the items on the page, simply double click it, or click it and then press the **Ok** button (Fig 175 **C**).



Every user, depending on the permissions held, will be permitted to select only the locations for which he/she is responsible. The permissions of every user are specified during configuration by the system administrator.

The "hospital unit selection" window makes it possible to search for the item required. To do so, simply enter the first letters of the name of the item being searched for in the search field (Fig 176 **A**) then click the **Search** button (Fig 176 **B**).

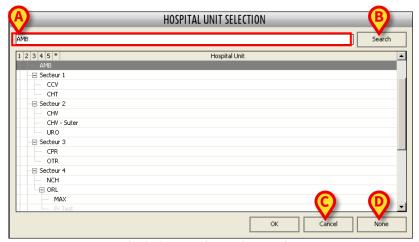


Fig 176 – Hospital unit selection

The Cancel button (Fig 176 C) makes it possible to close the window without making any changes.

The **None** button (Fig 176 **D**) makes it possible to "clean the field", i.e., to eliminate any previously selected items.

The "Requesting Hospital Unit" field is a mandatory field. This information cannot be omitted.

12.4.1. Selecting the hospitalization unit

The field shown in Fig 177 A makes it possible to specify the location where the patient will be hospitalized.



Fig 177

To specify the hospitalization unit

- Click the **Edit** button on the command bar of the "Operation Record" page.
- Enter the first letters of the name of the hospital unit required in the "H.U. Hospitalization" field.

Or

> click the button alongside the "Hospitalization H.U." field.

The window shown in Fig 175 and Fig 176 opens. See the previous paragraph for the selection procedure.

12.4.2. Selecting the requesting doctor

The field shown in Fig 178 A makes it possible to specify the name of the doctor requesting the operation.

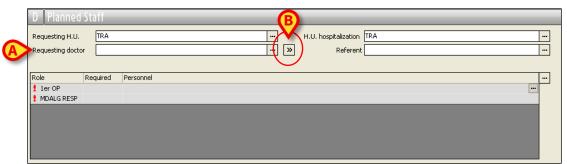


Fig 178

To specify the requesting doctor

Click the **Edit** button on the command bar of the "Operation Record" page.

Enter the first letters of the name of the person required in the "Requesting doctor" field.

Or

> click the button alongside the "Requesting doctor" field.

The following window opens (Fig 179).

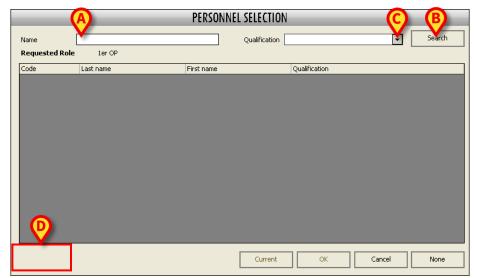


Fig 179 – Select the requesting surgeon

To search for the name, enter the name (or part of it) of the person being searched for in the "Name" field (Fig 179 **A**) then click the **Search** button (Fig 179 **B**).

Click the **Search** button without entering any letter to obtain the list of all those with permission to perform that function.

You can limit the search exclusively to people who occupy a specific role.

To do so, use the "Qualification" field. Click the arrow indicated in Fig 179 C to open a menu containing the possible options (Fig 180 A). Select one of these options to display only the names of the people with the qualification specified.



Fig 180 - Selection by Qualification

The "requested role" area (Fig 180 **B**) indicates the qualification necessary for selection as doctor requesting the operation. In the example shown, only those with the qualification of first operator can request an operation. This specification is made during configuration and cannot be changed by the users.

Once the role requested has been selected, it is possible to select a name only from those who possess the specified qualification.

If the system is so configured, the name of the user connected can appear in the area indicated in Fig 179 **D**. If the user connected has the qualification necessary to cover the role of requesting doctor, he/she can simply click the **Current** button to enter his/her name in the "Requesting Doctor" field.

The **Cancel** button makes it possible to close the window without making any changes.

The **None** button makes it possible to "clean the field", i.e. to eliminate any previously selected items.

The button in Fig 178 **B** and Fig 181 **A** makes it possible to assign the name of the requesting doctor also to the "Referent" field and to the role of "First Operator" of the operating room staff (Fig 181 **B**).



Fig 181

12.4.3. Referent doctor

The "Referent" field indicates the name of the person who is the direct referent for the patient in question (Fig 182 $\bf A$).

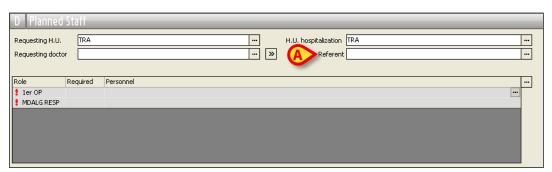


Fig 182

To specify the patient referent

- ➤ Click the **Edit** button on the command bar of the "Operation Record" page.
- Enter the first letters of the name of the person required in the "Referent" field,

or

> click the button alongside the "Referent" field.

The following window opens (Fig 183).

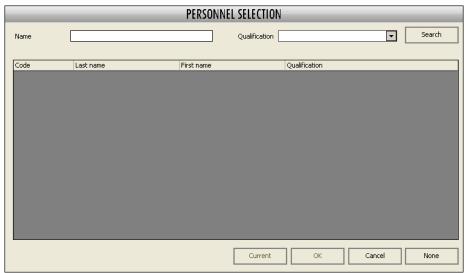


Fig 183 – Select the referent doctor

The function of this window is the same as that of the window shown in Fig 179, so see the previous paragraph for the selection procedure.

The only difference is that the specification of the role requested is not shown here (Fig 180 B).

12.4.4. Cost center selection

Some configurations require the specification of the cost center to which the operation must be associated. When the cost center specification is required it is performed through an additional field placed under the "Requesting doctor" field.

To specify a cost center,

- > click the **Edit** button on the command bar of the "Operation Record" page.
- Enter the first letters of the name of the cost center required in the "Cost Center" field,

or

> click the button alongside the "Cost Center" field.

A window enabling the cost center search and selection will open.

12.4.5. The "Planned Staff" table

The "Planned Staff" table makes it possible to specify ad/or request the staff to perform the operation (Fig 184 A).

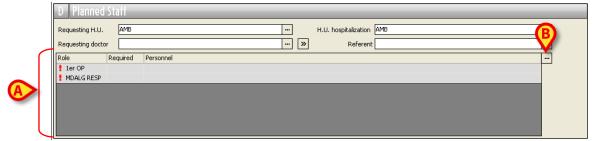


Fig 184 - Room staff selection

Before making any selection, the area contains the list of roles indispensable to the operation. In Fig 184 there are two roles indicated as indispensable (the first operator and the "Mdalg Resp", i.e. the anaesthetist).



By configuration, for every type of operation, you can specify the minimum indispensable staff to perform it. In this case, after specifying the operation, the system enters all the indispensable roles as mandatory.

To select the room staff

- Click the **Edit** button on the command bar of the "Operation Record" page.
- Click the button alongside the table (Fig 184 **B**).

The following window opens (Fig 185).

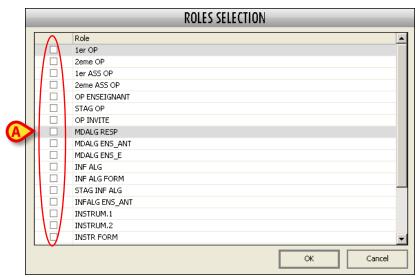


Fig 185 - Select roles

This window makes it possible to select the roles but <u>not</u> the names of the room staff.

The window contains the list of all possible roles. Alongside every role there is a selection box (Fig 185 A).

To select the roles

Click the checkbox corresponding to the role required.

The corresponding role appears as selected (Fig 186 A).



Fig 186 - Selected roles

➤ Click the **Ok** button (Fig 186 **B**).

The list of selected roles is displayed in the "Planned Staff" table (Fig 187).

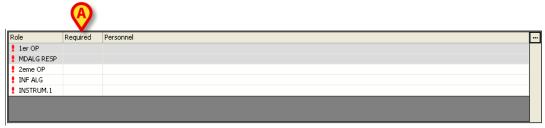


Fig 187 – Selected staff

The exclamation mark alongside every role indicates that no name has been specified for that role and there has been no declaration that any person qualified for that role is acceptable.

To declare that any person qualified for that role is acceptable, click the "Required" column in the box alongside the role (Fig 187 A). The list of roles changes as shown in Fig 188.

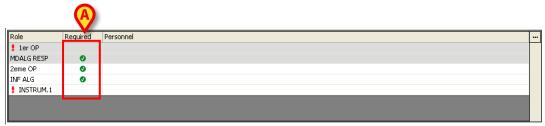


Fig 188 - Requested staff

The **②** icon alongside the role means that any person qualified for that role is acceptable (Fig 188 **A**).

To specify the name of the person requested, click the line corresponding to the role.

The following window appears (Fig 189).

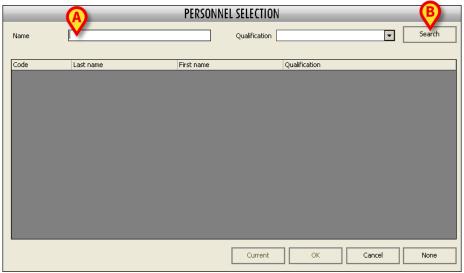


Fig 189 – Select room staff

To search for a specific person type his/her name (or part of it) in the "Name" field (Fig 189 A) and then click the **Search** button (Fig 189 B).

The list of names containing the search string appears on the window. Select the wanted name and click **Ok**. The name appears on the line selected (Fig 190).

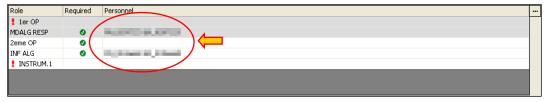


Fig 190 – Selected staff

You can either add or remove an item from the table by right clicking. Right click the "Planned staff" table to open the menu shown in Fig 191.

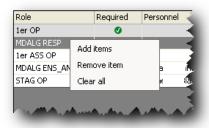


Fig 191

Click "Add items" to open the window shown in Fig 186, and add new roles.

Click "Remove item" to remove an item selected from the list of roles.

Click "Clear all" to clear all items from the list.



Staff can be also scheduled, with different procedures, on the "Staff management" module, described in paragraph 14.

A "System Option" has been defined in order to avoid conflicts between the staff planned on the "Operation Record" (described in this paragraph) and the staff planned on the "Staff management" module.

This "System Option", named **DisablePlannedStaffEditingOnOperationRecord**, if activated, enables staff editing on the "Operation Record" only if the operation is either in "Foreseen" or "Requested" state. The staff of the planned operations is only managed on the "Staff management" module.

To activate the system option set its Value=Yes.

12.5. The "Special Services" area

The "Special Services" area (Fig 192) makes it possible to specify any room devices required for the operation.

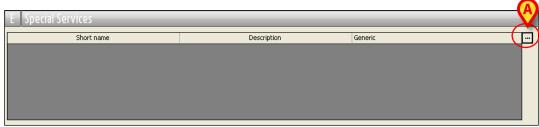


Fig 192 - The "Special Services" area

To specify the devices required

- Click the Edit button on the command bar of the "Operation Record" page.
- > Click the button alongside the area (Fig 192 A).

The following window opens (Fig 193).

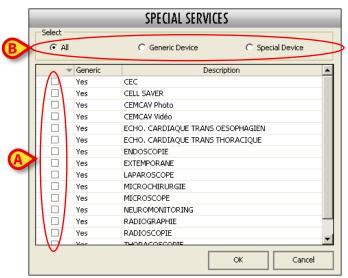


Fig 193 - Add devices

The window contains the list of all possible devices. There is a selection box alongside every device (Fig 193 \mathbf{A}).

To select a device

click the checkbox corresponding to the device required.

The box will be selected (Fig 194 A).

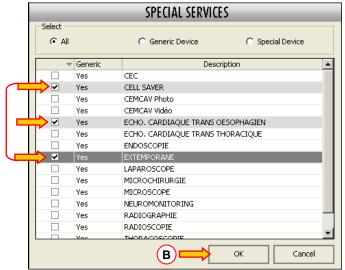


Fig 194 – Devices selected

Click the button (Fig 194 **B**)

The list of devices selected appears in the "Special Services" table of the "Operation Record" page (Fig 195).



Fig 195 – List of devices

This table is split into three columns.

- The "Short name" column contains the abbreviation which identifies the device.
- The "Description" column contains a brief description of the device.
- The "Generic" column indicates whether it is a generic device (Yes) or a special device (No).

The same distinction between generic and special devices is found in the selection window (Fig 193 **B**).

Select "Generic devices" in this window to display the list of generic devices only, "Special devices" to display the list of special devices only and "All" to display the list of all devices.

The presence of devices in an operating room will be indicated by special icons on the scheduling pages (see paragraph 13.2.1 and Fig 226).

You can add or remove a device from the table by right clicking. Right click the "Special Services" table to open the menu shown in Fig 196.



Fig 196

Click "Add items" to open the window shown in Fig 194 and add new devices.

Click "Remove item" to remove an item selected from the list of devices.

Click "Clear all" to clear all items from the list.

12.6. The "Materials" area

The "Materials" area makes it possible to schedule the required room materials (Fig 197).

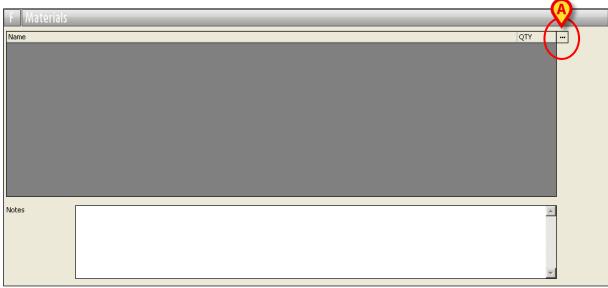


Fig 197

To schedule the room materials

- 1. Click the **Edit** button on the command bar.
- 2. Click the button placed alongside the "Materials" area (Fig 197 A).

The following window is displayed (Fig 198).

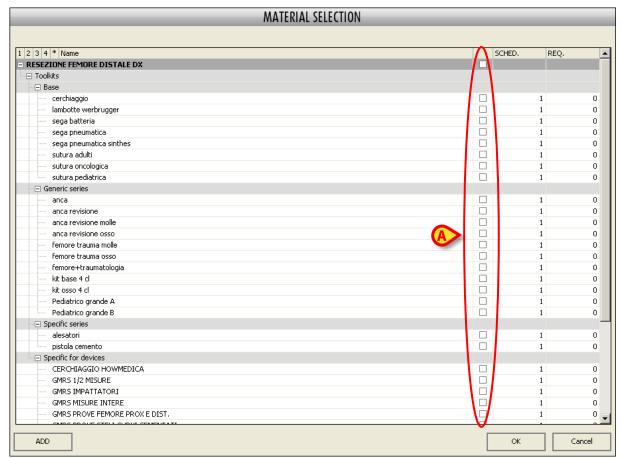
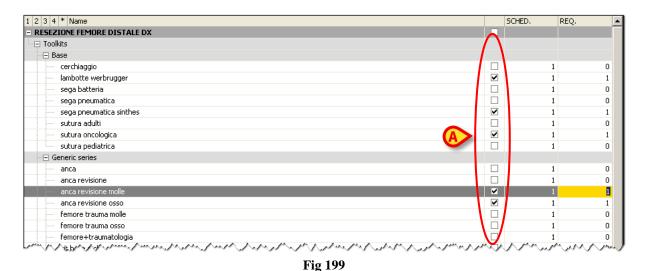


Fig 198

The resources that are linked by configuration to the operation selected as "Main operation" are listed on the window. The resources are ordered in a tree-structure and grouped in "baskets" and operating "kits". The tree-structure is described in paragraph 12.6.1.

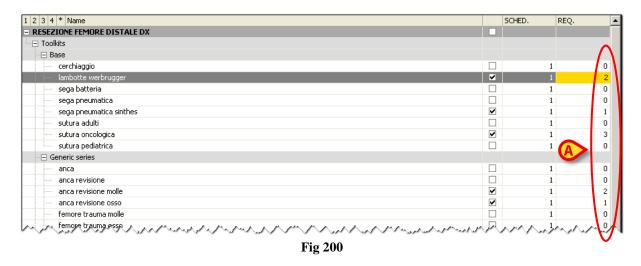
3. Click the checkbox corresponding to the resources to be planned (Fig 198 A).

The box is this way checked (Fig 199 A).



4. Set the required quantity of each resource to be planned.

The required quantity is indicated in the last column on the right (Fig 200 A). The required quantity is set to 1 by default. This value can be edited when the corresponding cell is highlighted yellow. The cell is highlighted either when the resource is selected or by double-clicking the cell itself.



When all the resources to be planned have been specified and the corresponding quantities have been indicated,

5. Click the **Ok** button on the window, in the bottom-right corner of the window.

The planned resources are displayed in the "Materials" area of the "Operation record". The tree-structure is maintained (Fig 201).

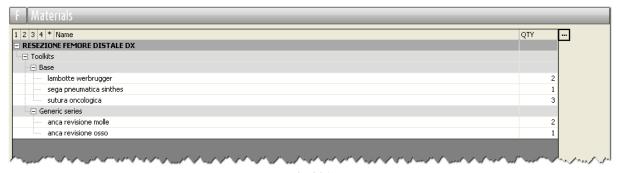


Fig 201

6. Click the **Update** button on the command bar.

12.6.1. Table contents description

The resources are ordered on the table in a four levels tree-structure. These four levels are indicated in the top-left area of the window (Fig 202 A). Each one of the five buttons - 1234* - displays the "tree" up to the level corresponding to the clicked number. The star makes it possible to expand the whole tree. The different levels can be either hidden or displayed by clicking on the tree nodes. The nodes are represented by the \blacksquare and \boxplus symbols (Fig 202 B). The first one, when clicked, hides the node; the second one displays it.

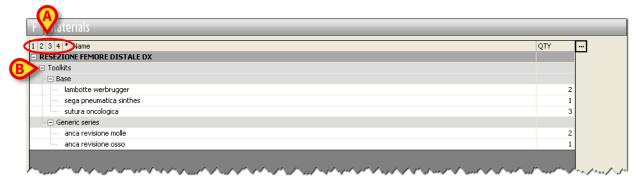


Fig 202

The first level represents the main operation (Fig 203).



Fig 203

Either kit, toolkits, series or single resources can be represented in the second level (Fig 204).



Fig 204

The kind of kit, series, toolkit or resource is specified in the third level (Fig 205).

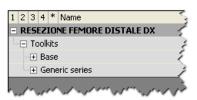


Fig 205

The fourth level lists the single resources (Fig 206).



Fig 206

12.6.2. How to schedule all the materials displayed by configuration

It is possible to quickly specify all the materials listed on the selection window.

To do that, on the "Materials selection" window (Fig 207),

1. Click the checkbox placed on the row corresponding to the main operation name (Fig 207 A).

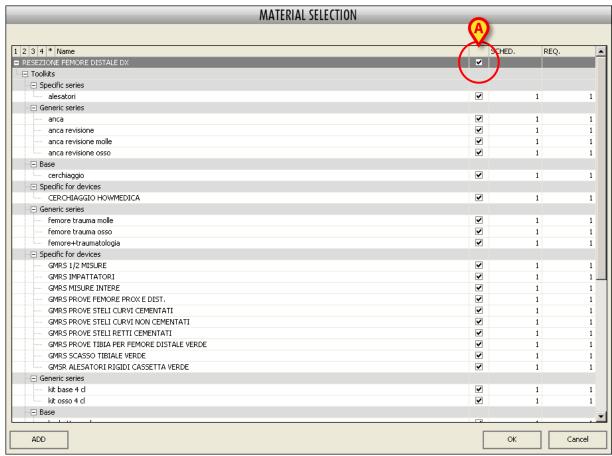


Fig 207

2. Click the **Ok** button on the window (bottom-right corner).

All the materials are this way inserted in the operation record (1 piece for each item if not differently specified - Fig 208).

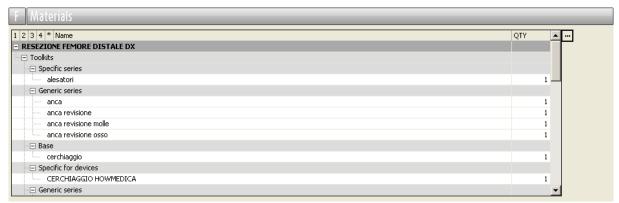


Fig 208

12.6.3. How to add a resource

To schedule a resource that is not already present in the pre-configured list, on the materials selection window (Fig 209),

1. Click the **Add** button (Fig 209 **A**).

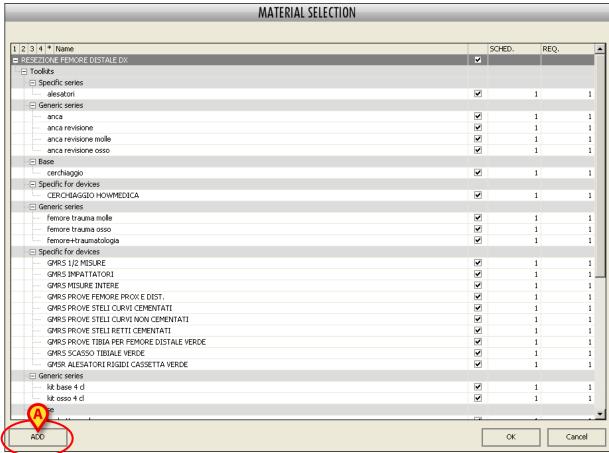


Fig 209

The following window opens (Fig 210).

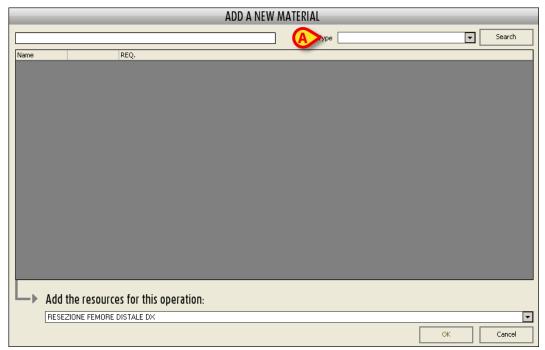
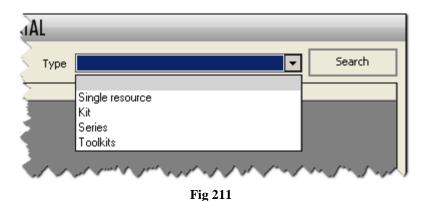


Fig 210

2. Use the drop down menu indicated in Fig 210 **A** and enlarged in Fig 211 to indicate the kind of material to insert.



menu makes it possible to choose the kind of i

This menu makes it possible to choose the kind of item to be searched (either single resource, basket, kit or series). In the example shown in Fig 212 the "basket" option has been selected. All the possible baskets are now listed on the window. If, for example, the option "single resource" had been selected, the list of all the single resources would have been displayed. The same thing is true for the kits and the series.

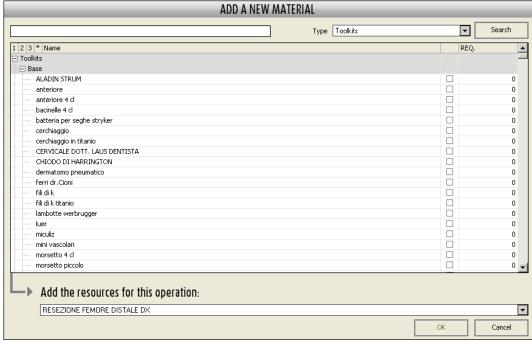


Fig 212

3. Insert the name (or part of the name) of the wanted toolkit in the field indicated in Fig 213 A.

The list of all toolkits corresponding to the typed text is displayed on the window.

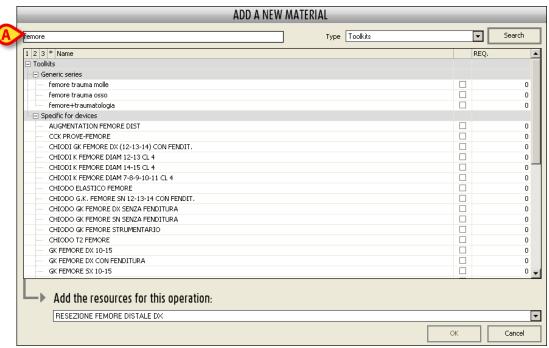


Fig 213

4. Click the checkbox corresponding to the toolkit (or toolkits) to be scheduled (Fig 214).



Fig 214

- 5. Specify the required quantity on the cell indicated in Fig 214 A. The default quantity is 1.
- 6. Click the **Ok** button (Fig 214 **B**).

The selected toolkit (or toolkits) will be added to the list of pre-configured resources, on the materials selection window, in the specified quantity (Fig 215 A).

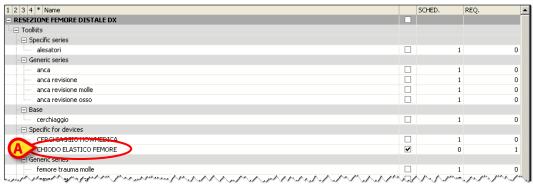


Fig 215

Repeat the procedure, if necessary, to add other resources. Otherwise,

7. Schedule the selected materials using the procedure described in paragraph 12.6.

12.6.4. How to add a note

The "Notes" field placed in the "Materials" area of the "Operation record" (Fig 216 **A**) makes it possible to add all the information that can be meaningful for an accurate materials scheduling (for example: possible indications on the kind of material required, or on the way a certain material must be handled etc...).

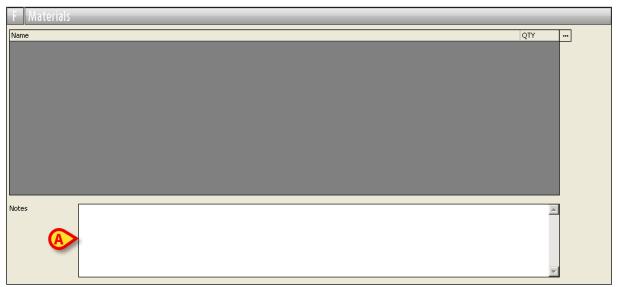


Fig 216

It is a free text field. To add a note

- 1. Click the **Edit** button on the command bar.
- 2. Click inside the "Notes" area.

A cursor appears on the area.

3. Type the note (Fig 217).



Fig 217

4. Click the **Update** button on the command bar.

13. The "Schedule" Module

The "Schedule" module of the Smart Scheduler system makes it possible to add the operations requested to the operating schedule. This module makes it possible to schedule when and where an operation will be performed.

13.1. How to access the scheduling page

To access the "Schedule" module main page

Click the corresponding icon on the lateral bar (Fig 218).



Fig 218

Otherwise you can use the menu activated by the **Change** button on the command bar of the "Operation list" and "Operation record" screens (Fig 219 A)

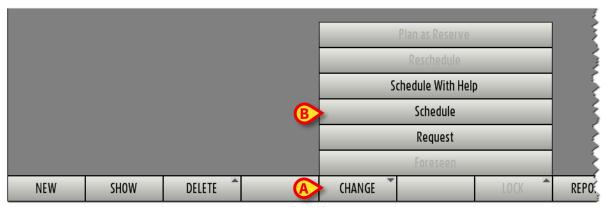


Fig 219

➤ Click, when enabled, the "Schedule" option (Fig 219 **B**).

The screen shown in Fig 220 will open.

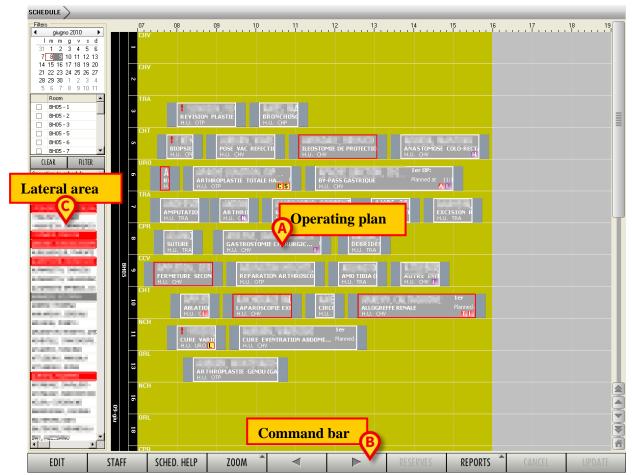


Fig 220 - Scheduling Page

This screen is formed of three areas.

- 1) The central part of the screen represents in a graphic form the operations schedule (Fig 220 **A** see paragraph 13.2 for the description).
- 2) The command bar contains the function-button making it possible to perform different procedures (Fig 220 **B** see paragraph 13.4 for a description).
- 3) The lateral area contains several tools making it possible to operate on the screen contents (Fig 220 C see paragraph 13.3 for a description).



Scheduling an operation makes the operation progress from "Requested" state to "Planned" state.

13.2. The operating schedule

The central part of the page offers a graphic representation of the operating schedule of one or more operating day/s (Fig 220 A).

Every line represents the day of an operating room. Fig 221 highlights the line that represents the operating day in room 11. The number (or the name) of the room is indicated at the start of every line (Fig 221 A).

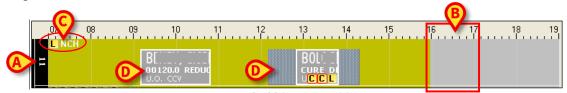


Fig 221 - Room 11

Every box represents a time of day. Fig 221 **B** highlights the box that indicates the hour from 16:00 to 17:00.

The number line above the central part of the page indicates the time.

The ochre yellow part indicates the hours during which the room is open and available for scheduling.

The gray part indicates the hours during which the room is closed. The room shown in Fig 221 is open from 7:00 to 16:00.

The letters highlighted in Fig 221 C indicate the devices in the room (yellow letters) and the location (NCH in this case). Every yellow letter represents a device. The letter is the initial of the name of the device. For more details on the devices present move the mouse pointer on the letter. A tooltip containing the full list of the room devices appears (Fig 222).



Fig 222 – Devices list

The gray rectangles highlighted in Fig 221 **D** represent the operations scheduled.

The various rooms are grouped into surgical blocks.

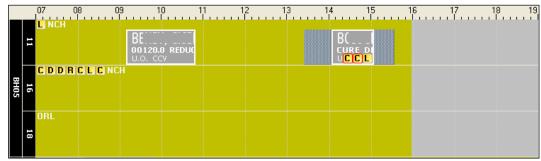


Fig 223 - Block BH05

In Fig 223, rooms 11, 16 and 18 are in block BH05.

The various blocks displayed make up the operating day.

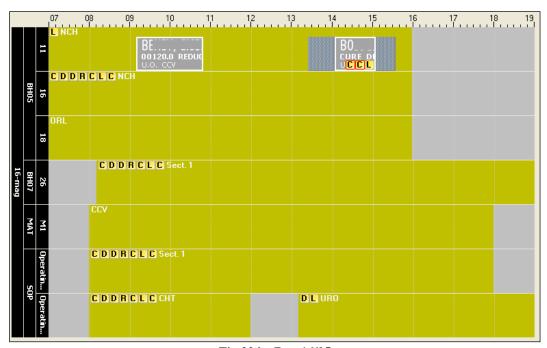


Fig 224 - Day 16/05

Fig 224 shows May 16.



Every user sees only the rooms in which he/she is permitted to work. This depends on the permissions held by the user. For information on the user definition procedure, contact the system administrator.

The scheduling grid can contain dark gray hatched areas (Fig 225 A).



Fig 225 – Unavailable Slot

These areas indicate periods of time in which the room displayed, despite being open, is not available for scheduling (due to tests, maintenance or other reasons).

13.2.1. The graphic representation of the operation

Every scheduled operation is represented on the daily schedule by a gray rectangle.

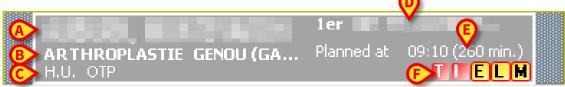


Fig 226 - Operation

The rectangle contains a variety of information.

- The name of the patient (Fig 226 A).
- The type of operation (Fig 226 **B**).
- The requesting hospital unit (Fig 226 C).
- The name (if indicated) of the first operator (Fig 226 **D**).
- The scheduled start time and duration of the operation (Fig 226 E).
- The devices required for the operation, the transmissible diseases, the allergies, the infections and the priority of the operation (Fig 226 **F**, Fig 227).



Fig 227 – Indication of Devices

The yellow letters - **ELM** - indicate the devices required for the operation. Every yellow letter indicates a device. The letter is the initial of the name of the device. When the letter is circled it means that the device is not currently present in the room for which the operation is scheduled.

The purple letters \mathbb{N} , \mathbb{H} and \mathbb{M} indicate the priority assigned to the operation. The priority indicators (the specific letters used) are configurable.

The blue letter № indicates that the operation has been scheduled to take place before the date suggested on the "Not before…" field on the "Operation record screen" (see paragraph 12.2.7).

The red letters - II, III - indicate the transmissible diseases, the allergies and the infections.

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. In all cases, to know the meaning of an icon, you can place the mouse pointer on it. The meaning will be displayed inside a "tooltip".

A red exclamation mark - - placed on the top-left corner of the operation rectangle indicates that the information on the patient is provisional (see paragraph 9.3.1.1).

The three icons — - — placed on the top-left corner of the operation rectangle indicate that the operation is locked. The icon indicates the lock level. See paragraph 7.3 for the explanation of the operation "lock/unlock" functionalities.

The icon placed on the top-left corner of the operation rectangle means that the current user cannot edit the operation.

The length of the operation rectangle is proportional to the operation duration. The longer the rectangle, the longer the duration.

The position of the operation rectangle in the scheduling grid indicates the scheduled start and end time and the room where the operation will be performed.

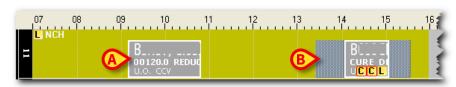


Fig 228 - Position of operations in the grid

The operation shown in Fig 228 A is scheduled for room 11, at 09:10 and should end at 10:50.

The operation shown in Fig 228 B is scheduled for room 11, at 14:00 and should end at 15:00

The dark gray areas indicated in Fig 229 represent the pre-surgical time (left) and post-surgical time (right) indicated on the "Operating record" screen. See paragraphs 12.2.15 and 12.2.16.



Fig 229

Click the operation rectangles to display a window containing a summary of the information available on the operation (Fig 230).



Fig 230 - Operation data

Click the **Select** button in the window (Fig 230 **A**) to access the "Operation Record" page relating to the operation clicked (Fig 98).

The window disappears automatically when you move the mouse. To "fix it" to the page, click the thumbtack in the window (Fig 230 **B**).

13.2.1.1. Operation schedule direct editing

Right click the operation rectangles to open a menu making it possible to directly edit the operation schedule (Fig 231).

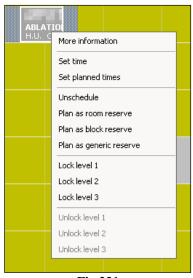


Fig 231



The functions described here are schedule changes and are only enabled after pressing the **Edit** button (see paragraph 13.5).

- The "More information" option opens the window shown in Fig 230.
- The "Set time" options displays a window in which you can enter a new start time scheduled for the operation (Fig 232).



Fig 232 - Set time

To set the new start time, enter the time required in the box and press the ENTER key. The rectangle is automatically moved to the point corresponding to the start time entered.



An operation start time can also be changed using the mouse or keyboard. With the mouse: after clicking the **Edit** button, simply drag the operation to the start time required.

With the keyboard: after selecting the operation (i.e., after clicking the **Edit** button and then the operation box) using the combinations of the "Alt $+\leftarrow$ " and "Alt $+\rightarrow$ " keys, move the rectangle to the left and right.

• The "Set planned times" option displays a window in which it is possible to enter separately the pre-surgical, surgical and post-surgical times (Fig 233).



 $Fig\ 233-Set\ planned\ times$

To set a new duration, enter (in minutes) the duration required in the box and press the ENTER key. The rectangle will be automatically enlarged or shrunk depending on the new duration entered. In case of transmissible diseases and infections specified for the operation, the post-surgical time cannot be less than that added after the disease/infection specification.



The scheduled duration of an operation can also be changed using the mouse or keyboard.

With the mouse: simply move the mouse to the right side of the rectangle, click and, keeping the button pressed, "enlarge" or "shrink" the rectangle.

With the keyboard: after selecting the operation (i.e., after clicking the **Edit** button and then the operation box) using the combinations of the " $Ctrl + \leftarrow$ " and " $Ctrl + \rightarrow$ " keys, shrink or enlarge the rectangle.

- The "Unschedule" option makes it possible to remove the operation from the daily schedule. Click this option to eliminate the operation rectangle from the scheduling grid and return the operation to the list of operations to be scheduled. See paragraph 13.5 for the operation scheduling procedures.
- The "Plan as room reserve" option makes the operation a room reserve. Click this option to eliminate the operation rectangle from the scheduling grid and indicate it as room reserve (see paragraph 13.5.5 for the explanation of the concept of reserve and for the connected procedures).
- The "Plan as block reserve" option makes the operation a block reserve. Click this option to eliminate the operation rectangle from the scheduling grid and indicate it as block reserve (see paragraph 13.5.5 for the explanation of the concept of reserve and for the connected procedures).
- The "Plan as generic reserve" option makes the operation a generic reserve. Click this option to eliminate the operation rectangle from the scheduling grid and indicate it as generic reserve (see paragraph 13.5.5 for the explanation of the concept of reserve and for the connected procedures).
- The various "lock/unlock operation" options make it possible to lock/unlock the operation at the wanted level. Only the options are enabled, that are logically consistent both with the context (i.e. with the possible lock level already specified) and with the permissions of the current user. See paragraph 7.3 for an explanation of the lock/unlock functionalities.

13.2.2. Color of boxes and operation state

In the Smart Scheduler system, the operation boxes corresponding to operations in "Scheduled" state are light gray (Fig 234).



Fig 234 – Smart Scheduler operation box

The emergencies are red circled on the planning grid (Fig 235).



Fig 235 - Emergency

The Smart Scheduler system manages an operation in three states (see paragraph 7.2). These are:

- Foreseen
- Requested
- Scheduled

The Smart Scheduler-OranJ combined system envisages three further state for an operation. These are:

- Ready
- In progress
- Completed

These three states, which no longer refer to scheduling but to the performance of the operation, are managed by the DIGISTAT® OranJ system. The OranJ system indicates the operation state by the color of the relevant operation rectangle.

The "Ready" state is characterized by the color green (Fig 236).



Fig 236 – Operation state: "Ready"

The "In progress" state is characterized by the color cyan (Fig 237).



Fig 237 – Operation state: "In progress"

The "Completed" state is characterized by the color dark gray (Fig 238).



Fig 238 - Operation state: "Completed"

When the Smart Scheduler and OranJ systems work together, the changes in state recorded by OranJ are also visible in Smart Scheduler.

Therefore, an operation which progresses to "ready" state in OranJ will be displayed in Smart Scheduler as a green rectangle; an operation which progresses to "in progress" state in OranJ will be displayed in Smart Scheduler as a cyan rectangle and an operation which progresses to "completed" state in OranJ will be displayed in Smart Scheduler as a dark gray rectangle.

Once an operation has begun (i.e. it progressed to "in progress" state – cyan) it can no longer be changed using Smart Scheduler.

There are rare cases in which two operations overlap, having been scheduled at the same time from two different workstations. In this case, the operation rectangle will be red (Fig 239).



Fig 239 – Overlapping operations

In this case we suggest the rescheduling of the operation.



In the case of overlapping operations, we suggest the rescheduling of the operation. See paragraph 13.5 for the scheduling procedure.

The current day displayed on the Smart Scheduler "Schedule" module may not correspond to the current day displayed on the OranJ "Plan" module. This occurs due to the different purposes for which the two types of software are designed. Smart Scheduler is largely a scheduling tool, also suitable over the long term, for the activities of the surgical block, while OranJ is a tool for managing and monitoring the actual performance of the operating activity. The activity of a block may change suddenly and radically as a result of unscheduled activities which take absolute priority, and this means that the actual performance of the operating activity (correctly displayed by Oranj Plan) is different from that displayed in the scheduling of Smart Scheduler. The Smart Scheduler system updates its own plan on the basis of the changes registered by OranJ, but in the event of several changes made at the same time, it may not be usable to precisely display all the changes made.

Therefore, we suggest that you DO NOT use Smart Scheduler as a tool for monitoring the activities of a room, preferring the plan displayed by OranJ for this purpose.



DO NOT use Smart Scheduler as a tool for monitoring the activities of a room. Use the plan displayed by OranJ for this purpose.

13.3. The lateral area

The left side of the scheduling page (Fig 220 C, Fig 240) is divided in three areas.

- a date filter (Fig 240 A),
- a block and room filter (Fig 240 **B**),
- a table containing the list of all the operation in "Requested" state, ready to be scheduled (Fig 240 C).



Fig 240 – Lateral area

13.3.1. Date filter

The calendar indicated in Fig 240 A and Fig 241 makes it possible to select the day displayed on screen.



Fig 241 - Calendar

The day displayed on the scheduling grid is highlighted grey. The figure shown displays the 10^{th} of November. The operations indicated on the scheduling grid are those relating to the 10^{th} of November.

If the current day is different from that selected, it appears in a red box.

To display the schedule for a different day, click the number of the date required.

The arrows alongside the name of the month make it possible to change the month displayed (Fig 241 A).

In the example shown in the figure, the month of October 2009 is displayed by clicking the left arrow and the month of December 2009 is displayed by clicking the right arrow.

You can select (and therefore display) more than one day at a time. To do so, simply move the mouse to the days you wish to display, keeping the left button pressed. For example, if you select 10th and 11th of November together, the calendar will look like this.



Fig 242 – Selecting several days together

The schedule of the two days will be displayed on the same screen.

You can display a maximum of 7 days at the same time.

13.3.2. Room filter

The "room" area makes it possible to display only the rooms selected (Fig 240 **B**, Fig 243).

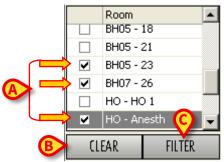


Fig 243 - Room Selection

The area shown contains the list of rooms which can be displayed. Alongside each room there is a selection box.

To display certain rooms only

Click the checkboxes alongside the wanted room.

The boxes appear as selected (Fig 243 A).

➤ Click the **Filter** button (Fig 243 **C**)

In the example shown we have selected room 23 of block BH05, room 26 of block BH07 and room "Anesth" of block HO. After clicking the **Filter** button, the following grid is displayed.

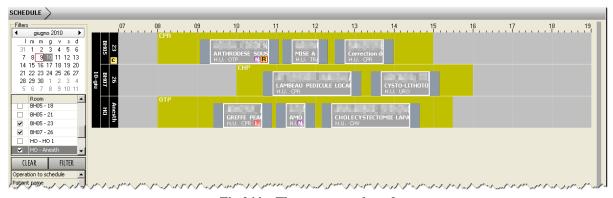


Fig 244 – Three rooms selected

To go back to displaying all the rooms

Click the **Clear** button (Fig 243 **B**).

The rooms previously selected are deselected.

➤ Click the **Filter** button (Fig 243 **C**)

The grid containing all the rooms will be displayed again.

13.3.3. Operations to schedule

The "Operations to schedule" contains the list of operations still to be scheduled (Fig 240 C, Fig 245). The list comprises all and only those operations which have "requested" state and are in the rooms that the connected user has permission to see.



Fig 245 – Operations to Schedule

The area is split into four columns. For space-related reasons only one column can be displayed at a time.

The first column contains the names of the patients for whom an operation is requested.

Use the bar indicated in Fig 245 A to display the other columns. The other columns display the following information:

- the operation name;
- the planned duration;
- the priority of the operation;
- the emergency level (when the operation is an emergency it is highlighted red);
- the name of the first operator.

Click one of the lines in this area to display a window summarizing the information available on the operation (Fig 246).

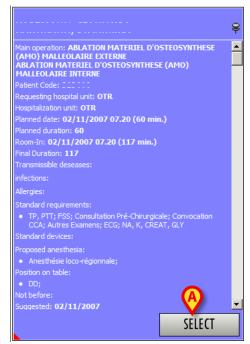


Fig 246 – Operation Data

Click the **Select** button in the window (Fig 246 **A**) to access the "Operation Record" screen relating to the operation clicked (Fig 98).

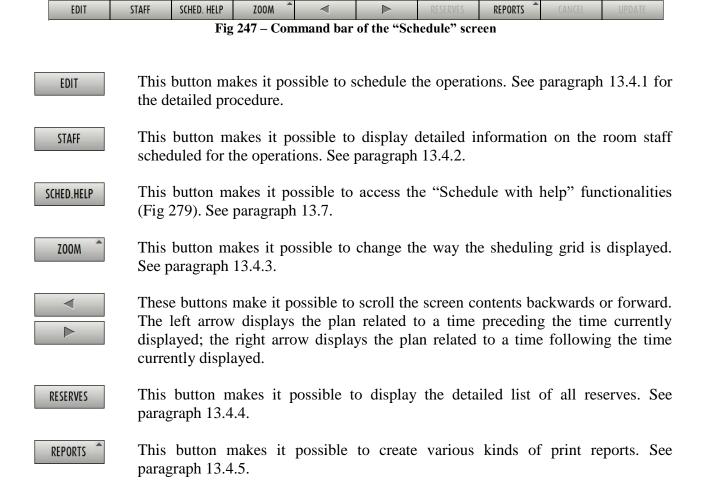
When you are in "edit" mode, i.e., after the **Edit** button has been clicked, to display this information window you must right click the line corresponding to the operation.

A window like that shown in Fig 246 opens but this window has no **Select** button.

The list of operations contained in this table makes it possible to create a proper schedule. See paragraph 13.5 for the description of the scheduling procedures.

13.4. The command bar of the scheduling page

The control bar on the page (Fig 247) contains various buttons which make it possible to perform various operations. This paragraph briefly lists the functions of the different buttons. They will be explained in detail in the paragraphs indicated.



13.4.1. How to edit the operations schedule

The **Edit** button on the command bar (Fig 248) makes it possible to change the operations schedule.



Fig 248 - Command bar of the "Schedule" screen

Before making any changes to the schedule, it is necessary to click the **Edit** button.

After clicking this button, the control bar changes appearance and looks like the one shown in Fig 249.



Fig 249 - "Edit" mode

The **Edit** button appears as selected.

The Cancel and Update buttons are active.

The page is in "edit" mode meaning that it can be changed.

To make any changes to the schedule, in terms of time, date, room, duration, block, etc..., it is necessary to

> click the **Edit** button.

The screen turns to "edit" mode.

- ➤ Make the change required.
- Click Update to save the data.

The detailed procedure is explained in paragraph 13.5.

13.4.2. How to display information on the operating staff

The **Staff** button (Fig 250) makes it possible to access a page containing all the information on the room staff requested for the scheduled operations (Fig 251).



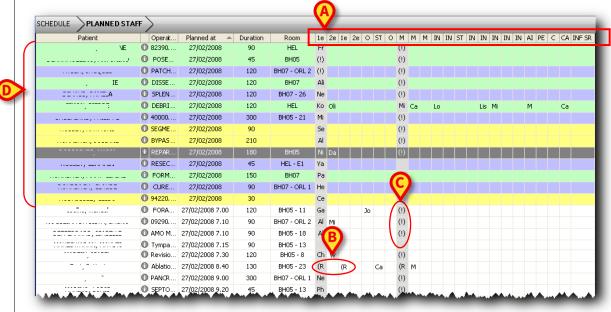


Fig 251 – "Planned Staff" Page

The table shown in Fig 251 contains the main information on every operation scheduled during the day and in the rooms displayed.

Every line contains data relating to an operation.

The first 6 columns contain, in the following order

- The name of the patient to be operated on.
- The "information" symbol. Click the symbol to open a window containing further information on the operation (see Fig 246).
- The type of operation scheduled.
- The start time and date scheduled for the operation.
- The scheduled duration.
- The scheduled block and room (if specified).

The remaining columns (Fig 251 A) show details of the information available on the operating staff.

Every column corresponds to a role.

The name of the person holding a specific role in a specific operation is found in the box where the role column and operation column intersect.

Not all roles are associated with a person. This is because the room staff need not necessarily be specified or may not be requested for a particular operation.

If a role has been indicated as "requested" but no specific name has been indicated for that role, the system places an (R) in the corresponding box (Fig 251 B).



The (D) on the staff page corresponds to the $^{\circ}$ symbol of the "planned staff" page on the "Operation Record" screen (Fig 188 A).

If a role has been entered among the scheduled staff but neither the name nor the fact that the role has been requested are specified, the system places an (!) in the corresponding box (Fig 251 C).



The (!) symbol on the staff page corresponds to the ! symbol of the "planned staff" area on the "Operation Record" page (Fig 188).

The operations that appear highlighted on the staff page are reserves (Fig 251 \mathbf{D}). See paragraph 13.5.5 for the explanation of the concept of reserve.

Operations highlighted in yellow are generic reserves.

Operations highlighted in green are block reserves.

Operations highlighted in blue are room reserves.

13.4.3. Zoom

The **Zoom** button on the command bar (Fig 252) makes it possible to change the time range displayed.



Fig 252 – Command bar of the "Schedule" screen

Click this button to open the different options possible (Fig 253).



Fig 253 - Change time range displayed

To change the time range displayed

> Click the **Zoom** button.

The options available appear (Fig 253).

> Click one of the options offered.

The page changes consequently. Click **4 hours**, for example, to display a range of 4 hours. Click **8 hours** to display a range of 8 hours etc.

13.4.4. How to display the reserves list

The **Reserves** button (Fig 254) makes it possible to display the detailed list of all reserves (Fig 255 **A** - See paragraph 13.5.5 for the explanation of the concept of reserve).



Fig 254 - Command bar of the "Schedule" screen

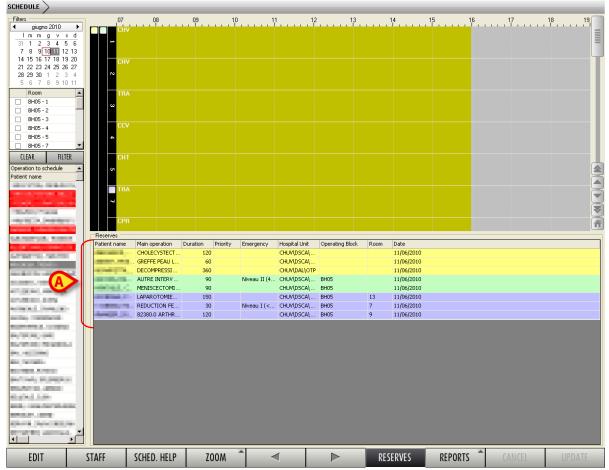


Fig 255 - All reserves

The list of reserves is presented in a table (Fig 255 A, Fig 256).

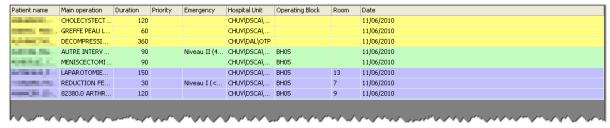


Fig 256

Every line of the table shows data relating to an operation.

This data, arranged into columns, is

- the name of the patient,
- the type of operation scheduled,
- the scheduled duration,
- the level of priority assigned,

- the hospital unit of reference,
- the surgical block (if specified),
- the operating room (if specified),
- the scheduled date.

Operations highlighted in yellow are generic reserves (the block, room and time are not specified).

Operations highlighted in green are block reserves (the room and time are not specified).

Operations highlighted in blue are room reserves (the time is not specified).

13.4.5. Reports

The **Reports** button (Fig 257) makes it possible to create a document which shows the information available on the operations scheduled.



To create the document

> Click the **Reports** button.

Several options are available. Their number and their nature depend on the configuration. Once the kind of document is selected, the system displays a print preview.

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

13.5. How to schedule an operation

The list of operations with "requested" state awaiting scheduling appears in the portion of the screen that appears in the bottom left corner of the page (Fig 258 A).

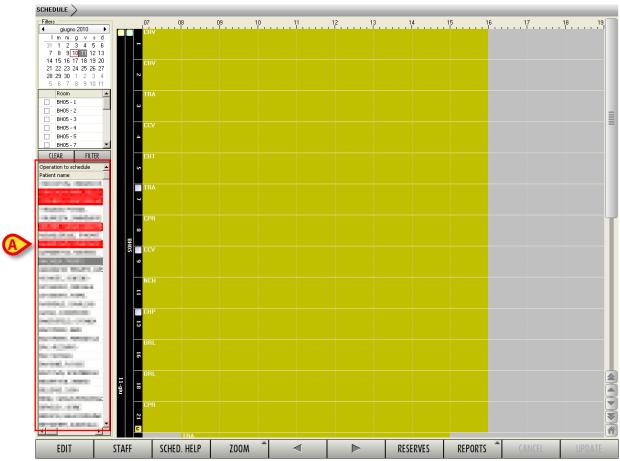


Fig 258 – List of operations to schedule

To schedule an operation, you must

Click the Edit button on the command bar.

The screen turns to "edit" mode.

- Move the mouse pointer over the item in the list of "operations to schedule" that you wish to schedule (in the area indicated in Fig 258 A).
- > Drag it to the scheduling grid, on the point corresponding to the wanted time and location.



To "drag", move the mouse pointer over the object required, left-click and, keeping the button pressed, physically move the object to the position required. The object (the box in this case) moves with the cursor.

The operation disappears from the list of operations to schedule and appears, in the form of an operation rectangle, inside the scheduling grid (Fig 259 A).

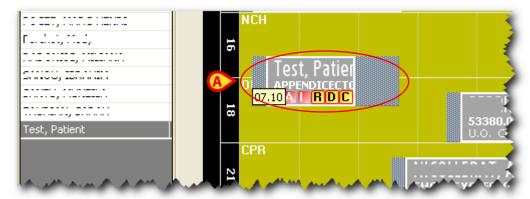


Fig 259 - Operation rectangle being dragged

Release the mouse button.

The operation rectangle remains in the point required and the patient's name disappears from the list of operations to schedule (Fig 260 A).

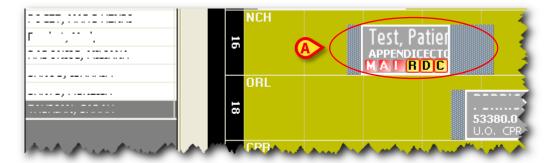


Fig 260 - Scheduled Operation

Click the **Update** button on the command bar to save the change made.

The operation is now scheduled for the room and time required.

13.5.1. How to schedule an emergency operation

The "Emergencies" are highlighted red in the "Operations to schedule" area on the left of the screen (Fig 261).

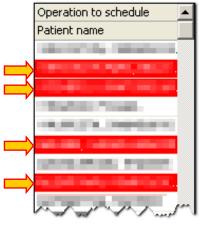


Fig 261

Specific user permissions are required in order to schedule an "Emergency". These permissions, specified by configuration, make it possible to

- a) enable to schedule the "Emergencies";
- b) enable to schedule the operations that are not "Emergencies" (called "Elective").

These permissions are separate, i.e. a user can have them both enabled.



When the scheduling of an "Elective" operation causes the re-scheduling of an "Emergency" operation the permissions to schedule the emergencies are required.

The "Emergencies" are red circled on the planning grid (Fig 262).



Fig 262

13.5.2. How to remove an operation from the plan

To remove an operation from the planning grid

- > Click the **Edit** button on the command bar.
- Move the mouse pointer over the operation-rectangle that must be removed from the plan.
- > Drag the rectangle back on the "Operations to schedule" list (Fig 261 A).

Click the Update button on the command bar to save the changes.

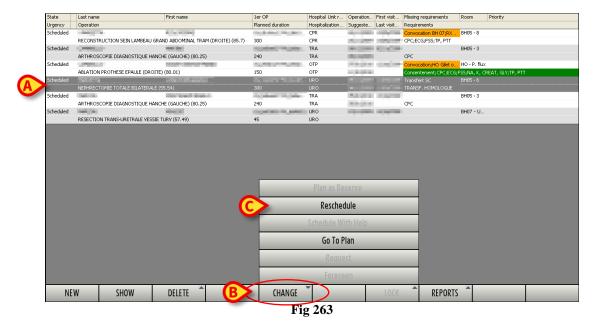
The operation goes back to "Requested" state.

13.5.3. How to reschedule an operation

To reschedule an operation, if you are on the scheduling page,

- > click the **Edit** button on the command bar.
- Move the mouse pointer over the operation rectangle for which you wish to change schedule.
- > Drag the rectangle to the point on the grid corresponding to the new time and/or new room.
- Click the Update button on the command bar.

Otherwise it is possible to change the scheduling of an operation by selecting it directly from the "Operation List" page (see paragraph 9).



To do so, you must

- Access the "Operation list" screen (see paragraph 9).
- Search for the operation you wish to reschedule (see paragraph 9.1 for the search modes).

This operation must have "Scheduled" state.

Click the row corresponding to the operation to reschedule.

The row will be highlighted (Fig 263 **A**).

Click the **Change** button on the command bar (Fig 263 **B**).

A menu containing different options opens.

Click the **Reschedule** option (Fig 263 C).

A window requesting confirmation of the operation opens (Fig 264).

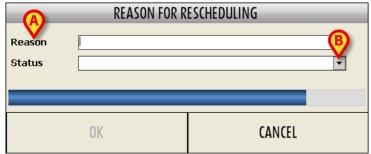


Fig 264 – Rescheduling an operation

Enter the reason for rescheduling in the "Reason" field (Fig 264 A).

The possible reasons can be pre-defined during configuration. In this case you can click the button alongside the "Reason" field and choose from the options offered.

•

Click the button alongside the "State" field (Fig 264 B).

A menu offering the choice between four options opens (Fig 265).

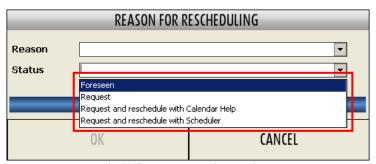


Fig 265 - Rescheduling options

Each of them allows the performance of a different operation.

The "Foreseen" option makes it possible to take the operation back to the "Foreseen" state.

The "Request" option makes it possible to take the operation back to the "Requested" state.

The "Request and reschedule with calendar help" option takes the operation back to the "Requested" state and gives direct access to the "Schedule with help" page (Fig 279, paragraph 13.7).

The "Reschedule" option takes the operation back to the "requested" state and gives direct access to the scheduling page (Fig 220, paragraph 13.2).

- ➤ Click the option required.
- Click the **Ok** button.

13.5.4. Locked operations

It is possible, on the scheduling screen, to lock a single operation. It is also possible to lock all the operations of a room, a slot, a block, a day at the same time. A locked operation is an operation which cannot be rescheduled.



The term "slot" indicates the length of time in which an operating room is available to a hospital unit for scheduling. From the graphic point of view, the slot is indicated on the scheduling grid as an ochre yellow colored area.



Fig 266 - Slot

The goals and features of the "Lock/unlock operation" functionalities are described in paragraph 7.3.

To lock/unlock an operation

- > Click the **Edit** button on the command bar.
- ➤ Move the mouse pointer on the rectangle corresponding to the operation to be locked/unlocked.
- > Right click.

A window containing various options appears (Fig 267). The lock/unlock options are indicated in Fig 267 **A**.

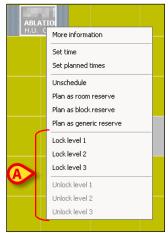


Fig 267 – Lock Operations

Only the options that are consistent with the context and the user permission level are available.

➤ Click the required "Lock" option.

On the operation rectangle, in the top-left corner, the icon corresponding to the lock level chosen appears (Fig $268 \, A$).



Fig 268 - Operation locked level 2

Click the **Update** button on the command bar to save the change made.

To lock/unlock all the operations of a slot

- > Click the **Edit** button on the command bar.
- Move the mouse pointer on the relevant slot.
- > Right click.

The window shown in Fig 267 appears.

➤ Click the required "Lock" option.

All the operation in the slot will be locked/unlocked.

Click the **Update** button on the command bar to save the change made.

To lock/unlock all the operations in a room the procedure is the same, only you must right click the black bar indicating the room number (Fig 269 A) and then click the required "lock" option.

To lock/unlock all the operations in a block you must right click the black bar indicating the name of the block (Fig 269 **B**) and then click the required "lock" option.

To lock/unlock all the operations in an operating day you must right click the black bar indicating the date (Fig 269 C) and then click the required "lock" option.

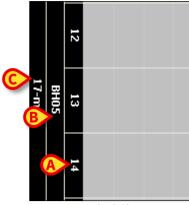


Fig 269



Only the operations scheduled either for the current day or for a day in the future can be locked/unlocked. The operations scheduled for a day in the past and not yet performed cannot be locked/unlocked.



When all the operations of either a room, a slot, a block or a day are unlocked at a certain level, the action affects only the operations that are locked at that same level.

That is, for instance:

there are three operations scheduled in a room: two of them are locked at level 2, one of them is locked at level 3. If the room is "unlocked level 2", then only the operations locked level 2 will be unlocked (and will pass to level 1). The operation locked at level 3 remains locked at level 3.

13.5.5. Reserves

Reserves are those operations for which no time slot, block or room have been assigned, but which are 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".

The Smart Scheduler system envisages three types of reserve:

- 1) room reserve (the operation has been assigned a block and an operating room but not a time this type of reserve is identified by the color blue);
- 2) block reserve (the operation has been assigned a block, but neither an operating room nor a time this type of reserve is identified by the color green);
- 3) generic reserve (the operation has been assigned neither a block, nor an operating room nor a time this type of reserve is identified by the color yellow).

The list of all reserves can be displayed by clicking the **Reserves** button on the command bar (see paragraph 13.4.4 and Fig 255 for the description of the relative page).

13.5.5.1. How to create a reserve

To create a reserve,

> click the **Edit** button on the command bar.

The screen turns to "edit" mode.

Move the mouse pointer over either one of the operations in the list of "operations to schedule" (Fig 270 A) or one of the operations already in the scheduling grid.

Left-click it and drag it to the black bar indicating the day, block or room (Fig 270 **B**, **C**, **D**). If the operation is dragged to the bar indicating the day (Fig 270 **B**) a generic reserve is created. If the operation is dragged to the bar indicating the block (Fig 270 **C**) a block reserve is created. If the operation is dragged to the bar indicating the room (Fig 270 **D**) a room reserve is created.

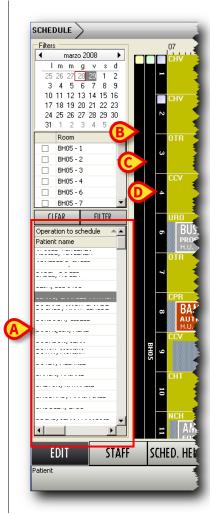


Fig 270 - Reserves

When there are reserves, special icons appear on the black bar (Fig 271).

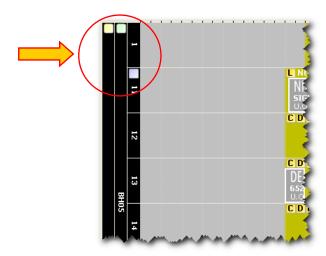


Fig 271 - Reserve Indication

The \square icon indicates the presence of at least one generic reserve for the day displayed.

The \square icon indicates the presence of at least one block reserve for block BH05.

The icon indicates the presence of at least one room reserve for room 11.

Click one of the icons to open the list of all reserves (Fig 255).

To add a reserve to the scheduling grid, after clicking the **Edit** button on the command bar, click the corresponding row in the "reserves" table (Fig 256) and drag it to point of the grid corresponding to the room and time required.

To return a reserve to the list of operations to schedule, after clicking the **Edit** button on the command bar, click the corresponding row in the "reserves" table (Fig 256) and drag it back to the "Operations to schedule" area.

13.6. Calendar

The "Calendar" screen of the DIGISTAT® "Smart Scheduler" system offers an overview of the operating room and block schedule (Fig 273).

To access this screen

> click the icon on the lateral bar.



Fig 272

The screen shown in Fig 273 will open.

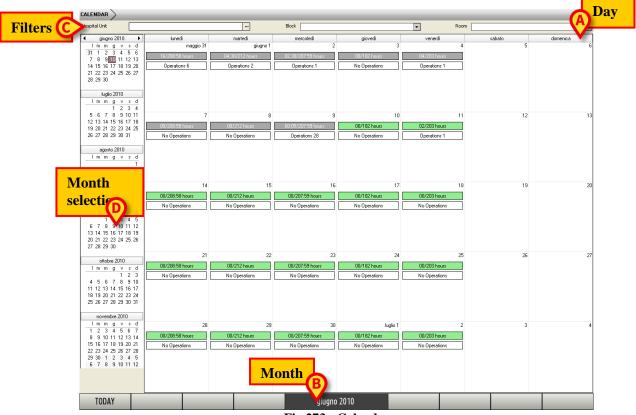


Fig 273 - Calendar

The central part of the page displays the calendar of the month you have decided to look at.

Every box represents an operating day (Fig 274).

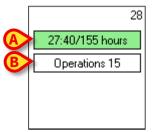


Fig 274 – Operating Day

The number in the top right corner of every box indicates the day to which the box refers.

The name of the day can be read on the bar at the top (Fig 273 **A**), the name of the month can be read on the central button of the control bar (Fig 273 **B**).

The box contains information on the scheduling of the operating rooms in the hospital units selected.



Every user, depending on his role and level of permissions, may display the situation only of the rooms for which he is responsible.

The square indicated in Fig 274 A indicates the number of hours allocated with respect to the total hours available. The box shows that, of the total 155 available for scheduling, 27 hours and 40 minutes are already allocated to operations.

The color green indicates that the day considered has time available for scheduling. If the day of reference has passed, the square is gray.

The square highlighted in Fig 274 **B** indicates the number of operations scheduled for that day.

Click this box to open a window containing detailed information concerning the situation of every room (Fig 275).



Fig 275 – Information Window

The example shown in Fig 275 **A** informs us, for example, that room 7 of block BH05 has 1 operation reserved for the day selected (you can read the patient's name, the type of operation and the duration scheduled), that the total time available in this room is 480 minutes and that the time occupied by operations is 120 minutes.

Moving downwards, we find information on all the rooms managed by the user connected on the day selected. In Fig 275 **B** for example, we can see that room 8 of block BH05 has two operations scheduled, that the total time available is 480 minutes and that 420 minutes are occupied.

13.6.1. Selecting the month

The left side of the page makes it possible to select the month to display (Fig 273 **D**). This part of the screen displays 6 months. Click one of them to display it, enlarged, in the center of the page.



The arrows indicated in Fig 276 make it possible to display and select past months (left arrow) and future months (right arrow).

The month may also be selected by clicking the name of the month. A menu which makes it possible to directly select the month required opens (Fig 277).



Fig 277

Click the **Today** button in the bottom left corner of the command bar to return to display the current month.

13.6.2. Selection filters

The fields in the upper part of the "Calendar" page make it possible to select the Hospital Unit, Block or Room to which the data on screen are referring (Fig 273 C, Fig 278).



Fig 278

If any value is specified inside these fields the data displayed on screen are calculated only referring to the Hospital Unit, Block, Room specified.

13.7. Schedule with help

The schedule with help page (Calendar Schedule - Fig 279) makes it possible to schedule the operations selected using certain automatic calculation functions for the availability of the different rooms.

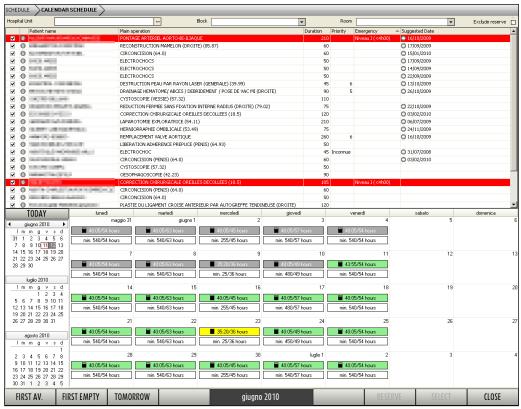


Fig 279 - Calendar Schedule

13.7.1. How to access the page

The calendar schedule page can be accessed from three different pages. These are:

- 1) the "Operation List" page;
- 2) the "Operation Record" page;

3) the "Scheduling" page.

13.7.1.1. Access from the "Operation List" page

On the "Operation List" page (Fig 93, paragraph 9),

- > select the operations to schedule.
- Click the **Change** button on the command bar (Fig 280 A).

The menu shown in Fig 280 will open.

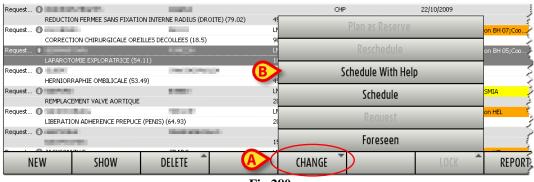


Fig 280

Click the Schedule with help option (Fig 280 B).

The "Calendar schedule" screen will open (Fig 282). All and only the selected operations will be shown on this screen.



To select more than one operation at a time, you must click the lines corresponding to the operations to be selected, keeping the CTRL key on the keyboard pressed.

13.7.1.2. Access from the "Operation Record" page

- ➤ On the "Operation Record" page (Fig 98, paragraph 10).
- Click the **Edit** button on the command bar (Fig 281 A)

The screen turns to "edit" mode.

Click the **Change** button on the command bar (Fig 281 **B**).

The menu shown in Fig 281 opens.

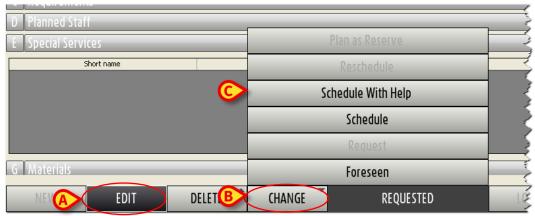


Fig 281

Click the "Schedule with help" option (Fig 281 C).

This accesses the "Schedule with help" page (Fig 282). Only the operation referred to by the initial "Operation Record" page will be shown on this page.

13.7.1.3. Access from the "Scheduling" page

On the "Scheduling" page (Fig 220, paragraph 13).

Click the **Sched. Help** button on the command bar.

This accesses the "Schedule with help" page (Fig 282). All the operations listed on the initial "Scheduling" page in the "Operation to schedule" area will be shown on this page.

13.7.2. Page description

The "Schedule with Help" page is made up of 5 areas.

- 1) The "Hospital Unit", "Block" and "Room" selection filters (Fig 282 A).
- 2) The month selection area (Fig 282 **B**).
- 3) The area containing the list of operations (Fig 282 C).
- 4) The central area, the calendar of the month selected (Fig 282 **D**).
- 5) The command bar (Fig 282 **E**).

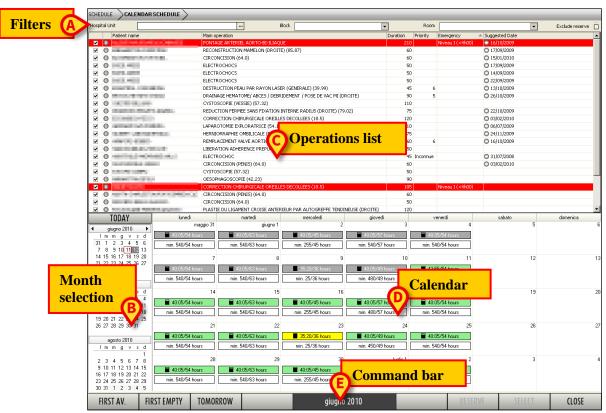


Fig 282

The characteristics and operation of areas A (selection filters) and B (month selection) are the same as those described in paragraph 13.6 for the "Calendar" page. See this paragraph for their description.

13.7.2.1. The list of operations

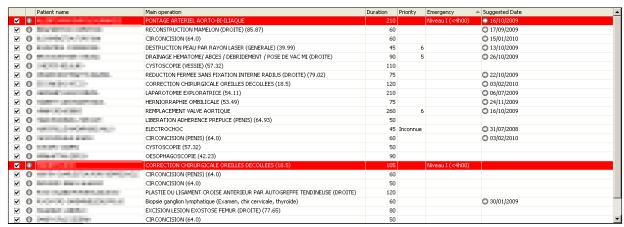


Fig 283 - List of operations

The table shown contains the list of operations to be scheduled using the functions of the schedule with help.

Every line corresponds to an operation.

The columns contain, in this order:

• the selection boxes.

The schedule with help functions are active only for the operations selected. Therefore, you can choose the operations on the list for which you wish to use the schedule with help functions by selecting or deselecting the box corresponding to the operation.

• The information icon



Click this icon to display a window summarizing the information available on the operation (Fig 284).



Fig 284 - Operation data

Click the **Select** button in the window to access the "Operation Record" page relating to the operation clicked (Fig 98).

- The name of the patient to be operated on.
- The operation.
- The scheduled duration.
- The degree of priority of the operation.

The operations scheduled as "Emergencies" are highlighted red.

• The date suggested for the operation (if indicated on the "Operation Record" page - Fig 98).

Click the circon alongside the suggested date to highlight the corresponding day in blue on the calendar (Fig 285 A). In this way you can immediately check the availability of time on the day suggested for a specific operation.

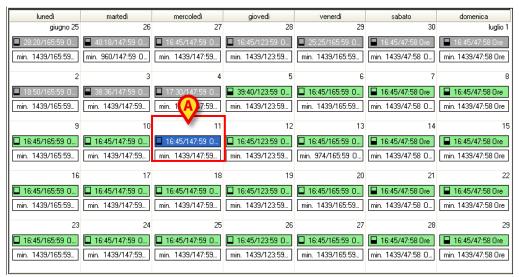


Fig 285 - Suggested date

13.7.2.2. The calendar of the selected month

The central part of the page shows, in a calendar form, the information on the availability of time in the operating rooms managed by the connected user (Fig 286).

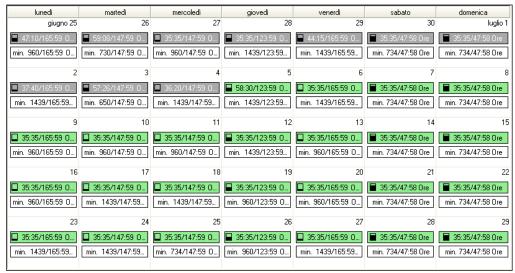


Fig 286 - Month selected

Every box corresponds to an operating day (Fig 287).

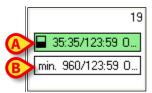


Fig 287 – Operating day

The upper box (Fig 287 **B**) indicates how much time, of the total time available that day, is already reserved for operations.

The \Box icon indicates that, for the day in question, the time occupied by operations is less than 50% of the total time.

6 possible icons of this type may occupy the same position.

- means that the total time is all available.
- means that the time occupied by operations is less than 25% of the total time.
- means that the time occupied by operations is less than 50% of the total time.
- means that the time occupied by operations is less than 75% of the total time.
- means that the time occupied by operations is less than 90% of the total time.
- means that the time is all occupied by operations.

The same information is contained in detail in text form alongside the icon. In the example shown in Fig 287, the time available is 35 hours and 35 minutes out of a total 123 hours and 59 minutes.

The green color of the box means that every operation selected on the list of operations (Fig 283) can be planned on that day.

The box in question can appear in yellow (Fig 288).

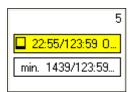


Fig 288

The color yellow means that at least one of the operations (but not all of the operations) selected on the list of operations (Fig 283) can be planned on that day.

The box can appear in red (Fig 289).

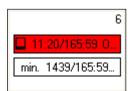


Fig 289

The color red means that none of the operations selected on the list of operations (Fig 283) can be planned on that day.

When the box appears in gray, the day in question is in the past. Therefore it is not possible to perform any operation on that day (Fig 290).

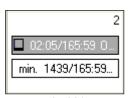


Fig 290

The lower box (Fig 287 **B**) indicates the longest range of time available in all the rooms managed by the user connected. This range is indicated in minutes to enable immediate comparison with the scheduled duration of the different operations (also indicated in minutes). The example shown in Fig 287 **B** indicates that the longest range of time that day in 960 minutes. Any operation with a scheduled duration of less than 960 minutes can therefore be scheduled on that day.

Click one of the operations selected on the list of operations to obtain additional information.



Fig 291 - Selecting an operation

The operation clicked appears highlighted (Fig 291 A) and new icons appear inside the boxes indicating the various days (Fig 291 B, Fig 292).

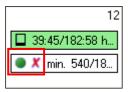


Fig 292

The • icon means that the operation highlighted can be planned on that day.

The • icon means that the operation highlighted <u>cannot</u> be planned on that day.

The \checkmark icon means that there has been a crosscheck with other IT systems and that there is no overlap of reservations for that patient on that day (the patient could, for example, have arranged a test or check-up for the same day).

The \times icon may mean two things: 1) that there has been no crosscheck with other IT systems and that there is no data regarding possible overlapped reservations; 2) that there is an overlap of reservations for that patient on that day.

Click the lower portion of every box (Fig 287 **B**) to open a window containing detailed information on the situation of every room in the day corresponding to the box.



Fig 293 – Day Details

The example shown in Fig 293 informs us, for example, that room 7 of block BH05 has 1 operations scheduled (you can read the patient's name, the type of operation and the duration), that the total time available in this room is 480 minutes and that the time occupied by operations is 120 minutes.

Moving downwards, you will find information on all the rooms managed by the user connected. Once again in Fig 293 you can see, for example, that two operations are scheduled in room 8 of block BH05, that the total time available in this room is 480 minutes and that the time occupied by operations is 360 minutes.

The "exclude reserves" checkbox indicated in Fig 291 C can be used to exclude the room, block or generic reserves from the calculation of available hours and minutes (see paragraph 13.5.5 for an explanation of the concept of "reserve"). By default, when the system calculates the times, it considers reserves as operations to be calculated. Select the "exclude reserves" checkbox to exclude the reserves from the time calculation. A room reserve, for example, with a scheduled duration of 100 minutes, will implicate a subtraction of 100 minutes from the time available in the room in which it has been scheduled. Select the "exclude reserves" checkbox to prevent subtraction of these 100 minutes.

To select one of the calendar days, simply click the corresponding box. The day selected appears highlighted in dark gray. Day 28 is selected in Fig 294.

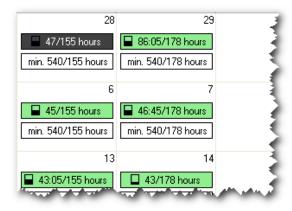


Fig 294 - Day Selected

13.7.2.3. Example: how to schedule an operation



Below there is an example of one of the possible ways of using the schedule with help page. To keep things simple we have selected just one operation. The procedure however is the same for multiple selections.

To plan an operation using the "Schedule with help" functionalities

- ➤ Access the "Schedule with help" window (Fig 279 Calendar Schedule) so that the operation appears in the list of operations Fig 283 (see paragraph 13.7.1 for instructions).
- Click inside the corresponding checkbox to select the operation.

The boxes indicating the various days will be colored depending on whether or not it is possible to schedule the operation (green if it fits, red if it doesn't - Fig 286).

- > Select the most suitable of the green boxes.
- Click the box to select it.

The box will be highlighted (Fig 294).

Click the Select button on the command bar.

The scheduling page opens (Fig 220) for the day selected and with only the operation selected in the "Operations to schedule" area.

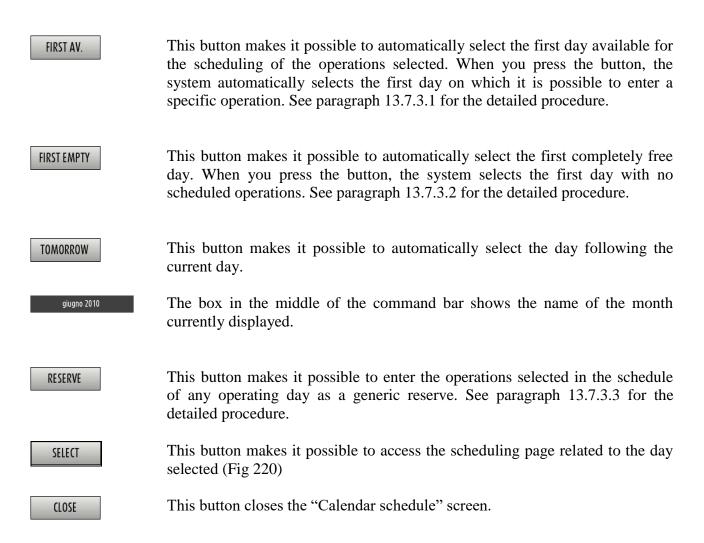
Enter the operation in the scheduling grid according to the procedure described in paragraph 13.5.

13.7.3. The command bar of the "Calendar schedule" screen

The control bar of the schedule with help page contains various button to perform different operations (Fig 295).



The functions of the different buttons are briefly listed in this paragraph and, when necessary, described in detail in the paragraphs indicated.



13.7.3.1. First available day

The **First Av.** button (Fig 296) makes it possible to automatically select the first day available for the scheduling of the operations selected. When you press the button, the system automatically selects the first day on which it is possible to enter a specific operation.



Fig 296 - "Calendar schedule" command bar

To use this function, you must

> click the box corresponding to the operation (or operations) to be scheduled (Fig 297).

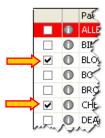


Fig 297

Click the **First Av.** button on the command bar (Fig 297 A).

The first day containing at least one empty slot is highlighted on the calendar.

Click the **Select** button on the command bar (Fig 297 **B**).

The scheduling page for the day chosen and the operation selected opens (Fig 220).

13.7.3.2. First empty day

The **First Empty** button (Fig 298 **A**) makes it possible to automatically select the first completely free day. When you press the button, the system selects the first day with no scheduled operations.



Fig 298 - "Calendar schedule" command bar

To use this function, you must

> click the box corresponding to the operation (or operations) to be scheduled (Fig 299).

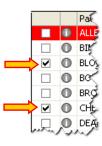


Fig 299

Click the **First Empty** button on the command bar (Fig 298 A).

The first completely free day is highlighted on the calendar.

Click the **Select** button on the command bar (Fig 298 **B**).

The scheduling page for the day chosen and the operation selected opens (Fig 220)

13.7.3.3. Create a generic reserve

The **Reserve** button (Fig 300 **A**) makes it possible to enter the operations selected in the schedule of any operating day as a generic reserve (see paragraph 13.5.5 for an explanation of the concept of "reserve").



Fig 300 - "Calendar schedule" command bar

To use this function, you must

click the box corresponding to the operation (or operations) to be scheduled as reserve (Fig 301).

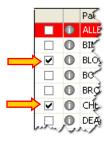
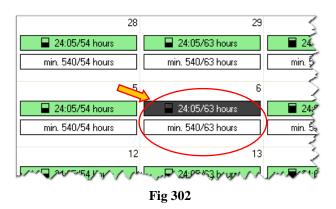


Fig 301

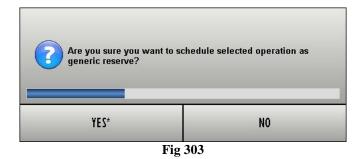
Click the box corresponding to the day on which you wish to enter the reserve.

The box appears highlighted (Fig 302).



Click the **Reserve** button (Fig 300).

A window requesting confirmation of the operation opens (Fig 303).



> Click **Yes** to schedule the operation as a reserve.

The operation selected disappears from the list of operations to schedule and appears as a generic reserve on the day chosen.

1

The functions performed by the **Reserve** and **Select** buttons can also be performed by right clicking. After selecting an operation, right click the box corresponding to the day required to open a window containing the two options, "Reserve" and "Select" (Fig 304).

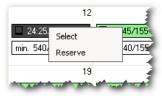


Fig 304

14. Room staff management

The "Staff management" module makes it possible to manage the planned staff of the operations. The module implements scheduling functionalities that are specific for the staff management. To access this module

Click the corresponding icon - on the lateral bar (Fig 305)



Fig 305

The "Staff Management" screen will open (Fig 306).



Staff can be also scheduled, with different procedures, on the "Operation Record" screen. The relating procedures are described in paragraph 12.4.

A "System Option" has been defined in order to avoid conflicts between the staff planned on the "Operation Record" and the staff planned on the "Staff management" module (described in this paragraph).

This "System Option", named **DisablePlannedStaffEditingOnOperationRecord**, if activated, enables staff editing on the "Operation Record" only if the operation is either in "Foreseen" or "Requested" state. The staff of the planned operations ("Planned" state) is only managed on the "Staff management" module.

To activate the system option set its Value=Yes.



If the operation data are changed while the staff is being edited, after the Update the system informs the user with a specific message. This message makes it possible to print a report containing the list of all the operations whose data changed.

This message is generated only once. It will not later be possible to print the list again.

The information that, if edited, triggers the message is: Operation status, Planned date, Planned time, Planned duration, Main operation, Planned Room, Planned Block.

14.1. Staff Management

The "Staff Management" screen (Fig 306) makes it possible to manage the operating staff for the planned operations.

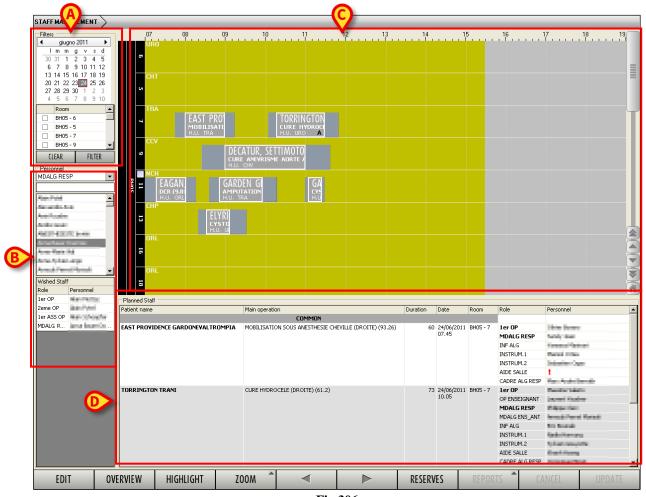


Fig 306

The screen is formed of four areas:

- The search filters area (Fig 306 A).
- The personnel editing tools panel (Fig 306 **B**).
- The area displaying either the operations plan or the reserves list (Fig 306 C).
- The area named "Planned Staff area" dedicated to show the planned staff (Fig 306 **D**).

These four areas are described in the following paragraphs.

14.1.1. Search filters

The search filters (Fig 306 A, Fig 307) make it possible to decide which operations are displayed in the "Planned operations" area (described in paragraph 14.1.3) by selecting the operation date and room.

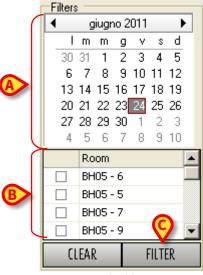


Fig 307

To display the operations planned for a specific date

- ➤ Click the cell corresponding to the wanted day on the calendar indicated in Fig 307 A.
- ➤ Click the **Filter** button (Fig 307 **C**).

The operations planned for the selected day will be displayed.

Multiple days selection is possible (maximum 5 days) by keeping the mouse button clicked while selecting the corresponding cells. The day after present day is selected by default.

The display the operations planned for a specific room

- > Select the checkbox corresponding to the room in the area indicated in Fig 307 **B**.
- Click the Filter button (Fig 307 C).

Only the operations planned for the selected rooms are this way displayed. Multiple room selection is possible.

14.1.2. Personnel editing tools

The personnel editing tools, shown in Fig 308, make it possible to search and select the staff members in order to associate (or dissociate) them to one or more operations. The room staff can be here defined as a team and later associated (the whole staff) to one or more operations.



Fig 308

The panel shown in the figure is formed of four tools.

- **Role filter** (Fig 308 **A**) this field makes it possible to specify the wanted role. Only the staff members enabled to cover that role are displayed in the personnel table (Fig 308 **C**).
- Name filter (Fig 308 B) this field makes it possible to specify the name of the wanted staff member. After three characters are typed, the list displays only the members whose names match the inserted characters.
- **Personnel table** (Fig 308 C) This table lists on one column the staff members according to what was specified in the fields described above (name and role).
- Wished Staff (Fig 308 D) This grid must be filled by the user with the names of the staff members required for an operation. The "Wished staff" area makes it possible to define the whole staff for one or more operations as an "operating team" that can be later associated to the specific operations. To add a staff member to the "Wished staff", drag the name of the person to be added from the personnel table and drop it on the "Wished staff" area. See paragraph 14.2.2 for the detailed procedure.

14.1.3. "Planned operations" area

The area shown in Fig 306 C and Fig 309 provides a view of the operating plan. The plan has the same structure and features of the "Operating Plan" described in chapter 13. See this chapter for a detailed description.

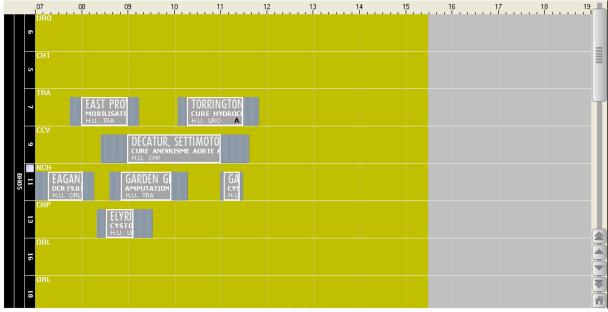


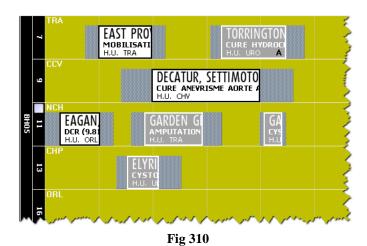
Fig 309

Scheduling functionalities are here disabled. The only possible action is the operation selection.

To select an operation

- > click the **Edit** button on the command bar.
- ➤ Click the rectangles corresponding to the operations to be selected.

The selected operation appears white with black borders (see Fig 310).



The selection of one or more operations displays the details of the selected operations in the "Planned staff" area (Fig 306 **D**, Fig 312). Most important, the details relating to the planned staff of the selected operations are displayed in the "Planned Staff" area. By default, if no operation is selected, the details of all the planned operations are displayed in the "Planned staff" area.

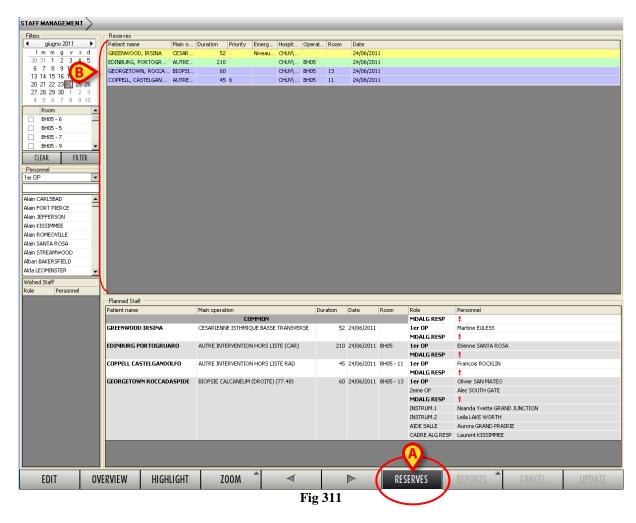
14.1.3.1. "Reserves" display

The "Planned operations" area (Fig 309) is also used to display the list of "Reserves" (see paragraph 13.5.5 for an explanation of the "Reserve" concept).

To display the "Reserves" list

Click the Reserves button on the command bar (Fig 311 A).

The list of "Reserves" will be displayed (Fig 311 **B**).



Each row in the "Reserves" list corresponds to an operation. For each operation the following information is provided:

- Patient name
- Operation
- Planned duration
- Priority
- Emergency level
- Requesting Hospital Unit
- Planned block
- Planned room
- Planned date

To select a "Reserve"

- > click the **Edit** button on the command bar.
- ➤ Click the row corresponding to the "Reserve" to be selected.

To select multiple "Reserves", keep the "Ctrl" button on the workstation keyboard pressed while clicking on the different rows.

The selection of one or more "Reserves" displays the details of the selected operations in the "Planned staff" area (Fig 306 **D**, Fig 312). Most important, the details relating to the planned staff of the selected operations are displayed in the "Planned Staff" area. By default, if no "Reserve" is selected, the details of all the "Reserves" are displayed in the "Planned staff" area.

14.1.4. "Planned staff" area

The area shown in Fig 312 and Fig 306 **D** displays, alongside the operation's main data, detailed information on the staff planned for the operations selected in the "Planned operations" area (Fig 309). If no operation is selected in the "Planned operations" area, the data relating to all the planned operations are displayed.

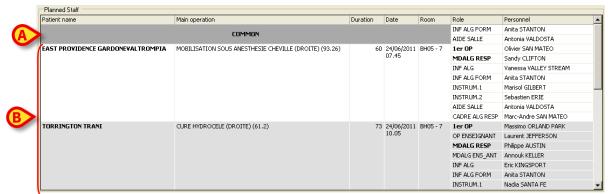


Fig 312

The operations are displayed on a grid. The first row, indicated in Fig 312 A and enlarged in Fig 313, named "Common", shows the (possible) staff members that are common to all the selected operations. The "Common" row is therefore displayed only if more than one operation is selected (or no operation is selected).



For each staff member the role and the name are indicated (Fig 313 A).



The option displayed instead of the name (no name) of the staff member indicates that every person enabled to cover the specified role is suitable for the operation.

The icon displayed instead of the name of the staff member indicates that the specific role is required but no information was provided regarding the person's name.

If the occupied icon is displayed alongside the name it means that only that specific person is suitable for the operation.

The rows placed below the "Common" row (Fig 312 **B**, Fig 314) indicate the selected operations. The operation main data are here provided (patient name, planned operation, planned date and time, planned duration and planned room) alongside the detailed planned staff.

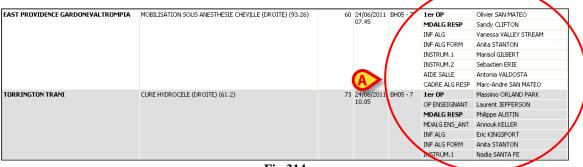


Fig 314

The name and the role of each staff member are displayed (Fig 314 A). If an operation requires the same role more than once, various rows are displayed, referring to the same role.

14.1.5. Highlight functionality

The **Highlight** button on the command bar makes it possible to highlight the name of a selected staff member in the "Planned staff" area. A user can activate this functionality to immediately know for which operations a determined person is a staff member.

To activate the functionality

- > Click the person's name either on the "Personnel" table or on the "Wished staff" area (Fig 315 A).
- Click the **Highlight** button (Fig 315 **B**).

The person's name will be highlighted in the "Planned staff" area (Fig 315 C). Also, the corresponding operation boxes are highlighted on the "Plan" (Fig 315 D).

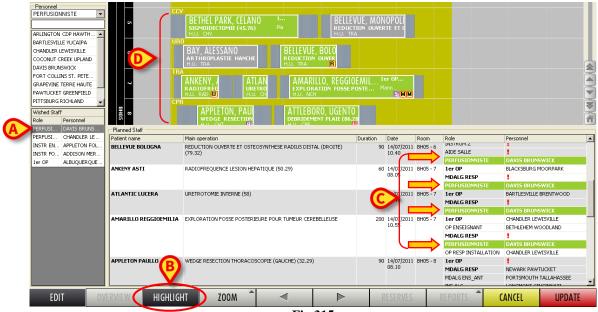


Fig 315

If the person's name was originally selected on the "Personnel" table, then it is highlighted not considering the role.

If it was originally selected on the "Wished Staff" area, then it is highlighted only in the operations for which it is associated with the specified role.

If the staff member name is clicked on the "Planned staff" area then the corresponding operation box is highlighted on the Plan.

You can also click the "Wished Staff" bar (Fig 316) to highlight all the wished staff members at once. In this case all their operations will be highlighted.



Fig 316

The "Highlight" functionality can also be used as a filter for the "Staff overview" screen (see paragraph 14.3). I.e. if the "Highlight" functionality is activated and the **Overview** button is clicked, then the displayed "Staff overview" screen shows only the operations for which the selected staff members are scheduled.

14.2. Staff management procedures

This paragraph describes the procedures that can be performed on the "Staff management" module, making it possible to manage the operating staff.

14.2.1. Possible destinations indication

Basically, the staff management procedures are performed using the drag and drop functionality. That is, the various items on screen can be dragged from one position and dropped onto another for staff management purposes (described later in the specific paragraphs).

In order to facilitate the procedures, every time a "draggable" item is clicked, the system indicates the possible destinations with a blue border. See for instance Fig 317, in which the "Personnel Table" and "Wished Staff" area are bordered (on the right).

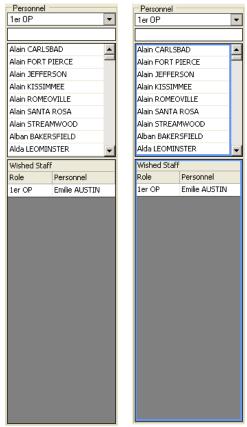


Fig 317

14.2.2. Adding a staff member to the "Wished staff"

The "Wished staff" area (Fig 318 B) makes it possible to define the whole staff for one or more operations as an "operating team" that can be later associated to the specific operations.



Fig 318

There are two ways to add a staff member to the "Wished staff". In both cases, first of all, click the **Edit** button on the command bar, then

1) First way: click the row corresponding to the wanted member on the "Personnel table" (Fig 318 A).

Drag the row onto the "Wished Staff" area (drag from Fig 318 A and drop onto Fig 318 B).

2) Second way: right-click on the row corresponding to the wanted staff member on the "Personnel table".

A contextual "Add to wished staff" option is displayed (Fig 319).



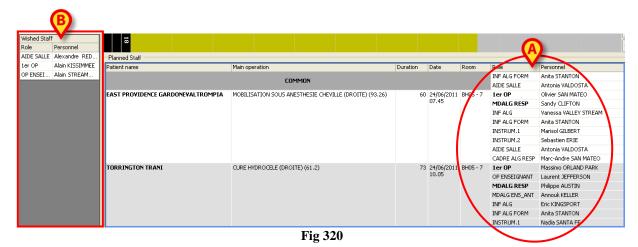
Fig 319

Click the "Add to wished staff" option.

In both cases the name of the staff member is displayed on the "Wished staff" area.

It is also possible to add a staff member by selecting him/her from the planned staff of an existing operation. Again, there are two ways to do that:

1) First way: click the row corresponding to the wanted staff member selecting it in the "Planned staff" area (Fig 320 A). Drag the item onto the "Wished staff" area (Fig 320 B).



2) Second way: right-click on the row corresponding to the wanted staff member on the "Planned staff" area.

A contextual menu opens (Fig 321)



Click, on the menu, the "Add to wished staff" option.

In both cases the name of the staff member is displayed on the "Wished staff" area.

At the end of each procedure, in order to save the changes made,

> click the **Update** button.

14.2.3. Remove a staff member from the "Wished Staff" area

There are two ways to remove a member from the wished staff. In both cases, first of all, click the **Edit** button on the command bar, then

- 1) First way: click the row corresponding to the member to remove on the "Wished Staff" area. Drag the row onto the "Personnel table" area (drag from Fig 318 **B** and drop onto Fig 318 **A**).
- 2) Second way: right-click on the row corresponding to the staff member to be removed on the "Wished saff" area.

A contextual menu opens (Fig 322).



Click, on the menu, the "Remove from wished staff" option.

Click the **Update** button.

In both cases the name of the staff member is removed from the "Wished staff" area.

Also, it is possible to remove the whole staff using the "Remove all" option on the same contextual menu.

14.2.4. Creating a "Wished staff" from the planned staff of an existing operation

To add the already existing staff of a planned operation to the "Wished staff" area

- Click the Edit button on the command bar.
- ➤ Click, on the "Planned staff" area, the operation whose staff must be added to the "Wished staff".

The row corresponding to the operation is highlighted (Fig 323 A).

➤ Drag the item to the "Wished staff" area (Fig 323 **B**).

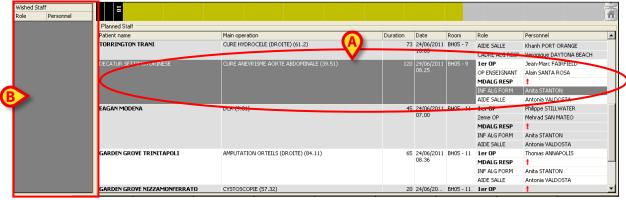


Fig 323

Click the Update button.

All the staff members of the selected operation are this way added to the wished staff.

14.2.5. Associating a staff member to one or more operations

To associate a staff member to one or more operations

- Click the **Edit** button on the command bar.
- ➤ Use the filters described in paragraph 14.1.1 to search for the person to be associated to the operating staff.
- > Drag the person's name onto the "Planned staff" area.

If the name is dragged onto the area relating to a specific operation, the staff member is associated only to that operation. If the name is dragged onto the "Common" area, the staff member is associated to all the selected (and therefore displayed) operations.

Click the Update button.

14.2.6. Associating the whole staff to one or more operations

To associate the whole operating staff to one or more operations

- > Click the **Edit** button on the command bar.
- ➤ Use the procedures described in paragraph 14.2.2 to define the operating staff.
- Click the "Wished staff" bar (Fig 324 A) and drag it onto the "Planned Staff" area (Fig 324



Fig 324

If the bar is dragged onto the area relating to a specific operation, the whole staff previously defined is associated only to that operation. If the bar is dragged onto the "Common" area, the whole staff is associated to all the selected (and therefore displayed) operations.

Click the Update button.

14.2.7. Removing a staff member

To remove a planned staff member either from a specific operation or from the "Common" list

- Click the **Edit** button on the command bar.
- Click, on the planned staff grid (Fig 325 A), the row corresponding to the staff member to be removed.
- ➤ Drag the item onto the Personnel Table (Fig 325 **B**).

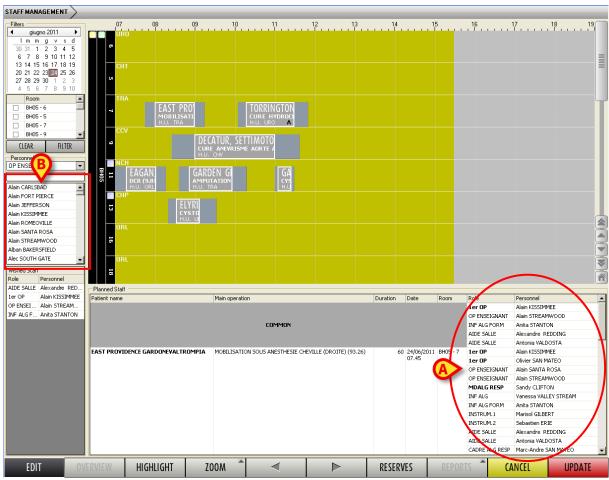


Fig 325

Click the Update button.

The staff member is this way removed either from the specific operation or from all the selected operations.

It is otherwise possible to right-click the staff member name on the planned staff grid.

A contextual menu is displayed (Fig 326).

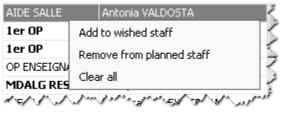


Fig 326

Three options are here available:

- ➤ Click the "Add to wished staff" option to add the selected person to "Wished staff" area (Fig 320 B). Note: this option does not remove the staff member from the planned staff, it only adds him/her to the wished staff.
- > Click the "Remove from planned staff" option to remove the selected member from the planned staff.
- > Click the "Clear all" option to remove the whole staff from the planned staff.

14.3. Staff overview

A specific screen displays a general overview of the staff schedule.

To access that screen

Click the **Overview** button on the command bar.

The following screen is displayed (Fig 327).

	DIAM C			N 105 7					15/07/2011				DUOT O			DUOT 44		DUIDE 40	
Personnel	BH05-6			BH05-7				BH05-8			BH05-9			BH05-11		BH05-13			
	REDUCT 07.00	ARTHRO 09.35	LIPOFILL 12.40	CURE HA 07.05	ARTHRO 08.55	REDUCT 10.38	REDUCT 12.13	07.00	POSE PO 09.05	CORREC 10.43		AMPUTA 07.05	CORREC 08.40	LIFTING 10.41	REPARA 07.05		CORREC 07.00		
ALBUQUERQUE ,LANSING	07.00	09.33	12.40	07.03	00.55	10.30	12.13	07.00	09.03	10.43	12.10	07.03	00.40	10.41	07.03	1er OP	07.00		
ATLANTIC ,SEATTLE			1er OP					2eme OP		1er OP						2eme OP			
BAY ,MISSOULA		1er OP																	
MY PERSONAL				1er OP															
NEW PROPERTY.															1er OP				
No. PERSONAL															201 01			1er C	
BEAUMONT ,MACON		INSTRUM.		INSTRUM.														INSTR	
BEND , WILSON																		INF A	
BLACKSBURG ,PLACENTIA																			
BLOOMINGTON ,KANNAPOLI S																		CADR ALG R MDAL ENS_A	
CAPE GIRARDEAU ,NOVATO				1er OP															
CYPRESS ,GILROY		OP ENSEIGNA NT		OP ENSEIGNA NT															
DUNCANVILLE ,BREMERTON			2eme OP																
FORT PIERCE ,EAU CLAIRE																			
GRAND JUNCTION ,OXNARD																			
GREENFIELD ,PAWTUCKET																			
WILLIAM TO A STATE OF THE STATE												1er OP							
HANFORD ,SOUTH GATE											1er OP								
HAWTHORNE , ARLINGTON CDP								1er OP											
LA MESA ,FOND DU LAC														1er OP			1er OP		
LEWISVILLE , CHANDLER									2eme OP										
MANCHESTER ,RANCHO SANTA MARGARITA	1er OP																		
MIRAMAR ,PALM SPRINGS																			
MURRIETA ,CLEVELAND HEIGHTS										1er ASS OP									
NORTHGLENN ,BERKELEY																			
RICHLAND ,PITTSBURG						1er ASS OP													
PLEASURE STREET, WELVE													1er OP						
SALINA ,SPRINGFIELD																			
SAN BUENAVENTURA (VENTURA) ,ARLINGTON HEIGHTS		1er OP					1er OP												
SHEBOYGAN ,REVERE					1er OP														
ST. PETERS ,ROSWELL						1er OP													
TERRE HAUTE , GRAPEVINE																		MDAI RESF	
WACO, YAKIMA									1er OP										
4																		Þ	
																	CLOS	ΣÉ	

Fig 327

Each row on this screen represents a staff member; each column represents an operation.

The cell corresponding to the place where a certain staff member and a certain operation meet displays the role that the staff member covers for that specific operation. See, for instance, Fig 328 **A**, indicating that the staff member "Bay Missoula" is first operator in the operation "Arthrodese…" scheduled in room 6 of block BH05 at 9:35.

		BH05-6		BH05-7					
Personnel	REDUCT	ARTHRO	LIPOFILL	CURE HA	ARTHRO	REDUCT			
	07.00	09.35	12.40	07.05	08.55	10.38			
ALBUQUERQUE ,LANSING									
ATLANTIC ,SEATTLE	_/		1er OP						
BAY ,MISSOULA	A	1er OP)						
Mary Address of the				1er OP					
ne promote									
and processes to									
BEAUMONT ,MACON		INSTRUM. 1		INSTRUM. 1					
BEND ,WILSON									
BLACKSBURG ,PLACENTIA									
BLOOMINGTON ,KANNAPOLI S									
CAPE GIRARDEAU ,NOVATO				1er OP					
CYPRESS ,GILROY		op Enseigna Nt		op Enseigna Nt					
DUNCANVILLE ,BREMERTON			2eme OP						
FORT PIERCE ,EAU CLAIRE									

Fig 328

The operations are ordered by date and time and the grouped by block and room. A heading placed on top indicates the operation's scheduled time, date and place.



The "Highlight" functionality can be activated to display, on the "Staff Overview" screen, only a selected subset of staff members and their operations. I.e. if, on the "Staff management" screen (Fig 325) one or more staff members are highlighted, the "Staff Overview" screen displays only the operations scheduled for the highlighted staff members. See paragraph 14.1.5 for more information on this functionality.

15. Contacts

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16. Residual risks

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

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

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

RISKS RELATING TO THE HARDWARE PLATFORM IN USE

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

Appendix: end-user license agreement



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

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

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

The product "DIGISTAT®" (also "PRODUCT") comprises computer software and may include associated storage media, printed materials and "online" or electronic documentation. The PRODUCT also contains updates, if any, and integrative components for the original PRODUCT supplied by Ascom UMS. Any software supplied with the PRODUCT and associated with a separate End-User License is licensed to the User in compliance with the said contract's terms and conditions. By installing, copying, downloading, viewing or otherwise using the PRODUCT, the User agrees to be bound by the terms of this EULA. If the User does not agree to the terms and conditions of this EULA, he is not authorized to use the PRODUCT and must immediately stop using it.

PRODUCT LICENSE

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

- 1. **GRANT OF LICENSE.** This EULA grants the User the following rights:
 - **Application Software.** The User may install, use, access, view, run or otherwise interact ("RUN") with one copy of the PRODUCT or any previous version for the same operating system on the licensed number of computers, workstations, terminals, palmtop computers, pagers, smartphones or other electronic digital devices ("COMPUTERS").
 - **Storage/Network Use.** The User may also store or install a copy of the PRODUCT on a storage device, such as a network server, which is only used to RUN the PRODUCT on other computers over an internal network. A PRODUCT license may not be concurrently shared or used on different COMPUTERS.
 - License Pack. If this package is an Ascom UMS License Pack, the User is authorized to RUN a number of additional copies of this PRODUCT's software up to the number of copies specified above as "Authorized Copies".

• Copyright. In compliance with legal regulations, Ascom UMS retains all rights not expressly granted in this EULA.

2. OTHER RIGHTS AND LIMITATIONS

- Limitations on Reverse Engineering, Decompilation, and Disassembly. The User may not reverse engineer, decompile, or disassemble the PRODUCT, except and only to the extent that such activity is expressly permitted by applicable law notwithstanding this limitation.
- **Separation of Components.** The PRODUCT is licensed as a single product. Its component parts may not be separated for use on more than one computer, to redistribute or to use them as development components. Only exception to this rule is the font UMSCondensed distributed under the Ubuntu Font license agreement (accessible at http://font.ubuntu.com/ufl/).
- **Trademarks.** This EULA does not grant the User any rights on any trademarks or Ascom UMS registered trademarks.
- **Sub-license and Rental.** The User may not rent, sub-license, lease, or lend the PRODUCT.
- Export Laws. The User acknowledges that the license of the PRODUCT is subject to the export control laws, restrictions and regulations and any amendments thereof of Italy, United States of America, Panama and UK, which restrict exports and re-exports of software, technical data, and direct products of technical data, including services and developed software. These restrictions include, but are not limited to: restricted countries, restricted end-users, and restricted end-uses. The User agrees that he/she will not export or re-export the PRODUCT, any part thereof, or any process or service that is the direct product of the PRODUCT, to any country, person, entity, or end user subject to export restrictions by one or more of the listed countries.
- Technical Assistance Service. Ascom UMS and/or the distributor may provide the User with a Technical Assistance Service for the PRODUCT ("Technical Assistance Service"). Use of the Technical Assistance Service is governed by Ascom UMS and/or distributor policies and programs, which are provided on request. Any additional software code provided to the User as part of the Technical Assistance Service shall be considered as part of the PRODUCT and subject to the terms and conditions of this EULA. Concerning technical information the User may give to Ascom UMS or to the distributor during the Technical Assistance Service, Ascom UMS may use such information for its business purposes, including product support and development.
- **Termination.** Without prejudice to any other rights, Ascom UMS may terminate this EULA if the User fails to comply with the terms and conditions of the same. In such an event, the User must destroy all copies of the PRODUCT and all its component parts.
- 3. **UPGRADES.** If the PRODUCT is labeled as an upgrade ("Upgrade"), the User must be properly licensed to use a product identified by Ascom UMS as being eligible for upgrades required to use the PRODUCT. A PRODUCT labeled as an upgrade replaces and/or supplements (and can deactivate) the PRODUCT that forms the basis for your eligibility for

the upgrade. The User may use the resulting upgraded PRODUCT only in compliance with the terms of this EULA. If the PRODUCT is an upgrade for a component of a software program package licensed to the User as a single PRODUCT, the PRODUCT may be used and transferred only as part of that single PRODUCT package and may not be separated for beyond the scope of the software license.

- 4. **COPYRIGHT.** PRODUCT rights and copyright (including, but not limited to, every image, photo, animation, video, audio, music, text and "applet" integrated with the PRODUCT), annexed printed material and any copy of the PRODUCT are the property of either Ascom UMS or its suppliers. Intellectual property title and rights on the contents the User may access by using the PRODUCT are the property of the respective owners and can be protected by copyright or by other laws and treaties on intellectual property. This EULA does not grant the right to use such contents. If the PRODUCT contains documentation supplied only in electronic format, the User is authorized to print a copy of the abovementioned electronic documentation. The User may not copy the printed material annexed to the PRODUCT.
- 5. **BACKUP COPY.** After installing a copy of the PRODUCT in compliance with the terms of this EULA, the User may preserve the original media on which Ascom UMS supplied him the PRODUCT only for backup or storage purposes. If the User needs the original media to use the PRODUCT, he/she may create only one copy of the PRODUCT for backup or storage purposes. Except for this EULA's express specifications, the User may not run copies of the PRODUCT or of the annexed printed material for other purposes.

LIMITED WARRANTY

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

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

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

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

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

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

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

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

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

Limitation of Liability. IN NO CASE WILL ASCOM UMS OR ITS SUPPLIERS BE HELD RESPONSIBLE FOR THE LOSS OF INCOME, PROFIT OR DATA OR FOR SPECIAL, INDIRECT, SUBSEQUENTIAL, INCIDENTAL OR PUNITIVE DAMAGES EITHER CAUSED, TRIGGERED OR RESULTING FROM THE USE OR INABILITY TO USE THE PRODUCT, EVEN IF ASCOM UMS OR ITS SUPPLIERS WERE INFORMED ABOUT THE POSSIBILITY THAT SUCH DAMAGES COULD OCCUR.

Under no circumstance will either Ascom UMS or its suppliers' responsibility cover compensation exceeding the price paid by the customer.

UNDER NO CIRCUMSTANCE WILL THESE GENERAL CONTRACT CONDITIONS INVOLVE ACKNOWLEDGEMENT OF ASCOM UMS OR IT'S SUPPLIERS' RESPONSIBILITY IN CASE OF DEATH OR PERSONAL INJURY RESULTING FROM THE USE OF THE PRODUCT.

The said limitations shall apply even if this warranty fails to meet its essential purpose.

THE ABOVEMENTIONED LIMITATIONS SHALL NOT APPLY IN THE STATES AND IN THE JURISDICTIONS THAT DO NOT ALLOW LIMITATION OR EXCLUSION OF INCIDENTAL OR CONSEQUENTIAL DAMAGE.

This EULA and the warranty concerning the PRODUCT shall be subject to the Italian law. The United Nations Convention on the International Sales of Goods shall not apply. Should one or more provisions of this EULA be held as null or void by a Court of competent jurisdiction, the remaining provisions shall be considered as fully valid and effective.

Except for what expressly provided for herein, this EULA constitutes the complete agreement between the parties on the license of the PPRODUCT and replaces any other conflicting or additional provision of the purchase order.

The date of delivery of the PRODUCT to customer is recorded in the shipment documentation or in the PRODUCT delivery documentation.

INTENDED USE

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

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

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

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

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

The Product is intended for use by trained healthcare professionals within a hospital/clinical environment and relies on proper use and operation of the IT and communication infrastructure in place at the healthcare facility, the display devices used and the connected clinical devices and systems.

Additionally, the Product provides specific functions and interfaces intended to be used by non-professional users in remote locations for non-clinical purposes for display of information, reports, charts and statistics, without any possibility to add, change or delete any information or data.

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

CONFLICTING TERMS

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

* * * * *

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

Date	Signature

SPECIFIC ACCEPTANCE OF CERTAIN PROVISIONS IN THIS EULA

IMPORTANT—READ CAREFULLY

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

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

Signature