DIGISTAT® OranJ

DIGISTAT® Version 4.2

User Manual

DIG UD ORJ IU 0004 ENG V01
06 DIC 2016

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

DIGISTAT® version 4.2
Copyright © ASCOM UMS srl. All rights reserved.
No part of this publication can be reproduced, transmitted, copied, recorded or translated, in any form, by any means, on any media, without the prior written consent of ASCOM UMS.

SOFTWARE LICENSE

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

WARNING

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

LICENSES AND REGISTERED TRADEMARKS

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

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

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

1. Contents

1. Contents 3
2. Using the manual 8
2.1. Aims 8
2.2. Charcters used and terminology 9
2.3. Symbols 10
3. Introduction to DIGISTAT® 11
3.1. Modular architecture 11
3.2. Intended use 11
3.2.1. Safety Advisories 12
3.2.2. “Off-label” use of the Product 13
3.3. Manufacturer’s responsibility 14
3.4. Product tracking 14
3.5. Post-market surveillance 14
3.6. Product life 15
3.7. CE mark and regulation conformity 15
4. Software/Hardware specifications 16
4.1. Bedside 16
4.1.1. Hardware 16
4.1.2. Operating System 16
4.2. Central 16
4.2.1. Hardware 16
4.2.2. Operating System 17
4.3. Server 17
4.3.1. Hardware 17
4.3.2. Operating System 17
4.3.3. System Software 17
4.4. Handheld device 17
4.5. Firewall and Antivirus 19
4.6. Local network features 19
4.6.1. DIGISTAT® impact on the hospital network 20
5. Before starting 21
5.1. Installation and maintenance warnings 21
5.2. Cleaning 22
5.3. Precautions and warnings 22

5.3.1. Electrical safety 23
5.3.2. Patient Area 23
5.3.3. Electromagnetic compatibility 24
5.3.4. Devices eligibility 24
5.4. Privacy Policy 25
5.4.1. User credentials features and use 25
5.4.2. System administrators 27
5.4.3. System logs 27
5.5. Back up policy 27
5.6. Out-of-order procedure 28
5.6.1. Reconfiguration/substitution of network equipment 29
5.7. Preventive maintenance 29
5.8. Compatible devices 31
5.9. System unavailability 32
6. "Control Bar" and DIGISTAT® environment 33
6.1. Introduction 33
6.2. Touch screen 33
6.3. Launching DIGISTAT® 34
6.4. DIGISTAT® Work Area 34
6.4.1. Selecting a module 35
6.5. Accessing the system 36
6.5.1. Barcode log in 37
6.5.2. Disabling the automatic log out 38
6.5.3. Recent users 39
6.5.4. How to use the "User List" 39
6.6. DIGISTAT® Control Bar 41
6.6.1. How to read the "Patient" button 42
6.7. Help 44
6.8. DIGISTAT® Main Menu 45
6.8.1. Patient reports 47
6.8.2. Print reports 47
6.8.3. Statistics 54
6.8.4. Change password 57
6.8.5. About DIGISTAT® 58
6.8.6. Quit DIGISTAT® 59
7. The OranJ system 61

7.1. Introduction 61
7.2. General structure 61
7.3. Colors and operation state in OranJ 61
7.4. The “List of operations” page 62
7.4.1. The list of operations 63
7.4.2. The filter buttons 66
7.4.3. “List of operations” screen command bar 66
8. The “OranJ” module 68
8.1. “OranJ Home” screen 69
8.2. Operation data 69
8.3. Command bar 71
8.4. Operation chronology: the “Markers” 71
8.4.1. Markers sequence 72
8.4.2. Patient identification 74
8.4.3. Markers and operation state changes 76
8.4.4. Markers management 77
8.5. “Drugs, events and notes” area 79
8.5.1. How to record an event 81
8.5.2. How to edit an existing event 87
8.5.3. How to delete an existing event 88
8.6. The “Notes” area 89
8.7. The “patient” area 91
8.8. The “room” area 92
8.9. The “residual time” area 93
8.10. The “staff” area 95
8.10.1. “Room Staff” page description 96
8.10.2. Operating staff management 97
8.11. The “materials and resources” area 100
8.11.1. Manual procedure 103
8.12. “Resources Used” screen description 105
8.12.1. Editing the “Resources used” screen 108
8.12.2. How to move a specified resource set to another operation 110
9. Operation and patient management 114
9.1.1. Patient 116
9.1.2. Operation 117
9.1.3. Other operations 119

9.1.4. Other information 121
9.2. How to schedule a new operation 122
9.2.1. How to cancel a scheduled operation 125
10. The OranJ "Plan" module 128
10.1. Screen description 129
10.2. The "OranJ Plan" command bar 134
10.2.1. How to edit the operation plan 134
10.2.2. How to change the block displayed 136
10.2.3. How to change the time range displayed 137
10.2.4. How to change the day displayed 137
10.3. The "not assigned" area 139
10.3.1. Planning a "Reserve" operation 141
10.4. Room Plan 141
10.4.1. Scheduling the single room 142
10.4.2. Room schedule 142
10.4.3. The command bar 145
10.4.4. The "daily program" area 146
10.4.5. The "not assigned" area 147
10.4.6. How to edit the operations schedule 147
10.4.7. Room markers 149
10.4.8. How to edit the room markers 150
11. The OranJ Central module 152
11.1. The main page 152
11.2. Operating Room detail 155
11.3. Room schedule 156
11.4. The command bar 160
11.5. "Room monitor" page contents 160
11.6. Operating times detail 161
11.6.1. Operation times 161
11.6.2. Room times 170
12. OranJ Chart module 172
12.1. Page features 172
12.1.1. The "Events" area 173
12.1.2. The "Chart" area 174
12.1.3. The command bar 175
13. Check-In configuration 176

13.1. Modules in use 176
13.1.1. OranJ Plan 176
13.1.2. OranJ Check-In 178
13.2. How to perform the patient check-in 179
13.2.1. Check-in procedure by barcode reading 179
13.2.2. Manual check-in procedure 180
13.3. How to perform the patient check-out 183
14. OranJ - "Bedside"Configuration 184
14.1. The Room Plan module 184
14.1.1. Room schedule 185
14.1.2. The command bar 188
14.1.3. The "daily program" area 188
14.1.4. The "not assigned" area 189
14.1.5. How to edit the operation plan 190
14.1.6. Room markers 191
14.1.7. How to edit the room markers 192
15. Contacts 194
16. Residual risks 195
Appendix: end-user license agreement 196

2. Using the manual

2.1. Aims

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

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

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

To be more precise, the differences may concern

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

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

2.2. Charcters used and terminology

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

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

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

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

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

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

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

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

2.3. Symbols

The following symbols are used in this manual.

Useful information

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

Caution!

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

3. Introduction to DIGISTAT®

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

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

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

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

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

3.1. Modular architecture

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

3.2. Intended use

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

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

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

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

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

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

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

3.2.1. Safety Advisories

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

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

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

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

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

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

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

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

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

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

PATIENT POPULATION

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

———————— • ————————

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

3.2.2. "Off-label" use of the Product

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

3.3. Manufacturer's responsibility

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

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

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

3.4. Product tracking

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

3.5. Post-market surveillance

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

The device details can be found on its labelling.

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

3.6. Product life

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

3.7. CE mark and regulation conformity

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

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

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

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

4. Software/Hardware specifications

The information provided in this chapter covers the manufacturer's obligations identified by the IEC 80001-1:2010 standard (Application of risk management for IT-networks incorporating medical devices).
According to the IEC 60601-1 regulation, for "bedside" PCs, or for PCs positioned within the "Patient Area", the use of "Medical grade" devices is required. In these places medical grade PANEL PCs are often used. If explicitely requested, ASCOM UMS is able to provide information on some suitable devices of this kind.

4.1. Bedside

4.1.1. Hardware

Minimum hardware requirements:

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

4.1.2. Operating System

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

4.2. Central

4.2.1. Hardware

Minimum hardware requirements:

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

4.2.2. Operating System

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

4.3. Server

4.3.1. Hardware

Minimum hardware requirements:

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

4.3.2. Operating System

Microsoft Corporation Windows Server 2012 R2

4.3.3. System Software

Microsoft SQL Server 2012/2014

4.4. Handheld device

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

4.5. Firewall and Antivirus

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

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

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

WARNING!

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

WARNING!

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

4.6. Local network features

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

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

ATTENTION!

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

ATTENTION!

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

4.6.1. DIGISTAT® impact on the hospital network

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

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

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

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

Average: 0.8 – 6 Mbit/s

Pitch: 5 – 25 Mbit/s

5. Before starting

5.1. Installation and maintenance warnings

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

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

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

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

5.2. Cleaning

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

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

5.3. Precautions and warnings

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

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

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

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

5.3.1. Electrical safety

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

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

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

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

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

5.3.2. Patient Area

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

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

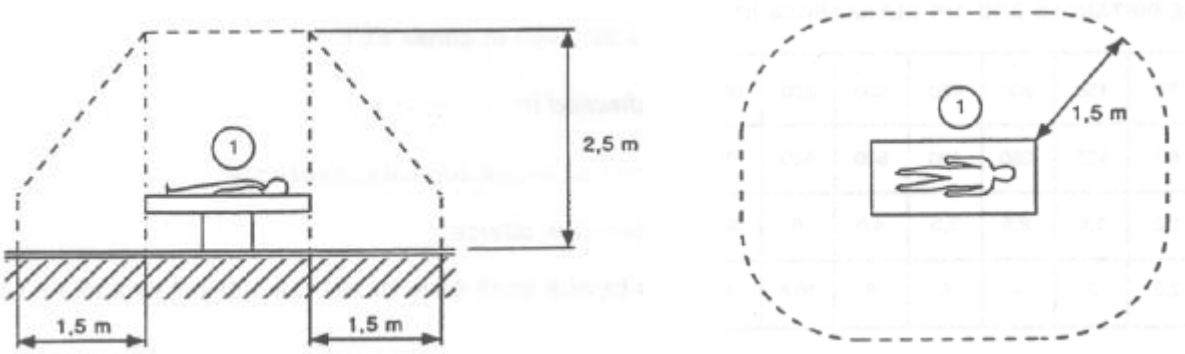


Fig 1

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

WARNING!

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

5.3.3. Electromagnetic compatibility

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

5.3.4. Devices eligibility

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

5.4. Privacy Policy

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

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

Please read the following precautions carefully and strictly observe them.

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

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

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

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

5.4.1. User credentials features and use

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

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

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

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

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

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

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

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

- Password must be at least 8 characters.

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

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

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

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

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

The following information is reserved to system administrators:

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

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

5.4.2. System administrators

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

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

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

5.4.3. System logs

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

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

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

5.5. Back up policy

It is recommended to regularly perform system backups.

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

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

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

5.6. Out-of-order procedure

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

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

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

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

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

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

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

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

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

5.6.1. Reconfiguration/substitution of network equipment

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

5.7. Preventive maintenance

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

This is the maintenence checklist:

Preparatory checks

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

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

- Schedule possible updates with the technical staff

Checks to be performed

Antivirus

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

Database

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

```
USE [DATABASENAME]
GO

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

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

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

EXEC (@INS);

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

DROP TABLE [#SpaceUsed]
```

Server

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

Workstations

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

DIGISTAT®

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

Connection to devices

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

Instruction for use

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

5.8. Compatible devices

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).

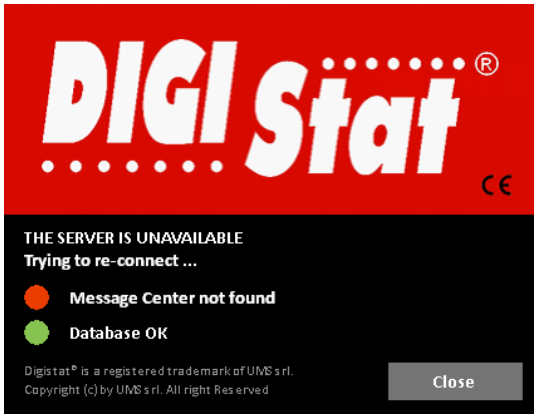


Fig 2

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).

WARNING!

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

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

See paragraph 15 for the contacts list.

6. “Control Bar” and DIGISTAT® environment

6.1. Introduction

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

6.2. Touch screen

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

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

6.3. Launching DIGISTAT®

To launch DIGISTAT®,

- double click the desktop icon (Fig 3).

Fig 3

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

Fig 4

6.4. DIGISTAT® Work Area

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

Fig 5 shows Control Bar with no module installed.

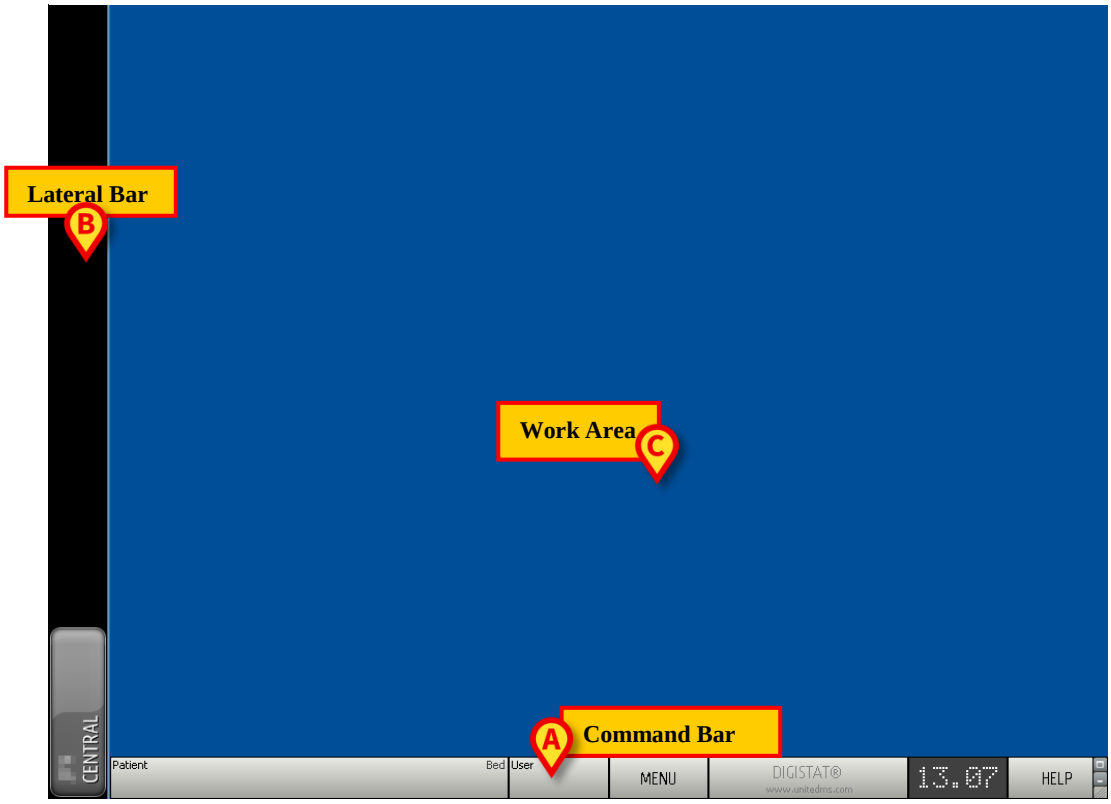


Fig 5

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

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

Fig 6

The module currently selected is highlighted (yellow).

6.4.1. Selecting a module

To select a module

- click the corresponding icon.

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

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

6.5. Accessing the system

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

The following page is displayed.

Fig 7

To access the system,

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

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

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

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

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

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

Fig 8

WARNING!

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

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

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

WARNING!

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

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

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

6.5.1. Barcode log in

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

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

- scan the user's personal barcode.

Fig 9

The user is immediately logged in.

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

6.5.2. Disabling the automatic log out

If the system remains idle for a certain configured time, the user is automatically disconnected (automatic log out).

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

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

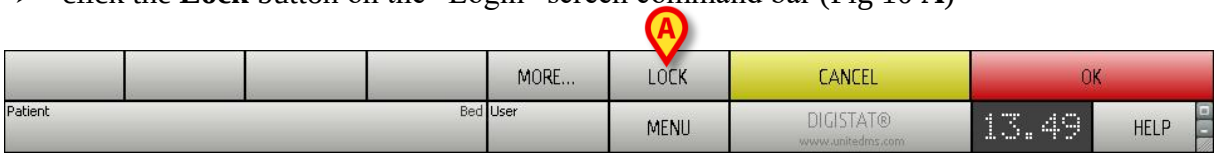


Fig 10

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

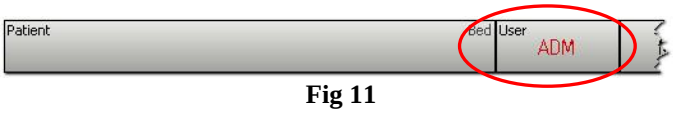


Fig 11

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

6.5.3. Recent users

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

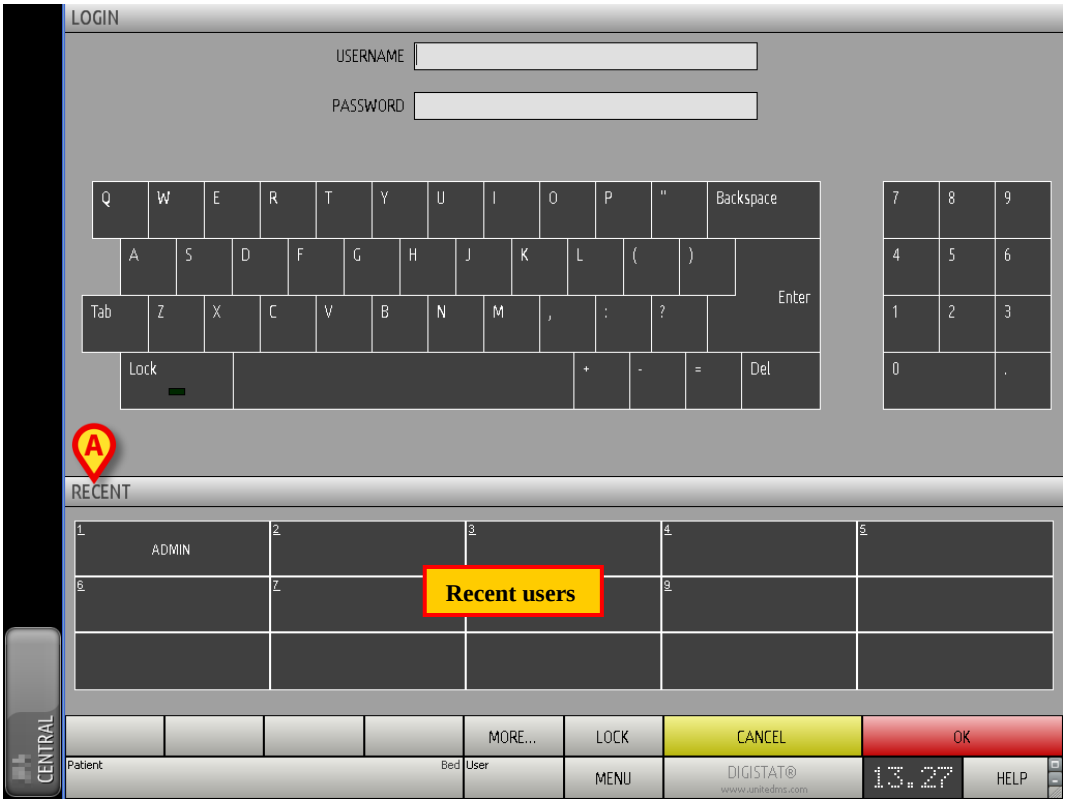


Fig 12

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

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

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

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

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

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

To select a user

- click the name of the user.

The name is this way highlighted, then

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

Otherwise it is possible to

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

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

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

6.6. DIGISTAT® Control Bar

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

Fig 15

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

Fig 16

The functionalities accessible from this menu are described later in this manual.

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

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

These three buttons are present only if enabled by configuration.

6.6.1. How to read the "Patient" button

Patient selected

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

Fig 17

Patient admitted

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

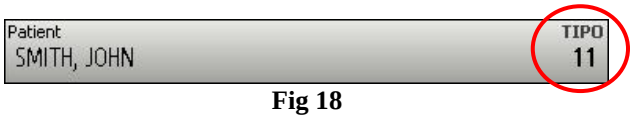


Fig 18

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

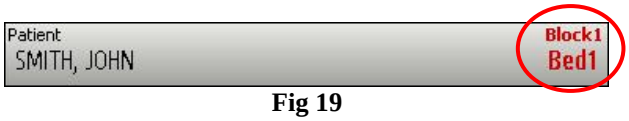


Fig 19

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

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

Fig 20

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

Fig 21

See the specific 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” is dedicated to the patient archives management. Please refer to the “Patient Explorer” module documentation for the related procedures.

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

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

WARNING!

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

6.7. Help

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

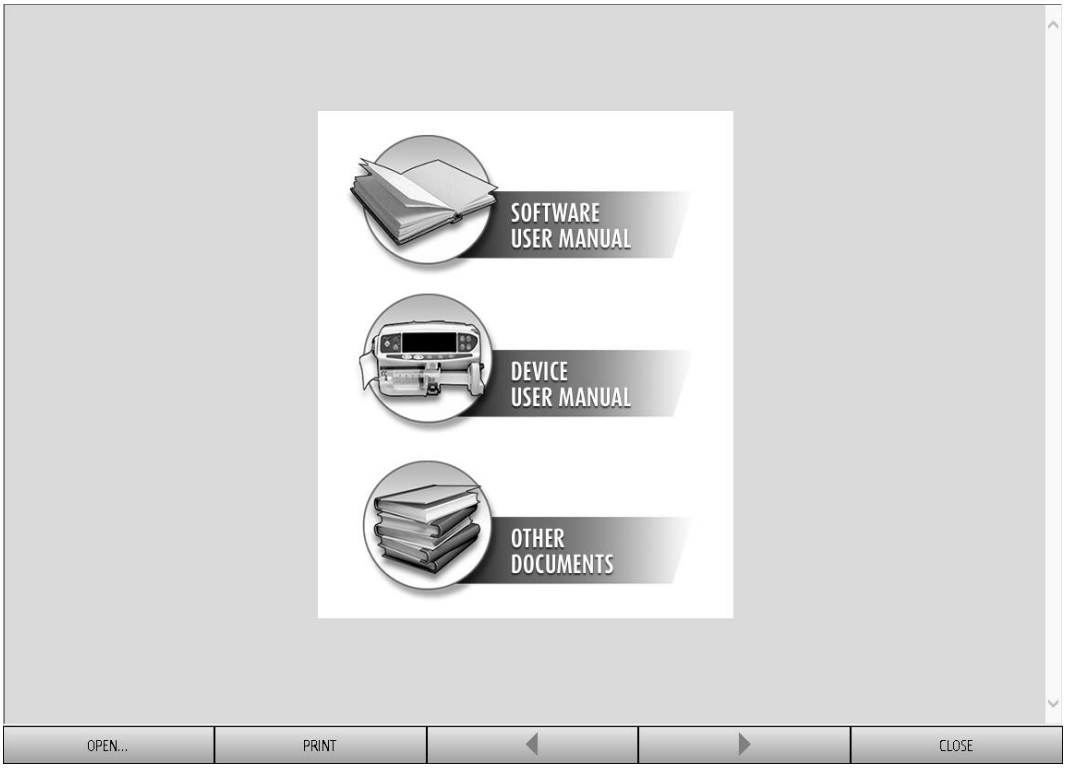


Fig 23

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

Fig 24

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

6.8. DIGISTAT® Main Menu

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

Fig 25

opens a menu containing several options (Fig 26).

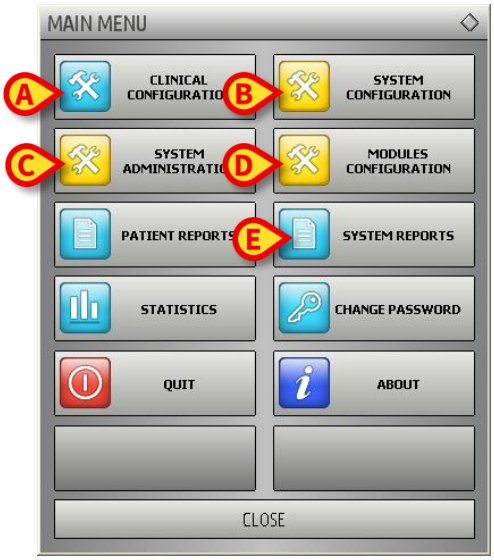


Fig 26

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

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

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

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

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

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

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

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

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

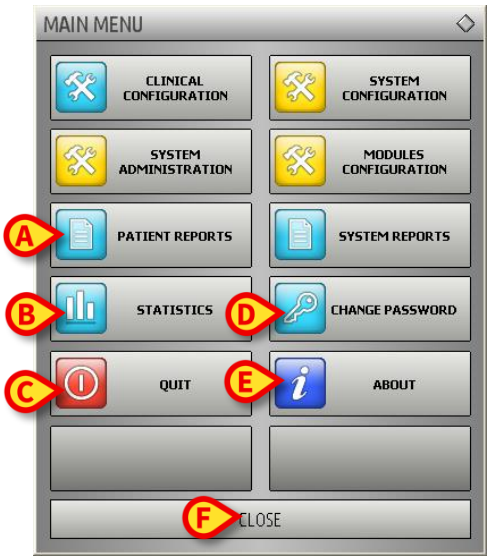


Fig 27

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

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

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

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

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

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

6.8.1. Patient reports

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

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

Fig 28

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

6.8.2. Print reports

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

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

To print a patient report

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

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

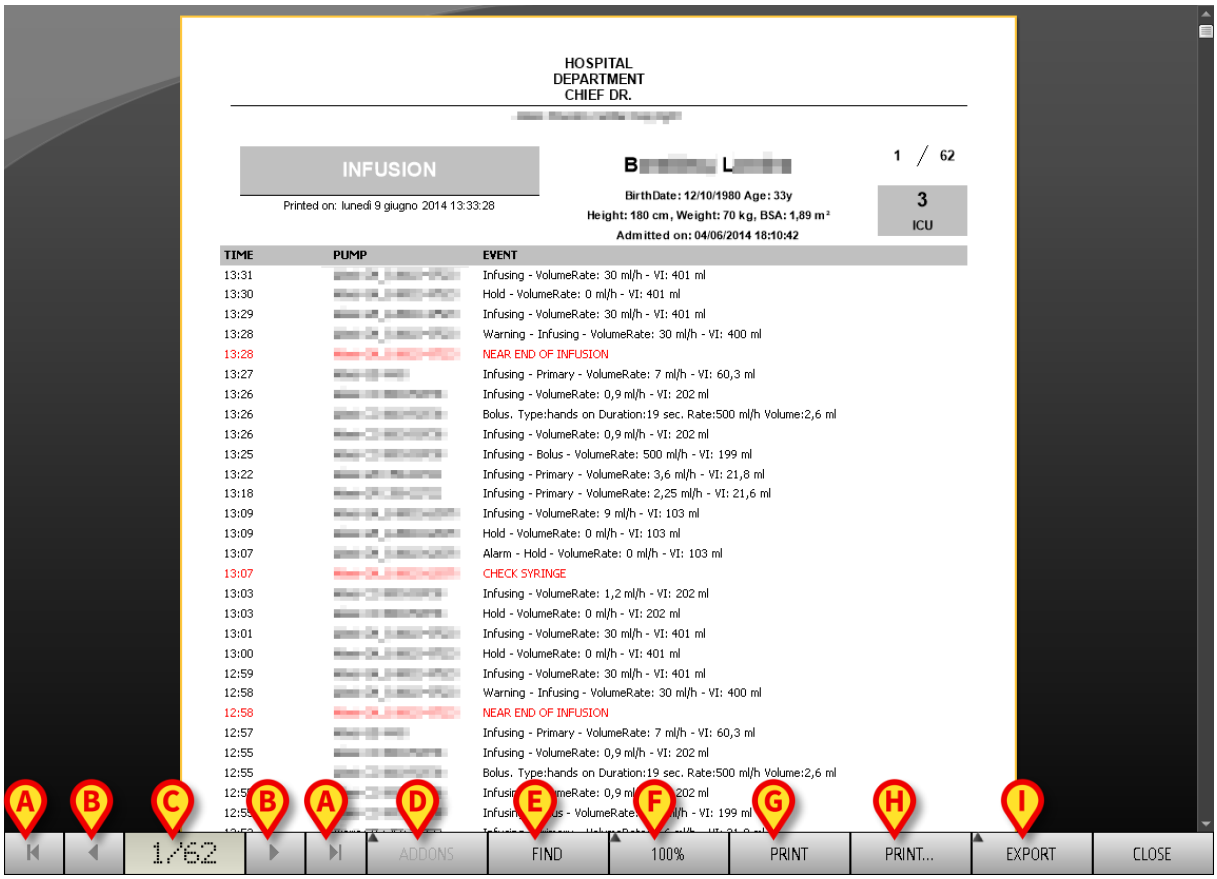


Fig 29

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

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

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

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

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

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

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

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

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

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

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

6.8.2.1. Addons

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

To display the available options,

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

Addons - Watermark

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

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

The following window is displayed (Fig 30).

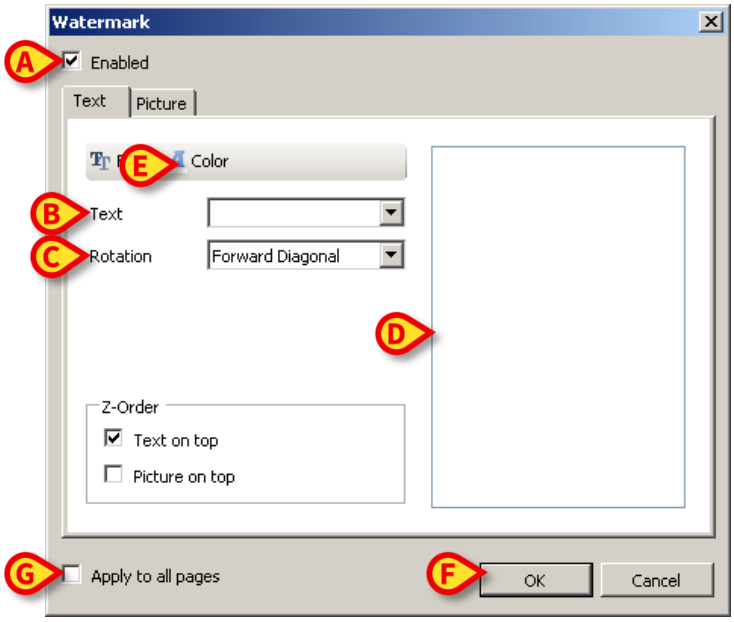


Fig 30

To add a textual watermark,

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

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

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

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

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

The text is this way inserted as watermark.

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

To insert a picture as watermark

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

The following window is displayed (Fig 31).

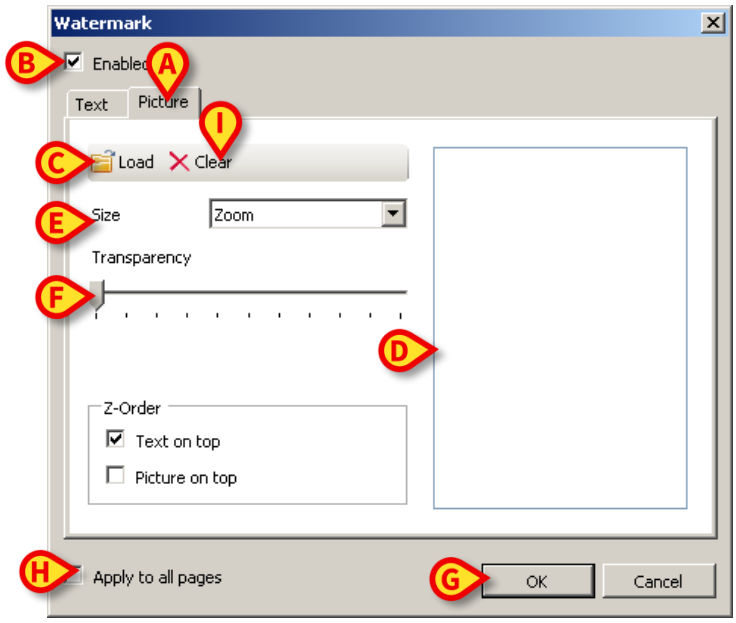


Fig 31

Follow these steps to insert an image as watermark,

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

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

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

- Search and select the image to be uploaded.

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

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

The watermark image is this way inserted.

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

To delete an already selected image,

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

6.8.2.2. Find

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

To search the print report,

- Click the **Find** button.

The following window opens (Fig 32).

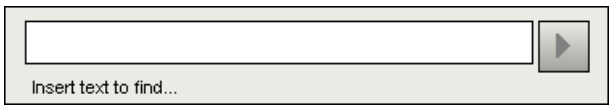


Fig 32

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

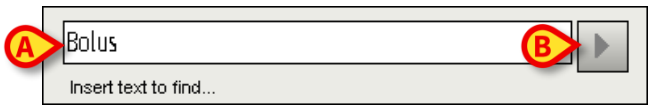


Fig 33

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

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

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

6.8.2.3. Zoom

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

To change the display mode,

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

Fig 34

- Click the wanted option on the menu.

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

The following options are available:

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

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

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

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

the 

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

6.8.2.4. Print

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

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

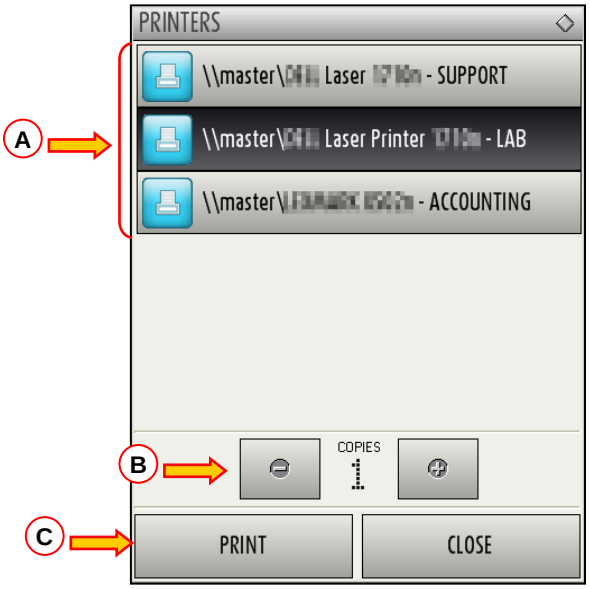


Fig 35

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

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

6.8.2.5. Export

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

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

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

- Click the option corresponding to the wanted extension.

The document is this way exported to the corresponding extension.

6.8.3. Statistics

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

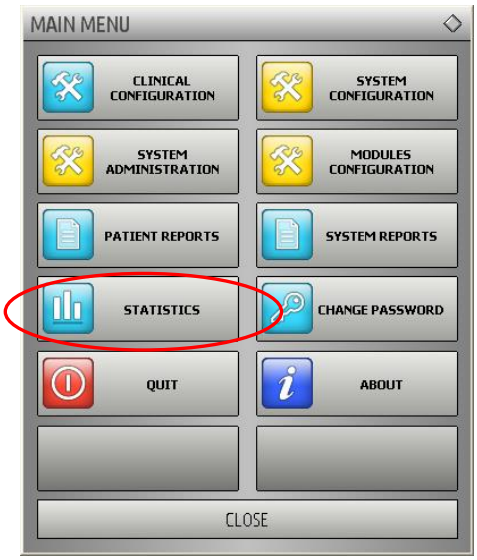


Fig 36

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

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

Fig 37

6.8.3.1. Query Assistant

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

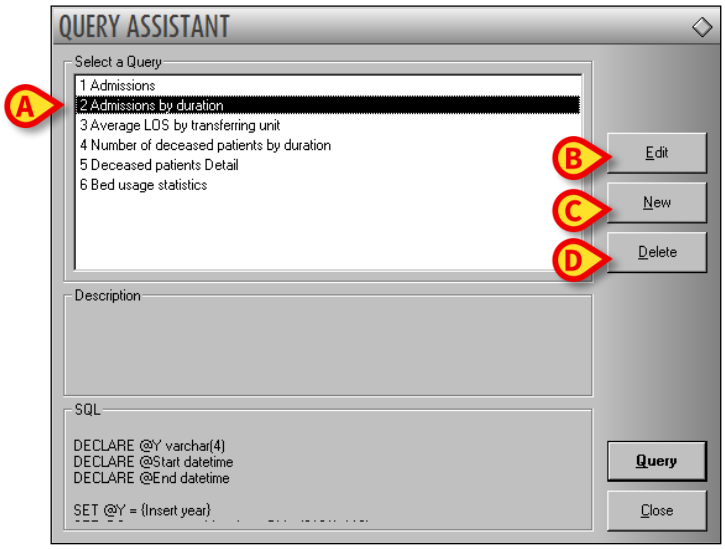


Fig 38

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

To run a query

- click the corresponding name on the list,

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

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

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

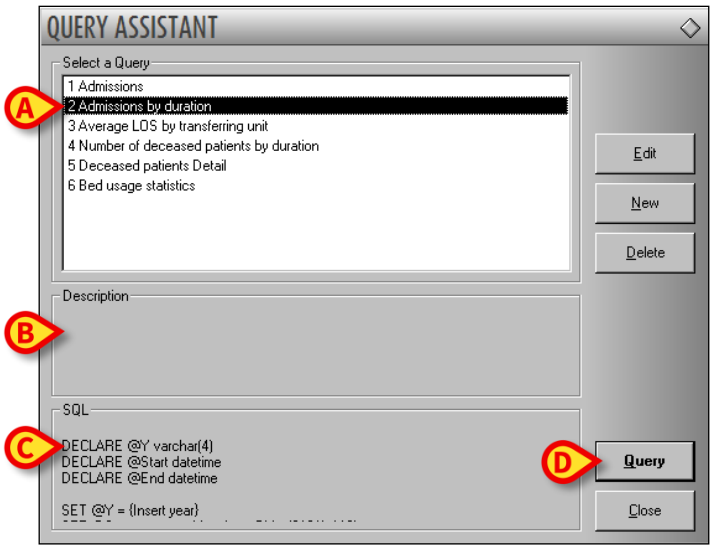


Fig 39

To run the query

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

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

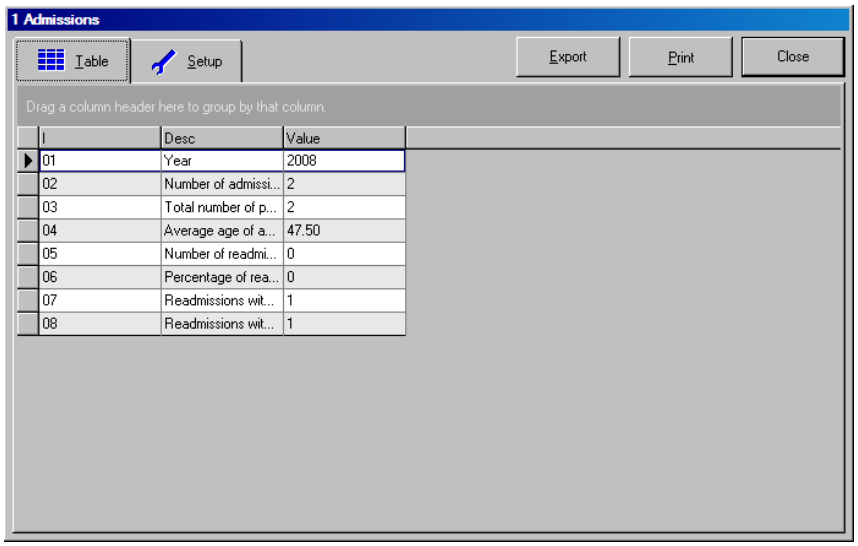


Fig 40

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

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

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

6.8.4. Change password

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

Fig 41

To change the user password

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

The "Change password" window opens.

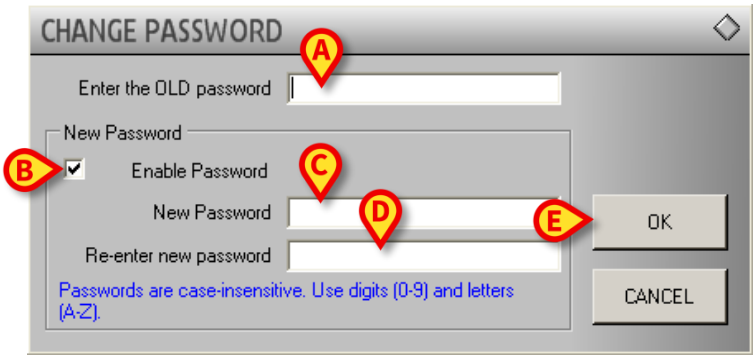


Fig 42

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

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

6.8.5. About DIGISTAT®

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

Fig 43

6.8.6. Quit DIGISTAT®

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

To quit DIGISTAT®

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

Fig 44

The DIGISTAT® main menu opens (Fig 45).

Fig 45

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

Another menu is displayed (Fig 46).

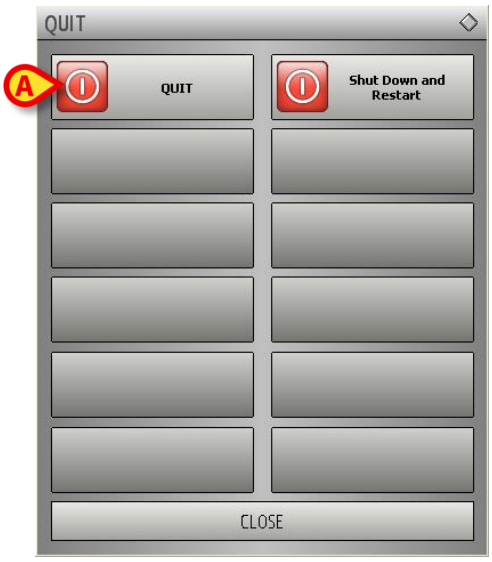


Fig 46

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

User confirmation is required (Fig 47).

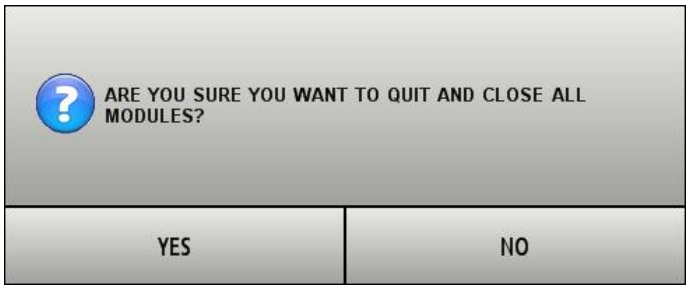


Fig 47

- Click **Yes** to exit DIGISTAT®.

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

7. The OranJ system

7.1. Introduction

The set of modules belonging to the OranJ (Operating Room and Anesthesia Journal) systemprovides a complete documentation of operations in the operating room at surgical block or individual room level.

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

7.2. General structure

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

1) GENERAL CENTRAL STATION: destined for use inside the surgical block. This makes it possible to display the situation of every single block and to operate on it.
2) BLOCK CENTRAL STATION: destined for use inside a specific surgical block. It has the same functions as the GENERAL CENTRAL STATION, but limited to block level.
3) OPERATING ROOM: destined for use inside the operating room. It makes it possible to manage all the activities of the individual room.
4) CHECK IN: destined for procedures relating to the admission of the patient to the surgical block.

7.3. Colors and operation state in OranJ

The term “operation state” indicates a standard meaningful moment in the patient’s operating process.

Four different operation states are possible.

1) Scheduled – the operation has been scheduled;

2) Ready – the patient has undergone block check-in;

3) In progress – the patient has entered the operating room;

4) Completed – the operation has been completed.

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

1) Light gray: indicates that the operation is scheduled (Scheduled).

2) Green: indicates that the patient has undergone block check-in (Ready).

3) Cyan: indicates that the patient has entered the operating room (In progress).

4) Dark gray: indicates that the operation has been completed (Completed).

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

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

7.4. The "List of operations" page

To access the "List of Operations" page (Fig 49)

- Click the **Patient** button on the DIGISTAT® Controlbar (Fig 48 **A**).

Fig 48 - Control Bar

A page similar to that shown in Fig 49 is displayed.

The "List of Operations" screen is formed of three main areas:

1) the lists of operations (grouped by state - Fig 49 **A**);
2) the filter buttons (Fig 49 **B**);
3) the command bar (Fig 49 **C**).

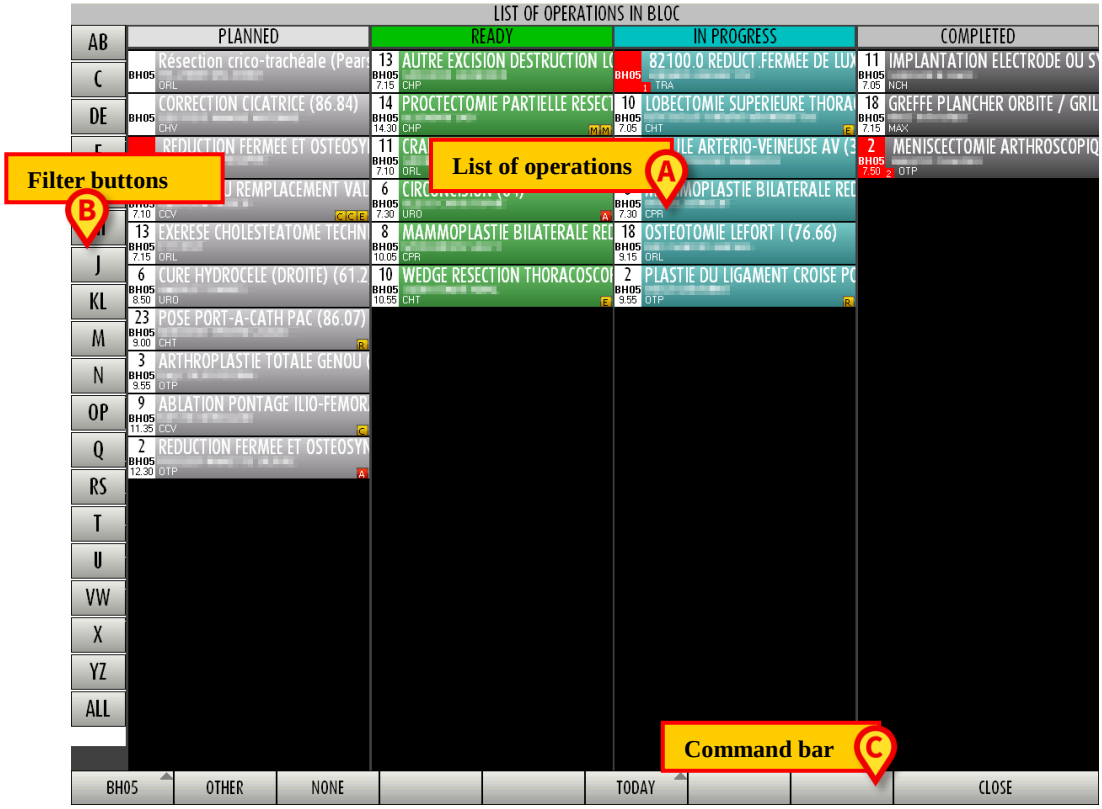


Fig 49 – List of operations

7.4.1. The list of operations

The operations are displayed as colored boxes (Fig 49 **A**, Fig 50).

Fig 50 – Operation

Boxes are arranged into four columns. Every column corresponds to an "operation state", it includes all the operations in that state that are scheduled for the selected day and operating block (see paragraph 7.3 for a description of the possible states)
The page shows all the operations scheduled for the current day, plus any operations begun on previous days and still in progress.

The color of the operation boxes indicates the "state" of the corresponding operation (See paragraph 7.3 for an explanation of the association between color and operation state).

Operation information about is displayed in the box. On the right (Fig 50 **A**) the following information can be displayed:

- the patient's name;
- the type of operation;

- the hospital unit requesting the operation.

On the left (Fig 50 **B**) the following information can be displayed:

- the planned room (room 6 in Fig 50);
- the planned block (BLO in Fig 50);
- the operation scheduled start time (10:35 in Fig 50).

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

If an operation is assigned to a block and a room thet are different from those specified in the scheduling phase, the corresponding operation box (Fig 50) shows the actual block and room (no longer the scheduled ones). The block and room originally scheduled are still indicated on the record shown on the "Patient and Operation Details" page (described in paragraph 9).

The box can contain small yellow or red letters (Fig 51).

Fig 51 – Allergies and devices

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

The red letters indicate the presence of infections, allergies or transmissible diseases. This information is specified on the DIGISTAT® Smart Scheduler system.

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 the operation, or to indicate that an operation requires no anesthesia. The requirement is displayed on the operation box as a small square, having customizable colour and indicating the first letter of the name of the requirement.

When the left part of a box is red (as in Fig 52) it means that the operation is an "Emergency".
"Emergencies" are displayed not only on the current day, but also on the pages referring to future days (see paragraph 7.4.3 for the procedure required to change the day displayed).
The small number indicated in Fig 52 **A** indicates the emergency level (level 1 in the figure - the configuration here described envisages three emergency levels).

Fig 52 - Emergency

If the ! icon (Fig 53 **A**) is displayed alongside the patient's nameit means that the patient's data is temporary. The "Temporary patient" related procedures are described in the DIGISTAT® "Smart Scheduler" system user manual.

The red triangle indicated in Fig 53 **B** means that the operation is a reserve planned for a day that is not the current day. See paragraph 10.3 for the explanation of the term "Reserve" in the "OranJ" context.

Fig 53 – Temporary patient

If a red cross is displayed before the operation name (Fig 54) it means that the patient entered the block and, for any reason, was not operated and checked-out immediately after.

Fig 54

The operation boxes are clickable. Click one of the boxes to access the corresponding "Home OranJ" screen. The "Home OranJ" screen makes it possible to display and manage all the information available for a specific operation. The "Home OranJ" screen, shown in Fig 138, is described in paragraph 8.1.

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

7.4.2. The filter buttons

On the left side of the screen there is a vertical bar comprising all the letters of the alphabet (Fig 49 **B**). This bar works like an index and makes it possible to display the patients whose names begin with a specific letter.
For example, click the **AB** button on the bar once and only patients whose names begin with the letter A appear.
Double click the same button and only patients whose names begin with the letter B appear.
Click the **All** button to see the complete list of patients.

7.4.3. "List of operations" screen command bar

The command bar of the "List of operations" screen (Fig 49 **C**, Fig 55) contains several buttons making it possible to perform specific operations.

Fig 55 – Command bar ("List of operations" screen)

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

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

7.4.3.1. Block selection

The first button on the left (**BH05** in the figure) shows the name of the operating block currently displayed.

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

- click the block selection button.

A list of all the blocks configured in the OranJ system opens (Fig 56).

Fig 56 – Block selection

- Click the button corresponding to the relevant block.

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

7.4.3.2. Selection of another patient

To select a patient that is not currently displayed on screen

- click the **Other** button on the command bar.

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

7.4.3.3. Patient deselection

The **None** button makes it possible to deselect the patient currently selected. The name of the selected patient is displayed on the **Patient** button on Control Bar. To deselect the patient currently selected.

- Click the **None** button.

The patient's name disappears from the **Patient** button.

7.4.3.4. Displayed day selection

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

To change the day displayed on screen

- click the **Today** button.

A calendar window opens (Fig 57).

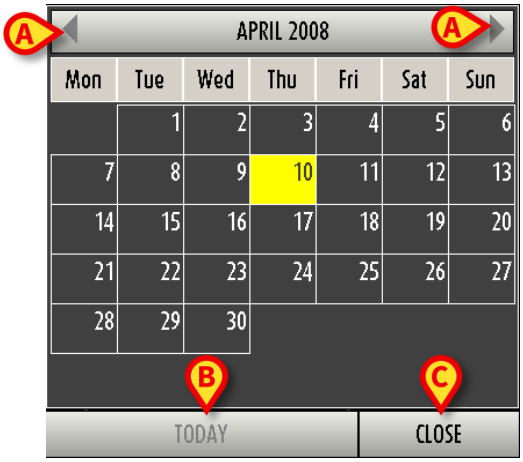


Fig 57 – Calendar

The selected day is highlighted in yellow.

You can use the arrows indicated in Fig 57 **A** to change month. If it is April, for example, click the right arrow to display the calendar for May and the left arrow to display the calendar for March.

After selecting the month

- Click the day you wish to display.

The day selected on the calendar will become yellow.

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

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

If the reference day is in the future, the only operations displayed will be those planned (there will be a single light gray column).
If you select a different day from the current one, the **Today** button will show the date of the day displayed.

To return to the current day

- click, on the calendar, the button indicated in Fig 57 **B**.

To close the calendar

- click the **Close** button indicated in Fig 57 **C**.

7.4.3.5. Closing the "List of operations" screen

To close the "List of operations" screen

- click the **Close** button on the command bar.

8. The "OranJ" module

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

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

8.1. “OranJ Home” screen

When accessing the “OranJ” module, the “OranJ Home” screen is displayed (Fig 59). This page is accessed when

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

;

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

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

1. the operation data (Fig 58 **A**);
2. the command bar (Fig 58 **B**);
3. the chronology of the operation (markers list - Fig 58 **C**).

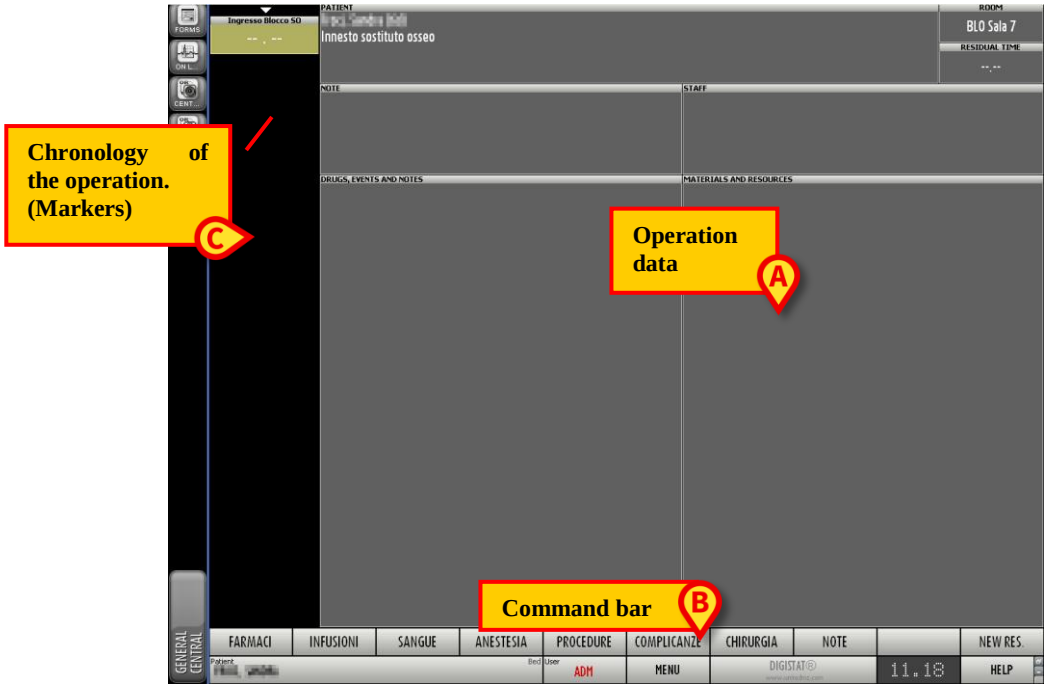


Fig 58 - OranJ Home

8.2. Operation data

The area shown in Fig 59 makes it possible to record and display all the operation’s relevant data.

Fig 59 – Operation data

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

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

- **"Patient"** area (Fig 59 **A**). Summarizes the data of the patient and the operation. Click it to access the "Patient and Operation Details" page (paragraph 9).

- **"Note"** area (Fig 59 **B**). Shows any notes concerning the operation or the patient. Click it to open a keyboard window and add a note (see paragraph 8.6 for the related procedures).

- "**Drugs, events and notes**" area (Fig 59 **C**). Shows the complete list of events recorded during the operation, the drugs administered and the notes added, in chronological order. Click it to access the "Events" page and enter, delete or edit these events (paragraph 8.5).

- "**Staff**" area (Fig 59 **D**). Shows the list of names and roles of staff involved in the operation. Click it to access a page to edit this list and manage changes in room staff in real time (paragraph 8.10).

- "**Materials and resources**" area (Fig 59 **E**). Shows the list of materials and instruments used during the operation. Click it to access a page to manage the resources scheduled and to add or eliminate them if necessary during the operation (paragraph 8.11).

- "**Room**" area (Fig 59 **F**). Indicates the surgical block and operating room. This section cannot be clicked. In the event of a change in the room scheduled for the operation, this

must be recorded using the OranJ Plan module (paragraph 10) or the "Patient and Operation Details" page (paragraph 9).

- "**Residual time**" area (Fig 59 **G**). Indicates the time remaining until the end of the operation according to the scheduled duration. This quadrant works like a countdown which starts when the patient enters the room (paragraph 8.9).

8.3. Command bar

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

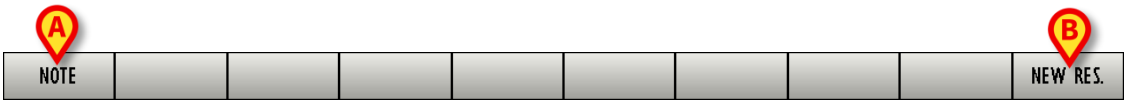


Fig 60 – OranJ module command bar

In the example shown here, the **Note** button (Fig 60 **A**) makes it possible to directly access the page used to add a note. Use the **New Res.** Button (Fig 60 **B**) to directly access the page to manage the operation room resources. Each of these pages is described in detail during this chapter.

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

8.4. Operation chronology: the "Markers"

The left side of the screen (Fig 59 **C**) shows the sequence of events that make up an operation, in chronological order.
It is assumed that certain events are repeated for all operations and that they occur in a specific order. These are known as "**Markers**".
A marker follows the other, both chronologically and logically. The OranJ system envisages 6 markers as standard:

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

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

8.4.1. Markers sequence

The markers appear as a sequence of boxes (Fig 61). The boxes are arranged in chronological and logical order.

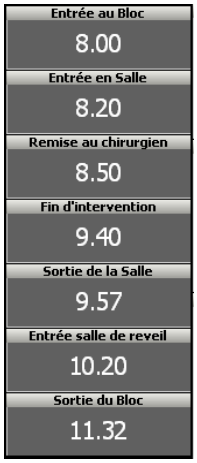


Fig 61 – Markers sequence

The first box, relating to entrance into the surgical block, appears when an operation is scheduled. The box is yellow and contains no information on the moment (date and time) in which the event occurred (Fig 62). This means that the event has not occurred (the patient has not yet entered the block).

Fig 62 – First marker

When the patient physically enters the surgical block, to record the event, the user has to simply click the box.
At this point, if specified by configuration, patient identification is necessary. Patient identification procedure is described in paragraph 8.4.2.

If an OranJ "Check In" workstation is active it is used to manage the patient's block entrance. OranJ "Check In" is described in paragraph 13.

After patient identification the box becomes gray and records the time at which it is clicked. A new ochre yellow box (or several boxes, depending on the configuration) indicating no time appears below it. New boxes refer to subsequent events (Fig 63).

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

Fig 63 – Second marker

The events this way recorded appear at the same time in the "drugs, events and notes" area of the page (Fig 64).

Fig 64 – Markers sequence

In general, to record a marker

- click the box corresponding to the event.

When the patient enters the operating room (the corresponding marker is called "room in") the system, if so configured, requests renewed confirmation of the patient's identity by means of a page similar to that shown in Fig 68. The identification procedure is the same as that described in paragraph 8.4.2, apart from the fact that identification can occur by means of barcode, patient code and also reservation number or the admission code (Fig 65).
This form enables to specify the actual room and block of the operation.

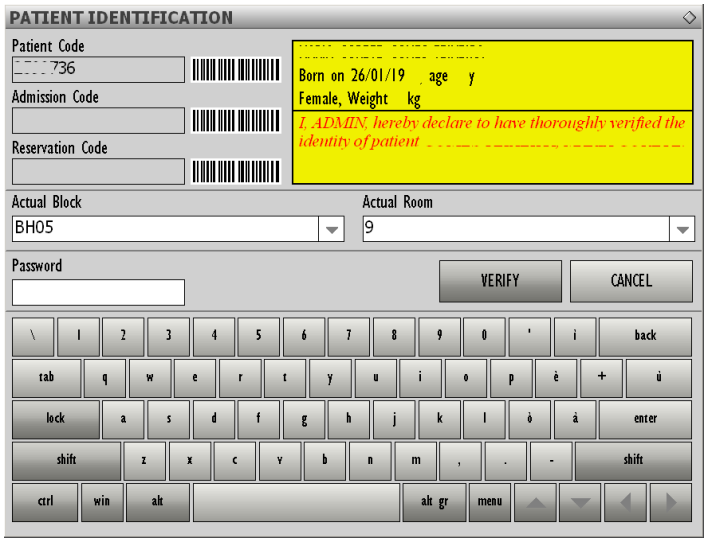


Fig 65 – Patient Identification

After identification, the "room in" box becomes gray and showns the room entrance time.
The event just recorded appears at the same time in the "drugs, events and notes" area of the page (Fig 66 **A**).
The patient's entrance into the operating room corresponds to the actual operation start time. Consequently, when the "room in" event is recorded, the length of time envisaged for the operation appears in the "residual time" area (Fig 66 **B**). This area works like a clock which performs a countdown (see paragraph 8.9 for a detailed description of this area).
The recording of the "room in" event sets off the countdown.

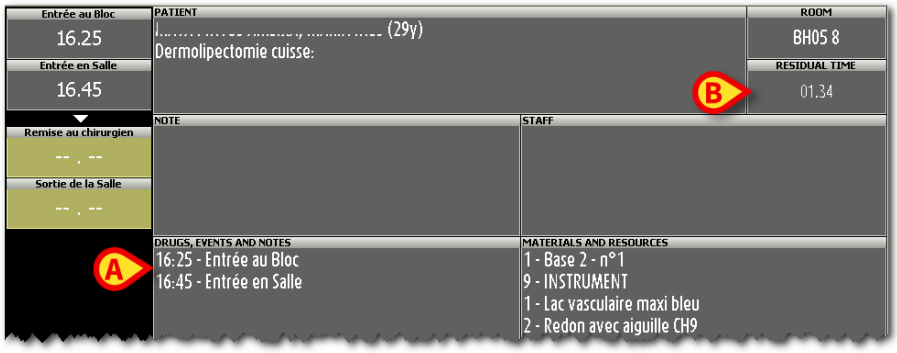


Fig 66 – Markers sequence

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

8.4.2. Patient identification

The possibility of entrance to the block and room is subject to identification of the patient if so specified by configuration. When the entrance of the patient into the block is recorded the system opens a specific window requesting confirmation of the patient's identity (Fig 67).

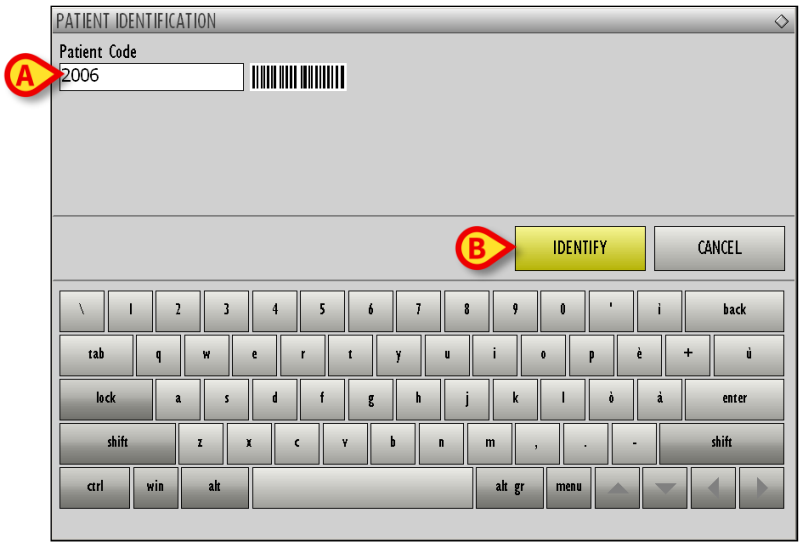


Fig 67 – Patient identification

To identify the patient

- Enter the patient code in the "Patient Code" field (Fig 67 **A**).
- Click the **Identify** button (Fig 67 **B**)

or, if the function is available

- Scan the patient's barcode.
- Click the **Identify** button (Fig 67 **B**)

A window containing the patient's data and a declaration of acceptance of responsibility by the user appears on the screen (Fig 68).

Fig 68 –Identification window

To complete the procedure the user has to

- Enter his/her password in the "Password" field (Fig 68 **A**).

- Click the **Verify** button (Fig 68 **B**).

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

You may abandon the procedure at any time by clicking the **Cancel** button (Fig 68 **C**).

8.4.3. Markers and operation state changes

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

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

8.4.4. Markers management

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

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

- Click the box corresponding to the marker (Fig 69 **A**).

A numeric keyboard is displayed (Fig 69 **B**).

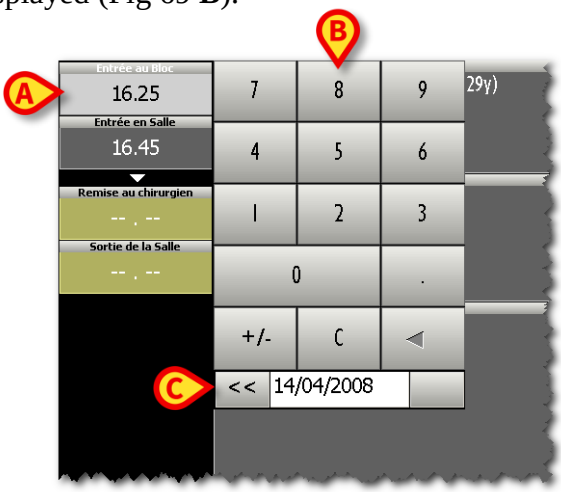


Fig 69 – Markers time change

- Enter the time required using the keyboard.
- Click again the box corresponding to the marker to record the new time.

The numeric keyboard disappears and the new time is displayed.

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

If the time entered is not coherent, the following error message pops-up (Fig 70).

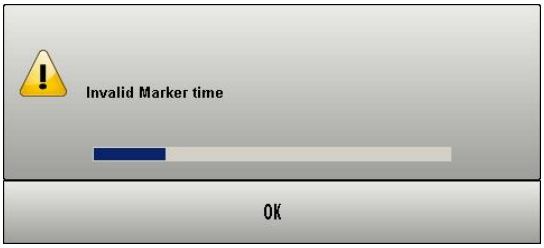


Fig 70 – Error: invalid time

8.4.4.2. Deleting a marker

To delete a recorded marker

- Click the (gray) box corresponding to the marker (Fig 69 **A**).

A numeric keyboard appears (Fig 69 **B**).

- Click the **C** button on the keyboard.

A message requesting confirmation of the operation is displayed.

Fig 71 – Marker cancellation confirmation window

- Click **Yes** to delete the marker.

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

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

8.4.4.3. How to change the date of a marker

To change the date of a marker

- Click the box corresponding to a marker (Fig 69 **A**).

A numeric keyboard appears (Fig 69 **B**). The keyboard displays the date on which the marker was recorded. Alongside the date there are two arrow-buttons (Fig 69 **C**).

- Click the left arrow << to bring the date of the event forward by one day.

- Click the right arrow >> to postpone the date of the event by one day.

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

8.5. “Drugs, events and notes” area

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

These events are recorded on the “Events” page (Fig 73).

To access the “Events” page, on the “OranJ Home” page (Fig 72),

- Click the “drugs, events and notes” area of the screen (Fig 72 **A**).

Fig 72 - OranJ Home

The “Events” page will open (Fig 73).

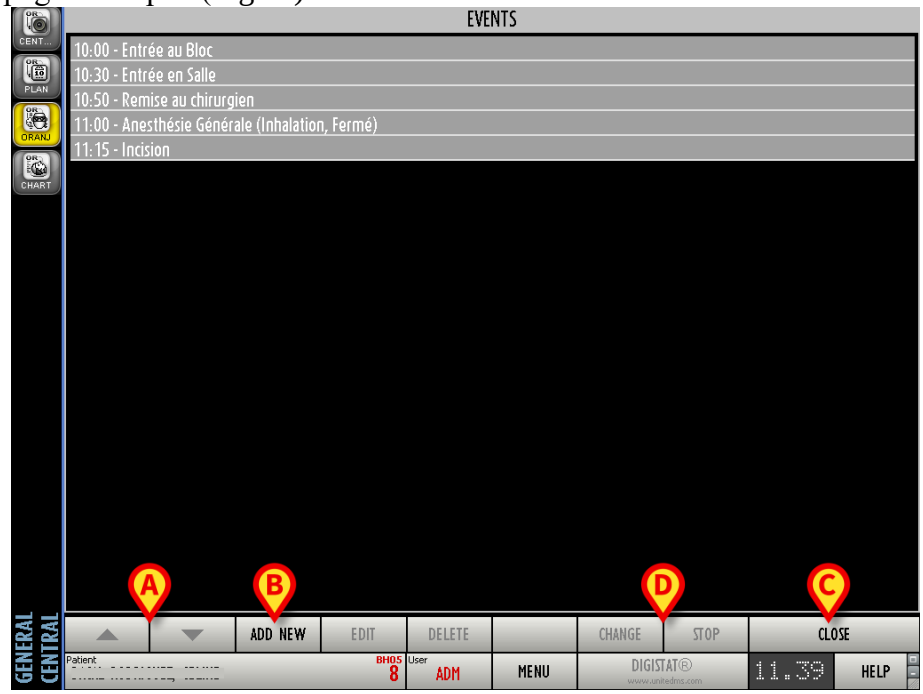


Fig 73 – “Events” page

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

Markers cannot be edited on this page. To edit a marker, you have to use the procedure described in paragraph 8.4.

If the whole list of events cannot be displayed on the screen, you can use the arrows on the control bar to scroll the list (Fig 73 **A**).

To close the “Events” page, on the control bar

- Click the **Close** button (Fig 73 **C**).

The system returns to the “OranJ Home” page (Fig 59).

The **Change** and **Stop** buttons (Fig 73 **D**) are used to manage those events that continue over time and which, while occurring, may be subject to changes. This is true, for example, for certain infusions for which it might be necessary to change the infusion speed while they are in progress.

- Click the **Change** button to access the page that makes it possible to manage the data related to the event (an example is shown in Fig 77; remember, however, that the page in question can be configured in numerous ways and changes according to the event selected).

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

8.5.1. How to record an event

To record an event

- Click the **Add New** button on the command bar (Fig 73 **B**).

A page similar to that shown in Fig 74 is displayed.

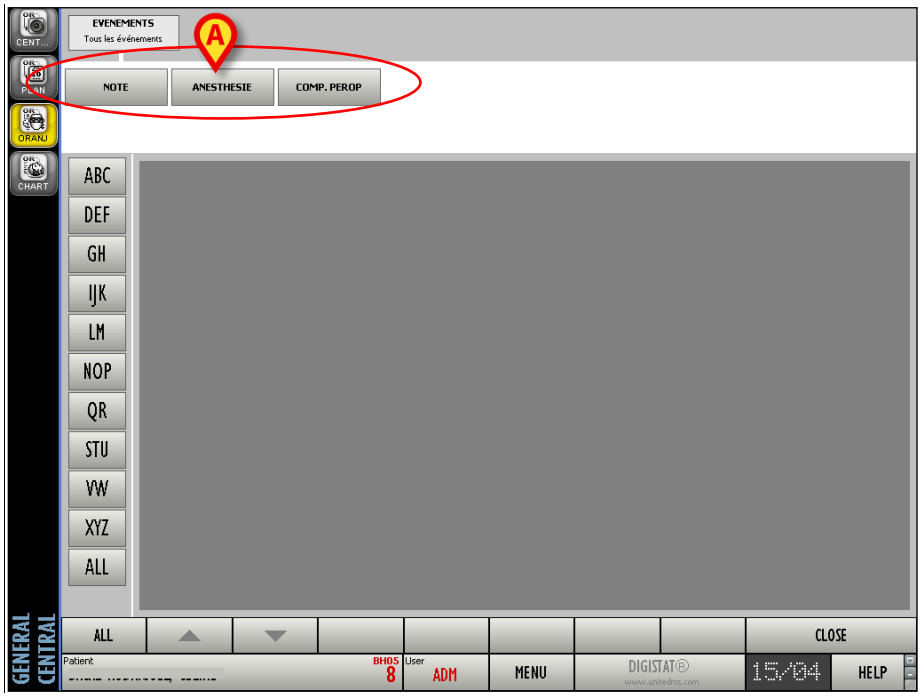


Fig 74 – Adding an event

Every type of event is represented by a gray rectangle (Fig 75).

Fig 75 – Type of event

In this example 3 types of events are configured: notes, type of anesthesia and operating procedures (Fig 74 **A**).

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

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

- Click the type of event required.

Every “type” of event can offer access to various sub-types. In the example shown in Fig 76, the “anesthesia” event gives access to four specific types of anesthesia. Likewise, the “drugs” event can give access to a list of types of drug (sleep inducers, anesthetics, painkillers, etc.), and every type of drug gives access to a list of specific drugs (Propofol, Midazolam, etc.).

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

- click the All button (Fig 76 **C**).

The elements on the list can be filtered using the index buttons on the left of the screen (Fig 76 A - See paragraph 7.4 for the explanation of how these buttons work).

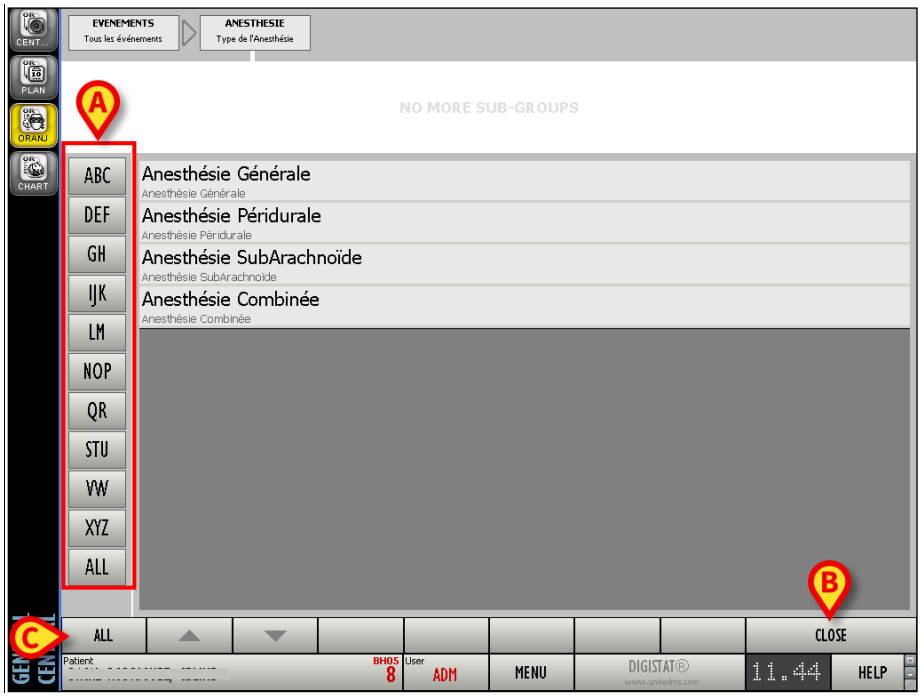


Fig 76 – Types of anesthesia

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

- Click the name of the event required.

By way of example, we have selected “Subarachnoid Anesthesia”. This selection gives access to the page shown in Fig 77.

Fig 77 – Event: subarachnoid anesthesia

The page makes it possible to specify, in detail, the type of anesthesia administered (Fig 77 **A**).

After entering the specific values, to record the new event

- Click the **Ok** button (Fig 77 **B**).

The new event recorded appears on the "events" page (Fig 73) and in the "drugs, events and notes" area of the "OranJ Form" page (Fig 72 **A**).

To cancel the operation

- Click the **Cancel** button (Fig 77 **B**).

The system returns to the page shown in Fig 76 without making any changes.

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

- click the **Close** button on the page (Fig 76 **B**).

You can also record an event using the shortcut buttons described in paragraph 8.3 (Fig 60). Click the buttons on the control bar to directly access the relative page for the addition of events.

The page which makes it possible to enter data relating to an event (Fig 77) changes depending on the type of event selected. While, for example, for an anesthesia you can specify the approach, location, needle, etc., for a drug to be administered, you can specify the dose, dilution, etc.

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

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

8.5.1.1. The "notes" area

The "notes" area (Fig 77 **C**) makes it possible to add a note.

To enter a note

- Click the "notes" area.

A cursor appears inside the area.

- Enter the note using your workstation keyboard.

or

- Click the **Keyboard** button (Fig 78 **D**) to display a virtual keyboard on the screen (Fig 78).

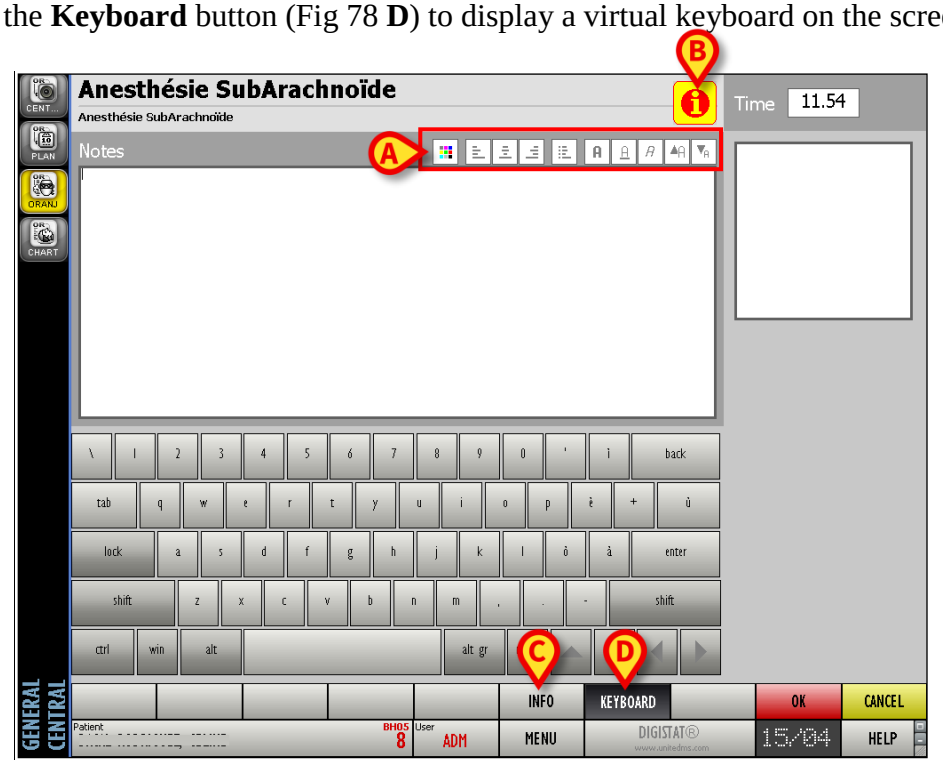


Fig 78 – Virtual keyboard

When the keyboard is displayed, the **Keyboard** button is black.

To hide the keyboard on the screen

- Click the **Keyboard** button again.

The buttons at the top of the notes area make it possible to use some of the most common text formatting functions (Fig 78 **A**).

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

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

The  button makes it possible to center the text.

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

The  button makes it possible to create bulleted lists.

The  button makes it possible to write in bold type.

The  button makes it possible to write underlined.

The  button makes it possible to write in italics.

The  button makes it possible to enlarge the character used.

The  makes it possible to shrink the character used.

8.5.1.2. Information

The  button (Fig 78 **B**), like the **Info** button (Fig 78 **C**), makes it possible to access a page containing information on the event being added (Fig 79).

Fig 79 – Event information

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

To exit the information page

- Click the  button again or click the **Info** button.

8.5.1.3. Time

The "Time" field (Fig 77 **D**) shows the current time if you are entering a new event and shows the time at which the event was entered when displaying an event entered previously.
The time can be changed using the numeric keyboard shown in Fig 77 **G**.

8.5.1.4. Picture

The white box on the right of the page (Fig 77 **E**) can contain a picture relating to the event being recorded; if it is a drug, for example, the box may contain the photo of the drug in question.

8.5.1.5. History

The history area (Fig 77 **F**) displays information on all the past recordings of the same event.

8.5.1.6. Numeric keyboard

The numeric keyboard (Fig 77 **G**) makes it possible to enter numeric values in the fields on the page. To do this, it is necessary to click the field in which you wish to write and then use the keyboard number buttons.

8.5.2. How to edit an existing event

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

on the "Events" page (Fig 73).

- Click the event to be edited.

The line corresponding to the event appears highlighted (Fig 80).

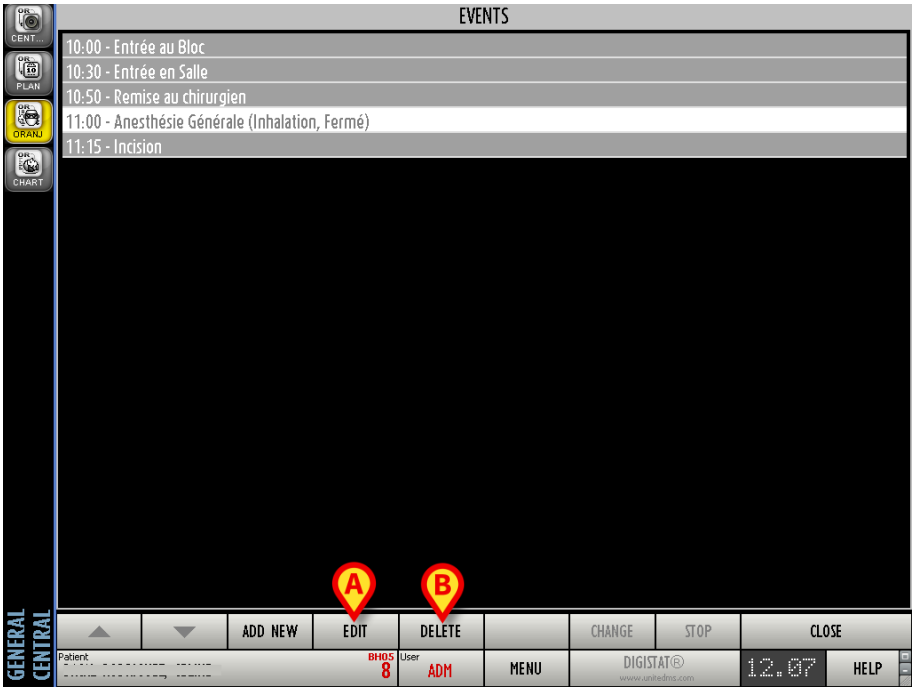


Fig 80 – Event selected

On the control bar

- Click the **Edit** button (Fig 80 **A**).

This directly accesses the page that shows the details of the event selected (Fig 81).

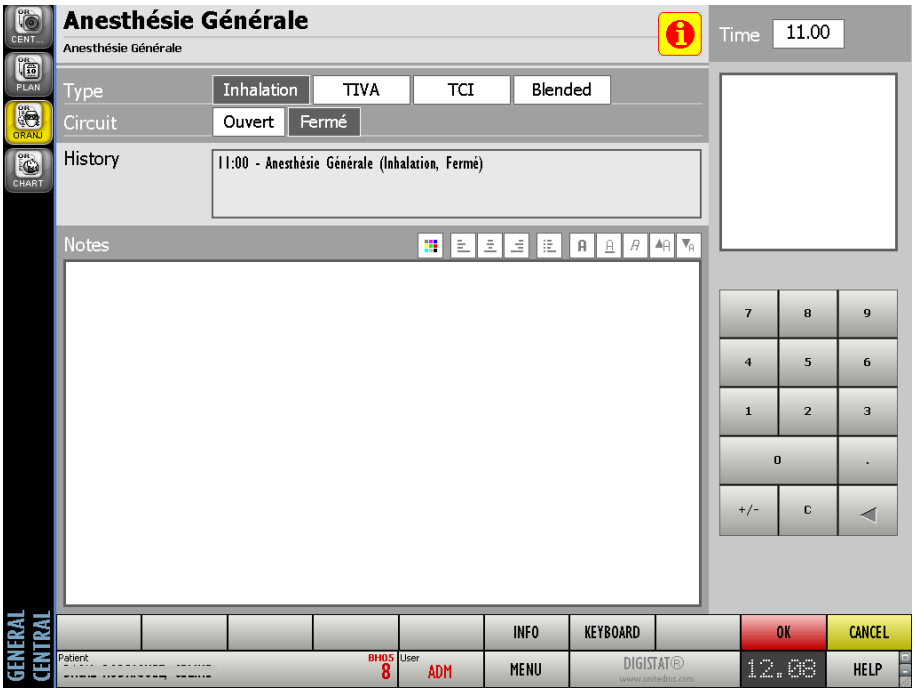


Fig 81 – Event details

The characteristics and functions of this page are described in paragraph 8.5.
You can now edit the data relating to the event. To save the changes made

- click the **Ok** button.

Remember that the markers cannot be edited or deleted from the "events" page. To edit markers it is necessary to use the procedure described in paragraph 8.4.4.

8.5.3. How to delete an existing event

To delete an event, on the "Events" page (Fig 73)

- Click the event to be deleted

The line corresponding to the event is highlighted (Fig 80).

- Click the **Delete** button on the command bar (Fig 80 **B**).

A window requesting confirmation of the operation is displayed (Fig 82).

Fig 82 – Event deletion confirmation

- Click **Yes** to delete the event.

The deleted event disappears from the "Events" page (Fig 80) and from the "Drugs, events and notes" area of the "OranJ Home" page (Fig 72 **A**).

Remember that the markers cannot be edited or deleted from the "events" page. To edit markers it is necessary to use the procedure described in paragraph 8.4.4.

8.6. The "Notes" area

To add a note to the operation selected

- Click the "Notes" area of the "OranJ Home" page (Fig 84 **A**).

Fig 83 - OranJ Home

A virtual keyboard appears on the screen (Fig 84).

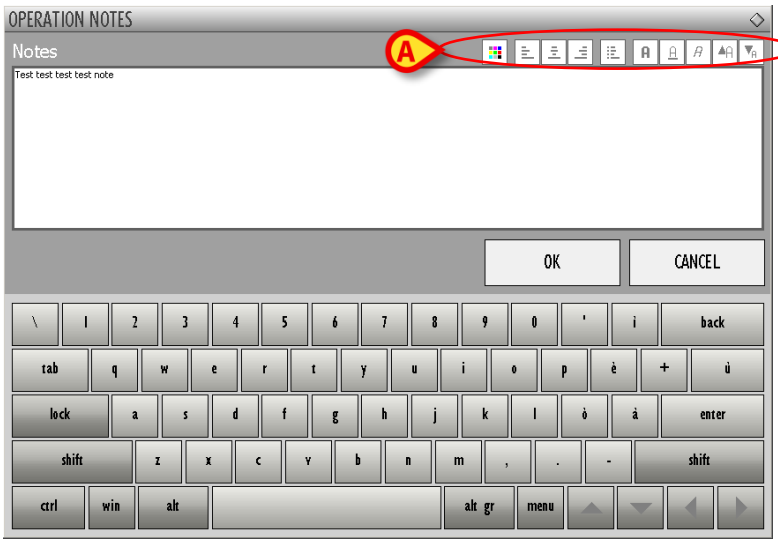


Fig 84 – Virtual keyboard

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

or

- Click **Cancel** to cancel the operation.

The buttons at the top of the keyboard (Fig 84 **A**) make it possible to use some of the most common text formatting functions.

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

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

The  button makes it possible to center the text.

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

The  button makes it possible to create bulleted lists.

The  button makes it possible to write in bold type.

The  button makes it possible to write underlined.

The  button makes it possible to write in italics.

The  button makes it possible to enlarge the character used.

The  makes it possible to shrink the character used.

The note is displayed in the “notes” area of the “OranJ Form” page (Fig 85).

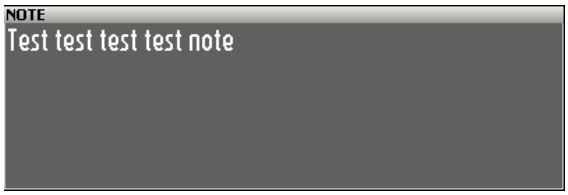


Fig 85 - Note

8.7. The “patient” area

The “patient” area of the “OranJ Form” page (Fig 86 **A**) shows the name of the patient for whom the operation is scheduled.

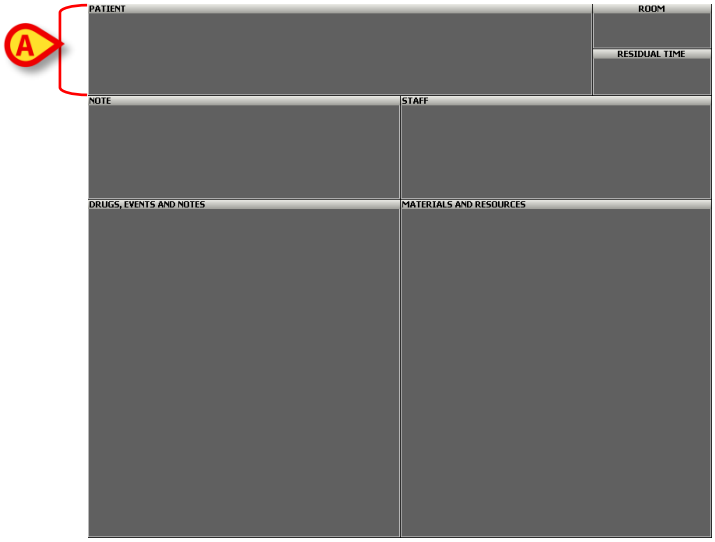


Fig 86 - OranJ Home

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

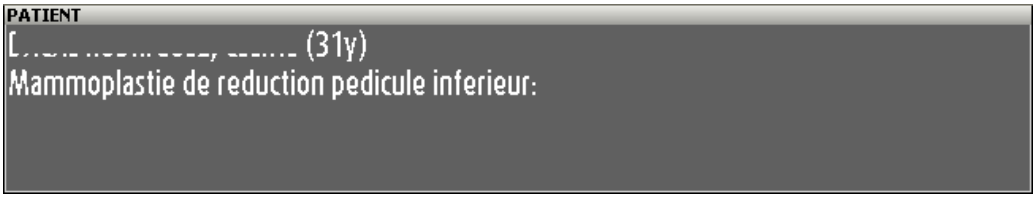


Fig 87 – “Patient” Area

The “patient” area makes it possible to access the “Patient and Operation Details” page (Fig 127).

To access the “Patient and Operation Details” page

- click the patient area.

The “Patient and Operation Details” page containing the data of the patient and the operation selected opens. See paragraph 9 for a detailed description of this page.

8.8. The “room” area

The “room” area (Fig 88 **A**) shows the block and the operating room scheduled for the operation.

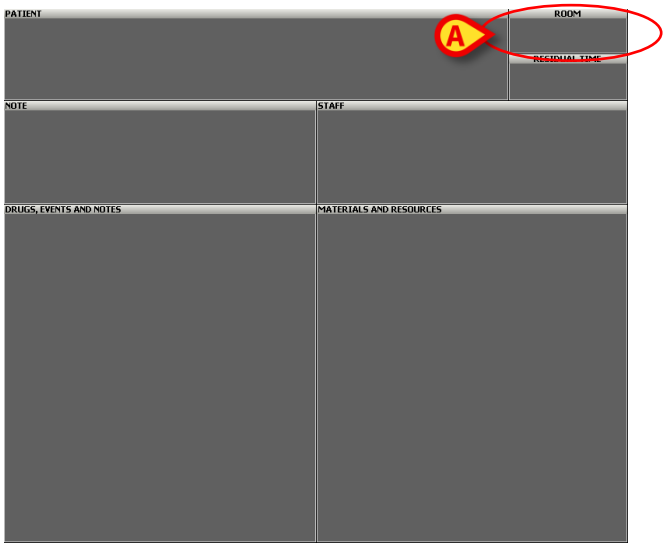


Fig 88 - OranJ Home

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

Fig 89 – “Room” area

The “room” area cannot be clicked. If there are changes concerning to the block or the room scheduled for an operation, these must be recorded on the “Patient and Operation Details” page (paragraph 9).

8.9. The “residual time” area

The “residual time” area (Fig 90 **A**) indicates the time remaining until the end of the operation with respect to the scheduled duration. The residual time is the sum of the pre-surgical, surgical and post-surgical times specified either on the “Patient and Operation Details” (Fig 131) or, if in use, on the DIGISTAT® “Smart Scheduler” system.

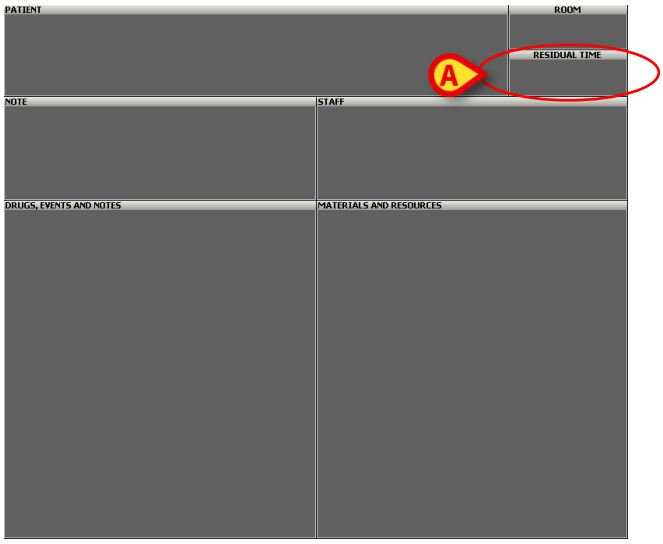


Fig 90 - OranJ Home

This quadrant works like a countdown. The example shown in Fig 91 indicates that there is 1 hour and 27 minutes left until the end of the operation (according to the planned duration).

Fig 91 – “Residual time” Area

The countdown starts when the “Room in” marker is recorded (see paragraph 8.4 for a description of the markers).

Before the patient enters the room, the area appears as shown in Fig 92.

Fig 92

When the countdown approaches zero (in the configuration used in the example, when the remaining time is less than thirty minutes) the residual time area turns yellow and starts flashing (Fig 93).

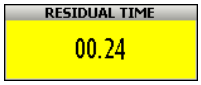


Fig 93

When the actual operation time exceeds the time scheduled, the “residual time” area continues flashing and turns red. The value shown on it becomes negative and starts indicating how much of a delay is being accumulated (Fig 94).

Fig 94

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

To do that

- click the “Residual time area”.

A quadrant containing four buttons opens (Fig 95).

Fig 95

- Click one of the buttons.

This first click brings the counter back to zero.

- Click the buttons to indicate the time remaining.

The 

button adds 10 minutes to the scheduled duration.

The 

button deducts 10 minutes from the scheduled duration.

The 

button adds an hour to the scheduled duration.

The 

button deducts an hour from the scheduled duration.

The “residual time” area indicates the new duration. Length of the operation-box on the OranJ planning screens changes accordingly (see paragraph 10 for more information about this feature).

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

8.10. The “staff” area

The “staff” area (Fig 96 **A**) indicates the names and relative roles of the room staff assigned to the operation.

Fig 96 - OranJ Home

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

To record a change in the room staff

- click the “staff” area (Fig 96 **A**).

The page shown in Fig 97 opens.

8.10.1. “Room Staff” page description

The “Room Staff” page (Fig 97) is formed of four columns.

Fig 97 – Room staff

The “role” column (Fig 97 **A**) contains a list of the possible roles of the staff involved in the operation. Every role is characterized by a color.

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

After the role has been selected, the “personnel” column (Fig 97 **B**) contains the list of persons who are able to cover the required role (see the following paragraph for the selection procedure).

After the person has been selected the “Operation staff” column (Fig 97 **C**) contains the names of the personnel actually involved in the operation (see the following paragraph for the selection procedure).

When the staff is selected, the fourth column (Fig 97 **D**) contains a numeric keyboard which makes it possible to specify the room entrance and exit times of every member of staff.

The buttons containing the letters of the alphabet (Fig 97 **E**) make it possible to filter the list of names displayed. Click one of the letters to display the names that begin with that letter only. Click the **All** button to display the list of all the names.

The arrows at the bottom of the two central columns (Fig 97 **F**) make it possible to scroll up and down the list of names displayed.

The control bar of the page contains three buttons

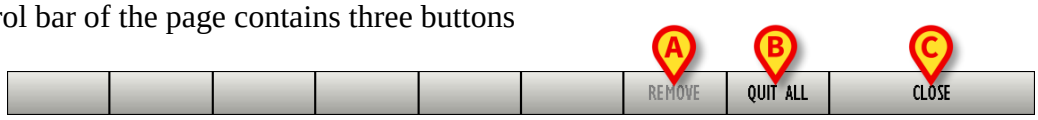


Fig 98 – Command bar of the "Room Staff" page

The **Close** button (Fig 98 **C**) closes the page. Click **Close** to return to the "OranJ Form" page (Fig 96).

The **Quit All** button (Fig 98 **B**) makes it possible to assign the whole staff the current time as the room exit time. For example, if an operation ends at 15.00, and the **Quit All** button is then clicked, 15.00 o'clock is indicated as the room exit time for the whole staff.

The **Remove** button (Fig 98 **A**) makes it possible to remove a member of the operation staff (see the following paragraph for the selection procedure).

8.10.2. Operating staff management

8.10.2.1. How to select a staff member

To select a member of the room staff

- click one of the roles indicated in the "role" column (Fig 97 **A**)

In the "staff" column, the list of all the people who can perform that function appears. For example, if I click "1er OP", the list of all the "first operators" appears in the second column (Fig 99).

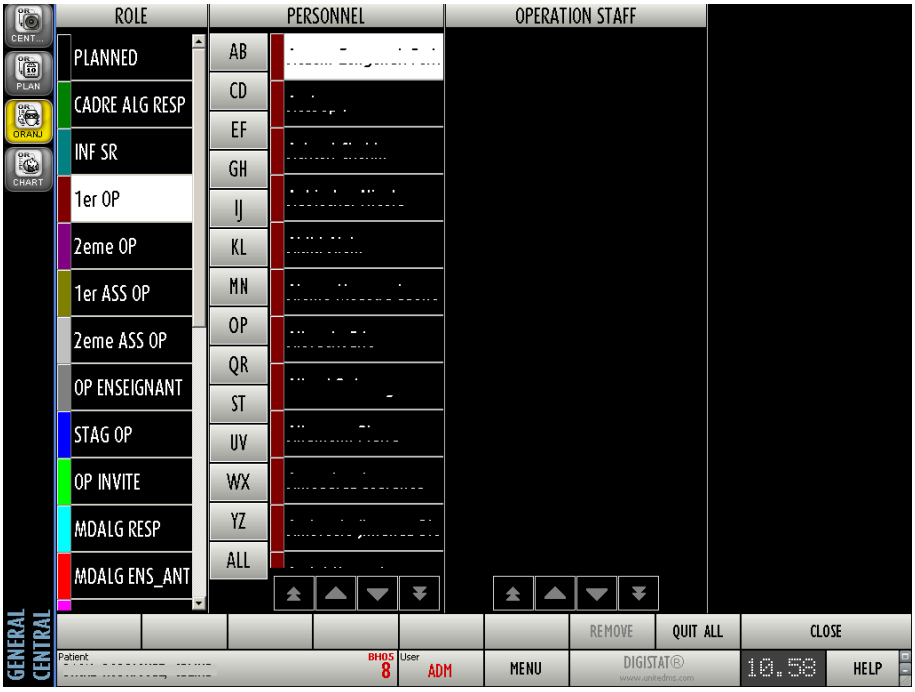


Fig 99 – List of operators

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

The box corresponding to the person disappears from the “staff” column and appears in the “operation staff” column (Fig 100). The name of the person selected is marked by the color that characterizes his/her function.

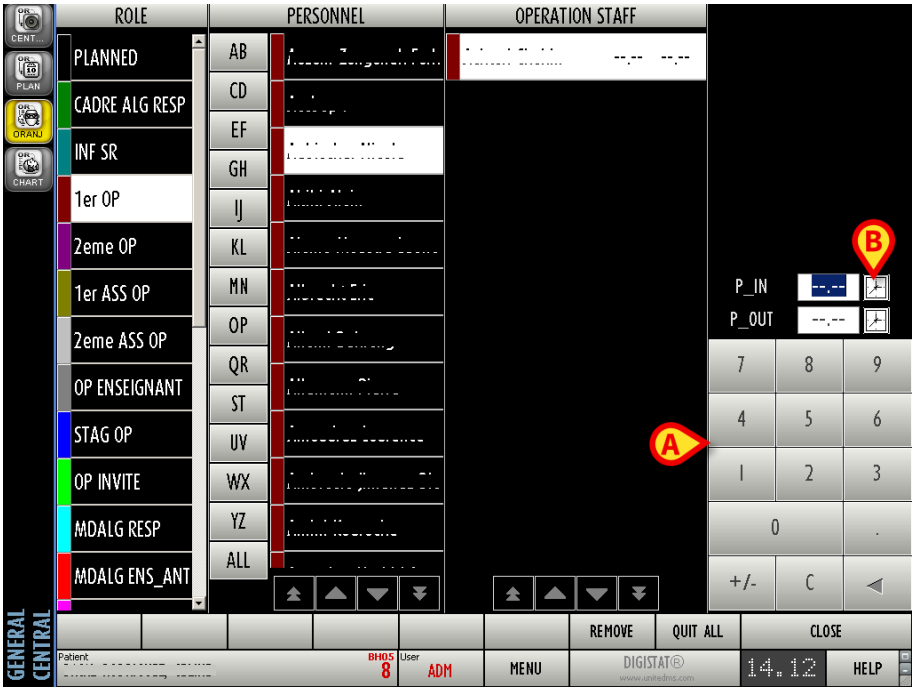


Fig 100 – Staff Selection

At the same time, a numeric keyboard appears in the column on the right, making it possible to specify the room entrance and exit time for the person specified (Fig 100 **A**).

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

The small clocks  highlighted in Fig 100 **B** make it possible to automatically assign the person selected the current time as the entrance or exit time.

The staff selected appears in the “staff” area of the “OranJ Form” page (Fig 101).

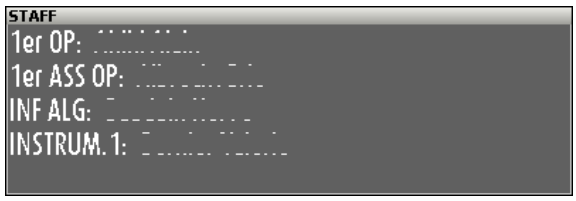


Fig 101 – Operation Staff

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

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

- Click the person’s name.

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

- Enter the entrance or exit time using the buttons on the keyboard

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

In both cases the entrance/exit time will be recorded and appear alongside the name of the member of staff selected (Fig 102).

Fig 102 – Time Recording

In alternative, to record the current time as the room entrance/exit time for a member of staff, simply click the little clock alongside the corresponding field (Fig 100 **B**).

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

8.10.2.3. Removing a member of the operating staff

To remove a member of the operating staff

- Click the member of staff you wish to remove.

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

The **Remove** button on the command bar becomes active (Fig 100 **C**).

- Click the **Remove** button.

User confirmation is required (Fig 103).

Fig 103

- Click **Yes** to confirm.

8.11. The “materials and resources” area

The “materials and resources” area (Fig 104 **A**) contains the list of all the resources and materials used during an operation

Fig 104 - OranJ Home

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

To add a new resource

- Click the materials and resources area.

The “Resources Used” page opens (Fig 106).

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

If barcode reading is not possible a manual procedure can be used. Manual procedure is described in paragraph 8.11.1.

Fig 105 – "Resources Used" page

- Scan the resource's barcode

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

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

Fig 106

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

or

- Enter the resource's "Serial Number" (Fig 106 **A**), then click the **Ok** button (Fig 106 **B**).

The window shown in Fig 106 does not show up if the resource is not configured to require "Serial number" specification.

The system adds the chosen resource to the "Resources used" list (Fig 107 **A**).

Fig 107 – Resource used

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

To complete the procedure

- click the **Ok** button on the command bar (Fig 107 **B**).

The recorded resource's name and quantity is displayed in the "materials and resources" area of the "OranJ Form" page (Fig 108 **A**).

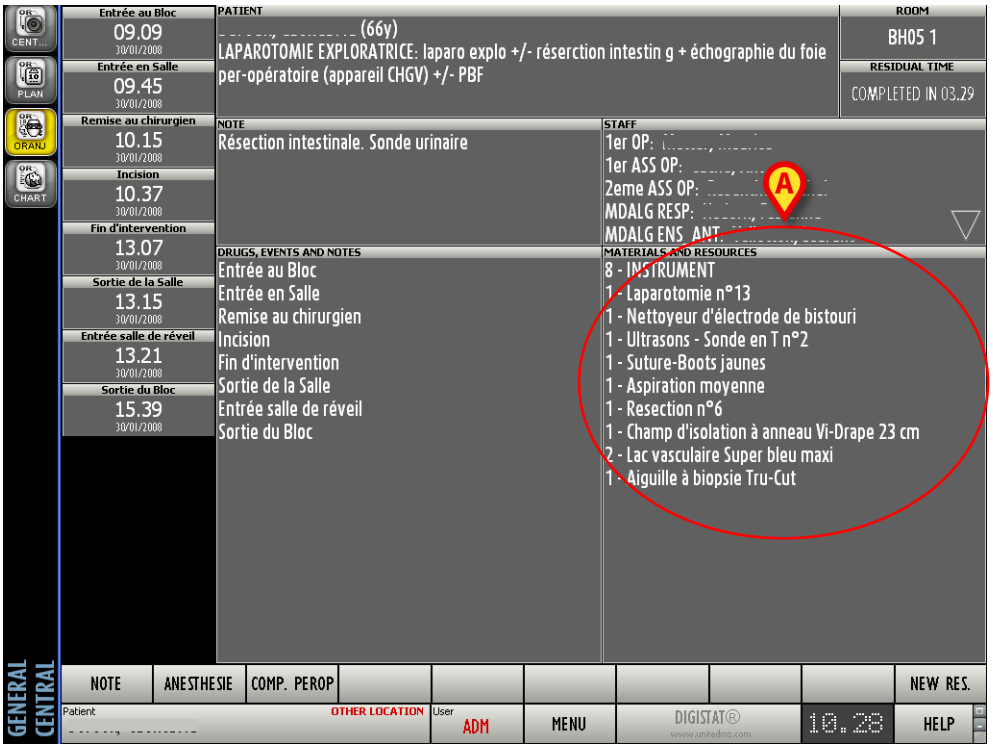


Fig 108

8.11.1. Manual procedure

To manually record a resource

- click the “Materials and Resources” area. The “Resources Used Screen” opens (Fig 107).
- Click the **Add New** button on the command bar (Fig 107 **C**). A page listing the available resources opens (Fig 109).

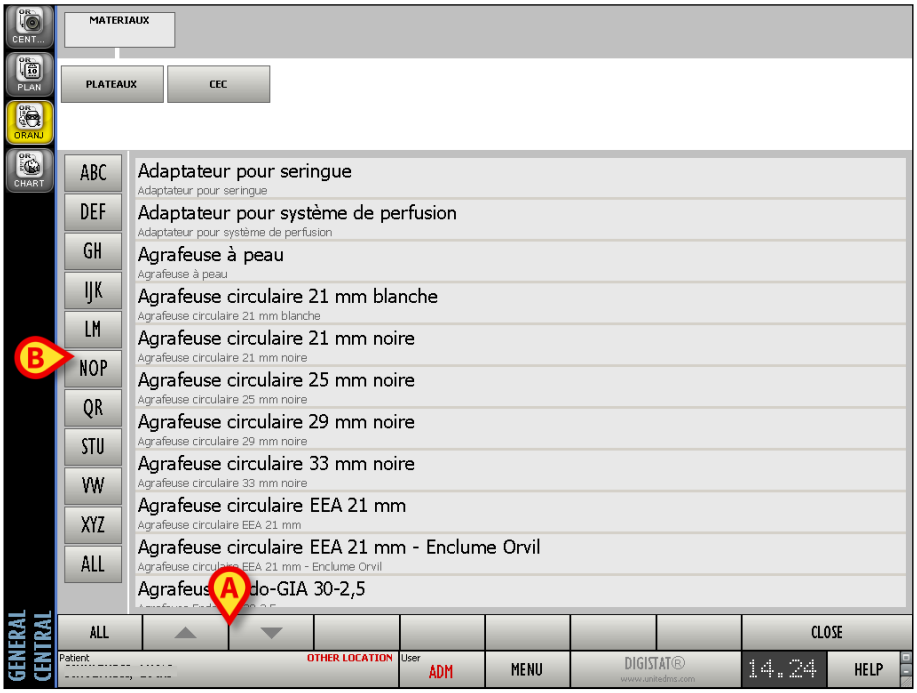


Fig 109 – List of Resources

In the example shown in Fig 109 the resources are grouped by type (“plateaux”, “CEC”). Click one of the boxes representing the type of resource to display all the resources of that type.

You can scroll the list using the arrows shown in Fig 109 **A**.
The buttons containing the letters of the alphabet (Fig 109 **B**) make it possible to filter the list displayed. Click one of the letters to display the resources whose names begin with that letter only. Click the **All** button to display the whole list.

To add a new resource

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

The system will open a specific window requesting specification of the resource’s “Serial Number” (if required by configuration - Fig 110).

“Serial Number” request depends on a configuration parameter.

Fig 110

- Enter the resource’s “Serial Number” manually (Fig 110 **A**) and then click the **Ok** button (Fig 110 **B**).

The system automatically adds the selected resource to the list of resources used (Fig 111).

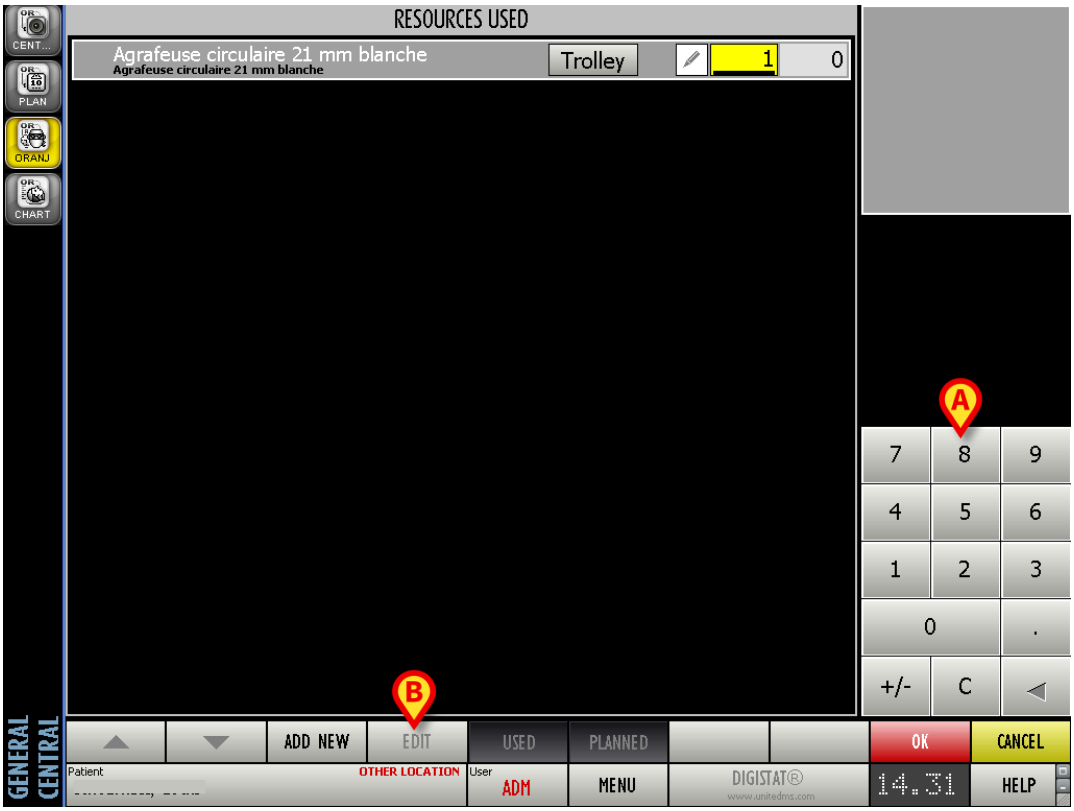


Fig 111 – Resource added

8.12. "Resources Used" screen description

On the "Resources used" screen (Fig 111) the resource is displayed on one line (Fig 112). Every line contains a variety of information.

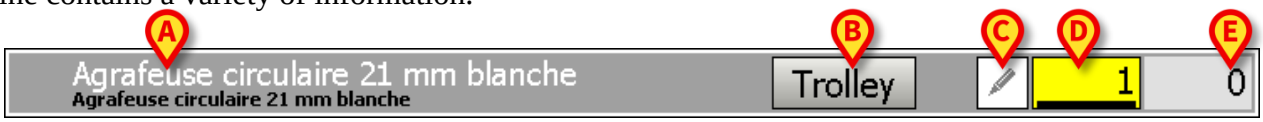


Fig 112 – Information on the Resource

- The name of the resource is indicated on the left side (Fig 112 **A**).
- The **Trolley** button (Fig 112 **B**) makes it possible to indicate whether or not the resource can be fitted onto a trolley. Clicking and highlighting the button indicates that the resource can be fitted onto a cart.
- The  button (Fig 112 **C**) makes it possible to add a note to the resource selected.

Click it to open a virtual keyboard which makes it possible to add possible notes (Fig 113). The operation of the virtual keyboard is described in detail in paragraph 8.6.

Fig 113 – Add note to the resource

To save the notes added

- Click the **Ok** button (Fig 113) on the command bar.

When there is a note referring to one of the resources entered in the list of "resources used", the  button (Fig 112 **C**) appears highlighted in yellow.

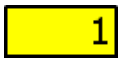
- Box  (Fig 112 **D**) indicates the quantity of resources to be added or removed.

This quantity is entered using the numeric keyboard in the bottom right corner of the "Resources Used" page (Fig 111 **A**, Fig 114).

Fig 114 – Numeric Keyboard

To specify the quantity of resources

- Click the **Edit** button (Fig 111 **B)**.

- Click box 

.

The cursor appears inside it.

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

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

The 

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

- Box 

(Fig 112 **E**) indicates the quantity of resources previously programmed and from which you are subtracting (or to which you are adding) a specific number.

When you have programmed the quantity required

- Click **Ok** to record the new resource.

The resource selected appears, together with the relative quantity, in the "materials and resources" area of the "OranJ Home" page (Fig 115).

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

Fig 115 – Resource Added

8.12.1. Editing the “Resources used” screen

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

- Click the “materials and resources” area (Fig 115).

The page shown in Fig 111 (“Resources Used”) opens.

The names of resources entered previously are flanked by the  square (Fig 116).

If there are notes, the square is yellow  (Fig 116).

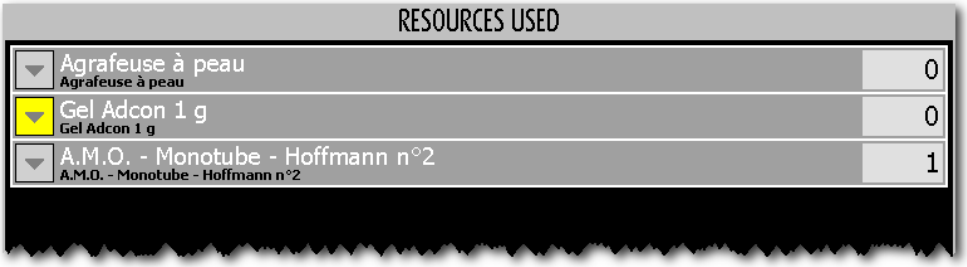


Fig 116

The square can be clicked. Click it to display the details of every editing (time of editing, notes added, name of the user who edited the resource - Fig 117 **A**).

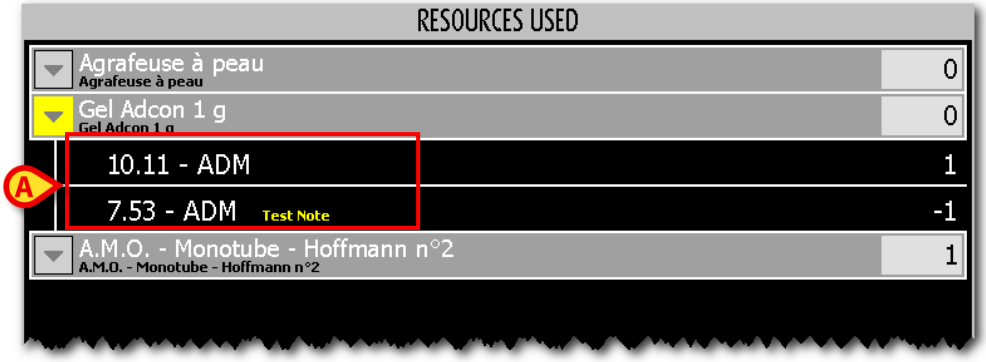


Fig 117 – Display Notes

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

- Access the “Resources Used” screen (Fig 111)
- Click the **Edit** button (Fig 111 **B**)
- Click the  button placed near the resource you want to remove.

The corresponding line will change as in Fig 118.

- Click the  button (Fig 118 **A**).

- Click **Ok**.

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

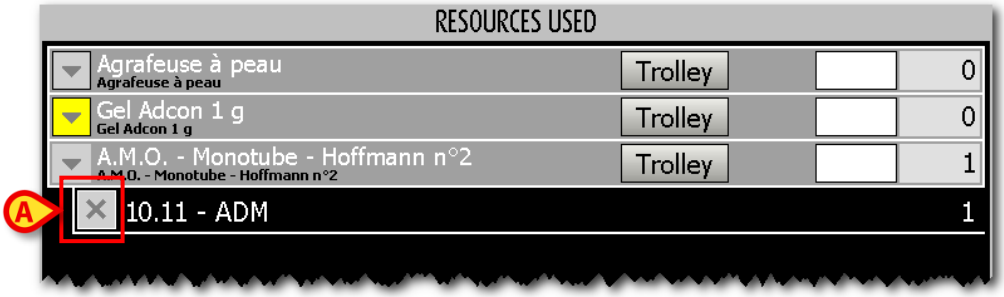


Fig 118

To change the quantity of an added resource,

The following procedure depends on the configuration in use. Some configurations require the identification of every resource by serial number. In these cases, to modify the quantity of a specific resource it is necessary to repeat the procedure described in paragraph 8.11. Contact your system administrator to know the details of the configuration in use.

- Click the "Materials and Resources" area (Fig 115).

The page shown in Fig 119 opens. The **Edit** button is enabled.

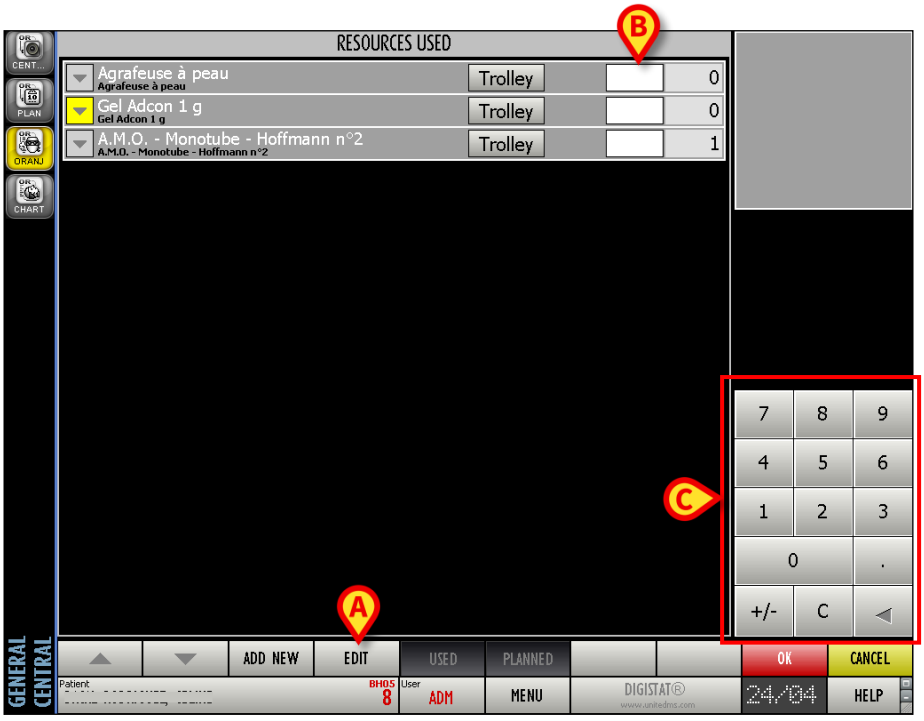


Fig 119 – Change Quantity

- Click the **Edit** button on the command bar (Fig 119 **A**).

Boxes which make it possible to program the quantity appear alongside every resource (Fig 119 **B**).

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

- Use the numeric keyboard (Fig 119 **C**) to enter the quantity of resources to be added to or deducted from the number previously programmed.

- Use the 

button of the numeric keyboard to specify weather the inserted number is positive or negative.

- Click the **Ok** button.

The new quantity will be calculated by the system and shown in the "materials and resources" area of the "OranJ Home" page (Fig 115).

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

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

To do that

- click the "Materials and Resources" area (Fig 120 **A**).

Fig 120

The "Resources Used" screen will open (Fig 121).

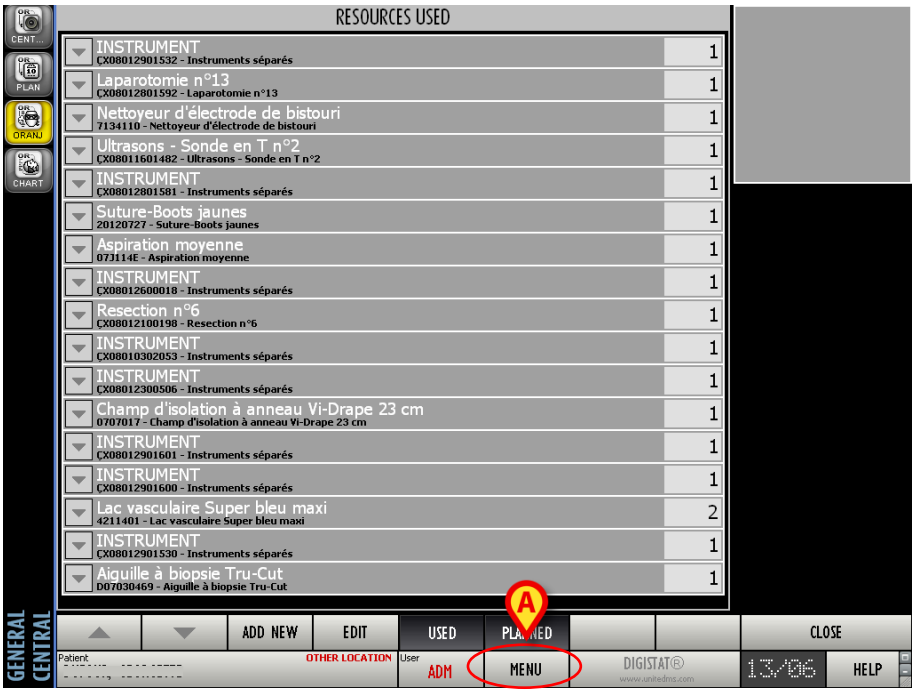


Fig 121

- Click the **Menu** button on the Control Bar (Fig 121 **A**).

The following menu is displayed (Fig 122 **A**).

Fig 122

- Click the **Clinical Configuration** button (Fig 122 **A**).

The following menu is displayed (Fig 123).

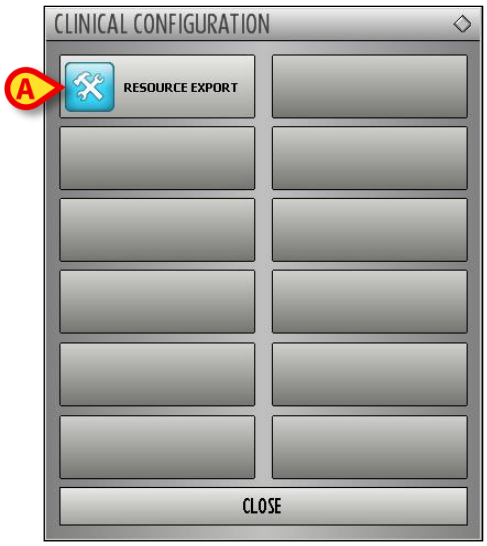


Fig 123

- Click the **Resource Export** button (Fig 123 **A**). User confirmation is required (Fig 124).

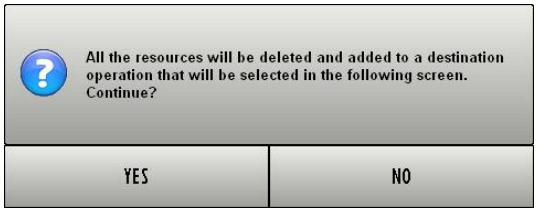


Fig 124

- Click **Yes** to confirm. The "Operation list" screen opens. The selection of the destination operation is now required (Fig 125 **A**).

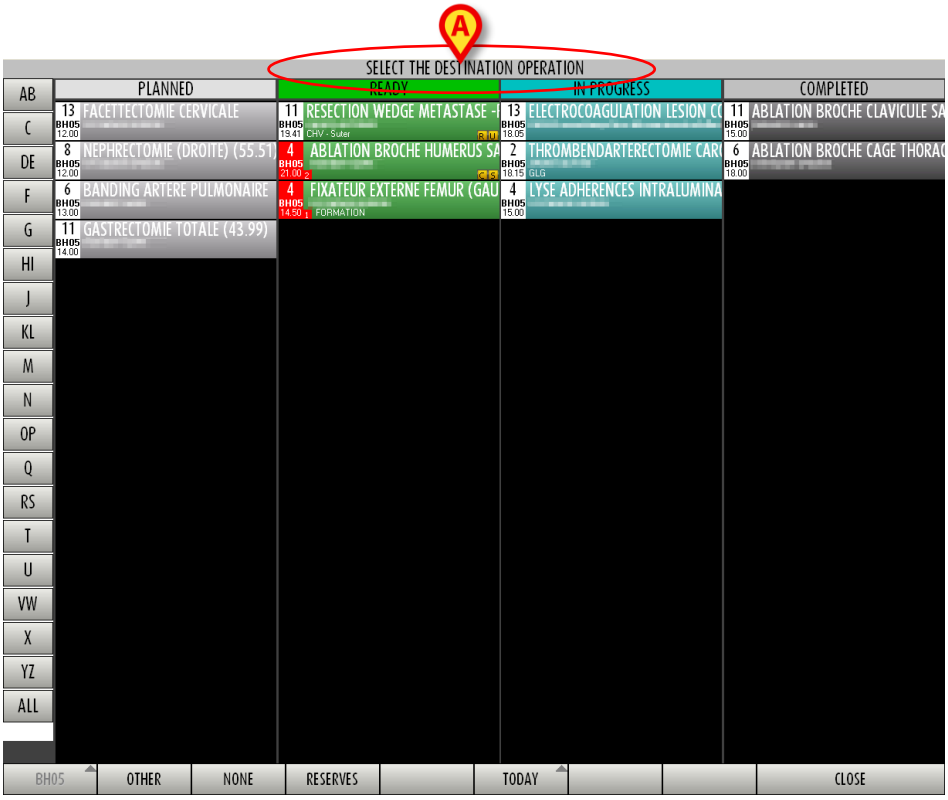


Fig 125

- Click the operation box corresponding to the destination operation.

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

9. Operation and patient management

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

Specifically, within the OranJ context, it is possible to

1) schedule a new operation for a patient (paragraph 9.1.2);
2) display and possibly edit the data relating to an operation (paragraph 9.1.3);
3) display and possibly edit the patient's personal data (paragraph 9.1.1).

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

To access these functionalities

- click the "Patient" area on the "OranJ Home" screen (Fig 126 **A**).

Fig 126 - OranJ Home

The "Patient and Operation Details" screen opens (Fig 127).

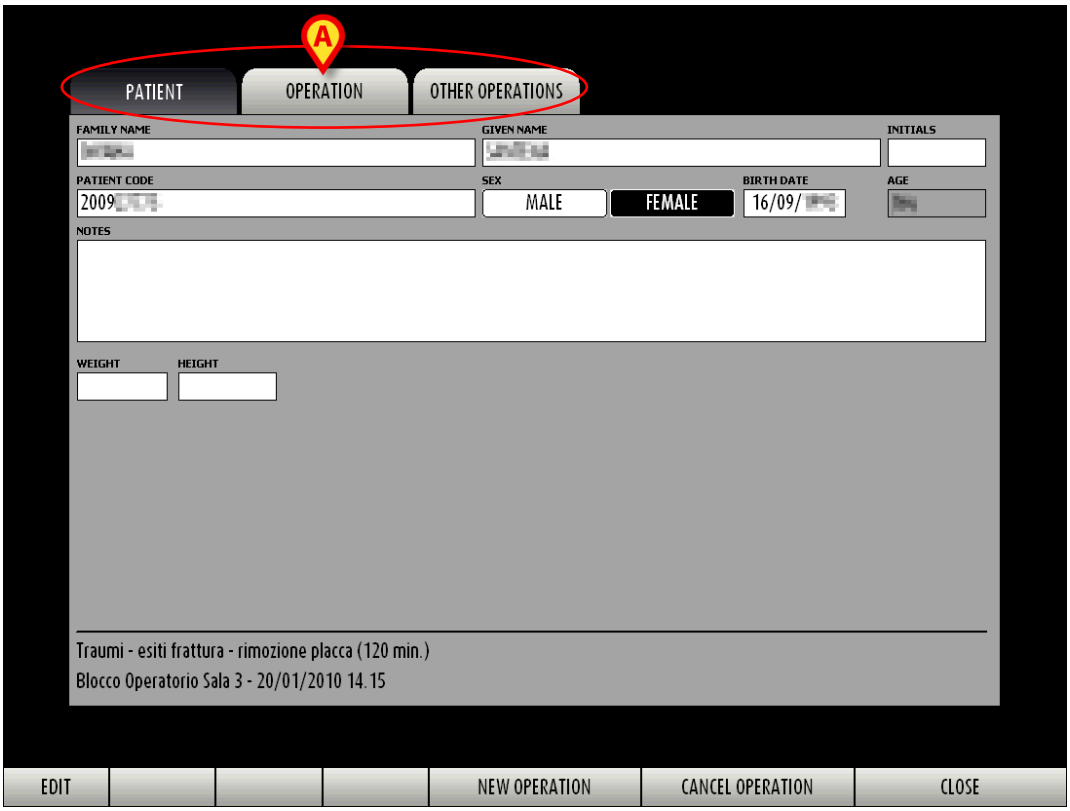


Fig 127 - Patient and operation details

This screen includes three "tabs" (Fig 127 **A**). Each "tab" makes it possible to access a specific subset of information and functionalities.

The "Patient" tab contains the selected patient data (see paragraph 9.1.1).
The "Operation" tab contains the selected operation data (paragraph 9.1.2).
The "Other operations" tab contains the data regarding the possible other operation of the selected patient (paragraph 9.1.3).

9.1.1. Patient

The “Patient” screen (Fig 128) contains the patient’s main data.

To access this screen,

- click the “Patient” tab (Fig 128 **A**).

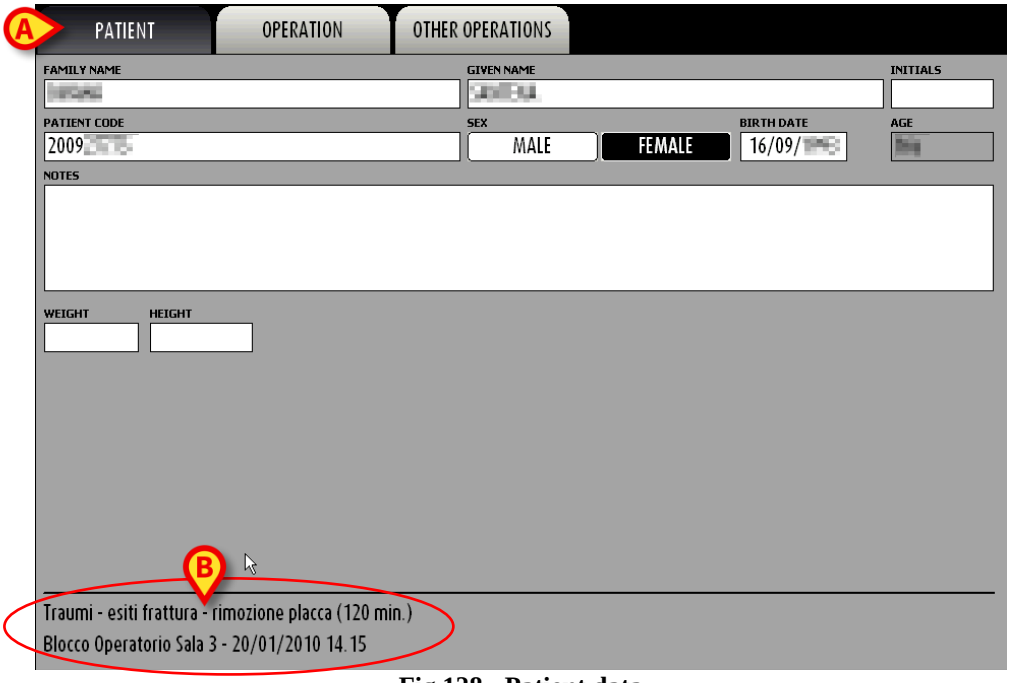


Fig 128 - Patient data

Information that can be here specified is:

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

If there’s an operation planned for the selected patient the main operation data (type of operation, planned duration, planned block, room and time) appear at the bottom-left corner of the screen (Fig 128 **B**).

To specify new data or to modify the existing ones

- click the **Edit** button on the command bar (Fig 129).

Fig 129

The screen will turn to "Edit mode". It will be now possible to modify the patient data.
The **Cancel** and **Update** buttons appear on the command bar (Fig 130).

Fig 130

After editing, click the **Update** button to save the changes made.

9.1.2. Operation

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

To access this screen

- click the "Operation" tab (Fig 131 **A**).

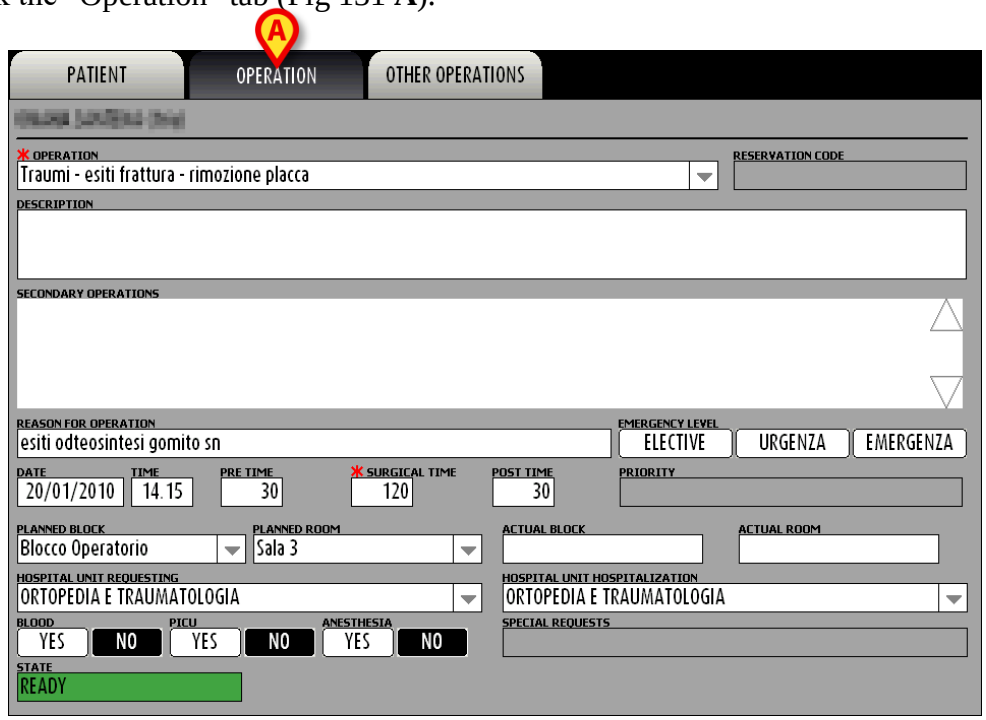


Fig 131 - Operation data

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

The information that can be specified on this page is

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

To specify new data or to modify the existing ones

- click the **Edit** button on the command bar (Fig 132).

Fig 132

The screen will turn to “Edit mode”. It will be now possible to modify the patient data.
The **Cancel** and **Update** buttons appear on the command bar (Fig 133).

Fig 133

After editing, click the **Update** button to save the changes made.

When editing the screen, some fields can be filled through specific pre-defined menus. These menus can be opened by the button.
For example, the button alongside the "operation" field opens a list of possible operations from which to choose.
To select one of the items on the list click on the item's name. The clicked item will be displayed on screen in the appropriatre field. This procedure is possible every time the button appears.

9.1.3. Other operations

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

To access this page

- click the "Other operations" tab (Fig 134 **A**).

The following screen opens.

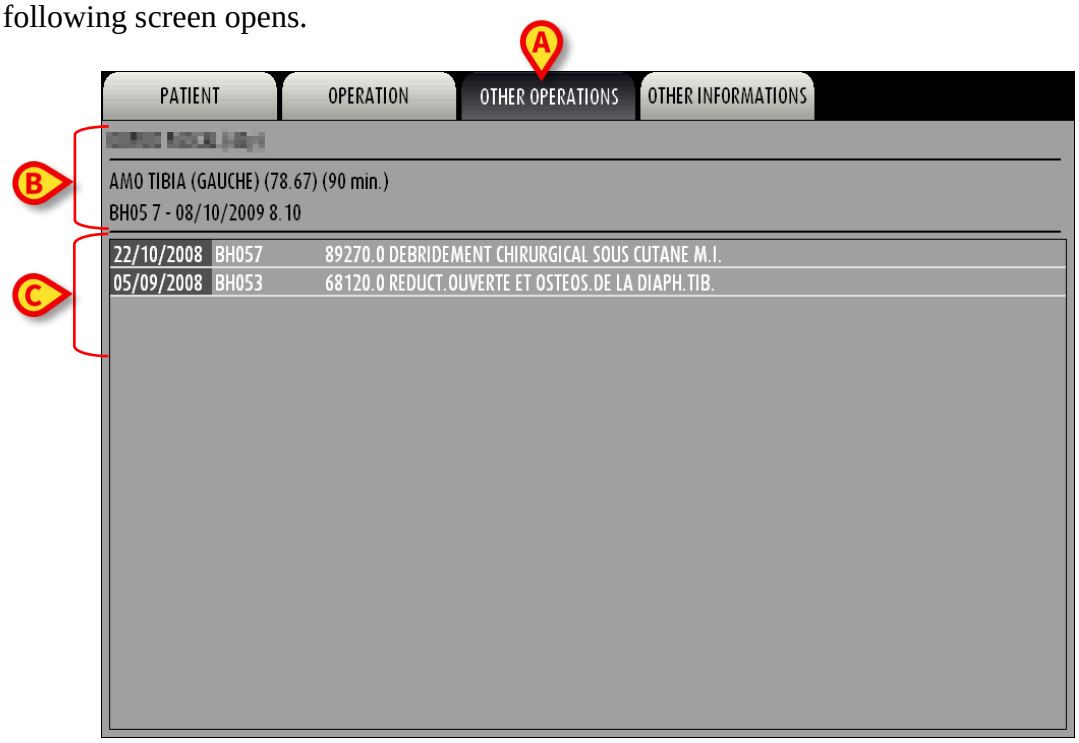


Fig 134 - Other operations

The name of the patient and the selected operation main data are an the top-left corner of the screen (Fig 134 **B**).

The different operations are displayed in chronological order, most recent on top (Fig 134 **C**).

Fig 135

Each line corresponds to an operation (Fig 135).

The information provided for each operation is:

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

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

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

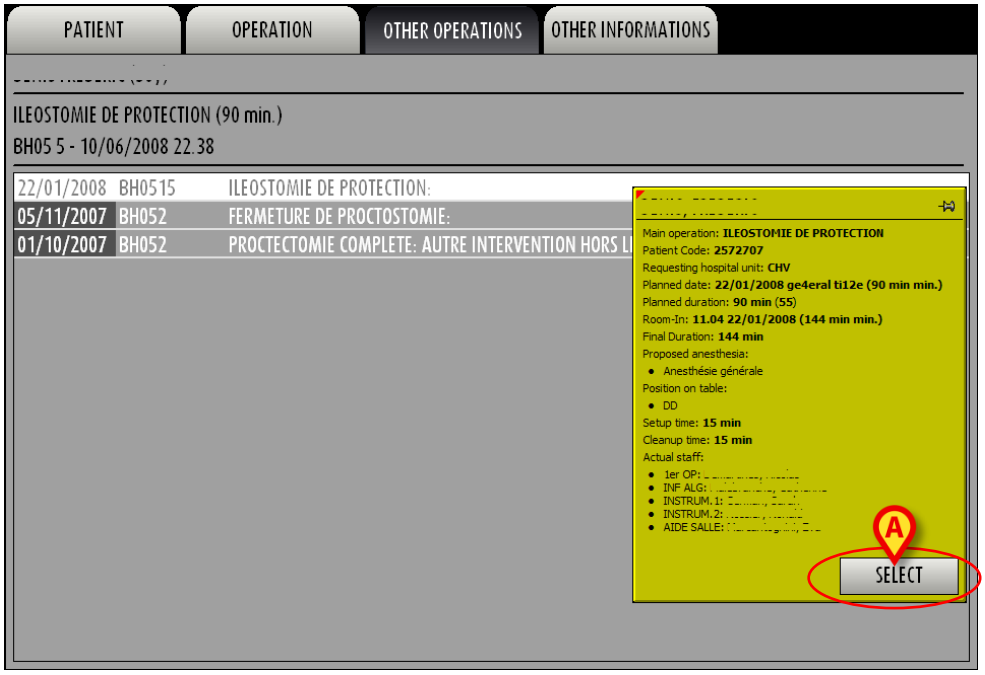


Fig 136

The **Select** button (Fig 136 **A**) on the information window can be clicked to access the “OranJ Home” page for the specific operation. See paragraph 8.1 for a description of the “OranJ Home” screen,

The info window shown in Fig 136 can be customized by the system administrator, i.e. the type and amount of information contained in the window is decided by the user. Therefore, it varies with every single configuration.

9.1.4. Other information

Some configurations use an additional tab to display more relevant data. The “Other informations” page contains a set of additional information regarding a selected patient/operation that are considered useful (Fig 137).

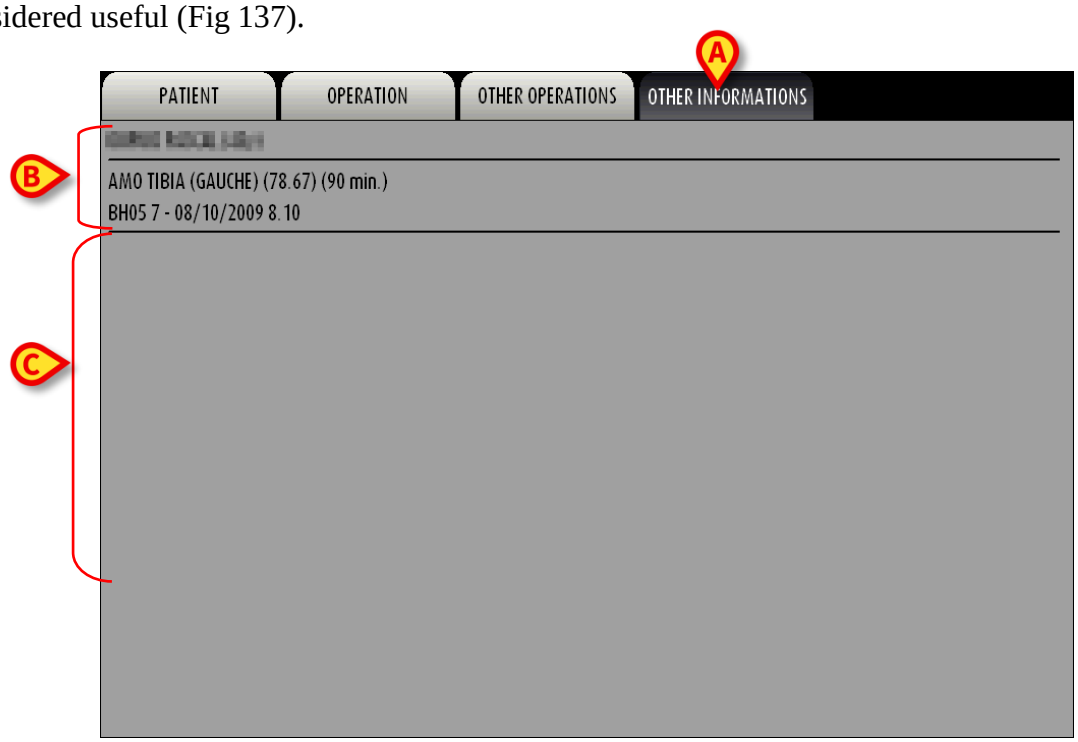


Fig 137

To access this screen

- click the “Other informations” tab indicated in Fig 137 **A**.

The patient and operation main data are displayed on the top left corner of the page (Fig 137 **B**).

The additional information is displayed in the area indicated in Fig 137 **C**.

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

9.2. How to schedule a new operation

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

To schedule a new operation

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

The“OranJ Home” screen relating to the selected patient will open (Fig 138 - See paragraph 8.1 for a detailed description of this screen).

Fig 138 – OranJ Home

- Click the “patient” area (Fig 138 **A**).

The “Patient and Operation detail” screen opens (Fig 139).

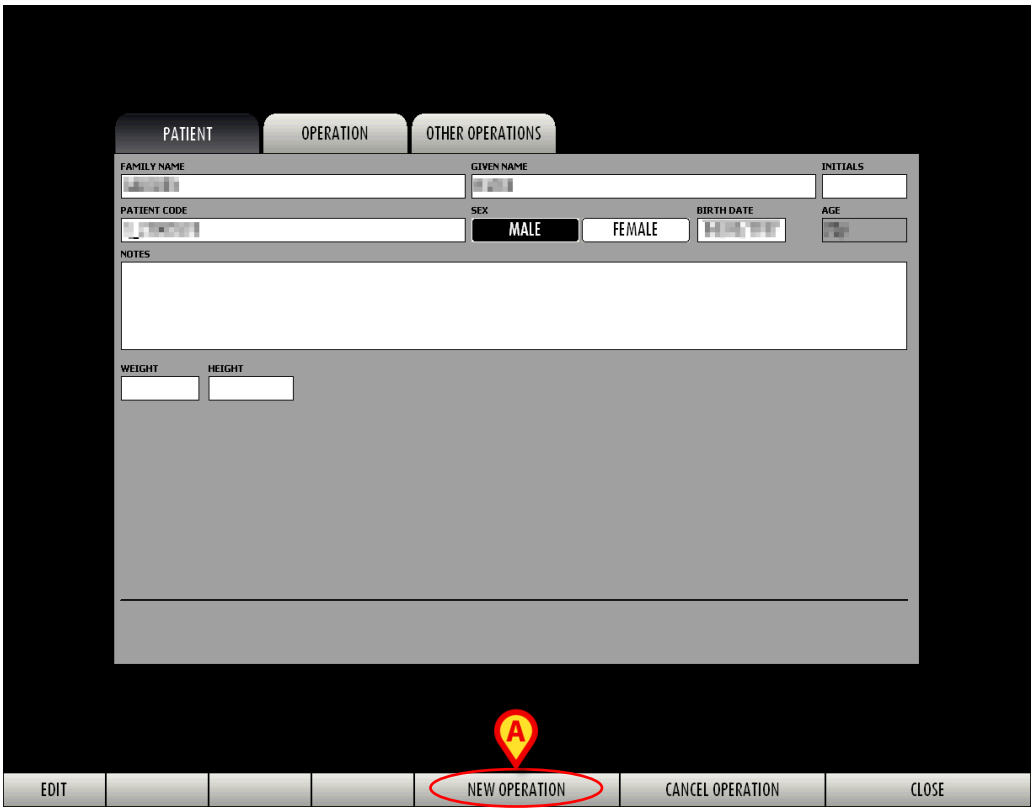


Fig 139

The "Operation" tab will be automatically selected, that will be in "edit" mode. It will be here possible to specify the new operation data (Fig 140).

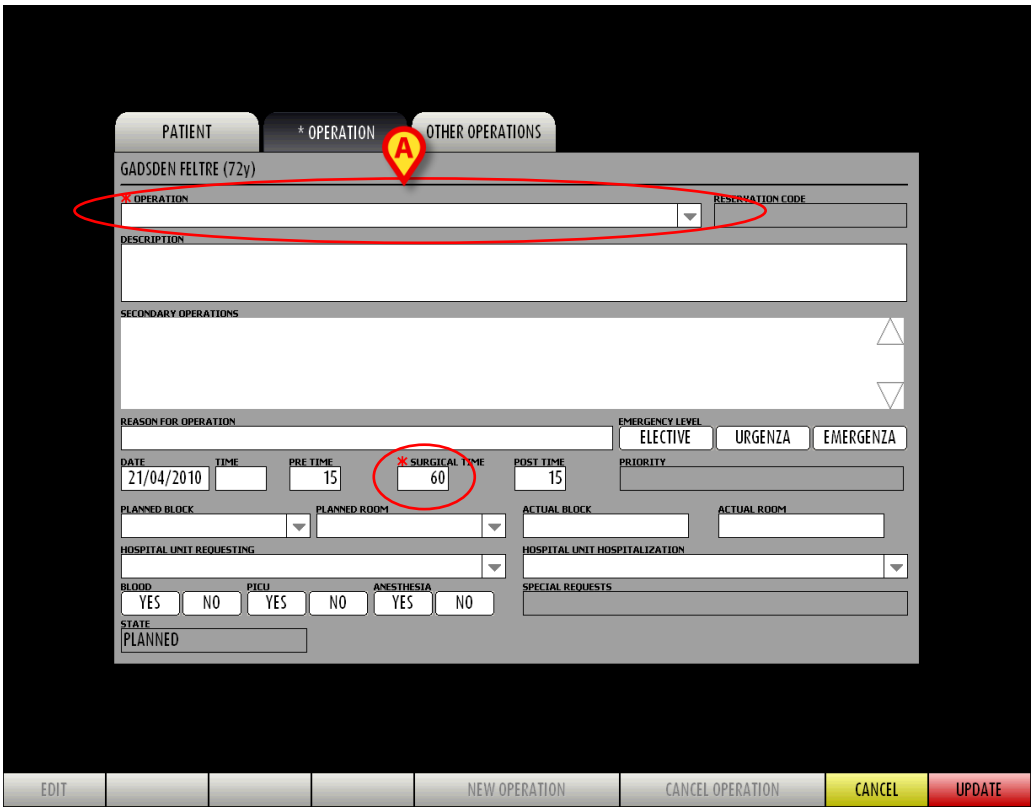


Fig 140 – New operation data specification

- Specify the operation details (operation name and planned duration - indicated in Fig 140 - are required)

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

For example, the button alongside the "operation" field (Fig 140 **A**) opens a list of possible operations from which to choose (Fig 141).

- Use the arrows on the right of the list (Fig 141 **A**) to scroll the list, or type the initial letter of the wanted operation to jump to the list of operations beginning with that letter.

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

The operation name is displayed in the "Operation" field.

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

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

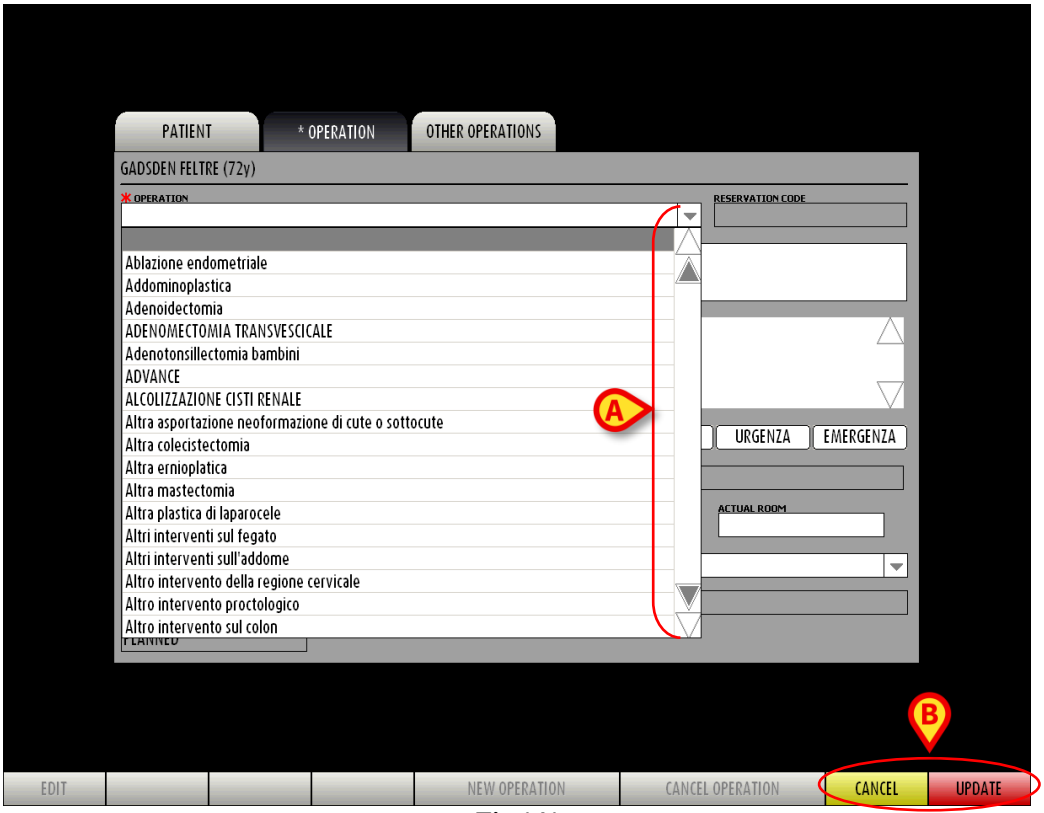


Fig 141

After entering all the data

- Click the **Update** button to save the data entered (Fig 141 **B**, Fig 142).

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

Otherwise, if you wish to cancel the data entered

- Click the **Cancel** button (Fig 141 **B**, Fig 142).

Fig 142

9.2.1. How to cancel a scheduled operation

To cancel a scheduled operation

- Select the operation that must be cancelled.

The "OranJ Home" screen relating to the selected operation opens (Fig 143).

Fig 143 - OranJ Home

- Click the "Patient" area (Fig 143 **A**).

The "Patient and Operation details" screen opens (Fig 144).

Fig 144

- click the **Cancel Operation** button on the command bar (Fig 144 **B**)

User confirmation is required (Fig 145).

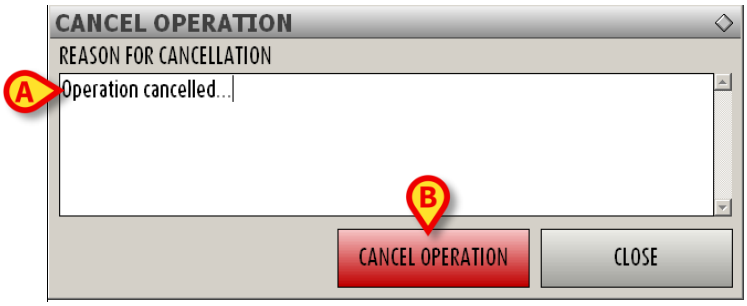


Fig 145 – Operation cancellation

The cancellation reason can be here specified.

- Specify the cancellation reason (Fig 145 **A**)
- Click the red **Cancel Operation** button (Fig 145 **B**)

Once the reason has been entered, it is displayed on the cancelled operation record in the "Reason for cancellation" field.

The operation state is now “Cancelled” (Fig 146 **A**).

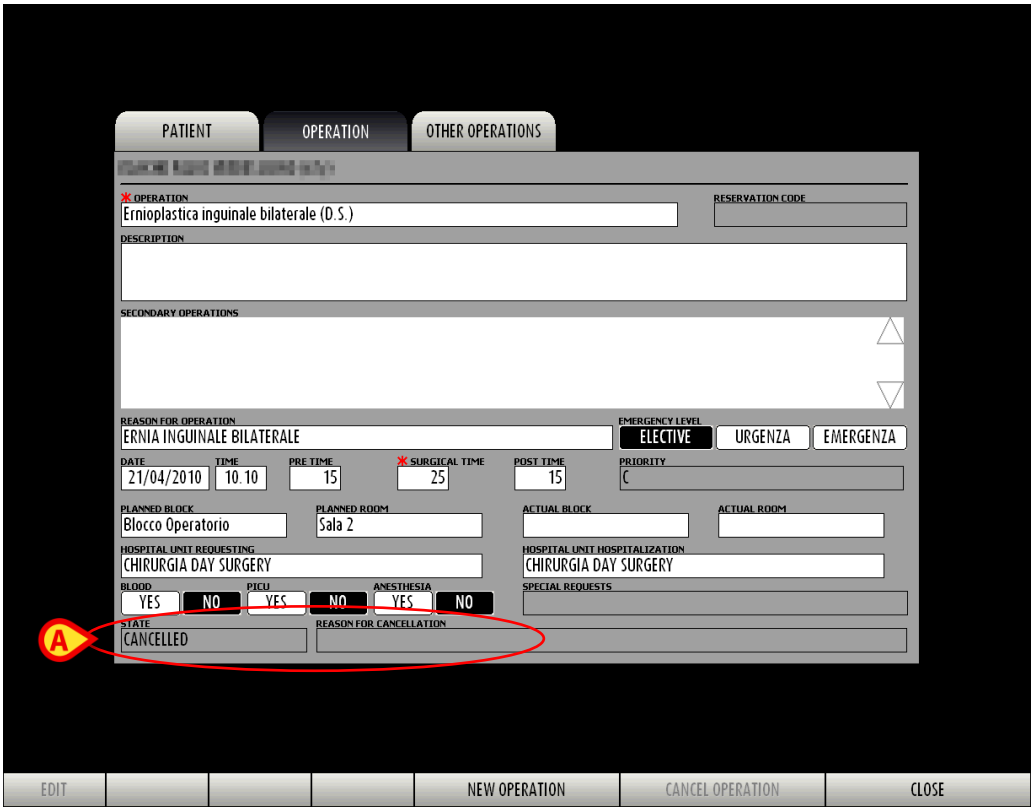


Fig 146 - Cancelled operation

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

10. The OranJ “Plan” module

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

- Click the corresponding icon 

on the DIGISTAT® lateral bar (Fig 147).

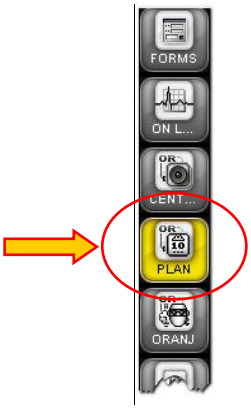


Fig 147

The “OranJ Plan” module screen opens. Fig 148 shows an example. The screen shows the state and the trends of the actual operations on a block in the current day.

Fig 148 - Operating day (example)

10.1. Screen description

Every numbered line represents an operating room. The box at the beginning of the line states the number of the room. In Fig 149 **A** rooms 1 e 2 are indicated.

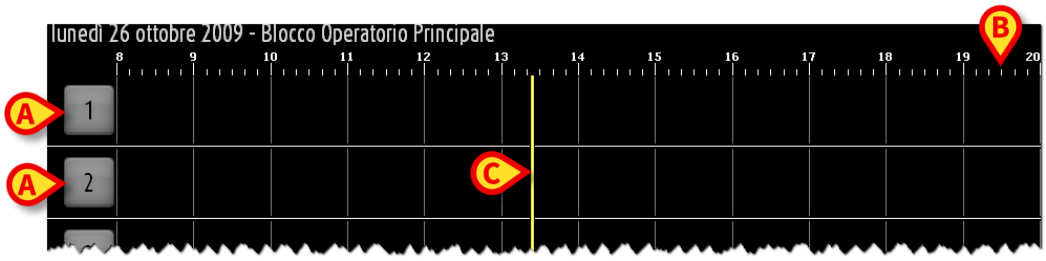


Fig 149

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

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

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

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

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

Fig 148 and Fig 150 show some examples.

Fig 150

The hours are indicated on top and bottom of the screen (Fig 149 **B**).

The yellow bar shown in Fig 149 **C** indicates the current time. In Fig 149 it is about 13:20. The bar runs as time goes by.

Possible yellow letters placed near the room box (Fig 151) indicate the devices that are in the room. The relation between a letter and a device is set by configuration.

Fig 151

The rectangles displayed on screen represent the various operations (Fig 152).

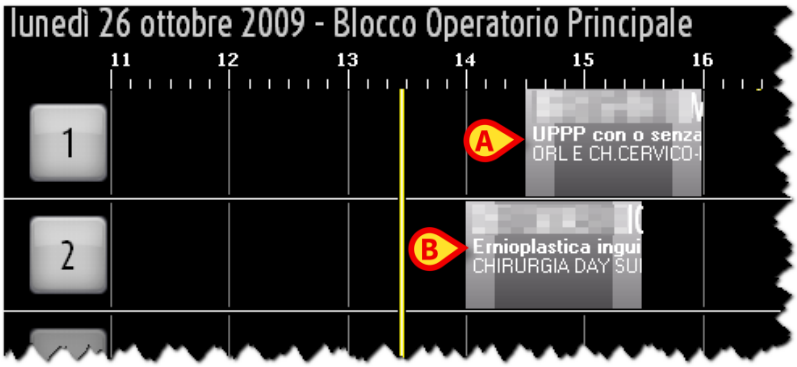


Fig 152

The rectangles on the right of the yellow time-bar represent scheduled operations (they are placed on a future time); their values (duration, room, time etc…) are planned values. The rectangles on the left of the yellow time-bar represent completed operations (they are placed on a past time); their values are actual values. The rectangles intersecting the yellow bar represent operations in progress. In Fig 148 some examples of all kinds are visible.

The position of every rectangle indicates the scheduled time and the room where the operation will be performed (or was performed if completed). In Fig 152, for example, an operation is planned at 14:30 in room 1 and an operation is planned at 14:00 in room 2.

The size of every rectangle is proportional to the scheduled duration of the corresponding operation (actual duration if the operation is completed). For example: the planned duration of the operation indicated in Fig 152 **A** is 90 minutes (from 14:30 to 15:00); the planned duration of the operation indicated in Fig 152 **B** is 90 minuts as well (from 14:00 to 15:30). The duration represented this way includes pre-surgical, surgical and post-surgical times.

These times are indicated by different shades of color (Fig 153).

Fig 153

The lighter part on the left (Fig 153 **A**) represents the pre-surgical time; the darker part in the middle (Fig 153 **B**) represents the surgical time; the lighter part on the right represents the post-surgical time (Fig 153 **C**).

Each rectangle displays certain operation information, depending on the configuration in use. In the configuration here described the patient name, the operation and the hospital unit requesting the operation are displayed in the rectangle (see Fig 154 for an instance).

The rectangle colour indicates the operation state.

Four different operation states are possible in the OranJ system.

- Planned – the operation has been scheduled; at least the operation day was specified. Light grey indicates the “Planned” state (Fig 154).

Fig 154 - “Planned” operation

- Ready – the patient has undergone block check-in. Green colour indicates the “Ready” state (Fig 155).

Fig 155 - “Ready” operation

- In Progress – the patient has entered the operating room. Cyan indicates the “In progress” state (Fig 156).

Fig 156 - “In progress” operation

- Completed – the operation has been completed; the patient is out of the operating room. Dark grey indicates the “Completed” state (Fig 157).

Fig 157 - “Completed” operation

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

The changes in the operation state are linked to the recording of certain markers on the “OranJ Home” screen (see paragraph 8.4 for a description of the “Markers”).

- The “Block In” marker recording implies passage from “Planned” state to “Ready” state.
- The “Room In” marker recording implies passage from “Ready” state to “In progress” state.
- The “Cut” marker recording implies the end of the pre-surgical time and the beginning of the surgical time. When this marker is recorded the operation rectangle looks like the one shown in Fig 156; here the different shading differentiate pre surgical and surgical times.
- The “Suture” marker implies the end of surgical time and the beginning of post surgical time. When this marker is recorded the operation rectangle looks like the one shown in Fig 158, the different shading here differentiate pre surgical, surgical and post surgical times.

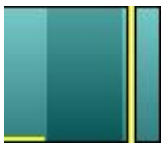


Fig 158

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

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

If enabled by configuration, the possible operation delay is visible on a yellow bar placed at the bottom of the operation-rectangle (Fig 159).

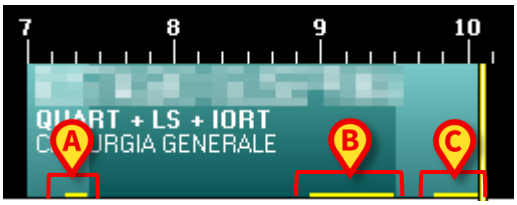


Fig 159

A configuration parameter makes it possible to display separately the possible delays in pre surgical, surgical and post surgical durations. That is the case shown in Fig 159. In the figure here displayed the three yellow bars indicate

1) a 12 minutes delay in the pre surgical planned duration (Fig 159 **A**);
2) a 40 minutes delay in the surgical planned duration (Fig 159 **B**);
3) a 21 minutes delay in the post surgical planned duration (Fig 159 **C**).

The operation shown in the figure is still in progress. Total delay is 73 minutes so far. This value is indicated in the "residual time" area on the "OranJ Home" screen (see paragraph 8.9).

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

The operations indicated as "Emergencies" on the "Patient and operation detail" screen (Fig 131 - or, if installed, on the DIGISTAT® "Smart Scheduler" system, or scheduled using a possible configured emergency procedure) are characterized by a red stripe on the left (Fig 160). The small box indicated in Fig 160 **A** specifies the emergency level. In the configuration here described there are three possible emergency levels.

Fig 160 - Emergency

Every operation box can be clicked. Click one of the boxes to open a window (Fig 161) containing the main data of the operation.

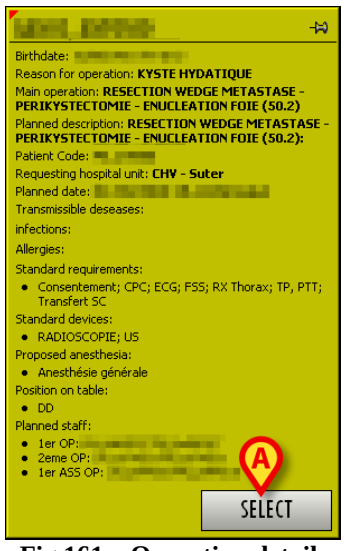


Fig 161 – Operation details

Click the **Select** button in the window (Fig 161 **A**) to access the "OranJ Form" page relating to the operation clicked (Fig 58).

10.2. The "OranJ Plan" command bar

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

Fig 162

This button makes it possible to edit the operation plan. The button must be selected before any editing procedure. See paragraph 10.2.1.

This button makes it possible to display the plan of a different block. This button is only active if working on a "General Central" station. See paragraph 10.2.2.

This button makes it possible to display a different time span. See paragraph 10.2.3.

This button makes it possible to display the plan of a different day. See paragraph 10.2.4.

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

This button is a filter for the operations in the "not assigned" area. If selected, only the operations of the currently selected block are displayed in this area, if not selected all the not assigned operations of all the blocks configured in the system are displayed. See paragraph 10.3.

10.2.1. How to edit the operation plan

The operation plan can be edited directly on the "OranJ Plan" module main screen. Before any editing it is necessary to click the **Edit** button (Fig 163).

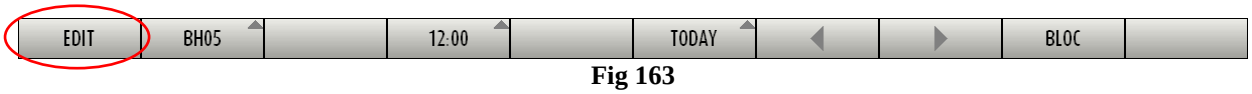


Fig 163

When the button is selected the screen is in "edit" mode. The selected button colour changes to dark grey.

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

- click the **Edit** button,

The “drag and drop” functionalities are this way enabled.

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

The rectangle stays where dragged, whereas the button deselects. The changes (operation time and room) are recorded on the other OranJ modules.

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

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

The **Edit** button makes it possible to:

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

10.2.2. How to change the block displayed

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

To display the page relating to another surgical block

- Click, on the command bar, the button indicated in Fig 164 (the button displays the name/code of the block currently displayed).

Fig 164

A list of all the blocks configured in the OranJ system opens (Fig 165).

Fig 165 – Block selection

- Click one of the names on the list. The corresponding block is this way displayed.

10.2.3. How to change the time range displayed

To change the time range displayed

- click the time button on the command bar (Fig 166 - the button displays the time range currently selected).

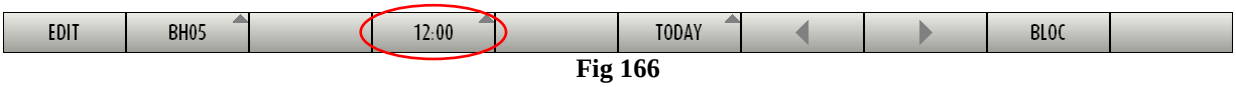


Fig 166

A drop-down menu offering three different options (6:00 – 12:00 – 24:00) opens (Fig 167).

Fig 167 – Time interval options

- Click the required option.

The screen changes accordingly. Click **6:00**, for instance, to display a 6 hours time range.

10.2.4. How to change the day displayed

The **Today** button (Fig 168) on the command bar makes it possible to change the date displayed.

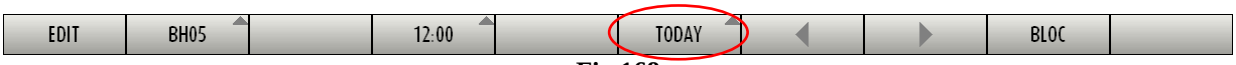


Fig 168

To do that

- Click the **Today** button.

A calendar window (current month) opens (Fig 169).

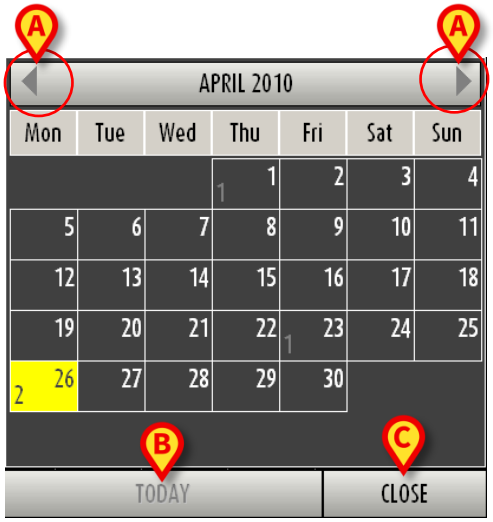


Fig 169 – Calendar

The current day is highlighted yellow. Inside every day the number of operations completed during that day is shown (dark gray).
Use the arrows (Fig 169 **A**) to change month. If it is April, for example, click the right arrow to display the calendar for May and the left arrow to display the calendar for March.

After selecting the month

- Click the day you wish to display.

The day selected on the calendar turns yellow. The page relating to the selected day is displayed.
If you select a different day from the current one, the **Today** button displays the date of the selected day. To return to the current day

- Click the **Today** button on the calendar (Fig 169 **B**).

To close the calendar window

- Click the **Close** button on the calendar (Fig 169 **C**).

10.3. The “not assigned” area

The “Not assigned” area on the right of the “OranJ Plan” screen (Fig 170 **A**, Fig 171), contains operations which have not been assigned a block, room or time.

Fig 170

This area can be used to add urgent operations to the daily schedule. The criterion observed for these urgent cases is “as soon as a room is free, the operation goes ahead”; the “not assigned” area makes it possible to display the operations waiting to be added to the daily schedule.

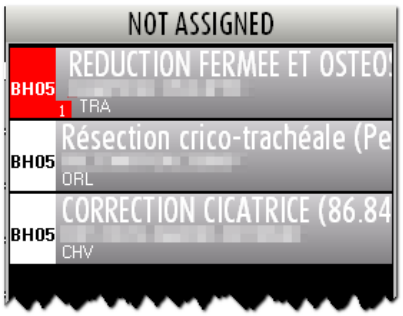


Fig 171 – “Not assigned” area

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

- the block is not specified;
- the room is not specified;

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

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

The "not assigned" area also displays operations which are indicated as "emergencies". These operations, regardless of the time, block and room specification, are marked red and are not only displayed on the day for which they are scheduled, but also on the days to come (so that the emergency is always visible. All the emergencies are grouped together on top of the list.
The small box indicated in Fig 172 **A** specifies the emergency level.

Fig 172

The **Block** button on the command bar (Fig 170 **B**) makes it possible to filter the operations of the "not assigned" group. If selected, only the operations relating to the block currently displayed are displayed. If not selected, all the "not assigned" operations of the surgical area are displayed. When you access the page, the Block button is selected by default.
The emergencies, when inserted in the plan, are characterized by a red stripe on the left (Fig 173).

Fig 173 - Emergency

When a day in the past is displayed on the plan, the "not assigned" area contains the list of the operations that were planned for that day but were not performed. Fig 174, for instance, shows the area referred to a day in the past. Note the title "planned" on top of the list instead of "not assigned".

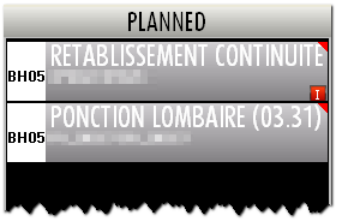


Fig 174

The operation boxes that appear in the not assigned area in the way indicated in Fig 175 **A** are reserves that were planned for a day that is different from the current day.

Fig 175

10.3.1. Planning a "Reserve" operation

To add a "Not assigned" operation to the daily plan

- Click the **Edit** button on the command bar.
- Drag the operation-rectangle and drop it to the position corresponding to the wanted room and time.

10.4. Room Plan

You can display the details of the schedule of every single operating room by clicking the box containing the room number (Fig 176).

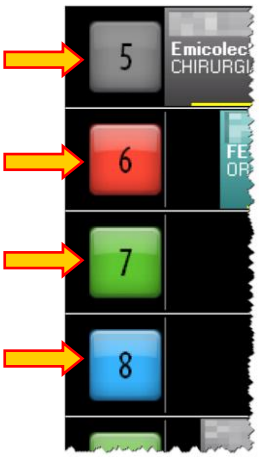


Fig 176

10.4.1. Scheduling the single room

Click one of the boxes indicated in Fig 176 to access a page showing information relating to the daily schedule of the single room (Fig 177).

Fig 177 – Room Plan

The figure shows the details of room 4.

10.4.2. Room schedule

There is a time line in the upper part of the page, schematically representing the schedule of the operating day (Fig 177 **A**, Fig 178).

Fig 178

The box on the left (Fig 178 **A**) displays the room number. If enabled by configuration, the colour of that box provides information on the state of the operation that is more relevant at present time.

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

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

- both operation states and late/close to end operations are highlighted .

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

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

Possible letters placed beside the room number (Fig 179) indicate the room devices. The relationship between a letter and a device is defined by configuration.

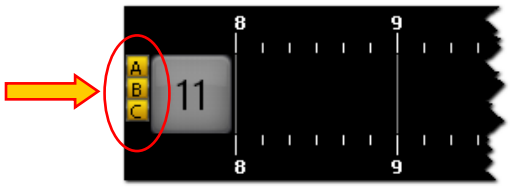


Fig 179

The numbers along the line represent the hours of the day. The boxes inside the line represent the operations scheduled, in progress or completed in that room. The color of the boxes corresponds to the operation state. The association between color and operation state is explained in paragraph 10.2

The lenght of every box is proportional to the scheduled duration of the corresponding operation. The longer the box, the longer the scheduled duration of the operation.
The position of every box indicates the scheduled time for the operation. The left side of the box is positioned in line with the start time scheduled for the operation.
For example, the box indicated in Fig 178 **B** corresponds to an operation which should start at 13:40 and should last one hour.

If the data relating to an operation is changed, i.e., if the scheduled time or duration is changed, the system automatically moves the corresponding box on the page and/or changes its dimensions.
See paragraph 9 to know how to change the data of a scheduled operation.

The vertical yellow cursor indicates the current time (Fig 178 **C**). In the example shown in the figure, the yellow cursor is in line with 11:50. The cursor runs across the page as time goes by.
If the cursor meets the start time established for an operation (i.e., the left side of a box) and the operation does not start at the established time, the box moves together with the cursor.

In general:

- completed operations (dark gray) are all on the left of the time cursor,

- scheduled operations (light gray) and those that have only undergone block check-in (green) are all on the right of the time cursor,

- in progress operations (cyan) are across the time cursor.

Data relating to completed operations (duration, start time, end time etc…) are actual data; data relating to scheduled operations are planned data.

If enabled by configuration, the possible operation delay is visible on a yellow bar placed at the bottom of the operation-rectangle (Fig 180).

Fig 180

A configuration parameter makes it possible to display separately the possible delays in pre surgical, surgical and post surgical durations. That is the case shown in Fig 180. In the figure here displayed the three yellow bars indicate

1) a 5 minutes delay in the pre surgical planned duration (Fig 180 **A**);
2) a 15 minutes delay in the surgical planned duration (Fig 180 **B**);
3) a 10 minutes delay in the post surgical planned duration (Fig 180 **C**).

The operation shown in the figure is still in progress. Total delay is 30 minutes so far. This value is indicated in the "residual time" area on the "OranJ Home" screen (see paragraph 8.9).
The operations envisaged after the overrunning operation will be automatically postponed by the system. The operations scheduled after the delayed ones are, if necessary, automatically postponed.

The operations indicated as "Emergencies" are characterized by a red stripe on the left (Fig 181). The small box indicated in Fig 181 **A** specifies the emergency level. In the configuration here described there are three possible emergency levels.

Fig 181 - Emergency

Every operation box can be clicked, whether on the page or the “not assigned” column (see paragraph 10.3). Click one of the boxes to open a window (Fig 182) containing the main data of the operation.

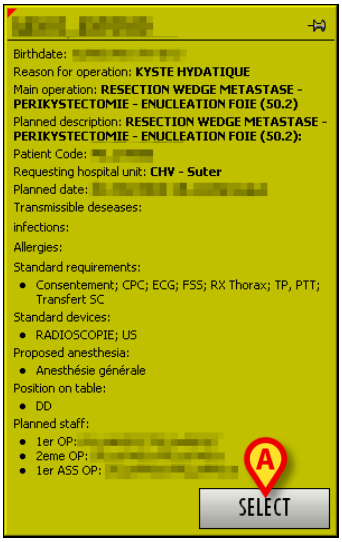


Fig 182 – Operation details

Click the Select button in the window (Fig 182 **A**) to access the “OranJ Form” page corresponding to the operation clicked (Fig 58).

10.4.3. The command bar

Fig 183 – Room Plan module command bar

On the control bar, the three buttons **6 Hours**, **12 Hours**, **24 Hours** (Fig 183 **A**) make it possible to change the time range displayed. By clicking the **6 Hours** button, for example, the time range of 6 hours is displayed, while the **12 Hours** button displays the time range of 12 hours.

The arrow buttons (Fig 183 **B**) make it possible to move backwards and forwards in the time range displayed. If, for example, you are displaying the time range going from 12:00 to 24:00, click once the right arrow to display the time range going from 15:00 to 3:00 of the following day. Likewise, click once the left arrow to display the time range going from 9:00 to 21:00.

The **Edit** button (Fig 183 **C**) makes it possible to edit the page contents. See paragraph 10.4.6 for a description of this function.

The **Not Assigned** button (Fig 183 **D**) makes it possible to select a scheduled operation and bring it to the “Not assigned” area. The related procedure is described in paragraph 10.4.6.

10.4.4. The “daily program” area

The “daily program” area (Fig 184 **A**) displays in textual form information on the schedule of the selected operating room.

Fig 184

Every row corresponds to an operation (Fig 185).

Fig 185

The color of the row indicates the operation state (see paragraph 10.2 for the association between colors and operation state in OranJ).
The left part of every row contains the start time scheduled for the operation (Fig 185 **A**). The rest of the row shows:

- the planned duration of the operation (Fig 185 **B**);
- the patient’s name (Fig 185 **C**);
- the type of operation scheduled (Fig 185 **D**).

If specified, the hospital unit which requested the operation is also indicated.

If the left part is highlighted red (Fig 186) it means that the operation is an “Emergency”.

Fig 186 - Emergency

10.4.5. The “not assigned” area

The module displays the list of not assigned operations. These are operations for which no start time, room or block have been scheduled (these operations are called “reserves”, see paragraph 10.3 for a description of these operations and the related procedures).

The “not assigned” area of this page contains the same operations displayed in the “not assigned” area of the OranJ “Plan” screen (Fig 171).

Each row of this section shows the scheduled duration for the operation, the name of the patient, the type of operation scheduled and, if specified, the department which requested the operation (Fig 184 **B**).
All the rows of the “daily program” and “not assigned” areas can be clicked. Click a row to open the window shown in Fig 182, containing the main data of the operation.

10.4.6. How to edit the operations schedule

You can edit the main page of the Room Plan module to change the operations schedule

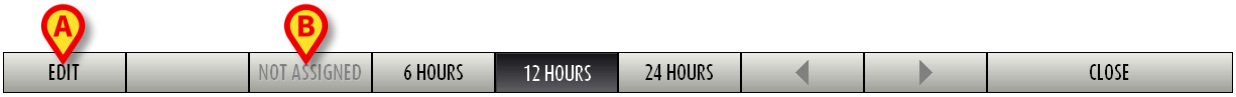


Fig 187 – Room Plan module command bar

To make any change it is necessary, first, to click the **Edit** button (Fig 187 **A**). When this button is clicked it appears as selected.

To edit the page:

- click the **Edit** button.
- make the change required.

Once the page is edited, the **Edit** button is automatically deselected. To edit the page again it is necessary to click it again.

When the **Edit** button is selected, the “drag and drop” functions are enabled.
The term “drag and drop” indicates the possibility to physically take one of the boxes corresponding to an operation, drag it to the point required on the time line and release it. Remember that the position of a box indicates the time scheduled for the corresponding operation, so moving a box from one position to another on the time line means changing the time of the corresponding operation. The changes will be automatically displayed on the other OranJ modules.

If you are working on a touch screen and there is no mouse, you can perform the same procedure using your fingers.

Likewise, you can add an operation from the "not assigned" list to the daily schedule by dragging the corresponding box.
You can also remove an operation from the daily schedule and add it to the "not assigned" list. To do so you have to

- click the **Edit** button.
- On the list of scheduled operations (Fig 184 **A**), click the row corresponding to the operation you wish to remove.

The rectangle on the left (the one displaying the scheduled time) turns yellow (Fig 188)

Fig 188

The **Not Assigned** button on the command bar activates.

- Click the **Not Assigned** button (Fig 187 **B**).

The operation is this way moved to the "not assigned" list.

Hence, use the **Edit** button on the on the main page of the Room Plan module to

- change the time scheduled for an operation.
- add one of the operations from the "not assigned" list to the daily schedule.
- remove one of the operations from the daily schedule and add it to the "not assigned" list.

10.4.7. Room markers

The markers relating to the room events (Fig 189) are displayed and recorded in the column on the left side of the page (Fig 177 **B**).

Fig 189 – Room markers

These markers make it possible to record any occurrence which is considered significant and of which a record is required. The system makes it possible to record the event and the time at which it occurred.
The number and nature of room events change according to the needs of the organization and depend on the particular configuration of the system used. Remember that the procedures explained in this paragraph are only an example of configuration. The room markers in this configuration are

- Room opens
- Start of maintenance
- Start of cleaning
- End of cleaning
- End of maintenance
- Room closes

The markers are displayed on the left side of the screen as a sequence of boxes. The boxes are arranged in chronological order.

The box relating to the marker initially appears in ochre yellow and does not contain any information on the moment (the time and day) in which the event took place. This means that the marker has not yet been recorded, the corresponding event has not yet occurred (Fig 190).

Fig 190 – First room marker

To record a marker, simply click the corresponding box. The box turns gray and records the time at which it was clicked. A new ochre yellow box (or several boxes, depending on the configuration) indicating no time appears below it. New boxes refer to subsequent markers (Fig 191).

Fig 191 – Second room marker

In general, to record a marker you have to

- click the corresponding box.

The system automatically records the time at which the box is clicked.

10.4.8. How to edit the room markers

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

- Click the box corresponding to the marker for which the time has to be changed.

A numeric keyboard is displayed (Fig 192).

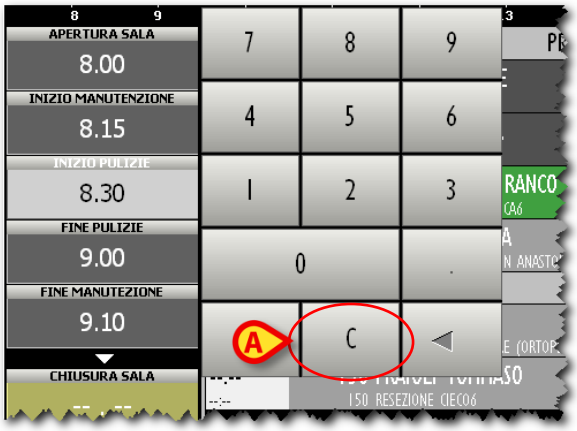


Fig 192 – Numeric keyboard

- Enter the time required using the keyboard.

To record the new time.

- Click again the box corresponding to the event.

The numeric keyboard disappears and the new time is displayed in the box.

If the time entered is impossible, the following error message pops-up (Fig 193).

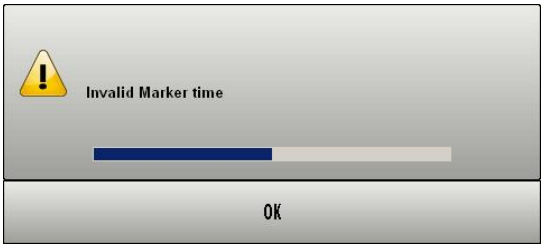


Fig 193

To delete a marker

- Click the box corresponding to the marker to be deleted.

The numeric keyboard appears (Fig 192).

- Click the **C** button on the keyboard (Fig 192 **A**).

User confirmation is required (Fig 194).

Fig 194

- Click Yes to delete the marker.

The deleting of an event implicates the deleting of all subsequent events.

The box corresponding to the event deleted becomes ochre yellow again, indicating no time, meaning that the event has not yet occurred.

11. The OranJ Central module

The OranJ Central module provides a general summary of the situation of the whole surgical area or block. OranJ Central can be used for monitoring the state and availability of the operating structures in real time.

The OranJ Central module is installed on the BLOCK CENTRAL STATION and GENERAL CENTRAL STATION workstations.

11.1. The main page

The main page of this module (Fig 195) represents a surgical block.

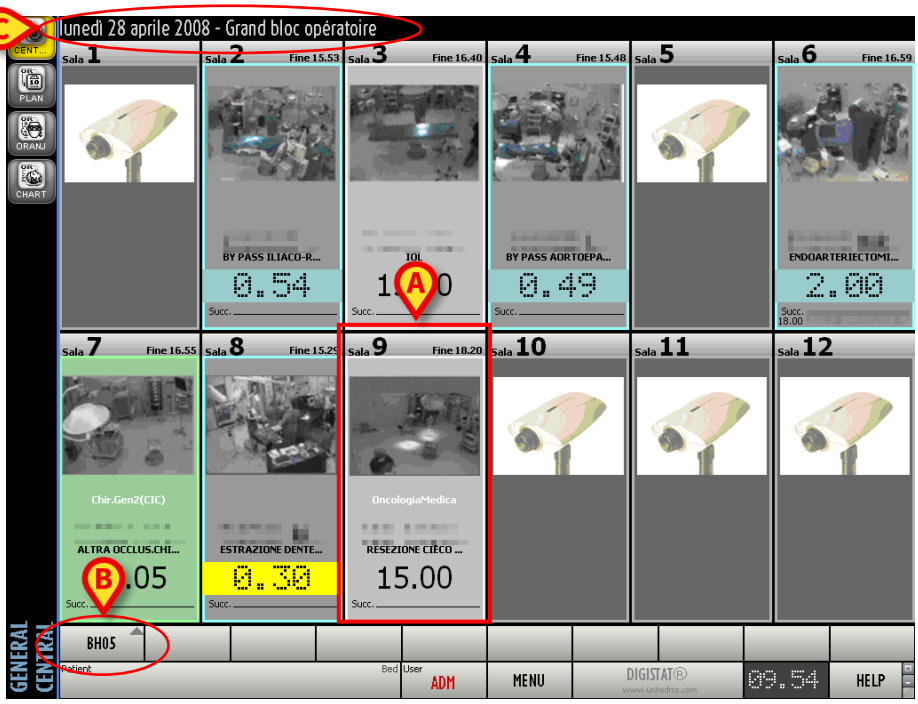


Fig 195 – OranJ Central

The **BH05** button on the command bar (Fig 195 **B**) makes it possible to select different blocks. It is only enabled when working with a General Central Station workstation, covering several surgical blocks. The name of the block displayed is displayed on the button (Fig 195 **C**).
If you are working on a Block Central Station workstation, which covers only one surgical block, this button is not enabled.

Every cell (Fig 195 **A**, Fig 196) represents an operating room.

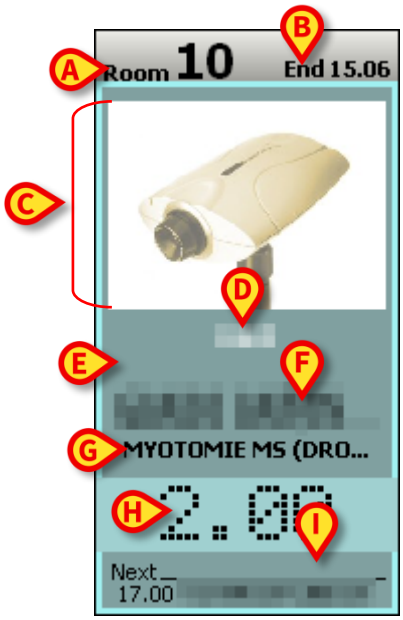


Fig 196 – Operating room detail

Every cell can contain the following information (Fig 196).

- The room number (Fig 196 **A**).
- The time envisaged for the end of the operation in progress (Fig 196 **B**).
- The picture of the operating table. This is only possible if a webcam is installed in the room (Fig 196 **C**).
- The name of the hospitalization unit requesting the operation (if specified - Fig 196 **D**).
- The name of the operating surgeon (if already assigned - Fig 196 **E**).
- The patient's name (Fig 196 **F**).
- The type of operation (Fig 196 **G**).
- The time remaining until the end of the operation in progress according to the planned duration (if the operation is in progress, this is the case shown in Fig 196 **H**).
- The scheduled operation start time (if the operation has not yet started, this is the case shown in Fig 195 **A**)
- The patient's name and the type of operation, if any, which will follow the one in progress (Fig 196 **I**).

When there is less than half an hour until the envisaged end of the operation the corresponding part of the cell becomes yellow and starts flashing.

When an operation exceeds the time envisaged, the corresponding part of the cell turns red, indicating, with a negative number, the delay time. The color of the cell indicates the current “state” of the operation.

Four different operation states are possible.

- Scheduled – the operation has been scheduled; i.e., an operation has been associated to a patient.
- Ready – the patient has undergone block check-in
- In progress – the patient has entered the operating room
- Completed – the operation has been completed.

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

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

Completed operations are not displayed on the main page of the OranJ Central module. Therefore, there will be no dark gray cells.

Click the box containing the picture of the room (or the picture of the webcam) to access a page containing detailed information of the selected operating room (Fig 198).

Click any other part of the cell to open a window (Fig 197) containing the main data of the operation.

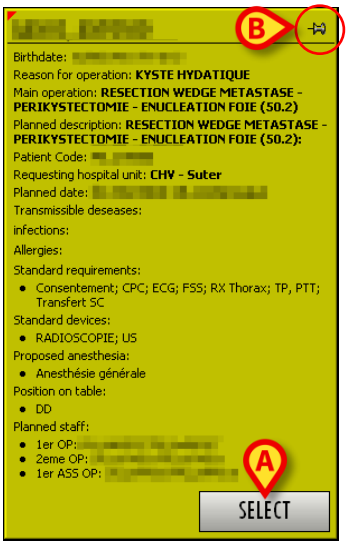


Fig 197 – Operation details

Click the **Select** button (Fig 197 **A**) to access the "OranJ Form" page relating to the operation clicked (Fig 58). The window shown in Fig 197 disappears after a few seconds. Click on it to make it disappear immediately. Click the "thumbtack" indicated in Fig 197 **B** to "pin" it to the page.

11.2. Operating Room detail

The page shown in Fig 198 displays all the details of the selected operating room.

Fig 198 – Operating room monitor

To access this page it is necessary to

- Click the area of the cell showing the picture of the room or the picture of the webcam (Fig 196 **C**).

The area on top shows the name of the surgical block, the room number, the patient's name and the type of operation (Fig 198 **A**).

Beneath it there is a time line displaying the daily schedule of the room (Fig 198 **B**).

11.3. Room schedule

There is a time line in the upper part of the page, schematically representing the schedule of the operating day (Fig 198 **B,** Fig 199).

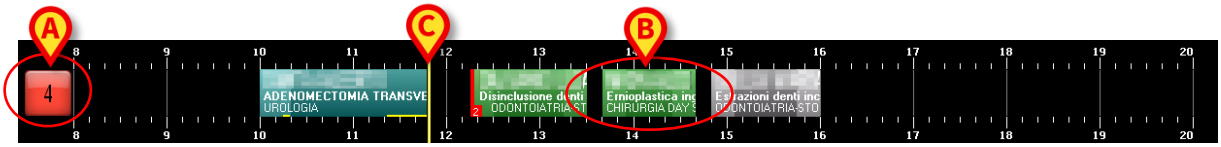


Fig 199

The box on the left (Fig 199 **A**) contains the room number. If enabled by configuration, the colour of that box provides information on the state of the operation that is more relevant at present time.

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

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

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

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

Possible letters placed beside the room number (Fig 200) indicate the room devices. The relationship between a letter and a device is defined by configuration.

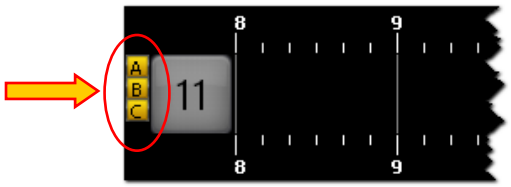


Fig 200

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

The boxes placed on the line represent the operations either scheduled, in progress or completed in that room. The color of the boxes corresponds to the operation state. The association between color and operation state is explained in paragraph 10.2

The size of every box is proportional to the scheduled duration of the corresponding operation. The longer the box, the longer the scheduled duration of the operation.

The position of every box indicates the scheduled time for the operation. The left side of the box is positioned in line with the start time scheduled for the operation.
For example, the box indicated in Fig 199 **B** corresponds to an operation which should start at 13:40 and should last one hour.

If the data relating to an operation is changed, i.e., if the scheduled time or duration is changed, the system automatically moves the corresponding box on the page and/or changes its size.
See paragraph 9 to find out how to change the data of a scheduled operation.

The vertical yellow cursor indicates the current time (Fig 199 **C**). In the example shown in the figure, the yellow cursor is in line with 11:50. The cursor moves with time. If the cursor meets the start time established for an operation (i.e., the left side of a box) and the operation does not start at the established time, the box moves in time together with the cursor.

In general

- completed operations (dark gray) are all on the left of the time cursor,
- scheduled operations (light gray) and those that have only undergone block check-in (green) are all on the right of the time cursor,
- in progress operations (cyan) are across the time cursor.

Data relating to completed operations (duration, start time, end time etc…) are actual data; data relating to scheduled operations are planned data.

If enabled by configuration, the possible operation delay is visible on a yellow bar placed at the bottom of the operation-rectangle (Fig 201).

Fig 201

A configuration parameter makes it possible to display separately the possible delays in pre surgical, surgical and post surgical durations. That is the case shown in Fig 201. In the figure here displayed the three yellow bars indicate

1) a 5 minutes delay in the pre surgical planned duration (Fig 201 **A**);
2) a 15 minutes delay in the surgical planned duration (Fig 201 **B**);
3) a 10 minutes delay in the post surgical planned duration (Fig 201 **C**).

The operation shown in the figure is still in progress. Total delay is 30 minutes so far. This value is indicated in the "residual time" area on the "OranJ Home" screen (see paragraph 8.9).

The operations envisaged after the overrunning operation is automatically postponed by the system. The operations scheduled after the delayed ones are, if necessary, automatically postponed.

The operations indicated as "Emergencies" are characterized by a red stripe on the left (Fig 202). The small box indicated in Fig 202 **A** specifies the emergency level. In the configuration here described there are three possible emergency levels.

Fig 202 - Emergency

Every operation box can be clicked, whether on the page or the "not assigned" column (see paragraph 10.3).

Click one of the boxes to open a window (Fig 203) containing the main data of the operation.

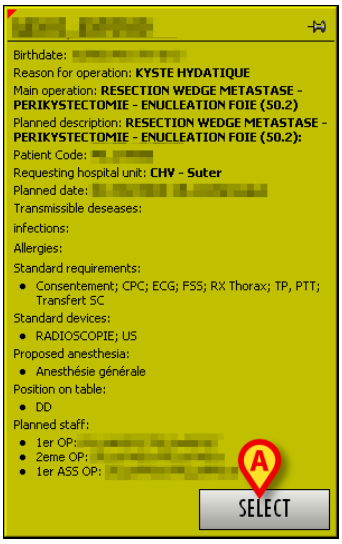


Fig 203 – Operation details

Click the **Select** button in the window (Fig 203 **A**) to access the “OranJ Form” page relating to the operation clicked (Fig 58).

11.4. The command bar

Fig 204 – Room monitor screen command bar

On the control bar, the three buttons **6 Hours**, **12 Hours**, **24 Hours** (Fig 204 **A**) make it possible to change the time range displayed. By clicking the **6 Hours** button, for example, the time range of 6 hours is displayed, while a click the **12 Hours** button displays the time range of 12 hours.

The arrow buttons (Fig 204 **B**) make it possible to move backwards and forwards in the time range displayed. If, for example, you are displaying the time range going from 12:00 to 24:00, click once the right arrow to display the time range going from 15:00 to 3:00 of the following day. Likewise, click once the left arrow to display the time range going from 9:00 to 21:00.

The **Close** button closes the window.

11.5. "Room monitor" page contents

The central part of the page (Fig 198 **C**) displays, on the left, the enlarged picture of the operating room taken by the webcam, if installed. The details of the operation in progress are displayed on the right. In particular, in this section of the screen you can read the start time scheduled for the operation, the patient's name and the type of operation.
The time specified is that at which the operation should have started and not that at which it actually starts.

The lower part of the page (Fig 198 **D**, Fig 205)) displays data relating to the operation in progress.

Fig 205 - Operating times detail

The area shown in Fig 205 is described in the following paragraphs.

11.6. Operating times detail

The area indicated in Fig 198 **A** and Fig 206 provides detailed information on both the room times and the current operation progresses.

Fig 206

There are three sections in the area:

1) the section indicated in Fig 206 **A** is formed of four timers displaying the currently selected operation times. These timers are described in paragraph 11.6.1;
2) the section indicated in Fig 206 **B** displays the chronologic list of all the markers and the events recorded for the currently selected operation;
3) the section indicated in Fig 206 **C** is formed of two timers displaying the overall operating room times. These timers are described in paragraph 11.6.2.

11.6.1. Operation times

Operation times indicated on the bottom-left corner of the screen (Fig 206 **A**, Fig 208) refer to the operation that is either in progress in the operating room or is the next planned operation. The operation main data are displayed near the screen header (Fig 207).

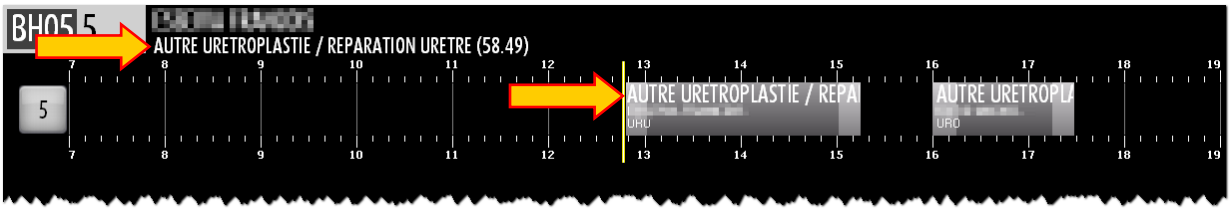


Fig 207

There are four timers indicating the operation times (Fig 206 **A**, Fig 208).

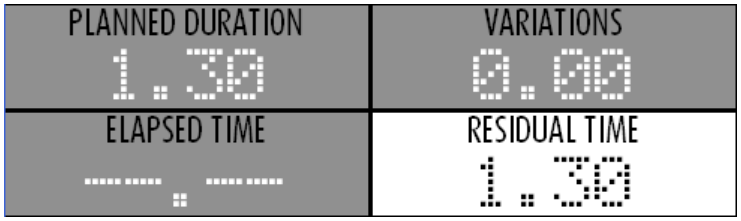


Fig 208

1) The "PLANNED DURATION" timer displays the planned duration of the selected operation and indicates the sum of the pre-surgical, surgical and post-surgical times. The value displayed on this timer changes only when the successive operation is selected.

2) The “ELAPSED TIME” timer displays the time actually elapsed since the beginning of the operation. This timer starts when the operation switches to the “In progress” state, i.e. when the “Room-in” marker is recorded on the “OranJ Home” screen.

3) The “VARIATIONS” marker displays the additional time possibly requested by the operating room staff on the “OranJ Home” screen through the relevant buttons on the “Residual time” area.

4) The “RESIDUAL TIME” timer displays the time remaining to the end of the operation (calculated both on the planned times and on the possible variations requested by the operating staff, those displayed on the “VARIATIONS” timers).
This timer displays the same time displayed on the “OranJ Home” screen, on the “Residual time” area.

Please note that the sum of the times displayed on the “PLANNED DURATION” and “VARIATIONS” timers is equal to the sum of the times displayed on the “ELAPSED TIME” and “RESIDUAL TIME” timers.

Times shown in Fig 208 correspond to an operation that is either in “Planned” or “Ready” state (i.e. the operation hasn’t started yet).

Next paragraphs explain the behaviour of the “Operating room monitor” screen timers and show the relation with the relevant markers recording on the “OranJ Home” screen.

11.6.1.1. Operation beginning - “Room in” marker

The operation switches to the “In progress” state (Fig 209 **A**) when the “Room in” marker is recorded on the “OranJ Home” screen. The “Room in” marker implies the beginning of the pre-surgical time.
When the pre-surgical time begins the “ELAPSED TIME” and “RESIDUAL TIME” timers start displaying their values (Fig 209 **B**).

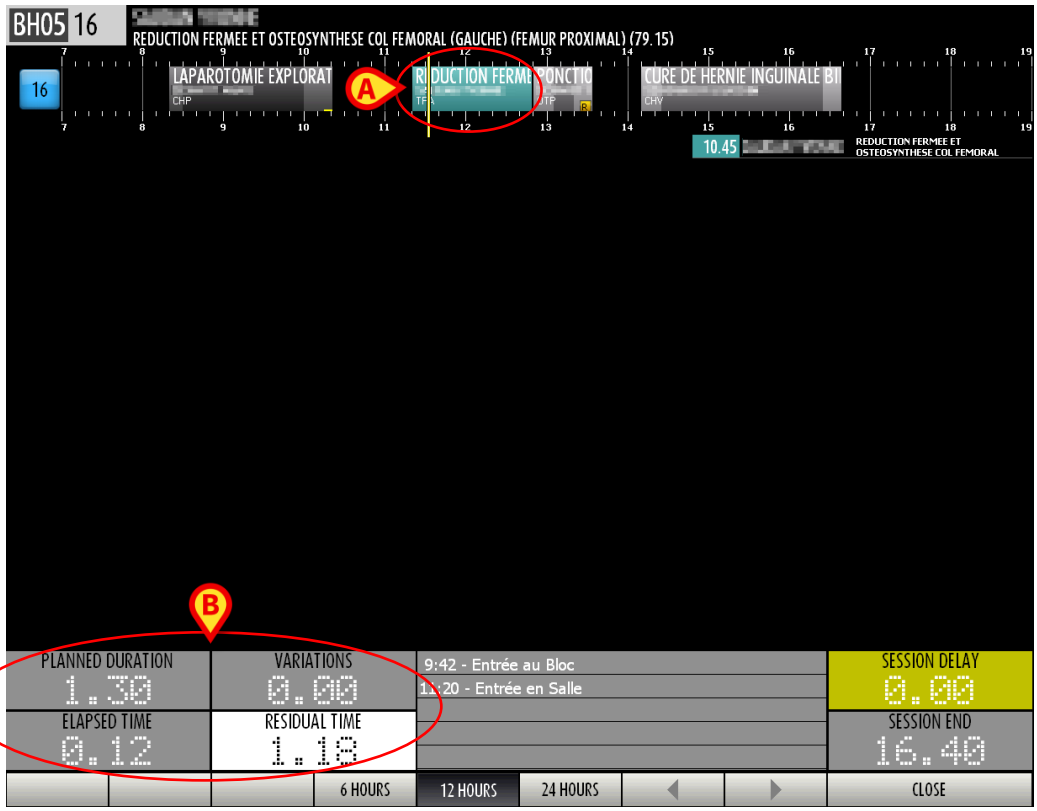


Fig 209

11.6.1.2. Surgical time beginning - “Cut” marker

Pre-surgical time ends when the “Cut” marker is recorded on the “OranJ Home” screen. If enabled by configuration, a yellow bar at the bottom of the operation-rectangle indicates the possible delay on the pre-surgical time (Fig 210 **A**). The yellow bar length is proportional to the delay amount.

Fig 210 - Pre-surgical time delay

The “Cut” marker implies the beginning of the surgical time. This change is highlighted on the operation-rectangle by a change in the colour shade (Fig 211 **A**).

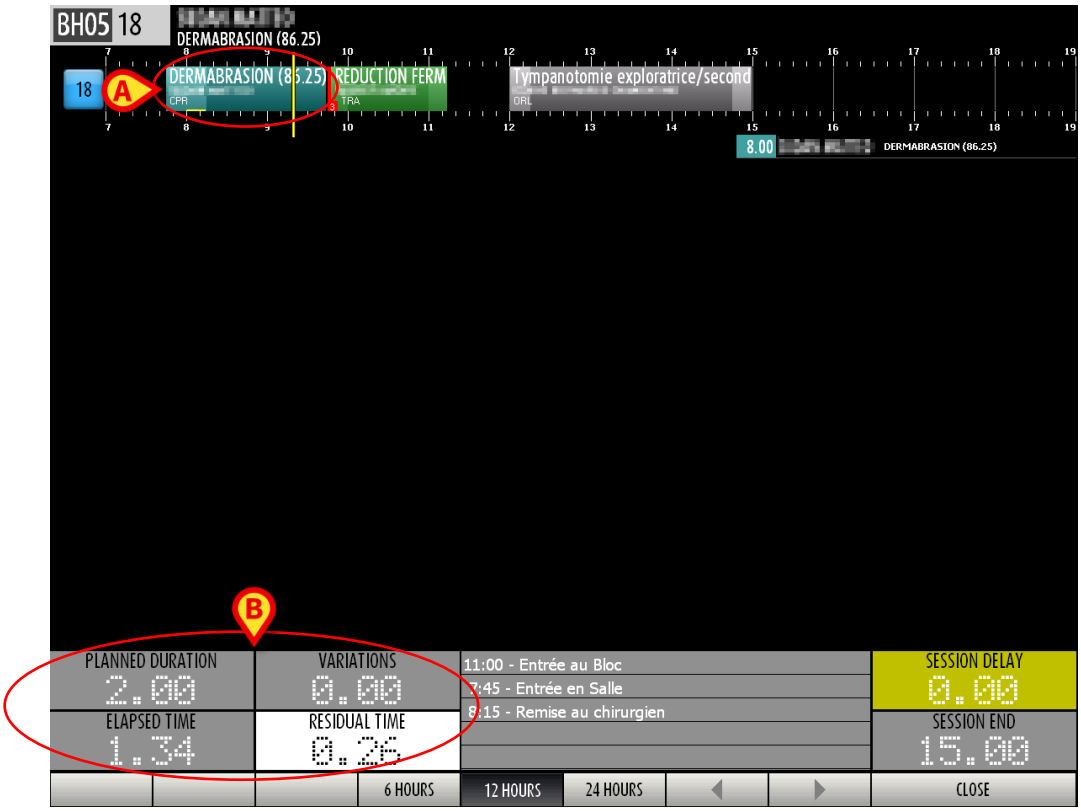


Fig 211

In Fig 211 **B** timers indicate that:

- 1 hour and 34 minutes passed since the operation began (ELAPSED TIME);
- planned residual operation duration is 26 minutes (RESIDUAL TIME);
- no additional time was requested by the operating staff (VARIATIONS);
- operation planned duration ***was*** 2 hours (PLANNED DURATION).

The "PLANNED DURATION" timer does not change until the current operation is completed. It displays in fact the duration that was planned before the operation started and does not depend on the possible variations recorded during the operation.

The time actually elapsed is displayed on the "ELAPSED TIME" timer.

If enabled by configuration, when the planned surgical time ends, the system starts indicating the delay with a yellow bar at the bottom of the operation-rectangle. The yellow bar length is proportional to the delay amount (Fig 212 **A**).

Fig 212 - Surgical time delay

11.6.1.3. Post-surgical time beginning - “Suture” marker

Surgical time ends when the “Suture” marker is recorded on the “OranJ Home” screen. A different shade of the operation-rectangle colour indicates this switch (Fig 213 **A**).
The “Suture” marker implies the beginning of the post-surgical time.

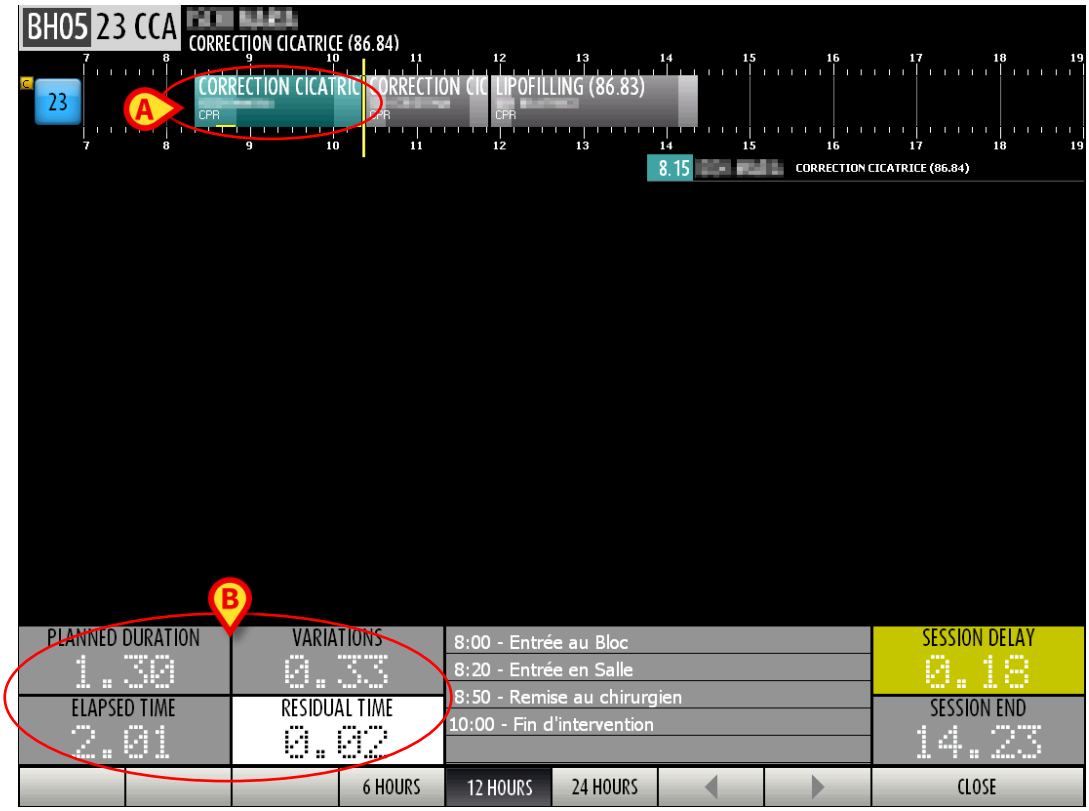


Fig 213

In Fig 213 **B** timers indicate that

- 2 hours and 01 minutes passed since the operation began (ELAPSED TIME);

- RESIDUAL TIME is 2 minutes. Residual time is calculated on the sum of the PLANNED DURATION value plus the VARIATIONS value (01:30h plus 00:33h in the example shown in Fig 213 **B**), less the ELAPSED TIME value (elapsed time is 02:01h, therefore residual time is 2 minutes).
  A negative value displayed on this timer indicates the possible delay amount. See for instance Fig 214 **A**.

- 33 additional minutes were requested by the operating staff (VARIATIONS);
- operation planned duration ***was*** 1 hour and 30 minutes (PLANNED DURATION).

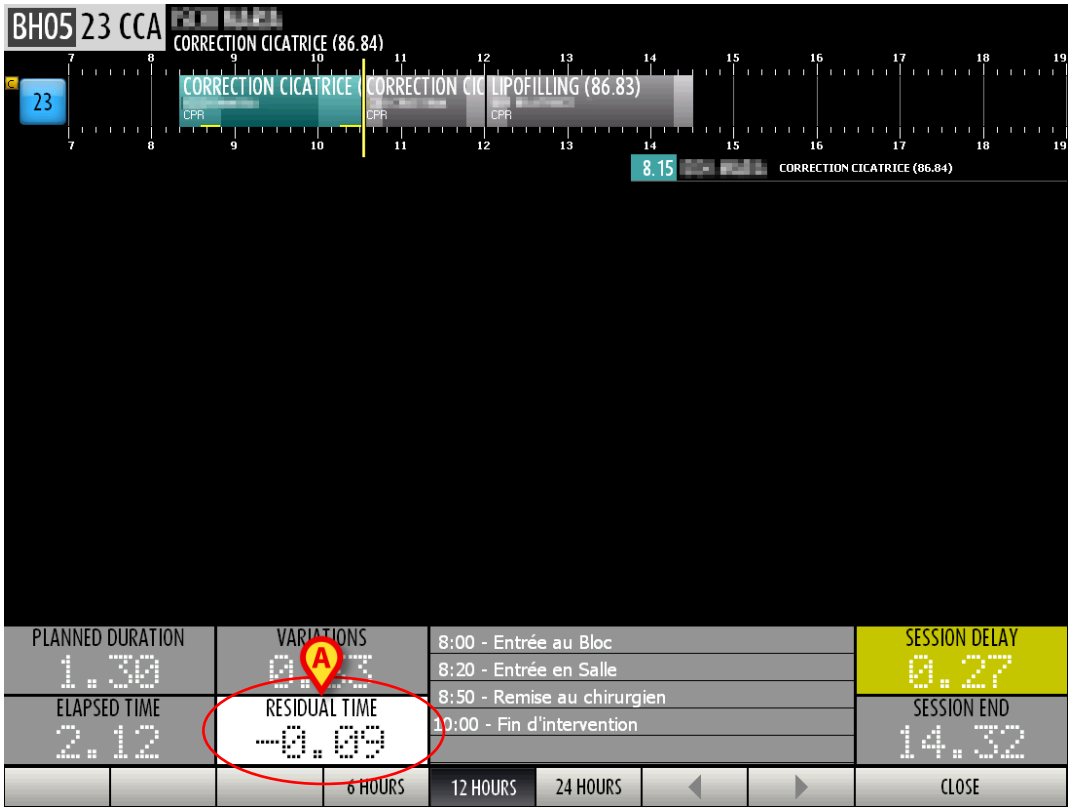


Fig 214 - Operation delay

If enabled by configuration, a yellow bar at the bottom of the operation-rectangle indicates the possible delay on the post-surgical time. The yellow bar length is proportional to the delay amount (Fig 215 **A**).

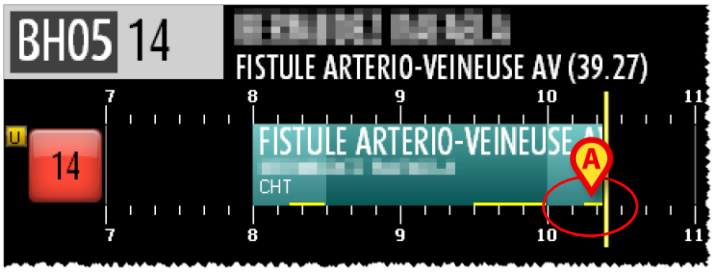


Fig 215 - Post-surgical time delay

The overall operation delay does not depend on the specific delays on the pre-surgical, surgical and post-surgical times indicated by the yellow bars at the bottom of the operation-rectangle.
In Fig 214, for instance, the overall operation delay is 9 minutes, but the post-surgical time delay is 17 minutes (planned post-surgical time was 15 minutes and it is in progress since 32 minutes).

11.6.1.4. Operation end - “Room out” marker

Operation ends when the “Room out” marker is recorded on the “OranJ Home” screen. The operation switches to “Completed” state. The operation-rectangle represents now the actual operation times and indicates both the overall duration and the specific durations and the delays (if enabled by configuration) of the pre-surgical, surgical and post surgical times (Fig 216 **A**)

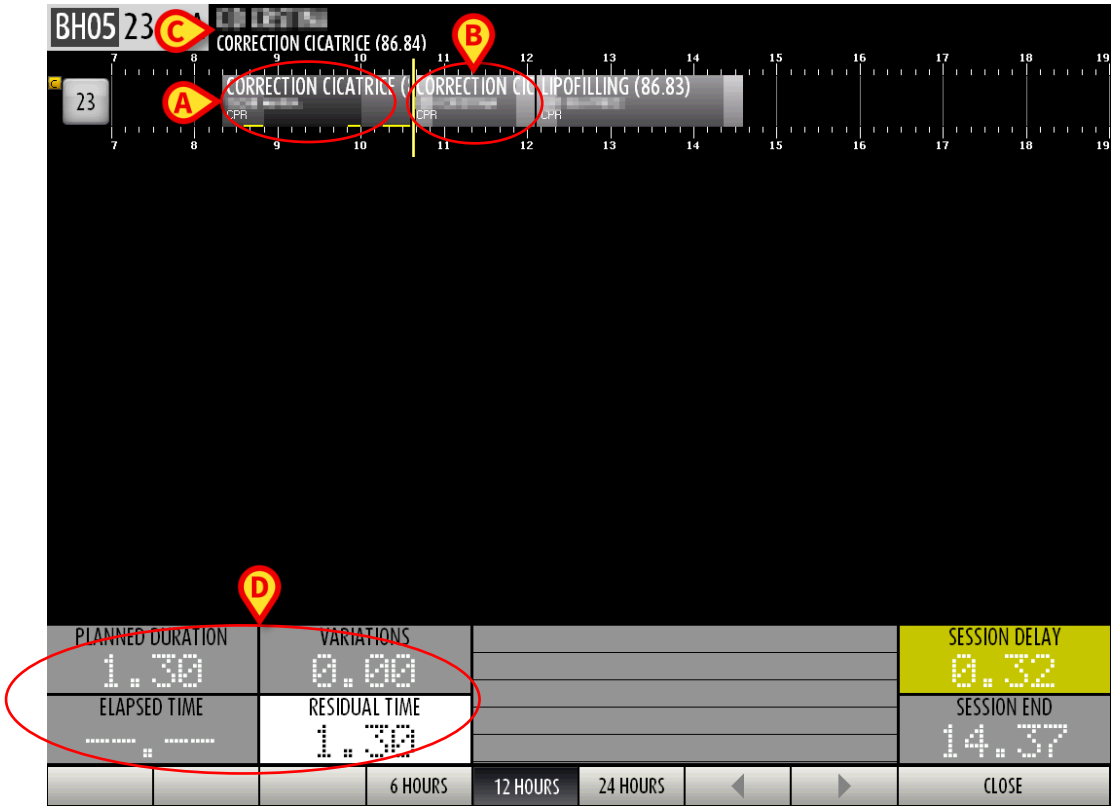


Fig 216

The successive operation is automatically selected (Fig 216 **B**), its main data are displayed alongside the screen header (Fig 216 **C**). Timers display the times of the selected operation (Fig 216 **D**).

11.6.1.5. Variations requests

The operating staff, when the operation is in progress, can request any moment additional time.

Duration variation requests are managed on the “OranJ Home” screen (paragraph 8.1).

The next two figures (Fig 217 and Fig 218) illustrate the changes on the operating room timers after a time variation request.

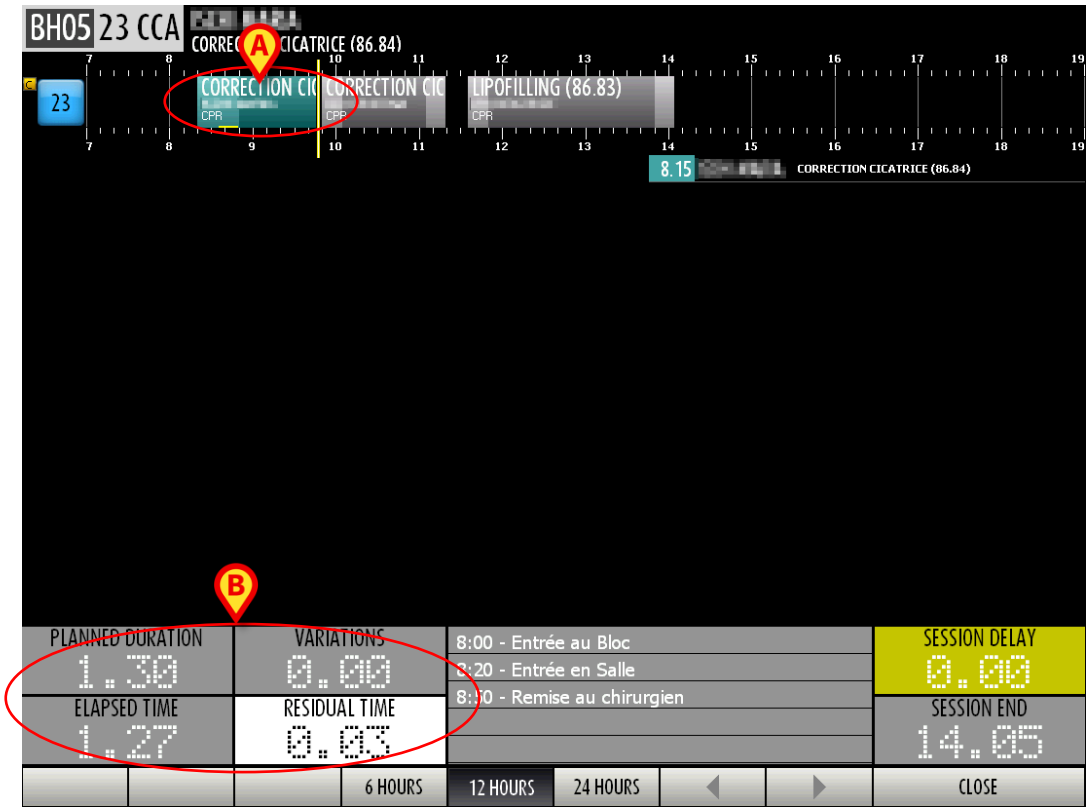


Fig 217 - Times before variation request

Before requesting additional time the "Operating room details" screen timers display the following values (Fig 217 **B**):

- 1 hour and 27 minutes passed since the operation began (ELAPSED TIME);
- planned residual operation duration is 3 minutes (RESIDUAL TIME);
- no additional time was requested by the operating staff (VARIATIONS);
- operation planned duration ***was*** 1 hour and 30 minutes (PLANNED DURATION).

The operating staff requests 33 additional minutes. The "Room monitor" screen displays this change in the following way (Fig 218).

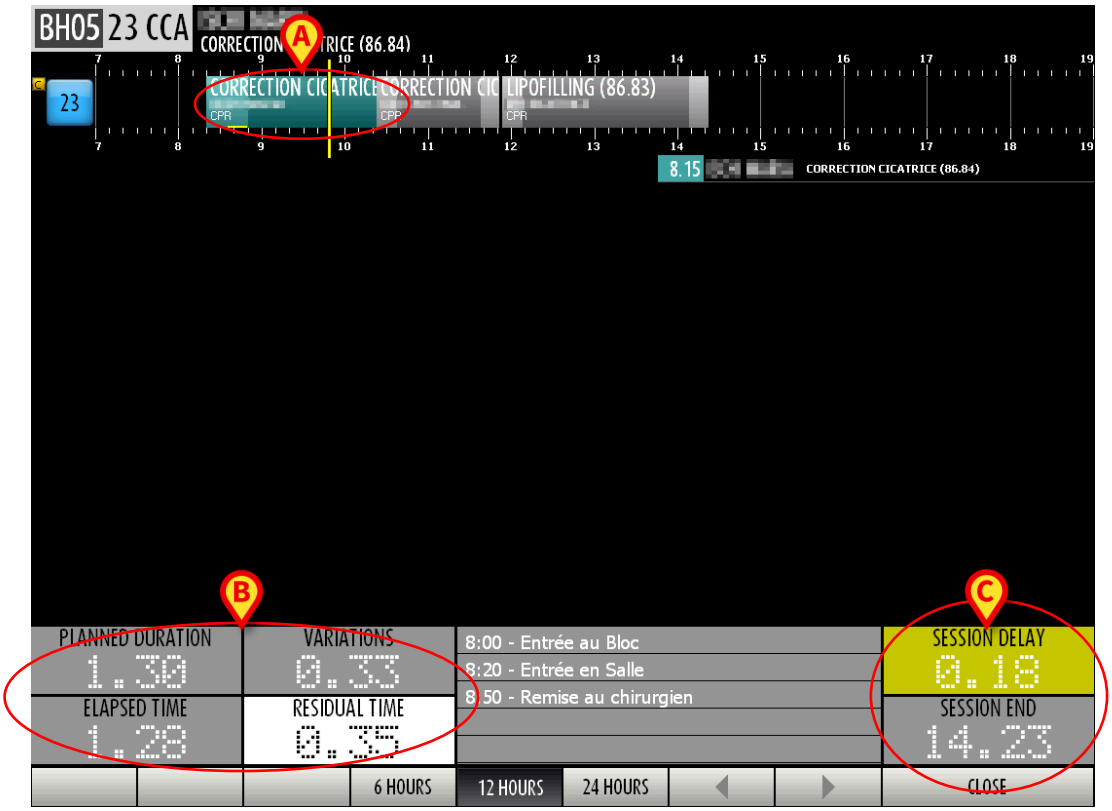


Fig 218 - 30 minutes variation

After requesting additional time the "Operating room monitor" screen timers display the following values (Fig 218 **B**):

- 1 hour and 28 minutes passed since the operation began (ELAPSED TIME);
- planned residual operation duration is 35 minutes (RESIDUAL TIME);
- 33 additional minutes were requested by the operating staff (VARIATIONS);
- operation planned duration ***was*** 1 hour and 30 minutes (PLANNED DURATION).

The corresponding operation-rectangle length indicates the overall duration (2 hours and 3 minutes, Fig 218 **A**).

Note that the variation causes a delay in the planned session end time (it was 14:05 before the variation). The new planned session end time and the session delay amount are now displayed on the timers on the right (Fig 218 **C** - see next paragraph 11.6.2 for the "Room times" timers description).

11.6.2. Room times

Room times refer to the overall timing of the operative session. Two timers display the relevant times: session delay and session end (Fig 206 **C**, Fig 219).

Fig 219

11.6.2.1. Session end

The SESSION END timer displays the planned end time of the last operation in the room. The time indicated by the SESSION END timer always corresponds to the right limit of the last operation-rectangle shown on the time bar (Fig 220 **A**)

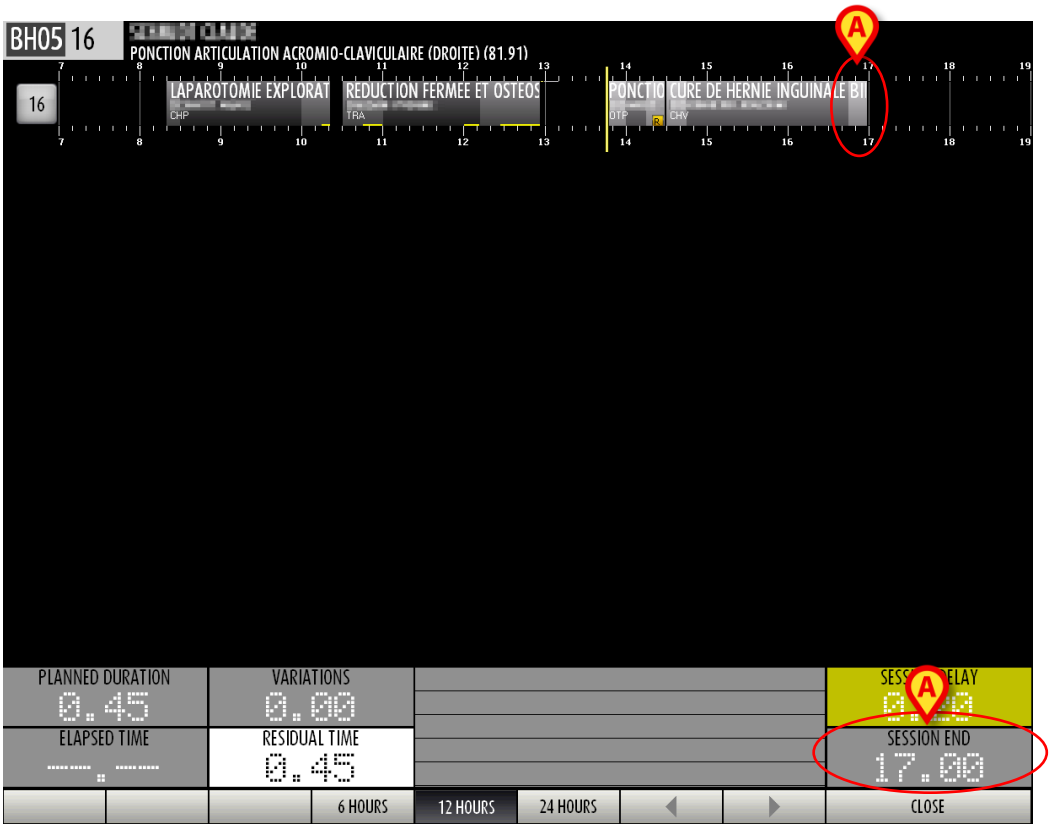


Fig 220 - Session end

11.6.2.2. Session delay

The SESSION DELAY timer indicates if the operations planned in the room are likely to cause a delay in the operative session and, in case, displays the possible delay amount. See for instance Fig 221 **A**.

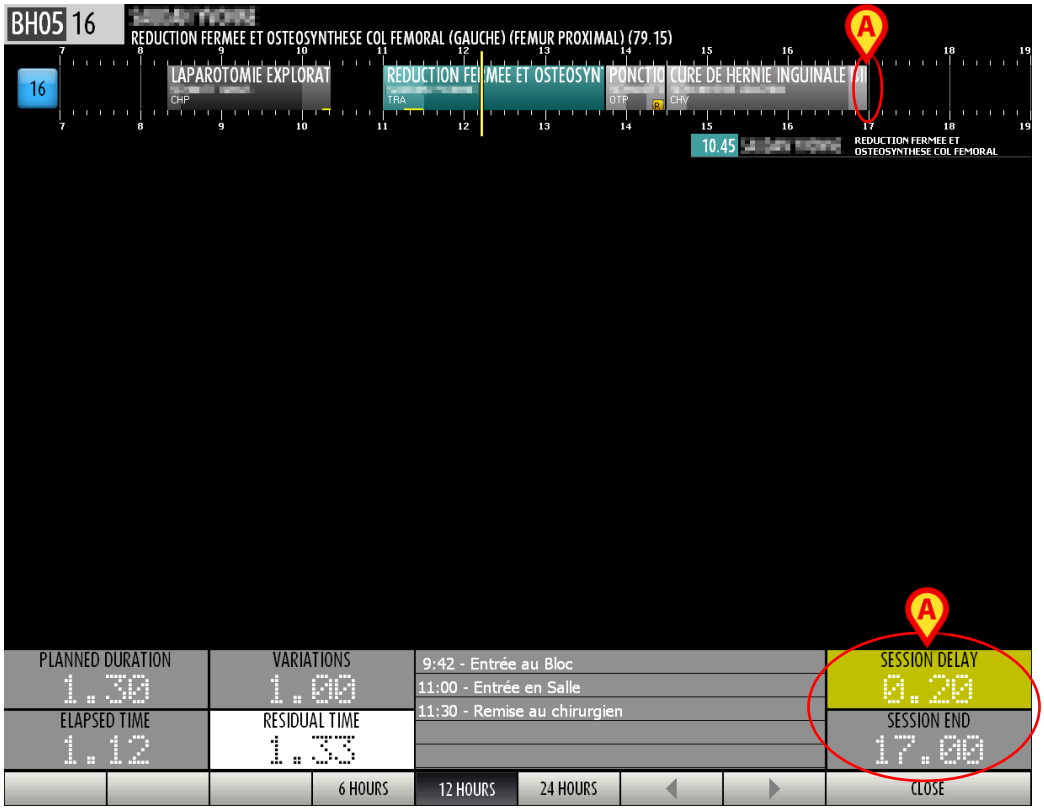


Fig 221 - Session delay

In Fig 221 the planned session end was 16:40 when the room opened. The delay caused by the operation times variations made the planned end of the last operation become 17:00.
The SESSION DELAY timer displays therefore a 20 minutes delay.
As long as the room is open and the operative session goes on it is a ***planned*** time, not an actual one. In case the operations in the room last longer than planned, this time increases, in case they last less, this time decreases.
When the last planned operation is completed the SESSION DELAY time becomes an actual value.

When the SESSION DELAY time is negative it means that the planned end of the last operation is anticipated.

12. OranJ Chart module

The OranJ Chart module provides a graphic representation in real time of some of the patient data collected during the operation; at the same time, this module makes it possible to display the events recorded on a time line.
The module is present on GENERAL CENTRAL STATION and OPERATING ROOM workstations.
The main page of the module can change considerably depending on the configuration chosen. That shown in Fig 222 is an example of configuration.

12.1. Page features

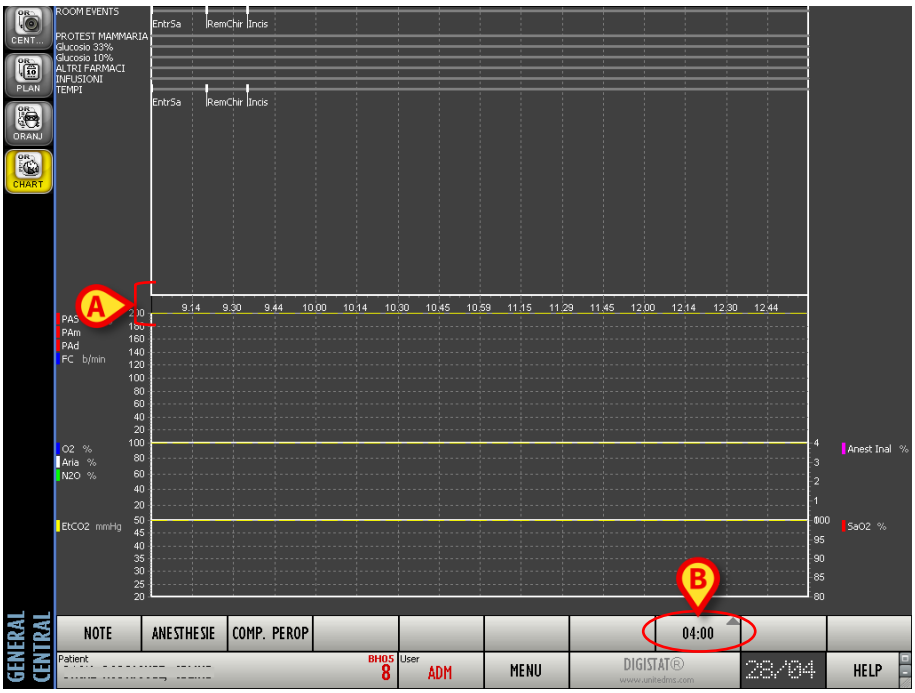


Fig 222 – OranJ Chart

The series of numbers highlighted in Fig 222 **A** indicates the time of the day. If the operation for which the data is displayed is still in progress, a vertical yellow cursor indicates the current time.

You can change the time range displayed using the button on the command bar highlighted in Fig 222 **B**.
Click the button to open a pull down menu that makes it possible to select 2, 4, 8, 12 or 24 hours (Fig 223).

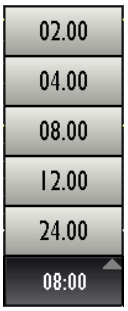


Fig 223 – Time range selection

The option selected is displayed on the button. In Fig 222, for example, an 8-hour time range is displayed.

You can display time ranges subsequent or prior to the current range using the mouse. To do so, simply move the mouse to the area of the chart for which you wish to change the display mode, left click it and, keeping the button pressed, move left/right as needed. The page moves together with the cursor of the mouse. If you are working with a touch screen, you can perform the same operation with fingers. The page is split into two areas: the "Events" area and the "Chart" area.

12.1.1. The "Events" area

The upper part of the screen (Fig 224) shows on different time lines the events recorded.

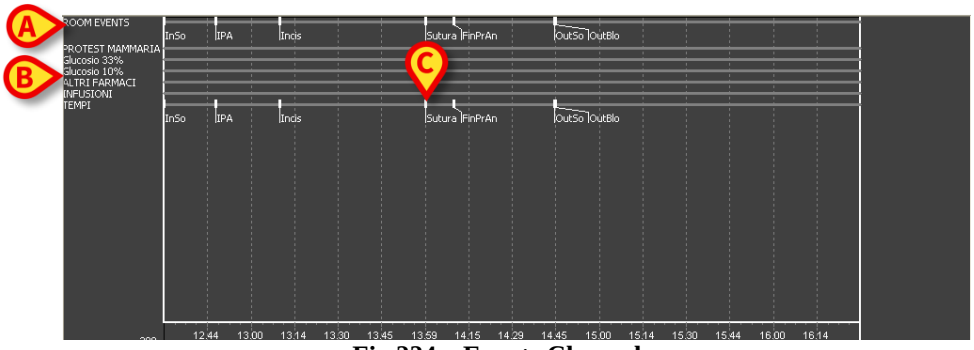


Fig 224 – Events Chronology

Both the markers (Fig 224 **A**) and other room events such as the drugs administered, any infusions, anesthesiological and surgical procedures implemented, etc. are shown (Fig 224 **B**). The number and nature of the events displayed depend on the configuration selected and the user's requirements. See paragraph 8.4 for details on the various types of event.
An event is marked on the time bar in correspondence with the moment in which it is recorded. In the figure, for example, the "Suture" event was recorded at 13:59 (Fig 224 **C**).

In the example chart, the markers are abbreviated this way:

- Block entrance - InBlo
- Room in - InSo
- Start of Anesthesiology Procedure - IPA
- Skin incision - Incis

- Suture - Sutura
- End of Anesthesiology Procedure - FinPrAn
- Room out - OutSo
- Block exit - OutBlo

Remember that the number and nature of the markers change according to the configuration chosen.

12.1.2. The "Chart" area

The lower part of the screen (Fig 225) displays the trends of the parameters acquired by the room devices.

Fig 225 - Charts

The charts are created in real time and updated every minute.
The number and nature of the parameters acquired change according to contingent requirements.

The side areas list the kind of data that can be displayed in the charts in the current configuration (Fig 225 **A**). Alongside every type of datum the color used to trace the line of the chart for that datum is displayed.

You can display different quantity ranges using the mouse. To do so, simply move the mouse to the area of the chart for which you wish to change the display mode, left click and, keeping the button pressed, move up or down as needed. The page moves together with the cursor of the mouse.

If you are working with a touch screen, you can perform the same operation using fingers.

12.1.3. The command bar

Fig 226 – OranJ Chart screen command bar

The buttons on the command bar (Fig 226) make it possible to record the configured room events directly from the OranJ Chart module.

The number and nature of the buttons depend on configuration. The procedure required to add a specific event is described in paragraph 8.5.

13. Check-In configuration

The Check-In configuration of the DIGISTAT® OranJ system is used to identify the patient at block check in and check out.
Identification is usually performed by scanning the patient's barcode. If barcode reading function is not enabled a manual procedure is available.
"Barcode" procedure is described in paragraph 13.2.1, manual procedure is described in paragraph 13.2.2.

Barcode technology is recommended when identifying a patient. Scanning the patient's barcode, instead of selecting it manually, statistically reduces the selection errors possibility.

13.1. Modules in use

The check-in configuration usually includes two modules: the OranJ Plan module, making it possible to monitor the state of the operating block, and the OranJ Check-in module, making it possible to identify the patient when entering the operating block.

13.1.1. OranJ Plan

The OranJ Plan module offers a birds-eye view of the state of the operations in the operating block.

To select the module

- click the corresponding icon 

on the DIGISTAT® lateral bar (Fig 227).

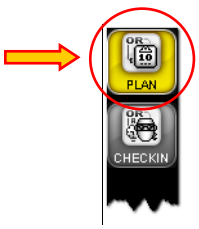


Fig 227

The following screen will is displayed (Fig 228).

Fig 228 - OranJ Plan

The OranJ Plan module is described in chapter 10 in this manual. See chapter 10 for a description of the module's functionalities.

Some buttons on the command bar are disabled because this configuration only enables monitoring one block on the current day. Thus it is not possible to use the "Edit" functionalities to change the operating plan; it is not possible to change the day displayed; it is not possible to display a different block.

The time span display functionalities are still active (i.e. it is possible to use the **12:00** button on the command bar to display either 6, or 12 or 24 hours on the same screen).

13.1.2. OranJ Check-In

The OranJ Check module can be used to identify the patient at block check in and check out. To select the module

- click the corresponding icon 

on the DIGISTAT® lateral bar (Fig 229).

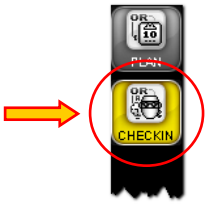


Fig 229

The following screen is displayed (Fig 230).

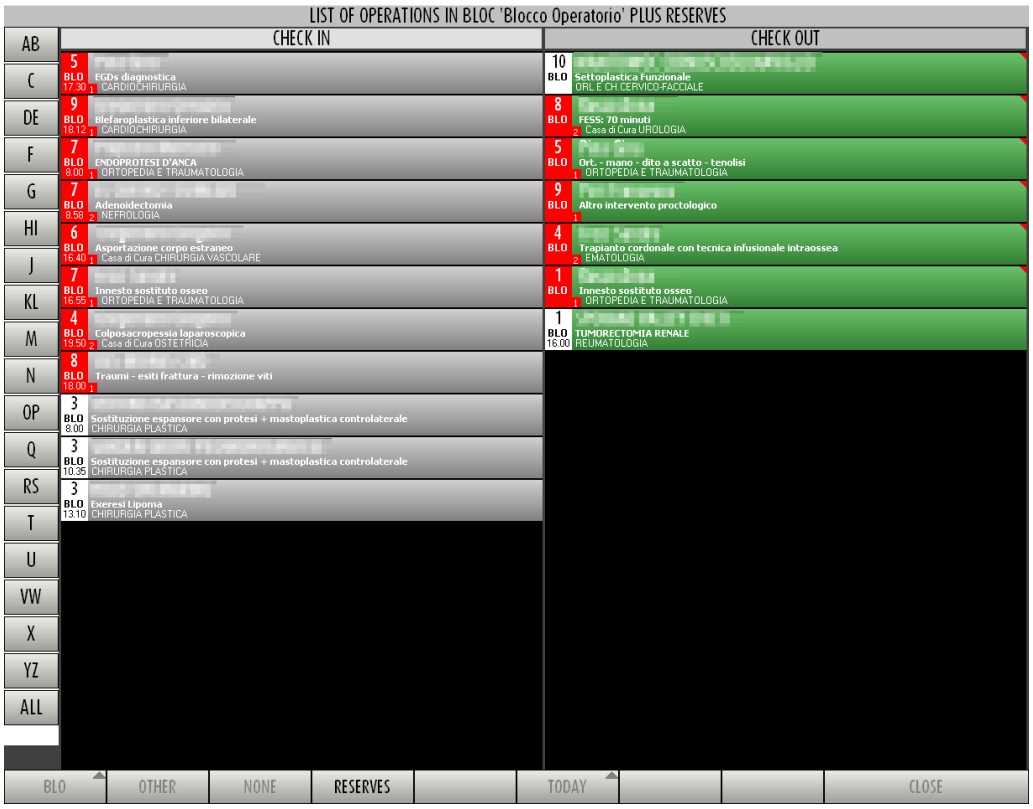


Fig 230 - OranJ Check-in

The screen is split in two columns. The operations for which the block check-in has not yet been performed are listed on the left column (Check-In). These operations are all in "Planned" state. The column on the right lists the operations for which the block check-out has not been performed yet.

In the OranJ system an operation is completed when the "Room out" marker is recorded. See paragraph 8.4 for the explanation of the "markers" in the DIGISTAT® OranJ system.

The **Reserves** button on the command bar can be selected to display, on the left column, the "Reserves" operations as well, for which the check-in procedure has not been completed. See paragraph 10.3 for an explanation of the meaning of "Reserve" operation.

13.2. How to perform the patient check-in

13.2.1. Check-in procedure by barcode reading

If barcode selection functionalities are enabled, to perform the patient check-in

- access the "Check-in" screen (Fig 230).
- scan the barcode of the patient who is entering the operating block.

A patient identification window is displayed (Fig 231).

Fig 231 - Patient identification

The patient code is visible in the field indicated in Fig 231 **A**.

- Click the **Identify** button (Fig 231 **B**).

The window changes in the following way (Fig 232).

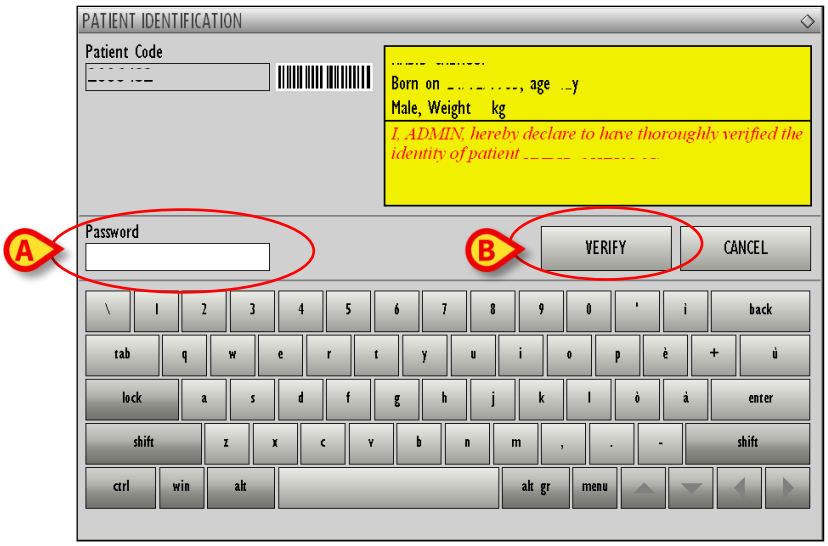


Fig 232 - User identification

The window shown in Fig 232 requires user identification. The logged user declares this way that he/she personally verified the patient identity.

- Insert user password in the field indicated in Fig 232 **A**.
- Click the **Verify** button (Fig 232 **B**).

The block check-in is this way completed. The corresponding operation-rectangle disappears from the "Check in" column on the screen. On the "OranJ Home" screen (Fig 58) the "Block-in" marker is this way recorded. The operation turns to "Ready" state; the corresponding rectangle is now green (Fig 233).

Fig 233

See paragraph 7.3 for a description of the possible operation states and the associated colours.

See paragraph 8.1 for a detailed description of the "OranJ Home" screen.

13.2.2. Manual check-in procedure

Manual check-in is possible if barcode selection is not available. To perform this procedure

- click the 

icon on the lateral bar to access the OranJ "Check in" module (Fig 234).

Fig 234 - OranJ "Check in"

On the left column ("Check in" column),

- click the rectangle corresponding to the patient/operation that is checking-in (Fig 234 **A**). A patient identification window opens (Fig 235).

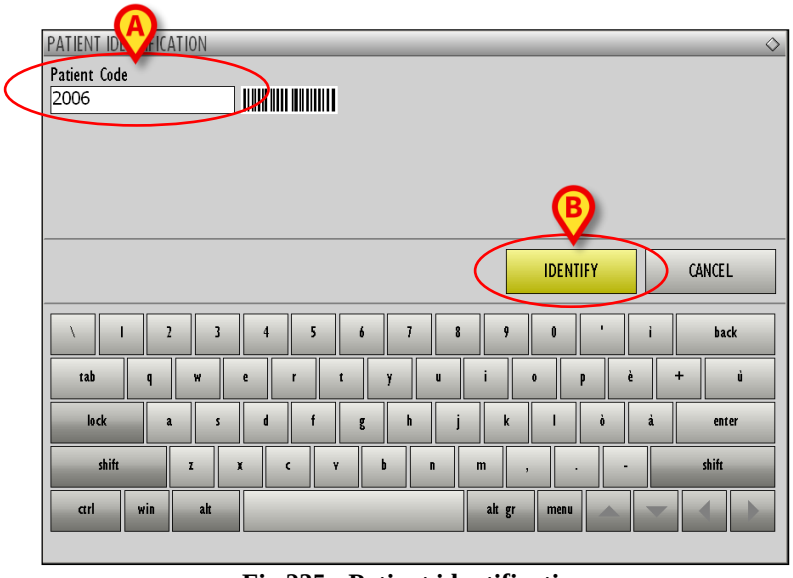


Fig 235 - Patient identification

- Type the patient code in the field indicated in Fig 235 **A**.
- Click the **Identify** button (Fig 235 **B**).

The window changes in the following way (Fig 236).

Fig 236 - User identification

The window shown in Fig 236 requires user identification. The logged user declares this way that he/she personally verified the patient identity.

- Insert user password in the field indicated in Fig 236 **A**.
- Click the **Verify** button (Fig 236 **B**). The block check-in is this way completed.

The corresponding operation-rectangle disappears from the "Check in" column on the screen shown in Fig 234. On the "OranJ Home" screen (Fig 58) the "Block-in" marker is this way recorded. The operation turns to "Ready" state; the corresponding rectangle is now green (Fig 237).

Fig 237

See paragraph 7.3 for a description of the possible operation states and the associated colours.

See paragraph 8.1 for a detailed description of the "OranJ Home" screen.

13.3. How to perform the patient check-out

The “Check-in” module makes it possible to record the patient check-out from the operating block. To do that:

- click the 

icon on the lateral bar to access the OranJ “Check in” module (Fig 238).

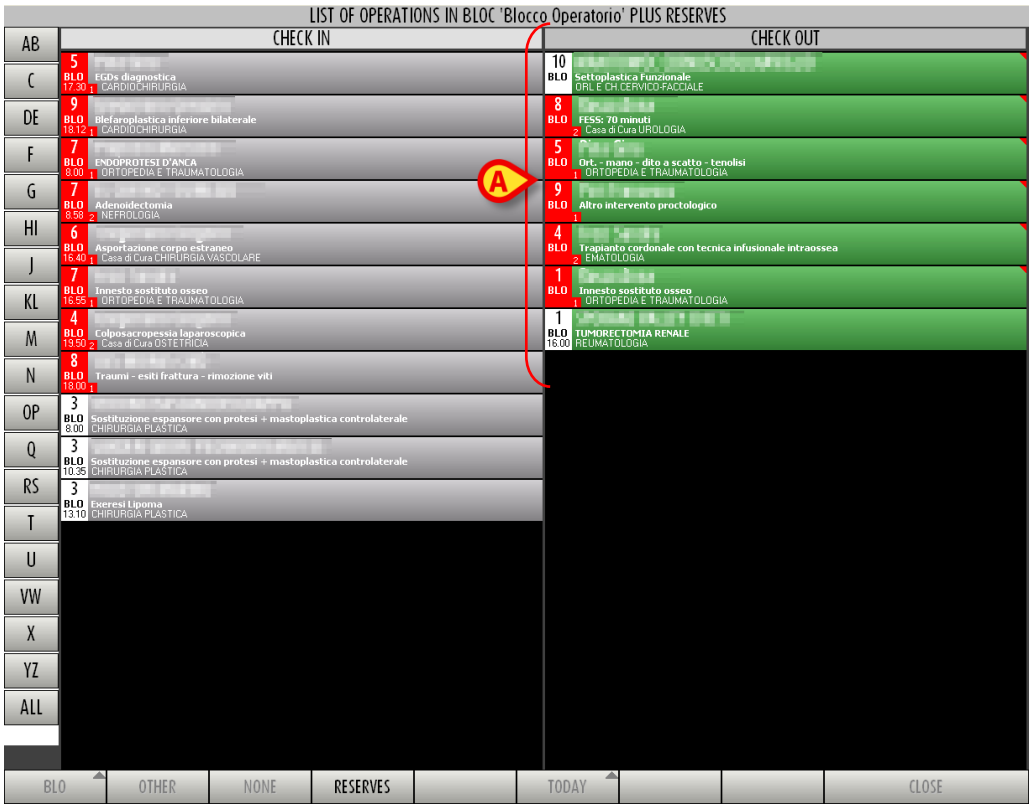


Fig 238 - OranJ “Check in”

On the column on the right (“Check out” column),

- click the rectangle corresponding to the patient/operation that is checking-out (Fig 238 **A**). User confirmation is required (Fig 239).

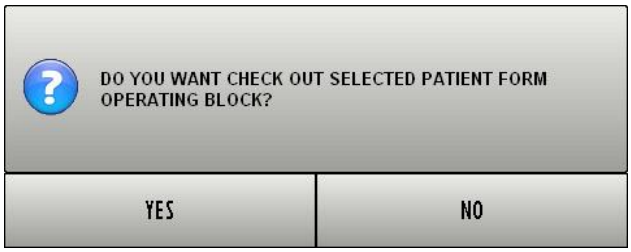


Fig 239

- Click **Yes** to record the patient’s check-out.

On the “OranJ Home” screen (Fig 58) the “Block Out” marker is this way recorded.

14. OranJ - “Bedside”Configuration

The OranJ system can be configured to be used inside the operating room and be this way dedicated entirely to the management of the single room. In these cases the system has specific characteristics and functionalities. This type of configuration is called “bedside”.
The bedside configuration of the OranJ system is formed of three modules:

- OranJ
- Charts
- Room Plan

In this case all the information is related to the configured room.

14.1. The Room Plan module

The main page of the Room Plan module (Fig 240) displays information on the daily schedule of the room for which the workstation is configured.

Fig 240 – Room Plan

The figure above shows the daily program of room 4.

14.1.1. Room schedule

There is a time line in the upper part of the page, schematically representing the schedule of the operating day (Fig 240 **A**, Fig 241).

Fig 241

The box on the left (Fig 241 **A**) contains the room number. If enabled by configuration, the colour of that box provides information on the state of the operation that is more relevant at present time.

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

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

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

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

Possible letters placed alongside the room number (Fig 242) indicate the room devices. The relationship between a letter and a device is defined by configuration.

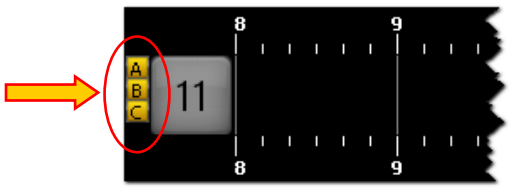


Fig 242

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

The boxes inside the line represent the operations scheduled, in progress and completed in that room. The color of the boxes corresponds to the operation state. The association between color and operation state is explained in paragraph 10.2

The size of every box is proportional to the scheduled duration of the corresponding operation: the longer the box, the longer the scheduled duration of the operation. The position of every box indicates the scheduled time for the operation. The left side of the box is positioned in line with the start time scheduled for the operation.
For example, the rectangle indicated in Fig 241 **B** corresponds to an operation that should start at 13:40 and should last one hour.

If the data relating to an operation is changed, i.e., if the scheduled time or duration is changed, the system automatically moves the corresponding box on the page and/or changes its dimensions.
See paragraph 9 to find out how to change the data of a scheduled operation.

The vertical yellow cursor indicates the current time (Fig 241 **C**). In the example shown in the figure, the yellow cursor is positioned at 11:50. The cursor runs across the page as time goes by.
If the cursor meets the start time established for an operation (i.e., the left side of a box) and the operation does not start at the established time, the box moves together with the cursor.

In general

- completed operations (dark gray) are all to the left of the time cursor,
- scheduled operations (light gray) and those that have only undergone block check-in (green) are all to the right of the time cursor,
- in progress operations (cyan) are across the time cursor.

Data relating to completed operations (duration, start time, end time etc…) are actual data; data relating to scheduled operations are planned data.

If enabled by configuration, the possible operation delay is visible on a yellow bar placed at the bottom of the operation-rectangle (Fig 243).

Fig 243

A configuration parameter makes it possible to display separately the possible delays in pre surgical, surgical and post surgical durations. That is the case shown in Fig 243. In the figure here displayed the three yellow bars indicate

1) a 5 minutes delay in the pre surgical planned duration (Fig 243 **A**);
2) a 15 minutes delay in the surgical planned duration (Fig 243 **B**);

3) a 10 minutes delay in the post surgical planned duration (Fig 243 **C**).

The operation shown in the figure is still in progress. Total delay is 30 minutes so far. This value is indicated in the "residual time" area on the "OranJ Home" screen (see paragraph 8.9).
The operations scheduled after the delayed ones are, if necessary, automatically postponed.

The operations indicated as "Emergencies" are characterized by a red stripe on the left (Fig 181). The small box indicated in Fig 244 **A** specifies the emergency level. In the configuration here described there are three possible emergency levels.

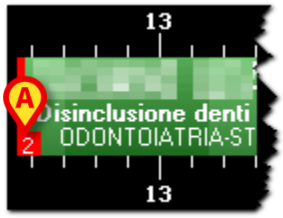


Fig 244 - Emergency

Every operation box can be clicked. Click one of the boxes to open a window containing the main data of the operation (Fig 245).

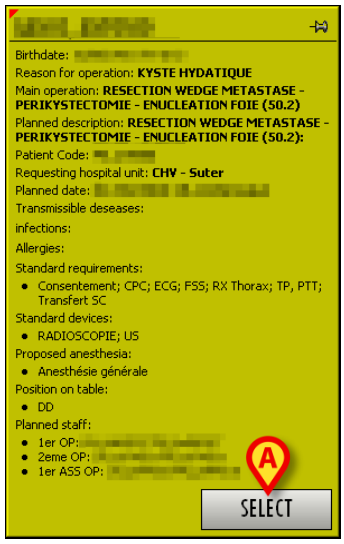


Fig 245 – Operation details

Click the **Select** button in the window (Fig 245 **A**) to access the "OranJ Form" page relating to the operation clicked (Fig 58).

14.1.2. The command bar

Fig 246 – Room Plan module command bar

On the control bar, the three buttons **6 hours**, **12 hours**, **24 hours** (Fig 246 **A**) make it possible to change the time range displayed. By clicking the **6 hours** button, for example, a time range of 6 hours is displayed.

The arrow buttons (Fig 246 **B**) make it possible to move backwards and forwards in the time range displayed. If, for example, you are displaying the time going range from 12:00 to 24:00, click the right arrow once to display the time range going from 15:00 to 3:00 of the following day. Likewise, click the left arrow once to display the time range going from 9:00 to 21:00.

The **Edit** button (Fig 246 **C**) makes it possible to edit the data on the page. See paragraph 14.1.5 for a detailed description of this functionality.

The **Not Assigned** button (Fig 246 **D**) makes it possible to select a scheduled operation and bring it to the "Not assigned" area. The related procedure is described in paragraph 14.1.5.

14.1.3. The "daily program" area

The "daily program" area (Fig 247 **A**) provides information on the schedule of the selected operating room.

Fig 247

Each row corresponds to an operation (Fig 248).

Fig 248

The color of the row indicates the operation state and follows the color-code used by all OranJ system modules (see paragraph 10.2 for the association between colors and operation state in OranJ).

The left part of every row contains the start time scheduled for the operation (Fig 248 **A**).The remainder of the row displays:

- the planned duration of the operation (Fig 248 **B**);
- the patient's name (Fig 248 **C**);
- the type of operation scheduled (Fig 248 **D**).

If specified, the hospital unit which requested the operation is also indicated.

If the left part is highlighted red (Fig 249), it means that the operation was indicated as "Emergency".

Fig 249 - Emergency

14.1.4. The "not assigned" area

The "Not assigned" operations are always visible on this module. Those are operations for which no start time, room or block have been scheduled (these operations are known as "reserves", see paragraph 10.3 for a description of these operations and the procedures connected to them).

Since we are working on a "Bedside" workstation, only the operations that could be scheduled for the current room will be displayed (that is: the emergencies, the room reserves, the block reserves and the general reserves - the reserves assigned to other blocks are not displayed).

Each row of this section shows the scheduled duration for the operation, the name of the patient, the type of operation scheduled and, if specified, the hospital unit which requested the operation (Fig 247 **B**).

All the rows of the "daily program" and "not assigned" pages can be clicked. Click a box to open the window shown in Fig 245 , containing the operation main data.

14.1.5. How to edit the operation plan

It is possible to edit the operation plan.

Fig 250 – Command bar

To make any change it is necessary, first, to click the **Edit** button (Fig 250 **A**).
When this button is clicked it appears as selected. To edit the page, it is necessary to

- click the **Edit** button.
- make the change required.

Once the change has been made the **Edit** button is automatically deselected. It is necessary to click it again to edit the page again.

When the **Edit** button is selected, the "drag and drop" functionalities are enabled.
The term "drag and drop" indicates the possibility to physically take one of the boxes corresponding to an operation, drag it to the point required on the time line and release it. Remember that the position of a box indicates the time scheduled for the corresponding operation, so moving a box from one position to another on the time line means changing the time of the corresponding operation. The changes are automatically displayed on the other OranJ modules.

If you are working with a touch screen and there is no mouse, you can perform the same operation with fingers.

Likewise, it is possible to add an operation from the "not assigned" list to the daily schedule by dragging the corresponding box.
It is also possible to remove an operation from the daily schedule and add it to the "not assigned" list. To do so it is necessary to:

- click the **Edit** button.
- On the list of scheduled operations (Fig 250 **A**), click the row corresponding to the operation you wish to remove.

The rectangle on the left turns to yellow (Fig 251)

Fig 251

The **Not Assigned** button on the command bar activates.

- Click the **Not Assigned** button (Fig 250 **B**).

The operation is this way moved to the “not assigned” list.

Hence, you can use the **Edit** button on the on the main page of the Room Plan module to

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

14.1.6. Room markers

The markers relating to the room events (Fig 252) are displayed and recorded in the column on the left side of the page (Fig 240 **B**).

Fig 252 – Room markers

These markers make it possible to record any occurrence which is considered significant and of which a record is required. It is possible to record the event and the time at which it occurred.

The number and nature of room events change according to the needs of the specific hospital and depend on the particular configuration of the system used. The procedures explained in this paragraph are only an example of configuration.

The room markers in this configuration are :

- Room opens
- Start of maintenance
- Start of cleaning
- End of cleaning
- End of maintenance

- Room closes

The markers are displayed on the left side of the screen as a sequence of boxes. The boxes are in chronological order.

The box relating to the marker initially appears in ochre yellow and does not contain any information on the moment (the time and day) in which the event took place. This means that the marker has not yet been recorded, the corresponding event has not yet occurred (Fig 253).

Fig 253 – First room marker

To record a marker, click/touch the corresponding box. The box turns to gray and records the time at which it was clicked. A new ochre yellow box (or several boxes, depending on the configuration) indicating no time is displayed below it. New boxes refer to subsequent markers (Fig 254).

Fig 254 – Second room marker

In general, to record a marker it is necessary to

- Click/touch the corresponding box.

The system automatically records the time at which the operation is performed.

14.1.7. How to edit the room markers

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

- Click the box corresponding to the marker for which the time has to be changed.

A numeric keyboard is displayed (Fig 255).

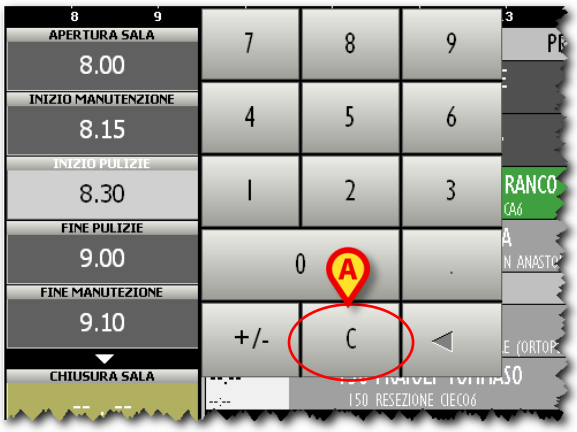


Fig 255 – Numeric keyboard

- Enter the time required using the keyboard. To record the new time.
- Click the box corresponding to the event again.

The numeric keyboard disappears and the new time is displayed in the box. If the time entered is impossible, the following error message pops-up (Fig 256).

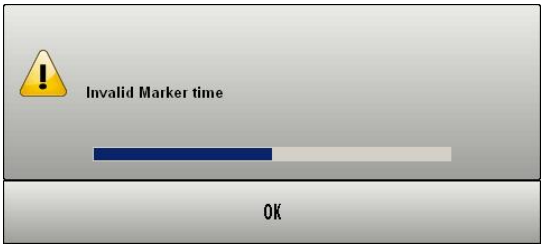


Fig 256

To delete a marker recorded

- Click the box corresponding to the marker to be deleted.

A numeric keyboard is displayed (Fig 255).

- Click the **C** button on the keyboard (Fig 255 **A**).

User confirmation is required (Fig 257).

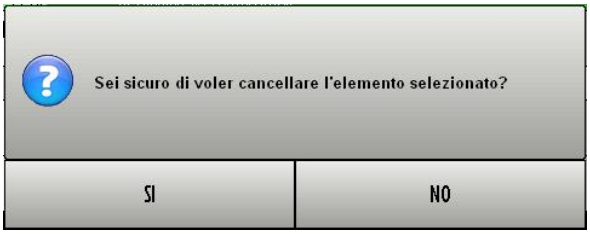


Fig 257

- Click **Yes** to delete the marker.

The deleting of an event implicates the deleting of all subsequent events.

15. Contacts

- **ASCOM UMS srl unipersonale**

Via Amilcare Ponchielli 29, 50018, Scandicci (FI), Italy
Tel. (+39) 055 0512161
Fax (+39) 055 8290392

- **Technical assistance**

support@unitedms.com

800999715 (toll free, Italy only)

- **Sales and products information**

sales@unitedms.com

- **General info**

info@unitedms.com

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.

Date Signature