DIGISTAT® Image Bank

DIGISTAT® Version 4.2

User Manual

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SOFTWARE LICENSE

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

WARNING

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

LICENSES AND REGISTERED TRADEMARKS

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

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

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

1. Contents

2. Using the manual

2.1. Aims

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

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

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

To be more precise, the differences may concern

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

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

2.2. Charcters used and terminology

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

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.

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

3.2.2. "Off-label" use of the Product

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

3.3. Manufacturer's responsibility

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

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

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

3.4. Product tracking

In order to ensure device tracking and on-going safety and efficiency checks on site, in compliance with ISO 9001 and EN 13485 quality standards and European law on medical devices 93/42/EEC, amended by the directive 2007/47/EC, the former owner is recommended to inform ASCOM UMS/Distributor about any ownership transfer by giving written notice stating the product, former owner and new owner identification data.
Device data can be found in the product labelling (either paper label provided at installation time or "About box" displayed within the product – see paragraph 6.8.5).
In case of doubts/questions about product labelling and/or product identification please contact ASCOM UMS/Distributor technical assistance (for contacts see paragraph 8).

3.5. Post-market surveillance

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

The device details can be found on its labelling.

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

3.6. Product life

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

3.7. CE mark and regulation conformity

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

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

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

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

4. Software/Hardware specifications

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

4.1. Bedside

4.1.1. Hardware

Minimum hardware requirements:

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

4.1.2. Operating System

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

4.2. Central

4.2.1. Hardware

Minimum hardware requirements:

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

4.2.2. Operating System

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

4.3. Server

4.3.1. Hardware

Minimum hardware requirements:

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

4.3.2. Operating System

Microsoft Corporation Windows Server 2012 R2

4.3.3. System Software

Microsoft SQL Server 2012/2014

4.4. Handheld device

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

WARNING!

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

4.5. Firewall and Antivirus

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

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

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

WARNING!

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

WARNING!

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

4.6. Local network features

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

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

ATTENTION!

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

ATTENTION!

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

4.6.1. DIGISTAT® impact on the hospital network

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

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

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

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

Average: 0.8 – 6 Mbit/s

Pitch: 5 – 25 Mbit/s

5. Before starting

5.1. Installation and maintenance warnings

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

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

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

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

5.2. Cleaning

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

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

5.3. Precautions and warnings

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

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

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

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

5.3.1. Electrical safety

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

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

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

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

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

5.3.2. Patient Area

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

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

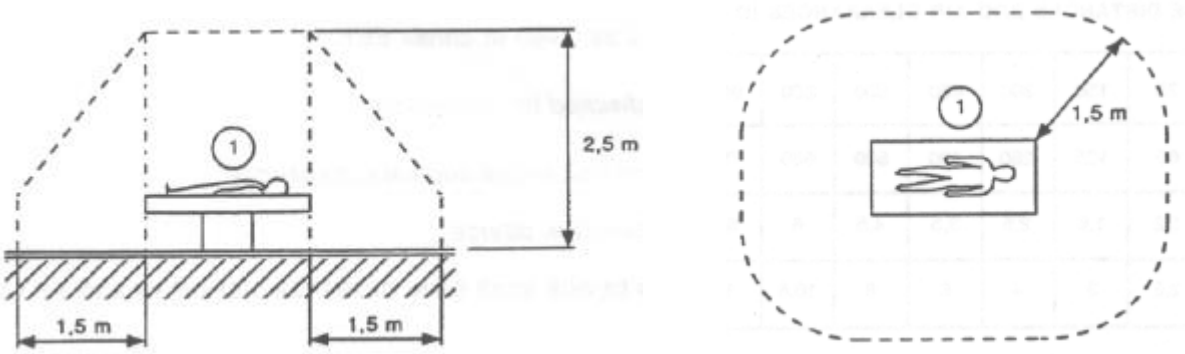


Fig 1

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

WARNING!

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

5.3.3. Electromagnetic compatibility

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

5.3.4. Devices eligibility

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

5.4. Privacy Policy

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

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

Please read the following precautions carefully and strictly observe them.

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

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

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

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

5.4.1. User credentials features and use

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

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

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

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

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

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

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

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

- Password must be at least 8 characters.

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

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

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

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

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

The following information is reserved to system administrators:

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

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

5.4.2. System administrators

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

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

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

5.4.3. System logs

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

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

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

5.5. Back up policy

It is recommended to regularly perform system backups.

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

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

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

5.6. Out-of-order procedure

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

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

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

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

In order to speed up replacement times, we suggest to have at disposal one or more substitution equipment with all the necessary 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).

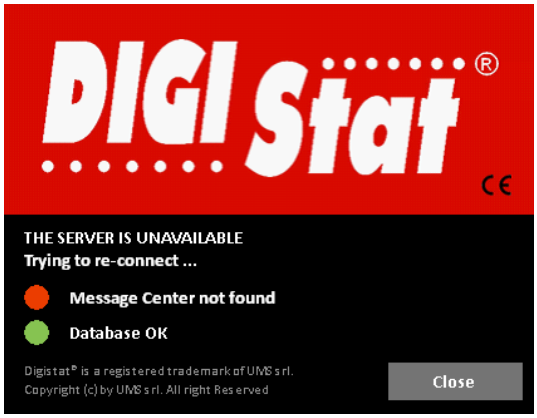


Fig 2

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 8 for the contacts list).

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

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

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

WARNING!

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

ASCOM UMS/Distributor offers full support for the definition of the above mentioned procedure. See paragraph 8 for the contacts list.

6. “Control Bar” and DIGISTAT® environment

6.1. Introduction

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

6.2. Touch screen

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

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

6.3. Launching DIGISTAT®

To launch DIGISTAT®,

- double click the desktop icon (Fig 3).

Fig 3

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

Fig 4

6.4. DIGISTAT® Work Area

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

Fig 5 shows Control Bar with no module installed.

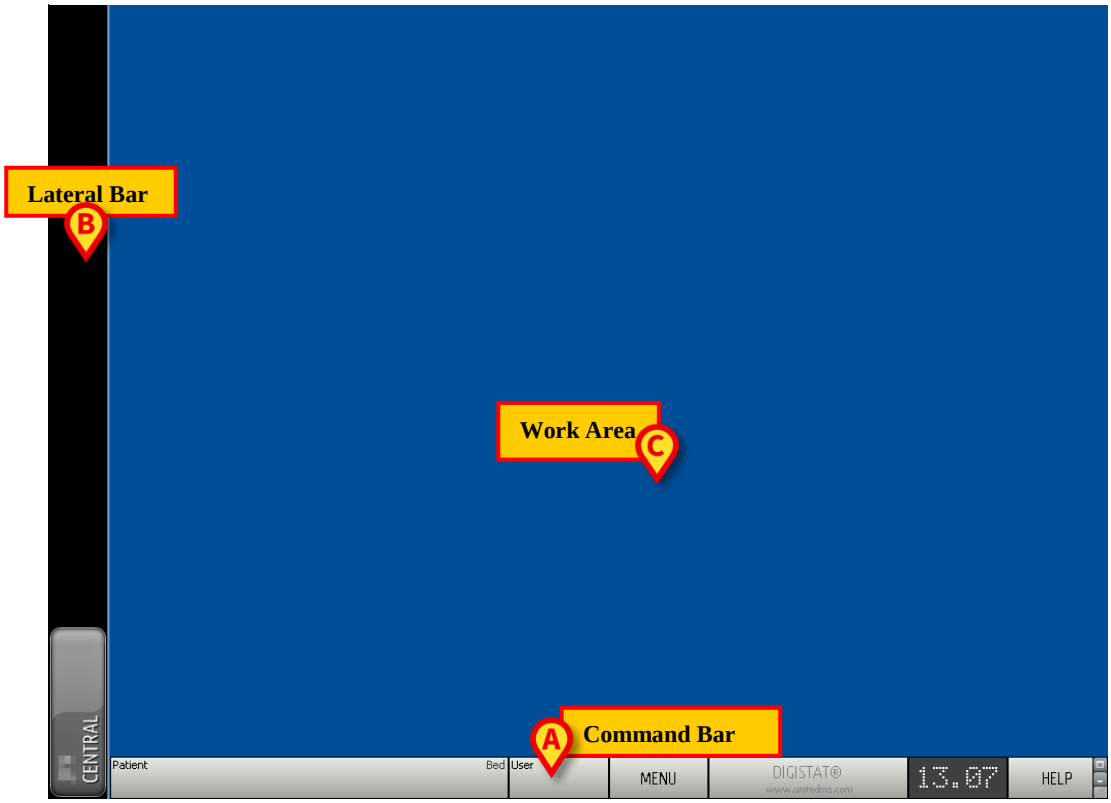


Fig 5

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

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

Fig 6

The module currently selected is highlighted (yellow).

6.4.1. Selecting a module

To select a module

- click the corresponding icon.

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

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

6.5. Accessing the system

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

The following page is displayed.

Fig 7

To access the system,

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

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

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

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

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

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

Fig 8

WARNING!

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

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

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

WARNING!

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

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

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

6.5.1. Barcode log in

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

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

- scan the user's personal barcode.

Fig 9

The user is immediately logged in.

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

6.5.2. Disabling the automatic log out

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

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

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

Fig 10

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

Fig 11

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

6.5.3. Recent users

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

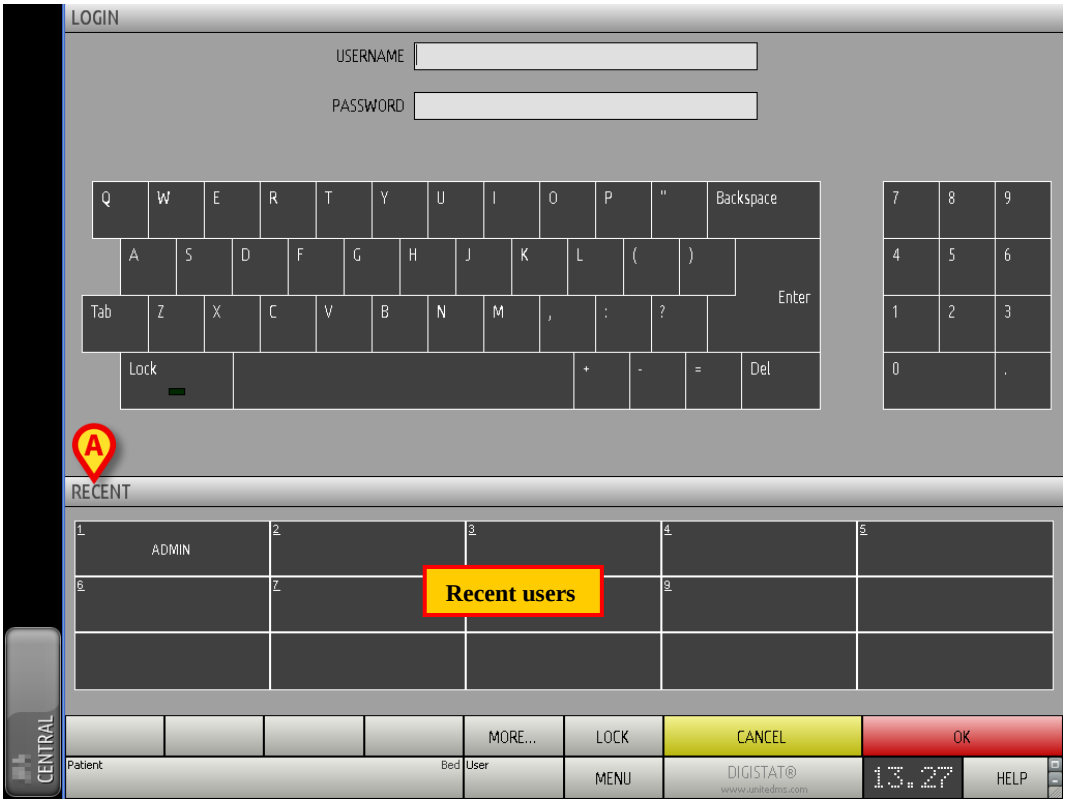


Fig 12

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

6.5.4. How to use the “User List”

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

Fig 13

To display the “User List”,

- click the **More** button.

The following window is displayed (Fig 14).

Fig 14

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

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

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

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

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

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

To select a user

- click the name of the user.

The name will be highlighted, then

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

Otherwise you can

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

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

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

6.6. DIGISTAT® Control Bar

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

Fig 15

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

Fig 16

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

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

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

These three buttons are present only if enabled by configuration.

6.6.1. How to read the "Patient" button

Patient selected

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

Fig 17

Patient admitted

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

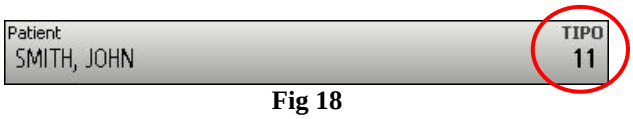


Fig 18

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

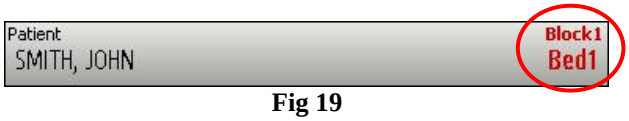


Fig 19

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

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

Fig 20

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

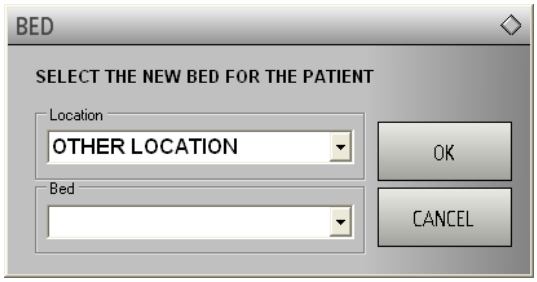


Fig 21

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

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

Fig 22

Patient management.

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

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

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

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

WARNING!

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

6.7. Help

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

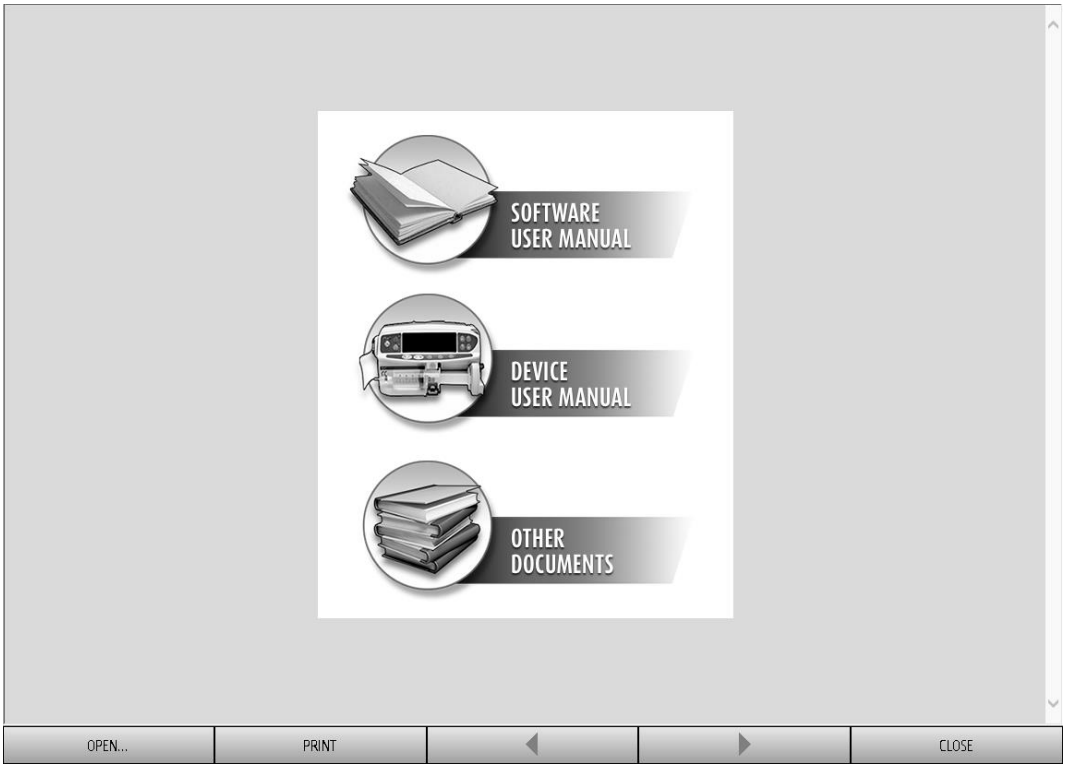


Fig 23

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

Fig 24

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

6.8. DIGISTAT® Main Menu

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

Fig 25

opens a menu containing several options (Fig 26).

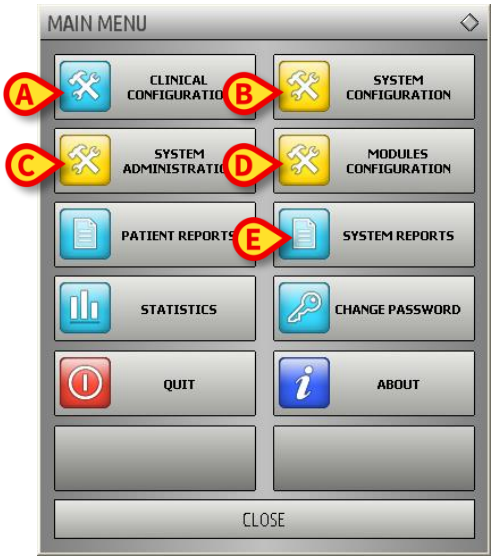


Fig 26

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

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

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

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

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

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

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

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

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

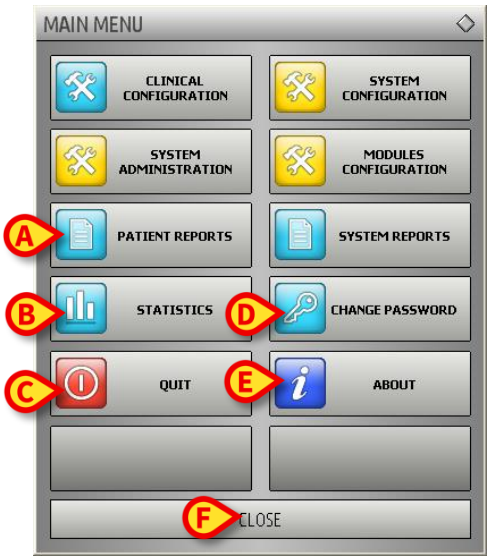


Fig 27

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

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

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

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

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

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

6.8.1. Patient reports

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

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

Fig 28

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

6.8.2. Print reports

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

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

To print a patient report

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

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

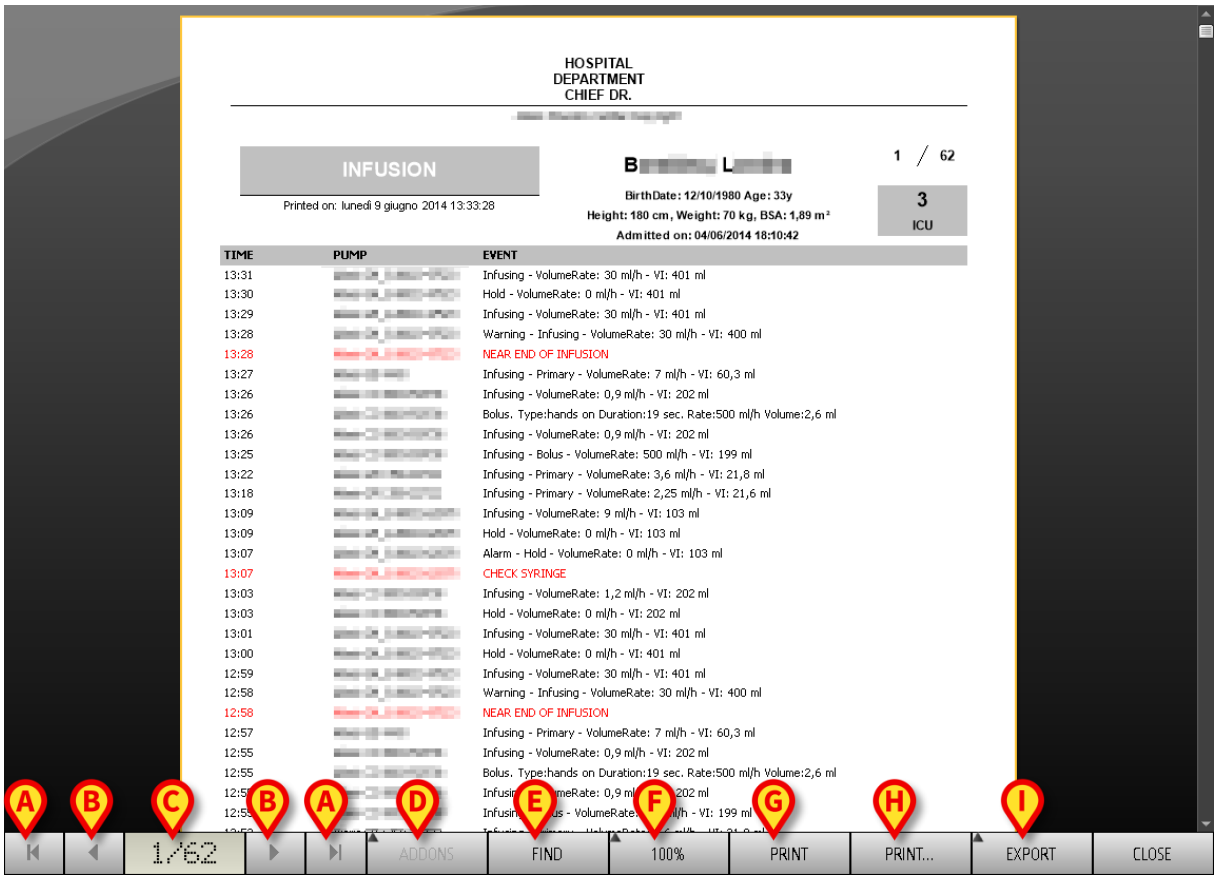


Fig 29

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

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

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

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

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

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

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

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

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

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

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

6.8.2.1. Addons

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

To display the available options,

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

Addons - Watermark

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

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

The following window is displayed (Fig 30).

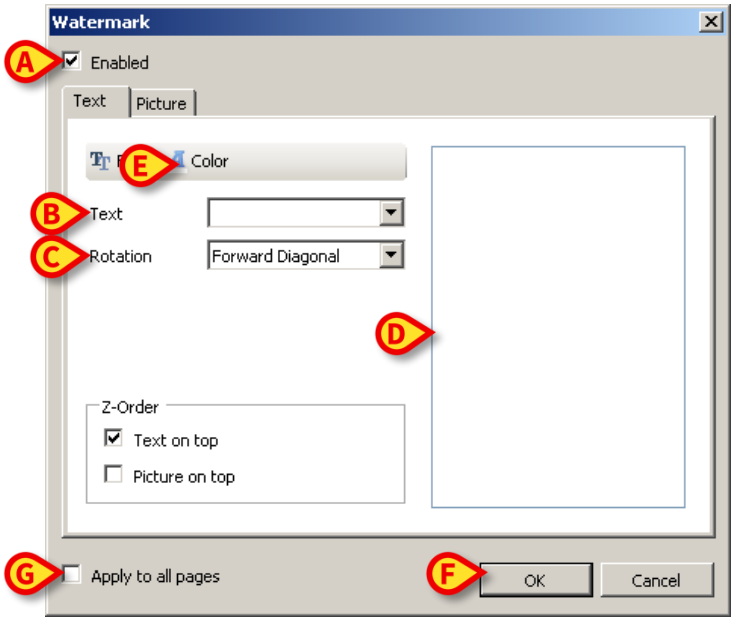


Fig 30

To add a textual watermark,

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

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

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

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

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

The text is this way inserted as watermark.

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

To insert a picture as watermark

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

The following window is displayed (Fig 31).

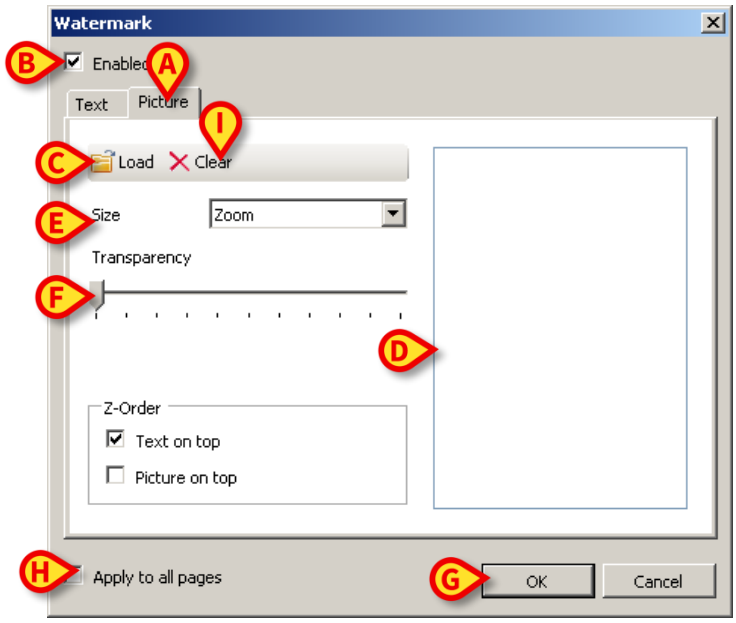


Fig 31

Follow these steps to insert an image as watermark,

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

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

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

- Search and select the image to be uploaded.

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

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

The watermark image is this way inserted.

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

To delete an already selected image,

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

6.8.2.2. Find

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

To search the print report,

- Click the **Find** button.

The following window opens (Fig 32).

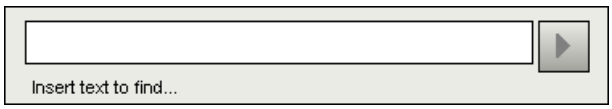


Fig 32

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

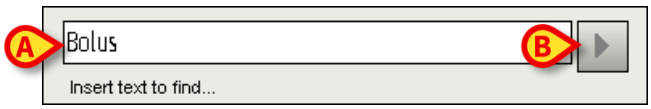


Fig 33

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

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

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

6.8.2.3. Zoom

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

To change the display mode,

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

Fig 34

- Click the wanted option on the menu.

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

The following options are available:

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

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

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

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

the 

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

6.8.2.4. Print

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

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

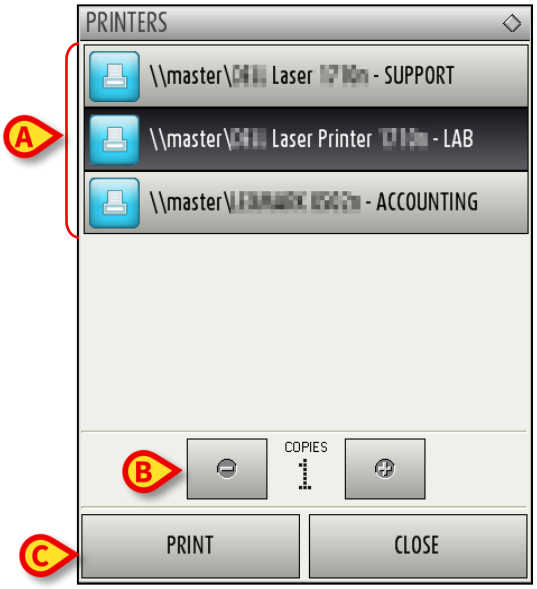


Fig 35

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

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

6.8.2.5. Export

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

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

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

- Click the option corresponding to the wanted extension.

The document is this way exported to the corresponding extension.

6.8.3. Statistics

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

Fig 36

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

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

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

Fig 37

6.8.3.1. Query Assistant

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

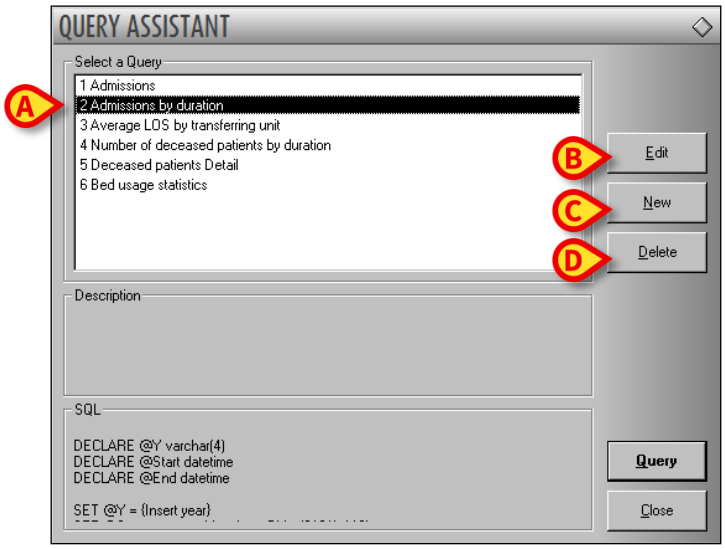


Fig 38

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

To run a query

- click the corresponding name on the list,

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

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

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

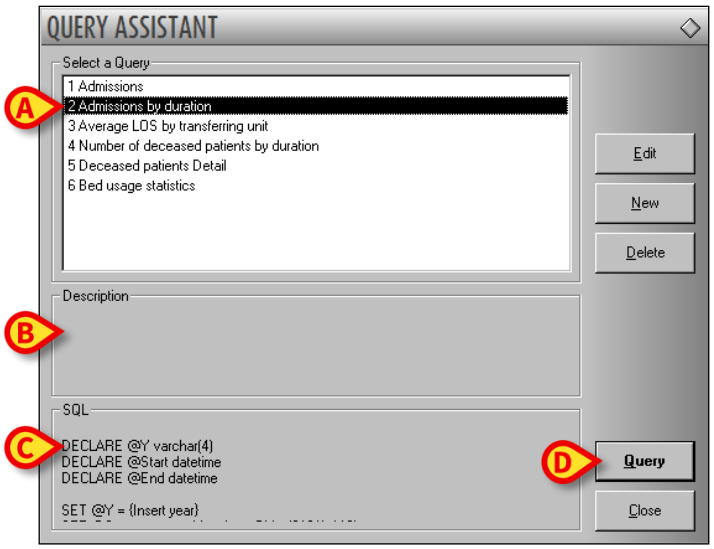


Fig 39

To run the query

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

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

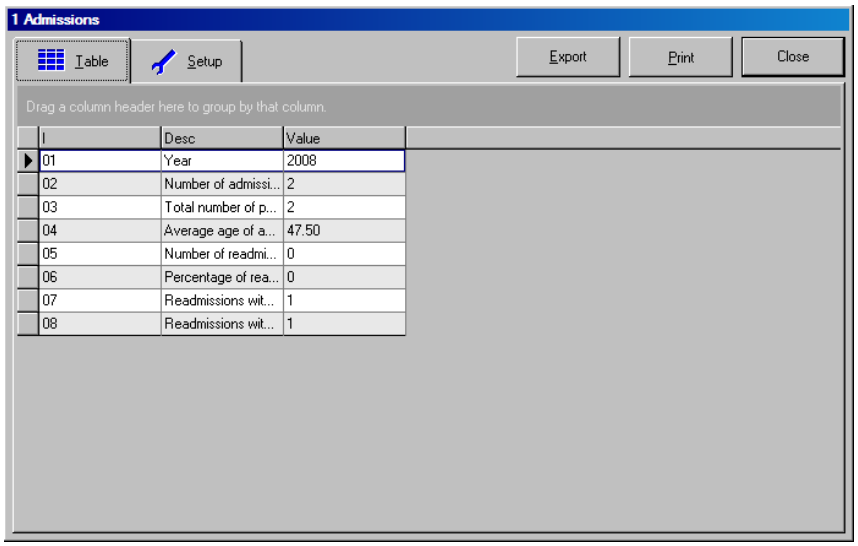


Fig 40

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

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

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

6.8.4. Change password

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

Fig 41

To change the user password

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

The "Change password" window will open.

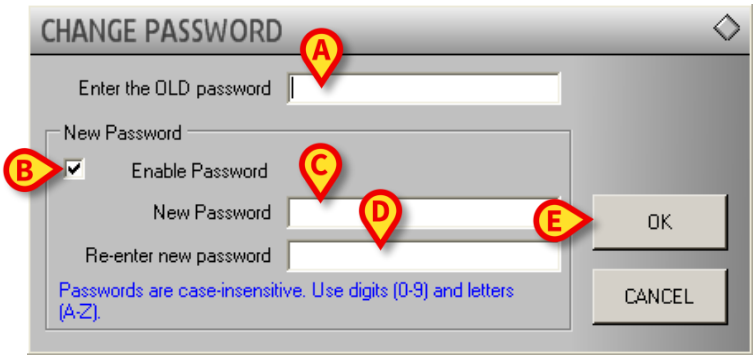


Fig 42

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

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

6.8.5. About DIGISTAT®

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

Fig 43

6.8.6. Quit DIGISTAT®

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

To quit DIGISTAT®

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

Fig 44

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

Fig 45

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

Another menu is displayed (Fig 46).

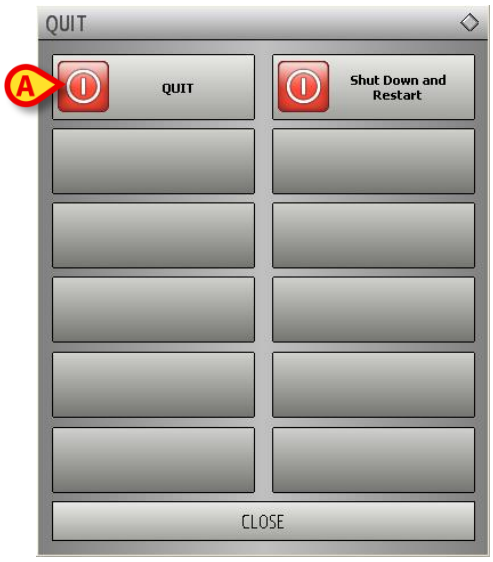


Fig 46

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

User confirmation is required (Fig 47).

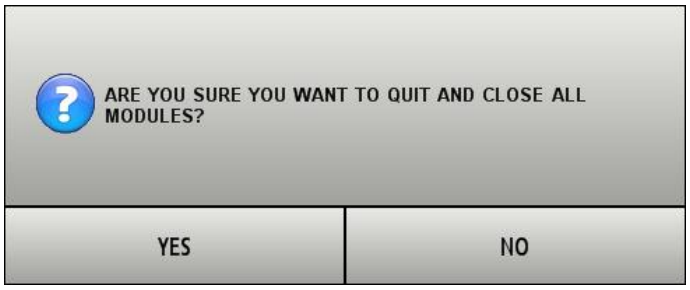


Fig 47

- Click **Yes** to exit DIGISTAT®.

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

7. Image Bank

The DIGISTAT® "Image Bank" module is a powerful and flexible solution for image and video acquisition. It has been developed for departments whose main working tool is photo and video documentation.

Image and video acquired from any standard video source can be easily archived and retrieved. Patient reports are widely configurable. An integrated word processor makes it possible to associate text notes to the images.

Image and video acquisition can be performed using either the mouse device or a remote control (a footswitch , for example).

DIGISTAT® "Image Bank" can work in background: image and video acquisition by remote control is active when the module is not selected.

7.1. Module selection

To select the "Image Bank" module:

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

Fig 48

The main screen of the module will appear. The data displayed on screen refer to the patient currently selected. If no patient is selected no value is displayed.

7.2. Patient search and selection

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

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

The DIGISTAT® Patient Explorer module, if installed, will open; otherwise the patient search and selection functions are accomplished by Control Bar. See the related technical documentation to know the specific search and selection procedures.

If the patient search and selection software in use is not a DIGISTAT® software see the related documentation.

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

7.3. Main screen description

When a patient is selected the main screen displays information about the previous examinations of the selected patient.

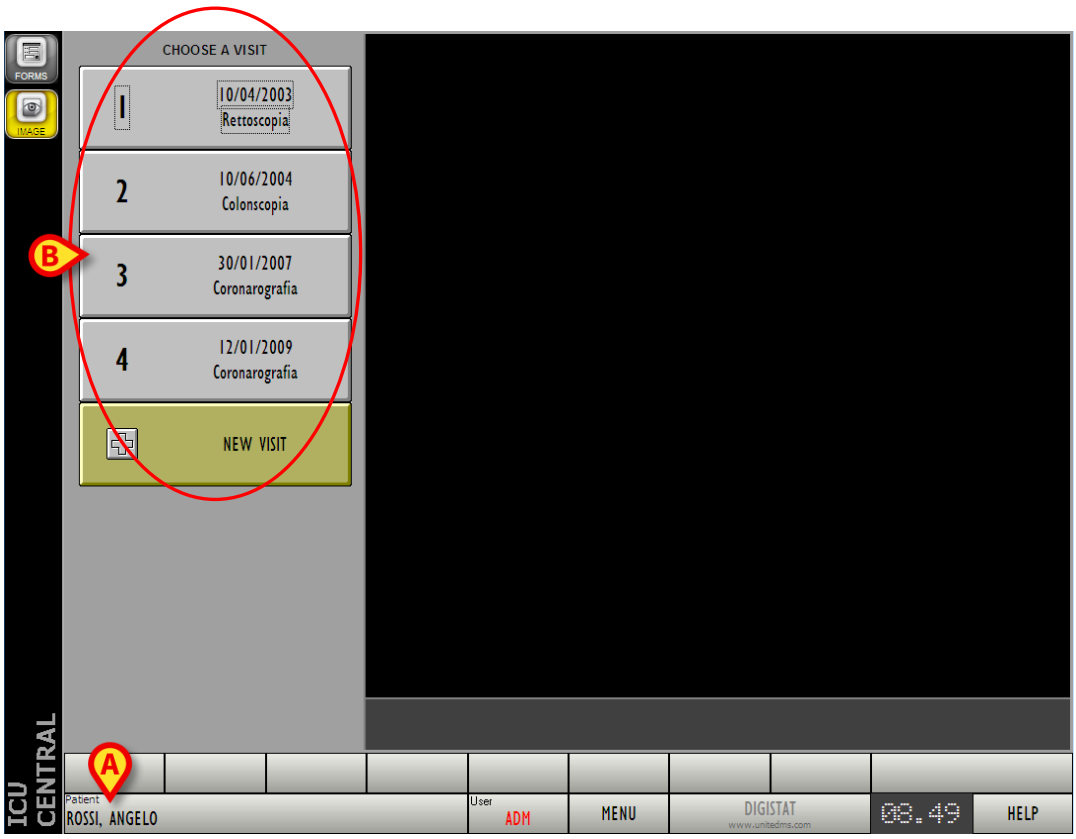


Fig 49 - Patient selected

In the example shown in Fig 49 the patient name is Angelo Rossi (Fig 49 **A**); his examinations are represented by the boxes indicated in Fig 49 **B**. Each box refers to an examination. The examination date and type are displayed within the box. Each box is a button. Click the button to access a screen containing all the information (text, images and videos) of the specified examination. To display the data of a previous examination

- click the corresponding button.

Button number 2, for instance, displays the data referring to the colonoscopy recorded on the 10th/06/2004.

7.4. “Examination details” screen

The “Examination details” screen makes it possible to display all the data referring to a selected examination (images, videos and textual data).

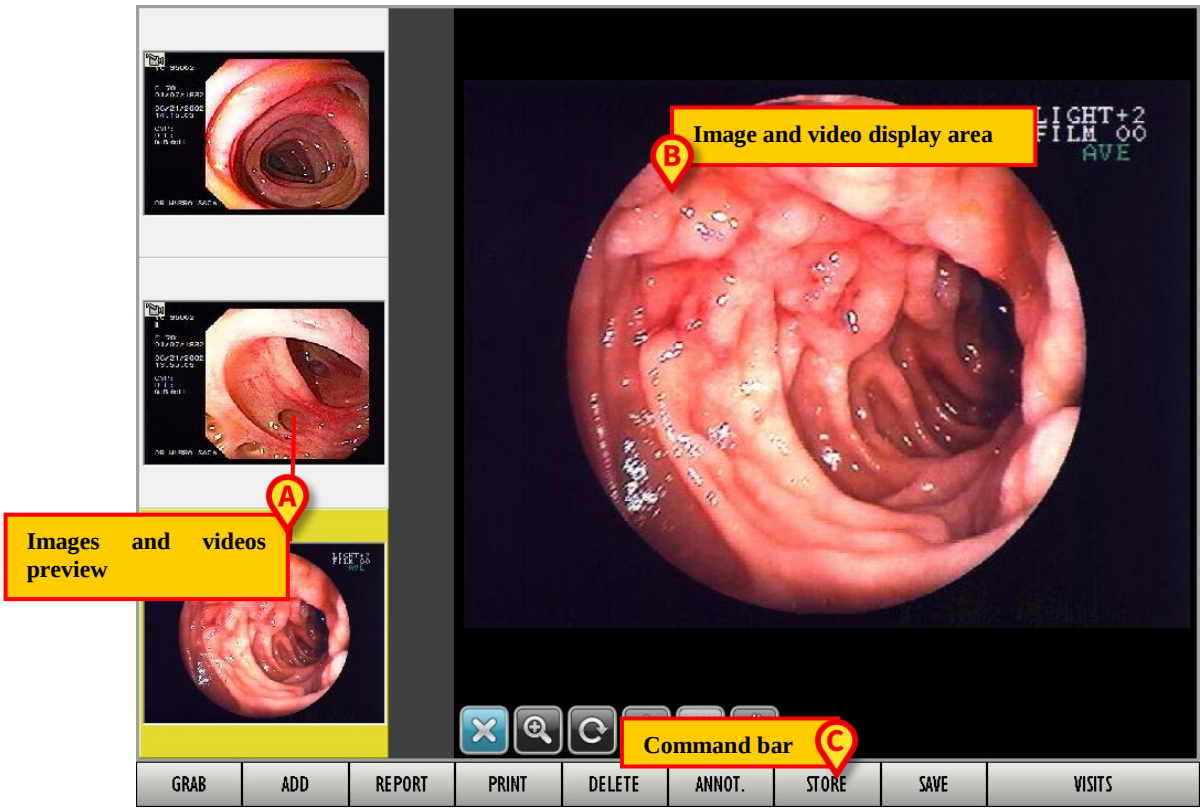


Fig 50 - Examination detail: colonscopy

The screen is formed by three main areas:

1) the area containing the images and videos thumbnails (Fig 50 **A**);
2) the images and videos display area (Fig 50 **B**);
3) the command bar (Fig 50 **C**).

7.4.1. Images and videos thumbnails

On the left a small preview (thumbnail) of each image and video is displayed (Fig 51). For the videos the first frame is displayed as preview.

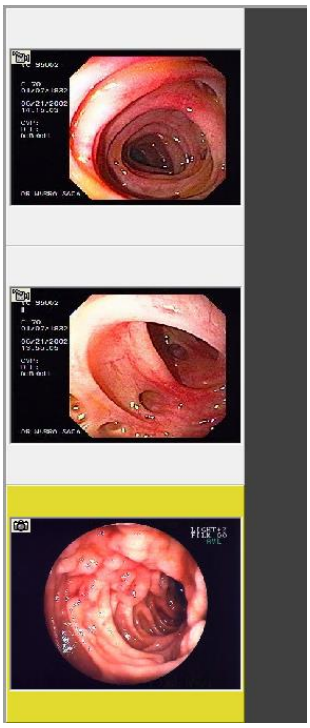


Fig 51 - Preview, thumbnails

To display the full picture or video

- click the thumbnail referring to the chosen image or video.

The thumbnail will be highlighted yellow (Fig 52 **A**). The image or video will appear, in full size, on the right (Fig 52 **B**).

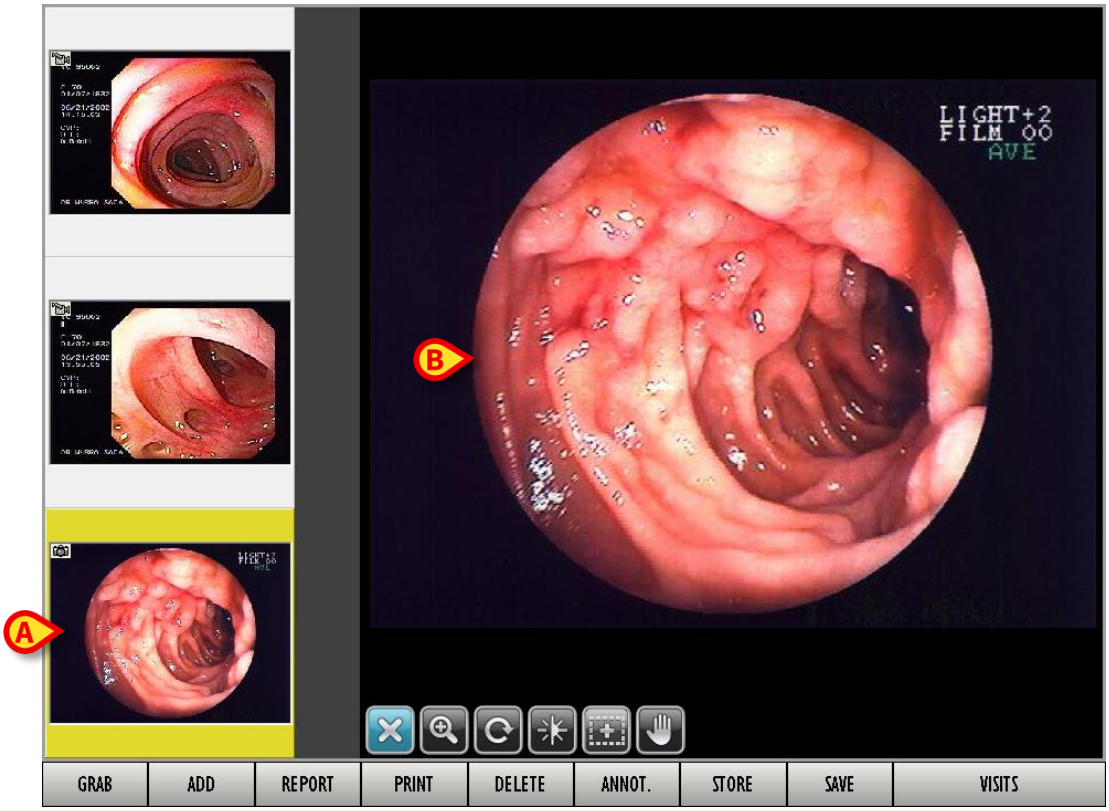


Fig 52 - Image selection

Thumbnails referring to images are characterized by the symbol (Fig 53)

Fig 53 - Image

Thumbnails referring to videos are characterized by the symbol (Fig 54).

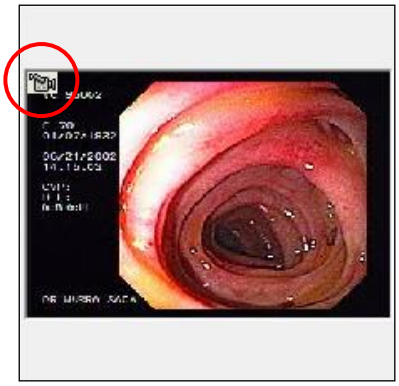


Fig 54 - Video

After the selection of a thumbnail referring to a video the corresponding video is immediately played on the display area.

7.4.2. Display area

The central part of the screen displays in full size the selected images and videos (Fig 50 **B**, Fig 55).

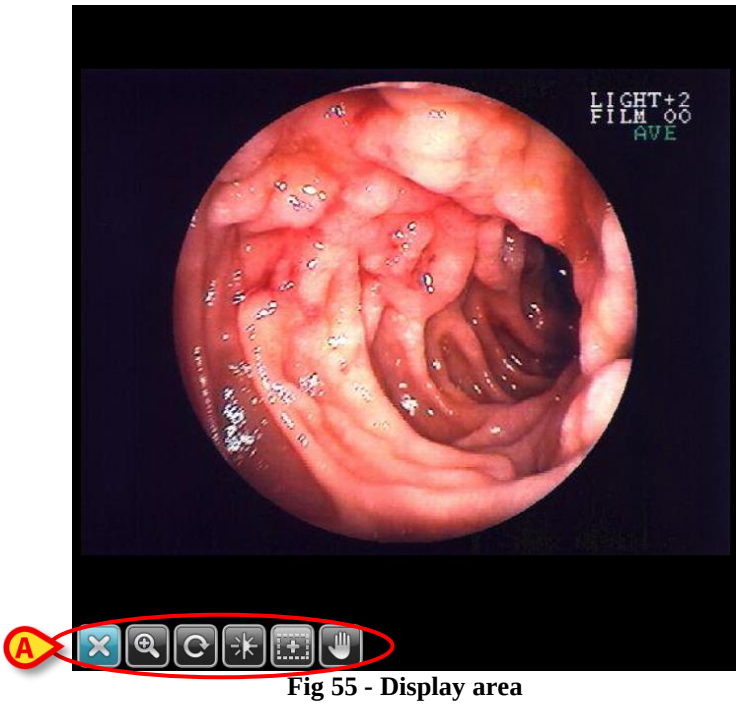


Fig 55 - Display area

Six buttons on the bottom-left corner make it possible to operate on the images and change their display mode (Fig 55 **A**).

The selected button is highlighted in sky-blu. In Fig 55, for instance, the selected button is  .

7.4.3. Functions of the buttons

WARNING!

The procedures described in this paragraph can be performed with the fingers only when using a "touch-screen". It is otherwise necessary to use the mouse device, moving the mouse pointer while keeping the left button clicked.

7.4.3.1. No option is selected - the  button

When the  button is selected none of the special display options is activated.

7.4.3.2. Zoom - the  button

The  button makes it possible to zoom-in and zoom-out. To zoom

- select the  button. The button is this way highlighted.
- Touch the image and move the finger horizontally on the touch-screen.

Move the finger left to right to *zoom in*. Move the finger right to left to *zoom out*.

7.4.3.3. Rotate - the  button

The  button makes it possible to rotate the image. To rotate the image

- select the  button. The button is this way highlighted.
- Touch the image and move the finger horizontally on the touch-screen. The image rotates by 90° clockwise.

7.4.3.4. Brightness - the  button

When the  button is selected it is possible to adjust the brightness of an image. To do that

- select the  button. The button is this way highlighted.
- Touch the image and move the finger horizontally on the touch-screen.

Brightness is increased when movement goes left to right. Brightness is reduced when movement goes right to left.

7.4.3.5. Contrast - the  button

To adjust the contrast of an image

- select the  button. The button is this way highlighted.
- Touch the image and move the finger horizontally on the touch-screen.

Contrast is increased when movement goes left to right. Contrast is reduced when movement goes right to left.

7.4.3.6. Magnifier - the  button

When the  button is selected an image magnifier makes it possible to enlarge selected portions of the image. To use the “Magnifier”

- select the  button. The button is this way highlighted.
- Touch the image. The image portion located near the finger is this way magnified.
- Move the finger to the area that must be magnified.

7.4.3.7. Grab - the  button

When the  button is selected it is possible to “grab” the image and move it around the display area. This function can be used to display the image portions that are not currently displayed when the image is too large to be fully displayed within the area. To do that

- select the  button. The button is this way highlighted.
- Touch the image with a finger.
- Move the finger around. The image moves together with the finger.

7.4.4. Videos

Four further buttons, making it possible to operate on the video reproduction, are present when playing a video (Fig 56 **A**). Their presence depends on the video format.

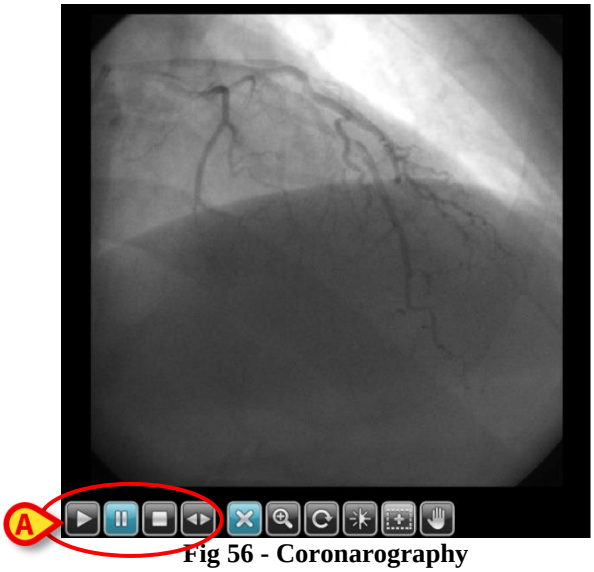


Fig 56 - Coronarography

The  button (Play) plays the video.

The  button (Pause) pauses the video.

The  button (Stop) stops the video.

The  button makes it possible to watch the video frame by frame. To do that

- select the video.
- Select the  button on the display area. The button is this way highlighted.
- Touch the image and move the finger horizontally.

When the finger moves left to right the video goes forward. When the finger moves right to left the video goes backwards.

Righ- click the image displayed to open a menu containing additional display options.

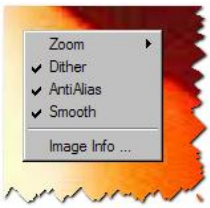


Fig 57

The possible options are:

- *zoom;*
- *dither;*
- *anti alias;*
- *smooth;*
- *image info.*

7.4.5. The command bar

The command bar (Fig 58) contains the function-buttons making it possible to perform different actions.
The different functions are briefly described in this paragraph. The detailed procedures will be described later in the paragraphs indicated here.

Fig 58 - Command bar

Use the **Grab** button to acquire an image or a video (see paragraph 7.6).
Use the **Add** button to acquire an image/video from an external source (see paragraph 7.7).
Use the **Report** button to display the examination clinical report (see paragraph 7.8).
Use the **Print** button to print the examination documentation (see paragraph 7.9).
Use the **Delete** button to permanently delete one of the images/videos (see paragraph 7.10).
Use the **Annotation** button to add a note to the image/video (see paragraph 7.11).
Use the **Store** button to store the currently selected image for comparison with other stored images (see paragraph 7.12).
The **Store** button is present on the command bar when no image is stored already. In case there is at least another image stored the button changes and becomes **Compare**.
Use the **Compare** button to access a specific screen making it possible to compare the image currently displayed with the ones previously stored. This screen is described in paragraph 7.12, Fig 97.

The command bar changes when a video (instead of an image) is selected. When a video is selected the **Trim** button is displayed instead of the **Store** and **Compare** buttons (Fig 59 **A**).

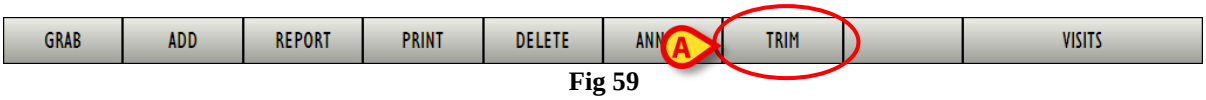


Fig 59

The **Trim** button gives access to a set of tools making it possible to perform various actions on the video (as, for instance, cut and save specific video portions, extract frames etc…). These tools are described in paragraph 7.13.
Use the **Save** button to manually save in a user-specified folder the image currently selcted. Click this button to open the usual "save" window of the operating system in use.
Use the **Visits** button to go back to the patient examinations list (Fig 49).
When no image or film is selected the command bar looks like in Fig 60.

Fig 60

The **Multi** button (Fig 60 **A**) is enabled, making it possible multiple selection of videos and images for quick deletion (see paragraph 7.10.1 for the procedure).

7.5. Creating a new examination

To create a new examination

- select the patient. See paragraph 7.2 for the patient selection procedure.

The Image Bank main screen opens. The patient's previous examination (if existing) are displayed on the left.

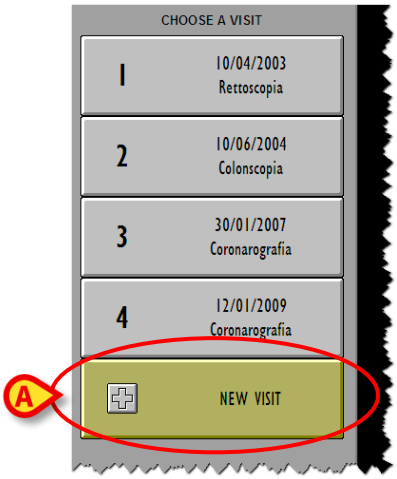


Fig 61 - New visit

- Click the **New Visit** button (Fig 61 **A**).

The "Examination details" opens. The screen is empty (Fig 62). A new visit is created independently from image and video acquisition.

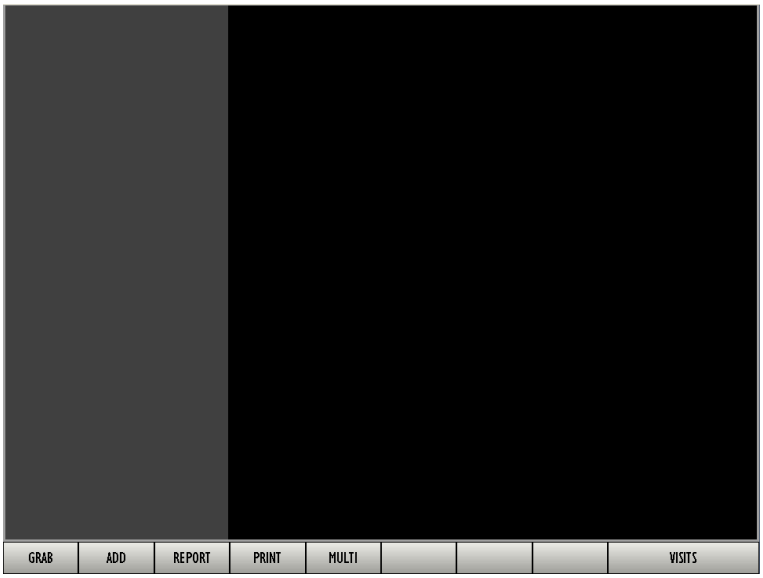


Fig 62 - New visit

Six buttons are on the command bar.

Use the **Grab** button to acquire an image or a video (see paragraph 7.6).
Use the **Add** button to acquire an image from an external source (see paragraph 7.7).
Use the **Report** button to display the examination clinical report (see paragraph 7.8).
Use the **Print** button to print the examination documentation (see paragraph 7.9).
Use the **Visits** button to go back to the patient examinations list (Fig 49).
Use the **Multi** button for multiple selection (see paragraph 7.10.1).
The new examination is recorded independently from any image/video acquisition and any report specification. A new visit-button has already been created on the examinations list screen (Fig 63 **A**).

Fig 63

7.6. How to grab images and videos

WARNING!

This paragraph describes the images and videos acquisition procedure to be used when no specific acquisition device is installed.

Images and videos can be grabbed by remote controls as pedals or manual swithces, radio-controls etc… If this is the case see paragraph 7.6.3 and the specific hardware documentation.

When a remote acquisition device is in use the DIGISTAT® Image Bank module can be activated in background as well. That is: module selection is not necessary to images acquisition.
It is necessary to select, on the module, the relevant patient and visit.

To grab an image/video

- Select the patient (See paragraph 7.2 for the patient selection procedure).

- Select the examination under which you want to record the new videos/images; otherwise create a new visit, if this is the case (the examination selection procedure is described in paragraph 7.3, the new examination creation procedure is described in paragraph 7.5).

- Click the **Grab** button. The images/videos acquisition screen opens (Fig 64).

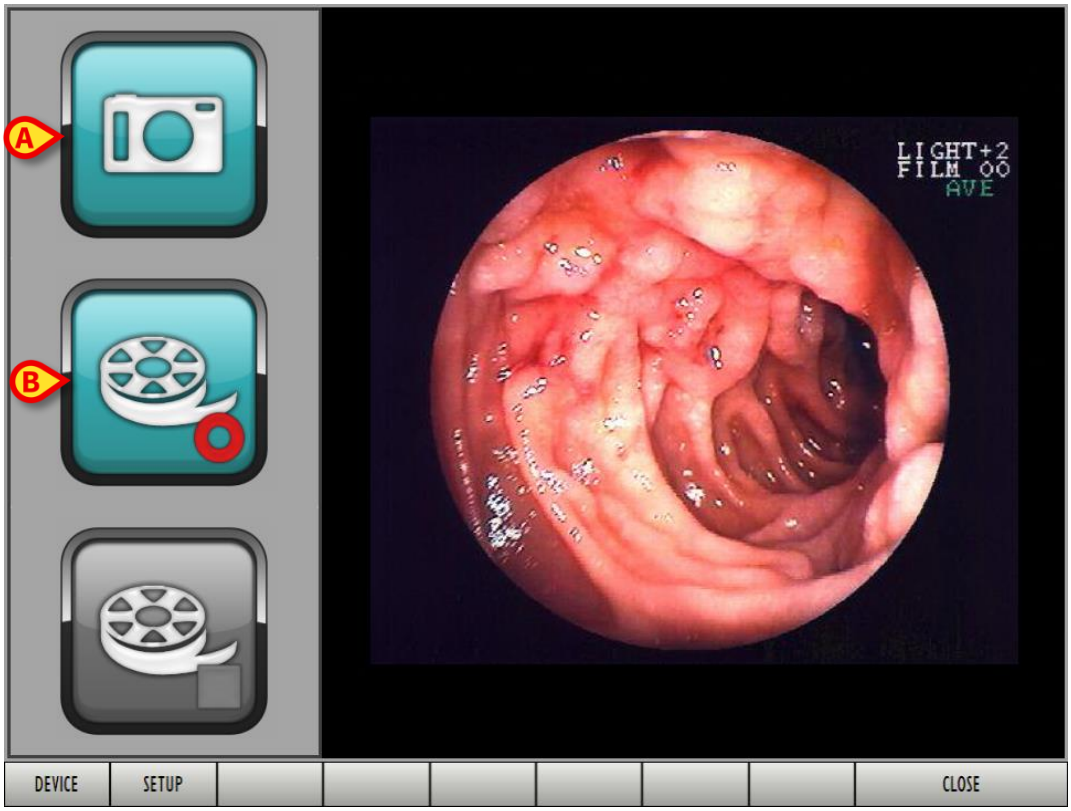


Fig 64 - Grab images and videos

The central part of the screen displays the images coming from the acquisition devices. On the left there are three large buttons.

- Click the  button (Fig 64 **A**) to acquire the image currently displayed and create a picture.

The image is this way saved and becomes visible on the "Examination detail" screen (see Fig 50 for an example) referring to the selected patient and visit.

- Click the  button (Fig 64 **B**) to start video acquisition.

When the acquisition is in progress the screen changes in the way displayed in Fig 65: the **Begin** button is selected and the **Stop** button is enabled.

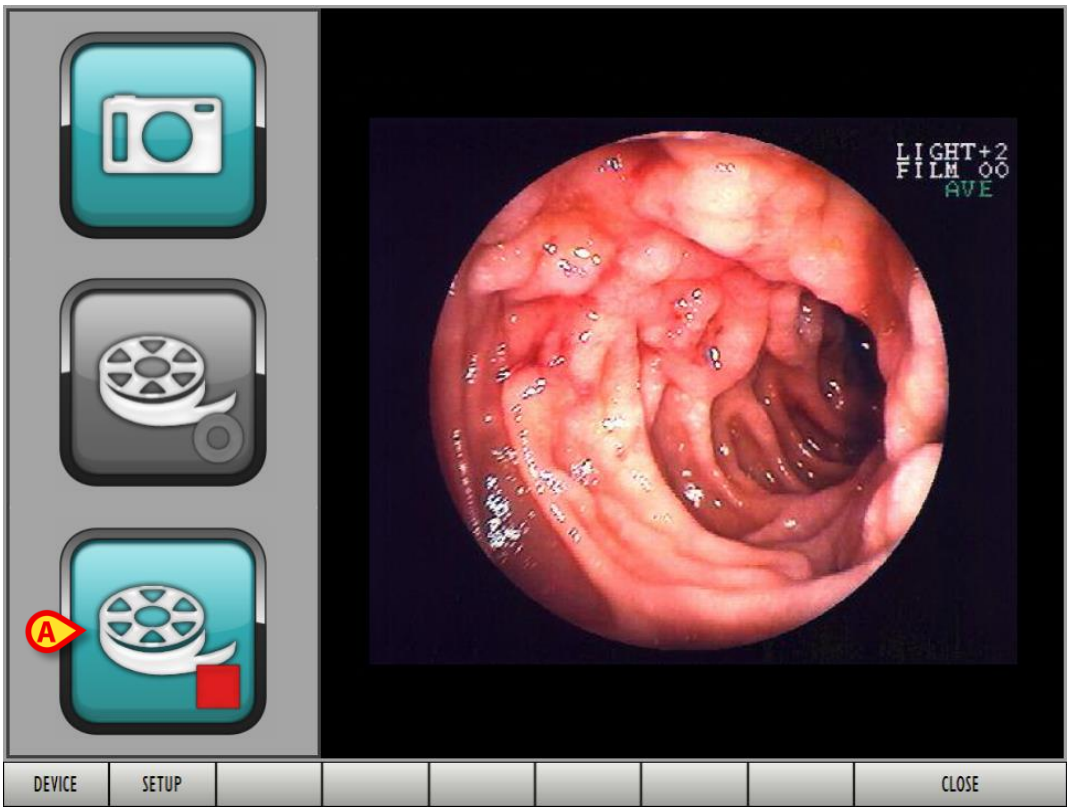


Fig 65 - Video acquisition

Video acquisition goes on until the "stop" button  is clicked.

- Click the  button to stop the video acquisition (Fig 65 **A**).

The video will be saved an will become visibile on the "Examination details" screen referring to the selected patient and visit (Fig 50 shows an example).

7.6.1. Acquisition screen command bar

The command bar of the "Acquisition screen" (Fig 66) contains three buttons.

Fig 66 - Acquisition screen command bar

- Use the **Close** button to close the "Acquisition screen" and display again the "Examination details" screen (Fig 50).

- Use the **Device** button to select the acquisition device from an existing list. To do that

- click the **Device** button. The list of all the available devices is displayed on the left (Fig 67 **A**).

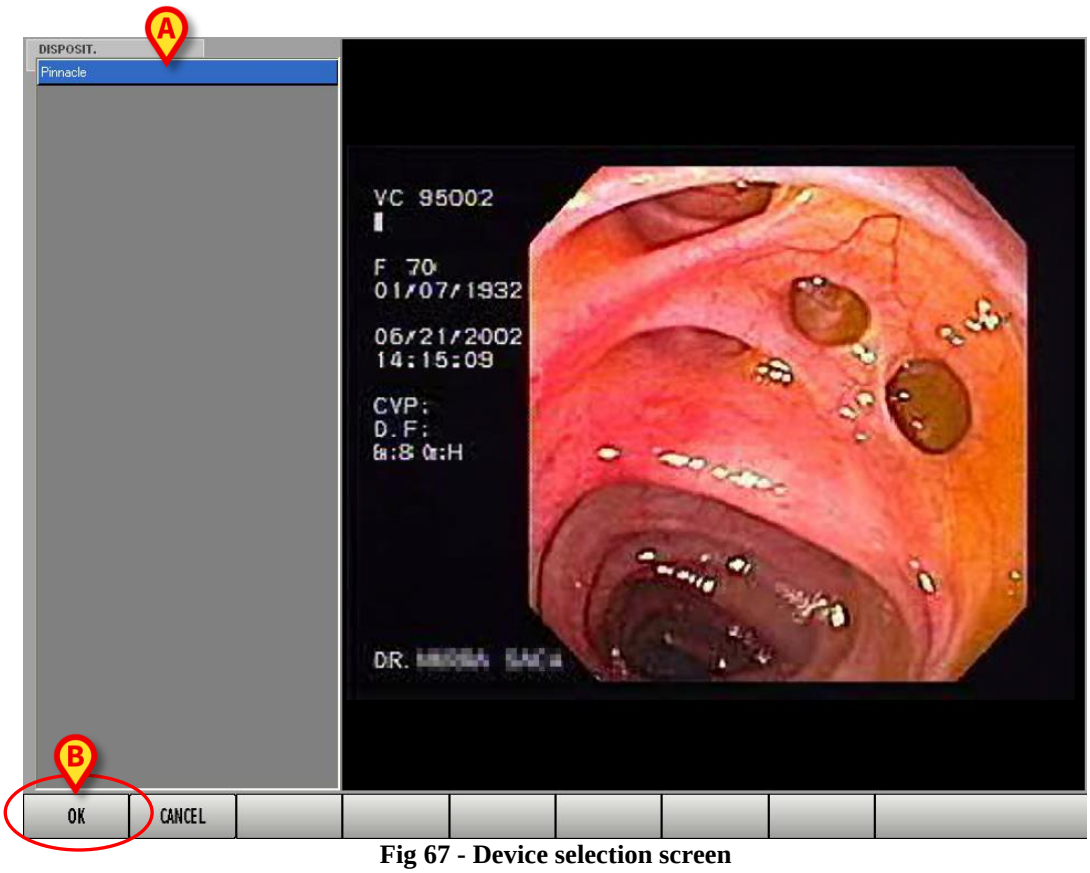


Fig 67 - Device selection screen

In the example shown in the figure only one device is available.

- Click the name of the wanted device. The name is this way highlighted.
- Click the **Ok** button on the command bar (Fig 67 **B**).

The system will go back to the "acquisition screen" (Fig 64). The wanted device will be selected.

- The **Setup** button makes it possible to access the acquisition devices configuration functions.

Click the button to display the specific device configuration window. The kind and the functions of the configuration window depend on the specific device selected. Fig 68 shows an example.

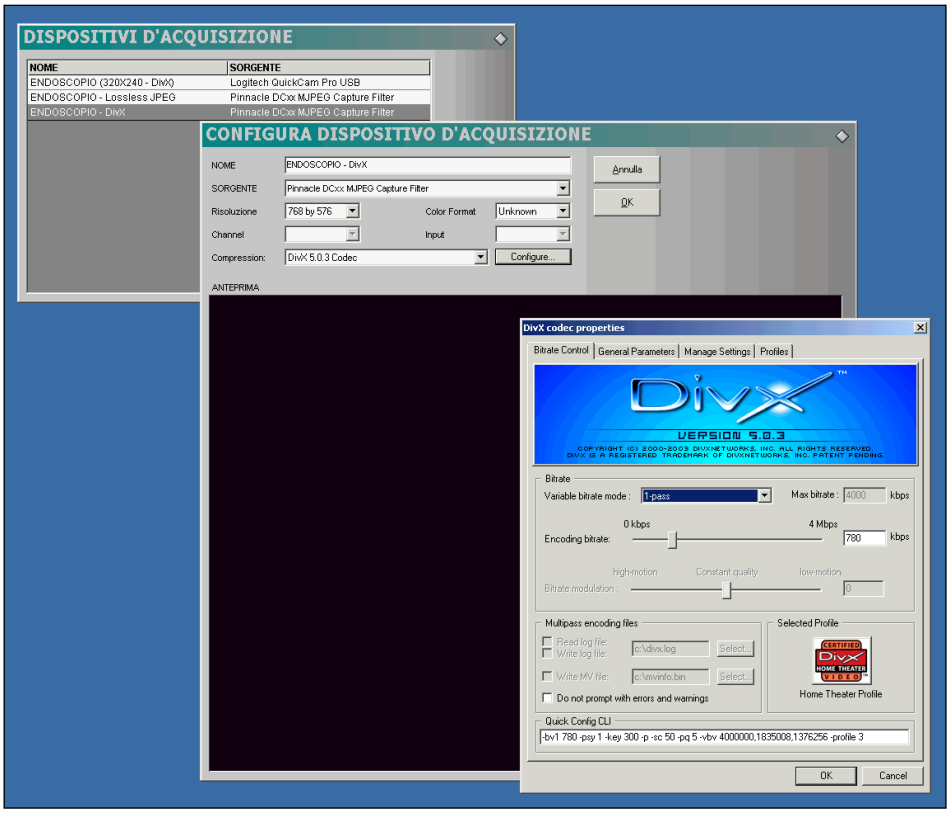


Fig 68 - Acquisition devices configuration

7.6.2. Alternative grabbing procedure

A configuration parameter makes it possible to set a different images and videos acquisition procedure.

Refer to your system administrator for the configuration alternatives.

When this procedure is activated the click on the **Grab** button on the command bar does not bring to the page shown in Fig 64. The page referring to the selected visit remains displayed instead (Fig 69).

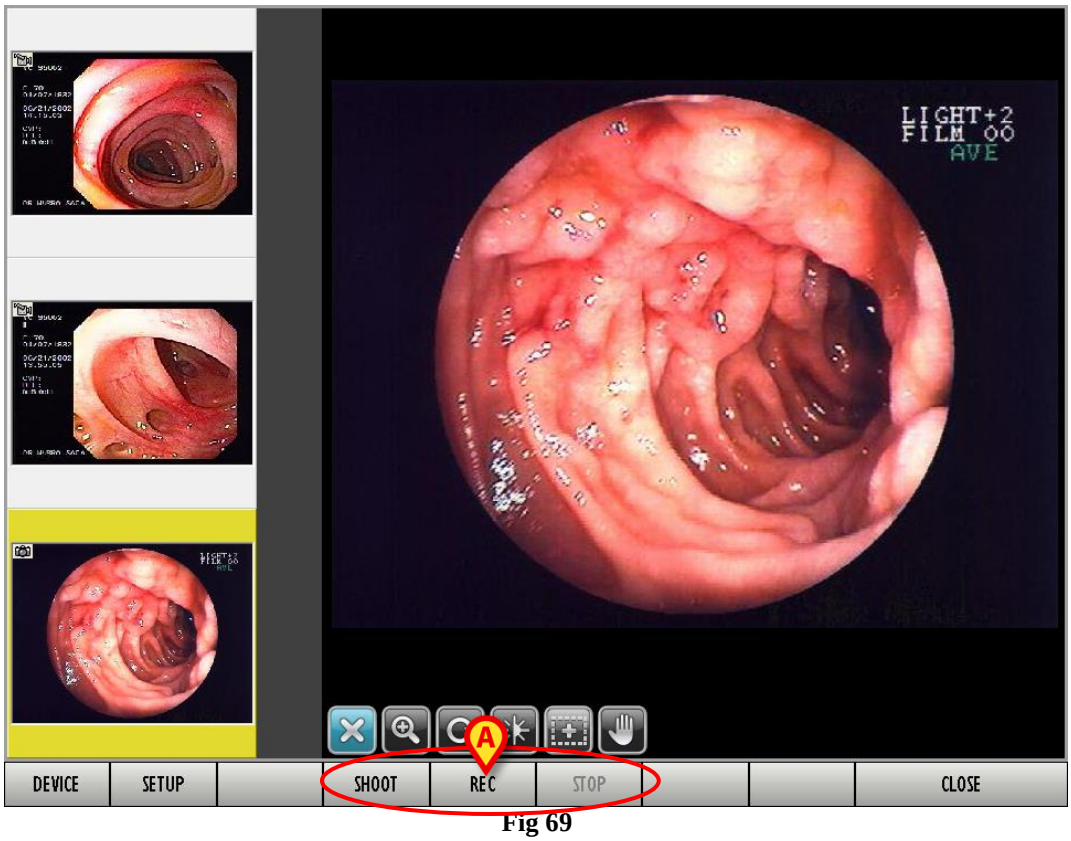


Fig 69

The command bar changes. The two buttons on the left - **Device** and **Setup** - are described in paragraph 7.6.1. The three buttons indicated in Fig 69 **A** have the following purposes:
The **Shoot** button grabs the image currently displayed on the page and creates a photograph. The image remains on screen for a certain (configurable) period.
The **Rec** button starts video recording. During recording the button appears as selected.
The **Stop** button stops the video acquisition.

7.6.3. Remote acquisition devices

Remote acquisition devices can be used to facilitate and speed-up the DIGISTAT® "Image bank" procedures. The presence of these devices depends on the clinical procedures in use. This paragraph briefly describes two of the devices most commonly used. Refer to the hardware's specific documentation for a detailed description of the devices.

7.6.3.1. Footswitch

This device is a pedal board containing two footswitches.

This device can be used independently from the page currently displayed on screen. If you are on the "Visit" page (Fig 50 shows an example) and the footswitch is pressed, the "Grab" page is automatically displayed (either Fig 65 or Fig 69, depending on the configuration chosen), otherwise the acquisition is performed in background. Background grabbing is also enabled when the "Image Bank" module is not currently selected.
Use the left footswitch to grab an image (analogous to the **Shoot** button).
Use the footswitch on the right to record a video. There are two possible video recording modes, decided by configuration:

1) press the footswitch once to start recording; press the footswitch twice to stop recording;
2) press the footswitch and keep it pressed while recording; release it to stop recording.

7.6.3.2. Manual device

This device is a roller that can be activated either clockwise or anticlockwise. The roller can also be pressed as a switch.
Use this device to grab images (in background as well) and to manage the way the items on the "Visit" page are displayed (Fig 50, for instance). This device can be used in three ways:

1) press the device to grab an image (analogous to the **Shoot** button);
2) roll the device to scroll and select one after the other the images and videos of the same visit;
3) press and roll at the same time the device to watch a selected video frame-by-frame either forward or backward.

7.7. Adding an image/video

The **Add** button on the command bar (Fig 70 **A**) makes it possibile to add an image/video taken from an external source.

Fig 70 - Command bar

To do that

- click the **Add** button.

A specific folder opens (the folder pathname is specified by configuration). In Fig 71 it is the "Sample pictures" folder. To access a different folder use the standard Windows® navigation functions.

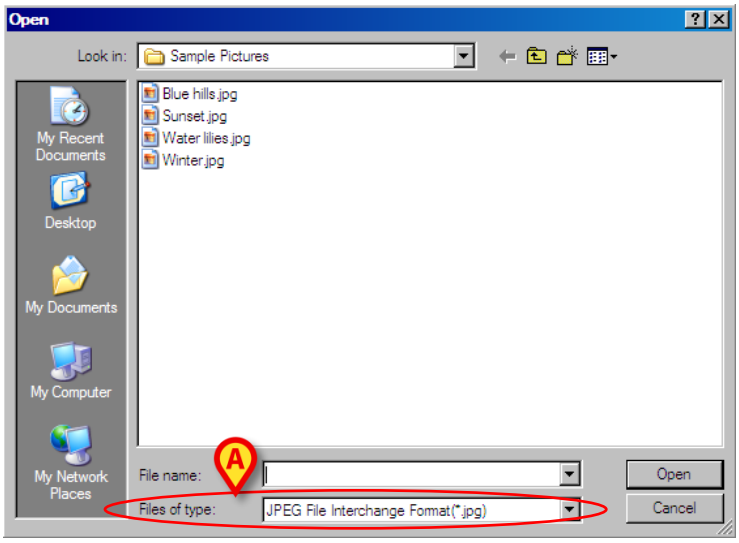


Fig 71

- Use the field indicated in Fig 71 to specify the file extension.
- Click the name of the wanted file. The name is this way highlighted (Fig 72 **A**).

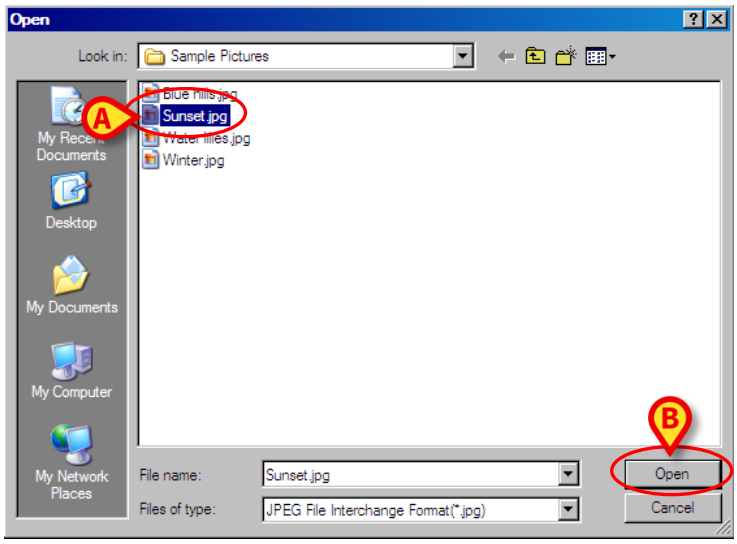


Fig 72

- Click the **Open** button (Fig 72 **B**).

The selected image/video is this way added to those already existing for the specific examination.

7.8. Examination report

To create or edit the current examination report

- click the **Report** button on the command bar (Fig 73).

Fig 73 - Command bar

The following screen opens (Fig 74).

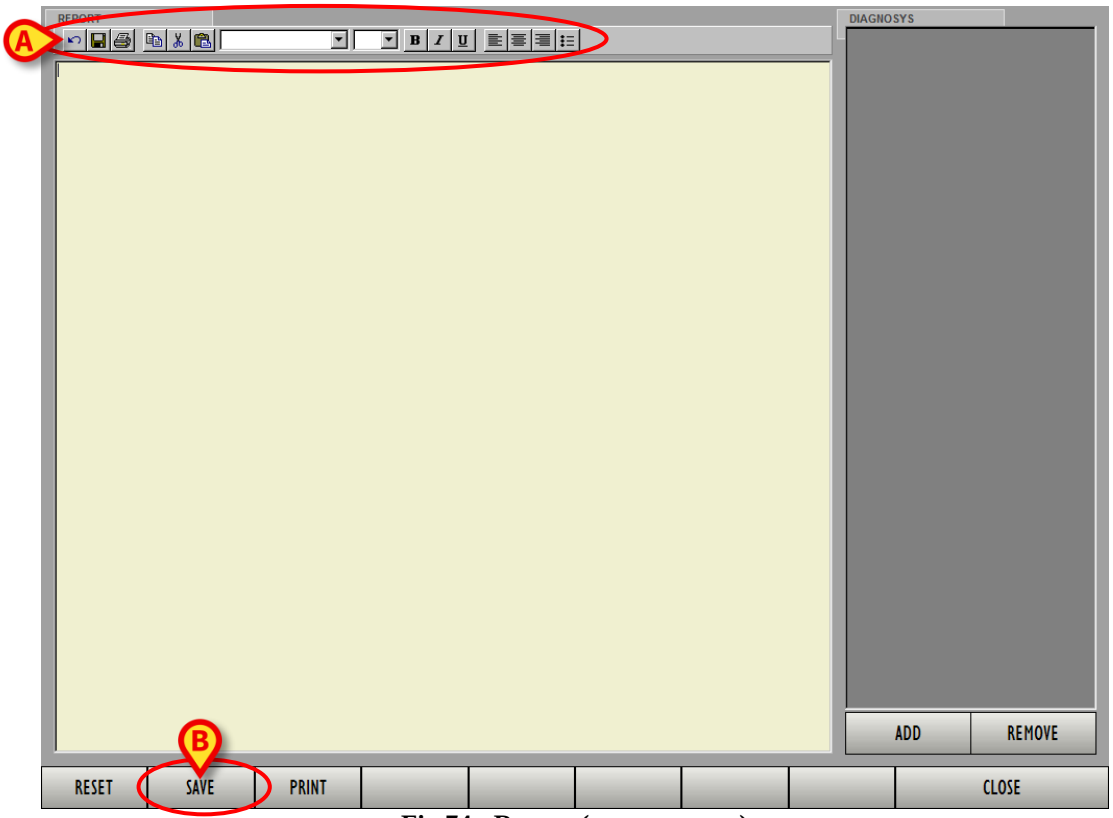


Fig 74 - Report (empty screen)

The screen shown in Fig 74 is empty, i.e. no information is specified on the report. When information already exists, this screen makes it possible to read it and edit it. See Fig 77 for an example of an actual examination report.
The "Report" screen is a word prcessor. Any text can be inserted here using the workstation keyboard. The buttons on the top left corner of the screen (Fig 74 **A**) are text formatting tools.
Their functions are:

 - Cancel latest operation
 - Save
 - Print
 - Copy
 - Cut

 - Paste

 - Font selection

 - Font size selection

 - Bold

 - Italic

 - Underlined

 - Left alignment

 - Centred text

 - Right alignment

 - List buttons

After any editing; to save the changes,

- click the **Save** button on the command bar (Fig 74 **B**). The text is this way saved.

Three other buttons are on the "Report" screen command bar (Fig 75).

Fig 75 - Command bar

Use the **Close** button to close the "Report" screen and display again the "Examination detail" screen (see Fig 62 for an instance).

Use the **Reset** button to cancel all the changes made from the last data saving (i.e. from the last time the **Save** button was clicked).

User confirmation is required after the **Reset** button is clicked.

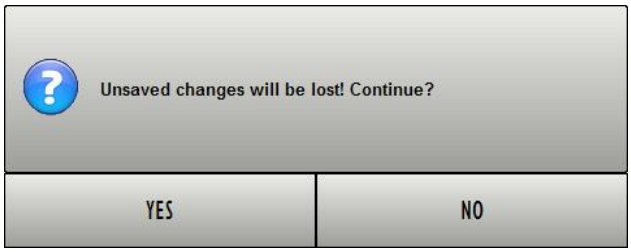


Fig 76

- Click **Yes** to reset.

The **Print** button makes it possible to print the examination report. Click the **Print** button to display a print preview. The system's print functionalities are described in paragraph 6.8.1.

7.8.1. Adding a pre-defined code to the examination report

The "Diagnosis" area on the right of the "Report" screen (Fig 77) makes it possible to search and insert coded diagnosys in the current report.

The DIGISTAT® Codefinder module is used for this purpose. See the specific documentation for a detailed description of this module.

Fig 77 - Diagnostic codes

To add a diagnosis,

- click the **Add** button indicated in Fig 77 **A**. The DIGISTAT® Codefinder module opens (Fig 78).

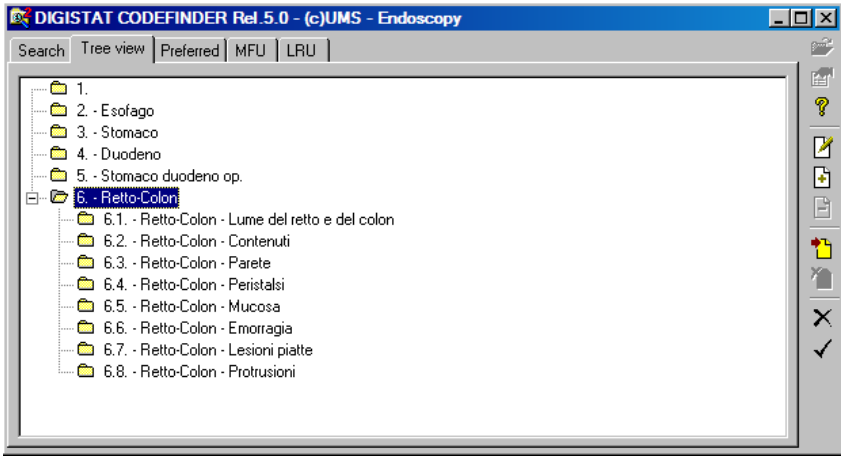


Fig 78

- Search the wanted diagnostic code (see the specific documentation for the "Codefinder" search and selection procedures).

- Double click the line corresponding to the wanted code.

The diagnostic code is this way added to the “Diagnosis” area. To remove a “Diagnosis”

- Click the diagnosis to be removed. The diagnosis is highlighted (Fig 79).

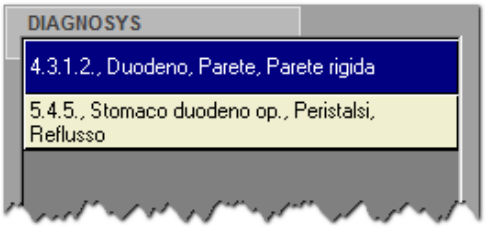


Fig 79

- Click the **Remove** button indicated in Fig 77 **B**. The selected diagnosis is this way removed.

7.9. Image Bank print functions

The **Print** button on the command bar of the “Examination record” screen (Fig 80) opens a screen used to define the kind of documentation to be printed.

Fig 80 - Command bar

To print a document

- select the relevant examination (use for this purpose the buttons on the visits list - Fig 81).

Fig 81 - Visits

The “Examination detail” screen opens (Fig 82).

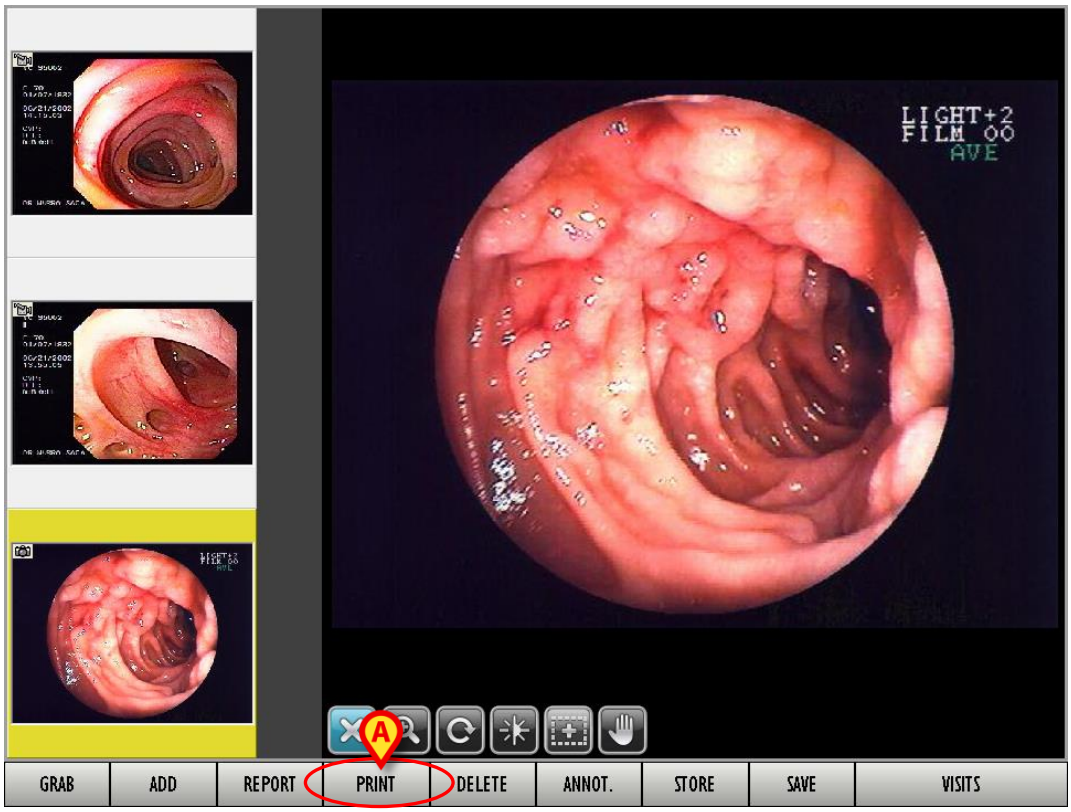


Fig 82 - Examination detail screen

- click the **Print** button on the command bar (Fig 82 **A**). The following screen opens.

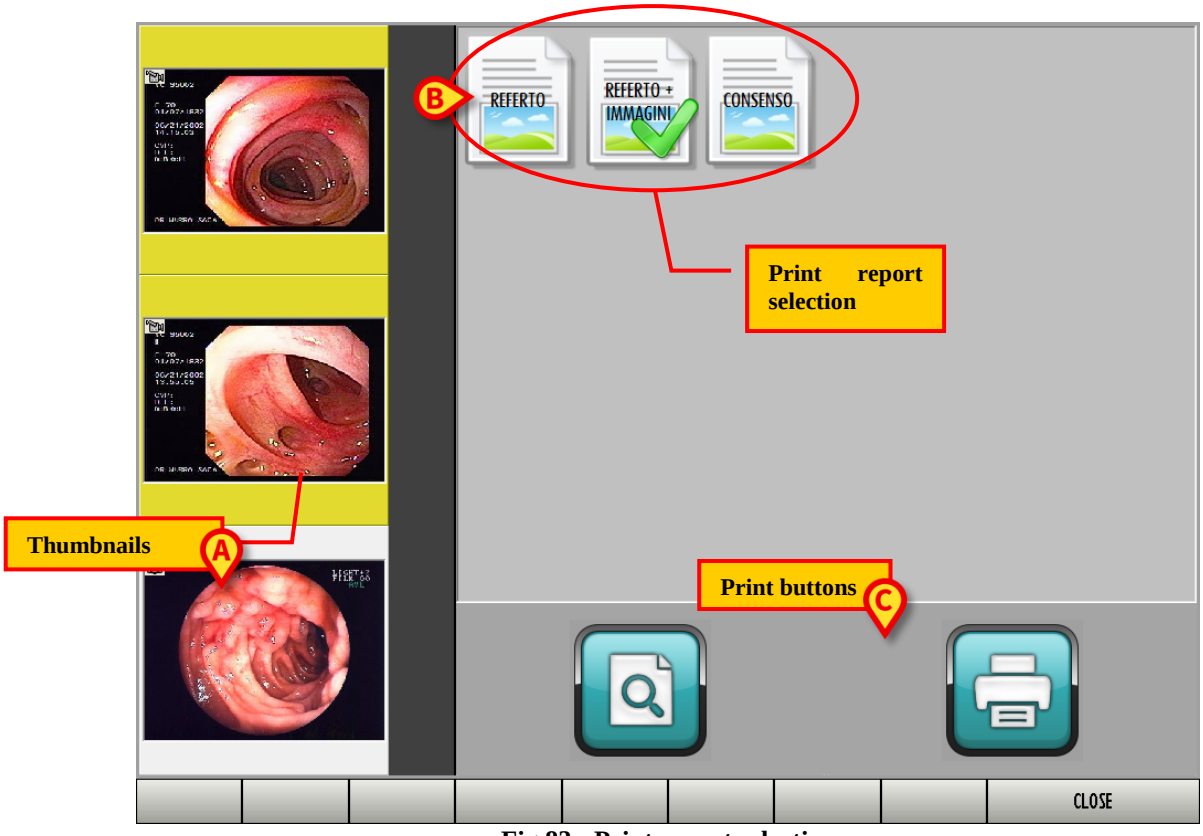


Fig 83 - Print report selection

It is possible to select the type of print report to create. The visit's thumbnails are still displayed on the left (Fig 83 **A**).
Several icons, each one corresponding to a specific kind of document, are displayed on the right (Fig 83 **B**).

- Click an icon to select the kind of document.

The clicked icon is selected (Fig 84 **A**).

Fig 84 - Report selection

In the configuration here described the following reports are possible:

- report only;
- report and images;
- informed consent.

The number and kind of print reports is in part configurable. Please contact your system administrator for more details.

Two large buttons on the bottom of the screen make it possible to print the selected report (Fig 83 **C**, Fig 85).

Fig 85

The left button (Fig 85 **A**) opens a print preview. The right button (Fig 85 **B**) prints the report without displaying the print preview. The system's print functionalities are described in paragraph 6.8.1.

7.9.1. How to create a print report (quick guide)

To create a print report

- select the relevant examination (use the buttons on the examinations list for this purpose - Fig 81). The “Examination detail” screen opens (Fig 82).
- click the **Print** button (Fig 82 **A**). The screen shown in Fig 83 opens.
- Select the kind of print report (Fig 84).
- Click either the  button to directly create the print report (Fig 85 **A**) or the  button to display a print preview.

7.10. Deleting an image or video

To delete an image or a video, on the “Examination detail” screen (Fig 86),

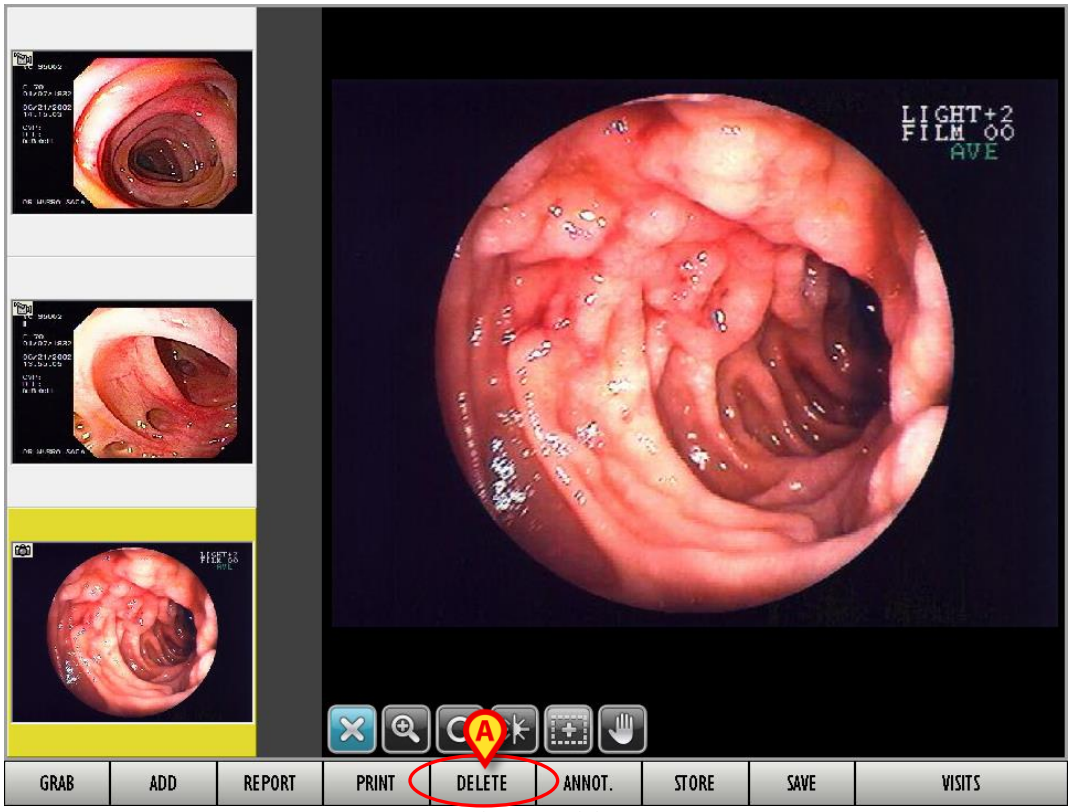


Fig 86 - Visit

- click the thumbnail corresponding to the image or video that must be deleted. The image or video is this way selected.
- Click the **Delete** button on the command bar (Fig 86 **A**). User confirmation is required (Fig 87).

Fig 87

- Click **Yes** to delete the selected image/video.

7.10.1. Simultaneous deletion of several items

It is possible to select several images/videos together to delete them all at once. To do that it is first necessary to deselect any image/video previously selected. To deselect an image/video click on its thumbnail on the left part of the screen. The thumbnail is this way deselected. The command bar is consequently displayed as in Fig 88.

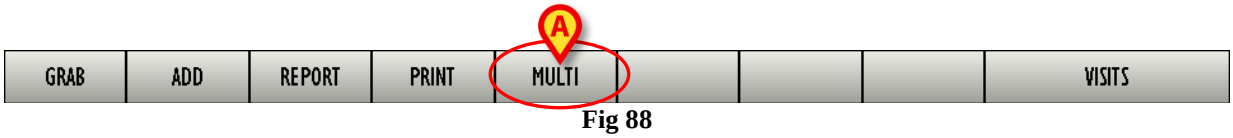


Fig 88

Then

- click the **Multi** button (Fig 88 **A**).

The command bar changes in the following way: the **Multi** button becomes **Single** (Fig 89).

Fig 89

On the left part of the screen,

- click the thumbnails corresponding to the images/videos that must be deleted. The clicked thumbnails are this way all highlighted

- Click the **Delete** button on the command bar. User confirmation is required (Fig 90).

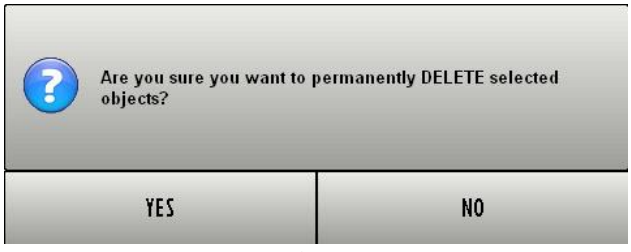


Fig 90

- Click **Yes** to delete the selected images/videos.

7.11. Image/video annotation

To associate a note to an image/video, on the “Examination detail” screen (Fig 91),

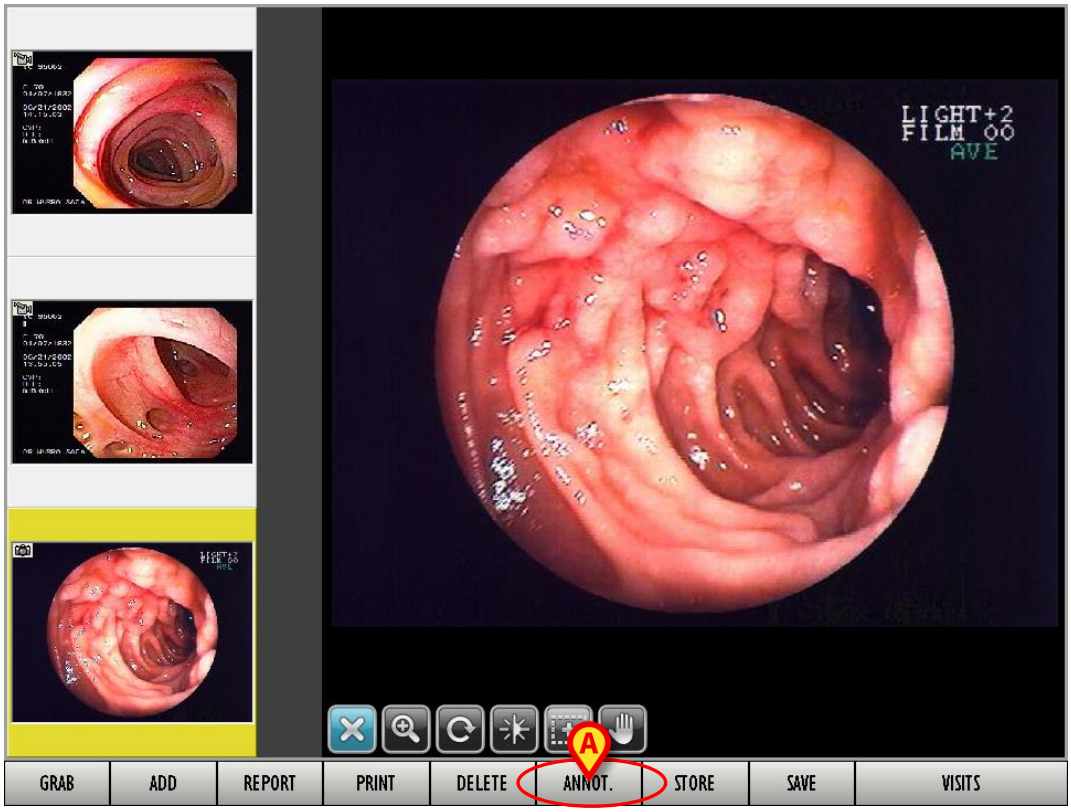


Fig 91 - Visit

- click the thumbnail corresponding to the relevant image/video. The image/video is this way selected.

- Click the **Annot.** button on the command bar (Fig 91 **A**). The following window opens.

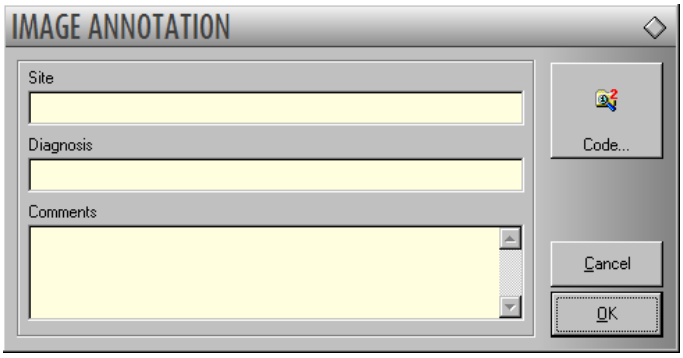


Fig 92 - Image annotation

- Type the relevant information in the fields “Site”, “Diagnosis”, “Comments” (Fig 93).

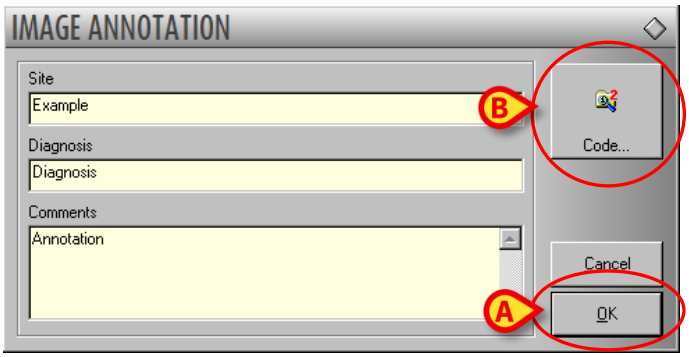


Fig 93 - Image annotation

- Click the Ok button (Fig 93 **A**). The annotation is displayed under the thumbnail corresponding to the selected image (Fig 94).

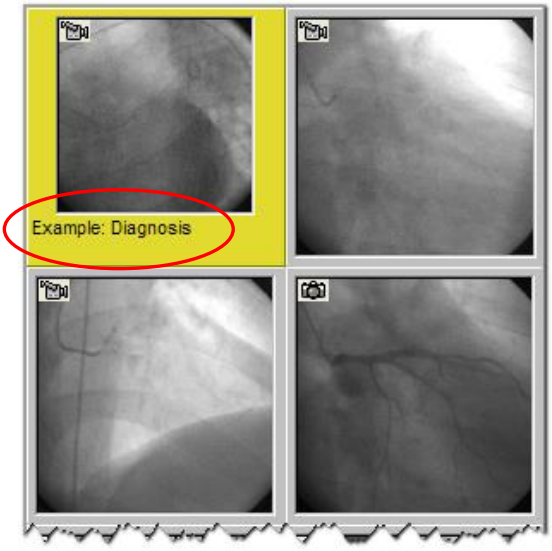
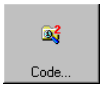


Fig 94

Use the 

button on the "Image annotation" window (Fig 93 **B**) to open the DIGISTAT® Codefinder module, making it possible to find and insert coded diagnosis in the appropriate fields. See the DIGISTAT® Codefinder specific documentation for the related procedures.

7.12. Compare images

The Image Bank module makes it possible to display two images on the same screen, one next to the other, for comparison. To do that, on the “Examination detail” screen (Fig 95),

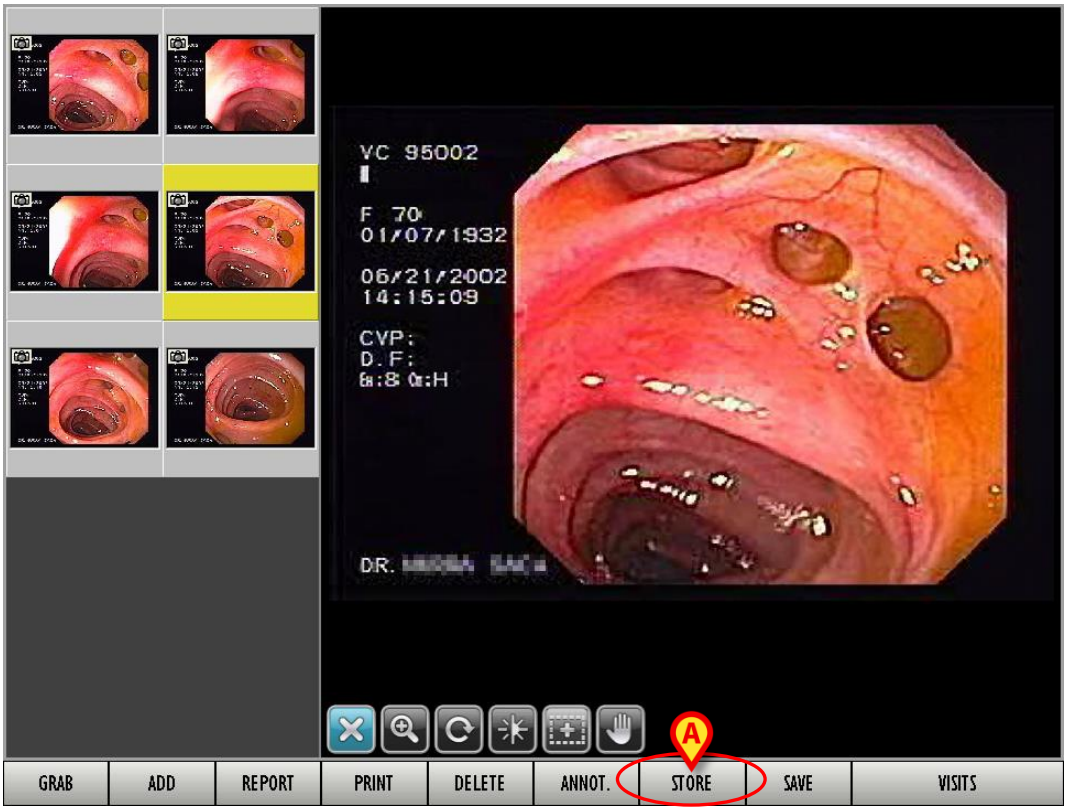


Fig 95 - Visit

- click the image you want to compare. The image is selected.
- Click the **Store** button on the command bar (Fig 95 **A**).

The selected image is this way stored. The **Store** button changes, becoming **Compare**. There are no changes in the image displayed on screen. It is now necessary to select the image to be compared with the stored one. To do that

- select the visit containing the image to compare (Fig 96).

The image can be selected on a different visit.

Fig 96 - Different visit

- Click the image to be compared. The image is selected.
- Click the **Compare** button on the command bar (Fig 96 **A**).

The following screen opens: the image stored for first is displayed on the right; the image selected later to be compared is displayed on the left. The header on top of area 1 (left) specifies the number of the visit, the date in which the image was grabbed, and the number of the image (Fig 97 **A**).

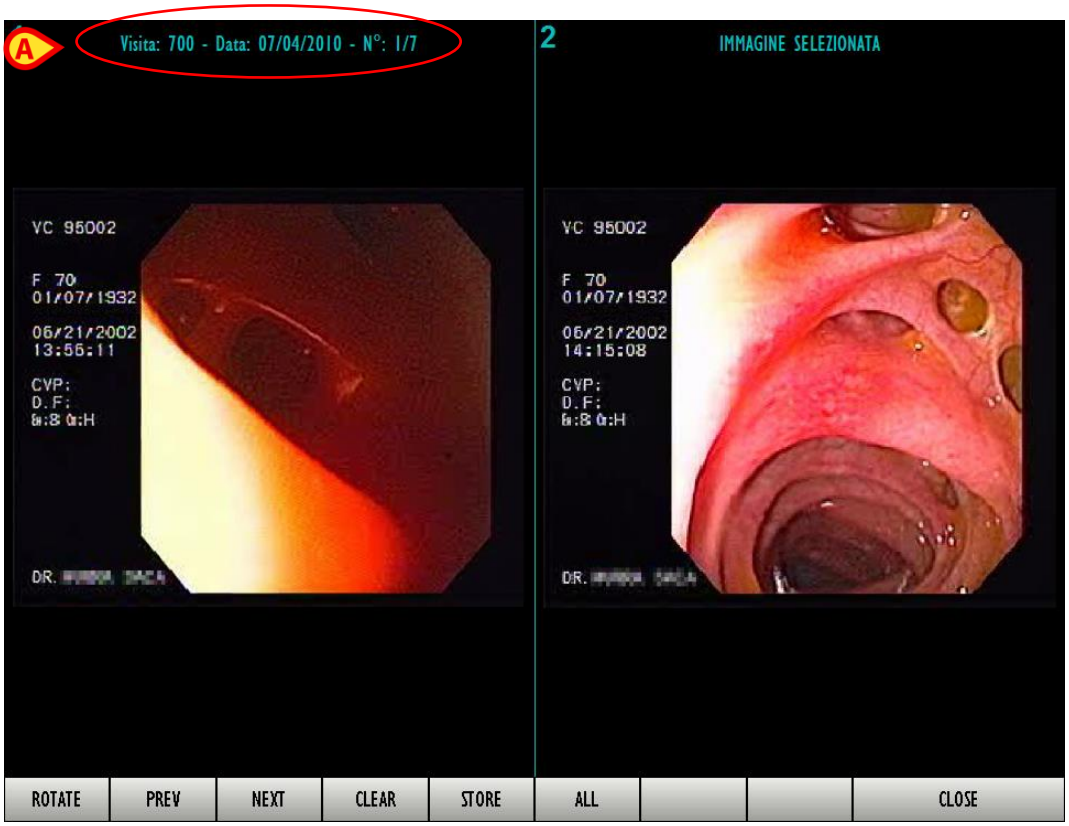


Fig 97 - Images comparison

The system keeps in memory all the images of a selected visit; use the **Prev** and **Next** buttons on the command bar to display, on the left half of the screen, all the other images.

- The **Rotate** button rotates the image displayed on the left 90° counterclockwise. Click the button 4 times to bring the image back to the original display mode.
- The **Store** button on the command bar makes it possible to change the image on the right with that currently displayed on the left. The image that was on the left is this way displayed on the right as "image in memory".
- The **Clear** button clears the stored image. Namely, it makes it possible to clear the image on the right (the one to which all the others are compared) and then store a different image in its place. After the **Clear** button is clicked , the **Store** button is displayed again on the command bar of the "Visit record" screen (as shown in Fig 95 **A**).
- The **All** button makes it possible to compare the selected image with all the other images of the same patient stored in different visits. The button appears as selected when the functionality is active. It is this way possible to use the **Prev** and **Next** buttons to display all the available images.
- The **Close** button closes the "comparison" screen and brings back to the previous "Visit Record" screen.

7.13. Video “editing” options

The user can operate in several ways on the videos. The user can, for example, cut portions of a video and save them as a separate film, or exctract frames from a video and save them as autonomous images. A specific tool, accessibile from the “Examination detail” screen, makes the above-mentioned operations possible. To open this tool

- access the “Examination detail” screen containing the video that will be edited (Fig 98).

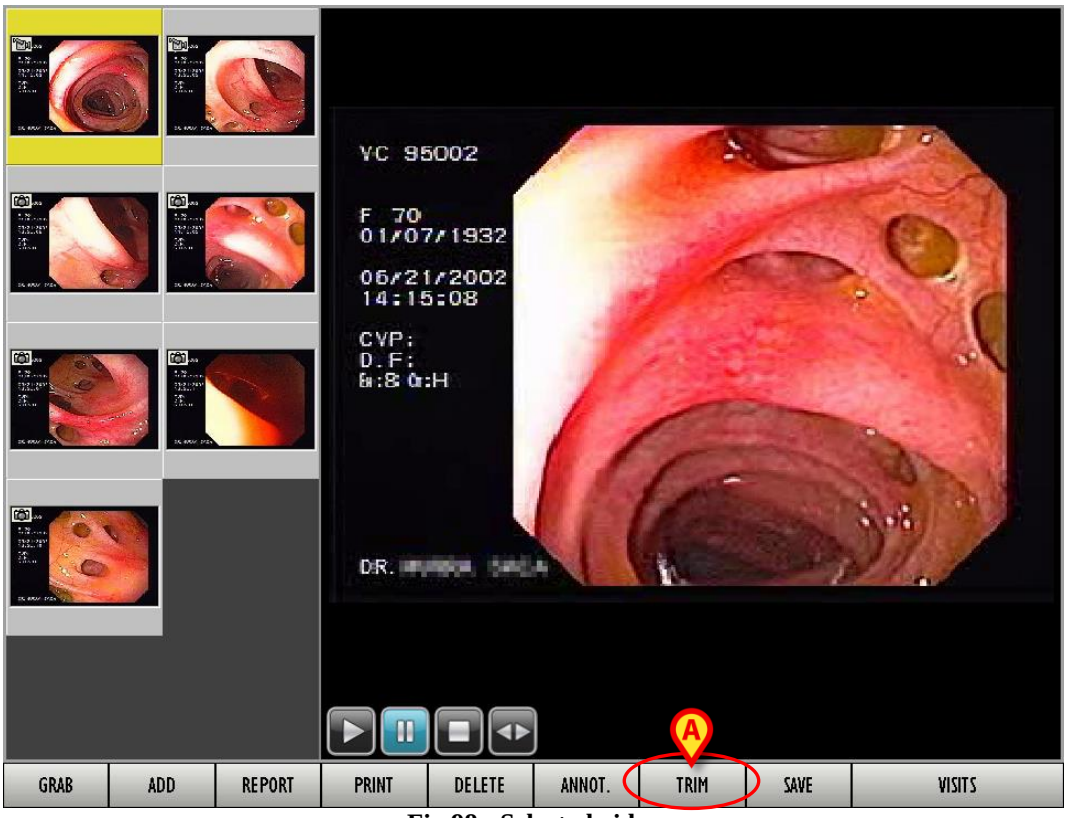


Fig 98 - Selected video

- Click the thumbnail corresponding to the video that will be edited. The video is selected; it runs on the central part of the screen.

- Click the **Trim** button on the command bar (Fig 98 **A**). The following screen opens.

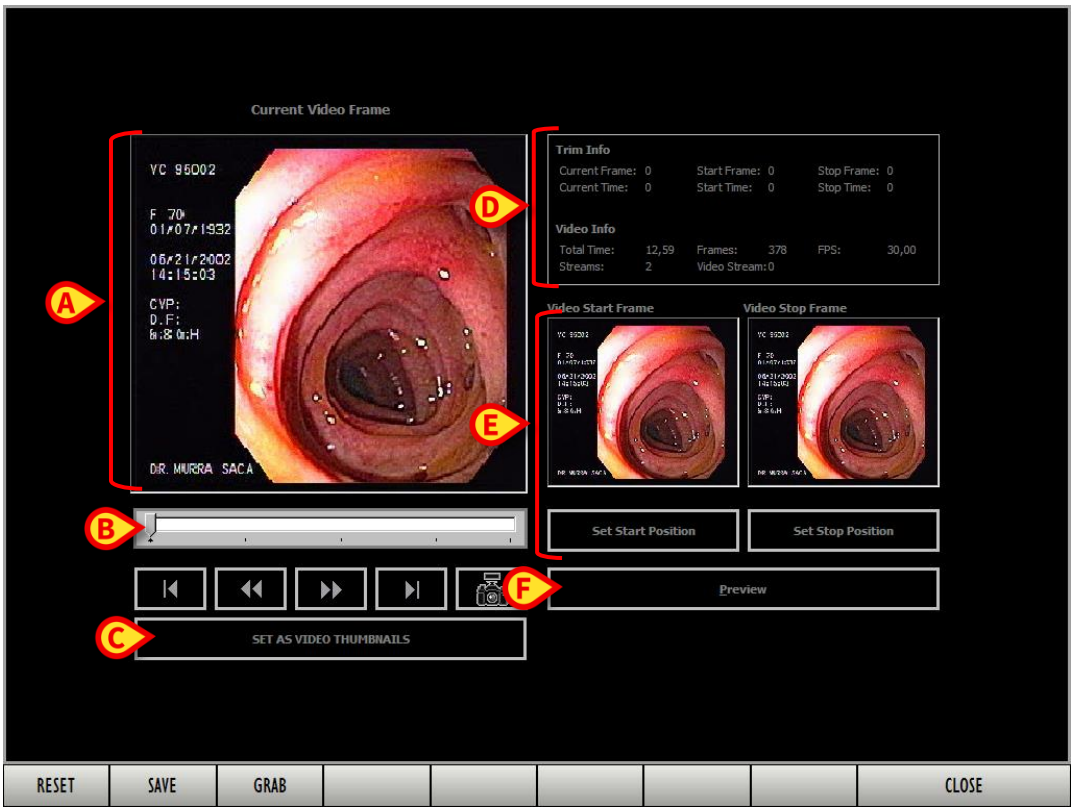


Fig 99 - "Trim" options

The screen displays, on the large image on the left, the frame currently selected (Fig 99 **A**). A time bar indicating the video flow is below the image (Fig 99 **B**).

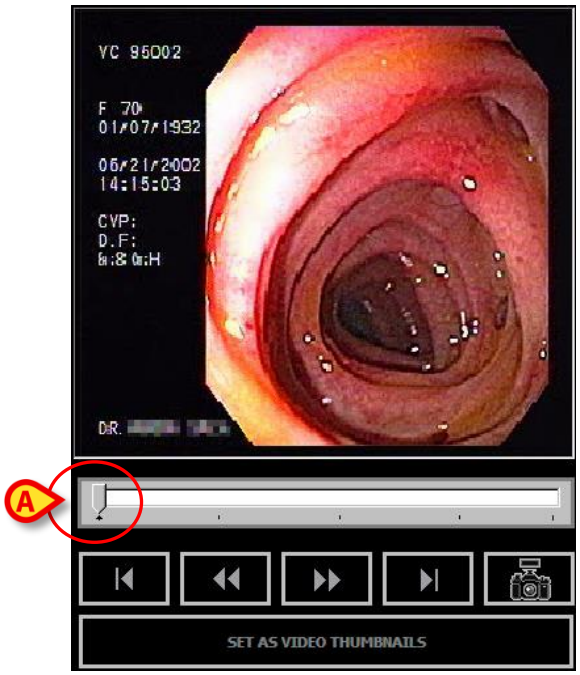


Fig 100 - Current frame

A cursor is on the bar. The bar length represents the video total length. The cursor indicates the position of the frame displayed in the image. In the example shown in Fig 100 **A** the frame is at the beginning of the video.

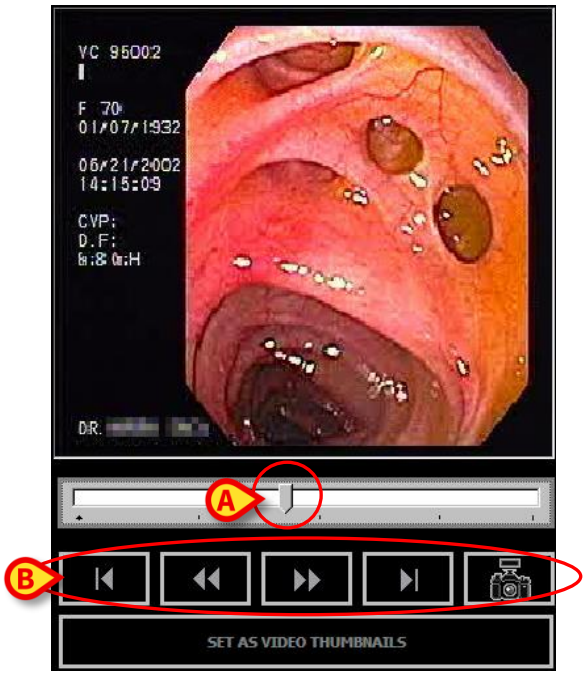


Fig 101 - Current frame (2)

In the example shown in Fig 101 **A** the displayed frame is placed just before the middle of the video. The cursor can be moved in two ways:

1) dragging:

   place the mouse pointer on the cursor and, keeping the left button clicked, drag the cursor either to the right or the left; if using a touch screen the same operation can be performed with a finger;

2) using the buttons below the image (Fig 101 **B**):

   use the  button to place the cursor at the beginning of the bar (and therefore at the beginning of the video);

   use the  button to bring the cursor back frame by frame (one frame per click);

   use the  to bring the cursor forward frame by frame (one frame per click);

   use the  button to place the cursor at the end of the bar (and therefore at the end of the video).

The  button has a different function. This button saves the frame currently displayed as an autonomous image. Click it to create a new image that will be added to those displayed on the "Examination detail" screen (Fig 98). Additional work tools are on the right of the "Trim" screen (Fig 99).
The box indicated in Fig 99 **D** and enlarged in Fig 102 displays information on the video and on the operations performed.

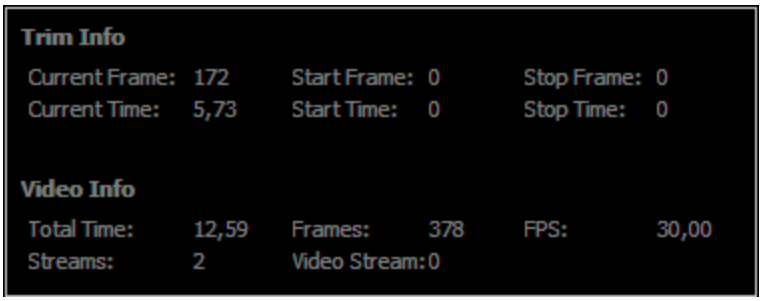


Fig 102

The following information is displayed within the box.

Trim info:

- current frame - currently displayed frame number;
- current time - currently displayed frame time;
- start frame - (possible) selected video portion start frame number (see paragraph 7.13.1 for the video selection functions);
- start time - (possible) selected video portion start time (see paragraph 7.13.1 for the video selection functions);
- stop frame - (possible) selected video portion stop frame number (see paragraph 7.13.1 for the video selection functions);
- stop time - (possible) selected video portion stop time (see paragraph 7.13.1 for the video selection functions);

Video info:

- total time - video duration (in seconds);
- frames - total frame number;
- FPS - frames per second;
- streams - number of streams until the current one;
- video stream.

7.13.1. Selecting and saving a video portion

The area indicated in Fig 99 **E** and enlarged in Fig 103 makes it possible to select a video portion. The selected portion can be saved as another autonomous video.

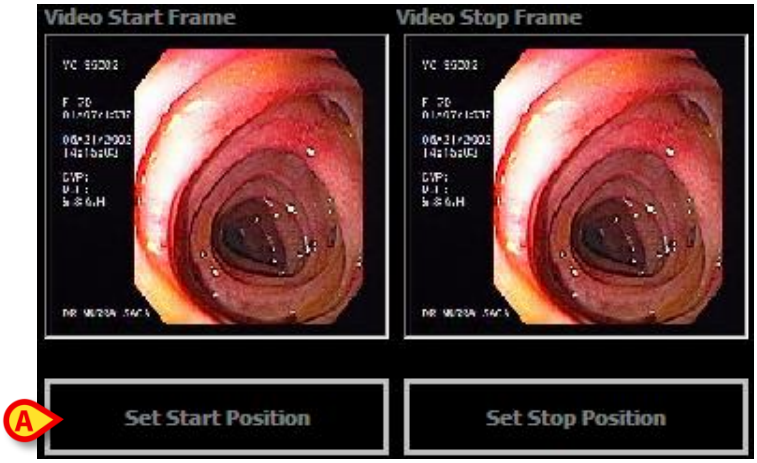


Fig 103 - Set start and stop frame

To do that it is necessary to set the first and last frame of the portion to be selected. To set the first frame,

- use the cursor or the buttons described in the previous paragraph (Fig 101) to display the frame that will be set as first frame (see the example in Fig 104).

Fig 104

- Click the **Set Start Position** button (Fig 103 **A**).

The frame displayed in Fig 104 will be set as start frame. The selected frame is displayed (small) within the area shown in Fig 105 **A**. The selected frame number is displayed above the area (Fig 105 **B**).

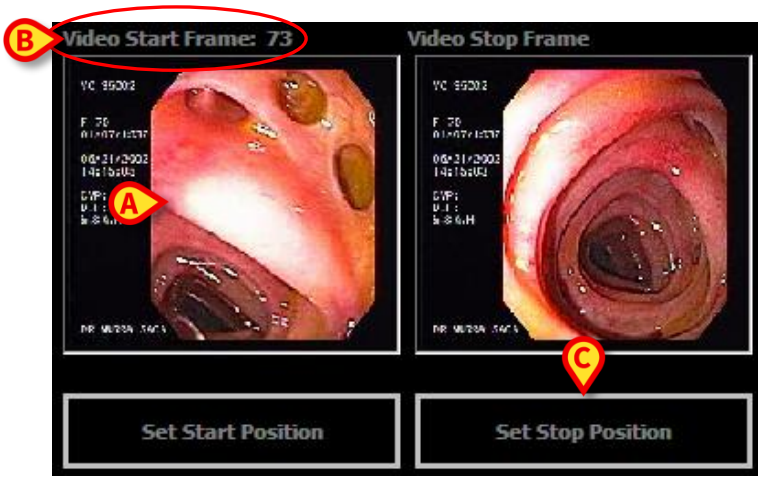


Fig 105 - Start frame

It is now necessary to set the stop frame. To do that:

- use the cursor or the buttons described in the previous paragraph (Fig 101) to display the frame that will be set as stop frame (see the example in Fig 106).

Fig 106

- Click the Set Stop Position button (Fig 105 **C**).

The selected frame is displayed (small) within the area shown in Fig 107 **A**. The selected frame number is displayed above the area.

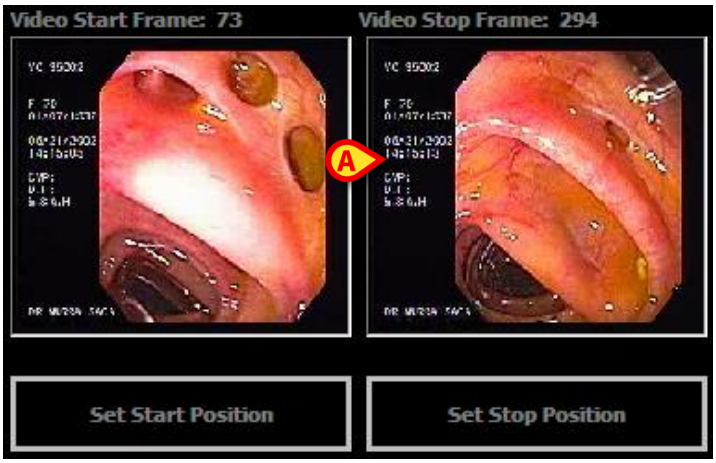


Fig 107

The video portion selected this way appears highlighted blu on the "time bar" on the left (Fig 108 **A**).

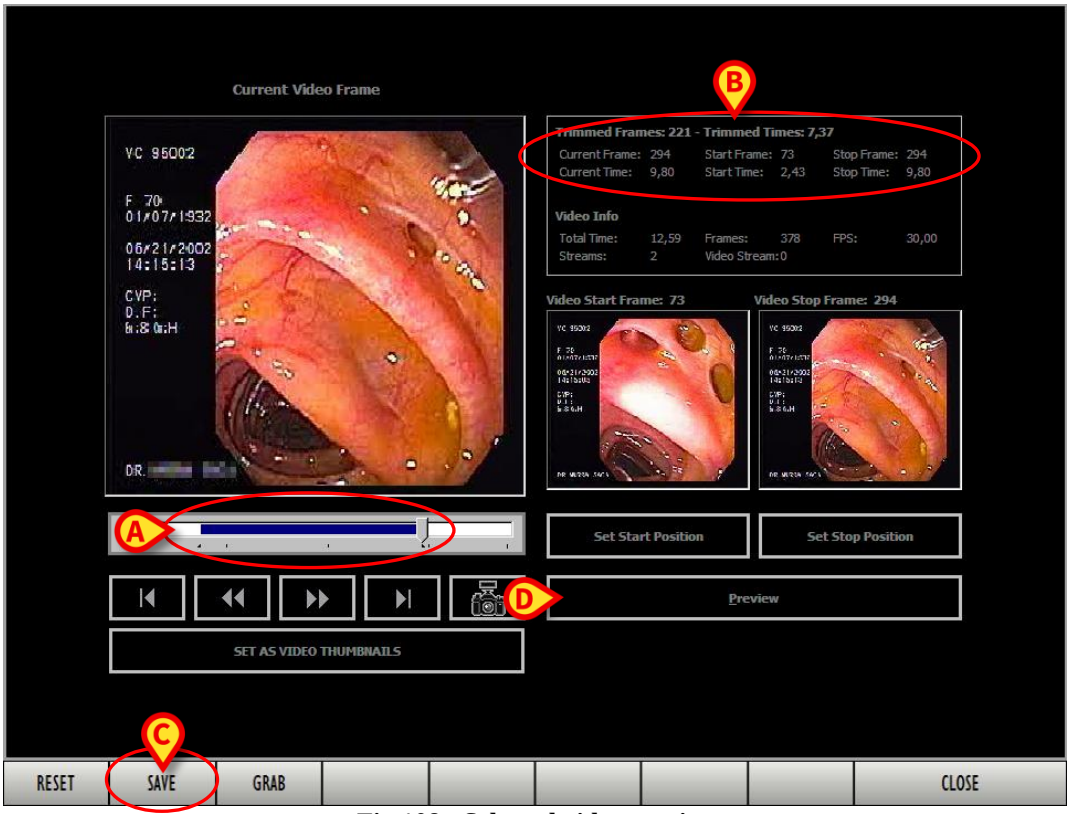


Fig 108 - Selected video portion

The area indicated in Fig 108 **B** contains information on the selected video portion (number of frames, duration, start frame time, stop frame time etc…). To save the selected portion as a new independent video,

- click the **Save** button on the command bar (Fig 108 **C**). A new thumbnail, corresponding to the new video, is displayed on the "Examination detail" screen (Fig 98).

7.13.1.1. Film preview

The **Preview** button indicated in Fig 108 **D** makes it possible to display a preview of the selected video. When the button is clicked the screen changes in the way shown in Fig 109:

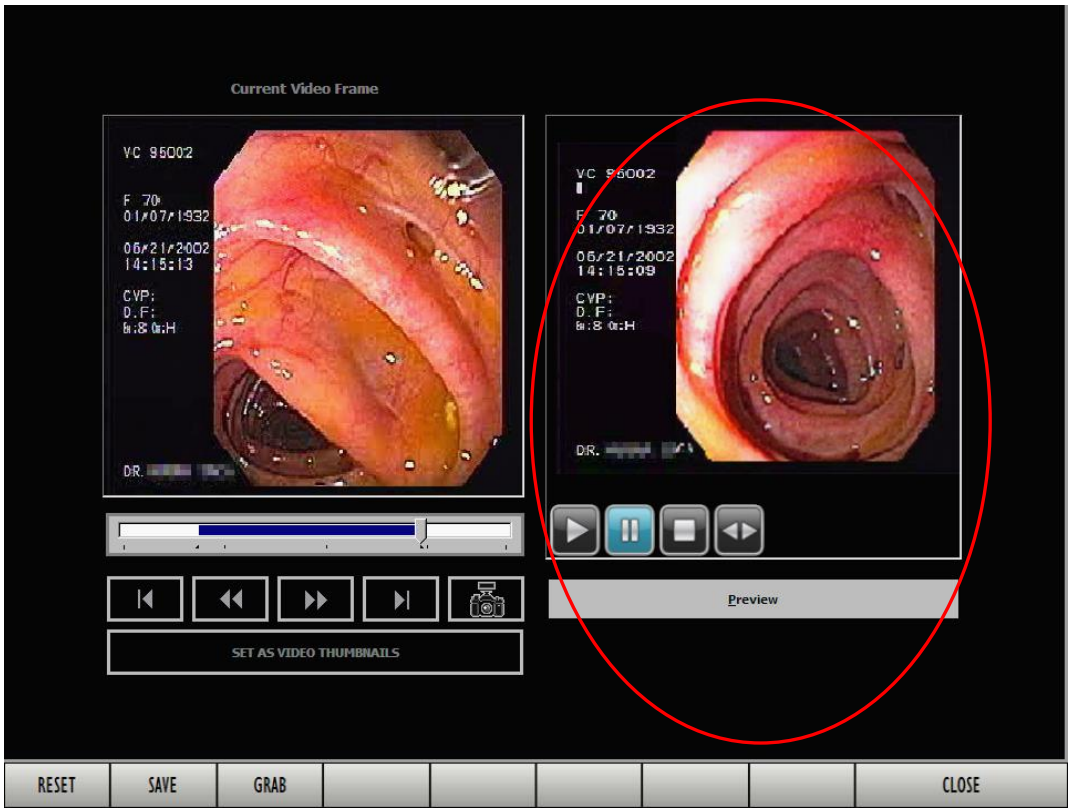


Fig 109 - Preview

The preview of the selected video portion is displayed on the right (Fig 109). Four buttons are below the "preview" area:

Use the  button to play the video preview.

Use the  button to pause the video preview.

Use the  button to stop the video preview.

Use the  button to watch the video preview frame by frame. To use this function,

- select the  button.
- Touch the video preview and move the finger horizontally.

Move the finger left to right to go forward frame by frame. Move the finger right to go backwards frame by frame.

WARNING!

This operation can be performed with the fingers only when using a "touch-screen". It is otherwise necessary to use the mouse device, moving the mouse pointer horizontally while keeping the left button clicked.

To close the video preview

- click the **Preview** button again. The screen returns this way to look as in Fig 108.

7.13.1.2. The "Trim" screen command bar

The command bar contains four buttons (Fig 110).

Fig 110 - Command bar

- Use the **Reset** button to reset all the data specified on the screen. Click this button to go back to the initial screen, prior to any selection.
- Use the **Save** button to save the selected video portion as a new independent video. The specific procedure is described in detail in paragraph 7.13.1 and in a concise way in paragraph 7.13.2.
- Use the **Grab** button to save the frame currently displayed on the left of the screen as a new independent image. The **Grab** button has the same function of the  button on the same screen. The related procedure is described in detail below Fig 101 and in a concise way in paragraph 7.13.3.
- The **Close** button closes the "Trim" screen. Click it to display the "Examination detail" screen again.

7.13.2. How to "trim" a video portion (concise procedure)

To select a video portion and save it as a new video

- access the "Examination detail" screen containing the relevant video (Fig 98).
- Click the thumbnail (on the left) corresponding to the relevant video.

The video is this way selected, it runs on the "display" area.

- Click the **Trim** button on the command bar (Fig 98 **A**). The "Trim" opens (Fig 99).
- Use the cursor or the buttons described in paragraph 7.13 (Fig 101) to display the start frame (see the example shown in Fig 104).
- Click the **Set Start Position** button (Fig 103 **A**).
- Use the cursor or the buttons described in paragraph 7.13 (Fig 101) to display the stop frame (see the example shown in Fig 106).

- Click the **Set Stop Position** button (Fig 105 **C**).

The portion corresponding to the selected video is highlighted on the "time bar" on the left (Fig 108 **A**).

- Click the **Save** button on the command bar (Fig 108 **C**).

The selected video portion is this way saved as a new independent video. A new thumbnail, corresponding to the new video, is displayed on the "Examination detail" screen (Fig 98).

7.13.3. How to grab a picture from a film (concise procedure)

To grab a frame from a film and save it as an image of a certain examination,

- access the "Examination detail" screen containing the film from which the frame must be extracted (Fig 98).
- Click, on the left of the screen, the icon corresponding to the relevant film. The film starts.
- Click the **Trim** button on the command bar (Fig 98 **A**). The "Trim" screen opens (Fig 99).
- Use either the cursor or the buttons described in paragraph 7.13 (Fig 101) to display the wanted frame.
- Click the **Grab** button on the command bar.

Otehrwise

- click the  button on the "Trim" screen. The frame currently displayed is this way saved as image.

7.14. Coordinated use of Image Bank and Clinical Forms

To display the examination information that is not immediately available on DIGISTAT® Image Bank select the DIGISTAT® Clinical Forms module. To do that

- click the corresponding icon on the lateral bar (Fig 111).

Fig 111

The examination record is this way displayed (Fig 112 shows an example).

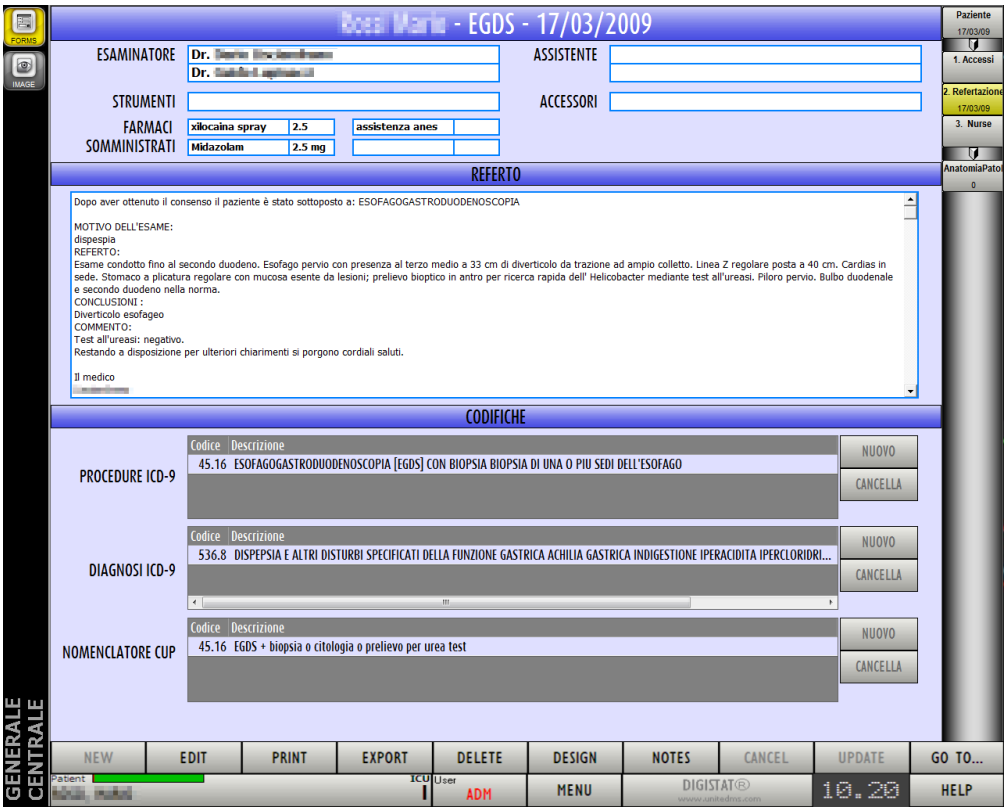


Fig 112

When DIGISTAT® Image Bank and Clinical Forms are used together some functionalities are coordinated to speed-up the procedures. That is, some of the operations performed on a module affect the screens and the functionalities of the other module. This happens mainly in two ways:

1) selecting an examination on a module automatically selects the same examination on the other module;
2) creating a new examination on a module automatically creates a new examination on the other module.

See the DIGISTAT® Clinical Forms module documentation for information aboute the module's goals and functionalities.

The functionalities described in this paragraph are active only if the DIGISTAT® Clinical Forms module is active on the DIGISTAT® configuration in use.

The screen shown in Fig 112 is an example. The DIGISTAT® Clinical Forms module is widely configurable. Its features change depending on the configuration in use.

8. Contacts

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- **Sales and products information**

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9. Residual risks

The risk management process has been actualized for the DIGISTAT® medical device according to the relevant technical regulations (EN14971, EN62304, EN62366). All the possible control measures have been defined to reduce all residual risks to the minimum level and make them this way acceptable considering the benefits brought in by the product. The total residual risk is also accettable if compared to the same benefits.

The risks listed below have been taken into consideration and reduced to the minimum level possible. Yet, given the inherent nature of the "risk" concept, it is not possible to completely remove them. It is therefore necessary, according to the regulations, let the users know each and every possible risk (even though remote).

- Impossibility in using the system or some of its functionalities, which can cause delays and/or errors in the therapeutic/diagnostic actions.
- Slowdown of device performance, which can cause delays and/or errors in the therapeutic/diagnostic actions.
- Circulation of users' and/or patients' sensible data.
- Unauthorized actions carried out by users, which can cause errors in the therapeutic/diagnostic actions and in the attribution of responsibilities of these actions.
- Wrong data insertion and display, which can cause errors in the therapeutic/diagnostic actions.
- Display of either partial or hard-to-read information, which can cause delays and/or errors in the therapeutic/diagnostic actions.
- Attribution of patient data to the wrong patient (patient exchange), which can cause errors in the therapeutic/diagnostic actions.
- Accidental data deletion, resulting in loss of data, which can cause delays and/or errors in the therapeutic/diagnostic actions.

RISKS RELATING TO THE HARDWARE PLATFORM IN USE

- Electric shock for the patient and/or the operator, which can cause injury and/or death for the patient/operator.
- Hardware components overheating, that can cause injury for the patient/operator.
- Infection contraction for the patient/operator.

Appendix: end-user license agreement

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

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

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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.

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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.

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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.

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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

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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