Alaris™ Infusion Central v1.2 User Manual

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ascom

BD

Alaris™ Infusion Central Version 1.2

Alaris™ Infusion Central is a configuration of the Digistat® Product.

Digistat® is manufactured by Ascom UMS srl (Ascom UMS hereafter)

http://www.ascom.com

The Product is $C \in$ marked according to 93/42/EEC ("Medical Device Directive") amended by the 2007/47/EC.

Ascom UMS is certified according to EN ISO 13485:2016 with the following scope: "Product and specification development, manufacturing management, marketing, sales, production, installation and servicing of information, communication and workflow software solutions for healthcare including integration with medical devices and patient related information systems".

Distribution

Alaris™ Infusion Central is exclusively distributed by BD. See page 162 for the distributors list.

Software license

The Product must be used only after obtaining a valid license from Ascom UMS or the Distributor.

Trademarks and copyrights

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Introduction

Aims of this manual

The effort that has gone into creating this manual provides all the necessary information to guarantee safe and correct use of the Alaris™ Infusion Central system (Alaris Infusion Central hereafter), and to identify the manufacturer.

Furthermore this document 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 Alaris Infusion Central requires a basic knowledge of information systems concepts and procedures. The comprehension of this manual requires the same knowledge.

Remember that Alaris Infusion Central must only be used by authorized and trained users.

Conventions

This documentation uses the following conventions:

- Names of buttons, menu commands, options, icons, fields are formatted in **bold**.
- Names/headings of screens and windows are quoted with "Double quotation marks".
- Programming code is formatted in `Courier`.
- ➢ indicates an action the user must perform to carry out a specific operation.

Warnings, cautions and notes

Product-specific warnings and cautions, covered in the applicable sections of this software User Manual, provide information needed to safely and effectively use the Alaris Infusion Central software .

WARNING: A WARNING is an alert to a potential hazard which could result in serious personal injury and/or product damage if proper procedures are not followed.

CAUTION: *A CAUTION is an alert to a potential hazard which could result in minor personal injury and/or product damage if proper procedures are not followed.*

NOTE: Notes contain supplementary information or emphasize a point or procedure.

The following symbols are used in the About box:

▲▲▲	Indicates the manufacturer's name and address
📖	Attention, consult accompanying documents

Digistat intended use

NOTE: Alaris Infusion Central (hereafter "Product") is a configuration of the Digistat product.

The Digistat software 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.

- Digistat 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.
- Digistat provides automated, secondary visual and audible announciation and display of acquired data, events, current status and operating conditions of connected clinical devices and systems on designated display device(s). Digistat can also be configured to forward data and information about events, statuses and operating conditions to the Ascom messaging system.
- Digistat supports the improvement of nursing workflows related to the management of alarms from the connected clinical devices and systems.
- Digistat supports the documentation of the prescribed therapy, its preparation and its delivery.
- Digistat supports the recording, validation and display of vital signs charting based on the acquired data and information.
- Digistat 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.

Digistat does not replace or replicate the original display of data and alarms for the connected devices and systems and does not control, monitor or alter the behavior of these connected devices and systems, or their associated alarms.

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

Digistat is intended for use by trained healthcare professionals within a healthcare facility 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, Digistat provides specific functions and interfaces intended for use by non-professional users in remote locations for non-clinical purposes for display of information, reports, charts and statistics, without the ability to add, change or delete any information or data.

Digistat is stand-alone software that is installed on servers and computers, which must comply with the technical hardware and software specifications provided with Digistat.

Safety Advisories

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

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 they have checked the correctness and completeness of the data present in the document.

When entering patient-related data, the user has responsibility to verify that the patient identity, healthcare organization department/care unit and bed information displayed in the Product are correct. This verification is of utmost importance in cases of critical interventions such as, for instance, in drug administration.

The healthcare organization is responsible for identifying and implementing 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 user. These procedures depend on the configuration of the Product and the method of use preferred by the healthcare organization.

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

The Product does not provide primary notification of alarms; it is not intended to 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 with the Product are located in the patient area or are connected to equipment present in the patient area, then the healthcare organization has responsibility to ensure that the whole combination complies with the international standard IEC 60601-1 and any additional requirement established by the local regulations.

Use of the Product must be granted, by means of specific configuration of user accounts 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 stand-alone software that runs on standard computers and/or standard mobile devices connected to the healthcare organization local network. The healthcare organization is responsible for adequately protecting computers, devices and local network against cyberattacks.

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

"Off-label" use of the Product

Every use of the Product outside what is explicitly stated in "Digistat 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 is explicitly stated by the "Digistat Intended use".

WARNING: The Product is not a primary distributed alarm system.

Patient population

The Product is a software application and is not in contact with the patient.
The patient population and patient conditions are established by the medical devices and systems with which the product is connected.
In addition the following limitations apply:

- Patient weight between 0.1kg and 250kg
- Patient height between 15cm and 250cm

Healthcare organization responsibilities

Ascom UMS declines all responsibility for the consequences on the safety and efficiency of the Product 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 healthcare organization where the Product is used is drawn to their responsibilities, in view of the local legislation in force on the matter of occupational safety and health and any additional local site safety.

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

WARNING: The Product is designed taking into account the requirements and best practices present in the IEC 80001 standard and its collateral technical reports. In particular, the IEC/TR 80001-2-5 has great relevance for the Product. As clarified in the IEC 80001 series part of the necessary activities and risk control measures are under the control and responsibility of the healthcare organization. Refer to the standard and its collaterals to identify the necessary activities and risk control measures; in particular refer to the current valid version of the following documents:
IEC 80001-1
IEC/TR 80001-2-1
IEC/TR 80001-2-2
IEC/TR 80001-2-3
IEC/TR 80001-2-4
IEC/TR 80001-2-5

Manufacturer's responsibility

Ascom UMS is responsible for the Product's safety, reliability and performance only if:

- Installation and configuration were performed by personnel trained and authorized by Ascom UMS;
- Use and maintenance comply with the instructions provided in the Product documentation (including this User Manual);
- Configurations, changes and maintenance are only performed by personnel formed and authorized by Ascom UMS ;
- The Product's usage environment complies with applicable safety instructions and applicable regulations;
- The environment in which the Product is used (including computers, equipment, electrical connections and so on) complies with applicable local regulations.

WARNING: Should the Product be part of a "medical electrical system" through electrical and functional connection with medical devices, the healthcare organization is in charge of the required safety verification and acceptance tests, even in the case that Ascom UMS /Distributors performed in whole or in part the necessary connections.

Product traceability

In order to ensure device traceability and on-site corrective actions, in compliance EN 13485 and MDD 93/42/EEC, the owner is requested 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 are found in the Product label ("About box" displayed within the Product – see page 60).

In case of doubts or questions about Product identification, contact Ascom UMS/ Distributor technical support (for contacts see page 162).

Post-market surveillance

The $C \epsilon$ marked device is subject to a post-market surveillance - which Ascom UMS and Distributor provide for each marketed copy - concerning actual and potential risks, either for the patient or for the User, during the life cycle of the Product.

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 health of the patient or user, or to environmental safety, the user must immediately give notice to either Ascom UMS or Distributor.

On receipt of user feedback, Ascom UMS /Distributor will immediately start the review and verification process and perform the necessary corrective actions.

Product life

The life time of the Product does not depend on wear or other factors that could compromise safety. It is influenced by the obsolescence of the software environment, such as the Operating System (OS) and .NET Framework, and is therefore set to 5 years from the release date of the Product version (in the About box).

Software and hardware specifications

WARNING: The Product must only be installed by trained authorized personnel. This includes Ascom UMS/Distributor staff and any other person specifically trained and explicitly authorized by Ascom UMS/Distributor. Without an explicit, direct authorization from Ascom UMS/Distributor, the healthcare organization staff is not authorized to perform installation procedures and/or to modify the Product configuration.

WARNING: The Product must only be used by trained personnel. The Product cannot be used without having a proper training, performed by Ascom UMS/Distributor staff.

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

According to the IEC 60601-1 standard, in case an electrical equipment is positioned close to the bed, the use of "Medical grade" devices is required. In these places medical grade PANEL PCs are normally used. If explicitly requested, Ascom UMS can provide information on some suitable devices of this kind.

WARNING: A supported Portable Document Format (PDF) reader must be installed on the workstation in order to display the online help. See sections "Stand-alone Workstation" and "Client Workstations" for the Software Requirements of Stand alone & Client workstations.

WARNING: The User Manual is a PDF file, version 1.5, compatible with Acrobat 6.x or higher. Alaris Infusion Central was tested with Acrobat Reader 10. The hospital organization may use a different version of Acrobat Reader; it is part of the verification of the installed Product to assure that the help system is working correctly.

Stand-alone Workstation (Stand-alone Edition)

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 (1920 x 1080 suggested)
- Mouse or other compatible device. Touch screen recommended.
- Ethernet interface 100 Mb/s (or higher)

Operating System

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

System software

- Microsoft SQL Server 2012 (every version except Express)
- Microsoft SQL Server 2014 (every version including Express)
- Microsoft SQL Server 2016
- Microsoft Framework .NET 4.5
- Adobe Acrobat Reader version 10

Client Workstation (Enterprise Edition)

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 (1920 x 1080 suggested)
- Mouse or other compatible device. Touch screen recommended.
- Ethernet interface 100 Mb/s (or higher)

Operating System

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

System Software

- Microsoft Framework .NET 4.5
- Adobe Acrobat Reader version 10

Server (Enterprise Edition or HL7 Gateway Edition)

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
- Ethernet interface 100 Mb/s (or higher). 1 GB recommended.

Operating System

- Microsoft Corporation Windows Server 2012 R2
- Microsoft Corporation Windows Server 2016

System Software

- Microsoft SQL Server 2012 (every version except Express)
- Microsoft SQL Server 2014 (every version including Express)
- Microsoft SQL Server 2016
- Microsoft Framework.NET 4.5

Warnings

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

WARNING: To correctly use Alaris Infusion Central, the Microsoft Windows display scaling must be set to 100%. Different settings may prevent the Product from starting or cause malfunctions in the way Alaris Infusion Central is visually displayed. Refer to the Microsoft Windows documentation for instructions on the display scaling settings.

WARNING: The minimum vertical resolution of 768 is supported only if Alaris Infusion Central is configured to run in full-screen mode or if the Windows taskbar is in Auto-hide mode.

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.

WARNING: For the Alaris Infusion Central workstations, the responsible organization shall implement a date/time synchronisation mechanism to a time reference source.

WARNING: **To use the Product together with any software other than that specified in this document may compromise the safety, effectiveness and design controls of the Product. Such use may result in an increased risk to users and patients. It is mandatory to consult an authorized technician before using any software with the Product other than that specified in this document.**
If the hardware on which the Product runs is a stand-alone computer, the user shall not install any other software (utilities or applications) on the computer. We suggest that you apply a permission policy that prevents users from performing procedures such as the installation of new software.

WARNING: **We recommend that you disable the access to the Internet on the client workstations on which the Product is used. Alternatively, the healthcare organization shall implement the necessary security measures in order to guarantee adequate protection from cyberattacks and installation of unauthorized applications.**

Firewall and Antivirus

To protect the Alaris Infusion Central system from possible cyberattacks, it is necessary that:

- Windows Firewall is active both on the client PCs and the server;
- An antivirus/antimalware software is installed and regularly updated both on the client PCs and the server.

The healthcare organization shall ensure that these methods of protection are activated. Ascom UMS tested the Product with F-SECURE antivirus but, considering the strategies and policies already existing in the hospital, the actual choice of the antivirus software is left to the Responsible Organization. Ascom UMS cannot ensure that the Alaris Infusion Central system is compatible with every antivirus or antivirus configuration.

WARNING: **Some incompatibilities have been reported between parts of Alaris Infusion Central and the Kaspersky Anti-Virus. The solution to these incompatibilities required the definition of specific rules in the antivirus itself.**

WARNING: **We suggest that you keep open only the Transmission Control Protocol (TCP) and User Datagram Protocol (UDP) ports actually needed. These may change according to the system configuration. Refer to technical support for more information.**

Further recommended precautions for cyber protection

In order to further protect the Product from possible cyberattacks, it is highly recommended that you:

- Plan and implement the "Hardening" of the IT infrastructure including the IT platform that represents the runtime environment for the Product,
- Implement an Intrusion Detection and Prevention System (IDPS),
- Perform a Penetration Test and, if any weakness is detected, perform all the required actions to mitigate the risk of cyber-intrusion,
- Dispose of all the devices that are no longer updatable,
- Plan and perform a periodic verification of the integrity of files and configurations,
- Implement a demilitarised zone (DMZ) solution for web servers.

Local network features

This section lists the features of the local network on which Alaris Infusion Central is installed in order to guarantee the full functionality of the system.

- Alaris Infusion Central uses a Transmission Control Protocol/Internet Protocol (TCP/IP) traffic protocol.
- The Local Area network (LAN) must not be congested and/or full-loaded.
- Alaris Infusion Central requires at least a 100 Mbps LAN available to the end user. 1 Gbps backbones are preferred.
- 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 between these subnets.
- It is recommended that you adopt redundancy strategies to ensure network service availability in case of malfunction.
- It is recommended that you schedule the maintenance calendar together with the Distributors for the Distributors to efficiently support the healthcare organization in managing the possible disservices caused by maintenance activities.

WARNING: If the network does not match the requested features, Alaris Infusion Central performance gradually deteriorates until timeout errors occur. The system may finally switch to "Recovery" mode.

WARNING: In case a Wi-Fi network is in use, given the possible intermittence of the Wi-Fi 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.

WARNING: In order to encrypt the data transmitted over wireless networks, it is recommended that you adopt the highest security protocol available; in any case no less than WPA2.

Alaris Infusion Central impact on the hospital network

This section provides information on the traffic generated by Alaris Infusion Central on the network in order to make it possible for the structure to evaluate and analyze the risks related to the introduction of Alaris Infusion Central.

The bandwidth used by an Alaris Infusion Central system depends on many different factors. The most important are:

- Number of workstations,
- Number of workstations configured as central stations
- Number and kind of Alaris™ Gateway Workstation (AGW) and connected pumps (data acquisition),
- Interfaces with external systems,
- Alaris Infusion Central configuration and mode of use.

For example, to provide an idea of the actual bandwidth occupancy, we will consider the case of AGWs having 5 infusion pumps connected. In this scenario the average bandwidth occupancy to the server is 1.5KB per second for every AGW. For each workstation, the traffic is 0.6KB for each AGW connected.

If you have 100 AGWs (each one with 5 pumps infusing) and 2 workstations, each one of them displaying 50 AGWs, the total average bandwidth occupancy is 210 KB per second.

Before starting

Installation and maintenance warnings

The following warnings provide important information on the correct installation and maintenance procedures of the Alaris Infusion Central Product. They must be strictly respected.

WARNING: **Installation, maintenance and repairs shall be performed in compliance with Ascom UMS procedures and guidelines only by Ascom UMS/Distributor technicians or personnel trained and authorized by Ascom UMS/Distributor.**

WARNING: **We recommend that the healthcare organization using the Product stipulates a maintenance contract with Ascom UMS or an authorized Distributor to make sure that the installed Product version is always the most recent and up-to-date.**

Alaris Infusion Central **must be installed and configured by specifically trained and authorized personnel**. This includes Ascom UMS /Distributors staff and any other person specifically trained and authorized by Ascom UMS/Distributors. Similarly, maintenance interventions and repairs on Alaris Infusion Central must be performed according to the Ascom UMS/Distributors guidelines only by Ascom UMS /Distributors personnel or other person specifically trained and authorized by Ascom UMS/Distributors.

- Use third-party devices recommended by Ascom UMS /Distributors.

- Only trained and authorized personnel can install third-party devices. Incorrect installation of the third-party devices can create a risk of injury to the patient and/or operators.

- Carefully observe the manufacturer's instructions for the installation of third-party hardware.

- Make provision for regular maintenance of the system according to the instructions present in this manual and those provided with the third-party devices.

- The healthcare organization is responsible for selecting the equipment that is suitable for the environment in which they are installed and used. The healthcare organization should consider, among the others, electrical safety, Electromagnetic Compatibility (EMC), radio signal interferences, disinfection and cleaning. Attention shall be payed to devices installed in the patient area.

General precautions and warnings

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

WARNING: The healthcare organization shall ensure that maintenance of the Product and any third-party device is implemented as requested to guarantee safety and efficiency and reduce the risk of malfunctioning and the occurrence of possible hazards to the patient and user.

WARNING: The Product shall be used only by trained and authorized clinicians.

Privacy policy

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

NOTE: 'Personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Special attention shall be dedicated to the data defined in "EU general data protection regulation 2016/679 (GDPR)" as "Special categories of personal data".

Special categories of personal data:
(…) Personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and (…) genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.

The healthcare organization must ensure that the use of the Product is in line with the requirements of the applicable regulation on privacy and personal data protection, specifically with respect to the management of aforementioned information.

The Product manages the following personal data:

- First name and surname
- Birthdate
- Sex
- Patient code
- Admission date
- Discharge date
- Patient weight
- Patient height

The Product can be configured to automatically hide this data on every application screen.

To do that, in the "Alaris Infusion Central configuration application", set the system option named **Privacy Mode** to **True**. (See the "Alaris Infusion Central configuration manual" for the detailed procedure.) Its default value is "true".

If the **Privacy Mode** option is set to **True**, the following cases are possible:

- With no user logged in, no patient information is displayed.
- With a user logged in, and the user does not have a specific permission, no patient information is displayed.
- With a user logged in, and the user does have a specific permission, patient information is displayed .

The option can be applied to a single workstation (that is, different workstations can be configured differently).

WARNING: Read the following precautions carefully and strictly observe them.

- The workstations must not be left unattended and accessible during work sessions. It is recommended that you log out when leaving a workstation. See "Accessing the system" for the "log out" procedure.

- Personal data saved in the system, such 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 it updated.

- The user is advised against the frequent use of the lock function (see page 40). Automatic log out protects the system from unauthorized access.

WARNING: Personal data can be present inside some reports produced by the Product. The healthcare organization must manage these documents according to the current standards on privacy and personal data protection.

WARNING: Client workstations do not store patient data on disk. Patient data is stored only in a database and database storage depends on the healthcare organization's procedures and choices (for example, physical machine, Storage Area Network (SAN), virtualization environment). Patient data shall be treated according to all the current standards on privacy and personal data protection.

WARNING: Patient data is not stored in proprietary files. The only place in which patient data is stored is in a database.

WARNING: In some circumstances personal data are transmitted in non-encrypted format and using a connection which is not physically secure. An example of this kind of transmission are the HL7 communications. The Responsible Organization (RO) is responsible for providing adequate security measures to comply with the local privacy laws and regulations.

WARNING: We suggest that you configure the database server so that the Alaris Infusion Central database is encrypted on the disk. To enable this option the SQL Server Enterprise Edition is required, and during its installation you must enable the Transparent Data Encryption (TDE) option.

WARNING: The healthcare organization is in charge of providing basic training regarding privacy issues such as basic principles, rules, regulations, responsibilities and sanctions in the specific work environment.
Ascom UMS/Distributor shall provide specialized training on the best use of the Product relating to privacy issues (such as database anonymization, privacy mode, user permissions and so on)

WARNING: The healthcare organization shall produce and keep the following documentation:

1) Updated list of the system administrators and maintenance personnel,
2) Signed forms of assignment and the certifications of attendance at the training courses,
3) Register of credentials, permissions and privileges granted to the users,
4) Updated list of the Product users.

WARNING: The healthcare organization shall implement, test and certify the mechanism of automatic deactivation of inactive users after a certain period.

WARNING: The healthcare organization shall codify, implement and document a procedure for the periodic verification of belonging to the role of system administrator and maintenance personnel.

WARNING: The healthcare organization shall carry out audits and checks on the correct behavior of the operators.

WARNING: Databases containing patient data/sensible information cannot leave the healthcare facility without being encrypted/obfuscated.

User credentials features and use

This section explains the user's Alaris Infusion Central 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 (username and password) to access the system. 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.

- Each user account shall be linked with a specific person. The use of generic roles (for instance, "ADMIN" or "NURSE") must be avoided. In other words, for traceability reasons, every user account must only be used by one user.

- Each user is characterized by a profile enabling them to access only the functionality that is relevant for their 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 "Alaris Infusion Central 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 and so on).

- The password is given by the system administrator at user account creation time. It must be changed by the user on first login (see page 59 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 the "Alaris Infusion Central configuration manual" for the configuration of this feature.

- User credentials must also be disabled if the user is not qualified any more for those credentials (it is the case, for instance, if a user is transferred to another department or structure). A system administrator can manually enable/disable a user login. The procedure is described in the "Alaris Infusion Central configuration manual".

The following information is restricted to system administrators:

The password must match a regular expression defined in the Alaris Infusion Central configuration (default is ^........* that is 8 characters). The password is assigned by the system administrator when a new account is created for a user. The system administrator can force the user to change the password to a personal one on first login. The password expires after a certain (configurable) period. After that period, the user must change the password. It is also possible (in the configuration settings) to avoid password expiration.

See the "Alaris Infusion Central configuration manual" for detailed information on user account creation procedures and password configuration.

System administrators

Staff of Ascom UMS /Distributors, when performing installation, updates and/or technical support may have access to and deal with personal sensible data stored in the Alaris Infusion Central database and act as "System Administrator" for the Product.

Ascom UMS /Distributors adopt procedures and working instructions complying with the current privacy regulation ("General Data Protection Regulation - EU 2016/679").

The healthcare organization should evaluate, among the others, the following technical measures:

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

System logs

Alaris Infusion Central 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 the "Alaris Infusion Central configuration manual" for the detailed configuration procedures.

Forensic log

A subset of the aforementioned system logs, defined according to the policy of each specific healthcare structure using the Product as "clinically relevant" or "clinically useful", can be sent to an external system (either SQL database or Syslog) to be stored according to the healthcare structure requirements and rules.

Backup policy

WARNING: It is recommended that you regularly back up the Product database

The healthcare organization using Alaris Infusion Central 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 organization 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 organization must protect these devices from unauthorized access. When these devices are not used any more, they must be either definitively deleted or destroyed.

Out-of-order procedure

WARNING: It is recommended that you perform the backup of the image of the hard drive of the workstations, so in case of replacement of the hardware, you can quickly restore the operating environment.

WARNING: Maintenance procedures and repairs shall be performed in compliance with Ascom UMS/Distributor procedures and guidelines and only by Ascom UMS/Distributor technicians or personnel specifically trained and explicitly authorized by Ascom UMS/Distributor.

This section describes the policy suggested by Ascom UMS in case an Alaris Infusion Central workstation becomes out of order. The goal of the procedure described here is to minimize the time required to replace the out-of-order workstation with one properly working.

In an "Enterprise" type of configuration it is a good rule, for this purpose, to have at your disposal, as substitute equipment, an additional PC on which Alaris Infusion Central is already installed.

In case an Alaris Infusion Central workstation is out of order, the substitute equipment can promptly replace the Alaris Infusion Central workstation.

Always remember that Alaris Infusion Central must only be installed by trained authorized personnel. This includes the staff of Ascom UMS/Distributor 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 Alaris Infusion Central configuration.

WARNING: The replacement of an out-of-order 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 domain with the workstation and displaying data that do not belong to the relevant patients/beds.

In case an Alaris Infusion Central workstation must be deactivated and replaced, the hospital staff must promptly call the Distributor and request the execution of this task.

We suggest the hospital management (or anyone who is in charge) defines for this purpose a clear, univocal operating procedure and shares this procedure with all the staff members involved.

The substitution equipment shall have all the necessary applications already installed (OS, firewall, antivirus, Remove Desktop Protocol and so on) and Alaris Infusion Central already installed, but disabled (that is, not executable by a user without the assistance of an Ascom UMS/Distributor technician).

In case an Alaris Infusion Central workstation is out of order, the substitution equipment availability ensures the minimization of restoration times.

In case an Alaris Infusion Central workstation is out of order, we suggest that you adopt the following procedure if a "substitution equipment" is available.

1) Hospital staff replace the out-of-order PC with the "substitution equipment"
2) Hospital staff call Distributor and requests the "substitution equipment" activation
3) Distributor staff disable the out-of-order workstation and correctly configure the "substitution equipment"
4) Out-of-order PC is repaired and prepared as "substitution equipment"

The instructions on how to enable/disable and replace an Alaris Infusion Central workstation, restricted to system administrators, are in the "Alaris Infusion Central configuration manual".

Reconfiguration/substitution of network equipment

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

Preventive maintenance

WARNING: Maintenance procedures and repairs shall be performed in compliance with Ascom UMS/Distributor procedures and guidelines and only by Ascom UMS/Distributor technicians or personnel specifically trained and explicitly authorized by Ascom UMS/Distributor.

We suggest that you perform the maintenance of the Product at least once a year. Maintenance frequency is a function of system complexity. In case of high complexity, we suggest that you perform maintenance more often, typically up to twice a year.

See the "Alaris Infusion Central configuration manual" for the maintenance checklist.

Compatible devices

Alaris Infusion Central supports the following versions of the AGW:

- v1.1.3
- v1.1.5
- v1.1.6
- v1.2.0
- v1.3.1
- v1.3.2
- v1.3.3
- v1.6.0 (ACE 1.1, ACE 1.1.1, ACE 2.0)
- v1.6.1 (ACE 1.1, ACE 1.1.1, ACE 2.0)

WARNING: ACE 2.0 support is partial.

There are two possible connection options:

- **AGW**: Supported through the AGW
- **Serial**: Supported via serial connection (direct cable and/or connection via remote port server)

The pumps that are supported by Alaris Infusion Central are listed in the following table.

Pump	AGW 1.1.3	AGW 1.1.5	AGW 1.1.6	AGW 1.2.0	AGW 1.3.x *	AGW 1.6.x	RS232 Serial
Alaris CC	X	X	X	X	X	For the list of supported pumps and any existing limitation refer to the ACE documentation	X
Alaris CC Guardrails	X	X	X	X	X		X
Alaris CC Plus & Plus Guardrails	X	X	X	X	X		X
Alaris GH	X	X	X	X	X		X
Alaris GH Guardrails	X	X	X	X	X		X
Alaris GH Plus & Plus Guardrails	X	X	X	X	X		X
Alaris PK	X	X	X	X	X		X
Alaris TIVA	X	X	X	X	X		X
Alaris Enteral	X	X	X	X	X		X
Alaris GP	X**	X**	X**	X**	X**		-
Alaris GP Guardrails	X**	X**	X**	X**	X**		-

Alaris GP Plus & Plus Guardrails	X**	X**	X**	X**	X**		-
Alaris VP Plus Guardrails	-	-	X	X	X		-
Alaris GW	X	X	X	X	X		X
Alaris SE	X	X	X	X	X		X
Alaris SE Guardrails	X	X	X	X	X		X
CME BG 5x5	-	-	-	-	-	-	X
CME BG 323	-	-	-	-	-	-	X

X = Supported; X** = Supported without bolus information; - = Not supported;

* = Support 3rd edition pumps

WARNING: Alaris Infusion Central is not designed to verify that connected devices are working correctly but rather to acquire and catalog clinical data.

WARNING: Disconnecting a device while it is running causes the interruption of data acquisition on Alaris Infusion Central. Device data that is lost during the disconnection period are not recovered by Alaris Infusion Central after reconnection.

WARNING: Never disable the alarm notification on the medical devices unless explicitly allowed by the medical device manufacturer documentation and the procedure of the healthcare organization.

WARNING: The correctness of parameters currently displayed by Alaris Infusion Central must always be double-checked on the original medical device that generated them.

WARNING: Never disable the audio on the workstations on which Alaris Infusion Central is running.

WARNING: For reasons that are outside the control of the software, such as the way the actual physical devices are installed/cabled, delays are possible between the alarm generation and the actual alarm display.

WARNING: If the generic Alaris^{TM} Driver is in use, you must wait at least ten seconds after disconnecting an infusion pump before connecting another.

WARNING: The update of data displayed on-screen caused by device connection, power off, disconnection and change of status depends on the time required by the device itself to communicate the changes. This time depends on various factors. Among them is the device type and type of connection. For some devices, there are conditions in which the delay in communicating changes might be important. Since they might change depending on device configuration and operational conditions, it is not possible to provide an indication of the delays for all the possible devices.

WARNING: The drivers used to read the data from the connected medical devices have a reading-cycle of less than 3 seconds (that is, all the data from the devices is read every 3 seconds at maximum). However, there are devices that communicate the information less frequently (5-10 seconds interval). Refer to the specific driver documentation for details on the reading-cycle.
In a test environment installed and configured as indicated in the "Alaris Infusion Central configuration manual", as soon as a driver detects an alarm, it takes a maximum of 1 second to display on the user interface.

WARNING: In case of electrical black-out, it takes a few minutes for the system to be fully operative again and therefore generate alarm notifications (usually this time is less than 3 minutes, however it depends on the configuration of the computers used).

System unavailability

If during startup there are problems connecting to the server the system provides a specific information message.

The connection problem is often automatically solved in a short time. If it does not happen, you must contact technical support (see page 162 for the contacts list).

There are extreme cases, rare but possible, in which it is not possible to use the Alaris Infusion Central software for reasons of force majeure .

It is responsibility of the healthcare organization using Alaris Infusion Central 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 the system availability as soon as possible (backup policy is part of this management. See page 28 for more information on the backup policy).

WARNING: It is responsibility of the healthcare organization using Alaris Infusion Central to define an emergency procedure to put into effect in case of system unavailability.

Ascom UMS/Distributors offer full support for the definition of the above-mentioned procedure.

See page 162 for the contacts list.

Alaris Infusion Central

Introduction to Alaris Infusion Central

Alaris Infusion Central manages procedures linked to the administration of drugs and solutions through infusion systems.

Alaris Infusion Central comprises three integrated modules:

- INFUSION continuously reads all data generated by syringes and infusion pumps, thus enabling you to monitor "infusion and drug history": infused volumes, administered drugs and doses, recorded pressure and other infusion events.
- FLUID BALANCE gives the patient's precise fluid balance by recording daily fluid input and output. INFUSION module automatically transmits all administered volumes to FLUID BALANCE.
- THE INVASIVE DEVICE MANAGEMENT makes it possible to display and manage the patient devices and the related nursing activities.

The Alaris Infusion Central software is not designed to change infusion pump usage, neither is it a centralized alarm system. Information is collected for documentation only. Alaris Infusion Central is not meant to either substitute or alter the usual infusion pump checks.

WARNING: Alaris Infusion Central is a "Central station" type of Product. It shall not be used on computers permanently located at the bedside because a workstation cannot be assigned to a specific bed.

Touch screen

Alaris Infusion Central can run both on touch and non-touch workstations. The same procedures can be performed using both fingers and a mouse device. In this manual a "mouse" terminology is used (with terms such 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/functionality, it is 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 scroll bars	Scroll
Zoom in	Two fingers tap

Launching Alaris Infusion Central

To launch Alaris Infusion Central:

> ➢ Double-click the desktop icon (Fig 1).

Fig 1

The following splash-screen appears while the system is loading.
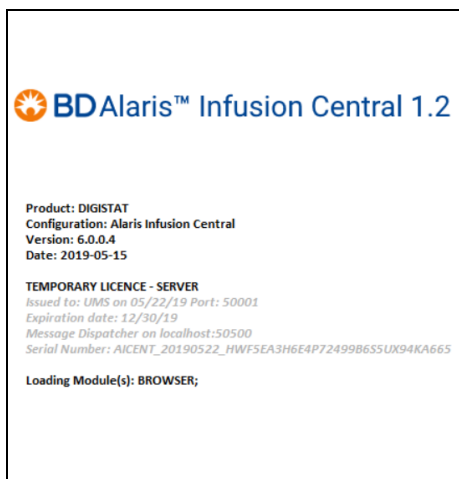
Fig 2

User Interface

In the Alaris Infusion Central Interface you can distinguish three areas: CONTROL BAR (Fig 3 **A**), LATERAL BAR (Fig 3 **B**) and DATA AREA (Fig 3 **C**).
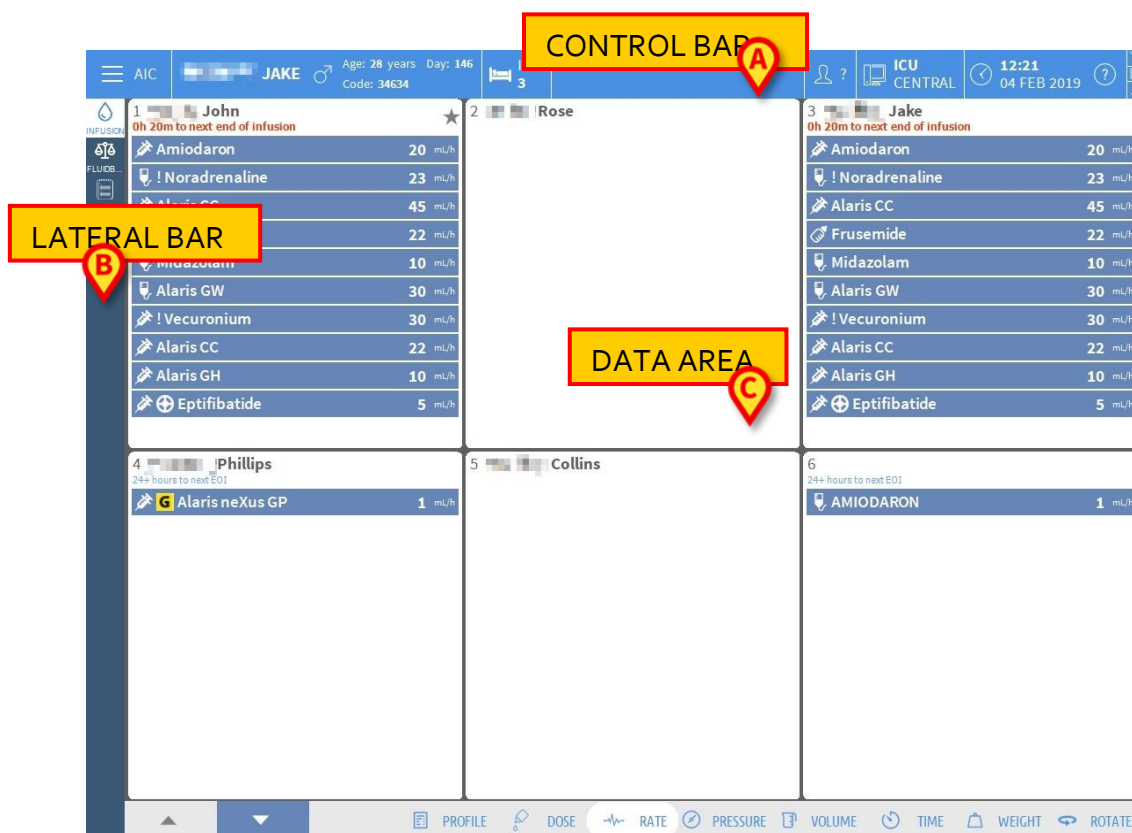
Fig 3

The "Control Bar" is described in Alaris Infusion Central "Control Bar".

NOTE: in Alaris Infusion Central, "Control Bar" is the name of the application that manages data relating to patients, users and other. In this manual, the term "Control Bar" refers to the application and its user interface (Fig 3 A).

The "Data Area" contains the active screens and functionality.

The lateral bar displays the three icons corresponding to the modules briefly described in "Introduction to Alaris Infusion Central": INFUSION, FLUID BALANCE and INVASIVE DEVICE MANAGEMENT.

Fig 4

Selecting a module

To select and activate a specific module,

> ➢ Click the corresponding icon on the "lateral bar".

The icon is highlighted. The module's functionality is displayed in the Data Area. It is possible to select a specific module only after the user logs in (see next section).

Accessing the system

The Alaris Infusion Central system must be accessed by entering the username and password ("Log in" procedure).

For this reason, at the beginning of every work session, you must click the **USER** button (Fig 5 **A**). The following page is displayed.

Fig 5

To access the system:

> ➢ Enter your **USERNAME** (Fig 5 **B**).
> ➢ Enter your **PASSWORD** (Fig 5 **C**).
> ➢ Click **OK** (Fig 5 **D**).

The user is logged in.

To cancel the operation

➢ Click **CANCEL** (Fig 5 **E**).

WARNING: 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 system.

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

After accessing the system, an acronym corresponding to the logged in user appears on the **USER** button on "Control Bar" (the acronym is **ADM** in Fig 6 **A**).

Fig 6

WARNING: The user whose credentials are displayed on the USER button is responsible for all the actions performed on Alaris Infusion Central. It is recommended that you log out before leaving the Alaris Infusion Central 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 back in, click the **USER** button again. The page shown in Fig 5 is redisplayed.

WARNING: Alaris Infusion Central does not support the Microsoft Windows "switch user" functionality. This means that, for instance, if:
1 - User 1 launches Alaris Infusion Central,
2 - User 1 switches to User 2 without logging out User 1,
3 - User 2 attempts to launch Alaris Infusion Central again,
then the second Alaris Infusion Central instance cannot be launched because the first one is still running.

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 you must, when logging in and before clicking **OK**:

➢ Click **LOCK** on the "Login" page command bar (Fig 7 **A**)

Fig 7

If the user account is locked, a padlock icon is displayed on the user icon (Fig 8).

Fig 8

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

Recent users

The **RECENT** area of the "Login" page (Fig 9 **A**) displays the names of users who have accessed the system recently.
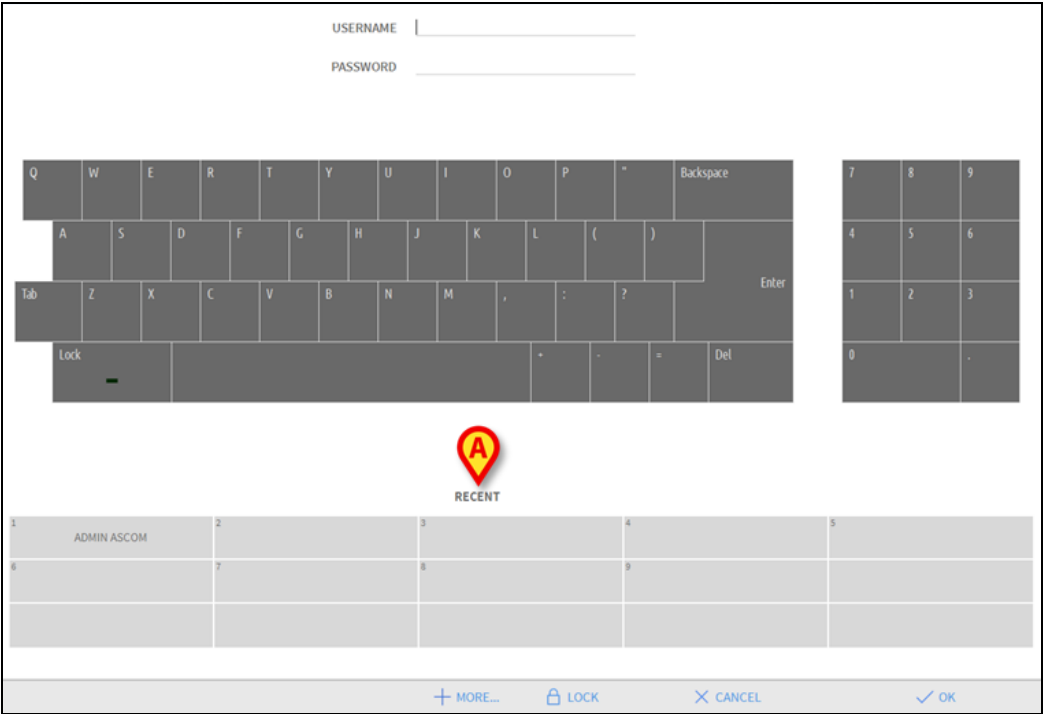
Fig 9

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.

How to use the "User List"

The **MORE** button on the command bar (Fig 10) makes it possible to display the complete list of possible users.

+ MORE...   **🔒 LOCK**   **✕ CANCEL**   **✓ OK**

Fig 10

To display the "User List":

> ➢ Click **MORE**.

The following window is displayed (Fig 11).
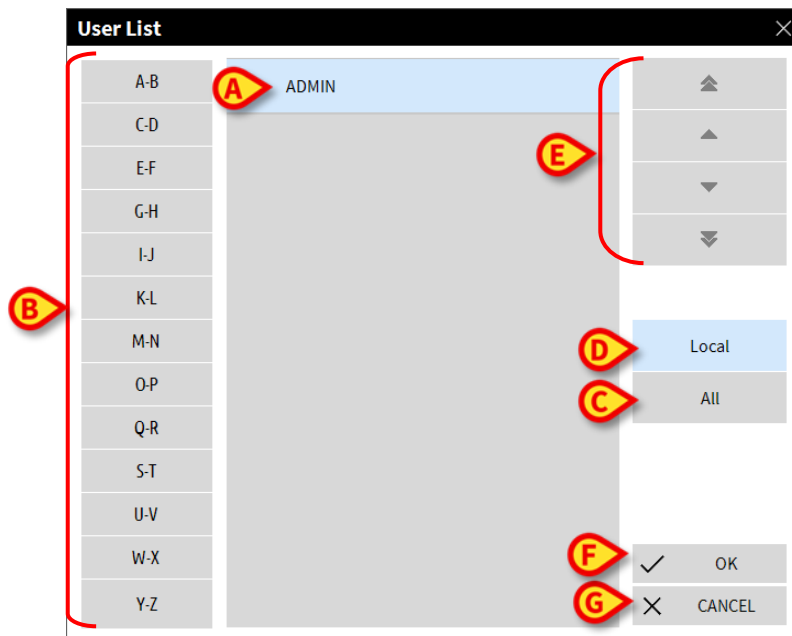
Fig 11

The window shown in Fig 11 can be used as an index book enabling you to search for and select a user in the list of all possible users. The central part of the window shows the names of possible users, in alphabetical order (Fig 11 **A**). The letters on the left side of the window (Fig 11 **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 users whose names begin with the letters C or D.

Use the **All** button (Fig 11 **C**) to see the list of all possible users.

Use the **Local** button (Fig 11 **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 11 **E**) to scroll up and down the list of users.

To select a user:

➢ Click the name of the user.

The name is highlighted, then:

➢ Click **OK** (Fig 11 **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 5 **A**).

Use the **CANCEL** button (Fig 11 **G**) to cancel the operation and close the "User List" window without selecting any user.

Alaris Infusion Central "Control Bar"

The main features and functionality of the Alaris Infusion Central "Control Bar" are briefly described in this section. A more detailed explanation is provided in the subsequent sections.

Fig 12

- The **PATIENT** button (Fig 12 **A**) contains, after a patient is selected, the patient's name and, if the patient has been admitted, their bed number.
- The **USER** button (Fig 12 **B**) shows the name of the user connected. See Fig 6.
- Use the **MENU** button (Fig 12 **C**) to open the following window (Fig 13).
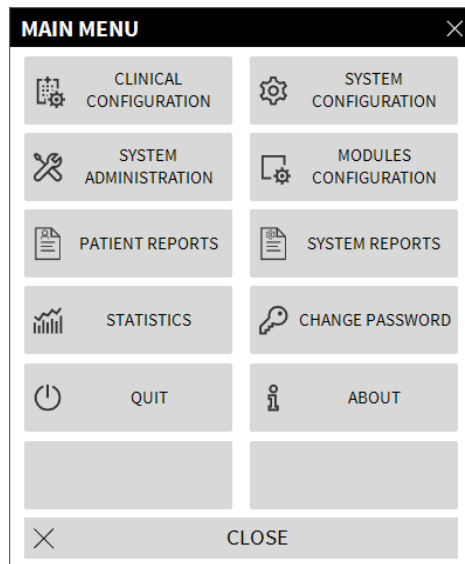
Fig 13

The buttons contained in this window provide access to functionality that is described later.

- The area indicated in Fig 12 **D** signals if there are either alarms or warnings occurring on one of the devices connected to the patient. This feature is explained on page 131.
- The display indicated in Fig 12 **E** shows the current date and time.
- Use the **HELP** button (Fig 12 **F**) to access the online documentation available.
- The small buttons highlighted in Fig 12 **G** are used to:
    1. Minimize the Alaris Infusion Central window (⬜ button);
    2. Select the full screen display mode (⬜ button);
    3. Select the window display mode (⬜ button).

NOTE: These three buttons are visible only if enabled by configuration.

How to read the **PATIENT** button

Patient selected

When a patient is selected, the **PATIENT** button displays the name of the selected patient (Fig 14). See page 66 for the patient selection procedure.

Fig 14

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 they are admitted (Fig 15).

Fig 15

The department name and the bed number are blue if the patient belongs to the workstation domain (Fig 15).

The department name and the bed number are highlighted yellow if the patient does not belong to the workstation domain (Fig 16 - the workstation domain is defined by configuration).

Fig 16

NOTE: Every workstation is associated in the configuration settings with a set of "beds" (domain). The user is enabled to perform certain actions only on the patients that are admitted to a bed belonging to this set. The red colour in the PATIENT button advises the user that the patient selected is not in this set.

Fig 17

The signal **Other** (Fig 17) appears when, at patient admission time, in the bed selection window, the user specified that the patient is not in one of the configured departments. See page 66 for the patient admission procedure.

WARNING: When entering patient-related data, you must double-check that the patient identity, hospitalization department and bed displayed in Alaris Infusion Central match with the actual ones. This is extremely important in case of critical actions such as, for instance, drug administration.

Help

Click ⬤ (**Help**) on "Control Bar" (Fig 12 **E**) to access the available online documentation. The page shown in Fig 18 is displayed.

Fig 18

The command bar (Fig 19) offers some navigation possibilities.

Fig 19

- The **OPEN** button opens 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 online help.

MAIN MENU

The **MENU** button on "Control Bar" (Fig 20) opens a menu containing several options (Fig 21).

Fig 20
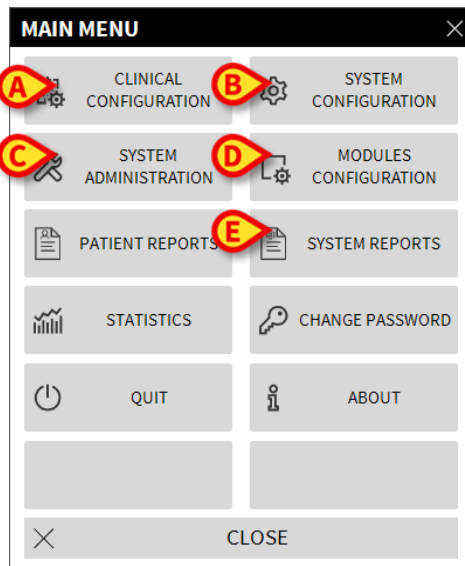
Fig 21

Each button on the menu accesses a specific set of functions. The procedures associated with the following buttons relate to system configuration and are therefore restricted to the system administrators.

- **CLINICAL CONFIGURATION** - (Fig 21 **A**)

- **SYSTEM CONFIGURATION** - (Fig 21 **B**)

- **SYSTEM ADMINISTRATION** - (Fig 21 **C**)

- **MODULES CONFIGURATION** - (Fig 21 **D**)

- **SYSTEM REPORTS** - (Fig 21 **E**)

Contact your system administrator for the procedures associated with these buttons. The other buttons, indicated in Fig 22, make it possible to access features and functions that some users can perform (according to their permission level). These are described in the following sections.
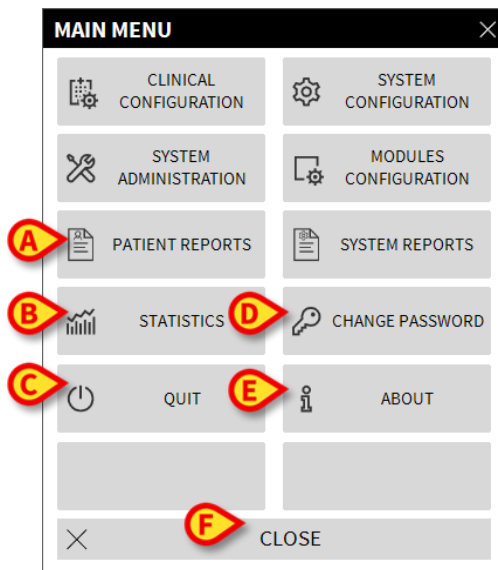
Fig 22

- **PATIENT REPORTS** - (Fig 22 **A,** see page 49)

- **STATISTICS** - (Fig 22 **B,** see page 56)

- **QUIT** - (Fig 22 **C,** see page 61)

- **CHANGE PASSWORD** - (Fig 22 **D,** see page 59)

- **ABOUT** - (Fig 22 **E,** see page 60)

- **CLOSE** (Fig 22 **F**) closes the "MAIN MENU".

PATIENT REPORTS

The **PATIENT REPORTS** button (Fig 22 **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.

Print reports

Use the buttons on the "PATIENT REPORTS" menu to access the system's print functionality.

NOTE: The type and the contents of some reports are customizable. 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 corresponding report is displayed (Fig 23 shows an example).

Fig 23

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 23 **A**) to go to the beginning and end of the document.

B - Use the ⟨ and ⟩ buttons (Fig 23 **B**) to go to the previous or next page.

C - The display 1/1 (Fig 23 **C**) indicates the current page number.

D - The **ADDONS** button (Fig 23 **D**) activates the possible additional print management options (in this configuration the **Watermarks** option is available - see "Watermark" for a description of these options).

E - The **FIND** button (Fig 23 **E**) makes it possible to search the displayed document. See "Find" for more instructions.

F - The **ZOOM** button (on which, by default, the **100%** size is selected - Fig 23 **F**) makes it possible to change the display mode. See "Zoom" for more instructions.

G - Use the **PRINT** button (Fig 23 **G**) to print the report.

H - Use the **PRINT...** button (Fig 23 **H**) to display the "PRINTERS" window (Fig 29). See "Print" for a description of this window and the related procedures.

I - Use the **EXPORT** button (Fig 23 **I**) to export the document contents to different file extensions. See "Export" for more instructions.

L - Use the **CLOSE** button to close the "Print Preview" screen.

Addons

The **ADDONS** button (Fig 23 **D**), if made available in the configuration, activates the possible additional print management options.

To display the available options:

➢ Click **ADDONS**.

A menu containing the available options is displayed.

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

Addons - Watermark

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

➢ Click **MARK**.

The following window is displayed (Fig 24).
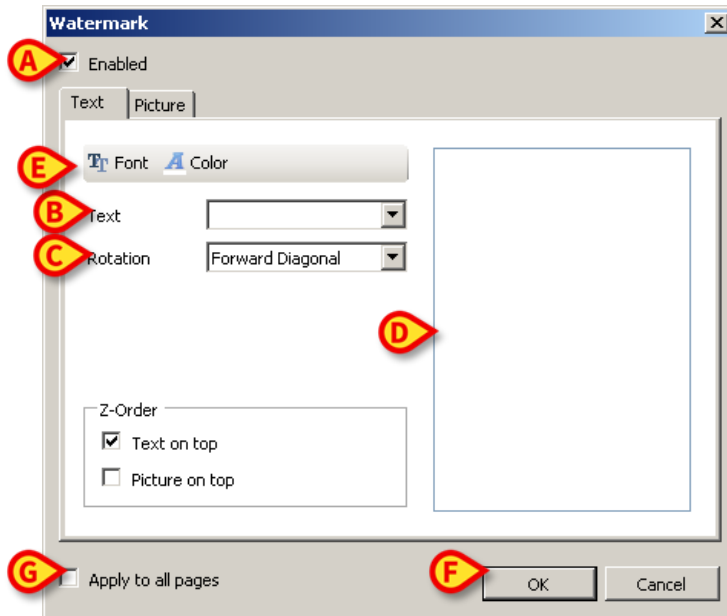
Fig 24

To add a textual watermark,

➢ Ensure that the **Enabled** checkbox is selected (Fig 24 **A**). If not, the window's contents cannot be edited.
➢ Enter the **Text** (Fig 24 **B**).
➢ Use **Rotation** (Fig 24 **C**) to specify the watermark orientation (diagonal, horizontal, vertical).

A print preview is displayed in the area indicated in Fig 24 **D**.

➢ Use the buttons indicated in Fig 24 **E** to select the watermark font and color.
➢ Click **OK** (Fig 24 **F**).

The text is inserted as watermark.

If the "**Apply to all pages**" checkbox is selected (Fig 24 **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 25 **A**.

The following window is displayed (Fig 25).
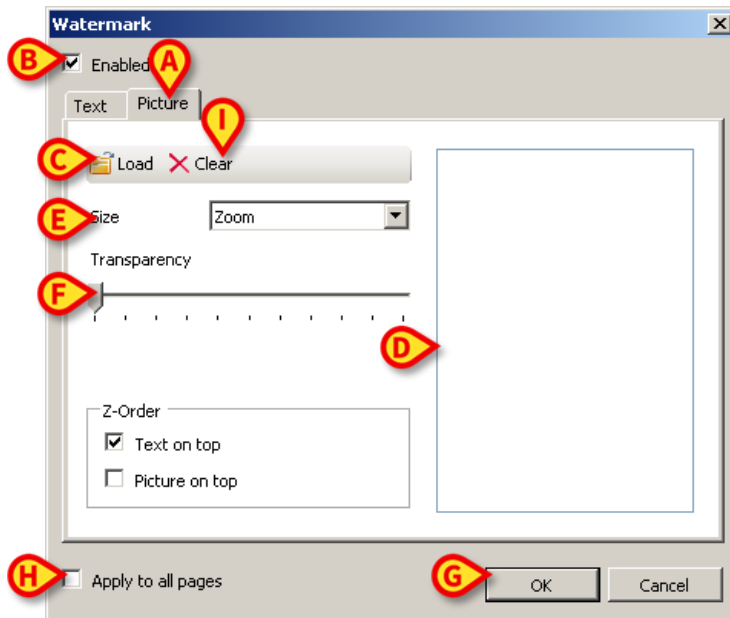
Fig 25

Follow these steps to insert an image as watermark:

➢ Ensure that the **Enabled** checkbox is selected (Fig 25 **B**). If not, the window's contents cannot be edited.
➢ Click **Load** (Fig 25 **C**).

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

➢ Search for and select the image to be uploaded.

The image is displayed in the area indicated in Fig 25 **D**.

➢ Use the **Size** drop-down menu to set the size of the image (Fig 25 **E**).
➢ Use the **Transparency** cursor to set the transparency level of the watermark image (Fig 25 **F** - maximum transparency when the cursor is on the left).
➢ Click **OK** (Fig 25 **G**).

The watermark image is inserted.

If the **Apply to all pages** checkbox is selected (Fig 25 **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 **Clear** (Fig 25 **I**).

Find

The **FIND** button (Fig 23 **E**) makes it possible to search the print report currently displayed.

To search the print report:

> ➢ Click **FIND**.

The following window opens (Fig 26).

Fig 26

> ➢ In the window, insert the text to be found (Fig 27 **A**).

Fig 27

> ➢ Click ▷ (Fig 27 **B**).

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

> ➢ Click ▷ again to search for the other instances of the text.

Zoom

The **ZOOM** button (on which, by default, the **100%** size is selected - Fig 23 **F**) is a zoom, making it possible to change the display size and mode.

To change the display mode:

> ➢ click **ZOOM**.

The following menu is displayed (Fig 28).
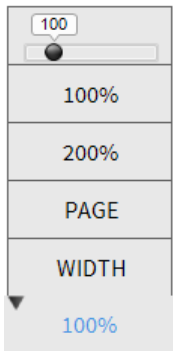
Fig 28

> ➢ Click the required option on the menu.

The page is resized accordingly. The mode currently selected is indicated on the button.

The following options are available:
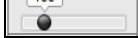
WIDTH displays the page using the full screen width;

PAGE displays the whole page;

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

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

The area contains a cursor that is used to zoom in or out 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.

Print...

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

> ➢ Click **PRINT...** (Fig 23 **H**) to display the "PRINTERS" window (Fig 29)
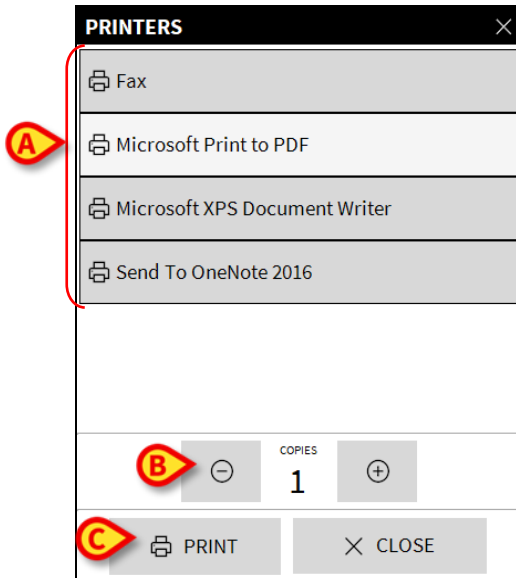
Fig 29

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

> ➢ Click the required option on the menu to select the printer (Fig 29 **A**).

> ➢ Use the ⊖ (one less copy) and the ⊕ (one more copy) buttons to specify the number of copies (Fig 29 **B**).

> ➢ Click **PRINT** (Fig 29 **C**) to print the report.

Export

The **EXPORT** button (Fig 23 **I**), if enabled in the configuration settings, exports 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 required extension.

The document is exported to the selected extension type.

STATISTICS

The **STATISTICS** button on the "MAIN MENU" (Fig 30) makes it possible to access the system's statistical calculation tools.
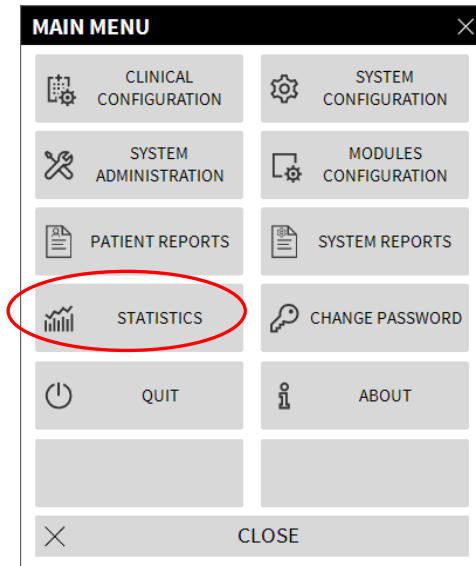
Fig 30

The button opens another menu (Fig 31) 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 restricted to the system administrators. See the specific technical documentation for a description.

The "Query Assistant" tool, which is accessible to users having specific permissions, is described in the next section.
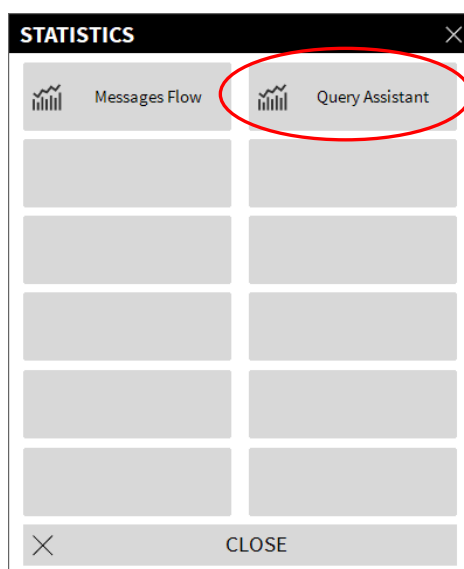
Fig 31

Query Assistant

The **Query Assistant** button (Fig 31) makes it possible to create, save and execute queries on the Alaris Infusion Central database (Fig 32).
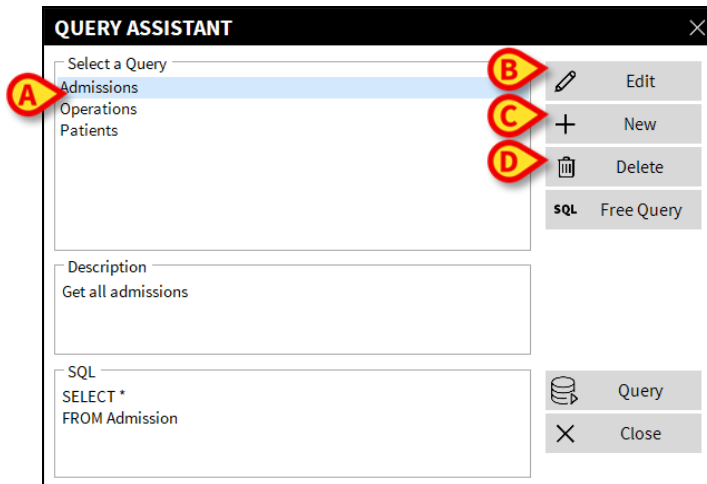
Fig 32

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 32 **A**).
To run a query:

> ➢ Click the corresponding name on the list.

The name is highlighted (Fig 33 **A**).

A textual description of the query is displayed in the "Description" area (Fig 33 **B**).
The "SQL" area (indicated in Fig 33 **C**) displays the content of the query in Structured Query Language (SQL).
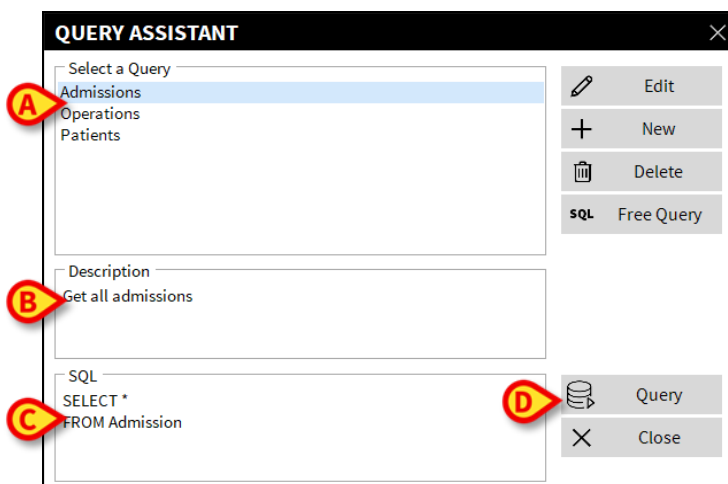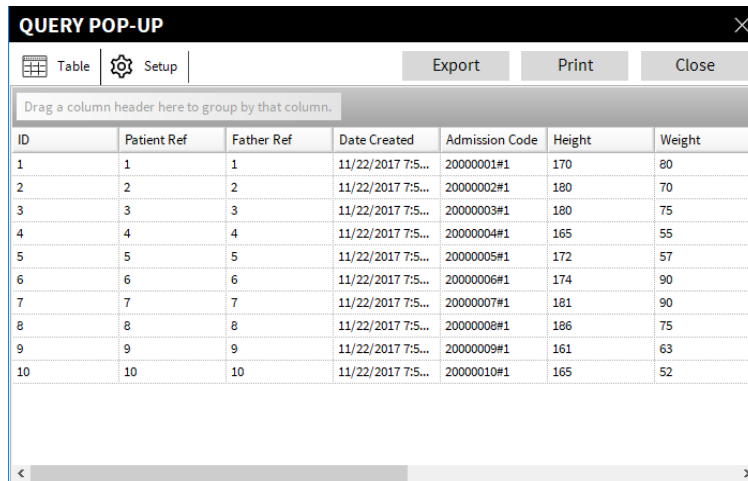
Fig 33

To run the query

> ➢ click **QUERY** (Fig 33 **D** - bottom right).

The results are displayed in a new window, in a table (Fig 34).

Fig 34

The **Edit** button on the right of the "QUERY ASSISTANT" window (Fig 32 **B**) makes it possible to edit an existing query.

The **New** button on the right of the "QUERY ASSISTANT" window (Fig 32 **C**) creates a new query.

The **Delete** button on the right of the "QUERY ASSISTANT" window (Fig 32 **D**) cancels an existing query.

CHANGE PASSWORD

The **CHANGE PASSWORD** button on the Alaris Infusion Central "MAIN MENU" (Fig 35 **A**) opens a window making it possible to change the password of the user currently logged in to the system.
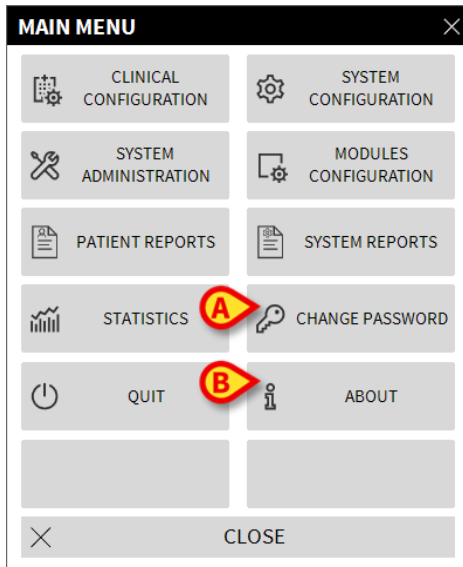
Fig 35

To change the user password:

➢ Click **CHANGE PASSWORD** (Fig 35 A). The "CHANGE PASSWORD" window opens.
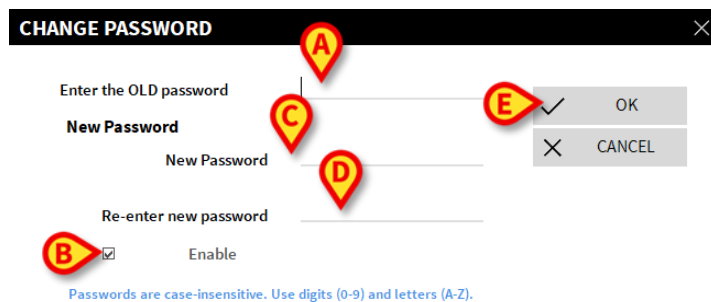
Fig 36

➢ Type the current password in the "**Enter the OLD password**" field (Fig 36 **A**).
➢ Verify that the **Enable** checkbox (Fig 36 **B**) is selected.
➢ Type the **New Password** (Fig 36 **C**).
➢ **Re-enter new password** (Fig 36 **D**).
➢ Click **OK** (Fig 36 **E**).

NOTE: Passwords are not sensitive to uppercase and lowercase. Passwords can only be formed by numbers (0 to 9) and letters (A-Z).

ABOUT Alaris Infusion Central

The **ABOUT** button on the Alaris Infusion Central "MAIN MENU" (Fig 35 **B**) displays a window containing information on the Alaris Infusion Central version installed and the related licenses (Fig 37).

Fig 37

QUIT Alaris Infusion Central

The **QUIT** button on the Alaris Infusion Central "MAIN MENU" (Fig 39 **A**) makes it possible to exit the Alaris Infusion Central system.

To quit Alaris Infusion Central

➢ Click **MENU** on "Control Bar" (Fig 38).

Fig 38

The Alaris Infusion Central "MAIN MENU" opens (Fig 39).
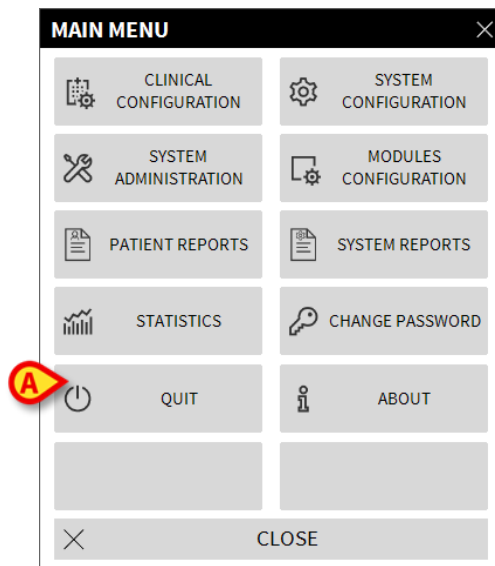
Fig 39

➢ Click **QUIT** (Fig 39 **A**).

Another menu is displayed (Fig 40).
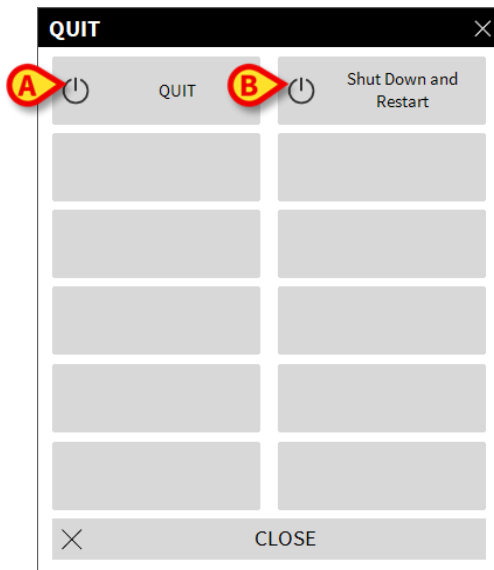
Fig 40

> ➢ Click **QUIT** again (Fig 40 **A**).

A confirmation is requested (Fig 41).
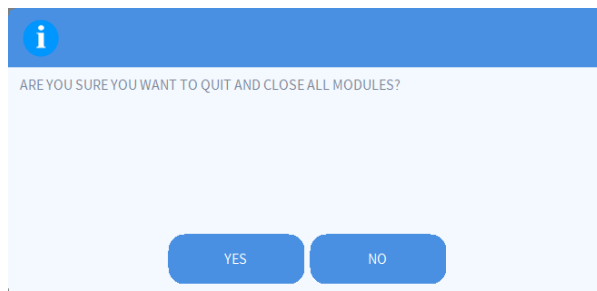
Fig 41

> ➢ Click **YES** to exit Alaris Infusion Central.

Use the **Shut Down and Restart** (Fig 40 **B**) button to quit Alaris Infusion Central and restart the workstation.

NOTE: A user must have a specific permissions level to exit Alaris Infusion Central.

Night and day mode

The Alaris Infusion Central system's brightness and sound volume settings automatically change for the night. A lower brightness and sound volume are set during night-time. Night and Day times (start and end) are configured by system administrators. Also, system administrators are in charge of setting brightness and volume at the appropriate values for day/night. It is possible to check night/day sound and brightness. To do that:

> Click the **MENU** button on "Control Bar" (Fig 42).

Fig 42

The "MAIN MENU" is displayed (Fig 43).
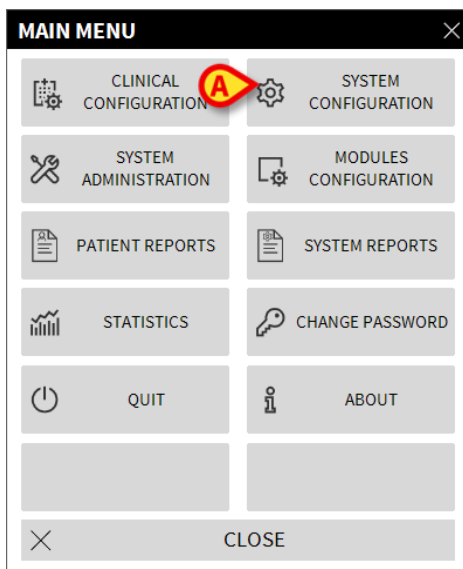
Fig 43

> Click **SYSTEM CONFIGURATION** (Fig 43 **A**).

The following menu opens (Fig 44).
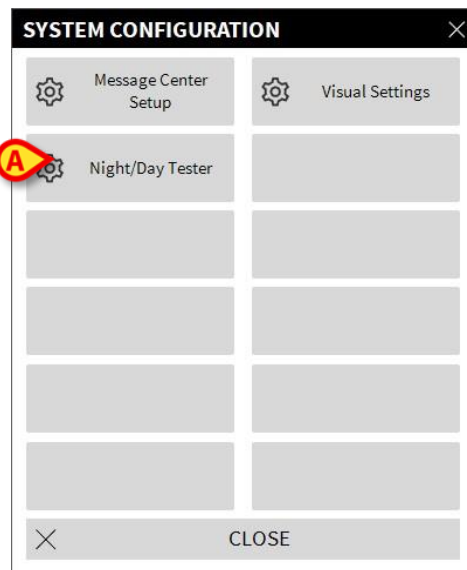
Fig 44

> ➢ Click **Night/Day Tester** (Fig 44 **A**).

The following window opens (Fig 45), making it possible to check night and day mode.
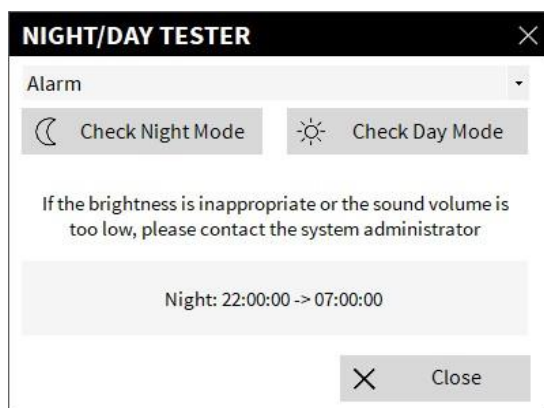
Fig 45

> ➢ Select the kind of notification to be tested from the drop-down menu
> (Fig 46 **A**).
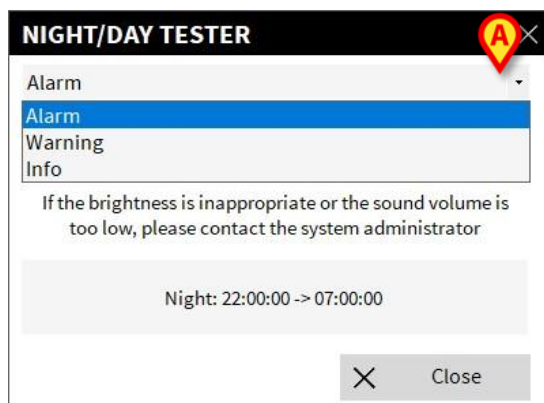
Fig 46

➢ Click **Check Night Mode** and **Check Day Mode** to play the corresponding sound and set the corresponding brightness.

In case brightness and/or sound are inappropriate, contact system administrators to correct them.

WARNING: It is recommended that you perform this procedure at least once in every work shift.

Patient selection

This section describes the patient search, selection and management procedures.

Admitted Patients

To display the data for a specific admitted patient, you must select that patient. When a patient is selected, the data displayed on-screen refer to them. There are two ways to select an already admitted patient:

1) Click their **Bed area** in the INFUSION module "Ward station". The "Patient Station" screen is displayed and the patient is automatically selected. See page 105 for this procedure.

2) Use the procedure described in this chapter.

To access this functionality, on any Alaris Infusion Central screen

> ➤ Click the **Choose patient** on "Control Bar" (hereafter **PATIENT** button. Fig 47).

Fig 47

The screen shown in Fig 48 opens.

Fig 48

This screen displays all the patients that are part of the workstation's domain. The numbered buttons represent beds (Fig 49).

Fig 49

On each bed button the following information is displayed (from left):

- Bed number and name of department.
- Name of the patient occupying that bed.
- Admission date and time (below the patient name).

WARNING: In case the patient has already been discharged but is still displayed as "in bed", a "DISCHARGED PATIENT" warning is displayed on the PATIENT button. In these cases we recommend to find the reasons of this incoherency and then correct them (such as the patient is either discharged or not).

To select a patient and display their data:

➢ Click the bed button.

The patient is selected. Their name is displayed on the **PATIENT** button on "Control Bar". The "Admitted patients" screen closes. The screen previously displayed (the one on which the **PATIENT** button was clicked) is redisplayed. If no module was selected before, only the "Control Bar" is displayed, with the patient name displayed on the **PATIENT** button.

WARNING: **The patient selected is always the one whose name is displayed on the PATIENT button.**

Patients "In Transfer"

Two buttons on the command bar, indicated in Fig 48 **A,** make it possible to display either the "In bed" patients or the "In transfer" patients.

If the **IN BED** button is clicked, the screen shown in Fig 48 is displayed.

If the **IN TRANSFER** button is clicked, the screen shown in Fig 50 is displayed.

NOTE: Patients "In transfer" are only displayed if the connections between Alaris Infusion Central and the hospital patient archives are implemented.
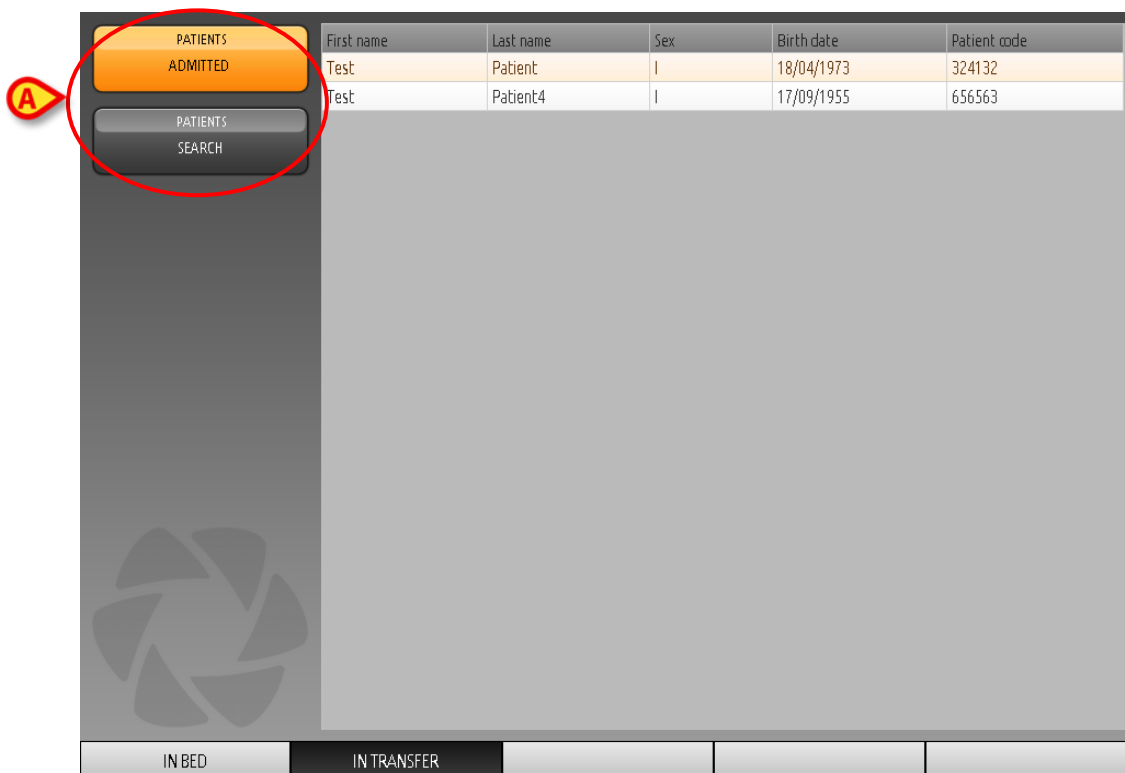
Fig 50

This screen lists all the patients "In transfer". Patients "In transfer" are the patients that have already been taken in charge by the hospital units covered by the workstation in use (that is, patients with an open admission) for which no bed is yet assigned.

Each row represents a patient, displaying first name, last name, sex, birth date and patient code.

> ➢ Double-click the row corresponding to the patient to assign them a bed.

The following window opens.

Fig 51

> ➢ Specify the destination **Location** (department) and **Bed** indicated in Fig 51.

> ➢ Click **OK**.

The patient is this way admitted to a specific location and bed. Their name is displayed on the corresponding bed button (seen in Fig 49).

Patient Search

The buttons in the upper-left corner of the screen (indicated in Fig 50 **A**) make it possible to select either the admitted patients list or the patient search functionality.

If the **PATIENTS ADMITTED** button is clicked (highlighted in yellow), the functionality described in the previous sections is activated (**IN BED** and **IN TRANSFER** patient selection).

If the **PATIENT SEARCH** button is clicked the functionality described in the following sections is activated (**PATIENT SEARCH** functionality). The screen shown in Fig 52 is displayed in this case.

Fig 52

There are two search possibilities, depending on which button is selected on the command bar (Fig 52 **A**):

1. **LOCAL SEARCH,** makes it possible to search the patients whose data are recorded in Alaris Infusion Central.
2. **REMOTE SEARCH,** makes it possible to search all the patients in the hospital patient archives.

The **ANONYMOUS** button (Fig 52 **B**) admits an anonymous patient (that is, all patient data are unknown) to one of the beds in the domain.

NOTE: REMOTE SEARCH is available only if the appropriate connection between Alaris Infusion Central and the hospital patients archive is implemented.

Local search

The search fields in the upper area make it possible to specify the relevant patient's information.

Fig 53

To search for a patient:

> ➢ Enter the data of the patient for whom you are searching in one or more fields (Fig 53 **A**).

> ➢ Click **SEARCH** (Fig 53 **B**).

The central area displays a table listing all the patients whose data match those specified (Fig 53 **C**).

If the **Location** is selected and an actual location is specified this way, the search is performed among the patients already in bed in the selected location.

> ➢ Double-click the row corresponding to a patient to select that patient.

The patient data is this way visible in the three Alaris Infusion Central modules.

> ➢ Use **CLEAR** to clear the search filters.

Remote search

If **REMOTE SEARCH** is clicked, the search is performed among all the patients in the hospital patients archives.

NOTE: REMOTE SEARCH is available only if the appropriate connection between Alaris Infusion Central and the hospital patient archive is implemented.

➢ Click **REMOTE SEARCH**.

The "REMOTE SEARCH" screen is displayed (Fig 54).

Fig 54
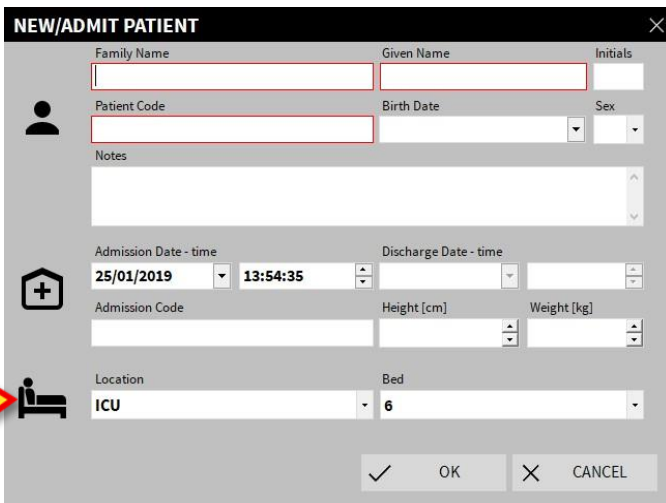
To search for a patient:

➢ Enter the data of the patient for whom you are searching in one or more fields (Fig 54 **A**).

➢ Click **SEARCH** (Fig 54 **B**).

The list of results is displayed (Fig 54 **C**).

➢ Double-click the row corresponding to the required patient.

The "NEW/ADMIT PATIENT" window is displayed (Fig 55).

Fig 55

> ➢ Specify the **Location** and **Bed** (Fig 55 **A**) and click **OK**.

The patient is admitted. Their name is displayed on one of the bed buttons on the "PATIENTS ADMITTED" screen (Fig 48).

Anonymous patient

This functionality makes it possible to admit to a bed a patient whose data are unknown.

To admit an anonymous patient:

> ➢ Click **ANONYMOUS** on the command bar (Fig 52 **B**).

A screen listing all the free beds in the domain is displayed (Fig 56).
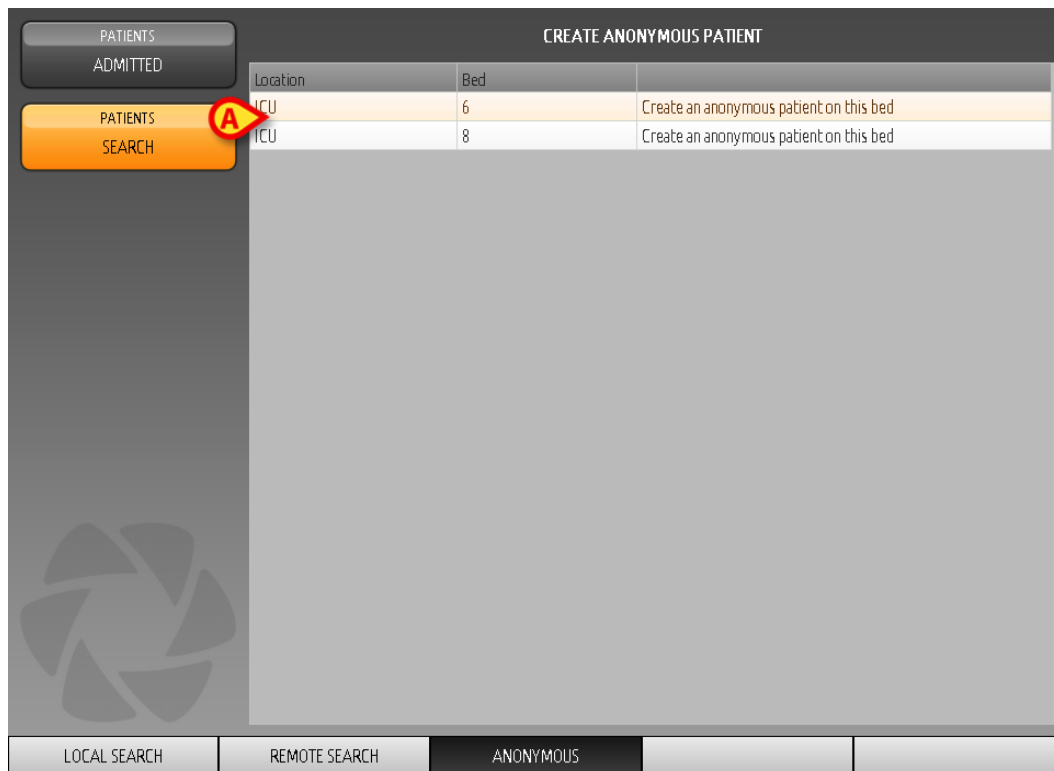
Fig 56

> ➢ Double-click the row corresponding to the bed to which you want to admit the patient (Fig 56 **A**).

User confirmation is requested.

The patient is admitted, with provisional data automatically assigned by the system (Fig 57 **A**).
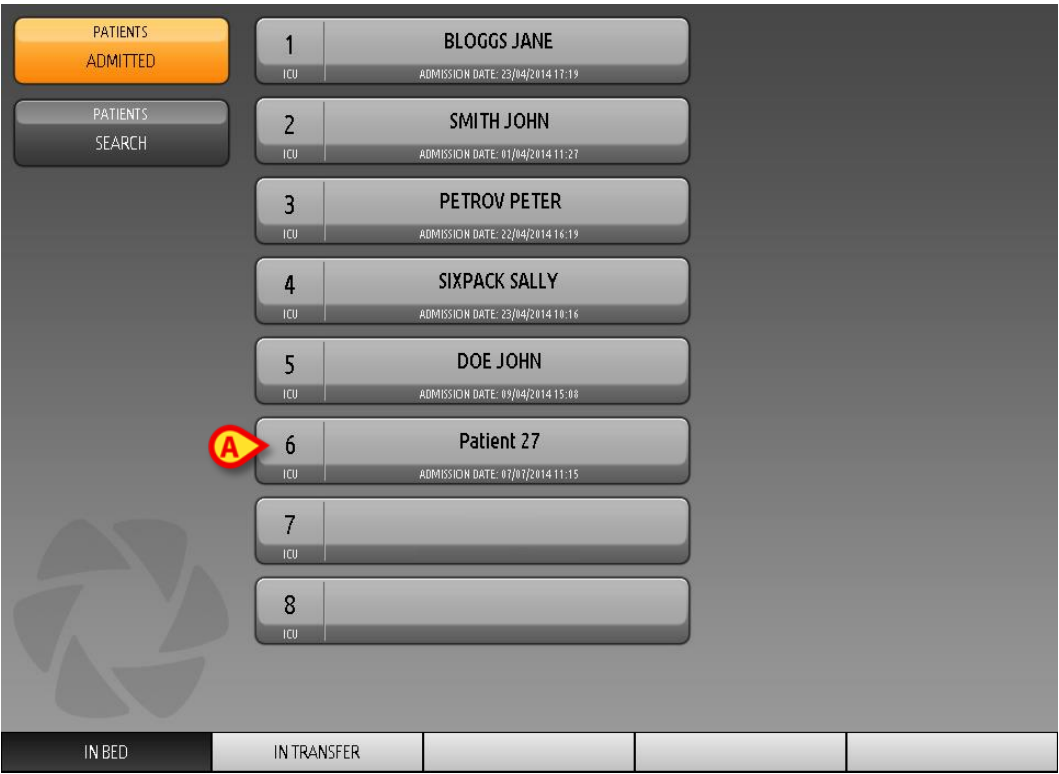
Fig 57

Patient data can be updated later using the **Edit** functionality (see page 78).

Command bar

On the command bar (Fig 58), there are four buttons making it possible to perform different procedures.

Fig 58

These are:

1) **NEW/ADMIT** (Fig 58 **A**) – This button makes it possible to enter a new patient in the database (see page 77 for the detailed procedure). This button is only available when the "PATIENTS ADMITTED" screen is selected (see Fig 50 **A**).

2) **EDIT** (Fig 58 **B**) – This button makes it possible to edit the patient's data (see page 78 for the detailed procedure). This button is only available when the "PATIENTS ADMITTED" screen is selected (see Fig 50 **A**).

3) The **NONE** button (Fig 58 **C**) deselects a patient when they are selected. After clicking **NONE**, the name of the previously selected patient disappears from the **PATIENT** button (see Fig 47).

4) The **CLOSE** button (Fig 58 **D**) closes the search page. The screen previously displayed is redisplayed. That is, the one displayed before clicking the **PATIENT** button.

New patient creation and admission

If the system is connected to the hospital patients archive, the patient can be selected and admitted using the procedures described on pages 68 and 72 (depending on the configuration in use). If the patient is not found in the hospital patients archive, you can create it in the Alaris Infusion Central local database using the procedure described in this section.

> Click **NEW/ADMIT** on the command bar (Fig 59).

Fig 59

The following window opens.

Fig 60

> Enter the new patient's data.

The red-circled fields are mandatory (Fig 60 **A**).

> Specify the destination **Location** and **Bed** as indicated in Fig 60 **B**.

> Click **OK** to confirm.

EDIT

The **EDIT** button (Fig 61) makes it possible to edit the data of a patient whose data already exist in the database.

Fig 61

The patient data can be edited only after the patient is selected. See the previous sections for the patient search and selection procedures. The "edit" procedures always refer to the patient whose name is displayed on the **PATIENT** button on "Control Bar" (Fig 62).

Fig 62

To edit the patient's data:

> ➢ Select the patient whose data must be edited.

> ➢ Click **EDIT**.

A menu containing five options opens (Fig 63).
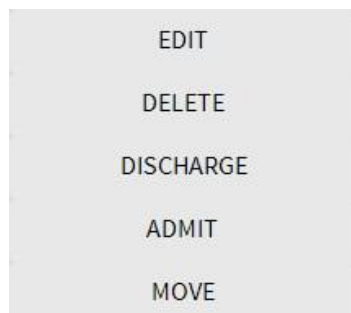
Fig 63

Each option makes it possible to perform a different operation. These are described in the following sections.

EDIT

The **EDIT** button makes it possible to edit the data of a selected patient.

To edit a patient's data:

> ➢ Select the patient.

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

> ➢ Click **EDIT** on the command bar.

The following menu is displayed (Fig 64).
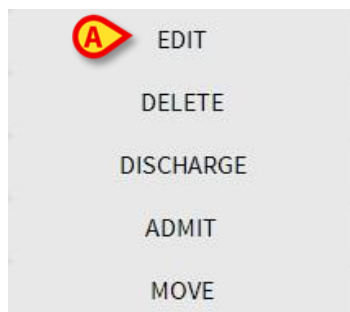
Fig 64

> ➢ Click **EDIT** (Fig 64 A).

A window containing the patient's data is displayed (Fig 65).
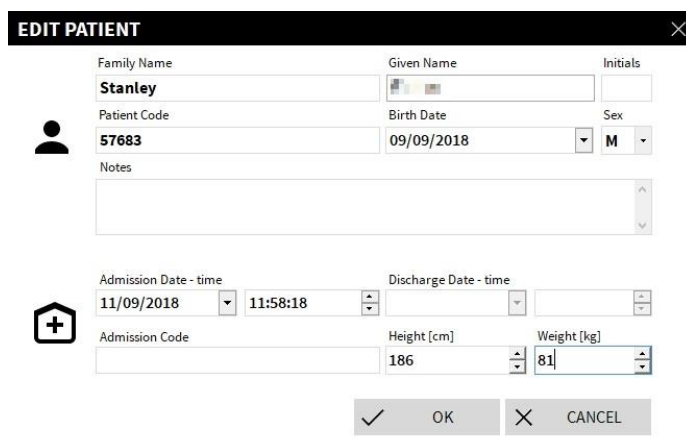
Fig 65

> ➢ Edit the patient's data.

> ➢ Click **OK** to confirm.

MOVE

Use the **MOVE** option (Fig 63 **A**) to move a patient to a different bed and/or location. To move a patient:

> ➢ Select the patient.

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

> ➢ Click the **EDIT** button on the command bar.

The following menu is displayed (Fig 66).

EDIT

DELETE

DISCHARGE

ADMIT

A ▷ MOVE
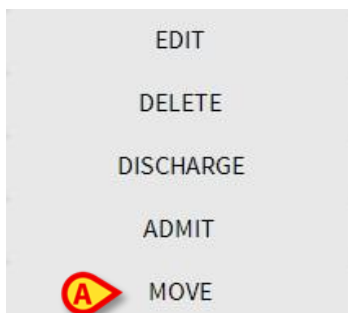
Fig 66

> ➢ Click **MOVE** (Fig 66 **A**).

The following window opens (Fig 67).

BED ✕

SELECT THE NEW BED FOR THE PATI **A**

Location

ICU

Bed

1 (▬▬ ▬, John)

✓ OK ✕ CANCEL
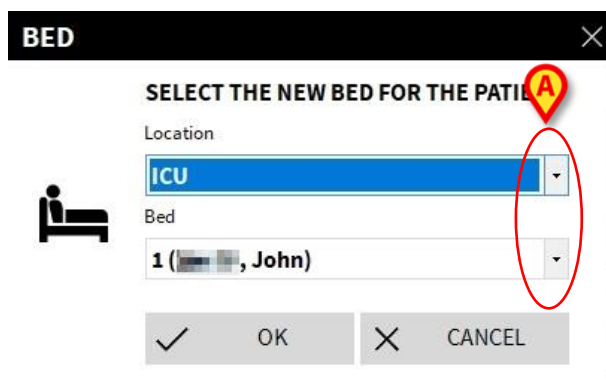
Fig 67

> ➢ Use the arrow buttons (Fig 67 **A**) to select the location and bed to which the patient will be transferred.

The upper button lists all the available locations.
The lower button lists all the beds available in the selected location.

> ➢ Click **OK** to confirm.

ADMIT

The **ADMIT** option registers the admission of a patient to a specific location.

To admit a patient:

> ➢ Select the patient.

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

> ➢ Click the **EDIT** button on the command bar.

The following menu is displayed (Fig 68).
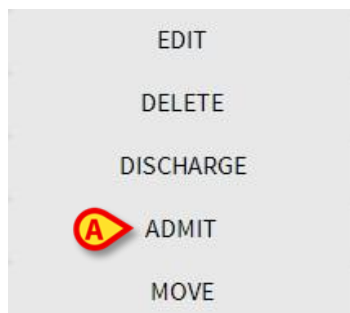
Fig 68

> ➢ Click the **ADMIT** option (Fig 68 **A**).

The following window opens (Fig 69).
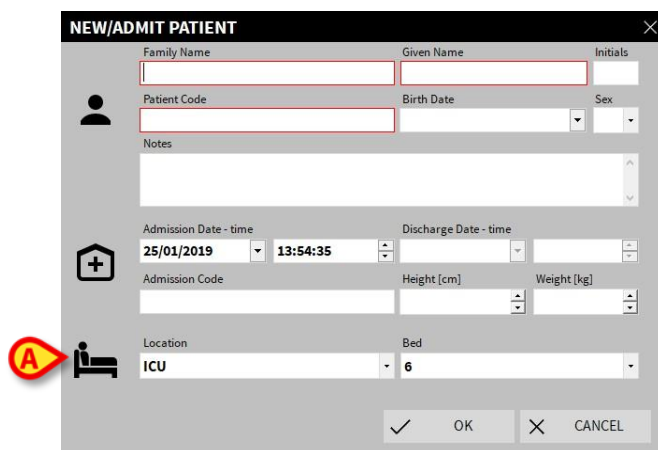
Fig 69

> ➢ Enter the patient data (for a new patient).
> ➢ To admit the patient, specify the destination **Location** and **Bed** as indicated in Fig 69 **A**.
> ➢ Click **OK** to confirm.

DISCHARGE

The **DISCHARGE** option registers the discharge of a patient.

To discharge a patient

> ➢ Select the patient.

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

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

The following menu is displayed (Fig 70).
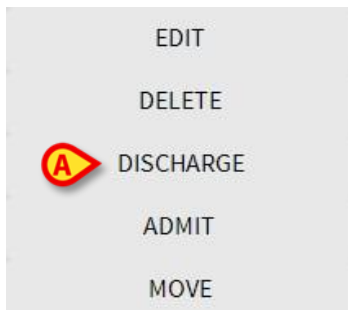
Fig 70

> ➢ Click the **DISCHARGE** option (Fig 70 **A**).

A confirmation is requested (Fig 71).
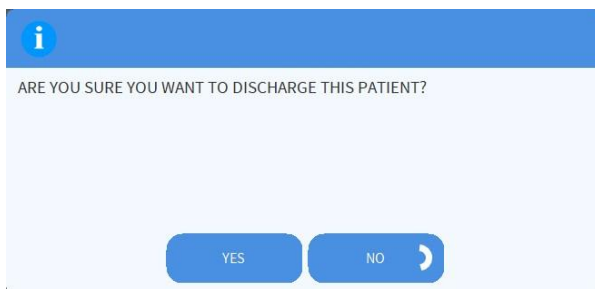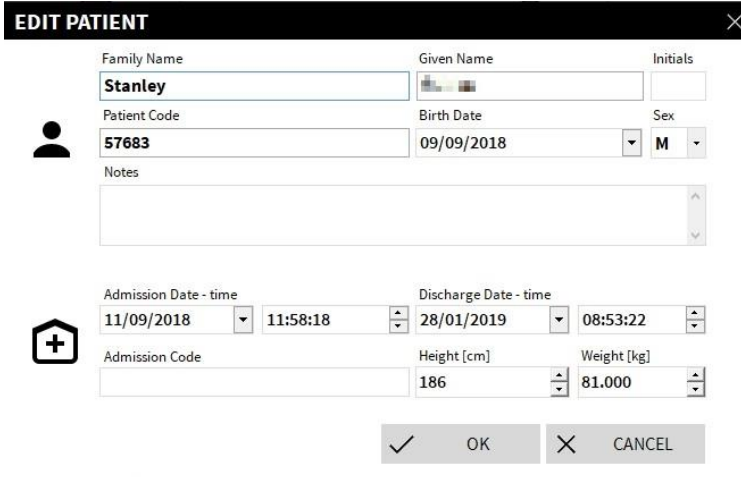
Fig 71

> ➢ Click **YES** to proceed with the discharge of the patient.

This action opens the window containing the patient's data (Fig 72). Here you can change the date and time of discharge).

Fig 72

> ➢ Click **OK** to complete the discharge procedure.

DELETE

The **DELETE** option deletes all data for a patient from the database.

To delete a patient's data:

> ➢ Select the patient.

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

> ➢ Click **EDIT** on the command bar.

The following menu is displayed (Fig 73).
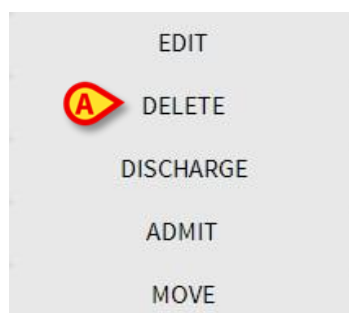
Fig 73

> ➢ Click **DELETE** (Fig 73 **A**).

Confirmation is requested (Fig 74).

Fig 74

> ➤ Click **YES** to delete the patient.

WARNING: Deleting a patient is an irreversible operation. When a patient is deleted it is no longer possible to access any document regarding them acquired through the Alaris Infusion Central system. Therefore you must perform this operation with extreme caution.
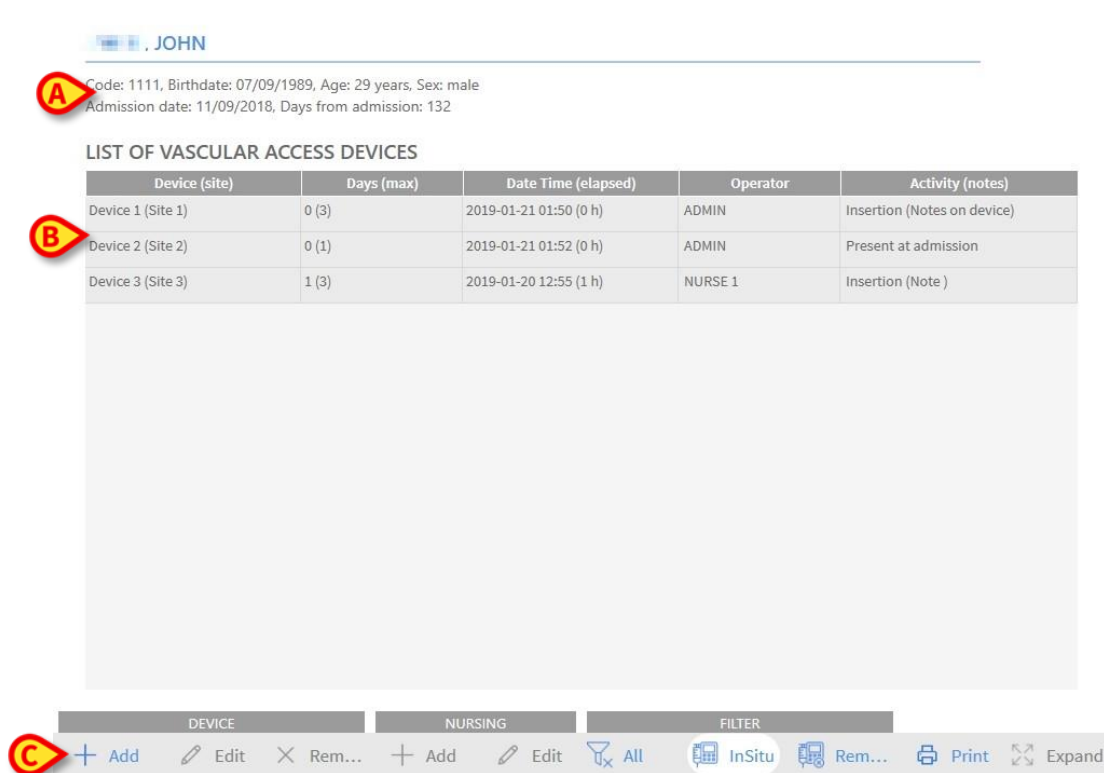
Invasive Device Management

This section describes the INVASIVE DEVICE MANAGEMENT module features and functionality. The INVASIVE DEVICE MANAGEMENT module is used to manage patient devices and nursing actions associated with devices.

To display the module:

> Click [icon] in the side toolbar.

The following page is displayed (Fig 75).

NOTE: **The module can only be accessed if a patient is selected.**

Fig 75

Patient data are displayed at the top of the screen, in two rows (Fig 75 **A**): patient name, ID, age and sex are displayed in the first row; Admission date, length of stay, weight, height are displayed in the second row.

Patient device data are displayed in the table indicated in Fig 75 **B** (see next section for a description).

A set of buttons making it possible to perform different actions is on the command bar at the bottom of the page (Fig 75 **C** - see page 87 for the description).

Devices list

All the devices are listed in the table shown in Fig 76. In the table columns, the following information is specified:

- Device name and site – in case of multiple occurrences of the same kind of device, a progressive number is displayed alongside the device name (for instance: CVC, CVC2, CVC3 …).
- Days since insertion and maximum allowed number of days, in this form: 3 (4).
- Date and time of application. If more than 24 hours have passed this row is yellow. If the maximum allowed number of days is exceeded (that is: the device is expired), this row is red.
- Name of the operator who performed the action.
- Kind of action performed or, in case of multiple actions on the same device, last action performed. User notes are displayed here as well.

Device (site)	Days (max)	Date Time (elapsed)	Operator	Activity (notes)
Device 1 (Site 1)	0 (3)	2019-01-21 01:50 (0 h)	ADMIN	Insertion (Notes on device)
Device 2 (Site 2)	0 (1)	2019-01-21 01:52 (0 h)	ADMIN	Present at admission
Device 3 (Site 3)	1 (3)	2019-01-20 12:55 (1 h)	NURSE 1	Insertion (Note)

Fig 76

The table can be either compact (as in Fig 76), or expanded (as in Fig 77).

Device (site)	Days (max)	Date Time (elapsed)	Operator	Activity (notes)
Device 1 (Site 1)	0 (3)	2019-01-21 01:50 (0 h)	ADMIN	Insertion (Notes on device)
Device 2 (Site 2)	**0 (1)**	**2019-01-21 01:59 (0 h)**	**ADMIN**	**Activity Y**
	0 (1)	2019-01-21 01:58 (0 h)	ADMIN	Activity X
	0 (1)	2019-01-21 01:52 (0 h)	ADMIN	Present at admission
Device 3 (Site 3)	1 (3)	2019-01-20 12:55 (1 h)	NURSE 1	Insertion (Note)

Fig 77

In compact mode, only the last action is displayed for a device. In expanded mode, all the actions for a selected device are displayed.

Use the **Expand** button on the command bar to either expand or collapse the table.

Command bar

This section lists the buttons on the command bar:

Fig 78

DEVICE:

Add - add a new device
Edit - edit the data of an existing device
Remove - remove a device

NURSING:

Add - add a new nursing action
Edit - edit the data of an existing action

FILTER:

All - display all devices
In Situ - display only the devices in situ
Removed - display only the removed devices

Use the **Print** button to print the configured invasive devices report.
Use the **Expand/Collapse** button to either expand or collapse the table.

How to add a new device

To add a new device:

> ➢ Under DEVICE, click **Add** on the command bar.

The following screen is displayed.

Fig 79

This screen makes it possible to specify the data for the new device. All information can be entered either by selecting the appropriate item on the drop-down menus or typing it in the relevant fields. Use the down-arrow to open the different menus. See page 93 for details on adding items to the menus. The information that can be specified here is:

- Device name
- Site
- Maximum allowed number of permanence days
- Activity performed
- Date/time of application
- Operator name
- Possible notes (free text field).

➢ Click **OK** on the command bar to add the device.

A new row is added to the table shown in Fig 76 and Fig 77.

The module's main screen is redisplayed (Fig 75).

How to edit the device data

To edit the data of an existing device:

➢ In the table, click the row corresponding to the relevant device.

➢ Under DEVICE, click **Edit** on the command bar.

A screen is displayed, containing the data for the selected device.

➢ Edit the data.

➢ Click **OK** on the command bar.

The module's main screen is redisplayed (Fig 75).

How to remove a device

To record the device removal:

➢ In the table, click the row corresponding to the relevant device.

➢ Under DEVICE, click **Remove** on the command bar.

NOTE: The row corresponding to the device is not deleted. The device is flagged as "removed".

How to delete an inserted device

To delete one of the inserted devices:

➢ In the table, click the row corresponding to the relevant device.

➢ Under DEVICE, click **Edit** on the command bar.

A screen is displayed, containing the data for the selected device.

> ➢ Click **Delete** on the command bar.

A confirmation is requested.

> ➢ Click **YES** to delete the device.

The module's main screen redisplayed (Fig 75). The row corresponding to the deleted device is no longer displayed.

How to add a nursing activity

To add a new nursing activity:

> ➢ In the table, click the row corresponding to the device to which the nursing activity refers.

> ➢ Under NURSING, click **Add** on the command bar.

The following screen is displayed.

Fig 80

This screen makes it possible to specify the data for the new nursing activity. The fields at the top of the screen (Fig 80 **A** - **Device, Site, Max days**) refer to the device and cannot be edited here.

The **Activity, Date/Time** and **Operator** fields (Fig 80 **B**) can be specified either by selecting the appropriate item from the drop-down menus or by typing it in the relevant fields. Use the down-arrows alongside the fields to open the different menus. See page 93 for details on adding items to the menus. If necessary, use the **Notes** box to add notes as free text.

> ➢ Click **Ok** on the command bar to add the nursing activity.

A new nursing activity is added to the device and is displayed in the device row as the most recent action. The module's main screen is redisplayed (Fig 75).

How to edit a nursing activity

To edit the data for an existing nursing activity:

> ➢ Click **Expand** on the command bar to display all nursing activities.

> ➢ Click the row corresponding to the nursing activity to be edited.

> ➢ Under NURSING, click **Edit** on the command bar.

A screen is displayed, containing the data of the selected nursing activity.

> ➢ Edit the data.

> ➢ Click **Ok** on the command bar.

The module's main screen is redisplayed (Fig 75).

How to delete a nursing activity

To delete an existing nursing activity:

> ➤ Click **Expand** on the command bar to display all nursing activities.

> ➤ Click the row corresponding to the nursing activity to be deleted.

> ➤ Under NURSING, click **Edit** on the command bar.

A screen is displayed, containing the data of the selected nursing activity.

> ➤ Click **Delete** on the command bar.

A confirmation is requested.

> ➤ Click **Yes** to delete the nursing activity.

The module's main screen is redisplayed (Fig 75). The row corresponding to the deleted activity is no longer displayed.

Adding an item to a drop-down menu

Whenever the + (plus) symbol is present, you can add a new item to an existing drop-down menu, so that the item is ready to be selected in the future.
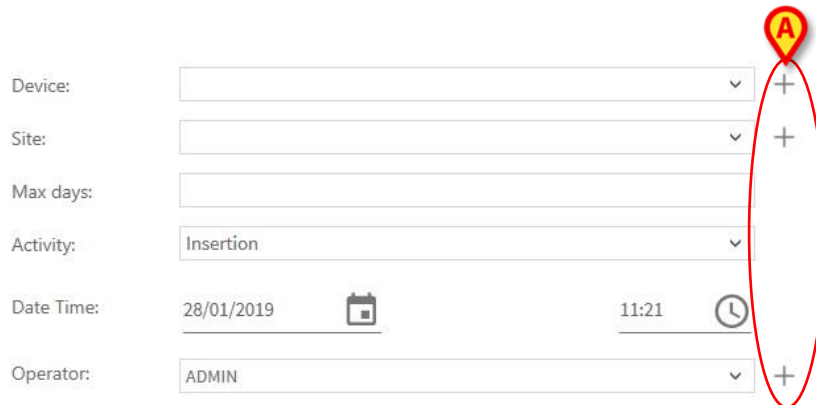
For example, see Fig 81 **A**.

Fig 81

To add a new item to an existing drop-down menu:

- ➢ Click **+** alongside the relevant field.

The field changes in the way shown in Fig 82.

Fig 82

- ➢ Type the item's name in the selected field (either **Device** or **Site** or **Activity** in Fig 81).

Fig 83

- ➢ Click ✓ **Ack** (Fig 83 **A**).

The item is inserted in the relevant drop-down list and is available for selection from that moment on for all patients (Fig 84 **A**).

Fig 84

Infusion

This section describes the INFUSION module features and functionality.

Introduction

The INFUSION module acquires online data from the infusion systems. INFUSION makes it possible to monitor drug infusions in progress: acquiring and displaying data as drug concentration, dosage and pressure in the drip and alarms.

Supported pumps and AGWs

See page 31 for the list of the supported pumps and AGWs.

Information for the user

Read the following warnings carefully.

WARNING: INFUSION is not designed to check correct pump function but rather to acquire and catalog clinical data. Pump information is not provided in real time and must be used solely as documentation. Do not use INFUSION as a remote alarm repeater but refer directly, for this purpose, to the existing specific instruments.

WARNING: Disconnecting the pumps while they are running causes the interruption of data acquisition on Alaris Infusion Central. The pumps' data that are lost during the disconnection period are not recovered by Alaris Infusion Central after reconnection.

WARNING: If the generic Alaris^TM Driver is in use, you must wait at least ten seconds after disconnecting a pump before connecting another.

WARNING: The user is advised that they must never change the infusion pump's serial number

WARNING: INFUSION is not a "Distributed Alarm System", as described in the EN 60601-1-8 regulation. Alarms are not visible in all conditions and they can lack sound. Also, they appear with a one minute delay.

WARNING: Alarms must be used for documentation only. INFUSION must neither be used as an alarm system nor should it influence the use of pumps.

WARNING: The update of data displayed on-screen caused by pump connection, power off, disconnection and change of status depends on the time required by the AGW to communicate the changes. This time depends on various factors, among them are AGW type and infusion pump type. In some conditions, the delay in communicating changes might be important. During the execution of tests the following times were observed:

- Communication of: new infusion pump connected – 10 to 120 seconds
- Communication of: infusion pump powered off – up to 120 seconds
- Communication of: infusion pump detached from AGW – up to 20 seconds
- Communication of: pump status (end of infusion, infusion start, alarm and so on) – 5 to 20 seconds

The times stated above must be considered just as an indication. They might change depending on device configuration and operational conditions.

Therefore, the data displayed on Alaris Infusion Central might temporarily be different from the actual situation of the devices.

Module selection

To select the INFUSION module:

➢ Click the ⬤ icon on the side toolbar.

If no patient is selected the "Ward station" screen opens, displaying all the pumps connected to each patient in the ward (Fig 85).

If a patient is already selected the "Patient Station" screen opens, displaying all the pumps connected to the selected patient (Fig 98).

Patient selection

There are two ways to select a patient:

1) Use the functionality described in "Patient selection" on page 66.

2) Select a patient on the ward station, by clicking their bed area (see section "Ward station"). The selected patient becomes the current Alaris Infusion Central patient.

When INFUSION returns to the ward station (either after user action or after time out), the patient can optionally be deselected (no current patient) or remain selected, depending on configuration (see section "Ward station").

Generic patient mode

The INFUSION module can acquire data without a selected patient. In this way, it is possible to monitor the infusion trends for a bed, without referring to a specific patient. The bed must be configured in the workstation domain.

Central and Bedside workstations

A workstation can either be central or bedside.

- Central Workstation works on a set of beds, named "domain". The domain definition (that is the definition of the set of displayed beds) is defined by configuration. The INFUSION home page of a Central Workstation is the "Ward station" screen (see Fig 85).
- Bedside Workstation works on a single bed, with or without patient. The bed is determined by configuration. The INFUSION home page of a Bedside Workstation is the "Patient station" screen (see Fig 98). A Bedside Workstation cannot display the "Ward station" screen.

Screen Timeout

From any screen, after a certain period of inactivity (defined by configuration), the system goes back to the home page ("Ward station" screen for Central Workstations and "Patient station" screen for Bedside Workstations).

Pharmacokinetic mode

The PK pumps can be set to pharmacokinetic mode. That is a target value is set on the pump. The target value can be either "plasmatic" or "effect site". When this mode is active, the INFUSION module:

a) displays specific icons and other graphic elements to indicate that the infusion is in pharmacokinetic mode;
b) displays the target value anywhere it is relevant.

Enteral Pumps

Enteral pumps are GH Plus pumps with a special firmware version. They are displayed as GH_G in the AGW and in Alaris Infusion Central. To have them correctly recognized and reported as "Enteral" in Alaris Infusion Central, you must set the pump ServiceMessage to "**Enteral**". Refer to the pump service manual for the detailed procedure.

Guided Relay process

The Guided Relay feature is designed to support clinicians in transitioning continuous infusion of critical drugs (mainly but not exclusively vasoactive/fast acting drugs such as Dopamine, Dobutamine, Epinephrine and Norepinephrine) which come to end and need to be changed with as minor an impact as possible on the blood's drug concentration. See page 108 for a detailed description of this feature.

Ward station

The "Ward station" screen displays all the pumps connected to each patient in the domain (Fig 85).
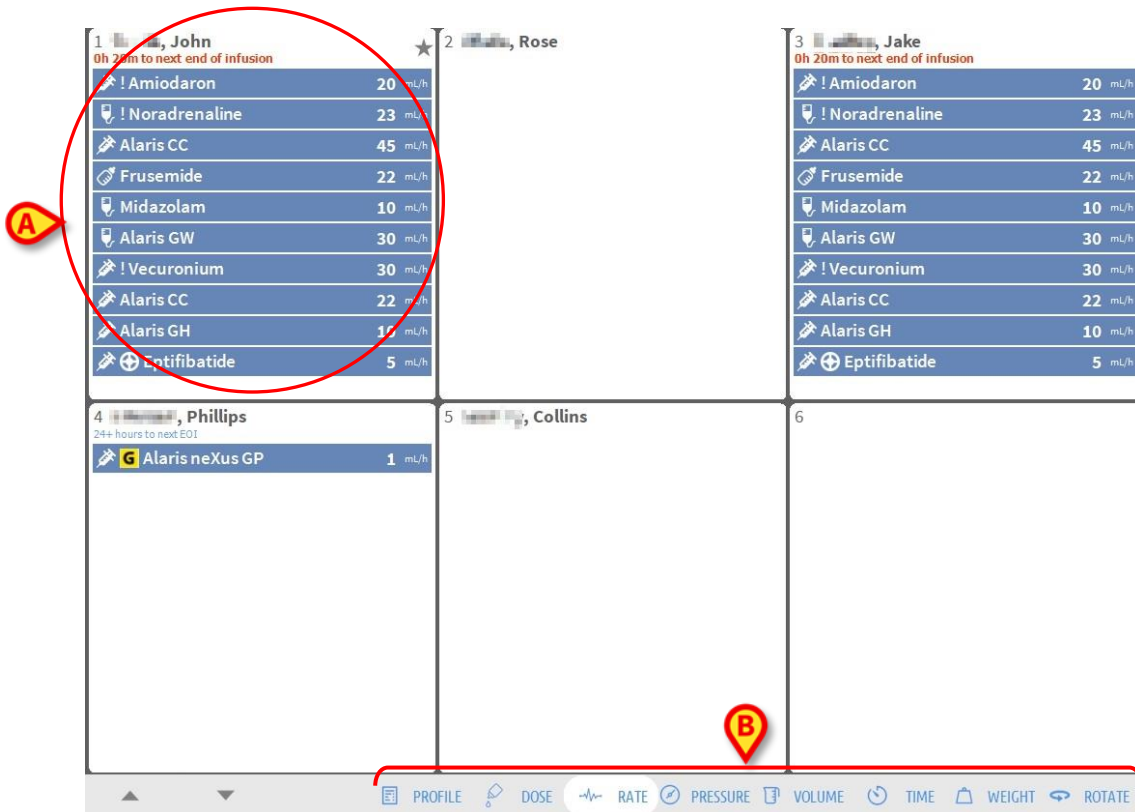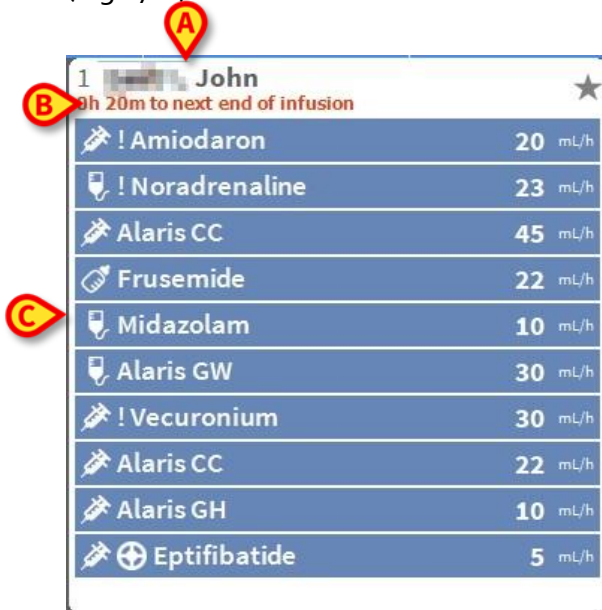

Fig 85

The screen is divided into rectangular areas (Fig 85 **A**). Every area, referring to a bed, is called "bed card". It contains a schematic representation of all the connected pumps.

When an alarm condition occurs, a specific sound is provided. The sound is differentiated for alarms with different priorities. The icon shown in Fig 86 is displayed in the background. Click the icon to make it disappear (meaning that the alarm condition is acknowledged).

Fig 86

On top of each "bed card", the bed number and patient name are displayed (Fig 87 **A**). Below the patient name, the time remaining until the next end of infusion is specified (Fig 87 **B**).

Fig 87

The rows indicated in Fig 87 **C** represent the connected pumps. Each row represents a pump. The rows can appear in four colors:

1) Blue if the pump is infusing (Fig 88). The icon displayed on the left depends on the type of pump/infusion:

Fig 88

2) Grey if the pump is paused.

3) Cyan if the pump is sending a low-priority alarm; in this case a phrase describing the kind of warning currently occurring appears inside the box, alternating with the name of the infused drug/pump name.

4) Yellow if there is a "medium priority alarm" on the pump; in this case a phrase describing the kind of warning currently occurring appears inside the box, alternating with the name of the infused drug/pump name.

5) Red if there is a "high priority alarm" on the pump; in this case a phrase describing the kind of alarm currently occurring appears inside the box, alternating with the name of the infused drug/pump name.

If the connected pump sends the name of the infused drug, the drug name is displayed in the corresponding pump box. If the connected pump does not send the name of the infused drug, the pump name is displayed in the corresponding pump box.

NOTE: If the pump provides the drug name, then the corresponding pump box displays the drug name. If the drug name is not available, then the corresponding pump box displays the pump name. The rule that the Alaris Infusion Central system adopts is:
- **If the AGW reports a DrugName, then the DrugName is displayed.**
- **If the AGW reports a DrugName empty (<Drug name="">), then the pump name is displayed.**
- **If the AGW reports a DrugName "Unknown" (<Drug name="Unknown"/>), then Alaris Infusion Central displays Unknown.**

The following icons can be displayed in the pump box, on the left of the pump/drug name.

- *Volumetric pumps:* The ⬜ icon indicates volumetric pumps

- *Enteral pumps:* The ⬜ icon on the left of the box indicates enteral pumps.

- *Syringe pumps:* The ⬜ icon on the left of the box indicates syringe pumps.

- *Guided Relay process:* The ⬜ and ⬜ icons indicate a Guided Relay administration. See page 108 for a description of the Guided Relay process.

- *Critical drugs:* Any drug can be labelled as critical. In this case an exclamation mark is displayed before the drug name (Fig 89).

Fig 89

See page 124 for the critical drugs setup procedure. If a drug is labelled as "critical", a specific, different sound is provided when alarmed.

WARNING: The "critical drugs" feature shall be considered only as a support for the drug management workflow.

- *Soft limit exceeded:* The [G] icon is displayed before the drug name when the soft-limit (set-up on the pump) is exceeded. If the mouse pointer is positioned over the icon, a tooltip provides additional information.

- *Pharmacokinetic mode*: The ⊚ and ⊕ icons indicate that the pump is set to "Pharmacokinetic" mode. See Fig 90 and related text for more information.

WARNING: If the pump is set to pharmacokinetic mode, when the Dose button is selected the value displayed is not the "Dose rate" but the target value instead. This is highlighted either by the ⊚ icon or by the ⊕ icon, displayed in the pump box, alongside the status icon. The first icon is displayed when a "plasmatic concentration" target value is set. The second icon is displayed when a "site effect" target is set.
See Fig 90 for an example of this.

Fig 90

Each pump box provides - on the right - information on the current infusion (Fig 91 **A**).

Fig 91

The parameters that can be displayed are:

- Dose rate (if the pump is working in pharmacokinetic mode, the target value is displayed),
- Volume rate,
- Total infused volume,
- Infusion circuit pressure. In the configuration, a "pressure threshold" can be set up. When this threshold is exceeded, the Pressure value is displayed in yellow.
- Time remaining to the end of the infusion,
- Patient weight set on the pump,
- Rotate mode, displaying all the available values in rotation.
- Profile string, defined in the configuration, referring to the patient/drug.

The displayed value depends on the button currently selected on the command bar (see page 102).

In the upper right corner of every bed card different icons can be displayed (Fig 92 **A**). Click the icons, or position the mouse pointer over them to display a tooltip providing additional information. The icons' meaning and number is set by configuration. Contact your system administrator for more information.
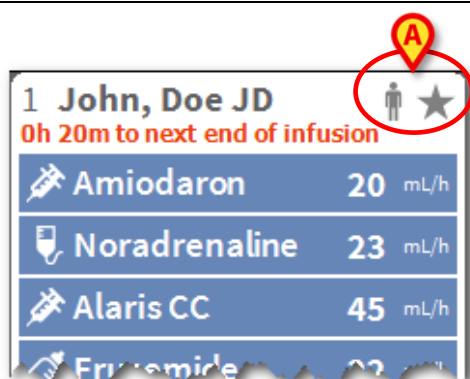
Fig 92

In Alaris Infusion Central, there are three pre-configured icons:

Patient weight mismatch/profile mismatch. This icon is displayed either when different weights for the same patient are set on the pumps in which the dose rate is influenced by the patient weight, or when different profiles are specified on different pumps for the same patient. A tooltip, displayed when the mouse pointer is positioned over the icon, provides information on the current occurrence.

Expired vascular access device. This icon is displayed when one of the vascular access devices associated with the patient exceeds the maximum number of days set in the Invasive Device Management module. See page 86 for the functionality of the Invasive Device Management module.

Guided Relay. This icon is displayed either when one or more of the administered drugs are eligible for a Guided Relay process, or a Guided Relay is running. See page 108 for a description of the Guided Relay process.

There are three display modalities for the bed cards, depending on the available space for the boxes and the number of connected pumps for each patient. These are normal, compact (showing only part of pump data) and minimal (showing no pump data).

Zoom in- Zoom out functionality

Click the bed number or the patient name to magnify the bed card (Fig 93). Any click inside this magnified bed card or anywhere else outside of it causes the bed card to return to its normal size and position. The zoom-in action can be performed on a touch screen as a "two fingers tap". Single tap to zoom out.
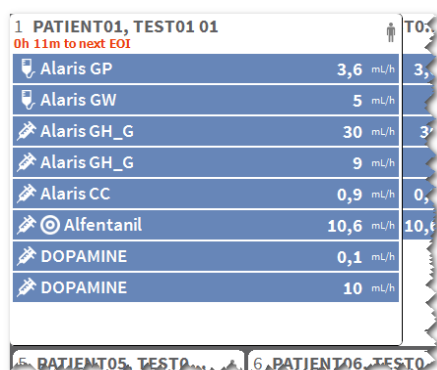

Fig 93

"Ward station" command bar

The user decides which parameter is displayed in the pump boxes (Fig 91 **A**) selecting one of the buttons on the "Ward station" command bar.

▲ ▼ 📄 PROFILE ✎ DOSE 〜 RATE ⊘ PRESSURE 🗎 VOLUME ⏱ TIME △ WEIGHT ⇆ ROTATE

Fig 94

The selected button is highlighted in white.

PROFILE: Displays, where defined, the drug profile as set up in the configuration.

DOSE: Displays the dose rate and dose rate unit of measure. When working in pharmacokinetic mode, the target value is displayed.

RATE: Displays the volume rate in the pump boxes.

PRESSURE: Displays the infusion pressure in the pump boxes. In the configuration a "pressure threshold" can be set up. When this threshold is exceeded the Pressure value is displayed in yellow.

VOLUME: Displays the total infused volume in the pump boxes.

TIME: Displays the time remaining to the end of the infusion in the pump boxes.

WEIGHT: Displays the patient weight set on the pump.

NOTE: The patient weight is displayed only if:
- **A PK pump is running in pharmacokinetic mode**
- **In a pump the dose rate is pro-kilo and the pump is set in "Dose rate" mode**

ROTATE: Displays all the different parameters in rotation. The currently displayed parameter is highlighted on the command bar (dark grey).

When the number of beds displayed on the screen is smaller than the number of beds configured in the domain (that is, when it is not possible to display all the configured beds on the same screen), two arrow buttons are dislayed on the command bar. The arrow buttons make it possible to "scroll" up and down the list of bed cards.

The color reflects the color of the highest priority alarm currently occurring on the non-displayed bed.

LOCATION: Only visible if the workstation is set up in the configuration to display beds belonging to different locations.

NOTE: The number of beds that can be displayed on the INFUSION "Ward station" screen (Fig 85) is configurable. That is, the user decides how many beds are displayed on one screen. Refer to your system administrator for more information.

Notification area

A notification area is displayed on the right of every Alaris Infusion Central screen, reporting various notifications sent by the connected pumps (Fig 95 **A**, Fig 96).
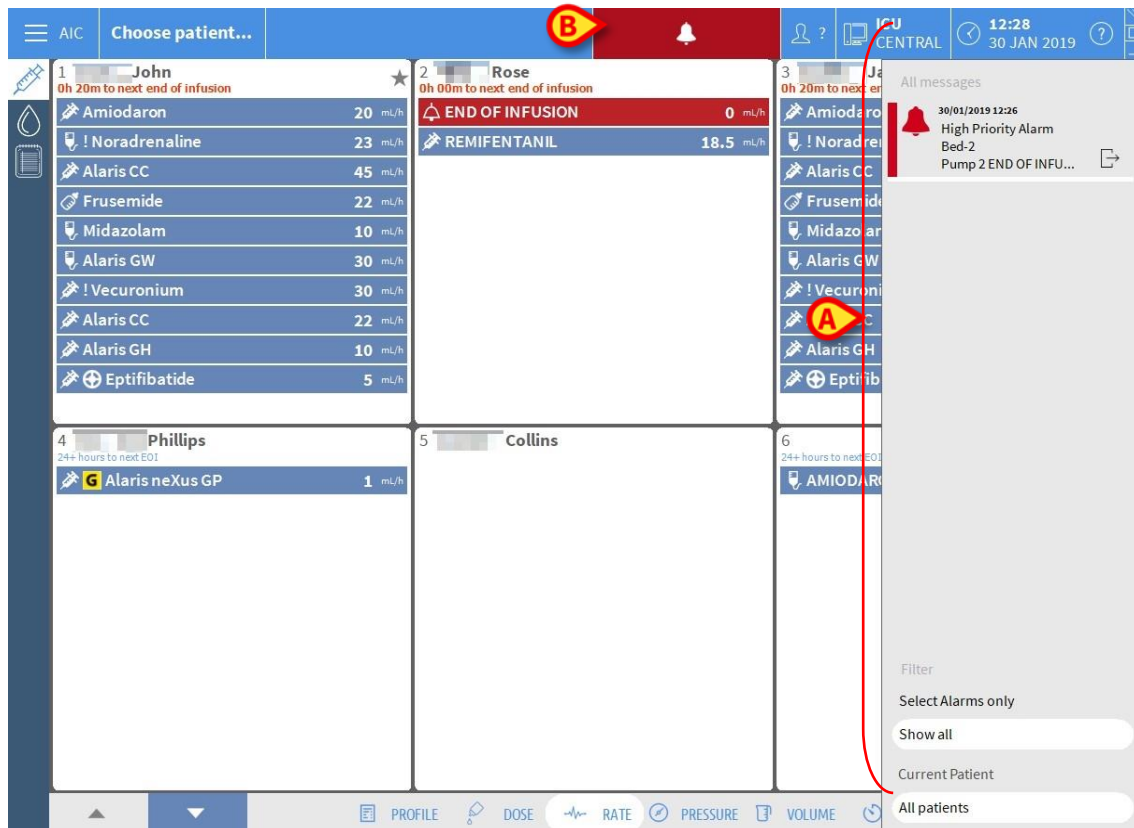

Fig 95

The notification area can be configured so that it is:

- Always visible
- Automatically displayed when a new notification arrives
- Only visible after a user clicks on the notification button on "Control Bar" (Fig 95 **B**).

The different messages are displayed in chronological order, (Fig 96 **A** - most recent on top) and by criticality.

WARNING: If the clinical staff decides to use the Guided Relay feature, it is mandatory to configure the notification area as "Always visible". See page 108 for the description of the Guided Relay feature.
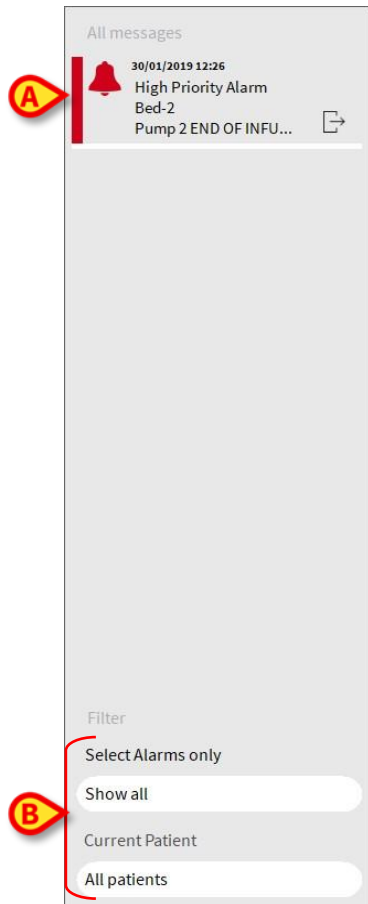
Fig 96

Each message is characterized by a color (red for high priority alarms, yellow for medium priority alarms, blue for low priority alarms).
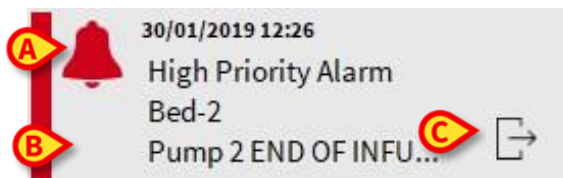
Fig 97

In the message box (Fig 97), the following information is displayed:

- Date and time of occurrence
- Number of the bed from which the message comes
- Actual message text
- Icon characterizing the message type (Warning, Alarm, Info - Fig 97 **A**)
- Icon indicating the message category (for example: "Guided Relay message" - Fig 97 **B**)
- A **Callback** button (Fig 97 **C**). The button accesses the patient station on which the notification occurred.

At the bottom of the notification area, four different filters are available, making it possible to choose the type of message to be displayed (Fig 96 **B**). The available filters are:

- Only alarms
- All messages
- Messages relating only to the selected patient
- Messages relating to all patients

Patient Station

Click one of the bed cards to open the "Patient station" screen, shown in Fig 98.

The "Patient station" screen (Fig 98) offers a detailed view of all the data coming from the pumps connected to a patient. The corresponding patient is automatically selected.

On the left of the screen is a list of syringes and infusion pumps connected to the patient (Fig 98 **A**); in the middle, a diagram displays drug infusion velocity changes in time and possible administered boluses (Fig 98 **B**).

Fig 98

On the left, each box represents a pump. These boxes are named "pump buttons". The pump button displays the drug name when the pump provides this kind of information. When it does not display the drug name, the pump name is displayed.

The color of the pump button changes according to the pump status, that is according to the priority of the possible alarms occurring on the pump.

Empty slots show no data.

The box representing the pump (Fig 99) can display different kinds of data.
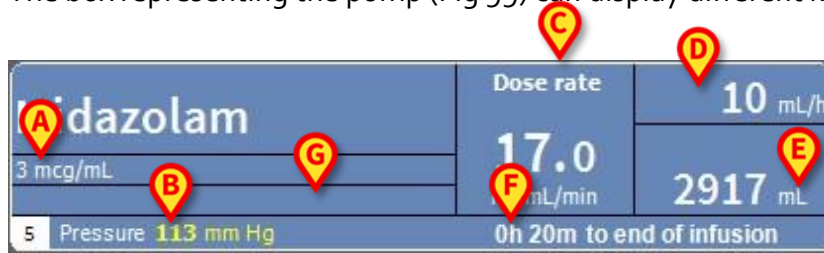
Fig 99

These are:

- Drug concentration (Fig 99 **A**);
- Circuit pressure (Fig 99 **B**). In the configuration, a "pressure threshold", can be set up. When this threshold is exceeded, the Pressure value is displayed in yellow;
- Dose rate (Fig 99 **C**); or the target dose when working in pharmacokinetic mode. In this case the "target" icon shown in Fig 90 is displayed as well;
- Volume rate (Fig 99 **D**);
- Total infused volume (Fig 99 **E**);
- Time remaining to the end of the infusion (Fig 99 **F**);
- Drug profile, if specified (Fig 99 **G**).

Infusion charts

The infusion chart displayed in the central area of the "Patient station" screen represents the trends of some of the infusion values (Fig 100).

The infused quantities are represented by colored rectangular areas (Fig 100 **D, B, E**).
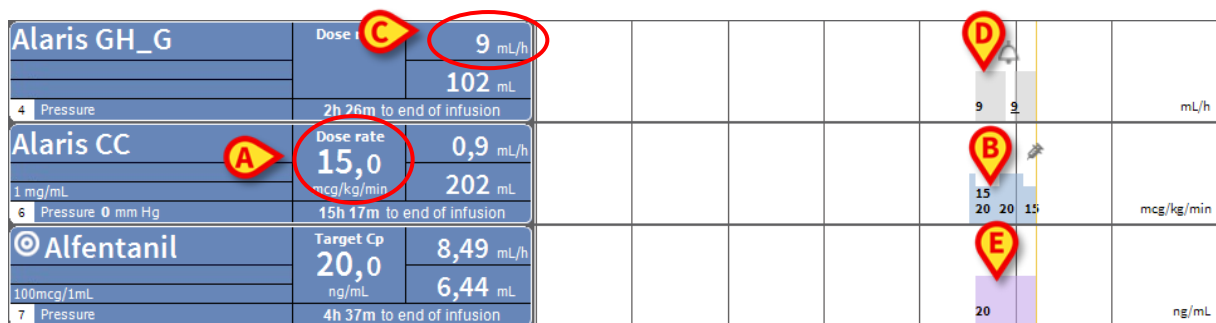
Fig 100

If the pump provides the dose rate value (Fig 100 **A**), the height of the chart is proportional to the dose rate. The dose rate value is displayed (in numbers) every time the dose rate changes. The chart is light blue (Fig 100 **B**).

If the dose rate value is not provided, the height of the chart is proportional to the infusion volume rate (this is the case indicated in Fig 100 **C**). The volume rate value is

displayed (in numbers) on the chart every time it changes. The chart is grey (Fig 100 **D**).

If the pump is set to pharmacokinetic mode, the chart displays the target trend (violet - Fig 100 **E**).

A specific dose rate/volume rate value corresponds to each moment in time. Time is indicated by a time bar placed at the bottom of the chart area.

Click the chart area to display a vertical yellow bar indicating (in labels) the dose rate/volume rate values corresponding to the clicked chart point. A specific label at the bottom indicates the corresponding time.

Each time a warning/alarm message is provided or a bolus is administered, a specific icon is displayed on the chart in the position corresponding to the time at which the event occurred (Fig 101 shows 2 boluses and two alarms). Click the icon to display information on the specific event.
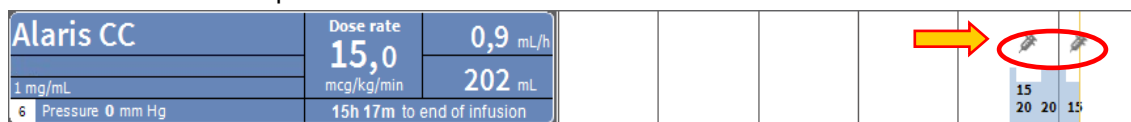
Fig 101

NOTE: In case a Guided Relay process is set up on two pumps, the infusion charts acquire specific features that are described later, in the "Guided Relay Workflow" section.

CAUTION: The infusions diagram is updated at one minute intervals; the connected syringe buttons are updated in real time.

The "Patient station" screen command bar

Five buttons are displayed on the "Patient station" screen command bar (Fig 102).
- **Guided Relay Setup** opens the Guided Relay setup window.
- **Guided Relay Info** opens a window showing the main information relating to the active Guided Relay processes.

See next section for the description of the Guided Relay process.
- **Print** gives you access to the Product's Print functionality (see page 49)
- **Log** opens the pump log history described on page 121.
- **Close** closes the "Patient station" screen and returns to the "Ward Station" screen described on page 96 (if working on a Central Workstation).
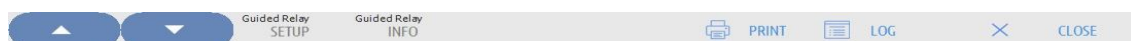

Fig 102

Two arrow buttons are displayed on the left when it is impossible to display all the connected pumps at the same time. These buttons make it possible to scroll up and down the information displayed on-screen.

Guided Relay process

Introduction

The "Guided Relay" feature is designed to support clinicians in transitioning continuous infusion of critical drugs which come to end and need to be changed with as minor an impact as possible on the blood's drug concentration.

This task is accomplished by pre-setting a gradual change of syringe, with one syringe gradually diminishing the infusion dose rate and another syringe (infusing the same drug at the same time) gradually increasing the infusion dose rate.

The dose rate changes (defined as "steps") must be performed on the pump by the nursing staff. Alaris Infusion Central provides a series of reminders that support the clinician in performing the dose rate adjustments at the right time. If the Alaris Infusion Central notifications are ignored, the Guided Relay process is automatically aborted.

WARNING: The clinical staff is in charge of managing the transition process of drugs. The presence of the Guided Relay functionality shall not change in any way the therapeutic process and the associated vigilance activities.

The goal of the Guided Relay functionality is to offer a configurable system of "reminders" that can be of help to the clinical staff in implementing the decisions made. The Guided Relay provides a set of options that the clinical staff can use as a support in the management of the transition process and does not automate the process.

Guided Relay set-up

There is a list of pre-configured "Guided Relay Drugs". That is a list of drugs (mainly but not exclusively vasoactive/fast acting drugs such as Dopamine, Dobutamine, Epinephrine and Norepinephrine) that are defined as "eligible" for a Guided Relay process.

For each drug, in the configuration, the plausible administration values and steps are defined.

When a drug is identified by the system as a Guided Relay drug (that is, it is a drug on the configured list), a notification is displayed in the notification area on the right (Fig 103 **A –** see page 103 for a description).
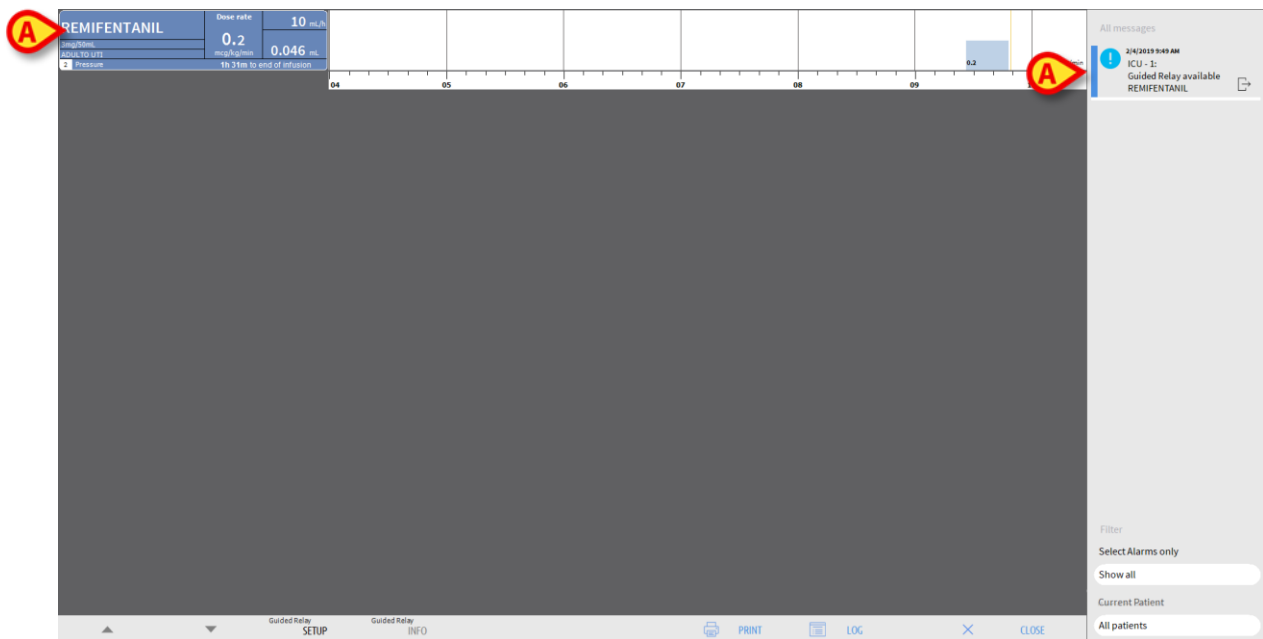
Fig 103

The nursing staff can now decide whether to start a Guided Relay process or not. There are two possible ways to start the process:

1. Change the syringe when it gets close to the end of infusion;
2. Prepare a change of syringe in advance.

NOTE: On the "Ward station" screen (Fig 85), either when a drug for a patient is identified by the system as a Guided Relay drug or a Guided Relay process is running, an ♥ icon is displayed in the bed card, alongside the patient name. See page 97 for the description of the bed card. Click the bed card to access the "Patient station" screen (shown in Fig 103, for example).

Changing the syringe when it gets close to the end of infusion

When a critical infusion is about to expire in the syringe infusing the critical drug (Dopamine in Fig 103 **A** – "Syringe 1" from now on), a notification is issued by the software, suggesting that a Guided Relay for that specific syringe should be initiated.

The nurse now starts a new infusion, using another syringe ("Syringe 2" from now on), that must have the following features:

- It must contain the same critical drug.
- Drug concentration must be the same.
- It must be started in an adjacent tile to the one of "Syringe 1".
- It must be started at 'Minimal rate'.

NOTE: Minimal rate is typically 0.1 ml/hr (it could be in a different unit when programmed in dose rate). This value must be between 0 and 5% of "Syringe 1" rate to be recognized by Alaris Infusion Central.

WARNING: Be careful in the priming of the relay syringe that a low volume rate combined with high static friction can lead to delayed delivery of infusion (this is particularly true for high volume syringes). The hospital organization shall implement adequate procedures to control this possible risk.

The system now identifies two syringes infusing the same drug at the same concentration in adjacent tiles, one being at 'Minimal rate'. A new notification is added to the notification area (See Fig 104 **A**).
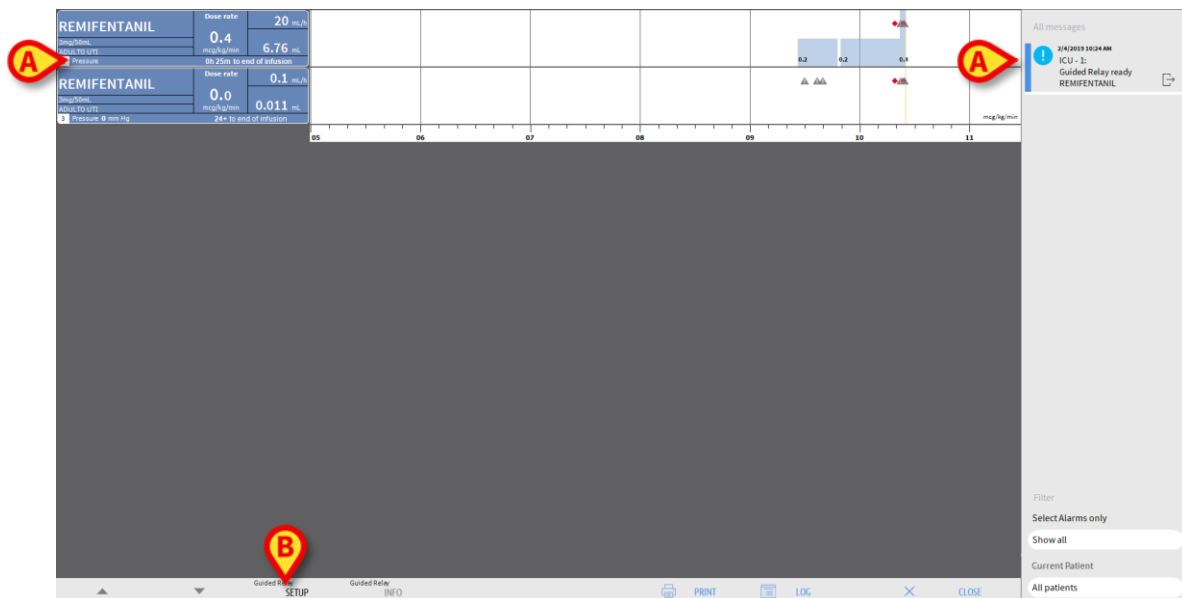
Fig 104

To start the Guided Relay procedure,

> Click **Guided Relay SETUP** (Fig 104 **B**).

The "Guided Relay setup" window opens (Fig 105).
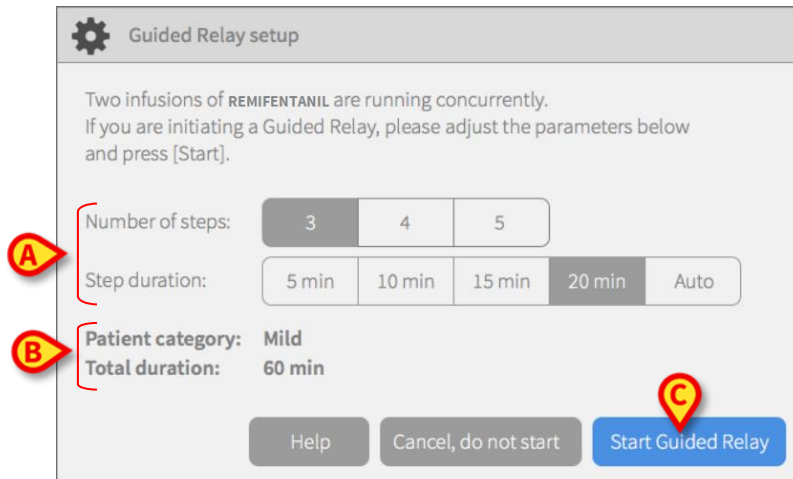
Fig 105

> Select the **Number of steps** and the **Step duration** (Fig 105 **A**).

This selection determines the patient category and the total process duration
(Fig 105 **B**).

NOTE: Patient categories refer to the patient haemodynamic status. They are defined as:
- **Haemodynamic Status = Mild - 1 step (50%)**
- **Haemodynamic Status = Moderate - 2 steps (70%, 30%)**
- **Haemodynamic Status = Severe - 3 steps (75%, 50%, 25%)**

> Click **Start Guided Relay** in this window (Fig 105 **C**) to start the process.

The Guided Relay procedure is described in the next section (page 113).

Preparing a change of syringe in advance

The nursing staff can prepare the change of syringe in advance, before Syringe 1 gets close to the end of infusion, and after deciding to set up a Guided Relay process.

To prepare the change of syringe:

> At any time, click **Guided Relay Setup** on the command bar (Fig 104 **B**).

If there is more than one "Guided Relay drug" for the same patient, the following message is displayed:

"Select the infusion that you want to setup for Guided Relay"

> Select the relevant drug and click **Next.**

The "Guided Relay Pre-Setup" window opens (Fig 106).

Fig 106

> Set up the Guided Relay process up as described previously (page 111).

> Click **Start Guided Relay** (Fig 106 **A**).

The Guided Relay setup is saved. The lateral notification bar displays a "Guided Relay scheduled" notification (Fig 107).
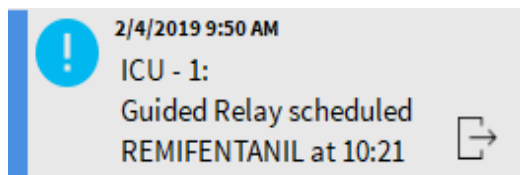
Fig 107

A notification is issued 5 minutes (default, configurable value) before the required start time of the Guided Relay process (Fig 108).
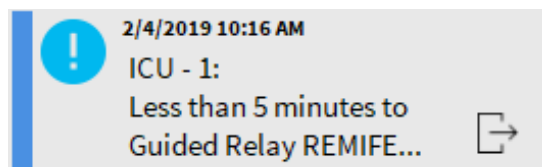
Fig 108

Start the infusion for "Syringe 2". The infusion must be set up as described in the previous section (page 110).

Guided Relay workflow

When the Guided Relay process is set up, the infusion charts change according to the specified Guided Relay settings. (Fig 109).
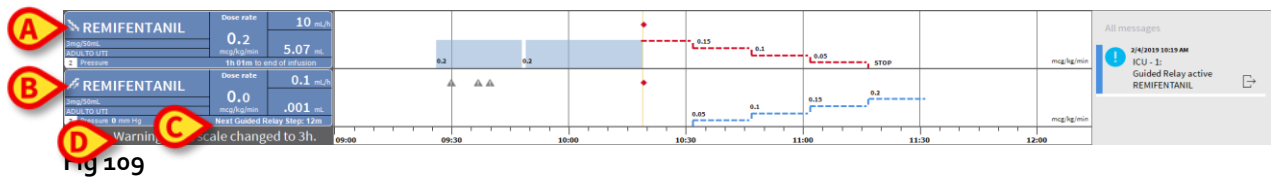
Fig 109

A ramp down icon is displayed on the Syringe 1 pump box (Fig 109 **A**). A ramp up icon is displayed on the Syringe 2 pump box (Fig 109 **B**). In addition to the time 'end of infusion', an additional 'next step' time is displayed (Fig 109 **C**).

The charts' time scale is automatically changed to three hours (Fig 109 **D**).
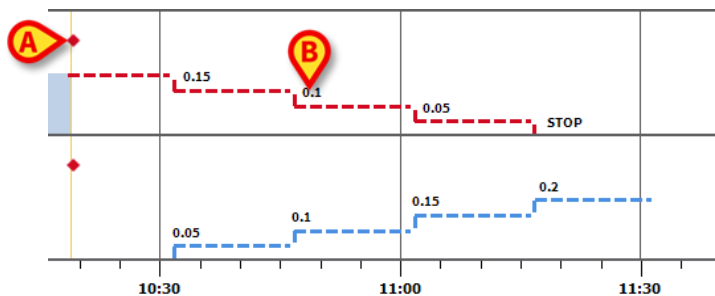
Fig 110

Each step of the process is displayed on the chart, on the right of the yellow "now-bar" (red down scale for syringe 1, blue up scale for syringe 2). The required changes to the dose rate are indicated for each step (Fig 110 **B**).

NOTE: The red dots shown in Fig 113 A indicate the moment at which the required change to the dose rate was performed for each step.

5 minutes (default, configurable value) before the end of step 1 a notification is issued.

At the end of the step time, unless the nurse already updated the rates in both Syringe 1 and Syringe 2, another notification is issued.

The process is the same for each step, until the end of the process.

If another Guided Relay process is required, the nursing staff must perform the procedure again from the beginning.

WARNING: At the end of nurse shift, adequate procedures shall be adopted by the hospital to communicate the relevant information about the running Guided Relay processes to the incoming staff members.

Titration change during Guided Relay

If the nurse notices a change in the patient haemodynamic features, they may decide to titrate up or down one of the transitioning syringes.

If the total dose is significantly different from the planned total dose, Alaris Infusion Central automatically detects the titration change and changes the planned steps accordingly (the dose change threshold is set in the configuration).

There are four possibilities:

1) If the titration is **up on Syringe 2,** a notification is issued.

   The software recalculates the new levels for Syringe 2 for each subsequent step: the new steps for Syringe 2 are incremented with the amount that was added when titrating up Syringe 2. Syringe 1 steps are not changed.

2) If the titration is **down on Syringe 2,** there is no patient risk. A notification is issued.

3) If the titration is **up on Syringe 1,** the Guided Relay process is interrupted. A notification is displayed.

4) If the titration is **down on Syringe 1,** another notification is issued.

   The duration of steps is not updated. There may be some residual drug in Syringe 1 at the end of the Guided Relay process.

Exceptions

This section describes some possible exceptions to the normal Guided Relay workflow.

1. *Conditions are not met*

If the following conditions are not met, the Guided Relay process does not start:

- Transitioning pumps are not in adjacent tiles.
- Drug name, unit of measure and concentration are not the same on both pumps.
- For pro-kilo dose rates, the two pumps do not have the same patient weight.
- Syringe 2 is not started at minimal rate.
- One of the pumps is not supported.

NOTE:Only CC and GH syringe pumps are supported. Volumetric pumps, PK, TIVA and GS syringe pumps are not supported.

In these cases the Guided Relay process does not start.

2. *Steps are violated*

Actions for each step (that is, update the syringe's dose rate) should be taken in a time window which is 5 minutes by default (configurable). When actions are not taken within the configured time span, a notification is issued. If no action is taken within another 5 minutes (default, configurable value), an abort notification is issued.

3. *Not enough fluid left in Syringe 1 or Syringe 2 to execute the Guided Relay workflow*

This situation is most likely to arise, to provide a few examples, if there was a delay in titrating down Syringe 1 after Guided Relay was already initiated, or some boluses were delivered, or some air in the line required re-priming/purging, and so on.

There are two possible cases:

Syringe 1 is short on fluid. As seen before in this section, in the case of a delay of more than 5 minutes (configurable) in titrating Syringe 1 (according to the planned Guided Relay steps), the Guided Relay process is automatically aborted. Therefore, this case refers to different situations such as: boluses, air in the line with consequent need to prime the syringe, delays in the execution of the Guided Relay steps that are shorter than 5 minutes (or other configured value).

In these cases, the system tries to recalculate the step durations but, if the duration of a single step is shorter than a configurable minimum value (system option "**Grminstepduration**"), the Guided Relay is interrupted. Otherwise the following notification is displayed:

"Guided Relay duration is shorter than originally programmed. Step durations have been adjusted."

Syringe 2 is short on fluid. If Syringe 2 is short on fluid, a notification is displayed. In this case, the Guided Relay process is aborted.

4. *Pump (Syringe 1 or Syringe 2) is alarmed*

If either Syringe 1 or Syringe 2 is alarmed, an action must be taken within 5 minutes (default, configurable value). If no action is taken within the configured time span, an abort notification is issued.

5. *Pump (Syringe 1 or Syringe 2) disappears*

If either Syringe 1 or Syringe 2 disappears (due to the pump being removed from the rack, or to network connectivity issues, for example) both syringes should reappear within 5 minutes (default, configurable value). If this does not happen an abort notification is issued. The Guided Relay procedure is aborted.

Infusion history

Click **Log** on the command bar of the "Patient station" screen to display a screen containing the history of all the infusions for the selected patient.
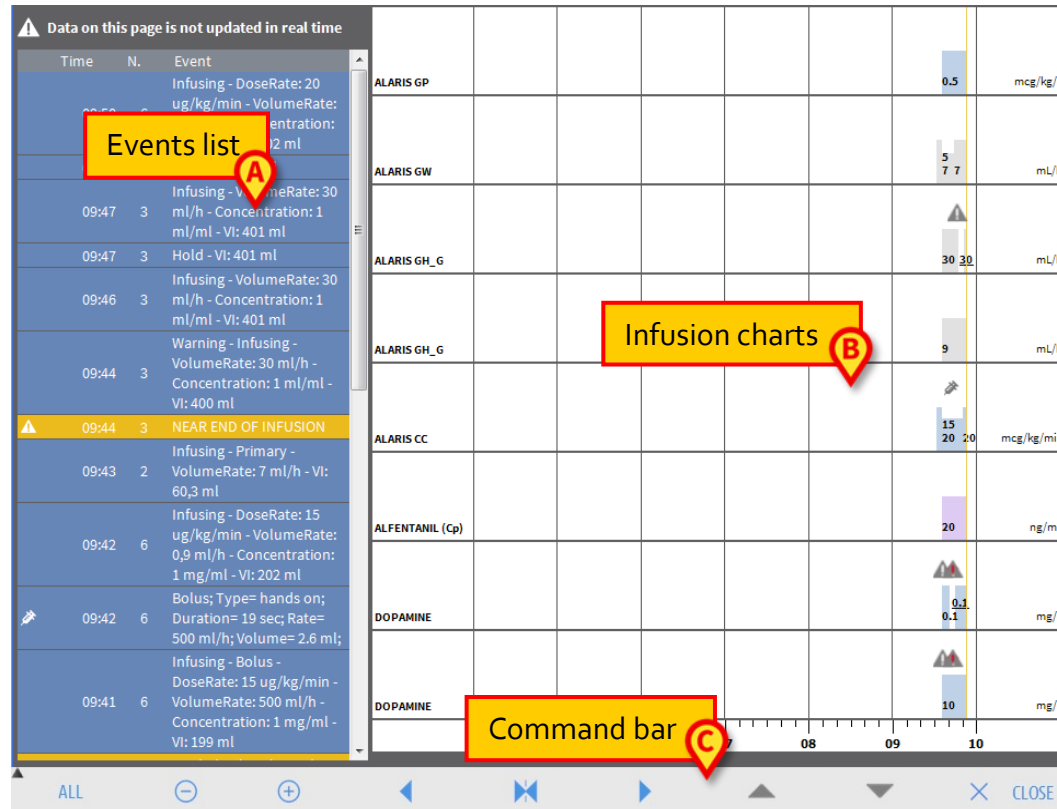
Fig 111

The screen consists of three main parts. These are a:

- List of all the events that occurred on all the pumps connected to the selected patient during their stay (Fig 111 **A** – see page 118);
- Chart representing all the patient's infusions (Fig 111 **B** – see page 120);
- Command bar making it possible to manage the chart display mode (Fig 111 **C** – see page 119).

WARNING: The data displayed on this screen are not updated in real time; they are updated every time the screen is accessed.

Events list

The table shown in Fig 112 contains a list of all the events that occurred on all the pumps connected to the selected patient during their stay.

Time	N.	Event
09:50	6	Infusing - DoseRate: 20 ug/kg/min - VolumeRate: 1,2 ml/h - Concentration: 1 mg/ml - VI: 202 ml
09:49	6	Hold - VI: 202 ml
09:47	3	Infusing - VolumeRate: 30 ml/h - Concentration: 1 ml/ml - VI: 401 ml

Fig 112

Every line on the list corresponds to an event. For every event the following information is provided:
- Time of occurrence,
- Number of the pump on which the event occurred,
- Short description of the event.

The kind of events that can be displayed are:

- Clinical events (such as boluses, for which the type, duration and quantities are specified, or Guided Relay step changes);

Two different, specific events are recorded in case of self-administered boluses: "auto-bolus" and "empty auto-bolus". The "auto-bolus" event is recorded if the bolus is actually administered. The "empty auto-bolus" event is recorded if the bolus is triggered by the patient but is not administered for clinical reasons. Two different icons ☝ and ☝ indicate these events.

- Events referring to the pump status (that is, alarms, connection/disconnection notifications and so on);
- Pump logs (the INFUSION module can be configured to list, in this area, some selected pump logs).

The "Infusion history" command bar

The buttons on the command bar of the "Infusion history" screen (Fig 113) are used to perform different actions.

Fig 113

The ▲ and ▼ buttons scroll up and down the chart area when there are too many charts to display at the same time.

⊖ decreases the chart scale and increases the way the time span is displayed.

⊕ increases the chart scale and decreases the time span displayed.

◀ displays a time preceding the time currently displayed (it makes it possible, namely, to move backwards on the time line).

▶ displays a time following the time currently displayed (it makes it possible, namely, to move forwards on the time line).

◄► displays the current time.

NOTE: When the display mode is changed using the ⊖ and ⊕ buttons, the ◄► button flashes.

The button indicated in Fig 113 **A** makes it possible to filter the kind of events displayed.

➤ Click this button to open the menu shown in Fig 114.

Fig 114

The first option on the menu displays the name of the pump currently selected. Click one of the events on the events list (Fig 112) to select a pump.

On the menu:

> ➢ Click the button displaying the pump name to display only the events that occurred on that pump.

BOLUS and **GUIDED RELAY** display only the events relating to boluses administration and Guided Relay.

LOW, MEDIUM and **HIGH PRIORITY ALARMS** display only the messages corresponding to the selected priority.

OTHER displays other events not relating to the above-mentioned categories.

ALL displays all the events.

The "Infusion history" charts

The charts on the "Infusion history" screen represent the trends of the infusions for the selected patient (or bed, if no patient is selected). The chart is analogous to the one of the "Patient station" screen, described on page 105.

See "Patient station" section for the chart explanation and the instructions on how to read it. Each row on this chart represents an infusion. On this screen, a new row is created each time that:

- A pump is connected,
- The drug is changed on an existing pump,
- The infusion unit of measure is changed.

Pump Details

On the "Patient station" screen (Fig 98), click one of the pump buttons on the left to display a screen containing detailed information on the pump (Fig 115).
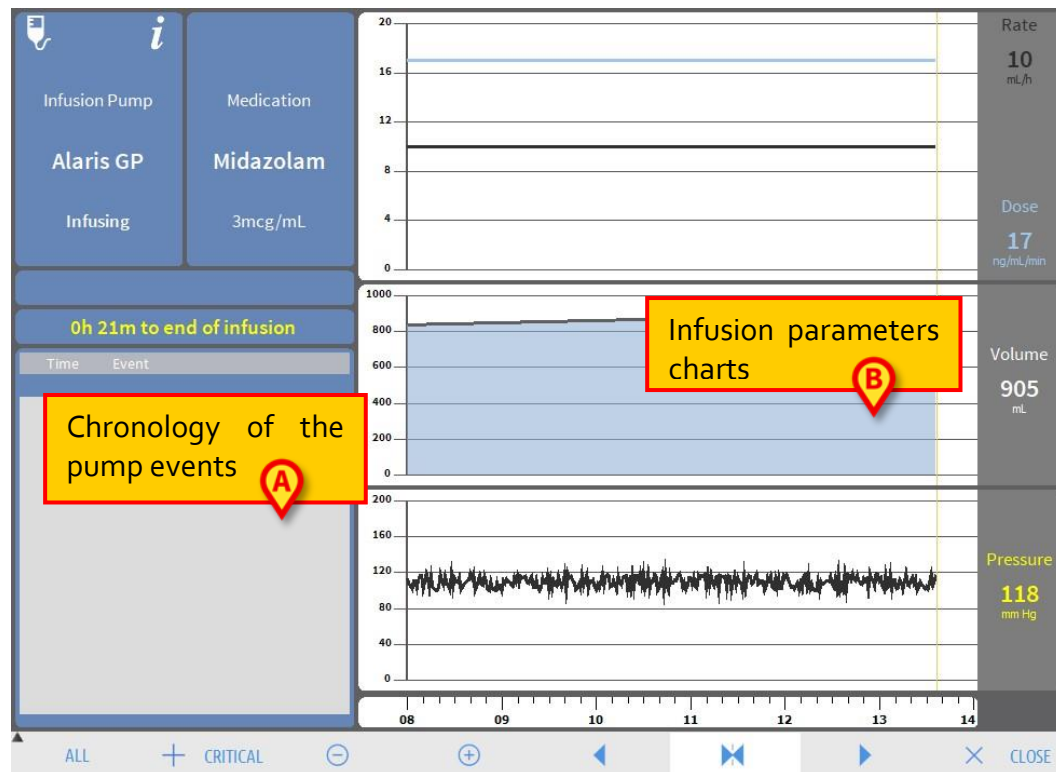
Fig 115

On the left, a list of all the events occurred on the selected pump is displayed (Fig 115 **A**). On the right three charts are displayed, representing some of the trends of the current infusion parameters (Fig 115 **B**).

WARNING: The events list (Fig 115 A) refers to the association of a given pump with a specific drug. Therefore, if a new drug is associated with a given pump, the event list starts all over again. The new combination is a new entity for INFUSION.

The charts on the "Pump detail" screen

The charts on the right of the screen (Fig 115 **B**) display the trends of some of the infusion parameters. The values of the different parameters are indicated along the vertical axis of the charts. The horizontal axis represents time. The represented parameters are:

- Volume rate and dose rate of the infused drug (Fig 116);
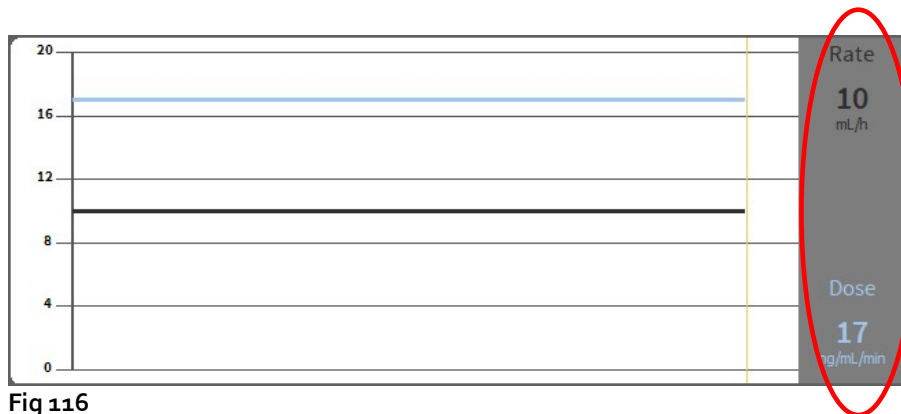
Fig 116

- If the pump is set to pharmacokinetic mode, three lines are displayed on the chart, corresponding to: 1) target value; 2) plasmatic concentration; 3) "effect site" concentration. The displays on the right show the three corresponding values (Fig 116);
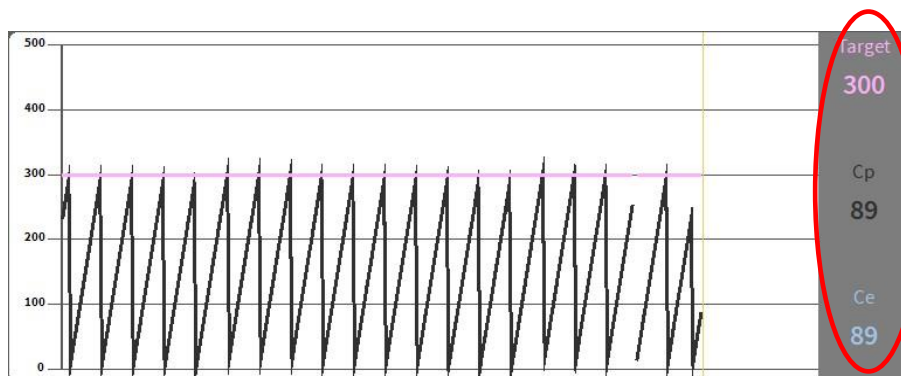
Fig 117

- Total infused volume (Fig 118);
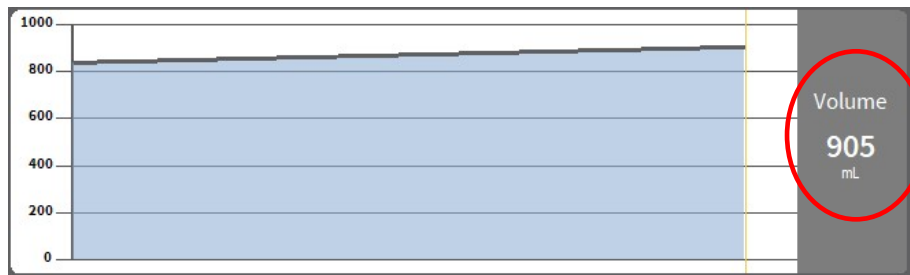
Fig 118

- Infusion circuit pressure (Fig 119).
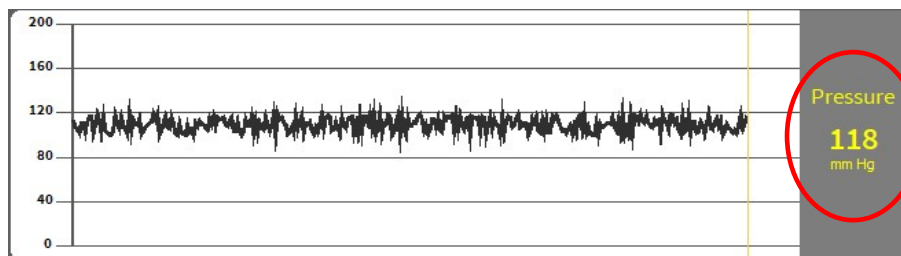
Fig 119

NOTE: For some pump models, it is not possible to display the infusion circuit pressure values.

The current values of the four parameters are indicated on the right of each chart (they are circled in red in the figures).

CAUTION: *Charts and displays are updated at one minute intervals.*

Click any of the charts to display a cursor. The corresponding time is displayed at the bottom, in a label. The corresponding values are visible on the displays on the right.

The "Pump detail" screen command bar

Fig 120 shows the command bar of the "Pump detail" screen. This section lists the functionality invoked by the buttons on the command bar.

Fig 120

All (Fig 120 **B**) filters the events list. See the next section for the events list description.

CRITICAL (Fig 120 **C**) marks the drug as "Critical". "Critical" drugs are characterized by different, specific alarm sounds. After clicking the button, user confirmation is requested before the drug is labelled as "Critical".

Five buttons, circled in Fig 120 **A**, make it possible to change the chart display mode:

⊖ decreases the chart scale and increases the way the time span is displayed;

⊕ increases the chart scale and decreases the way the time span is displayed;

◀ displays a time preceding the time currently displayed (it enables you to move backwards on the time line);

▸ displays a time following the time currently displayed (it enables you to move forwards on the time line);

◂▸ displays the current time again.

NOTE: When the chart display mode is changed with the ⊖ and ⊕ buttons, the ◂▸ button is highlighted. The user is constantly warned.

CLOSE closes the "Pump detail" screen and displays again the "Patient station" screen (Fig 98).

WARNING: The "critical drugs" feature shall be considered only as a support for the drug management workflow.

WARNING: The "critical drugs" list must be updated after a Guardrails™ update. That is, if a new drug is added to the Guardrails™ drugs list, then it must also be added to the list of "critical drugs".

Event list of a selected pump

A table on the left of the "Pump detail" screen lists all the events that occurred on the pump in chronological order (Fig 115 **A**, Fig 121).

Time	Event
09:50	Infusing - DoseRate: 20 ug/kg/min - VolumeRate: 1,2 ml/h - Concentration: 1 mg/ml - VI: 202 ml
09:49	Hold - VI: 202 ml
09:42	Infusing - DoseRate: 15 ug/kg/min - VolumeRate: 0,9 ml/h - Concentration: 1 mg/ml - VI: 202 ml
	Bolus; Type= hands on; Duration=

Fig 121

The rows in the list refer to single events. The time of occurrence and a short description are provided for every event. The kind of events that can be displayed are:

- Clinical events (such as boluses, for which the type, duration and quantities are specified);

Two different, specific events are recorded in case of self-administered boluses: "auto-bolus" and "empty auto-bolus". The "auto-bolus" event is recorded if the bolus is actually administered. The "empty auto-bolus" event is recorded if the bolus is triggered by the patient but is not administered for clinical reasons. Two different icons ☚ and ☚ indicate these events.

- Events referring to the pump status (that is, alarms, connection/disconnection notifications, and so on);
- Pump logs (the INFUSION module can be configured to list, in this area, some selected pump logs).

WARNING: The events list refers to the association of a given pump with a specific drug. Therefore, if a new drug is associated with a given pump, the event list starts all over again. The new combination is a new entity for INFUSION.

The button indicated in Fig 120 **B** on the command bar opens a menu that filters the events list (Fig 122).

| BOLUS AND GUIDED RELAY |
| LOW PRIORITY ALARMS |
| MEDIUM PRIORITY ALARMS |
| HIGH PRIORITY ALARMS |
| ALL |

Fig 122

BOLUS AND GUIDED RELAY displays only the events relating to boluses administration and Guided Relay.

The buttons referring to the different priorities display only the messages corresponding to the selected priority.

ALL displays all the events.

Pump and medication buttons

There are two buttons in the top left corner of the "Pump detail" screen, one referring to the pump, one referring to the medication (Fig 123).
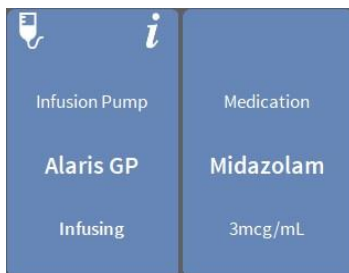
Fig 123

The information that can be displayed on the pump button is:

- Status icon indicating the pump status (infusing, paused, alarmed, and so on).
- Pump name.
- Brief description of the possible alarm, if the pump is alarmed.

The background color depends on the pump status:

- Red: high priority alarm
- Yellow: medium priority alarm
- Cyan: low priority alarm
- Grey: paused
- Blue: infusing

➢ Click the **Pump** button to access the available online pump documentation. The information displayed on the **Medication** button is:

- Medication name.
- Medication dose/dilution (if available).

➢ Click **Medication** to access the available online medication documentation (if configured).

Events print report

To print a report of the occurred events:

> ➤ Click the **MENU** button on the Alaris Infusion Central "Control Bar" (Fig 124).

Fig 124

The following menu is displayed (Fig 125).
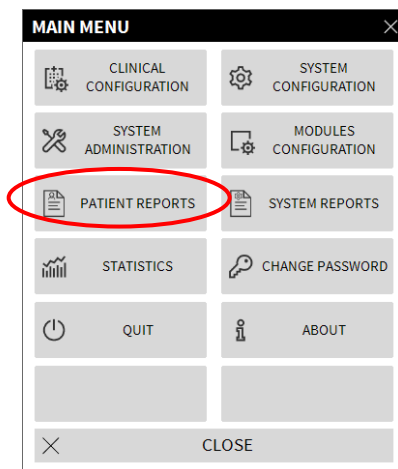
Fig 125

> ➤ Click **PATIENT REPORTS** (Fig 125).

The following menu is displayed (Fig 126).
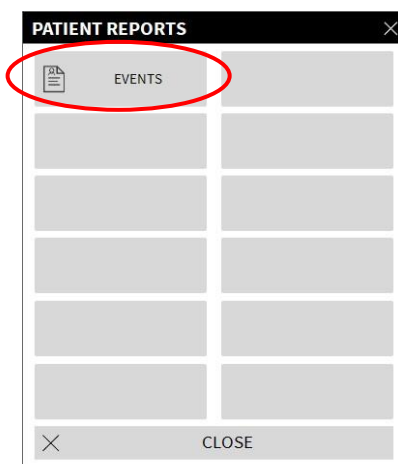
Fig 126

> ➤ Click **EVENTS** (Fig 126).

The following window opens (Fig 127).
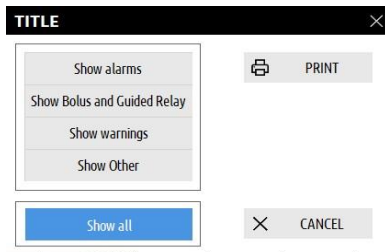
Fig 127

> ➢ Click the buttons on the left to select the information to be printed.

The buttons corresponding to the chosen options appear as selected (Fig 128 **A**).
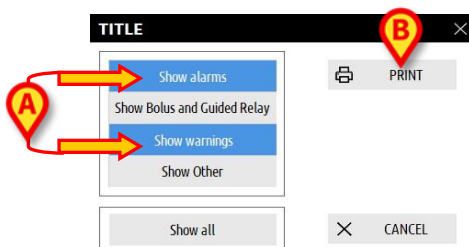
Fig 128

> ➢ Click **PRINT** (Fig 128 **B**).

A print preview is displayed. The system's print functionality is described in the "Print reports" section, page 49.

AIC Dashboard

Using the "AIC Dashboard" tool, you can generate detailed reports of any kind of notification that occurred on the pumps.

To activate this tool:

  ➢ Click the **MENU** button on the Alaris Infusion Central "Control Bar" (Fig 129).

Fig 129

The following menu is displayed (Fig 130).
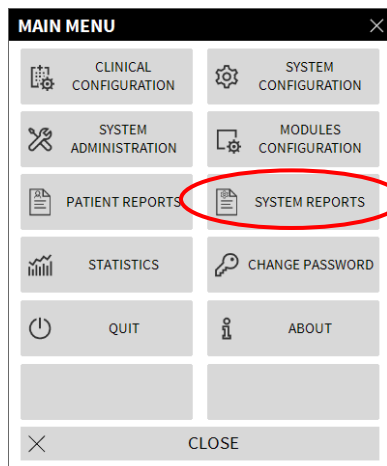
Fig 130

 ➢ Click **SYSTEM REPORTS** (Fig 130).

The following menu is displayed (Fig 131).
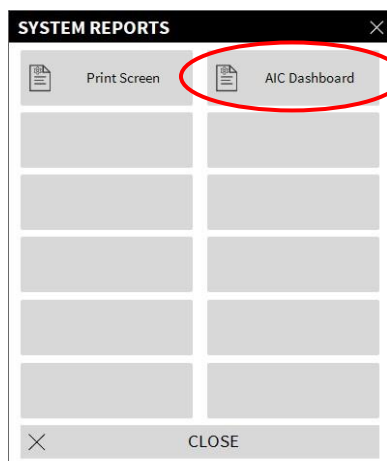
Fig 131

> ➢ Click **AIC Dashboard** (Fig 131).

The following window opens (Fig 132).

Fig 132

Use the filters to define the kind of report you want to generate:

- Either events referring to **All Patients** or the **Current Patient**.
- Date range of occurrence.
- Events referring to specific **Drugs**. The drop-down menu makes it possible to select either all drugs or only critical drugs (as defined on the "Pump detail" screen - see page 124, Fig 120 **C**). In here, you can type the name of a specific drug as free text.
- The **Include data from infusions without drug name** checkbox includes the data relating to drugs for which only the volume rate information is available (that is, the drug name is not specified on the pump).
- Specific **Events**.
- Specific **Pumps**.

Only available if **All patient**s is selected:

- **Wards**: Indicates whether all wards, single ward or single bed is considered for the report.
- **Ward**: Ward name (available if either **single ward** or **single bed** are selected).
- **Bed**: Bed number (available if **single bed** is selected).

Report View makes it possible to select the information display mode on the generated record (**Quarterly, Monthly, Weekly, Daily** view).

Notification display on "Control Bar"

The occurrence of events is notified on "Control Bar" (Fig 133).

Fig 133

The area circled in Fig 133 is an indicator of the possible events occurring on one or more infusion pumps. This notice is always visible, independent from the module currently selected. In this way, the user is informed on the status of the pumps at all times, even if the INFUSION module is not currently displayed.

If no notification is provided, the area looks as shown in Fig 133.

If a high priority alarm is activated, the button turns red.

In the case of a medium priority alarm, the button turns yellow.

In the case of a low priority alarm, the button turns cyan.

In the case of different alarms occurring at the same time, the highest priority alarm is notified on "Control Bar".

In all cases, the relevant alarms are specified in the lateral "Notification area"

(Fig 134 **A**).

If the system is not configured to always display the "Notification area" (Fig 134 **A**), then:

> ➤ Click the area indicated in Fig 133 to display the "Notification area".
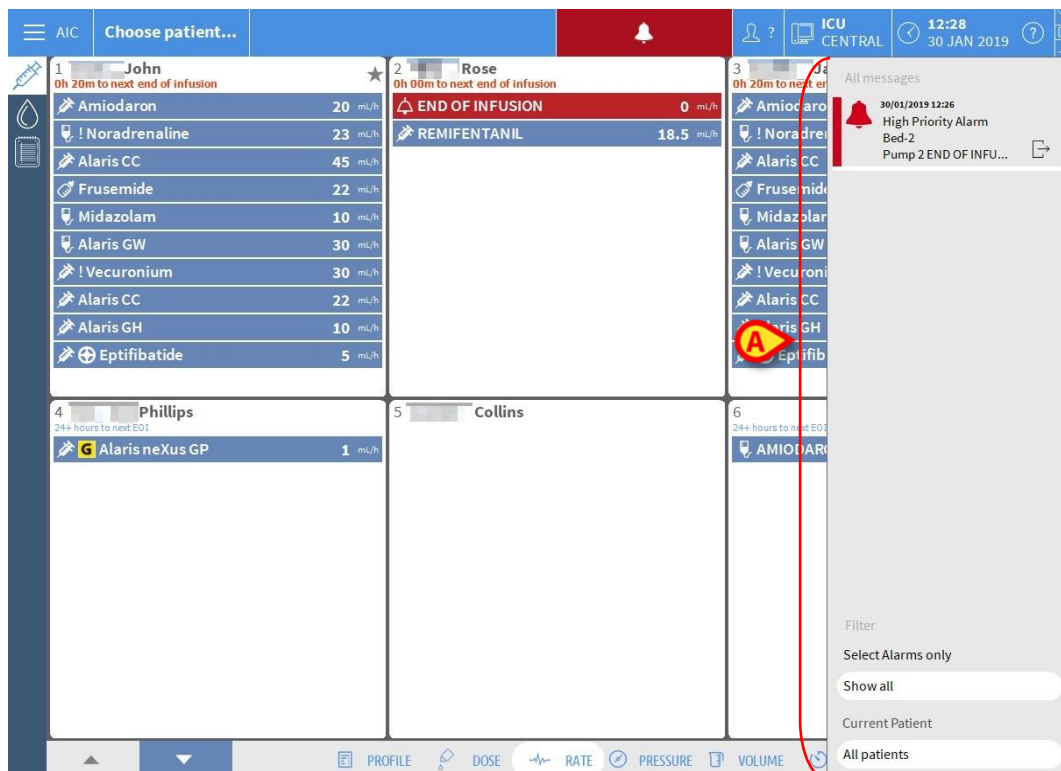
Fig 134

For a description of the "Notification area" see page 103.

Associating an AGW to a different bed

It is possible to associate an existing AGW with a different bed.

To associate an existing AGW with a different bed:

> ➢ Click the **MENU** button on the Alaris Infusion Central "Control Bar" (Fig 135).

Fig 135

The following menu is displayed (Fig 136).
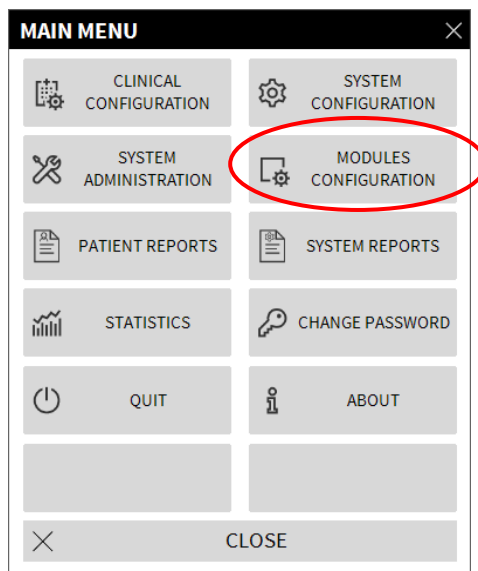
Fig 136

> ➢ Click **MODULES CONFIGURATION** indicated in Fig 136.

The following menu is displayed (Fig 137).
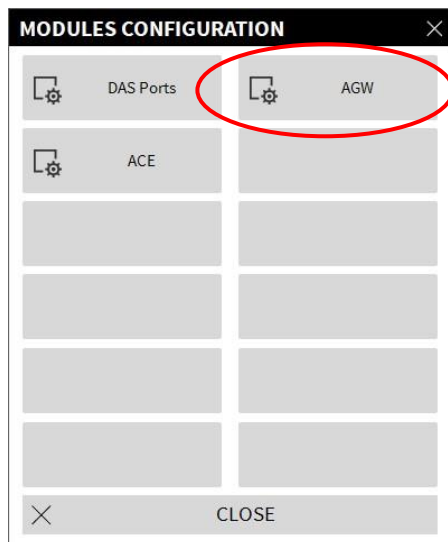
Fig 137

> ➢ Click **AGW** indicated in Fig 137.

The following window opens (Fig 138).
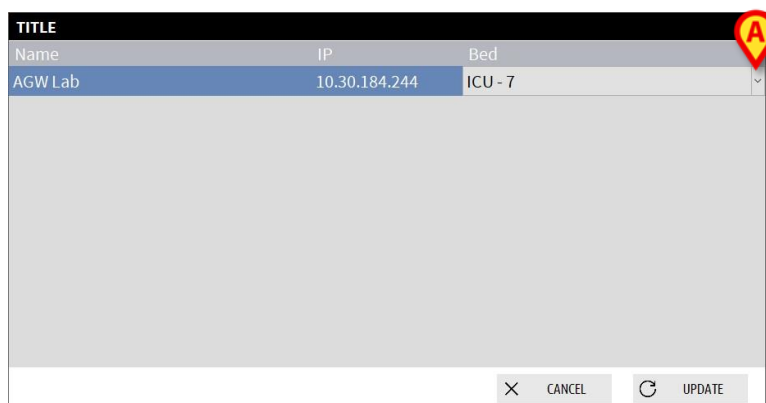
Fig 138

In this window, each row represents an AGW existing in the current domain. For each AGW, the Name, IP address and Bed with which it is associated are displayed.

To associate the AGW with a different bed:

> ➢ Click the button on the right of the row corresponding to the AGW to which you want to assign a different bed (Fig 138 **A**).

A menu containing a list of all the beds in the domain is displayed (Fig 139).
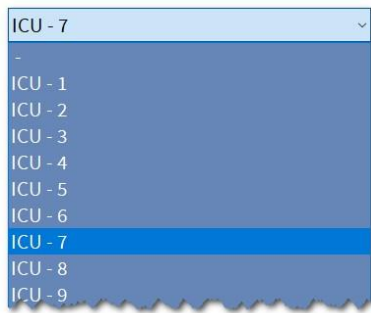
Fig 139

> ➢ Select the bed to associate with the AGW.

> ➢ Click **UPDATE** in the bottom right corner of the window.

Switching from standard time to daylight saving time

This section explains the way information is displayed on the module's charts when the time switches from standard time to daylight saving time and vice versa.

In both cases (standard time to daylight saving time and daylight saving time to standard time) a vertical bar is displayed on the chart at time of the switch.

When switching from standard time to daylight saving time (the clock "jumps" one hour forward), the time corresponding to 03:00 a.m. is not displayed. That is, the vertical bar is displayed at 02:00 a.m. and the next hour is 04:00 a.m.

When switching from daylight saving time to standard time (the clock "jumps" one hour back), the time corresponding to 02:00 a.m. is repeated twice. That is, the vertical bar is displayed at 02:00 a.m. and the next hour is again 02:00 a.m.

Fluid Balance

This paragraph describes the FLUID BALANCE module features and functionality.

The FLUID BALANCE module gives the precise fluid balance for each patient, because it records Input and Output data throughout the day.

The INFUSION module automatically sends all administered volume values to FLUID BALANCE. The clinical staff only has to enter non-automatically interfaced Input and Output fluids to obtain partial and total fluid balances. All Input and Output items can be configured by the user.

Module selection

To select the FLUID BALANCE module:

> ➢ click the corresponding icon on the lateral bar.

If a patient is selected, the screen displays the selected patient data.

If no patient is selected, the module's functionality is not available. A specific notification is provided in this case: "No Patient Selected".

Patient selection

See page 66 for the patient selection procedure. When a patient is selected, the data displayed on the screen refer to the selected patient.

"Fluid Balance" main screen

The main screen consists of three main areas:

- Table (Fig 140 **A,** see page 139 for the description),
- Chart (Fig 140 **B** see page 143),
- Command bar (Fig 140 **C** see page 144).
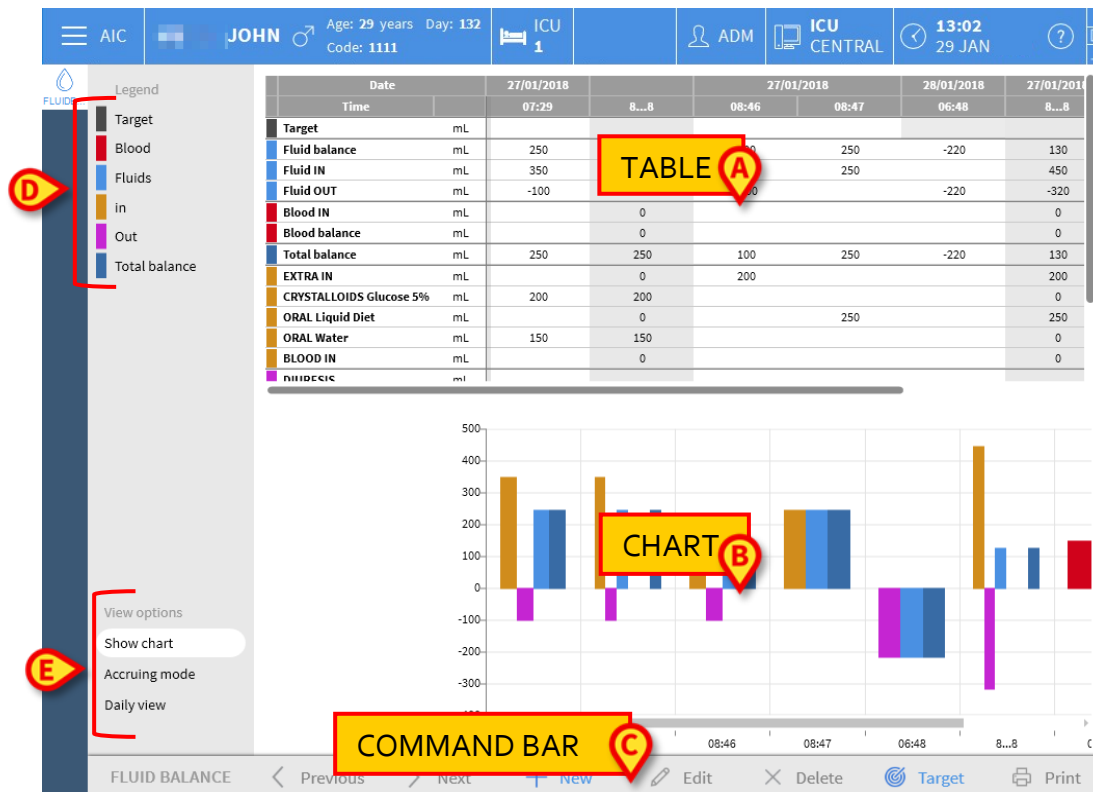
Fig 140

These areas are described in the referenced sections.

In the column on the left there:

a) Is a legend making it possible to understand the color code used for the balance items (Fig 140 **D**).

b) Are three balance display options (Fig 140 **E**).

Legend

The legend makes it possible to understand the meaning of the colors characterizing the various balance items (Fig 141).
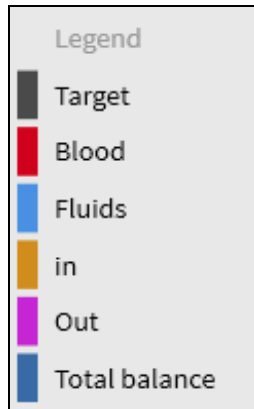
Fig 141

Target: Daily target. See page 158.

Blood: Items belonging to the "Blood" class.

Fluids: Items belonging to the "Fluids" class.

In: Input items.

Out: Output items.

Total Balance: Total balance.

Display options

In the area indicated in Fig 140 **E** and enlarged below, there are up to four data display options.
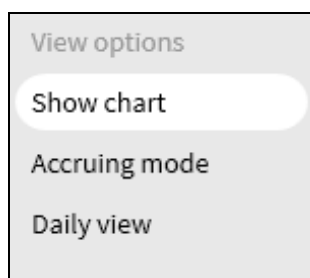
Fig 142

Show Chart: If selected, displays the fluid balance chart. Otherwise only the table is displayed. See page 143.

Accruing Mode: Displays the data in accruing mode. See page 156.

Daily View: Displays the data in daily mode. See page 157.

Values/g: Only visible if set up in the configuration. Given the patient weight, this option makes it possible to display data as fluid amount per gram.

Table

The table (Fig 143) displays all the "in" and "out" values of the fluids to and from the patient, providing total and partial fluid balances at the same time.

Date		28/01/2018				29/01/2018	
Time		09:22	10:39	12:09	8...8	09:03	8...8
Target	mL						
Fluid balance	mL	350	-180	110	280	80	80
Fluid IN	mL	350		110	460	80	80
Fluid OUT	mL		-180		-180		0
Total balance	mL	350	-180	110	280	80	80
EXTRA IN	mL				0	80	80
CRYSTALLOIDS Glucose 5%	mL	150			150		0
ENTERAL Nutrison MCT	mL			110	110	0	0
ORAL Water	mL	200			200		0
DIURESIS	mL		-180		-180		0
DRAINAGES	mL						
EXTRA OUT	mL						
PERSPIRATIO	ml						

Fig 143

How to read the table - Rows

On the left are the names of the fluid balance items whose values are specified in the table (Fig 143 **A**). The first cell of every row indicates the name of the balance item whose values are displayed in the row itself, the color characterizing its class and the unit of measure.

Date
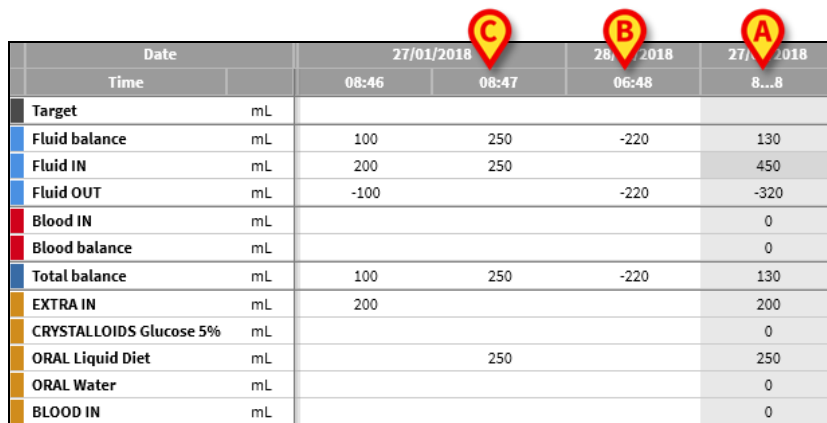
The first row indicates the date to which the values on the table refer.

Date		28/01/2018				29/01/2018	
Time		09:22	10:39	12:09	8...8	09:03	8...8

Fig 144

The system considers a 24-hour period (configurable) as one "clinical day". The "clinical day" usually begins at 08:00 a.m. (configurable). Therefore, a day starts at 08:00 and ends the morning after at 08:00. All the values recorded during this period are assigned by the system to the same clinical day and labelled together. That is, the balance of the 27th of January starts at 08:00 a.m. on the 27th and ends at 08:00 a.m. on the the 28th. A value entered at 06:48 a.m. on the 28th belongs to the balance of the previous day (27th). The table, in this case, looks like the one shown in Fig 145:

- Column **A** shows the total balance of the 27th of January
- Column **B** shows the last value inserted for that day, at 06:48 a.m. on the 28th.
- Column **C** shows the value inserted at 08:47 a.m. on the 27th.
- Columns **B** and **C** both belong to the balance of the same day (displayed in grey, column **A**).
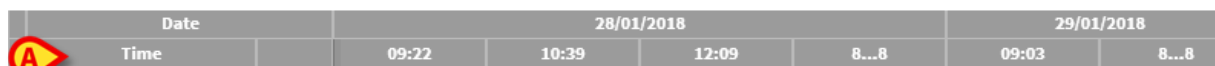
Fig 145

Time

The second row displays the time of every fluid balance calculation.
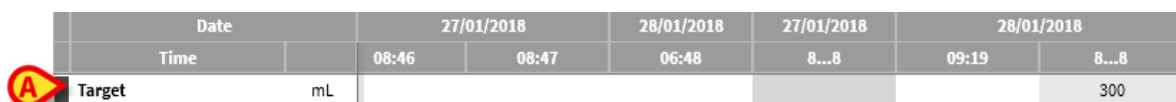
Fig 146

Time is automatically recorded every time a fluid value is recorded. See page 148 for the fluid balance values recording procedure. The column displaying the daily total balances is indicated by the "**8... 8**" label. In this column, the ⚠ icon is displayed when there are user notes referring to that balance.

Target

The third row displays the daily target, that is the target balance indicated for the patient.
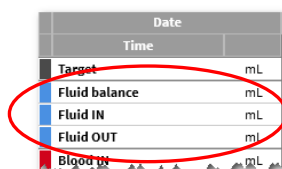
Fig 147

The daily target can be specified both for the current and for the following day. See page 158 for the daily target setting procedure.

Total balances

Three lines, highlighted in blue, display the total balances (Fig 148).

Fig 148

The total fluid balance (labelled as **Fluid balance** in the figure, not including blood), the total **Fuid IN** balance and the total **Fluid OUT** balance are displayed (in this order).

Blood balance

Up to three lines, highlighted in red, display the blood balances: **Blood IN**, **Blood OUT** and **Blood balance** (the sum of "Ins" and "Outs"). Fig 149 shows an example.

Fig 149

Total balance

The "Total Balance" row displays the total balance, considering all the in and out items, including blood.

Fig 150

Detailed IN and OUT values

The rows marked in yellow display the detailed fluids IN values (Fig 151 **A**).

The rows marked in magenta display the detailed fluids OUT values (Fig 151 **B**).

Fig 151

NOTE: The values coming from the infusion pumps are automatically acquired.

How to read the table - columns

A column is added to the table every time a user specifies any fluid values. See page 148 for the related procedure.

The first cell of every column displays the time the column was added. The time displayed, therefore, is the values insertion time (Fig 152 **A**).

Date		28/01/2018				29/01/2018	
Time	Ⓐ	09:22	10:39	12:09	8...8	09:03	8...8
Target	mL						
Fluid balance	mL	350	-180	110	280	80	80
Fluid IN	mL	350		110	460	80	80
Fluid OUT	mL		-180		-180		0
Total balance	mL	350	-180	110	280	80	80
EXTRA IN	mL			Ⓑ	0	80	80
CRYSTALLOIDS Glucose 5%	mL	150			150	Ⓒ	0
ENTERAL Nutrison MCT	mL			110	110	0	0
ORAL Water	mL	200			200		0
DIURESIS	mL		-180		-180		0
DRAINAGES	mL						
EXTRA OUT	mL						
PERSPIRATIO	ml						

Fig 152 - Table

The total fluid values referring to the previous day are displayed in a specific column, characterized by the grey background color (Fig 152 **B**). This column is automatically added when the clinical day begins and is updated during the day with the new values specifications. At daily balance closing time, the column is "frozen" and a new column is created. The daily balance closing time depends on a configuration parameter. In the configuration explained here, the clinical day ends at 08:00 a.m.. The last column of the table (Fig 152 **C**) displays the total values for the current day updated to the present time. The first cell of the "Totals" column displays the date to which the total balances refer (Fig 153 **A**); the second cell specifies the relevant time span (Fig 153 **B** - in the present configuration it is 08:00 to 08:00); the third column displays, if specified, the daily target (Fig 153 **C**).
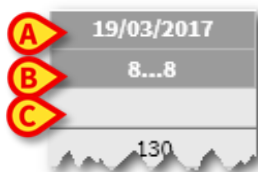
Fig 153

Specific information tooltips are displayed when the mouse pointer is positioned over the column headings in the table (Fig 154).

Fig 154

Chart

The lower part of the Fluid Balance main screen (Fig 155 **A**) displays, in a chart, the balance values specified in the table. The chart is displayed only when the corresponding display option is selected.
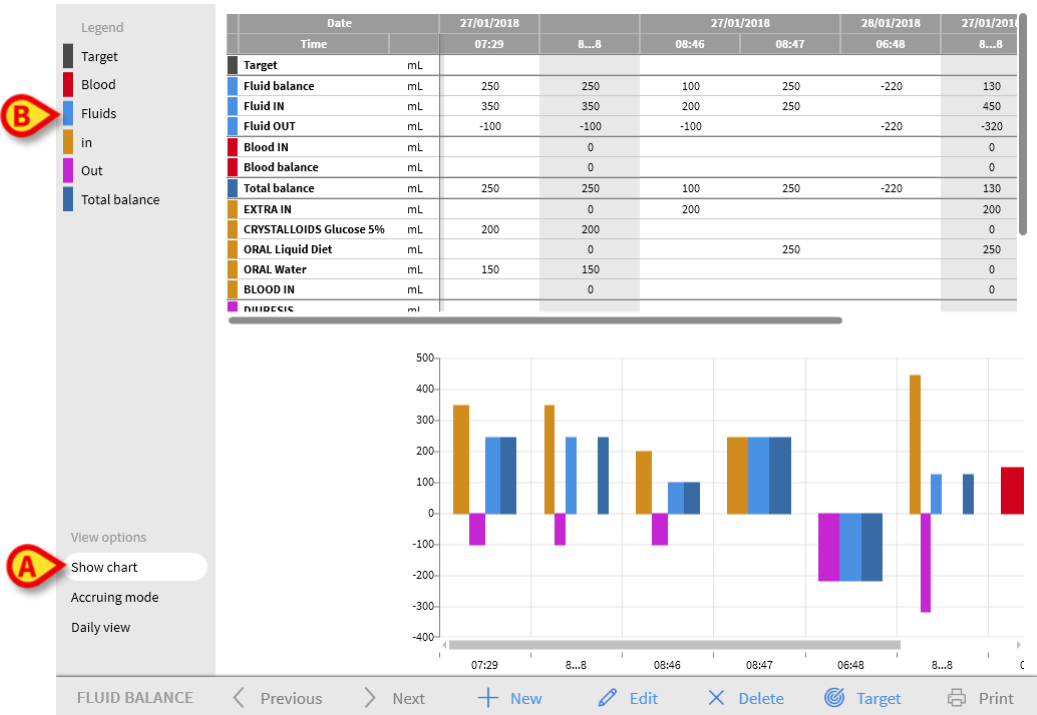

Fig 155

The fluid IN and OUT quantities can be read on the vertical axis (in mL - Fig 156 **A**).
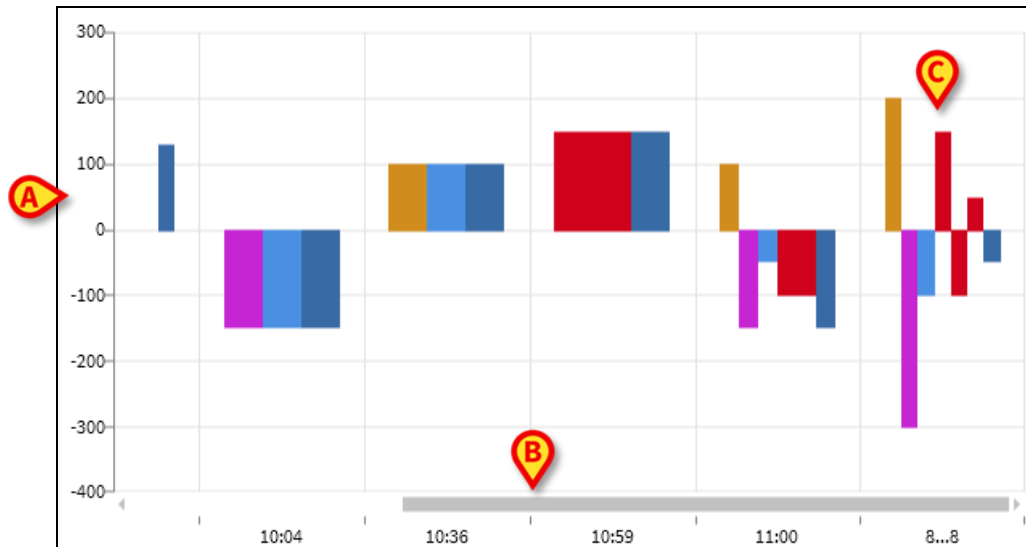The fluid variation date and time can be read on the horizontal axis (Fig 156 **B**).

Fig 156 - Chart

The variations in the fluid balance are represented by vertical bars. The color corresponds to the color of the corresponding class, as indicated by the legend

(Fig 155 **B**). Move the mouse pointer over the chart to display a tooltip indicating the reference class. The bars above **0** represent fluid INs, the bars below **0** represent fluid OUTs.

When the clinical day changes (at 8:00 a.m. in this configuration), a bar labelled as

8... 8 is added, showing all the daily total balances (Fig 156 **C**).

Command bar

The buttons on the command bar of the FLUID BALANCE module main screen make it possible to perform different procedures.

Fig 157 - Command bar

This paragraph briefly describes the functions of the different buttons. The related procedures are described later in the indicated sections.

The **Previous** and **Next** buttons make it possible to display the balance values inserted before or after the time currently displayed.

New - Enter values in the fluid balance table (see page 148).

Edit - Edit the values of an already existing balance (see page 153).

Delete - Delete one of the inserted balances (see page 155).

Target - Set the daily target (see page 158).

Print - Access the system's print functionalities (see page 160).

Data entry: the "New" button

The **New** button on the command bar (Fig 158) makes it possible to record a change in the patient's fluid balances (that is, to insert a fluid balance value - see page 148 for an example of this functionality).
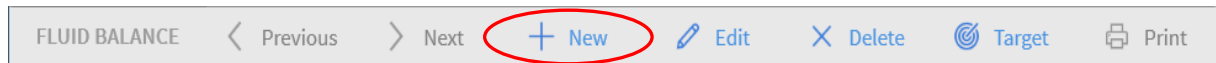
Fig 158

> ➢ Click **New** to access the following screen (Fig 159).

Fig 159

In the window, the following tools are available:

Date/Time indicator (Fig 159 **A**).

Current date/time are set by default, that is, the time at which the **New** button is clicked. To change the date, click the ▦ button. A calendar opens, in which you can select the date to which the balance refers (Fig 160).
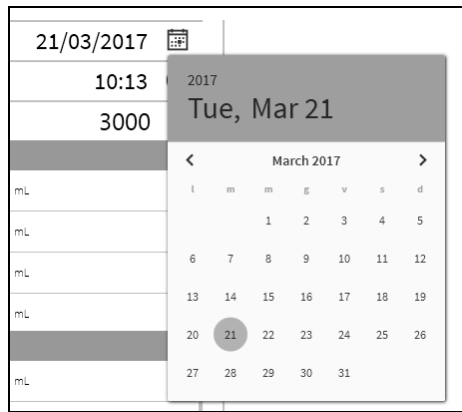
Fig 160

To change the time, click the ⊕ button. A clock is displayed, in which you can select the time to which the balance refers (Fig 161).
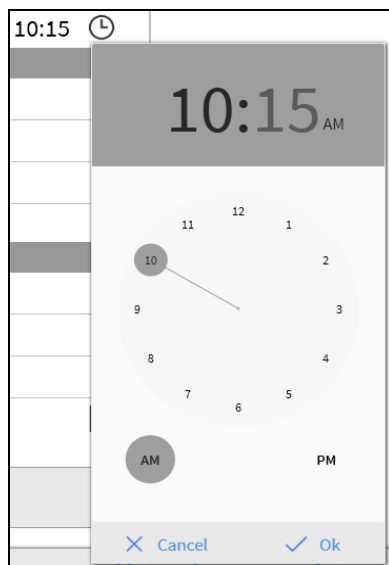
Fig 161
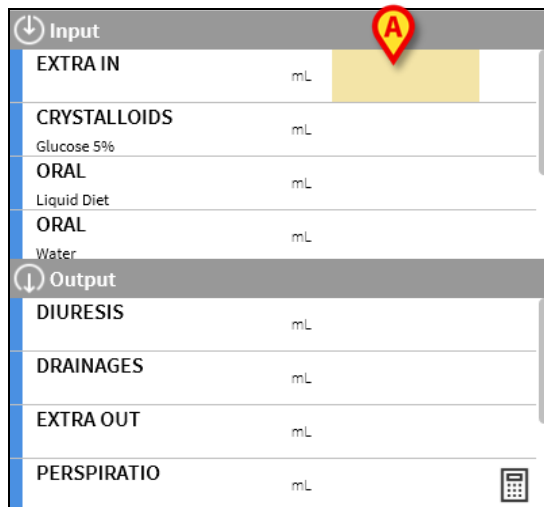
You cannot set a future time.

Patient weight indication (Fig 159 **B**)

The patient weight indication can be made available or unavailable in the configuration. If available, the patient weight must be specified here at every balance insertion. The patient weight indication enables the Value/Grams display mode described on page 158.

Balance items table (Fig 159 **C**)

In this table the balance items are inserted. To do that, click the balance item you want to add, on the right of the unit of measure (Fig 162 **A**).

Fig 162

To specify the balance values you can use either the workstation keyboard or the virtual keyboard indicated in Fig 159 **E**.

Notes (Fig 159 **D**)

In the **Notes** box, you can add any note as free text. If there is a note referring to a balance specification, a specific icon is displayed on the balances table, alongside the insertion time (Fig 164 **A**). Move the mouse pointer over the icon to display a tooltip containing the full note text.
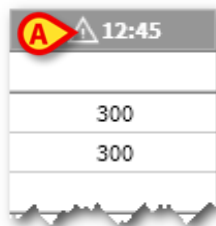
Fig 163

How to insert the balance values

This section gives an example of the fluid balance values insertion procedure.
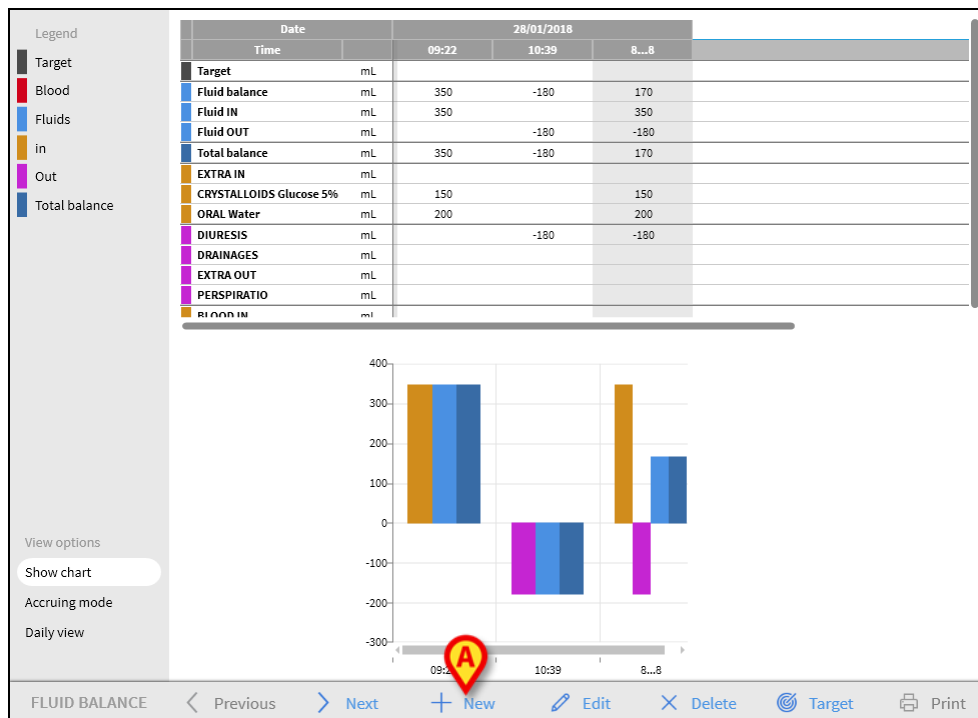
Fig 164

➢ Click **New** on the command bar (Fig 164 **A**).

The following window opens (Fig 165).

Fig 165

> ➢ Insert the balance values using either the workstation keyboard or the virtual keyboard on the right. See Fig 166 **A** for an example.

Fig 166

> ➢ Click **Save** (Fig 166 **B**).

A column is added to the balance table (Fig 167 **A**).
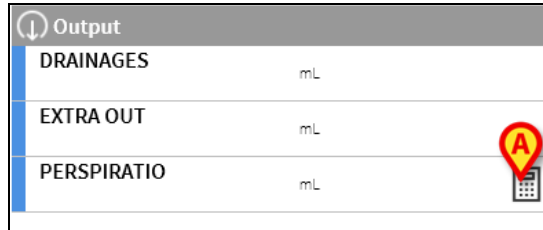

Fig 167

Total and partial balances calculations are automatically performed.

Values automatically acquired from the infusion devices are characterized by a specific ✎ icon.

Other balance items can be added to the table by selecting them from a set of pre-configured items. See page 151 for the procedure.
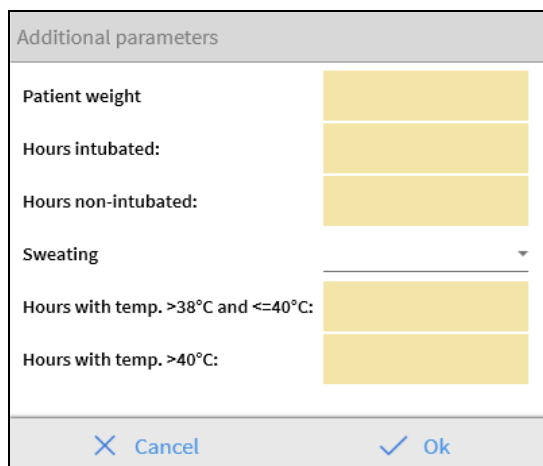
Perspiratio

The "Perspiratio" values can be inserted using an integrated calculation tool (if made available in the configuration). Click the ▦ button alongside "Perspiratio" in the data entry window (Fig 168 **A**).

Fig 168

The following window opens (Fig 169).

Fig 169

Enter the required data and click **Ok**. The perspiration value is automatically calculated.

How to add a balance item

You can add a new item to those listed in the "Fluid Balance items" table.

Fig 170

> Click **Add new item** in the data entry window (Fig 170 **A**).

The following window is displayed.

Fig 171

> Click the down-arrow indicated in Fig 171 **A**.

A menu containing all the configured items opens (Fig 172). The different items are described by the Fluid Balance module's color code. See the "Legend" described on page 138. Use the lateral scroll bar to display all the configured items.

Fig 172

> ➢ Double-click the item to be added.

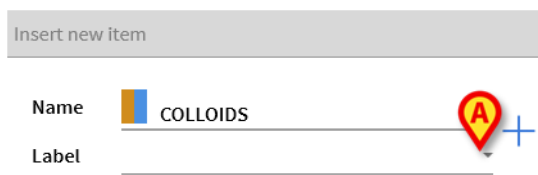The item's name is displayed in **Name** (Fig 173).

Fig 173

> ➢ Use the **Label** menu to further specify the item, if necessary. See Fig 174 for an example.
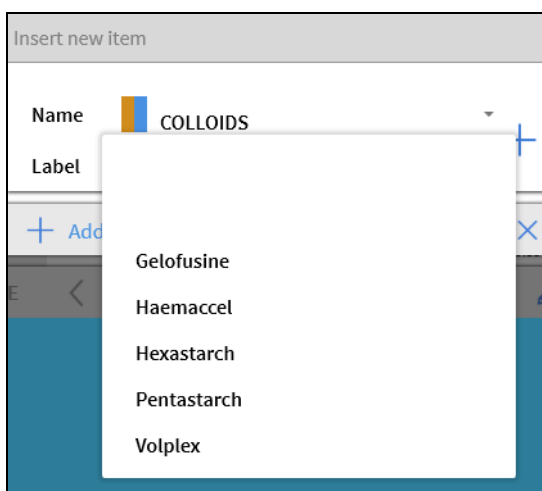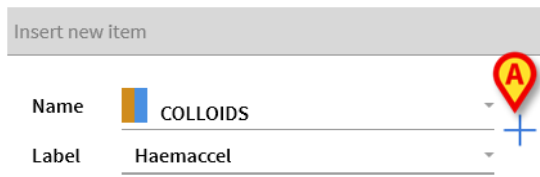
Fig 174

After label specification (not mandatory):

➢ Click the **+** button to add the item to the items table (Fig 175 **A**).

Fig 175

How to edit an existing balance

To edit an existing balance:

➢ Click the column corresponding to the balance to be edited.

The column is highlighted (Fig 176 **A**).
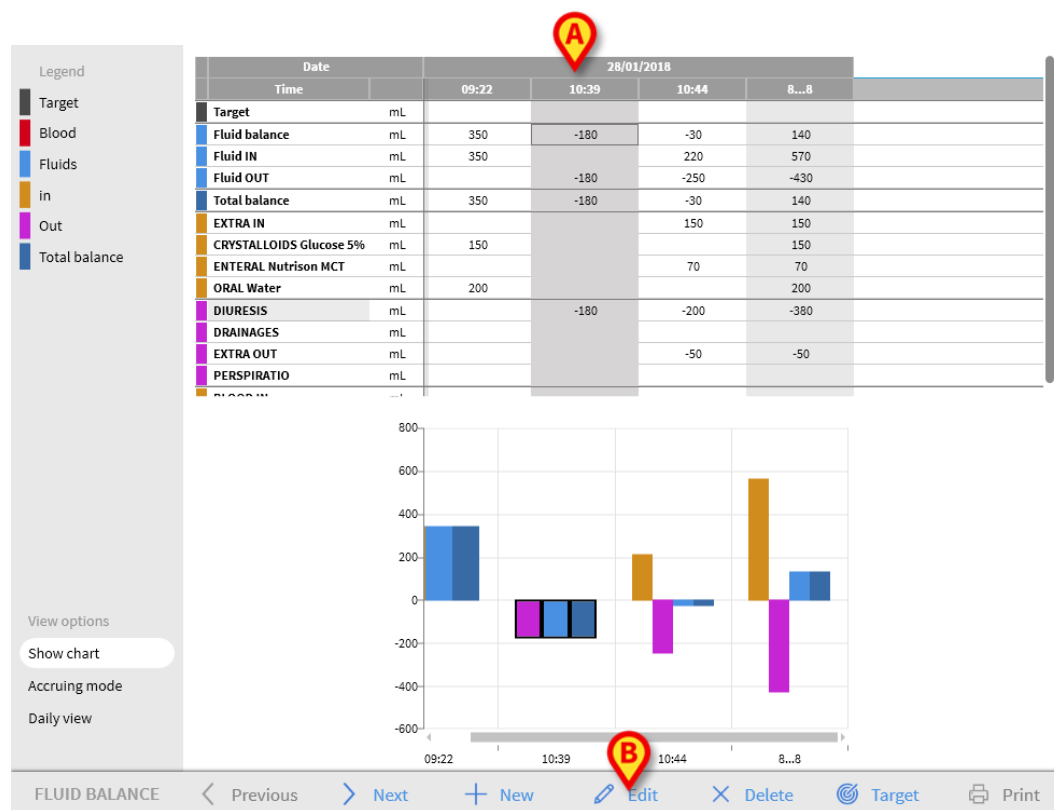
Fig 176

➢ Click **Edit** on the command bar (Fig 176 **B**).

The data entry window opens, containing the values of the selected balance/column (Fig 177).

Fig 177

It is now possible to:

 a) Edit the values of the already inserted items.
 b) Add new items using **Add new item** (Fig 177 **A**) as described on page 151.

 ➢ Click **Save** to save the changes made (Fig 177 **B**).

How to delete an existing balance

To delete an existing balance:

➢ Click the column relating to the balance to be deleted.

The column is highlighted (Fig 178 **A**).
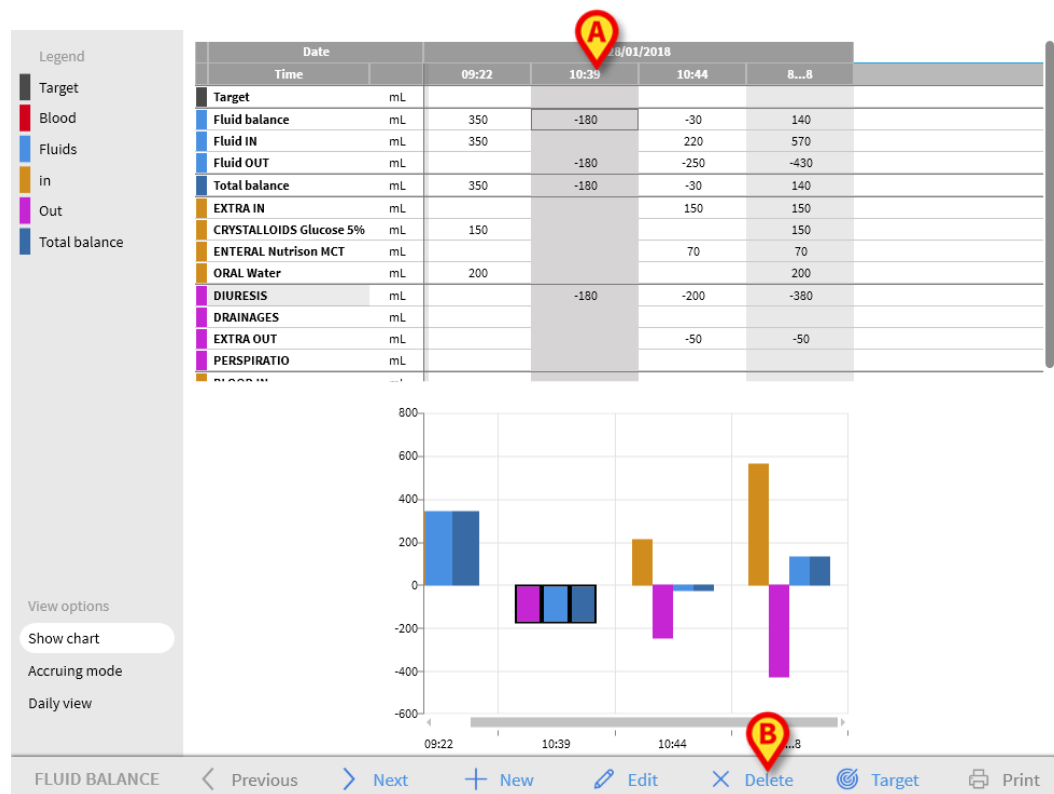

Fig 178

➢ Click **Delete** on the command bar (Fig 178 **B**).

User confirmation is requested.

➢ Click **Yes** to delete the balance/column.

"Accruing" fluid balance

The **Accruing mode** option (Fig 179) makes it possible to change the balance table display mode to "Accruing mode".
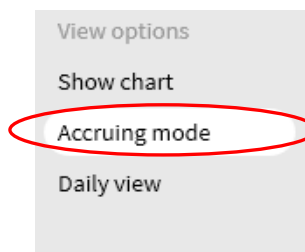

Fig 179

This option, when selected, displays the total values in every column in an "Accruing" mode.

The following examples show the difference between the two display modes (Fig 180 and Fig 181):

Date		28/01/2018			
Time		13:36	13:36	13:37	8...8
Target	mL				
Fluid balance	mL	-100	-100	-100	-300
Fluid OUT	mL	-100	-100	-100	-300
Total balance	mL	-100	-100	-100	-300
EXTRA IN	mL				
DIURESIS	mL	-100	-100	-100	-300
DRAINAGES	mL				
EXTRA OUT	mL				
PERSPIRATIO	mL				
BLOOD IN	mL				

Fig 180 - Normal mode

Date		28/01/2018			
Time		13:36	13:36	13:37	8...8
Target	mL	---→	---→	---→	
Fluid balance	mL	-100	-200	-300	-300
Fluid OUT	mL	-100	-200	-300	-300
Total balance	mL	-100	-200	-300	-300
EXTRA IN	mL	---→	---→	---→	
DIURESIS	mL	-100	-200	-300	-300
DRAINAGES	mL	---→	---→	---→	
EXTRA OUT	mL	---→	---→	---→	
PERSPIRATIO	mL	---→	---→	---→	
BLOOD IN	mL	---→	---→	---→	

Fig 181 - Accruing mode

The two tables shown in Fig 180 and Fig 181 refer to the same balance. The first one is displayed in "Normal" mode, the second one is displayed in "Accruing" mode.

The tables refer to three subsequent data entries.

The first one at 13.36 (100 mL DIURESIS); the second one at 11:36 (100 mL DIURESIS); the third one at 13:37 (100 mL DIURESIS).

Notice, in the tables, the values referring to the DIURESIS item (circled in red in the figures).

In Fig 180 (Normal mode), the second column displays the value 100, the third column displays the value 100.

In Fig 181 (Accruing mode), the second column displays the value 200 (100+100), the third column displays the value 300 (100+100+100).

Total values are displayed in the fourth column. They are the same in both figures (300 mL Out is the total balance value for the DIURESIS item).

"Daily" Fluid Balance

The **Daily view** option(Fig 182 **A**) makes it possible to change the fluid balance table display mode.
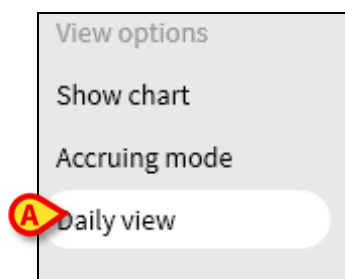

Fig 182

This option displays only the "grey" columns, those displaying the daily totals. See f Fig 183, for example.

Date		26/01/2018	27/01/2018	28/01/2018
Time		8...8	8...8	8...8
Target	mL			300
Fluid balance	mL	250	130	0
Fluid IN	mL	350	450	0
Fluid OUT	mL	-100	-320	0
Blood IN	mL	0	0	150
Blood balance	mL	0	0	150
Total balance	mL	250	130	150
EXTRA IN	mL	0	200	0
CRYSTALLOIDS Glucose 5%	mL	200	0	0
ORAL Liquid Diet	mL	0	250	0
ORAL Water	mL	150	0	0
BLOOD IN	mL	0	0	150
DIURESIS	mL			
DRAINAGES	mL	0	-220	0
EXTRA OUT	mL	-100	0	0
PERSPIRATIO	mL			
FECES	mL	0	-100	0

Fig 183

WARNING: It is possible to display the values in "Daily" and "Accruing" mode at the same time. This kind of display mode increases the possibility of the user entering values that are not exact. It is therefore necessary to pay particular attention to the exactness of data when using this display mode.

Value/grams display mode

The Value/grams display mode, when made available in the configuration, displays the values as amount per gram. To activate this mode, the current patient weight must be specified when fluid balance values are entered, in the data entry window. See page 148.

Target

The **Target** button on the command bar (Fig 184) can be used to specify the balance daily target.
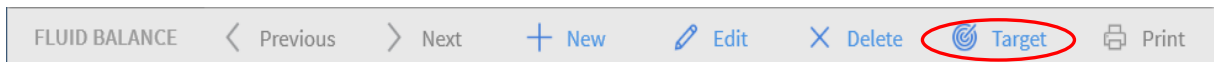

Fig 184

The daily target can be specified both for the current day and for the next day.

To specify the daily target:

> click **Target**.

The following window opens (Fig 185).

Fig 185

> Type the target value in **Current target** (Fig 186 **A**).

Fig 186

> ➢ Click **Save** (Fig 186 **B**).

The fluid balance target is displayed in the table (Fig 187 **A**).

Fig 187

"Fluid balance target" window description

The "Fluid balance target" window provides the following information.

Fig 188

Previous days (Fig 188 **A**): Displays a list of all the targets specified until now. The display format is "Date/Target value/Acronym of the user who specified the value".

Current target (Fig 188 **B**): Makes it possible to specify the target for the current day. Use the **Notes** box to enter a textual note.

Next target (Fig 188 **C**): Makes it possible to specify the target for the next day. Use the **Notes** box to insert a textual note.

Both **Current target** and **Next target** display the date on which the specified target applies.

Save (Fig 188 **D**): Records the specified target and inserts it into the fluid balance table.

Print reports

The **Print** button on the command bar creates a print report containing the patient's fluid balances data (Fig 189). Different print reports can be configured according to the healthcare organization needs.
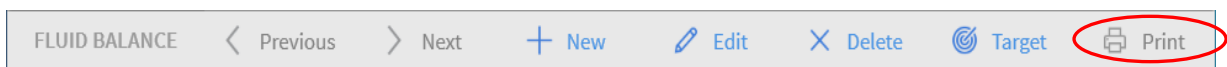

Fig 189

To create a print report:

> ➢ Click **Print**.

A menu listing the available print reports is displayed.

> ➢ Click the required template.

A print preview is displayed.

Residual risks

A risk management process has been implemented in the life cycle of the Alaris Infusion Central adopting the relevant technical standards. Risk control measures have been identified and implemented in order to reduce the risks to the minimum level and make them acceptable compared to the benefits brought in by the Product. The overall residual risk is also acceptable if compared to the same benefits.

The residual risks listed below have been taken into consideration and reduced to the minimum level possible. Given the inherent nature of the "risk" concept, it is not possible to completely remove them; these residual risks shall be disclosed to the users.

- Inability to use Alaris Infusion Central or some of its functionality as expected, which could cause delays and/or errors in the therapeutic/diagnostic actions.
- Unauthorized actions carried out by users, which could cause errors in the therapeutic/diagnostic actions and in the allocation of responsibilities of these actions.
- Attribution of information to the wrong patient (accidental patient exchange), which could cause delays and/or errors in the therapeutic/diagnostic actions.
- Wrong handling of patient data, including errors in visualizing, adding, modifying and deleting data that could cause delays and/or errors in the therapeutic / diagnostic actions.
- Off label use of Alaris Infusion Central (e.g. Product used as a primary alarm notification system, therapeutic or diagnostic decisions and interventions based solely on the information provided by the Product).
- Unauthorized disclosure of users and/or patient's personal data.

RISKS RELATING TO THE HARDWARE PLATFORM IN USE (NOT PART OF THE PRODUCT)

- Electric shock of the patient and/or the user, which could cause injury and/or death of the patient/user.
- Hardware components overheating, that could cause injury of the patient/user.
- Risk of infection of the patient/user.

Contacts

Alaris Infusion Central is a configuration of the Digistat Product. BD is the exclusive distributor of Alaris Infusion Central. This section contains all the relevant contacts information.

BD contacts

Country	Telephone	email
Australia	Freephone: 1 800 656 100	AUS_customerservice@bd.com
België	+32(0)53 720 556	info.benelux@bd.com
Canada	+1 800 387 8309	CanadaCapital@carefusion.com.
Danmark	+45 43 43 45 66	bddenmark@bd.com
Deutschland	+49 622 1305 558	GMB-DE-CustService-Alaris@bd.com
España	+34 902 555 660	info.spain@carefusion.com
France	+33 (0) 1 30 02 81 41	mms_infusion@bd.com
Italia	+39 02 48 24 01	customer.service-italy@bd.com
Magyarország	(36) 1 488 0233	info.cfn.export@bd.com
Nederland	+31(0)20 582 94 20	info.benelux@bd.com
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