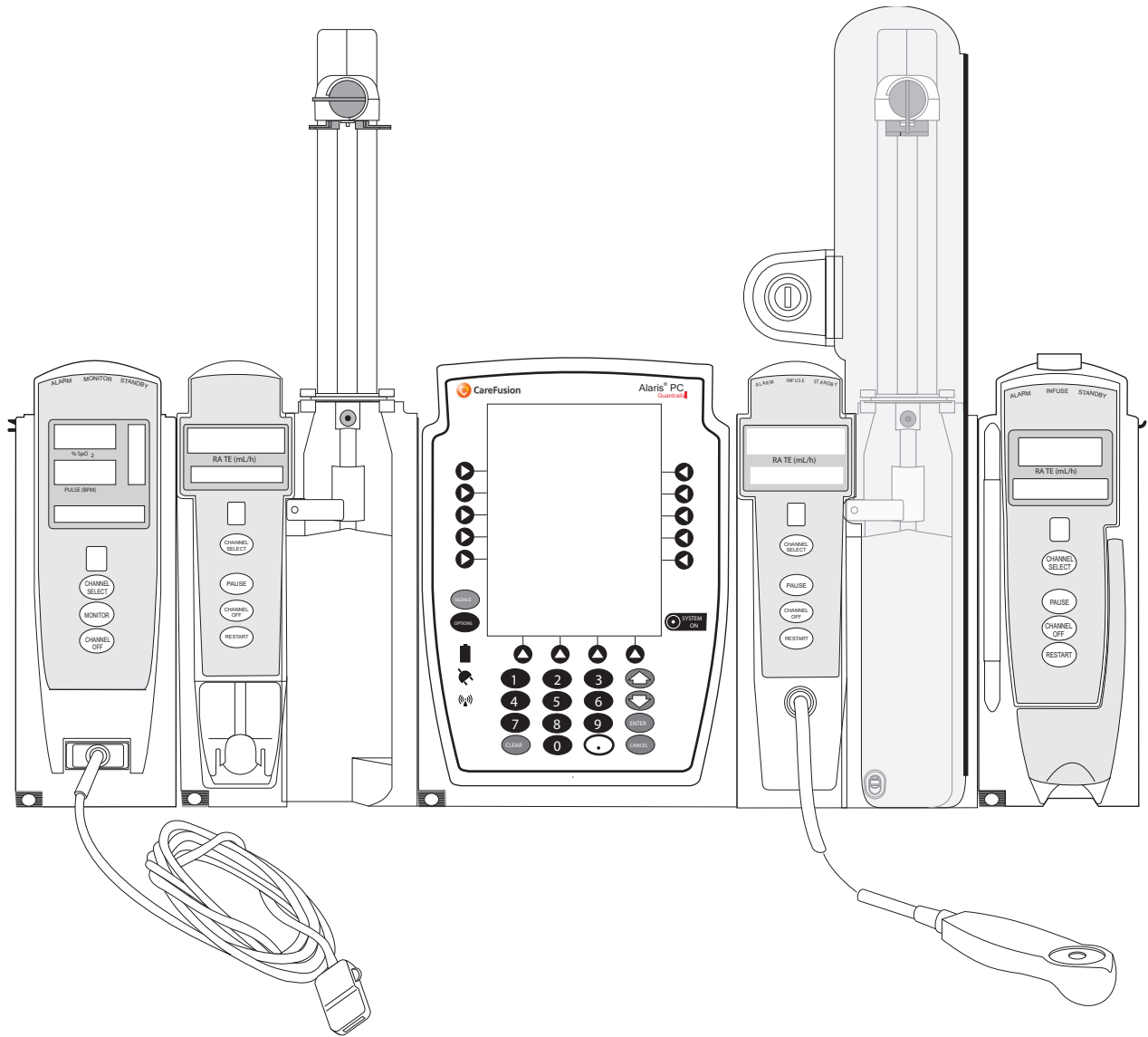


User Manual

Alaris™ System with Guardrails™ Suite MX
(with Alaris™ PC unit, Model 8015 Software Version 9.33)

February 2017



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Introduction

The Alaris™ PC unit section of this User Manual provides procedures and information applicable to the Alaris System and the PC unit. Each of the other major sections provides product-specific procedures and information.

The Alaris System is a modular system intended for adult, pediatric, and neonatal care. It consists of the PC unit, the Guardrails™ Suite MX, and up to four detachable infusion and/or monitoring modules (channels). The Alaris Auto-ID module can be included as a fifth module. The use of the Alaris System is restricted to one patient at a time.

Guardrails Suite MX for the Alaris System brings a new level of medication error prevention to the point of patient care. The Guardrails Suite MX features medication dosing, concentration delivery rate, and optional initial programming guidelines for up to 30 patient-specific care areas, referred to as Profiles. Each Profile contains a specific Drug Library, an IV Fluid library, and channel labels, as well as instrument configurations appropriate for the care area. Optional drug- or IV Fluid-specific Clinical Advisories provide visual messages. Dosing limits for each Guardrails drug entry or rate limits for each IV Fluid entry can be a Hard Limit that cannot be overridden during infusion programming and/or a Soft Limit that can be overridden, based on clinical requirements.

A Data Set is developed and approved by the facility's own multi-disciplinary team using the Guardrails Editor software, the PC-based authoring tool. A Data Set is then transferred to the Alaris System by qualified personnel. The approved Data Sets are maintained by the Editor Software for future updates and reference.

Information about an Alert that occurs during use is stored within the PC unit, and can be accessed using the Guardrails CQI Reporter software.

Documentation provided with Alaris System products might reference product not present in your facility or not yet available for sale in your area.

A superscript number (for example, ^①) identifies additional information provided as a NOTE at the end of the procedure.

WARNING



Read all instructions before using the Alaris System.

CAUTION



Rx Only

Introduction (Continued)

The Alaris™ System with Guardrails™ Suite MX is intended for use in professional healthcare facilities that utilize infusion devices for the delivery of fluids, medications, blood, and blood products. The Alaris System with Guardrails Suite MX is intended to provide trained healthcare caregivers a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps necessary to enter infusion data.

All data entry and validation of infusion parameters is performed by the trained healthcare professional according to a physician's order. The Alaris System with Guardrails Suite MX is an interoperable system capable of communicating and exchanging data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchanging data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

Essential Performance

The Alaris infusion modules are designed to accurately deliver the programmed amount of the medication or fluid over the programmed time period. The Alaris infusion modules ensure that an infusion is not being inadvertently delivered when the user expects the system to be in a paused, stopped, or off condition. The Alaris infusion modules employ measurement systems to detect and alarm for conditions adverse to safe administration of fluid. These include measurements of proper infusion set loading (free flow detection), pressure (occlusion detection), and air-in-line detection.


The EtCO₂ module will monitor and alarm when a patient physiological condition is out of range.


The SpO₂ module will monitor and alarm when a patient physiological condition is out of range.

Introduction (Continued)

WARNINGS AND CAUTIONS:

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

WARNING  A statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

CAUTION  A statement that alerts the user to the possibility of a problem with the device associated with the use or misuse of the device.

DEFINED TERMS:

The following table identifies the defined terms used throughout this document for certain trademarked products and product features.

| Product/Feature | Defined Term |
|----------------------------------|--------------------------|
| Alaris™ Auto-ID module | Auto-ID module |
| Alaris™ EtCO ₂ module | EtCO ₂ module |
| Alaris™ PCA module | PCA module |
| Alaris™ PC unit | PC unit |
| Alaris™ Pump module | Pump module |
| Alaris™ SpO ₂ module | SpO ₂ module |
| Alaris™ Syringe module | Syringe module |
| Alaris™ System Maintenance | System Maintenance |
| Alaris™ Systems Manager | Systems Manager |
| Guardrails™ alert | Alert |
| Guardrails™ clinical advisory | Clinical Advisory |
| Guardrails™ CQI Reporter | CQI Reporter |
| Guardrails™ data set | Data Set |
| Guardrails™ drug library | Drug Library |
| Guardrails™ Editor | Editor Software |

Introduction (Continued)

| Product/Feature | Defined Term |
|--------------------------------|--------------------|
| Guardrails™ hard limit | Hard Limit |
| Guardrails™ IV fluid | IV Fluid |
| Guardrails™ limit | Limit |
| Guardrails™ PCA pause protocol | PCA Pause Protocol |
| Guardrails™ soft limit | Soft Limit |
| SmartSite™ needle-free valve | Needle-Free Valve |

Approved Parts Recommendation

CareFusion recommends the use of CareFusion manufactured parts in the operation and maintenance of your CareFusion equipment. Customer's use of repair or service parts, add-ons, or disposables that are not approved by CareFusion is at Customer's own risk and may void the product warranty provided by CareFusion. Any 510(k) clearance from the Food and Drug Administration (FDA) or regulatory approval secured by CareFusion to market Alaris pumps was based on use of only CareFusion manufactured parts and equipment. If non-CareFusion parts, add-ons or disposables are used for the maintenance, repair or operation of your CareFusion equipment, those parts were not validated by CareFusion for safety and efficacy with our Alaris products, nor were they included in the review and approval/clearance of the products.

Installation

Instruments are tested and calibrated before they are packaged for shipment. To ensure proper operation after shipment, it is recommended that an incoming inspection be performed before placing the instrument in use.

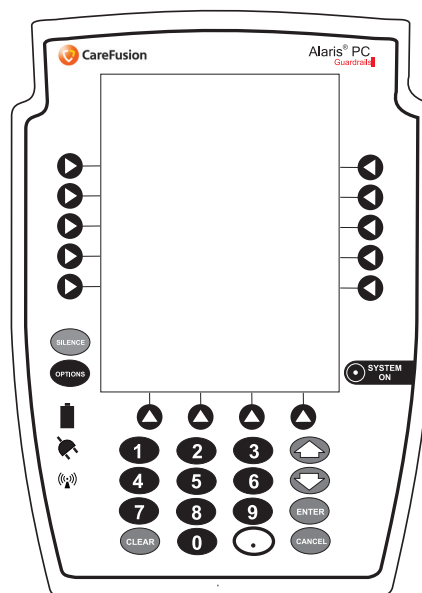
Prior to placing the Alaris System in use:

1. Perform check-in procedure using System Maintenance software.
2. Whether or not Profiles feature has been enabled (see PC unit section, "System Options," "System Configurations").^①

NOTE:

- ^① To enable the Profiles feature, a hospital-defined best-practice Data Set must be uploaded to the PC unit.

Alaris PC Unit Model 8015



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Getting Started

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General Setup and Operation

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Introduction

This section of the User Manual provides PC unit (Model 8015) and Alaris System instructions and information. It is used in conjunction with:

- *PC Unit/ Pump Module Technical Service Manual*
- Product-specific sections of this User Manual
- System Maintenance software (and its instructions) for Alaris System check-in, maintenance, and wireless configuration

The PC unit is the core of the Alaris System and provides a common user interface for programming infusions and monitoring, which helps to reduce complexity at the point of care. The display uses color to clearly communicate critical programming, infusion, monitoring and hospital-defined policy information.

The wireless network card provides wireless communication capability between the Alaris System and Alaris Systems Manager. The combined use of the Alaris System and Alaris Systems Manager is integrated into a facility's existing network infrastructure.

When enabled, the Alaris Systems Manager allows the exchange of information between the Alaris Systems Manager and the Alaris System. The PC unit can be operated manually or in concert with the information exchanged with the Alaris Systems Manager. If communication with the wireless network is interrupted (for example, out of range), the Alaris System can be used, as intended, in the manual mode.

WARNING



Read all instructions, including those for the attached module(s) and applicable accessories, before using the Alaris System.

CAUTION



Rx Only

Introduction (Continued)

Alarms and Alerts: See "Appendix A - Troubleshooting and Maintenance" for specific PC unit alarms and alerts.

Contraindications: None known.

Electromagnetic Environment: See "Appendix" section of this User Manual ("Regulations and Standards," "Compliance").

Attach and Detach Module

Modules can be attached to either side of the PC unit or to either side of another module. The process to attach or detach is the same for either side, whether attaching/detaching to/from a PC unit or another module.

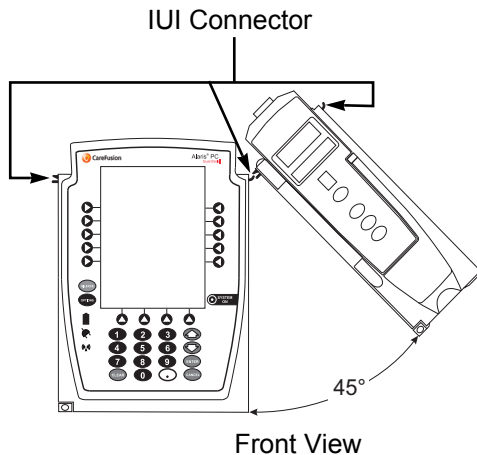
An individual hospital/facility can choose to permanently attach modules. To remove permanently attached modules, contact qualified service personnel. Inserting a finger or other object into the IUI connector, when the module is attached to the PC unit, could result in electrical shock.

Attach Module

The Alaris System is designed to operate a maximum of four infusion or monitoring modules. Modules added in excess of four are not recognized by the system. The Auto-ID module can be included as a fifth module. A module can be attached in any position; however, when mounted on an IV pole, it is recommended that a balanced configuration be maintained.

Application of adhesive tape or other materials to the sides of the PC unit and modules can prevent proper latching.

1. Position free module at a 45° angle, aligning IUI connectors.

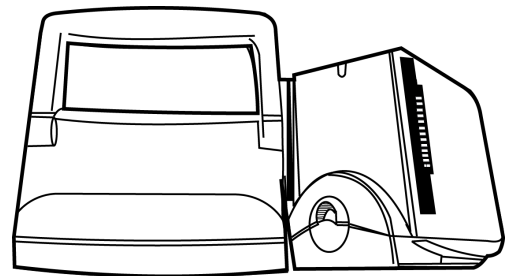


WARNING



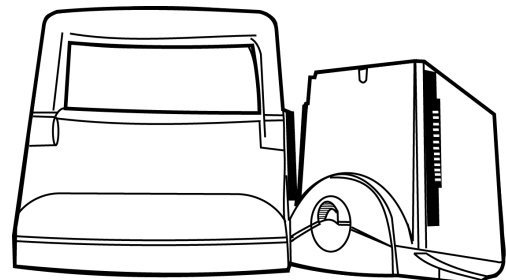
Inserting a finger or other object into the IUI connector, when the module is attached to the PC unit, could result in electrical shock.

Aligned IUI Connectors



Top View

IUI Connectors Not Aligned



Top View

Attach and Detach Module (Continued)

Attach Module (Continued)

2. Rotate free module down against PC unit or attached module until release latch snaps in place.

WARNING



When properly secured/snapped, the **release latch** provides a very secure connection between modules. If not properly latched, a module can be dislodged during operation.

WARNING



Failure to perform these operations can result in improper instrument operations.

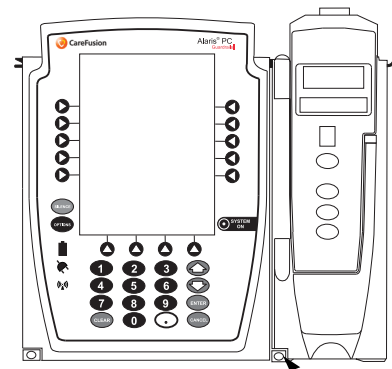
WARNING



Failure to follow these instructions may result in potential hazards associated with damaged IUI connectors.

Detach Module

1. Ensure that module is powered off before detaching.
2. Push module release latch and then rotate module up and away from PC unit or attached module (opposite to motion shown in "Attach Module" procedure) to disengage connectors.
 - Alaris System reidentifies and shows appropriate module identification (A, B, C, or D), from left to right.
 - Appropriate module position(s) (A, B, or C) for remaining module(s) appear on Main Display.



Release Latch

Attach and Detach Module (Continued)

Add Module While System is Powered On

Add module as described in "Attach Module."

- System tests module, causing all LED segments and indicator lights of displays to illuminate briefly.
- Appropriate module identification display (A, B, C, or D) illuminates. Modules are always labeled left to right, so if a module is added to left of other modules, all modules are reidentified. Module re-identification does NOT interrupt or affect infusion or monitoring on active modules.
- Module positions (A, B, C, or D) appear on Main Display.
- If any of the following conditions are observed, affected module must be removed from use and inspected by qualified personnel:
 - LED segments are not illuminated on displays during power-on test.
 - Indicator lights do not illuminate.
 - Appropriate module identification does not appear.

Power On System

1. Connect PC unit to an external AC power source.
2. Press **SYSTEM ON** key.
3. System self test begins:
 - Diagnostics test causes all LED display segments and Status Indicator lights of attached module(s) to illuminate briefly.
 - Power Indicator illuminates.
 - Appropriate module identification (A, B, C, or D) is displayed on attached module(s).
 - An audio tone sounds.
 - If PM Reminder option is enabled and scheduled preventive maintenance is due, **MAINTENANCE REMINDER** screen appears.
 - At completion of system-on test, **New Patient?** screen appears.
 - If either of the following conditions is observed, PC unit or affected attached module must be removed from use and inspected by qualified personnel:
 - System fails any part of self test.
 - Main Display does not appear backlit, appears irregular, or has evidence of a row of pixels not functioning properly.

NOTE:

- ① Previous infusion parameters are automatically cleared after 8 hours.
- ② The self test provides the clinician with verification of the operational safety and correct functioning of alarms for the Alaris System.

Start-Up (Continued)

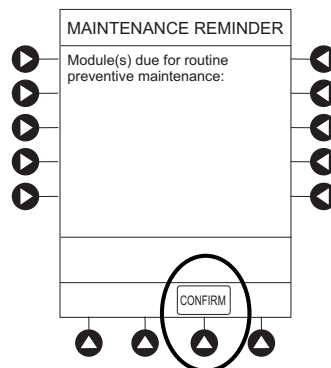
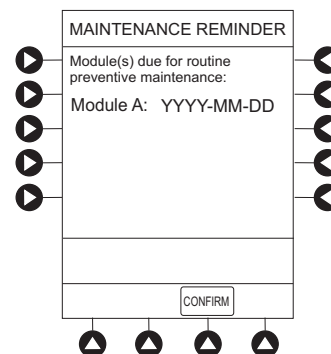
Respond to Maintenance Reminder

If the Preventive Maintenance (PM) Reminder option is enabled and the PC unit or an attached module is due for preventive maintenance, a **MAINTENANCE REMINDER** message appears at power up. If necessary, the reminder can be temporarily bypassed by pressing the **CONFIRM** soft key.

1. Notify the appropriate facility personnel when a **MAINTENANCE REMINDER** occurs and remove instrument requiring maintenance (see "Attach and Detach Module").
2. If Alaris System was powered off to replace PC unit, reinitiate start-up process.

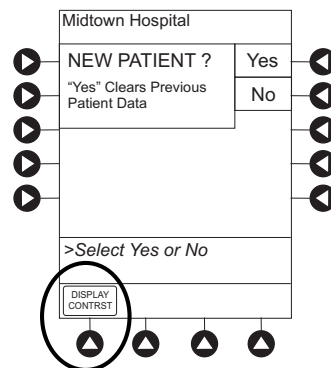
OR

If an attached module (such as a Pump module) was powered off and removed, **MAINTENANCE REMINDER** display reflects removal of that module. To continue start-up process, press **CONFIRM** soft key.



Adjust Display Contrast

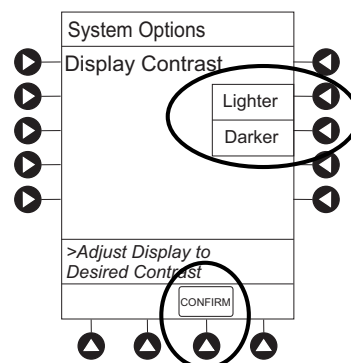
1. Press **DISPLAY CONTRAST** soft key.



Start-Up (Continued)

Adjust Display Contrast (Continued)

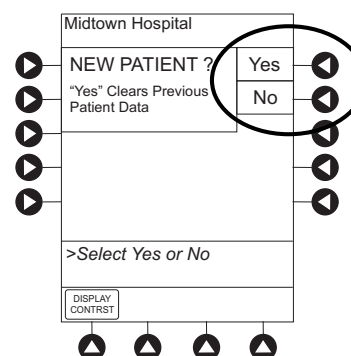
- To adjust display for optimum viewing, use **Lighter/Darker** soft keys.
- To return to main screen, press **CONFIRM** soft key.



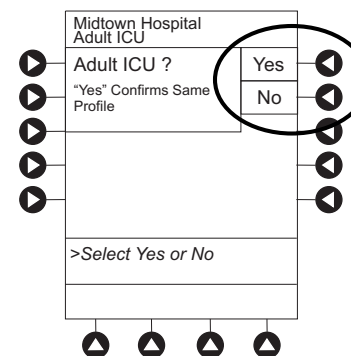
Select New Patient and Profile Options

The following procedures assume the Profiles feature is enabled.

- Select required **NEW PATIENT?** option.
 - To indicate programming is for a new patient and clear all stored patient parameters from memory, press **Yes** soft key.
 - To confirm programming is for same patient and retain all stored patient parameters, press **No** soft key.
 - Last used Profile is displayed.
 - If Profiles feature is disabled, main menu appears.



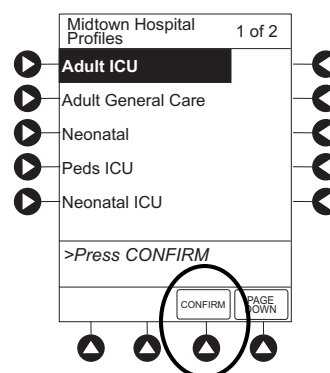
- Accept or change current Profile:
 - To accept current Profile, press **Yes** soft key. Main screen appears.
 - To change Profile, press **No** soft key and continue with next step. Profile selection screen appears.



Start-Up (Continued)

Select New Patient and Profile Options (Continued)

- To select a Profile, press corresponding left soft key.
To view additional choices, press **PAGE DOWN** soft key.
- To confirm Profile selection, press **CONFIRM** soft key.
Main screen appears.

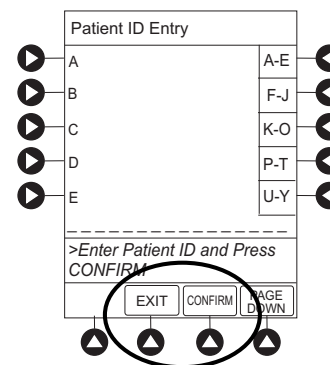


Patient ID Entry Feature

The option to enter and display a 16-character alphanumeric patient identifier is always available. The instrument can be configured to automatically display the **Patient ID Entry** screen during start-up or to provide access only through the **Systems Options** menu (see "System Options").

If **Yes** was selected to indicate programming for a new patient, perform one of following steps:

- If patient identifier is not required, press **CONFIRM** or **EXIT** soft key.
- To manually enter patient identifier, use numeric data entry keys and/or alpha speed keys.
 - An alphanumeric identifier, of up to 16 characters, can be entered.
 - Press soft key next to a letter group to list letters in that group. Press soft key next to an individual letter to enter that letter.
 - To access letter "Z" and special characters (hyphen, underscore, space), press **PAGE DOWN** soft key.
 - To clear an entire entry, press **CLEAR** key.
 - To back up a single character at a time, press **CANCEL** key.
- To scan barcode on patient identification band, see "Alaris Auto-ID Module Model 8600", section 6 of this User Manual.



Start-Up (Continued)

Adjust Audio Volume

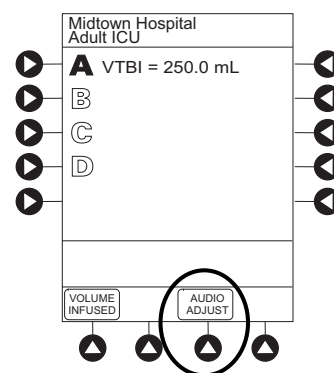
WARNING

The user should check that the current alarm preset is appropriate prior to use on each patient.

WARNING

A hazard can exist if different Alarm Presets are used for the same or similar equipment in a single area, such as an Intensive Care Unit or a Cardiac Operating Theatre.

1. Press **AUDIO ADJUST** soft key.



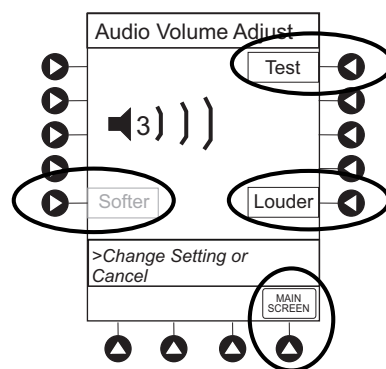
2. To change volume to desired level, press either **Louder** or **Softer** soft key. To sample alarm loudness level, press **Test** soft key.
3. To return to PC unit screen, press **MAIN SCREEN** soft key.
After 30 seconds without a key press, Main Display appears.

CAUTION

Setting the audio volume to the **lowest level** will lower all system alarms, including secondary alarms such as End of Infusion.

NOTE:

The Minimum Audio Volume defaults to level 1. Levels 1-5 may be set per profile. The user is able to lower the device AUDIO VOLUME to the minimum limit set. When the minimum AUDIO VOLUME LEVEL has been reached, the Louder/Softer soft keys are unavailable and the PC unit emits an illegal key press audio.



Start-Up (Continued)

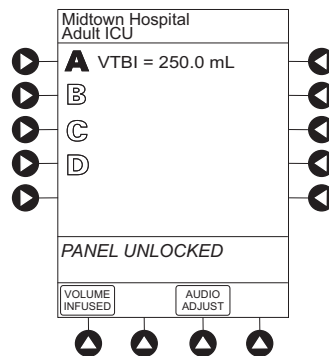
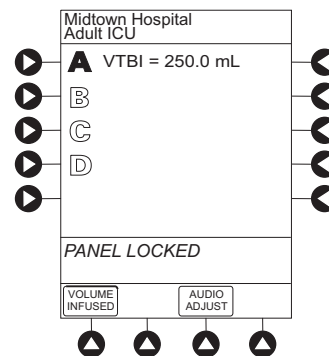
Lock/Unlock Tamper Resist

1. Initiate operation of applicable module.
2. Press and hold Tamper Resist Switch, on back of PC unit, for 3 to 4 seconds (see "General Information," "Features and Displays," "Operating Features, Controls, Indicators").
 - An advisory tone (if **Key Click Audio** is enabled) and a three-second **PANEL LOCKED** prompt on Main Display confirm activation.
 - When Tamper Resist is active, keypad panel is locked; however, clinician can:
 - Silence audio alarm.
 - View volume(s) infused.
 - View and test audio alarm setting.
 - View selected parameters on attached modules.

Any other key press results in a visual **PANEL LOCKED** prompt and, if **Key Click Audio** is enabled, an illegal key-press audio advisory.

3. To unlock keypad panel, press and hold Tamper Resist Switch for 3 to 4 seconds.

An advisory tone (if **Key Click Audio** is enabled) and a three-second **PANEL UNLOCKED** prompt on Main Display confirm activation.

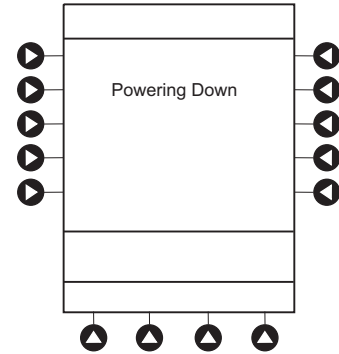


Power Off System

Press and hold **CHANNEL OFF** key until a beep is heard (approximately 1.5 seconds) and then release to initiate power down.

- During power off sequence, Main Display flashes **Powering Down**.
- To interrupt power down sequence, quickly press any key (except **SYSTEM ON**) on PC unit.

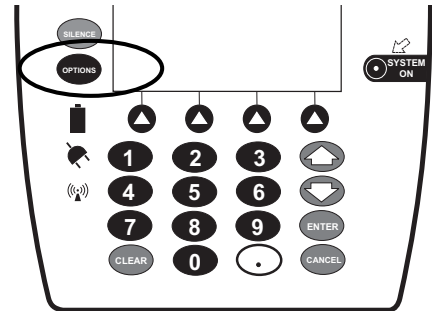
Once all attached modules are powered off, PC unit automatically powers down.



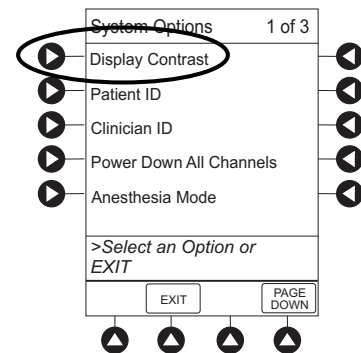
System Options

Display Contrast

1. Press **OPTIONS** key.



2. Press **Display Contrast** soft key.

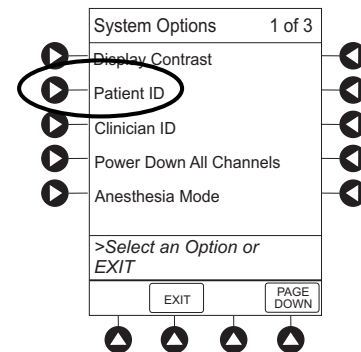


3. Adjust display and return to main screen (see Start-Up, "Adjust Display Contrast" procedure).

Patient ID

Enter

1. Press **OPTIONS** key.
2. Press **Patient ID** soft key.

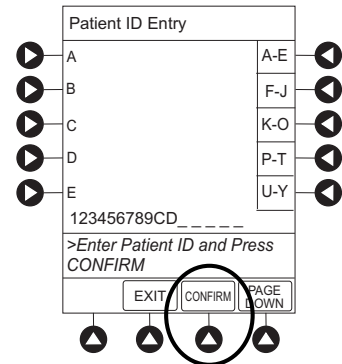


System Options (Continued)

Patient ID (Continued)

Enter (Continued)

3. Scan or manually enter patient identifier:
 - To manually enter patient identifier, use numeric data entry keys and/or alpha speed keys.
 - An alphanumeric identifier, of up to 16 characters, can be entered.
 - Press soft key next to a letter group to list letters in that group. Press soft key next to an individual letter to enter that letter.
 - To access letter "Z" and special characters (hyphen, underscore, space), press **PAGE DOWN** soft key.
 - To clear an entire entry, press **CLEAR** key.
 - To back up a single character at a time, press **CANCEL** key.
 - To scan barcode on patient identification band, see AUTO-ID section of this User Manual.
4. To verify correct entry, press **CONFIRM** soft key.



System Options (Continued)

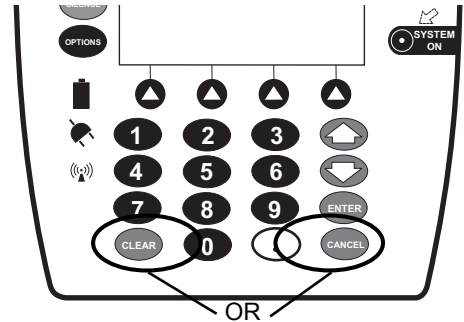
Patient ID (Continued)

Modify

1. Press **OPTIONS** key.
2. Press **Patient ID** soft key.
3. To clear entire entry, press **CLEAR** key.

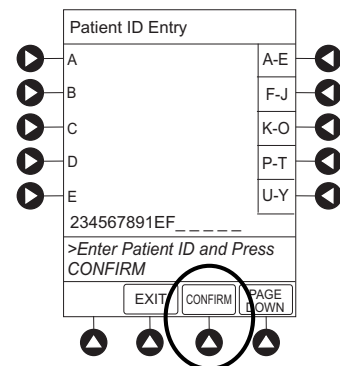
OR

To back up a single character at a time, press **CANCEL** key.



4. To enter modified patient identifier, use numeric data entry keys and/or alpha speed keys.
 - An alphanumeric identifier, of up to 16 characters, can be entered.
 - Press soft key next to a letter group to list letters in that group. Press soft key next to an individual letter to enter that letter.
 - To access letter "Z" and special characters (hyphen, underscore, space), press **PAGE DOWN** soft key.
5. To verify correct entry, press **CONFIRM** soft key.

New Patient ID Entry verification screen appears.



System Options (Continued)

Patient ID (Continued)

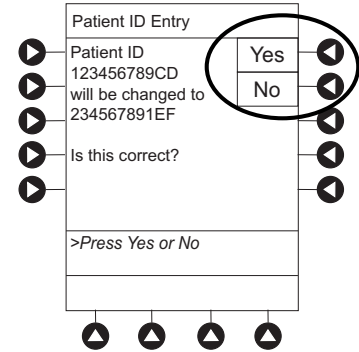
Modify (Continued)

- To accept modified Patient ID, press **Yes** soft key.
Main screen appears with new Patient ID.

OR

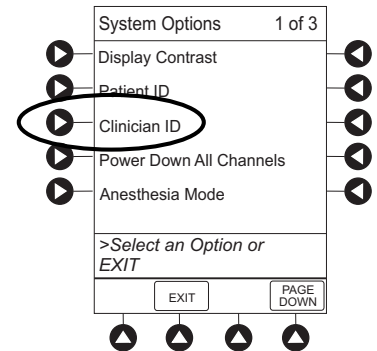
To retain original (old) Patient ID, press **No** soft key.

Main screen appears with old Patient ID.



Clinician ID

- Press **OPTIONS** key.
- Press **Clinician ID** soft key.

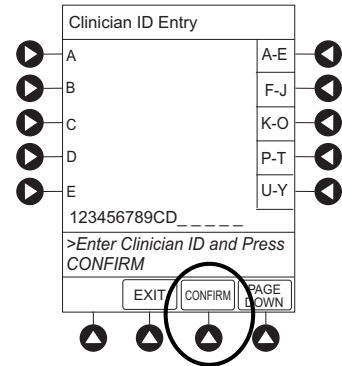


- Scan or manually enter clinician identifier:
To manually enter clinician identifier, use numeric data entry keys and/or alpha speed keys.
 - An alphanumeric identifier, of up to 16 characters, can be entered.
 - Press soft key next to a letter group to list letters in that group. Press soft key next to an individual letter to enter that letter.
 - To access letter "Z" and special characters (hyphen, underscore, space), press **PAGE DOWN** soft key.
 - To clear an entire entry, press **CLEAR** key.
 - To back up a single character at a time, press **CANCEL** key.

System Options (Continued)

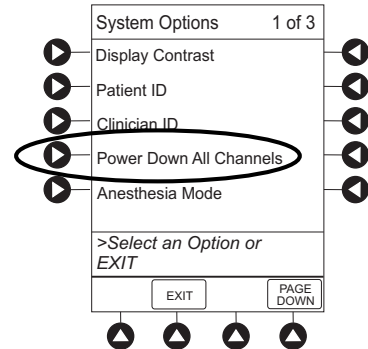
Clinician ID (Continued)

- To verify correct entry, press **CONFIRM** soft key.

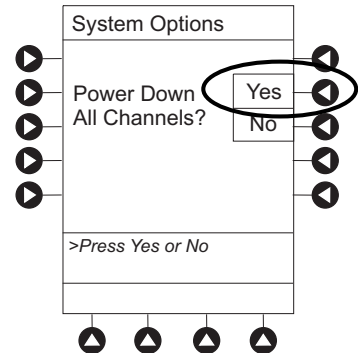


Power Down All Channels

- Press **OPTIONS** key.
- Press **Power Down All Channels** soft key.



- Press **Yes** soft key.
During power off sequence, Main Display flashes **POWERING DOWN**.



System Options (Continued)

Anesthesia Mode

When the Anesthesia Mode is enabled and then the pause feature is used - the module remains in an indefinite pause until restarted.

When Anesthesia Mode is enabled:

- A channel can be paused indefinitely without an alarm.
- The air-in-line associated with the Profile can be set up to 500 micro liters.
- All limits are set to **Soft**.
- Limit Checking mode is set to **Smart**.
- Key-press audio is turned off.
- Auto-Restart for Anesthesia Mode is set to 9 and is not configurable.
- Panel Lock through Tamper Resist Mode or Authorized User Mode is not available.
- Guardrails drug list defaults to drugs designated by Editor Software as anesthesia only. All Guardrails drugs in a Profile can be viewed by pressing **ALL DRUGS** soft key.
- Bolus Dose is automatically available for:
 - Guardrails drugs that have Bolus Dose limits defined
 - generic drug calculation setup
- **Anesthesia Mode**, alternating with other required prompts, is displayed in prompt bar of Main Display.
- Callback audio for paused module is permanently silenced.
- Review of drug calculation setup page is omitted when restoring a stopped drug calculation.
- Clinical Advisories are not displayed.

NOTE:

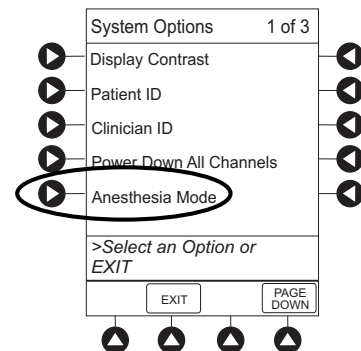
If an infusion is paused in regular mode and then the anesthesia mode is enabled - the device will alarm at the 2 minute warning.

Enable

1. Press **OPTIONS** key.

WARNING

When the Alaris System is set up for use in Anesthesia Mode, it is important to **select the** Profile that corresponds with the care area the patient will be taken to when the Anesthesia Mode is discontinued. This ensures that the Alaris System will be in the correct Profile following the use of the Anesthesia Mode.

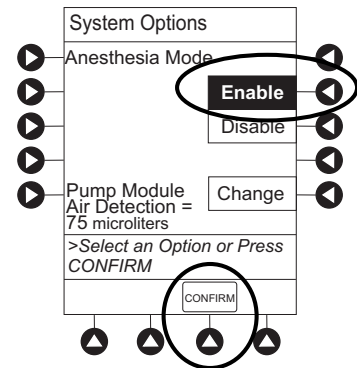


System Options (Continued)

Anesthesia Mode (Continued)

Enable (Continued)

2. Press **Anesthesia Mode** soft key.
3. Press **Enable** soft key.
4. Press **CONFIRM** soft key.



Disable

The Anesthesia Mode can be disabled, and normal operation resumed, using either of the following three methods:

- System Options menu.
- Disconnecting from AC power.
- Connecting to AC power.

From System Options Menu

1. Press **OPTIONS** key.
 2. Press **Anesthesia Mode** soft key.
 3. Press **Disable** soft key.
 4. Press **CONFIRM** soft key.
- Anesthesia Mode** no longer appears on Main Display, indicating it has been disabled.

System Options (Continued)

Anesthesia Mode (Continued)

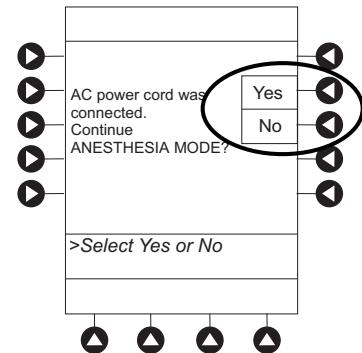
Disable (Continued)

Connect to AC Power

1. Connect system to AC power.
2. To continue using Anesthesia Mode, press **Yes** soft key.

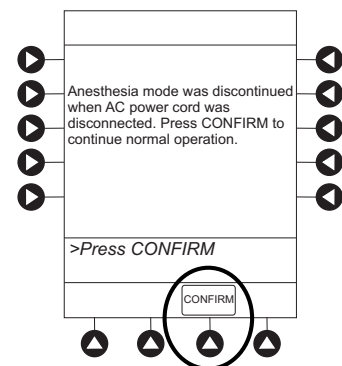
OR

To discontinue Anesthesia Mode, press **No** soft key.



Disconnect from AC Power

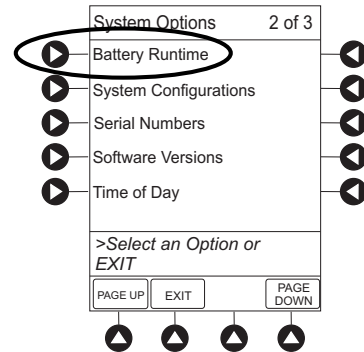
1. Disconnect system from AC.
 - Anesthesia Mode is automatically disabled.
 - All currently running infusions continue.
 - A prompt appears as an alert that Anesthesia Mode has been discontinued.
2. Press **CONFIRM** soft key.



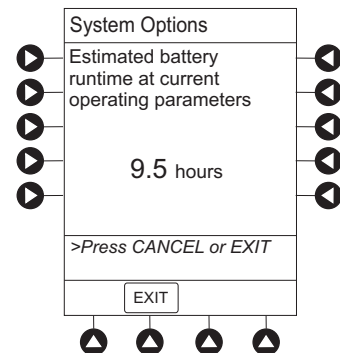
System Options (Continued)

Battery Runtime

1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key.
3. Press **Battery Runtime** soft key.

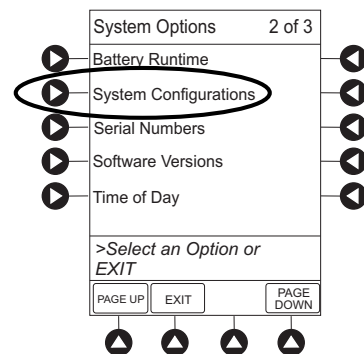


4. To return to main screen, press **CANCEL** key or **EXIT** soft key.



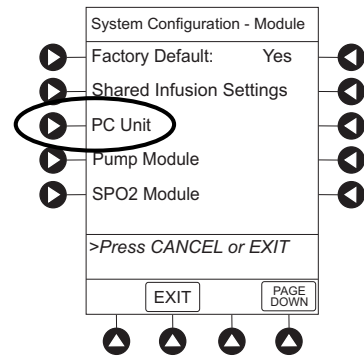
System Configurations

1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key.
3. Press **System Configuration** soft key.

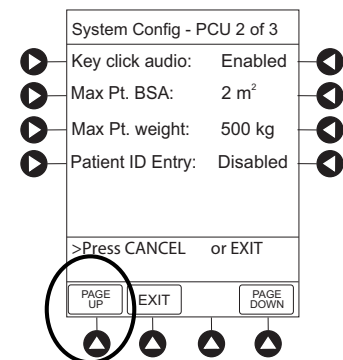
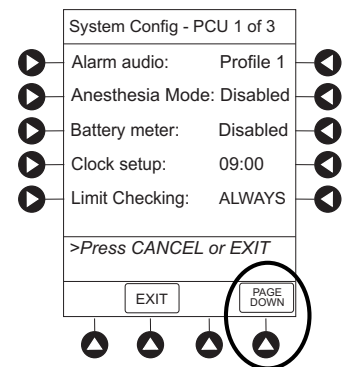


System Options (Continued)

4. Press **PC Unit** soft key.



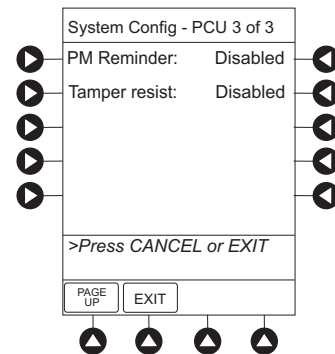
5. To review various system configuration settings, press **PAGE DOWN** and **PAGE UP** soft keys. ①②



System Options (Continued)

System Configurations (Continued)

- To return to main screen, press **CANCEL** key or **EXIT** soft key.

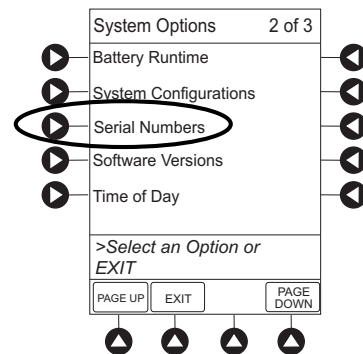


NOTE:

- The **Profiles** option is listed only if it is **disabled**.
- The **Limit Checking** and **Max Pt. BSA** options are listed only if the **Profiles** option is **enabled** and a valid Data Set is loaded.

Serial Numbers

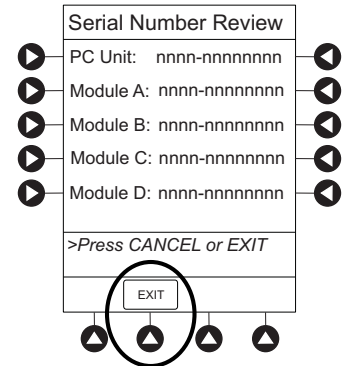
- Press **OPTIONS** key.
- Press **PAGE DOWN** soft key.
- Press **Serial Numbers** soft key.
Serial numbers for PC unit and all attached modules display.^①



System Options (Continued)

Serial Numbers (Continued)

- To return to main screen, press **EXIT** soft key.

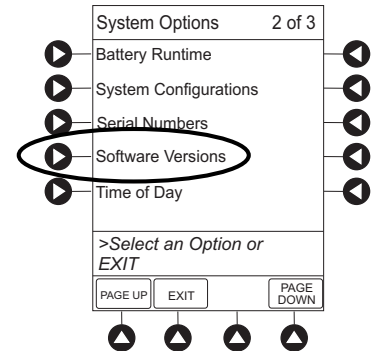


NOTE:

- "nnnn-nnnnnnnn" in the illustrated display represents a model and serial number.

Software Versions

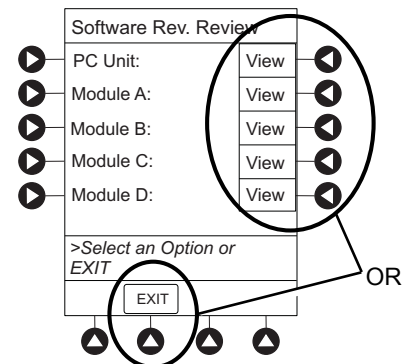
- Press **OPTIONS** key.
- Press **PAGE DOWN** soft key.
- Press **Software Versions** soft key.



- To review software version information, press **View** soft key next to applicable module.

OR

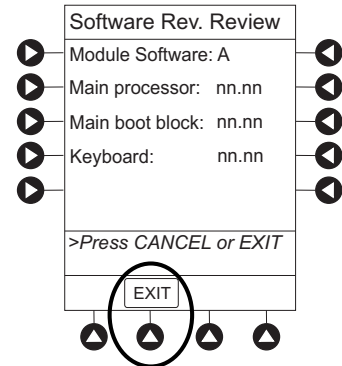
To return to main screen, press **EXIT** soft key.



System Options (Continued)

Software Versions (Continued)

- To return to previous screen, press **EXIT** soft key.^①

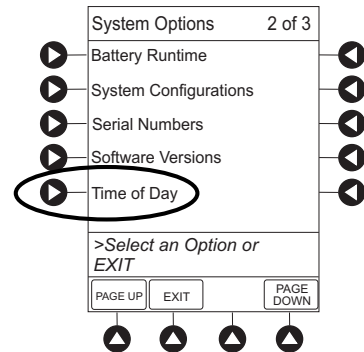


NOTE:

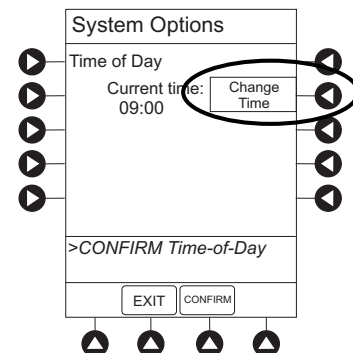
- "nn.nn" in the illustrated display represents a software version.

Time of Day

- Press **OPTIONS** key.
- Press **PAGE DOWN** soft key.
- Press **Time of Day** soft key.



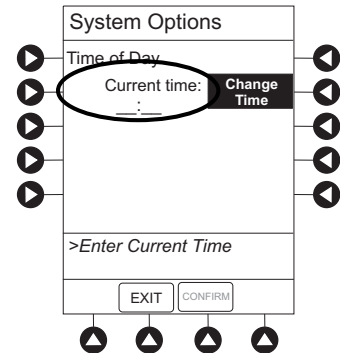
- If time is correct, press **CONFIRM** soft key.^①
OR
To change time, press **Change Time** soft key.



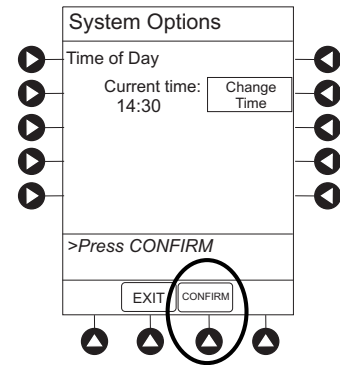
System Options (Continued)

Time of Day (Continued)

5. Enter current Time of Day.



6. Press **CONFIRM** soft key.



NOTE:

- ① The format is a 24-hour clock (military time).

Network Status

The displayed status updates immediately when a status change takes place.

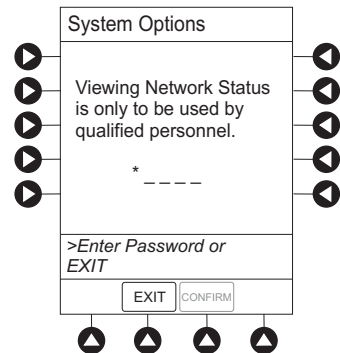
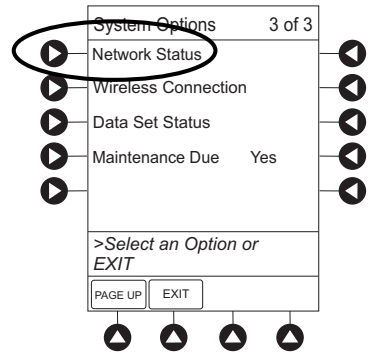
1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key two times.

System Options (Continued)

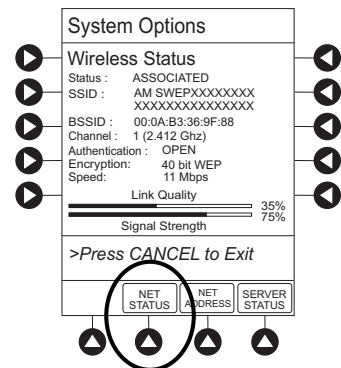
Network Status (Continued)

3. To view network status and wireless status information, press **Network Status** soft key.

4. Enter password (refer to v9.5 or later System Maintenance software instructions) and press **CONFIRM** soft key.



- Information based on a wireless status of **DISABLED**, **DISASSOCIATED**, **CONFIGURING**, **ASSOCIATING**, **ASSOCIATED**, or **AUTHENTICATING** is displayed.
- If wireless status is **ASSOCIATED**, following information is displayed:
 - Wireless connectivity: **SSID**, **Channel**, **Authentication**, and **Encryption** types being used; **BSSID**—MAC address of access point that system is connected to; **Speed**—transfer rate up to 11 Mbps for 802.11b, 54 Mbps for 802.11a or 802.11b/g and 72 Mbps for 802.11a/b/g/n.
 - **Link Quality**—a minimum of 20% recommended for good wireless connectivity.
 - **Signal Strength**—greater than 20% recommended for good wireless connectivity.

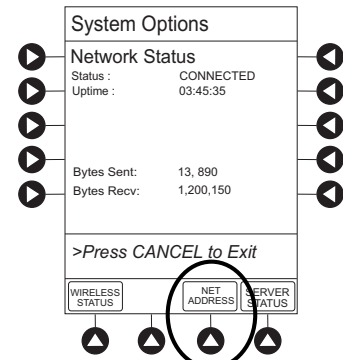


5. To view network connectivity information, press **NET STATUS** soft key.
 - A status of **DISABLED**, **DISCONNECTED**, **CONFIGURING**, **INVALID CONFIG**, or **CONNECTED** is displayed.
 - If status is **CONNECTED**:
 - PC unit is connected to wireless network.
 - **Profile** being used is displayed.

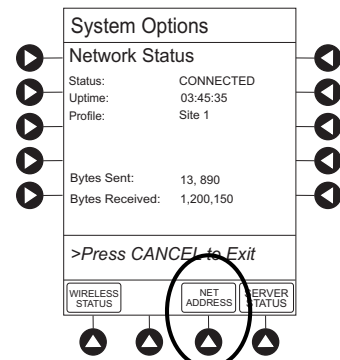
System Options (Continued)

Network Status (Continued)

- To view network address information, press **NET ADDRESS** soft key.
 - MAC Address** of wireless RF card attached to PC unit is displayed.
 - If **DHCP** displays **NO**, PC unit is set to use a Static IP address.
 - When PC unit is connected to wireless network, **IP Address**, **Subnet Mask**, **Gateway**, and **DNS** information is displayed.

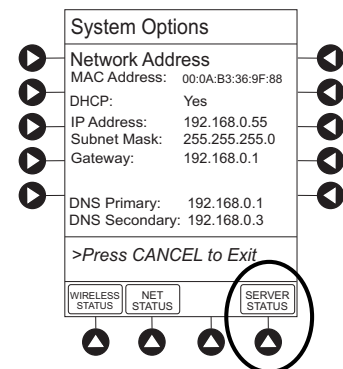


Pre-v9.5 PC unit:



v9.5 and later PC unit:

- To view server connectivity information, press **SERVER STATUS** soft key.

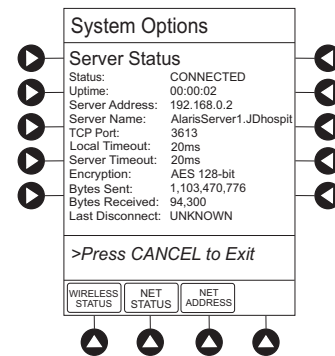


System Options (Continued)

Network Status (Continued)

- Information based on a status of **DISABLED**, **DISCONNECTED**, **CONNECTING**, or **CONNECTED** is displayed.
- If status is **CONNECTED**, PC unit is connected to Alaris Systems Manager and the following information is displayed:
 - **Uptime**—length of time PC unit has been connected.
 - **Server Address**—IP Address of Alaris Systems Manager.
 - **TCP Port** being used to establish connection.
 - **Encryption** type (AES 128-bit) used to encode data on payload and protect patient-sensitive information sent through wireless network.
 - **Bytes Sent**—cumulative total of data sent.
 - **Bytes Received**—cumulative total of data received.
 - **Server Name** first 20 characters of fully qualified domain name of Alaris Systems Manager.

v9.5 and later PC unit:



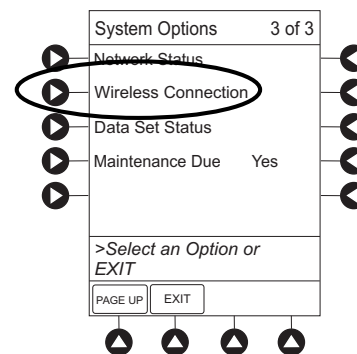
Wireless Connection

1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key two times.
3. Press **Wireless Connection** soft key.

If **Wireless Connection** soft key is inactive (grayed out), the PC unit has the following configuration:

- the System Maintenance software was used to disable wireless connection
- the CF card flashing process was done without the programming of the proper AppConfig file (v9.12 or later) For more information, refer to the *Alaris PC Unit Model 8015 Software and Hardware Upgrade Instructions to v9.33*.
- A valid network configuration was never transferred

To enable wireless connection, use v9.5 or later System Maintenance software. Send the PC unit to Biomed to resolve wireless connectivity issues.

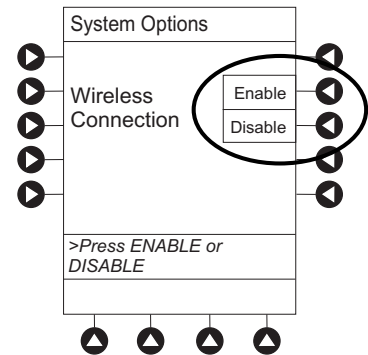


System Options (Continued)

Wireless Connection (Continued)

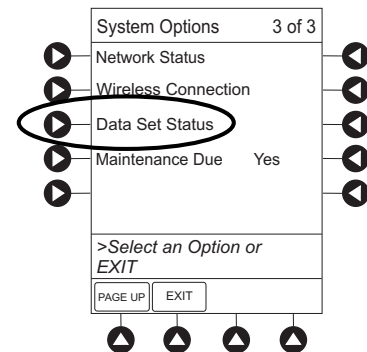
4. Wireless connection can be disabled or enabled:
 - To disable wireless communication, press **Disable** soft key.
 - If wireless connection is disabled, it remains disabled until PC unit is powered off. Setting defaults to **Enable** when PC unit is powered back on.
 - v10.33 or later System Maintenance software instructions also includes a procedure on how to disable a wireless RF card on a PC unit being used in a non-wireless environment. Wireless connection remains disabled until System Maintenance software is used to enable it.
 - To enable wireless connection, press **Enable** soft key.

Pre-v9.5 PC unit: View **Network Status** after pressing **Enable** soft key. If a **Status** of **DISABLED** is identified, System Maintenance software was used to disable wireless connection. Use v9.5 or later System Maintenance software to enable wireless connection.



Data Set Status

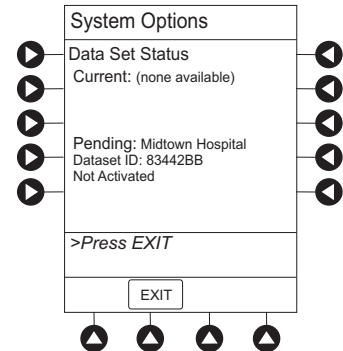
1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key two times.
3. To view Data Set status, press **Data Set Status** soft key.



System Options (Continued)

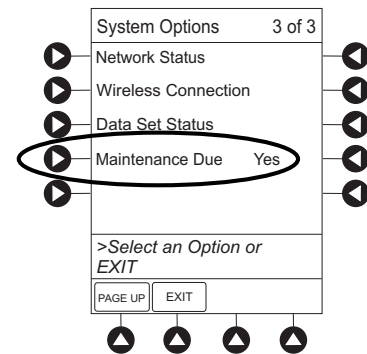
Data Set Status (Continued)

A status of **Current**, **Pending**, **Transferring**, or **Not Activated** is displayed.

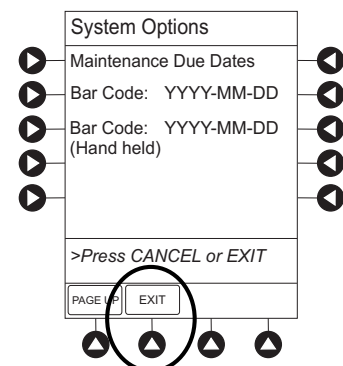
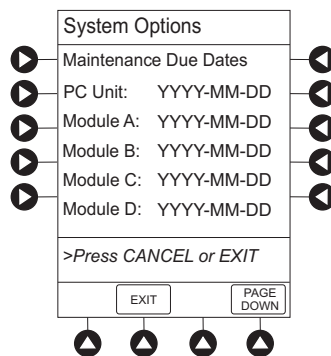


Maintenance Due

1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key two times.
3. Press **Maintenance Due** soft key.



4. To return to main screen, press **EXIT** soft key.^①



System Options (Continued)

Maintenance Due (Continued)

NOTE:

- ① **PAGE DOWN** soft key appears only if an Auto-ID module is attached.

Warnings and Cautions

General

WARNINGS



- **Explosion risk** if used in the presence of flammable anesthetic agents or gasses.
- Assess patient's condition **before silencing an alarm**. Do not silence alarm if patient safety might be compromised.
- Before each use, **verify that the alarm limits** are appropriate for the patient.
- The Alaris System performs a **self check during power up**. The PC unit should beep, no errors should occur, and if a module is connected, all LED segments should flash. If the Alaris System fails the self check, remove the failing PC unit or module from use.
- When properly secured/snapped, the **release latch** provides a very secure connection between modules. If not properly latched, a module can be dislodged during operation.
- Disconnect from main (AC) and battery power when performing **maintenance**.
- Use only CareFusion batteries. The use of third party batteries could affect the safety and efficacy of Alaris products.
- The battery cannot be repaired and should not be opened.
- The battery is intended as a backup system. Leave the power cord connected to a hospital grade AC power source whenever available.
- Battery replacement should be performed by qualified service personnel while the instrument is not in use.

Warnings and Cautions (Continued)

General (Continued)

WARNINGS

- Electrical shock hazard. **Do not open case.** Refer to qualified service personnel.
- Due to the **intermittent nature of a wireless environment**, some data can be lost if a connection cannot be established or is lost. The Alaris Systems Manager and wireless network card are designed to minimize these incidents but cannot eliminate them.
- The Alaris System is not intended to replace **supervision by medical personnel**. The user must become thoroughly familiar with the Alaris System features, operation, and accessories prior to use.

Warnings and Cautions (Continued)

General (Continued)

CAUTIONS



- Always use a grounded **three-wire receptacle**. Where the integrity of the protective earth grounding system is in doubt, operate on internal battery.
- **Hyperbaric Chamber Operation:**
 - The Alaris System is not certified for use in oxygen-enriched environments.
 - The Alaris System, with the exclusion of the EtCO₂ module, has been verified to operate with no malfunction alarms due to the hyperbaric chamber environment or unintentional key presses when used in a hyperbaric chamber.
 - The healthcare facility's hyperbaric safety director is responsible for all equipment used in the hyperbaric chamber environment.
- Should an instrument or accessory be **dropped or severely jarred**, it should be immediately taken out of use and inspected by qualified service personnel to ensure its proper function prior to reuse.
- If an instrument appears **damaged**, contact CareFusion for authorization to return it for repair.

Warnings and Cautions (Continued)

Electromagnetic Compatibility

WARNINGS

- Do not use the Alaris System near Magnetic Resonance Imaging (**MRI**), including Stereotaxis technology.
- Do not use the Alaris System near **Therapeutic Radiation** equipment, such as Linear Accelerators.
- Use of any **accessory, transducer or cable** other than those specified can result in increased emissions or decreased Alaris System immunity.
- Do not use an **RF device** within 7.8 inches/20 cm of the Radio Card on the PC unit. FCC approval of the Radio Card excludes co-location with any other transmitter.
- Per FCC regulations, **maintain a distance** of at least 7.8 inches/20 cm between the Radio Card on the PC unit and a human body.

Warnings and Cautions (Continued)

Electromagnetic Compatibility (Continued)

CAUTIONS

- The Alaris System should not be used **adjacent to or stacked with other equipment**. If adjacent or stacked use is necessary, monitor the Alaris System to verify that it is operating normally in that setup.
- **Portable and mobile RF communications** can affect medical electrical equipment.
- **Interconnected data communications systems** must be certified to IEC 60950 (data processing equipment) or IEC 60601–1 (electromedical equipment).
- The Alaris System is intended for use by healthcare professionals only. This is a CISPR 11 Class B Group 1 medical system. In a domestic environment, this system **can cause radio interference**. Reorienting, relocating or shielding the system, or filtering the connection to the public mains network, are examples of steps that can be taken to reduce or eliminate interference.
- Medical electrical equipment **needs special precautions regarding EMC** and needs to be installed and used according to the EMC information provided in the "Appendix" section of this User Manual (see "Regulations and Standards," "Compliance").

Features and Displays

Features and Definitions

See the product-specific section of this User Manual that applies to the attached module(s) for features and definitions specific to that module.

| Feature | Definition |
|---------------------|---|
| Clinician ID | An optional alphanumeric 16-character clinician identifier that can be entered and displayed. |
| Data Set | Created using Editor Software authoring tool and then transferred to PC unit. A Data Set reflects facility's best-practice guidelines for IV Drug administration and includes: Profile Drug Libraries, Clinical Advisories, instrument configurations, and Channel Label Libraries. |

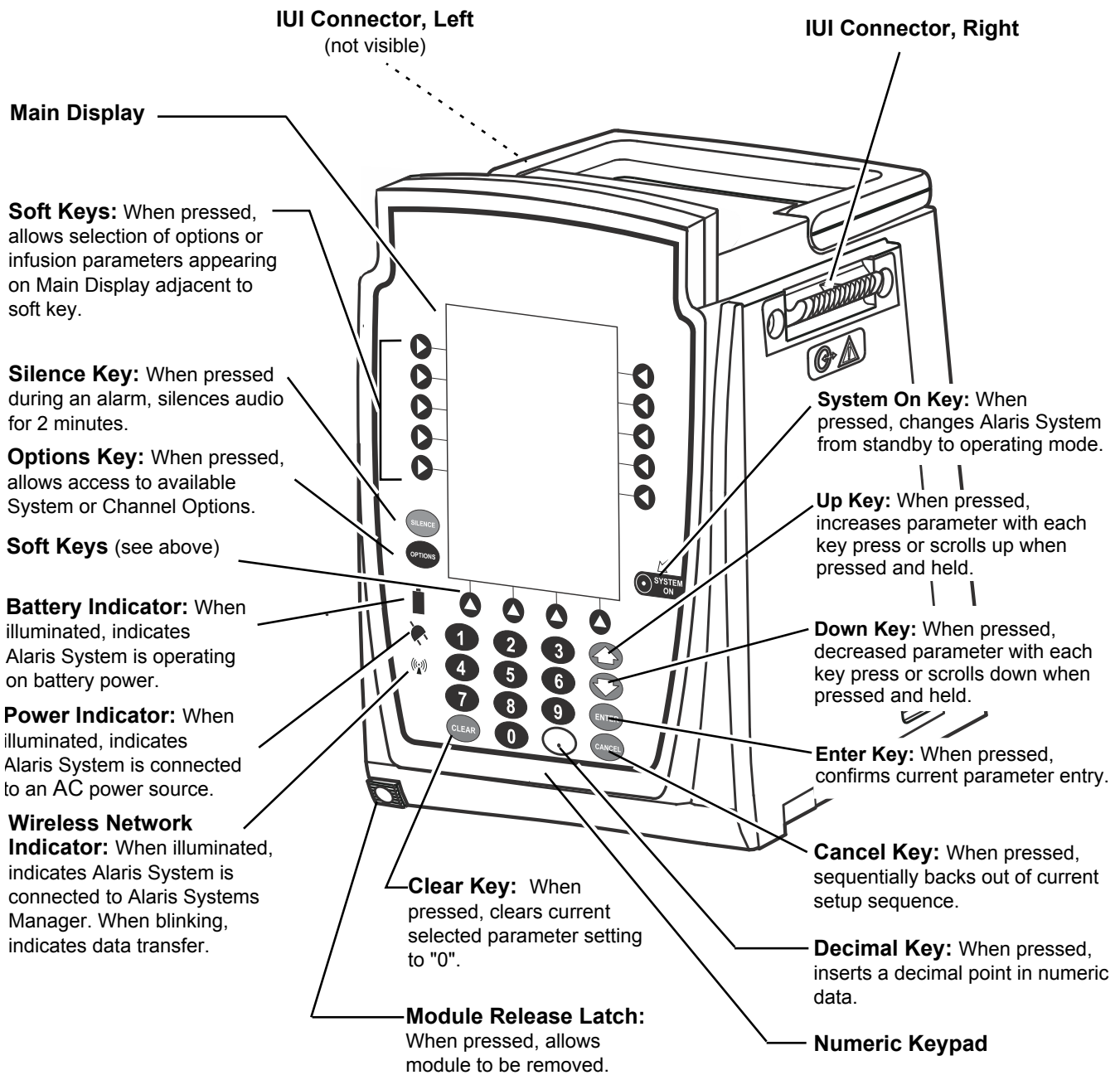
Features and Displays (Continued)

Features and Definitions (Continued)

| Feature | Definition |
|-----------------------------|---|
| Guardrails Suite MX | <p>Designed to help prevent programming errors by:</p> <ul style="list-style-type: none"> • Customizing device configurable settings to meet need of selected hospital/facility area/unit (Profile). • Comparing user-programming with hospital-defined best-practice guidelines. • Providing a visual and audio prompt if an out-of-limits entry is made. |
| Patient ID | <p>An optional alphanumeric 16-character patient identifier that can be entered and displayed</p> <ul style="list-style-type: none"> • When enabled, ID entry defaults to Startup screen. • When disabled, ID entry is only accessible from System Options screen. |
| Profile | <p>A unique set of system configuration settings and best-practice guidelines for a specific patient population or patient type, and can consist of following components:</p> <ul style="list-style-type: none"> • Instrument configuration settings. • A Drug Library, which includes drug names, standard concentrations, dosing units, duration limits, and optional associated Clinical Advisories for both continuous and Bolus Dose infusion. • An IV Fluid library, an optional library consisting of IV Fluids (for example, TPN) and limits around rate of delivery. • A Channel Label Library with text (alphanumeric) labels, which allows identification (on modules) that can be used to indicate route of delivery (for example, epidural). <p>Profile settings are established by the facility's own multi-disciplinary team prior to system implementation. Profile parameters are used to create a Data Set, which is then transferred to the PC unit.</p> |
| System Configuration | <p>Allows system settings to be customized. If Profiles feature is enabled, the system settings defined for selected Profile are automatically activated.</p> |
| Tamper Resist | <p>Provides a quick one-touch lockout of the front panel keypad when the infusion is running, during a delay, or a SpO₂ or EtCO₂ module is actively monitoring. You cannot lockout the front panel keypad during KVO. An alarm can be silenced even though the panel is locked.</p> |

Features and Displays (Continued)

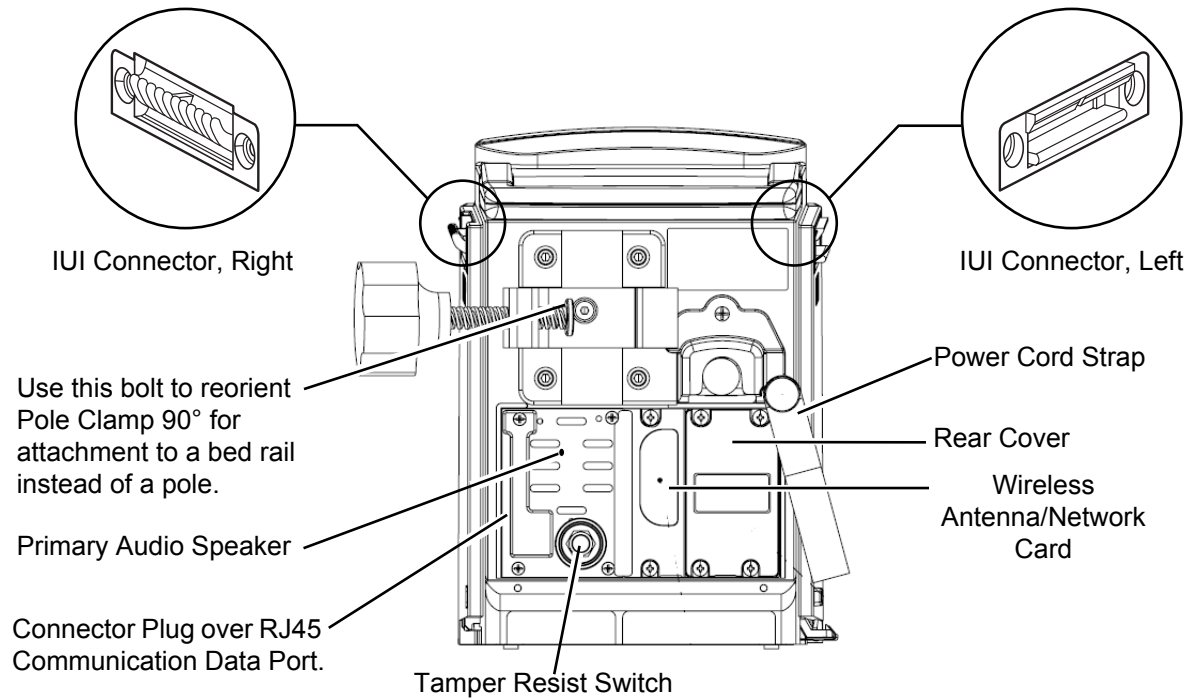
Operating Features, Controls, Indicators



Features and Displays (Continued)

Operating Features, Controls, Indicators (Continued)

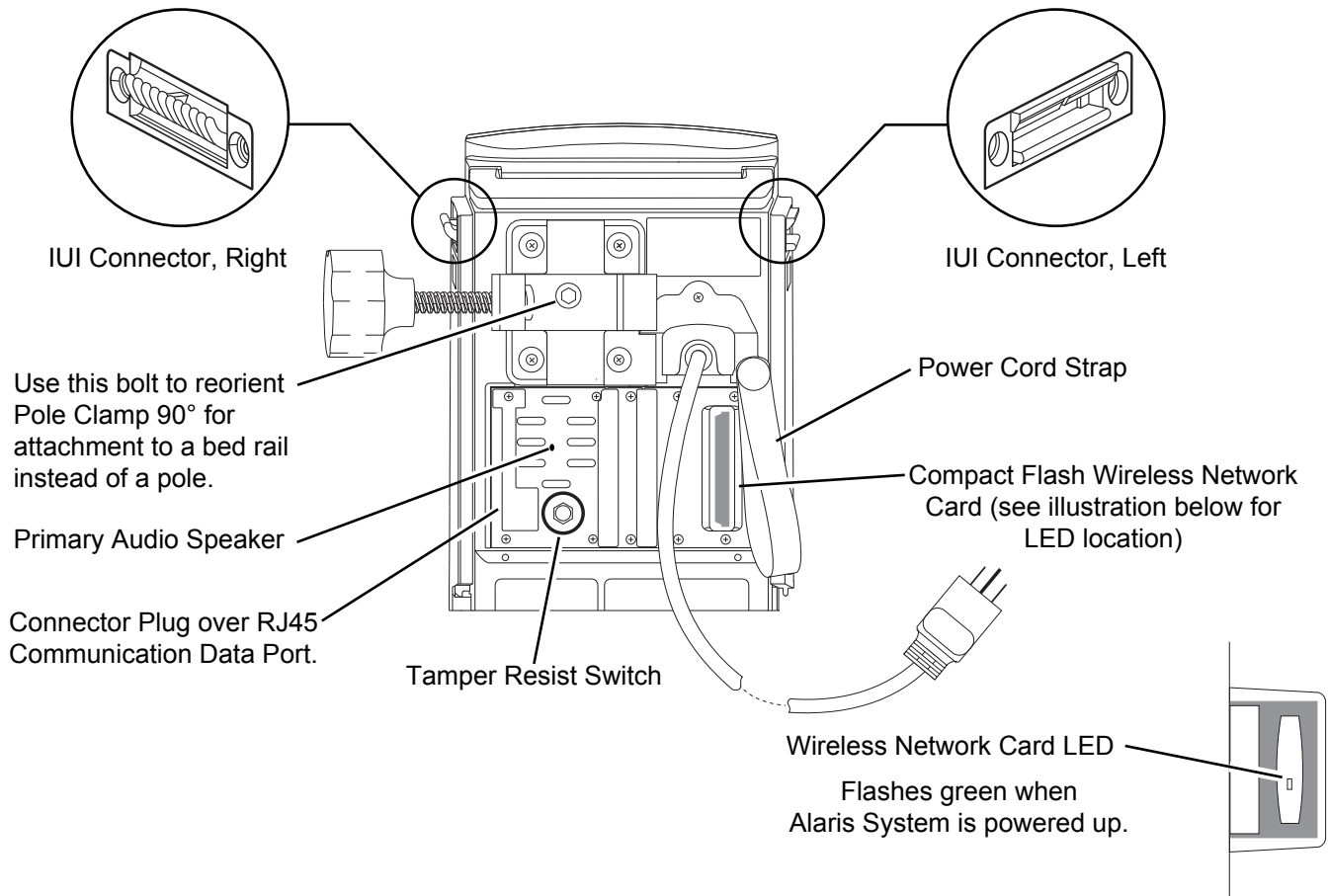
Rear Panel - IEC 802.11 a/b/g/n Wireless Network Card



Features and Displays (Continued)

Operating Features, Controls, Indicators (Continued)

Rear Panel - Compact Flash b/g or a/b/g Wireless Card



Features and Displays (Continued)

Displays

The displays illustrated throughout this document are for illustration purposes only. The display content varies, depending on configuration settings, hospital-defined Data Set uploaded using the Guardrails Suite MX, and many other variables.

A color versus monochrome display option is available when creating a hospital-defined, best-practice Data Set. If no Data Set is present or the Profiles feature is disabled, the default is a color display. During normal operation, the title and prompt bars are blue when a color display is enabled. See "Troubleshooting and Maintenance," "Alarms, Errors, Messages" for additional color categories.

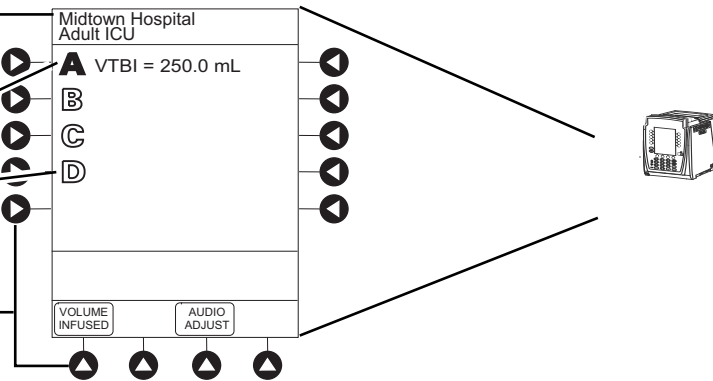
Main Display

Title Bar

Module Status

- A solid letter display indicates module is operating.
- An outlined letter display indicates module is attached and ready for use.

Soft Keys



Module Selected Indicator

"Inactive" Soft Key

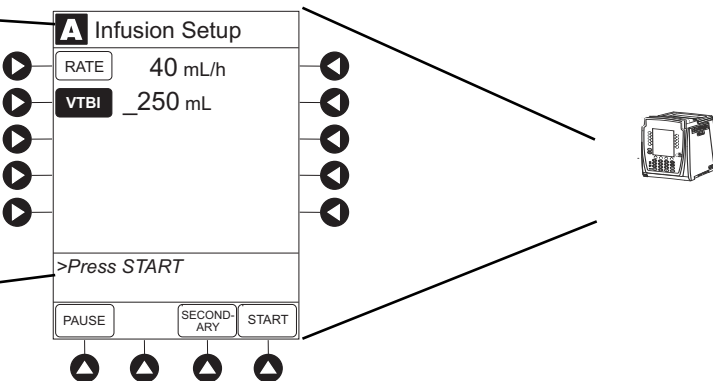
Non-highlighted indicates a non-selected soft key.

"Active" Soft Key

Highlighted indicates a selected soft key.

Prompt Bar

Look here for user prompts.



System Configurable Settings

If the configuration settings need to be changed from the **Factory default** settings, refer to the applicable Technical Service Manual or contact CareFusion Technical Support, for technical, troubleshooting, and preventive maintenance information.

With the Profiles feature enabled, the settings are configured independently for each Profile. A hospital-defined, best-practice Data Set must be uploaded to enable the Profiles feature. Date and Time is a system setting and is the same in all Profiles.

| Feature | Default Setting | Options |
|---|-----------------|-----------------------|
| Alarm Audio | Profile 1 | Profile 1, 2, 3, or 4 |
| Anesthesia Mode | Disabled | Enabled - Disabled |
| Battery Meter | Disabled | Enabled - Disabled |
| Clock Setup (Date and Time) | Not Applicable | Set date and time |
| Key Click Audio | Enabled | Enabled - Disabled |
| Max Patient Weight | 500 kg | 0.1 - 500 kg |
| Patient ID Entry | Disabled | Enabled - Disabled |
| PM Reminder (Preventive Maintenance) | Enabled | Enabled - Disabled |
| Profiles | Disabled | Enabled - Disabled |
| Tamper Resist | Disabled | Enabled - Disabled |

Specifications and Symbols




Specifications

- Battery Operation:** Battery run time is a function of the number of modules attached and module activity. With a new, fully charged battery, the system operates as follows before a "BATTERY DISCHARGED" message occurs:
- 1 hour with four Pump modules infusing at 999 mL/h and one Auto-ID module
 - 6 hours with one Pump module infusing at 25 mL/h
 - 6 hours with one Pump module infusing at 25 mL/h and one Auto-ID module
 - 3 hours with four Pump modules infusing at 25 mL/h
 - 3 hours with four Pump modules infusing at 25 mL/h and one Auto-ID module
 - 4.5 hours with one active SpO₂ module
 - 6 hours with one Syringe module or PCA module infusing at 5 mL/h
 - 3 hours with four Syringe modules, or one PCA module and three Syringe modules, infusing at 5 mL/h
 - 4 hours with one active EtCO₂ module
- Communication Data Port:** RS-232 with an RJ45 connector.
- Dimensions:** 6.9" W x 8.8" H x 9" D (including pole clamp)
- Electric Classification:** Class 1, Internally Powered Equipment
- Electronic Memory:** The System configuration/data set is stored in compact flash memory along with operating software.
- The events and error logs, CQI, and historical reporting logs, and the system alarm settings are stored in the on-board flash memory in the Alaris PC unit and modules. This is nonvolatile memory and can be held indefinitely or until replaced with new data. Logs and alarm settings are maintained even during a total loss of power to the system. The date and time of system power down is captured in the event log. The older log entries are purged as the log file reaches capacity. The Alaris System's Tamper Resist Mode/Authorized User Modes restricts access to making changes to logs or to the storage of logs.
- Module-specific parameters are stored for 8 hours when system is turned off. After 8 hours of continuous off-time, or if a module is detached, module-specific trend data (if applicable) and module-specific operating parameters are automatically purged. If a PCA, SpO₂ or EtCO₂ module is detached and replaced with another PCA, SpO₂, or EtCO₂ module, its module-specific trend data is purged.
- Memory will not be lost due to a weak/discharged battery as data is stored on flash memory as noted.
- Compact flash memory:** Stores application software, audio wave files, Data Set, and hex files data for operating system software, all needed to operate the Alaris System.
- On-board flash memory:** Contains software needed to initially turn on Alaris System. Stores boot software application, and events, errors and battery logs.

Specifications and Symbols (Continued)

Specifications (Continued)

Environmental Conditions:

| Symbol | Meaning | Operating | Storage/Transport |
|---|---|-------------------------------------|------------------------------------|
|  | Atmospheric Pressure | 525 - 4560 mmHg (700 - 6080 hPa) | 375 - 760 mmHg (500 - 1013 hPa) |
|  | Relative Humidity (Avoid prolonged exposure to relative humidity >85%) | 20 - 90% Noncondensing | 5 - 85% Noncondensing |
|  | Temperature Range | 41 - 104°F (5 - 40°C) | -4 - 140°F (-20 - 60°C) |

Equipment Orientation: To ensure proper operation, Alaris System must remain in an upright position.

Fluid Ingress Protection: IPX1, Drip Proof

Mode of Operation: Continuous

Power Requirements: 100 - 240V ~, 50/60 Hz, 150 VA MAX












Shock Protection: Type CF, Defibrillator-Proof patient applied part

Weight: 7.2 lbs

Specifications and Symbols (Continued)










Symbols

See the product-specific section of this User Manual that applies to the attached module(s) for symbols specific to that module.

| Symbol | Meaning |
|---|--|
|  | Alternating Current: Indicates device should be attached to alternating current source, 50/60 Hz only. |
|  | Warnings or Caution: Refer to accompanying documentation. |
|  | Canadian and U.S. Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety and performance standards. |
|  | Communications connector for RS-232 attachment. |
|  | Consult Instructions for Use. |
|  | Follow Instructions for Use |
|  | Type CF defibrillation-proof patient applied part. |
|  | Electrostatic discharge (ESD). |
|  | Fuse Replacement: Replace fuse only with same type and rating. |
| IPX1 | Protection against fluid ingress: Drip Proof. |
|  | IUI Connector: Inter-Unit Interface connector used to establish power and communications between PC unit and attached modules. |
|  | Manufacturing Date: Number adjacent to symbol indicates month and year of manufacture. |

Specifications and Symbols (Continued)

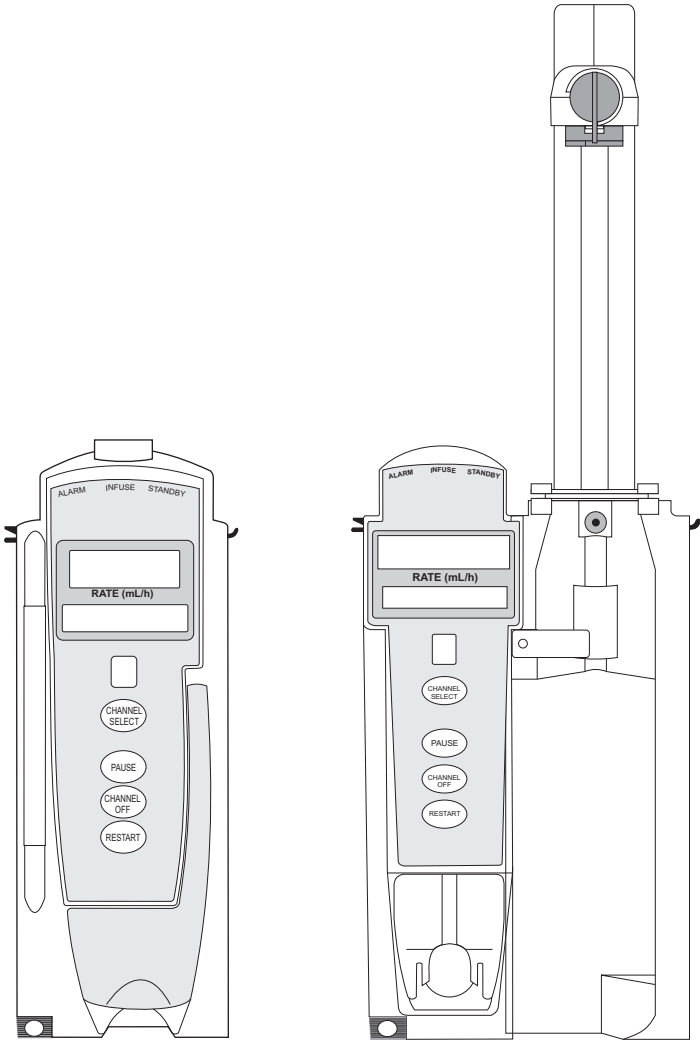
Symbols (Continued)

| Symbol | Meaning |
|---|--|
|  | Manufacturer |
|  | Potential Equalization Conductor (if so equipped). Note: If integrity of PEC or Hospital Earth System is in question, operate instrument using internal battery power. |
|  | Radio frequency (RF) transmission. |
| R_x Only | Caution: Federal (U.S.A) law restricts this device to sale by or on order of a physician. |
|  | Tamper Resist activate/deactivate switch. |
|  | Conformité Européenne (CE marking) notified body 0086: British Standards Institution. |
|  | Australian Communications Authority. |
|  | Federal Communications Commission. |
|  | Pursuant to Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003, on waste electrical and electronic equipment (WEEE). |
|  | Authorized representative in European Community. |

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Alaris Pump Module, Model 8100

Alaris Syringe Module, Model 8110



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Introduction

This section of the User Manual provides Pump module (Model 8100) and Syringe module (Model 8110) instructions and information. It is used in conjunction with:

- Alaris™ product administration set instructions
- Drug product labeling
- PC unit section of this User Manual
- *Alaris™ Pump Module Set Compatibility Card*
- *Alaris™ Syringe Module Set Compatibility Card*
- *Pump Module Technical Service Manual*
- *Syringe Module Technical Service Manual*
- System Maintenance software (and its instructions) for Alaris System check-in, maintenance, and wireless configuration

WARNING



Read all instructions, for both the infusion modules and PC unit, before using the Alaris System.

Essential Performance

The Alaris infusion modules are designed to accurately deliver the programmed amount of the medication or fluid over the programmed time period. The Alaris infusion modules ensure that an infusion is not being inadvertently delivered when the user expects the system to be in a paused, stopped, or off condition. The Alaris infusion modules employ measurement systems to detect and alarm for conditions adverse to safe administration of fluid. These include measurements of proper infusion set loading (free flow detection), pressure (occlusion detection), and air-in-line detection.

The EtCO₂ module will monitor and alarm when a patient physiological condition is out of range.

The SpO₂ module will monitor and alarm when a patient physiological condition is out of range.

The Pump and Syringe modules are intended for facilities that utilize infusion and/or syringe pumps for the delivery of fluids, medications, blood, and blood products using continuous or intermittent delivery through clinically acceptable routes of administration; such as, intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irrigation of fluid spaces. The Pump and Syringe modules are indicated for use on adults, pediatrics, and neonates. Up to four Pump and/or Syringe modules can be connected to the Alaris System.

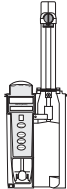
Introduction (Continued)

If a procedure/information applies to a specific module, the following identifiers indicate the module it applies to.

Pump module:



Syringe module:



Administration Sets/Syringes: See "General Information" for specific "Administration Set/Syringe Information."

Alarms and Alerts: See "Appendix A" "Troubleshooting and Maintenance" for module-specific alarms and alerts.

Contraindications: None known.

Electromagnetic Environment: See "Appendix A" section of this User Manual ("Regulations and Standards," "Compliance").

Prepare Administration Set (Pump Module)

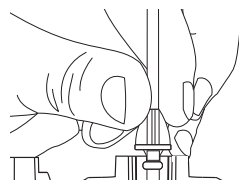
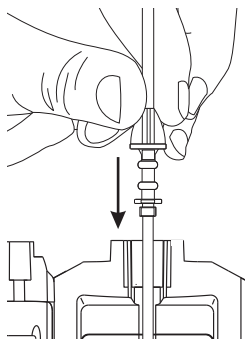
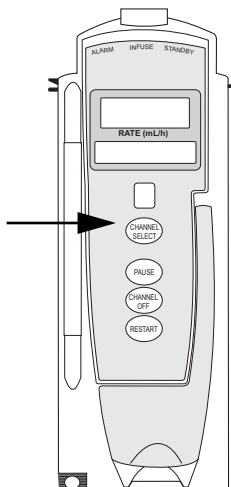


For instructions on how to go from checking in a Pump module to preparing it for an infusion setup, see "General Setup and Operation."

Load

1. Ensure that the instrument is as close to the level of patient's heart as possible - the patient's heart should be in line with **CHANNEL SELECT** key.

Align with Patient's heart level



WARNING

- **Administration Sets:**
- Use only **Alaris Pump module/GEMINI™ Infusion System administration sets**. The use of any other set can cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard. For a list of compatible administration sets, please refer to the Alaris™ Pump Module Set Compatibility Card.
- **Discard if** packaging is not intact or protector caps are unattached.

CAUTION

- Ensure that the device is as close to level of patient's heart as possible. Patient's heart level should be in line with the **CHANNEL SELECT** key.
- Use compatible components which have the smallest internal volume or "dead-space" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (e.g., < 5 mL/h, and especially flow rates < 0.5 mL/h). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times.

Prepare Administration Set (Pump Module) (Continued)



Load (Continued)

2. If a new set is being loaded, prime the set, see *Prime* on page 2-6.
3. Open the Pump module door.
4. Load administration set, as follows:
 - a. Hold upper fitment above fitment recess and lower into recess.
 - b. Ensure that tubing is not twisted.

CAUTION



- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (e.g., 50 - 200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (e.g., < 5 mL/h, and especially flow rates < 0.5 mL/h).
- Failure to follow **proper administration set loading instructions** might lead to an instrument malfunction.
- Before operating the instrument, verify that the administration set is **free from kinks and correctly installed**.
- Insert upper fitment **before installing safety clamp**^① fitment.
- When **reloading an administration set**, leave the safety clamp^① fitment in the **closed** position (see “General Information,” “Safety Clamp Fitment”).

Prepare Administration Set (Pump Module) (Continued)



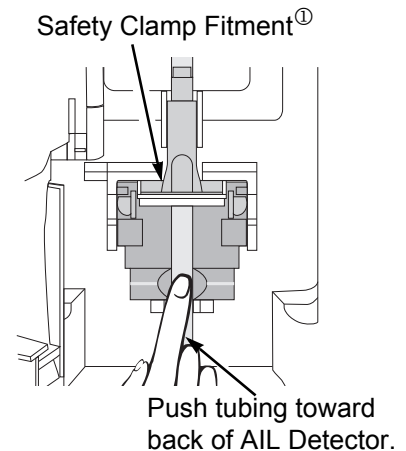
Load (Continued)

- c. Press safety clamp fitment into recess below mechanism.
- d. Using a finger tip, firmly push tubing toward back of Air-in-Line (AIL) Detector.

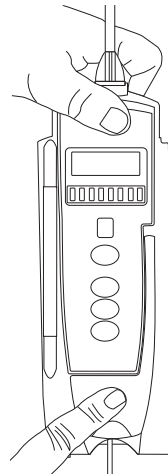
CAUTION



To reduce the potential for nuisance AIL alarms, **ensure that tubing is fully inserted** in the AIL Detector.



5. Close door and latch, as follows:
 - a. Close door and hold in a closed position by grasping door and instrument case with one hand.
 - b. Gently lower latch.
Safety clamp device is automatically disengaged.^①



WARNING



- **Do not touch** the administration set while closing the door. Failure to follow this instruction can result in infusion rate inaccuracy.
- To **prevent a potential free-flow condition**, ensure that no extraneous object (for example, bedding, tubing, glove) is enclosed or caught in the Pump module door.

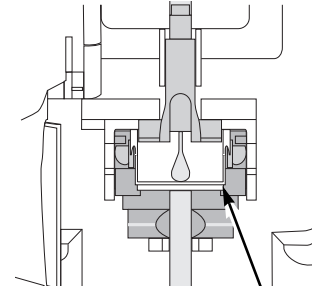
6. Open roller clamp.
7. Verify that no fluid is flowing through drip chamber.

Prepare Administration Set (Pump Module) (Continued)



Remove

1. Close roller clamp.
2. Open Pump module door.
Set's safety clamp fitment automatically closes to prevent accidental free-flow.
3. Remove set, as follows:
 - a. Gently pull tubing below Air-in-Line Detector forward and out.
 - b. Lift upper fitment from upper fitment receptacle.
4. If set is being removed to begin a gravity flow:
 - a. Depress the blue ridged release tab on upper side of safety clamp device.
 - b. Slide the white slide clamp into blue fitment (open position).
 - c. Adjust the flow rate using set's roller clamp.



White Slide Clamp
(shown in closed position)

Prime

1. Prepare primary solution container in accordance with manufacturer's User Manual.
2. Open administration set package, remove set, and close roller clamp. (Refer to set's User Manual.)
3. Insert administration set spike into prepared fluid container, following accepted hospital/facility procedure, and hang container 20 inches above Pump module.
4. Fill drip chamber to $\frac{2}{3}$ full.

Prepare Administration Set (Pump Module) (Continued)



Prime (Continued)

5. If container requires venting, open vent cap on administration set spike.
6. To prime tubing and clear air from injection sites and tubing fittings, slowly open roller clamp.
7. When priming is complete, close roller clamp.
8. Verify no fluid flow.



Prepare Syringe and Administration Set (Syringe Module)

To decrease potential start-up delays, delivery inaccuracies, and delayed generation of occlusion alarms, each time a new syringe is loaded:

- Use smallest syringe size possible (for example, if infusing 2.3 mL of fluid, use a 3 mL syringe).
- Use compatible components which have the smallest internal volume or "dead-space." For example:
 - Tubing internal diameter: Smallbore or microbore tubing is recommended when infusing at low rates
 - Tubing length: Tubing length should be minimized, when possible
 - Filters: Internal volume (dead-space) of in-line filters should be minimized
 - Connection sites: The number of connection sites such as stopcocks and y-sites should be limited, and high risk or life-sustaining solutions should be connected as close to the vascular access site as possible

Prepare Syringe and Administration Set (Syringe Module) (Continued)



WARNINGS

- Raising a syringe pump may result in a bolus of medication or fluid due to changes in hydrostatic pressure. Lowering a syringe pump while infusing may result in a delay in the infusion (or possible under-infusion) due to the changes in hydrostatic pressure.
- Ensure syringe sizes and models are compatible with the Syringe module. Use of incompatible syringes can cause improper pump operation resulting in inaccurate fluid delivery, insufficient occlusion (blockage) sensing, and other potential problems.
- Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h). Using a larger syringe when infusing at low rates can lead to inadequate syringe pump performance including delivery inaccuracies, delay of therapy, and delayed generation of occlusion alarms. This is due to the increased friction and compliance of the syringe stopper with larger syringes.
- Electronically prime the syringe pump system before starting an infusion or after replacing a near-empty syringe with a replacement syringe.
- Failure to use the PRIME SET WITH SYRINGE feature after every syringe change can significantly delay the infusion delivery start-up time and lead to delivery inaccuracies.

Prepare Syringe and Administration Set (Syringe Module) (Continued)



CAUTION



- Use compatible components which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (e.g., < 5 mL/h, and especially flow rates < 0.5 mL/h). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times
- Ensure that the device is as close to level of patient's heart as possible. Patient's heart level should be in line with the **CHANNEL SELECT** key.
- Use the **PRIME SET WITH SYRINGE** channel option on the Alaris Syringe module to speed up the engagement of the module's mechanical components and decrease the syringe's internal friction (see "Prime - Using Options Menu").
- If using a pre-run infusion practice (to allow for medication equilibration prior to connection to the patient), ensure that the distal end of the administration set is level with or higher than the device.
- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (e.g., 50 - 200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (e.g., < 5 mL/h and especially flow rates < 0.5mL/h).

These recommendations are especially important when infusing high-risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h and especially at flow rates < 0.5 mL/h).

Prepare Syringe and Administration Set (Syringe Module) (Continued)



For instructions on how to go from checking in a Syringe module to preparing it for an infusion setup, including how to change a syringe during infusion, see "General Setup and Operation."

1. Prepare syringe (For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page 2-136 and the *Alaris™ Syringe Module Set Compatibility Card*) in accordance with manufacturer's User Manual.
2. Prepare administration set in accordance with manufacturer's User Manual.
3. Attach upper fitting of administration set to syringe tip.

NOTE:

For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page 2-136 and the *Alaris™ Syringe Module Set Compatibility Card*. For a listing of administration sets, refer to the *Alaris™ Pump Module Set Compatibility Card*.

Prepare Syringe and Administration Set (Syringe Module) (Continued)



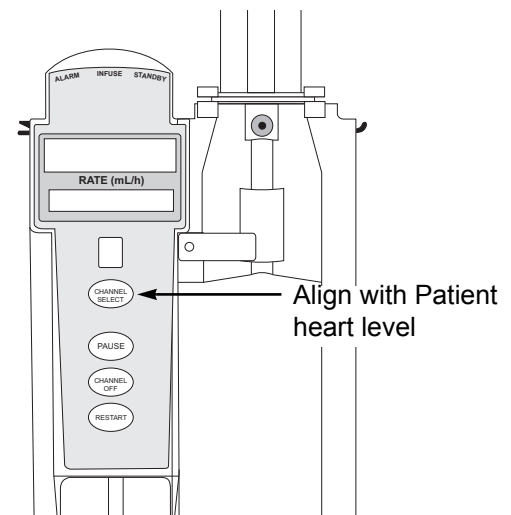
Load

WARNING



Before loading or unloading the syringe, always turn off fluid flow to the patient, using the tubing clamp or stopcock. Uncontrolled fluid flow can occur when the administration set is not clamped or turned off, and can cause serious injury or death.

4. Ensure that instrument is as close to level of patient's heart as possible—patient's heart level should be in line with **CHANNEL SELECT** key.
 - Keep the Alaris System level with the patient's heart to maintain positive pressure.
 - If using a pre-run infusion practice (to allow for medication equilibration prior to connection to the patient), ensure that the distal end of the administration set is level with or higher than the device.



WARNING



Raising a syringe pump may result in a bolus of medication or fluid due to changes in hydrostatic pressure. Lowering a syringe pump while infusing may result in a delay in the infusion (or possible under-infusion) due to the changes in hydrostatic pressure.

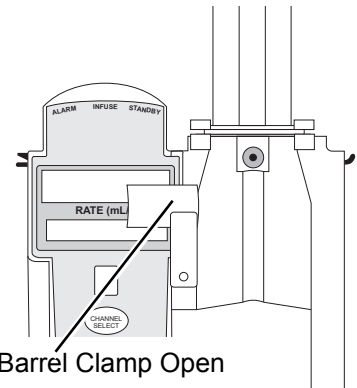
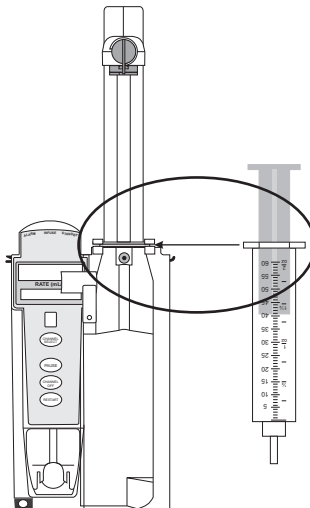
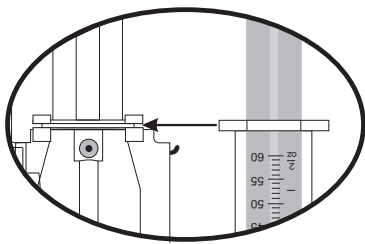
Prepare Syringe and Administration Set (Syringe Module) (Continued)

Load (Continued)

5. Open syringe barrel clamp.
 - a. Pull syringe barrel clamp out and hold.
 - b. Rotate clamp to left (clockwise or counter clockwise) until it clears syringe chamber.
 - c. Gently release clamp.

6. Raise drive head to its fully extended position.
 - a. Twist gripper control clockwise and hold in position. ①
 - b. While holding gripper control in open position, raise drive head to full extension.
 - c. Gently release gripper control.

7. Insert syringe (from front of instrument) by sliding flat edge of syringe barrel flange between barrel flange grippers.

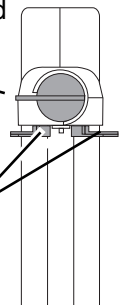


Syringe Barrel Clamp Open

Drive Head Fully Extended

Gripper Control/Drive Head Release in Open Position

Plunger Grippers Open



WARNING



Before loading the syringe, check it for damage or defects.

CAUTION



When initially loading the syringe, allow for the volume of fluid contained in the administration set and retained in the syringe at the end of an infusion, as this “dead space” will not be infused.

Prepare Syringe and Administration Set (Syringe Module) (Continued)



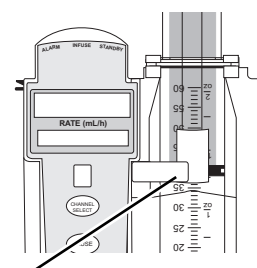
Load (Continued)

8. Lock syringe in place.
 - a. Pull syringe barrel clamp out and hold.
 - b. Rotate clamp to right (clockwise or counter clockwise) until it lines up with syringe.
 - c. Gently release clamp against syringe.

WARNING

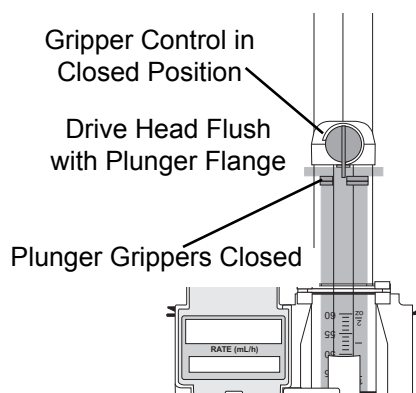


Ensure that syringe barrel, flange, and plunger are installed and secured correctly. Failure to **install syringe correctly** can result in uncontrolled fluid flow to the patient, and can cause serious injury or death.



Syringe Barrel Clamp Closed

9. Lower drive head and lock plunger in place with plunger grippers.
 - a. Twist gripper control clockwise and hold in position. ①
 - b. While holding gripper control in open position, gently lower drive head until it makes contact with plunger flange.
 - c. Gently release gripper control.
 - d. Ensure that plunger grippers lock and hold plunger in place.



CAUTION



- To **avoid an occlusion** when loading a smaller size syringe, use extra care to close off administration set tubing and gently lower drive head against syringe plunger.
- For **smaller syringes** (such as; 1, 3, or 5 mL), stabilize the syringe plunger with thumb and index finger while carefully lowering the drive head. Ensure that the syringe plunger head makes contact with the small black sensor, located on the bottom of the drive head (between the plunger grippers).

Prepare Syringe and Administration Set (Syringe Module) (Continued)



Load (Continued)

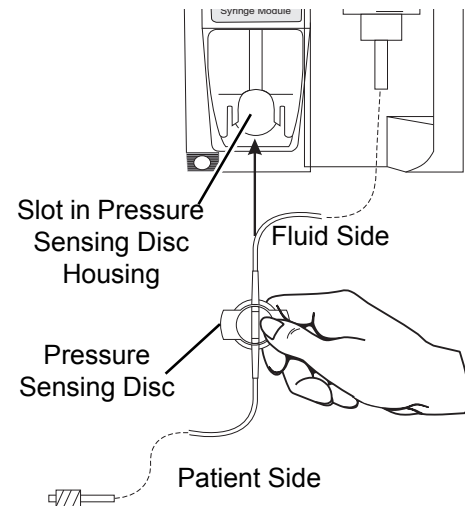
10. Insert pressure sensing disc (if used), as follows:②

WARNING

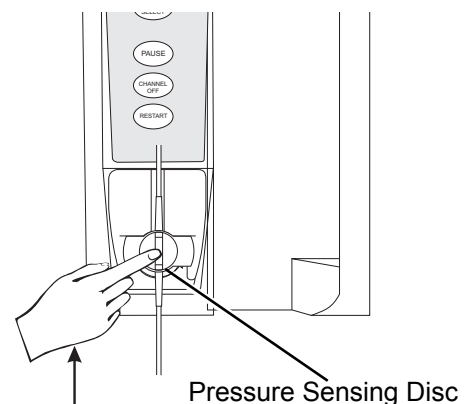


When the **pressure sensing disc is not being used** and an occlusion occurs, there is a risk of infusing pressurized buildup of infusates upon correction of the occlusion. To avoid an inadvertent bolus, relieve the pressure before restarting the infusion.

- a. Orient pressure sensing disc, as follows:
- fluid side up (patient side down)
 - cavity forward (membrane toward instrument)



- b. Gently slide pressure sensing disc up into slot in pressure sensing disc housing.
- c. Apply firm upward pressure on pressure sensing disc (not tubing) until disc snaps into place.



Prepare Syringe and Administration Set (Syringe Module) (Continued)



Load (Continued)

NOTES:

- ① The gripper control is spring loaded. When twisted to the open position and then released, it (and the plunger grippers) returns to the closed position.
- ② The following Syringe module features are available only with extension sets fitted with a pressure sensing disc:
 - Auto Pressure
 - Back Off (upon occlusion)
 - Customized Pressure Alarm Settings (see “Occlusion Pressure” feature definition)
 - Dynamic Pressure Display
 - Numeric Pressure Display
 - Fast Start(See “General Information,” “Features and Displays” for definitions.)

Prime—Using Options Menu

The Priming option can be enabled at the time the Alaris System is configured for use. The Priming selection (**PRIME** soft key) is available only after the syringe and infusion type have been selected, and prior to beginning an infusion.

If a pressure sensing disc is in use, it should be removed from the instrument before priming. See the applicable procedure (as follows) depending on whether or not a pressure sensing disc is used.

WARNING



Electronically prime the syringe pump system before starting an infusion or after replacing a near empty syringe with a replacement syringe. Using the syringe pump's prime feature engages the mechanical components of the pump and decreases the syringe's friction and compliance to minimize startup delays and delivery inaccuracies, especially at low infusion rates. Failure to use the prime feature on the syringe pump after every syringe change and/or tubing change can significantly delay the infusion delivery startup time and lead to delivery inaccuracies.

WARNING



When priming:

- Ensure that administration set is not connected to patient.
- Ensure that air is expelled from line prior to beginning infusion (unexpelled air in line could have serious consequences).

Failure to prime correctly can delay infusion delivery and cause the total volume to be infused to read higher than the actual total delivered to the patient.

CAUTION



During priming, the pressure limit alarms are temporarily increased to their maximum level.

Prepare Syringe and Administration Set (Syringe Module) (Continued)

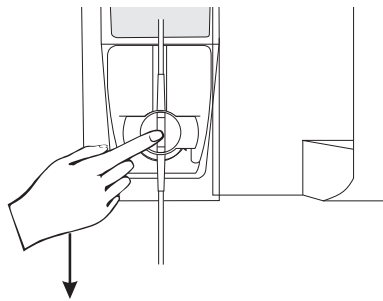


Prime—Using Options Menu (Continued)

Administration Set With Pressure Sensing Disc

1. Ensure that administration set is not connected to patient.
2. If installed, remove pressure sensing disc from instrument.

Using a finger, apply firm downward pressure on pressure sensing disc (not tubing) until disc snaps loose from slot in pressure sensing disc housing.

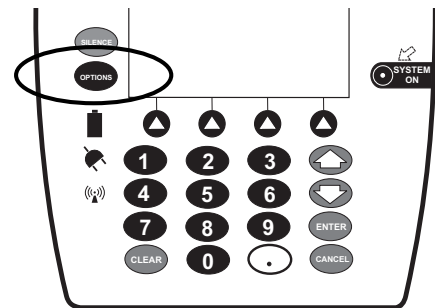


CAUTION

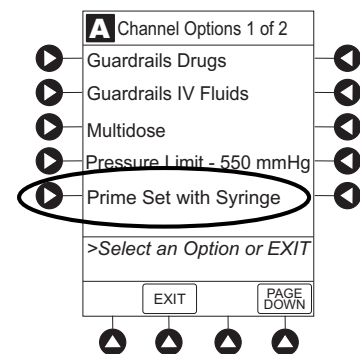


The pressure sensing disc, if left installed during priming, can trap air that might not be totally expelled. To **ensure that entrapped air is eliminated**, it is recommended that the pressure sensing disc be removed prior to priming and the membrane gently massaged with a finger while priming. After priming is completed, reinstall the pressure sensing disc.

3. Press **OPTIONS** key.



4. Press **Prime Set with Syringe** soft key.



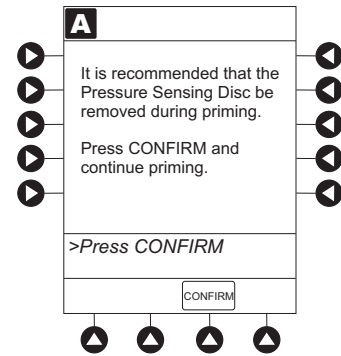
Prepare Syringe and Administration Set (Syringe Module) (Continued)



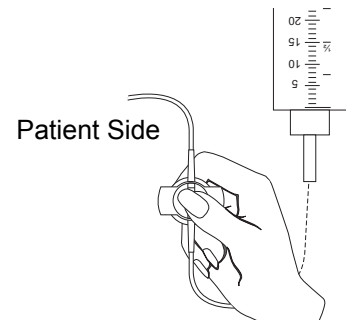
Prime—Using Options Menu (Continued)

Administration Set With Pressure Sensing Disc (Continued)

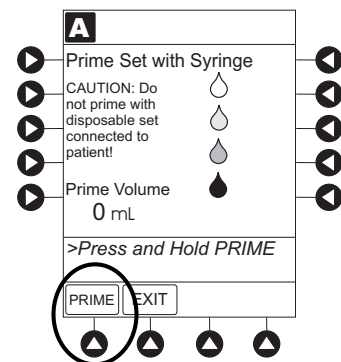
If pressure sensing disc was not removed prior to pressing **Prime Set with Syringe** soft key, a pressure sensing disc removal prompt is displayed.



5. Invert pressure sensing disc so that patient side is up.
6. Hold pressure sensing disc between two fingers.



7. Press and hold **PRIME** soft key.



Prepare Syringe and Administration Set (Syringe Module) (Continued)

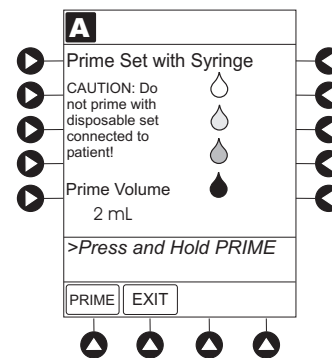


Prime—Using Options Menu (Continued)

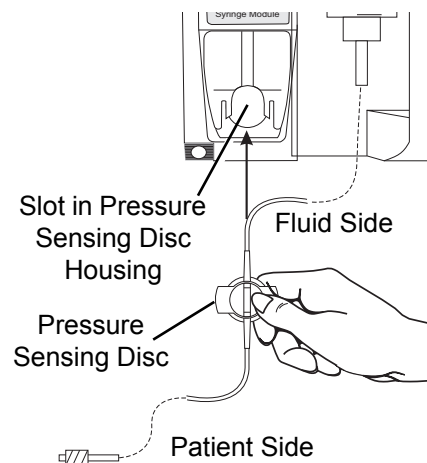
Administration Set With Pressure Sensing Disc (Continued)

8. Gently massage pressure sensing disc to ensure that all air is expelled. The disc must remain inverted only until the air is expelled. Continue to gently massage disc throughout priming to ensure that it does not become under- or over- filled.
9. Continue to prime until fluid flows and priming is complete. Fluid is delivered during priming only while **PRIME** soft key is pressed. Each press of **PRIME** soft key delivers up to 2 mL of priming fluid at the maximum rate of the selected syringe per continuous press. To deliver additional amounts, press **PRIME** soft key again. (See *Rate Restriction by Syringe Size*: on page 2-157)
10. When priming is complete, release pressure sensing disc and **PRIME** soft key.

Volume used during priming is displayed but not added to VTBI or VI.



11. Reinstall pressure sensing disc, as follows:
 - a. Orient pressure sensing disc, as follows:
 - fluid side up (patient side down)
 - cavity forward (membrane toward instrument)
 - b. Gently slide pressure sensing disc up into slot in pressure sensing disc housing.



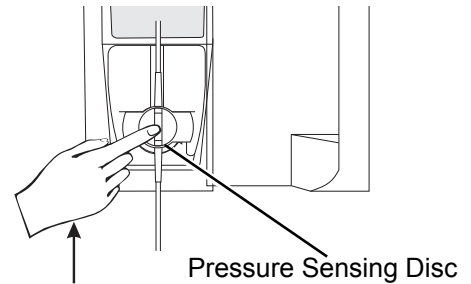
Prepare Syringe and Administration Set (Syringe Module) (Continued)



Prime—Using Options Menu (Continued)

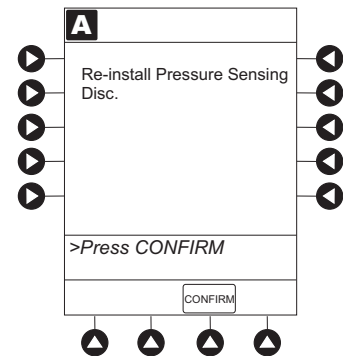
Administration Set With Pressure Sensing Disc (Continued)

- c. Apply firm upward pressure on pressure sensing disc (not tubing) until disc snaps into place.



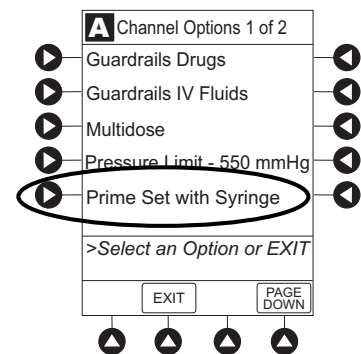
12. To return to main screen, press **EXIT** soft key.

If **EXIT** soft key is pressed before pressure sensing disc is reinstalled, a prompt to reinstall pressure sensing disc is displayed.



Administration Set With No Pressure Sensing Disc

1. Press **OPTIONS** key.
2. Press **Prime Set with Syringe** soft key.



Prepare Syringe and Administration Set (Syringe Module) (Continued)



Prime—Using Options Menu (Continued)

3. Press and hold **PRIME** soft key until fluid flows and priming is complete.

Fluid is delivered during priming only while **PRIME** soft key is pressed. Each press of **PRIME** soft key delivers up to 2 mL of priming fluid per continuous press. To deliver additional amounts, press **PRIME** soft key again.

4. Release **PRIME** soft key.
Volume used during priming is displayed but not added to VTBI or VI.
5. To return to main screen, press **EXIT** soft key.

Prime—Manual

Use the following procedures to manually prime the administration set.

WARNING



When priming:

- Ensure that administration set is not connected to patient.
- Ensure that air is expelled from line prior to beginning infusion (unexpelled air in line could have serious consequences).

Failure to prime correctly can delay infusion delivery and cause the total volume to be infused to read higher than the actual total delivered to the patient.

Prepare Syringe and Administration Set (Syringe Module) (Continued)



Prime—Manual (Continued)

Administration Set With Pressure Sensing Disc

1. Ensure that administration set is not connected to patient.
2. If installed, remove pressure sensing disc from instrument.

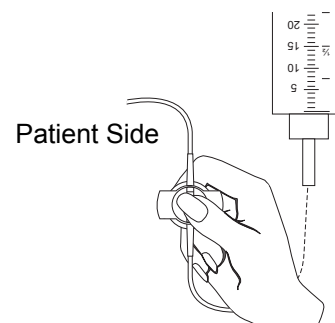
Using a finger, apply firm downward pressure on pressure sensing disc (not tubing) until disc snaps loose from slot in pressure sensing disc housing.

CAUTION



The pressure sensing disc, if left installed during priming, can trap air that might not be totally expelled. To ensure that entrapped air is eliminated, it is recommended that the pressure sensing disc be removed prior to priming and the membrane gently massaged with a finger while priming. After priming is completed, reinstall the pressure sensing disc.

3. Invert pressure sensing disc so that patient side is up.
4. Hold pressure sensing disc between 2 fingers. ①
5. Slowly prime set while gently massaging pressure sensing disc to ensure that all air is expelled. The disc must remain inverted only until the air is expelled. Continue to gently massage disc throughout priming to ensure that it does not become under- or over-filled.
6. When priming is complete (no air exists), close set clamp.



NOTE:

- ① When manually priming (per hospital/facility protocol) and an administration set having a pressure sensing disc is in use, depress the disc between 2 fingers while priming and prime uphill (distal end of pressure sensing disc/tubing pointing upward).



Prepare Syringe and Administration Set (Syringe Module) (Continued)

Prime—Manual (Continued)

Administration Set With No Pressure Sensing Disc

1. Prime per hospital protocol.
2. When priming is complete (no air exists), close set clamp.

Eliminate Mechanical Slack

To eliminate mechanical slack or free play, and minimize start-up delays and delivery inaccuracies, especially when infusing at low flow rates, it is recommended that the instrument be primed per the following procedure.

1. Load syringe (see "Load" procedure). If a pressure sensing disc is being used, do not install disc until priming is complete.
2. Select syringe and infusion type (see "Programming" chapter).
3. Open administration set clamp.
4. Prime, as follows, using Priming option (see "Prime -Using Options Menu"):
 - a. Follow applicable procedure (based on whether or not pressure sensing disc is installed) through step to press and hold **PRIME** soft key.
 - b. Prime until fluid drips from end of tubing.
 - c. Complete procedure (installing pressure sensing disc, if applicable, and exiting options menu).

Introduction

The Alaris System can be programmed with Guardrails Suite MX Protection or with no Guardrails Suite MX protection:

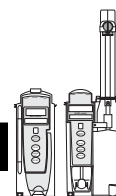
- Guardrails Suite MX Protection
 - Manual Programming (see *page 2-24*)
 - Programming with Interoperability (see *page 2-58*)
 - Auto-ID (Refer to Section "Auto-ID")
- No Guardrails Suite MX Protection
 - Manual Programming Basic Infusion
 - Manual Programming Basic Infusion with Drug Calculation

References throughout this procedure to specific drugs and drug doses are for illustration purposes only. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

See "General Information," "Features and Displays" and the PC unit section of this User Manual for information about:

- Displays
- Operating Features, Controls, Indicators

The majority of user interface programming is identical for both the Pump module and Syringe module. When referring to both modules, the term "infusion modules" is used. The modules are referred to singularly as the Pump module and the Syringe module.

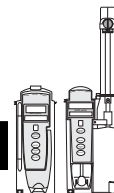


Manual Programming—Primary Infusion


The following procedures are to be used only when the drug to be infused is listed in the Drug Library. To access the Drug Library, a hospital-defined best-practice Data Set must be transferred to the Alaris System and the Profile feature must be enabled.

1. Perform following steps (see PC unit section of this manual, "General Setup and Operation," "Start-Up"):
 - a. Power on system.
 - b. Choose **Yes** or **No** to **New Patient?**
 - c. Confirm current Profile or select a new Profile.
 - d. Enter patient identifier, if required.
2. Prepare and load syringe/administration set (see "Getting Started").
3. Prime (see "Getting Started").

Manual Programming—Primary Infusion (Continued)



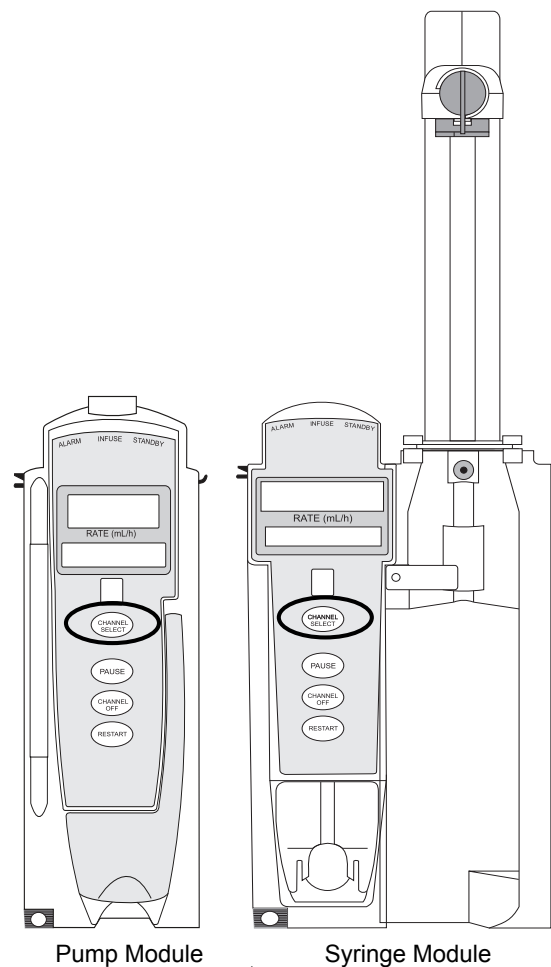
4. Press **CHANNEL SELECT** key.

5.  Syringe module: Select syringe type and size, as follows; otherwise, proceed to step 6. ^① If the installed syringe is loaded correctly, but not recognized, check for the following:

- If a label is between the syringe barrel and the barrel clamp, make sure that the label does not erroneously enlarge the barrel size of the syringe.
- If a needle-free valve or other component is added to the syringe, ensure that it is no larger than the diameter of the syringe barrel.

NOTE:

Thick labeling or adding a component to the syringe that is larger than the diameter of the syringe may prevent the device from correctly recognizing the installed syringe. If the issue continues despite the above troubleshooting, send the device to your facility's biomedical engineering department for servicing.




Pump Module

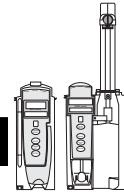
Syringe Module

WARNING



Ensure that the displayed **syringe manufacturer and syringe size** correctly identify the installed syringe. Mismatches might cause an under-infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page 2-136 and the *Alaris™ Syringe Module Set Compatibility Card*. 

Manual Programming—Primary Infusion (Continued)

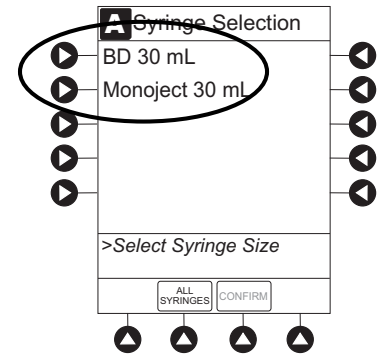


WARNING



Selecting an incorrect syringe may cause an under infusion or over infusion to the patient.

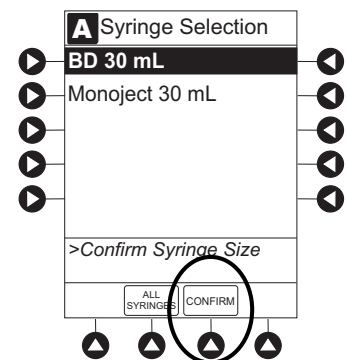
- c. Press soft key next to installed syringe type and size. If a default syringe list has been enabled and correct syringe cannot be found, press the **ALL SYRINGES** soft key to select from a list of all compatible syringes.



- d. To accept, press **CONFIRM** soft key.

6. Start applicable infusion, as described in following procedures:

Continuous Infusion
Bolus Dose
Intermittent Infusion
Fluid Infusion



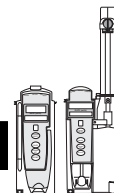
NOTE:

- ① At the start of a Syringe module infusion program, the system prompts to select and confirm the syringe type and size. The system automatically detects the syringe size, and lists syringe types and sizes that most closely match the installed syringe. If the syringe is not recognized, **Syringe not recognized** is displayed.

NOTE:

It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PC unit for the Pump module. However, due to space limitations on the Pump module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the Pump module. This value is only used for display purposes and the Pump module is actually infusing at the more precise rate noted on the PC unit.

Manual Programming—Primary Infusion (Continued)

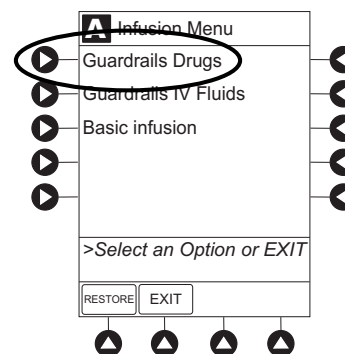


Continuous Infusion

When using a drug listed in the Drug Library, the drug parameters are automatically calculated, based on:

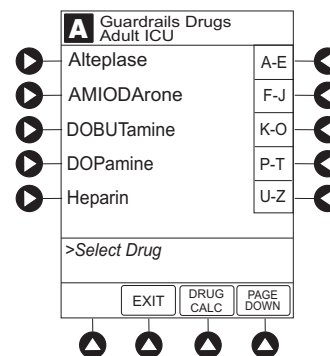
- drug selected
- weight entry (if required)
- rate or dose entry
- VTBI entry (Syringe module—if other than All)

1. Press **Guardrails Drugs** soft key.



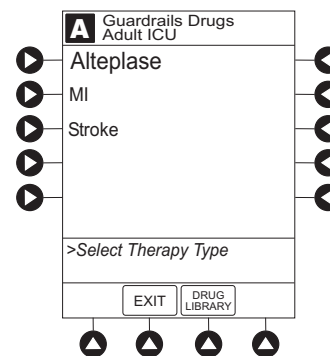
2. Press soft key next to desired drug.

- To view additional drugs/concentrations, press a soft key next to a letter group to navigate through alphabet, and/or **PAGE UP** and **PAGE DOWN** soft keys.

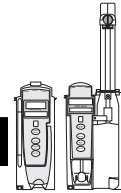


- If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion could appear—as in illustrated example, which reflects use of Alteplase. Different limits can be defined for same drug with different therapeutic indications.

Therapy indication appears on drug or IV fluid confirmation screen. Once drug or IV fluid has been confirmed, therapy indication appears in title bar.

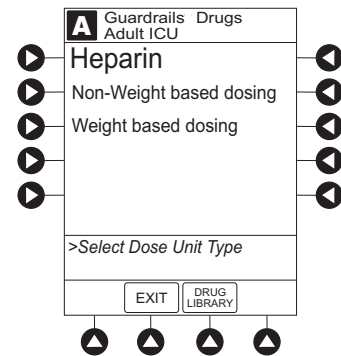


Manual Programming—Primary Infusion (Continued)

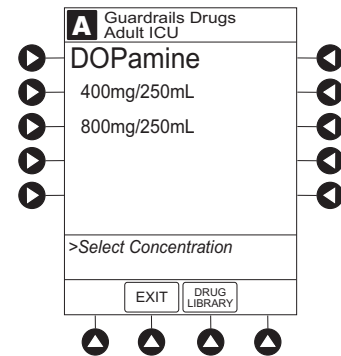


Continuous Infusion (Continued)

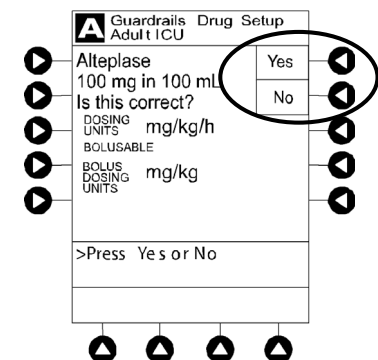
- If applicable, a weight-based or non weight-based option for delivery of this infusion could appear (as in illustrated example, which reflects use of Heparin).



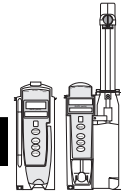
- If applicable, multiple concentration listings for delivery of this infusion could appear (as in illustrated example, which reflects use of Dopamine).



- To continue programming, press **Yes** soft key.^①
Bolus Dose units appear if Bolus Dose is enabled.
OR
To change selection, press **No** soft key.

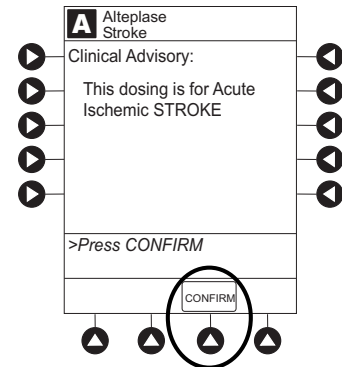


Manual Programming—Primary Infusion (Continued)

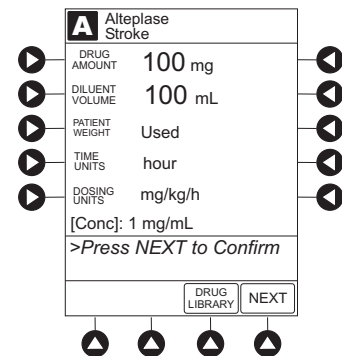


Continuous Infusion (Continued)

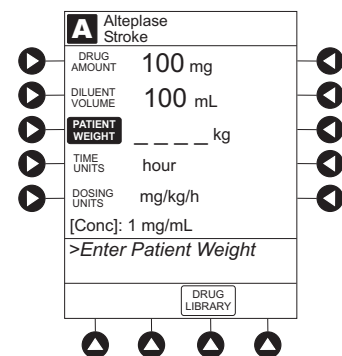
- If **YES** was selected and facility has defined a Clinical Advisory for that drug, a message appears. To indicate information has been noted and continue programming, press **CONFIRM** soft key.



- If **Yes** was selected to continue programming, drug amount and diluent volume (if defined in Drug Library) are automatically entered for selected drug.

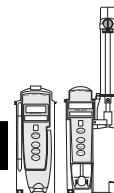


- If selected drug had "__ / __ mL" concentration, drug amount and diluent volume need to be entered.
- If selected drug is not weight-based, **Not Used** is displayed in **PATIENT WEIGHT** field.
- If hospital/facility practice guidelines identify selected drug as weight-based, prompt for a patient weight in kilograms appears (as in illustrated example, which reflects use of Alteplase).^②



- Verify correct parameters and press **NEXT** soft key to confirm.

Manual Programming—Primary Infusion (Continued)

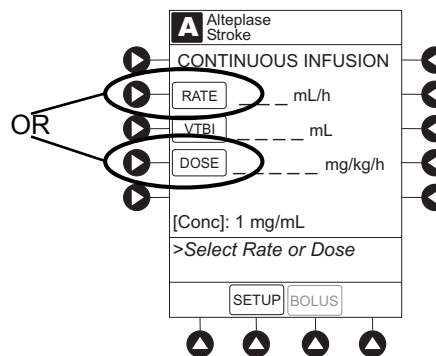


Continuous Infusion (Continued)

- An optional hospital-defined and editable starting value for Continuous Infusion dose might already be entered.

OR

To make a rate or dose entry, press applicable soft key, **RATE** or **DOSE**, and use numeric data entry keys (other value is calculated and displayed).



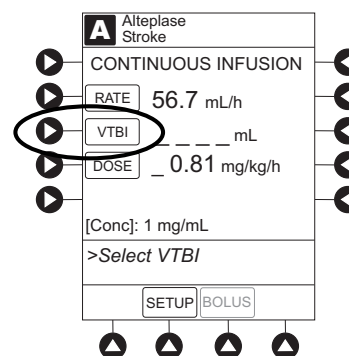
- To enter volume to be infused, press **VTBI** soft key and enter value.

- Pump module:

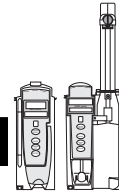


- When VTBI is less than 10 mL, entry can be to two decimal places (one-hundredth of a mL).
- In Drug Calculation mode, system infuses at calculated rate rounded to nearest one-hundredth of a mL per hour (as displayed on the programming screen on the PC unit). The rate shown in Rate Display on the Pump module is rounded to nearest one-tenth of a mL per hour.

- BOLUS** soft key appears only if Bolus Dose is enabled within selected Profile, drug is bolusable, and a VTBI is entered.

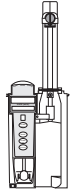


Manual Programming—Primary Infusion (Continued)



Continuous Infusion (Continued)

- Syringe module:

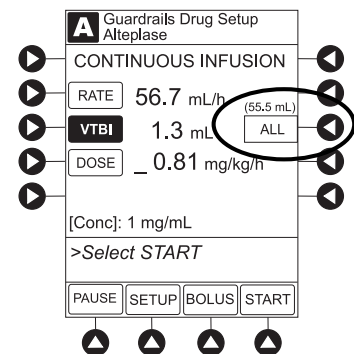
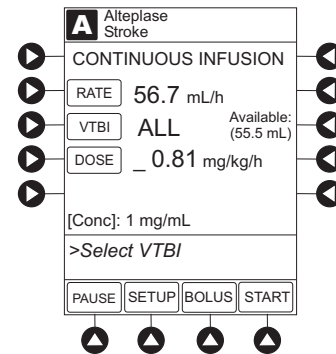


- If ALL Mode is enabled for syringe configuration in Data Set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

OR

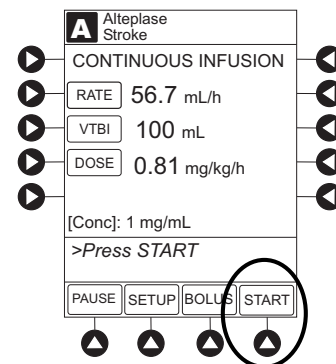
If ALL Mode is disabled for syringe configuration in Data Set, estimated available volume in syringe is displayed when **VTBI** soft key is pressed.

- To enter or change a numeric VTBI value, press **VTBI** soft key and enter value.
- To deliver entire contents of syringe: Keep an **ALL VTBI** value, or press **ALL** soft key to change a numeric VTBI value to **ALL**.

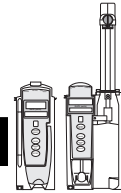


7. Verify correct parameters and press **START** soft key.

- For a Continuous Infusion, the drug name and dose will scroll on the module Message Display

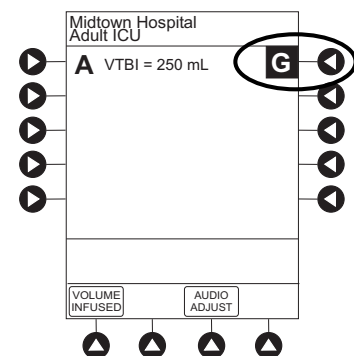
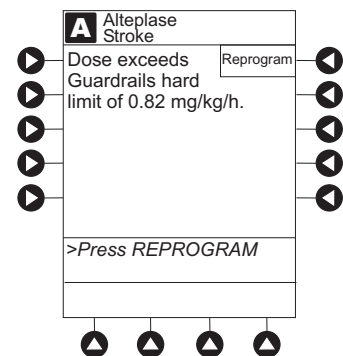
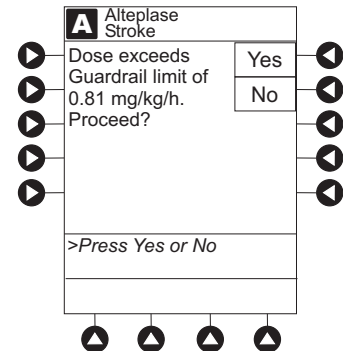


Manual Programming—Primary Infusion (Continued)

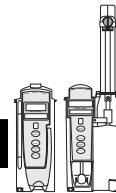


Continuous Infusion (Continued)

- If the programmed continuous dose infusion is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
- If the programmed continuous dose infusion is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
- If a dose outside of the Soft Limits has been entered and verified as correct, Message Display also shows either "LLL" for a low dose or "^^^" for a high dose.
- If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

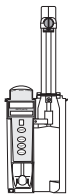


Manual Programming—Primary Infusion (Continued)



Continuous Infusion (Continued)

8. Syringe module:



- Unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

NOTES:

- ① The facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (__ / __ mL) and allow the clinician to enter the desired concentration.
- ② Patient weight can be edited during a Continuous Infusion.
- ③ Once a patient weight is entered and an infusion is started for any module, the patient weight is automatically entered for any additional weight-based calculation. The patient weight remains an editable field, therefore patient weight can be adjusted for any module. Changing the patient weight on one module does not affect the patient weight on any other module.

NOTE:

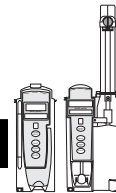
It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PC unit for the Pump module. However, due to space limitations on the Pump module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the Pump module. This value is only used for display purposes and the Pump module is actually infusing at the more precise rate noted on the PC unit.

Bolus Dose

A Bolus Dose can be programmed at the beginning of, or during, a continuous infusion. The drug being programmed must be a bolusable drug selected from the Drug Library or a non-library drug, as described in the following procedures. ①②③④

1. Set up infusion as described in "Continuous Infusion" procedure, but do not start infusion.

Manual Programming—Primary Infusion (Continued)



Bolus Dose (Continued)

2. Press **BOLUS** soft key.
 - If the programmed continuous dose infusion is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
 - If the programmed continuous dose infusion is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. The infusion needs to be reprogrammed.

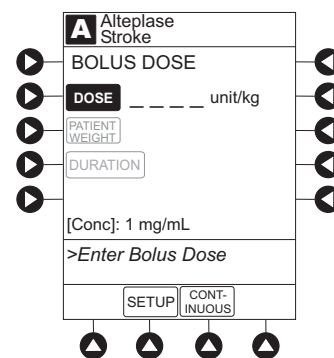
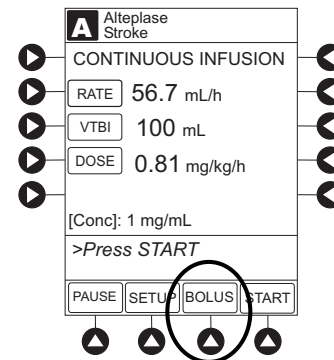
3. An optional hospital-defined and editable starting value for Bolus Dose and/or bolus rate duration might already be entered.

OR

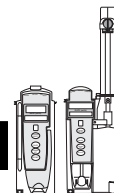
To enter Bolus Dose, use numeric data entry keys.

 - After a Bolus Dose and weight (if used) are entered, bolus VTBI and concentration [conc] alternate in Main Display.
 - If no weight has previously been programmed in system and Bolus Dose is weight-based, weight entry is empty.
 - If the programmed continuous dose is weight-based, programmed weight is displayed.
 - If Bolus Dose is not weight-based, **Not Used** is displayed in **PATIENT WEIGHT** field.
 - A Bolus Dose can be either weight based or non weight-based independent of whether the Continuous Infusion is weight based or non weight-based.

4. Enter or change patient weight (if used), use applicable following procedure, depending on whether or not continuous dose is weight-based.



Manual Programming—Primary Infusion (Continued)



Bolus Dose (Continued)

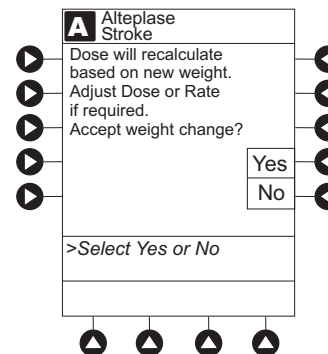
- a. To enter a weight when continuous dose is not weight-based:
 - Press **PATIENT WEIGHT** soft key
 - To enter patient weight, use numeric data entry keys.

OR

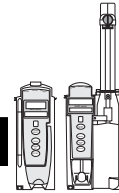
- b. To change weight when continuous dose is weight-based:
 - Press **SETUP** soft key.
 - Press **PATIENT WEIGHT** soft key.
 - To change patient weight, use numeric data entry keys.
 - Press **NEXT** soft key.

If a Continuous Infusion is running, a prompt to confirm weight change appears.

- Press **BOLUS** soft key.
 - To enter Bolus Dose, use numeric data entry keys.
5. Press **DURATION** soft key.



Manual Programming—Primary Infusion (Continued)



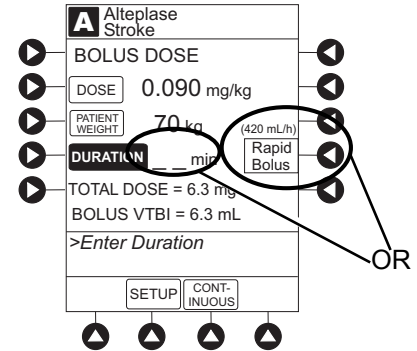
Bolus Dose (Continued)

6. To enter bolus duration, use numeric data entry keys.

OR

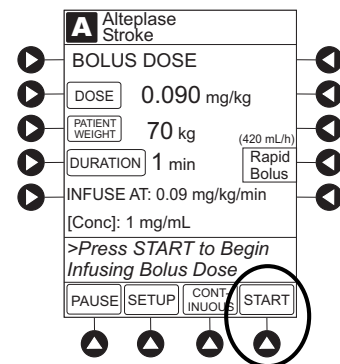
To deliver Bolus Dose at maximum safe rate possible for selected drug and setup, and automatically calculate bolus duration, press **Rapid Bolus** soft key.

- **TOTAL DOSE** alternates with **INFUSE AT** rate.

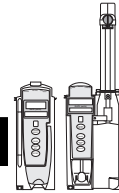


7. Verify correct parameters and press **START** soft key. ⑤

- If the programmed Bolus Dose and/or Bolus Dose duration is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
- If the programmed Bolus Dose and/or Bolus Dose duration is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.



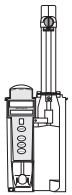
Manual Programming—Primary Infusion (Continued)



Bolus Dose (Continued)

- If a Bolus Dose outside of Soft Limits has been entered and verified as correct, Message Display also shows either "LLL" for a low dose or "↑↑↑" for a high dose.
- If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

8. Syringe module:

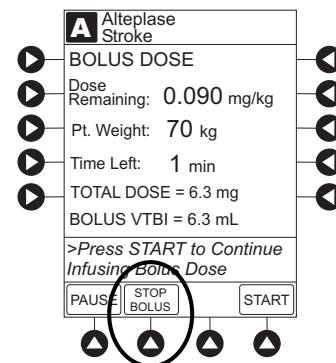


- If Bolus Dose was programmed at beginning of infusion, unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

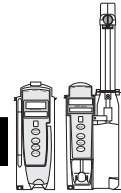
Stop Bolus Dose

The display examples in this procedure represent stopping a Bolus Dose which was programmed using the Drug Library. Even where the displays are different when stopping a Bolus Dose which was programmed using a non-library drug, the procedure is the same.

1. Press **CHANNEL SELECT** key.
2. Press **STOP BOLUS** soft key.



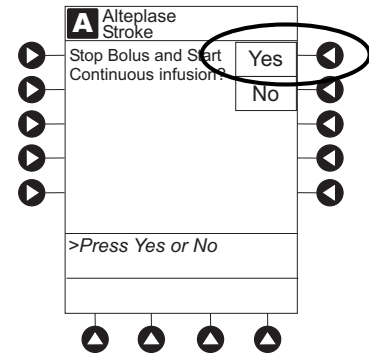
Manual Programming—Primary Infusion (Continued)



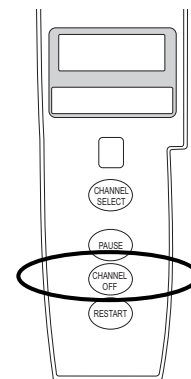
Bolus Dose (Continued)

Stop Bolus Dose (Continued)

- To stop bolus and start Continuous Infusion, press **Yes** soft key.



- To stop Continuous Infusion, press and hold **CHANNEL OFF** key until a beep is heard (approximately 1.5 seconds).^①



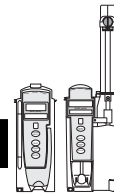
Restore Bolus Dose

A Bolus Dose can be restored after it has completed, either prior to or after the module has been turned off, as indicated in the following procedures.

The display examples in this procedure represent restoring a Bolus Dose which was programmed using the Drug Library. Even where the displays are different when restoring a Bolus Dose which was programmed using a non-library drug, the procedure is the same.

- Bolus Dose completed - module not turned off:
 - Press **CHANNEL SELECT** key.
 - Verify infusion parameters and press **BOLUS** soft key.

Manual Programming—Primary Infusion (Continued)



Bolus Dose (Continued)

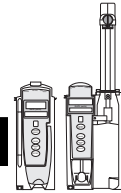
Restore Bolus Dose (Continued)

- c. Press **RESTORE** soft key.
 - d. Verify dosing parameters and press **START** soft key.
2. Bolus Dose completed - module turned off:
 - a. Press **CHANNEL SELECT** key.
 - b. Press **RESTORE** soft key.
 - c. Verify parameters and press **NEXT** soft key.
 - d. Verify infusion parameters and press **BOLUS** soft key.
 - e. Press **RESTORE** soft key.
 - f. Verify dosing parameters and press **START** soft key.

NOTES:

- ① If the Bolus Dose feature is enabled, the **BOLUS** soft key appears in the Continuous Infusion screen and becomes active when a VTBI is entered.
- ② The bolus VTBI cannot exceed the programmed Continuous Infusion VTBI.
- ③ Programming and starting a Bolus Dose deletes any programmed delay.
- ④ If no continuous rate is entered or if the Bolus Dose VTBI equals the Continuous Infusion VTBI, the infusion ends when the bolus has been delivered. No KVO infusion follows.
- ⑤ To see details during the bolus infusion, press the **CHANNEL SELECT** key.
- ⑥ The Pump module keypad is used in the illustration but the key is the same for the Syringe module.

Manual Programming—Primary Infusion (Continued)



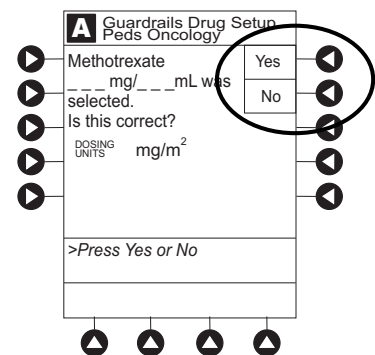
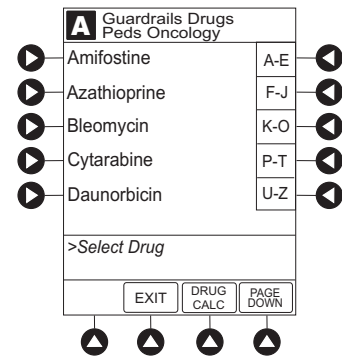
Intermittent Infusion

When using a drug listed in the Drug Library, the drug parameters are automatically delivered, based on:

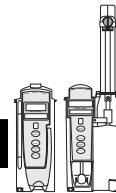
- drug selected
- weight or body surface area (BSA) entry (if required)
- dose entry
- rate or duration dose entry
- VTBI entry

Syringe module: The KVO option is disabled when an Intermittent Infusion is programmed.

1. Press **Guardrails Drugs** soft key.
2. Press soft key next to desired drug.
 - To view additional drugs, press a soft key next to a letter group to navigate through alphabet, and/or **PAGE UP** and **PAGE DOWN** soft keys.
 - If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion could appear. Different limits can be defined for same drug with different therapeutic indications.
 - If applicable, a weight-based, non weight-based, or BSA-based option for delivery of this infusion could appear.
 - If applicable, multiple concentration listings for delivery of this infusion could appear.
3. To continue programming, press **Yes** soft key. ^①
OR
 To change selection, press **No** soft key.

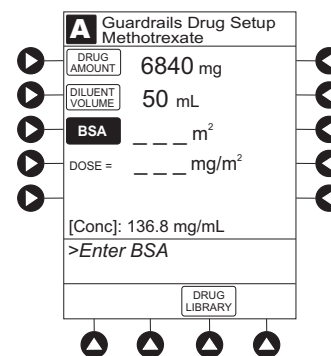


Manual Programming—Primary Infusion (Continued)



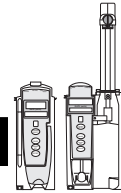
Intermittent Infusion (Continued)

- If **Yes** was selected and facility has defined a Clinical Advisory for that drug, a message appears. To indicate information has been noted and continue programming, press **CONFIRM** soft key.
- If **Yes** was selected to continue programming, drug amount and diluent volume (if defined in Drug Library) are automatically entered for selected drug.
- If selected drug had "__ / __ mL" concentration, drug amount and diluent volume need to be entered.
- If selected drug is not weight-based, **Not Used** is displayed in **PATIENT WEIGHT** field.
- If hospital/facility practice guidelines identify selected drug as weight-based or by BSA, a prompt for a patient weight in kilograms or BSA appears (as in illustrated example, which reflects the use of Methotrexate).²



4. Verify correct parameters and press **NEXT** soft key to confirm.
 - If the programmed total dose drug amount is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
 - If the programmed total dose drug amount is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.

Manual Programming—Primary Infusion (Continued)



Intermittent Infusion (Continued)

- If a dose outside of Soft Limits has been entered and verified as correct, Message Display also shows either "LLL" for a low dose or "↑↑↑" for a high dose.
- If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

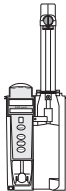
5. VTBI entry:

• Pump module:



- When VTBI is less than 10 mL, entry can be to two decimal places (one-hundredth of a mL).
- VTBI is pre-populated with diluent volume of infusion. To change VTBI, press **VTBI** soft key and enter new value.

• Syringe module:

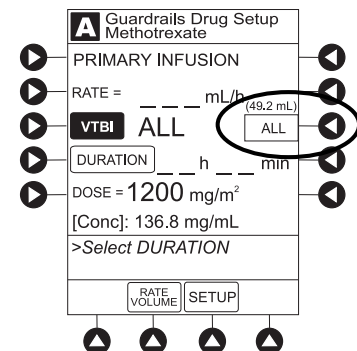
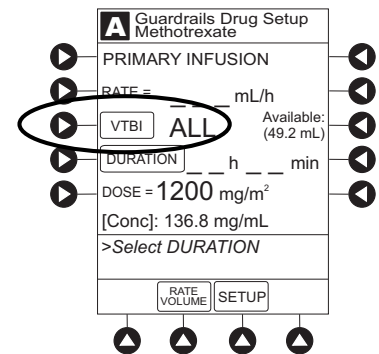


- If ALL Mode is enabled for syringe configuration in Data Set, **ALL** is displayed in VTBI field and estimated available volume in syringe is displayed.

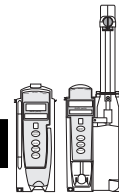
OR

If ALL Mode is disabled for syringe configuration in Data Set, estimated available volume in syringe is displayed when **VTBI** soft key is pressed.

- To enter or change a numeric **VTBI** value, press **VTBI** soft key and enter value.
- To deliver entire contents of syringe: Keep an **ALL VTBI** value, or press **ALL** soft key to change a numeric **VTBI** value to **ALL**.



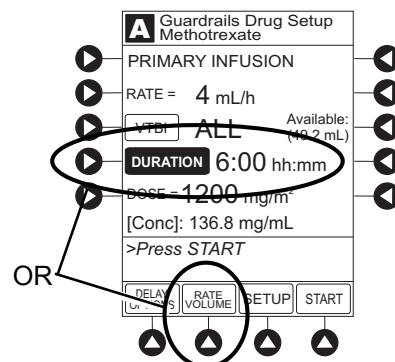
Manual Programming—Primary Infusion (Continued)



Intermittent Infusion (Continued)

6. If an optional hospital-defined and editable starting value for intermittent duration is not already entered, enter duration or rate, as follows:
 - To enter duration, press **DURATION** soft key and use numeric data entry keys (rate value is calculated and displayed).
 - To enter rate, press **RATE VOLUME** soft key and enter infusion rate.

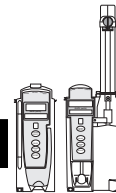
7. Verify correct parameters and press **START** soft key.
 - If the programmed duration is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
 - If the programmed duration is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
 - If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
 - For an Intermittent Infusion, the drug name and dose will scroll on the module Message Display.



NOTE:

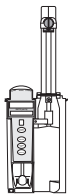
For an Intermittent Infusion, depending on how the drug library is programmed, the dose may display as a total dose, drug amount/kg or drug amount/BSA.

Manual Programming—Primary Infusion (Continued)



Intermittent Infusion (Continued)

8. Syringe module:



- Unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

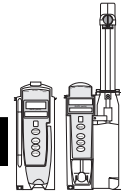
NOTES:

- ① The facility can choose to prepopulate standard drug concentrations, or leave a custom concentration (__ / __ mL) and allow the clinician to enter the desired concentration.
- ② Patient weight or BSA is not editable during an Intermittent Infusion.
- ③ Once a patient weight or BSA is entered and the infusion started, the patient weight or BSA is automatically entered for any additional weight-based or BSA calculation. Prior to the start of an intermittent infusion, the patient weight or BSA remains an editable field so that patient weight or BSA can be adjusted for any module. Changing the patient weight or BSA on one module will not affect the patient weight or BSA on any other module.

NOTE:

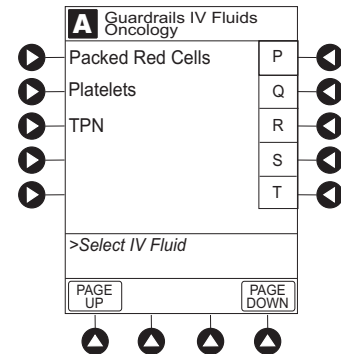
It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PC unit for the Pump module. However, due to space limitations on the Pump module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the Pump module. This value is only used for display purposes and the Pump module is actually infusing at the more precise rate noted on the PC unit.

Manual Programming—Primary Infusion (Continued)



Fluid Infusion

1. Press **Guardrails IV Fluids** soft key.
2. Press soft key next to IV fluid to be delivered.

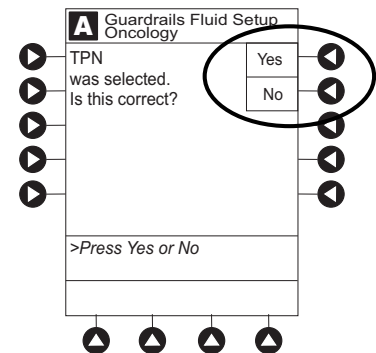


3. To confirm selection, press **Yes** soft key.

OR

To return to IV Fluid library list, press **No** soft key.

If **Yes** was selected and facility has defined a Clinical Advisory for that drug, a message appears. To indicate information has been noted and continue programming, press **CONFIRM** soft key.

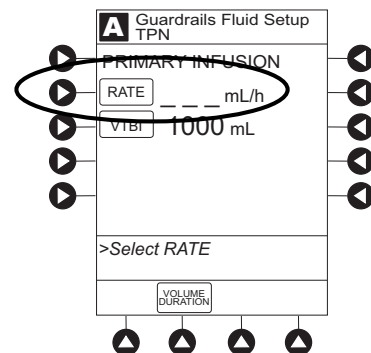


4. Start applicable infusion, as described in following procedures:

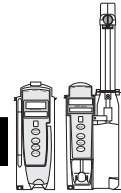
Rate/Volume Infusion
Volume/Duration Infusion

Rate/Volume Infusion

1. To enter flow rate, press **RATE** soft key and use numeric data entry keys.



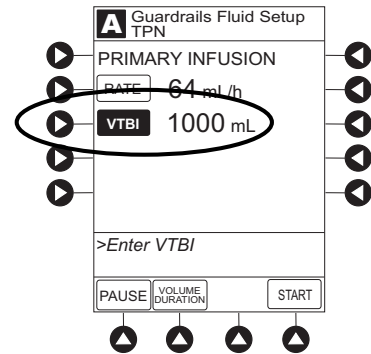
Manual Programming—Primary Infusion (Continued)



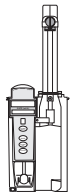
Fluid Infusion (Continued)

Rate/Volume Infusion (Continued)

- To enter **VTBI**, press **VTBI** soft key and use numeric data entry keys.



- Syringe module:

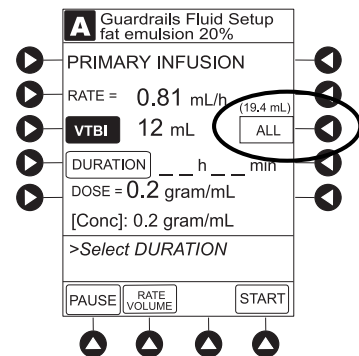
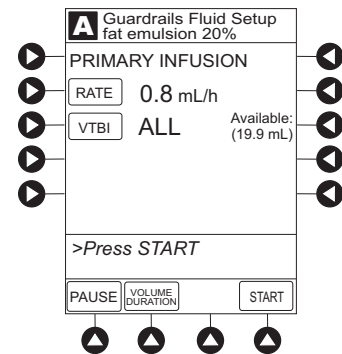


- If ALL Mode is enabled for syringe configuration in Data Set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

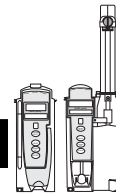
OR

If ALL Mode is disabled for syringe configuration in Data Set, VTBI ALL option is not available and estimated available volume in syringe is displayed when **VTBI** soft key is pressed.

- To enter or change a numeric **VTBI** value, press **VTBI** soft key and use numeric data entry keys.
 - To deliver entire contents of syringe: Keep an **ALL VTBI** value, or press **ALL** soft key to change a numeric **VTBI** value to **ALL**.



Manual Programming—Primary Infusion (Continued)



Fluid Infusion (Continued)

Rate/Volume Infusion (Continued)

- Verify correct infusion parameter entry and press **START** soft key.^①
 - If the programmed IV fluid is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
 - If the programmed IV fluid is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
 - If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

- Syringe module:



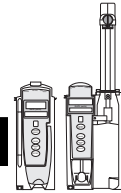
- Unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

Volume/Duration Infusion

- Press **VOLUME DURATION** soft key.



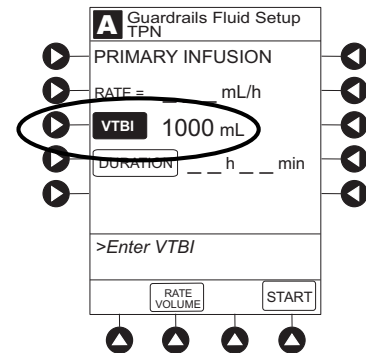
Manual Programming—Primary Infusion (Continued)



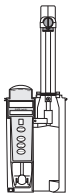
Fluid Infusion (Continued)

Volume/Duration Infusion (Continued)

- To enter **VTBI**, press **VTBI** soft key and use numeric data entry keys..



- Syringe module:

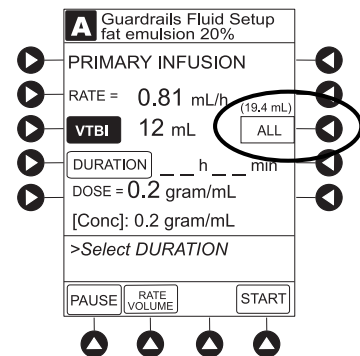
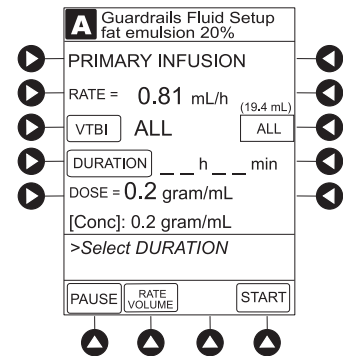


- If ALL Mode is enabled for syringe configuration in Data Set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

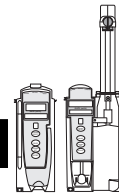
OR

If ALL Mode is disabled for syringe configuration in Data Set, VTBI ALL option is not available and estimated available volume in syringe is displayed when **VTBI** soft key is pressed.

- To enter or change a numeric **VTBI** value, press **VTBI** soft key and use numeric data entry keys.
- To deliver entire contents of syringe: Keep an **ALL VTBI** value, or press **ALL** soft key to change a numeric **VTBI** value to **ALL**.



Manual Programming—Primary Infusion (Continued)

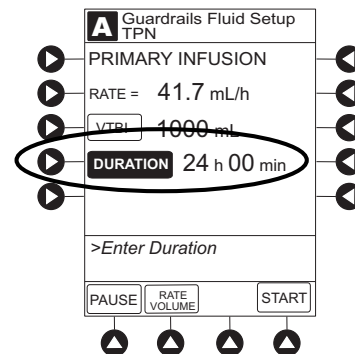


Fluid Infusion (Continued)

Volume/Duration Infusion (Continued)

- To enter volume duration, press **DURATION** soft key and use numeric data entry keys.

Rate is automatically calculated.



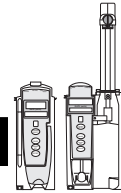
- Verify correct infusion parameter entry and press **START** soft key.²
 - If the programmed IV Fluid is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
 - If the programmed IV Fluid is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
 - If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

- Syringe module:



- Unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

Manual Programming—Primary Infusion (Continued)



Fluid Infusion (Continued)

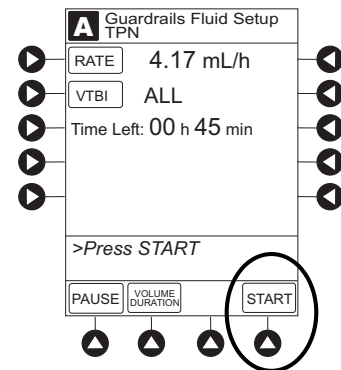
Volume/Duration Infusion (Continued)

NOTES:

- ① The infusion can be paused by pressing the **PAUSE** soft key. See "Pause, Change, Restart Infusion," "Pause and Restart Infusion" procedure.
- ② To view infusion **Time Left** during a volume/duration infusion, press **CHANNEL SELECT** key. To return to previous screen, press **START** soft key.

NOTE:

It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PC unit for the Pump module. However, due to space limitations on the Pump module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the Pump module. This value is only used for display purposes and the Pump module is actually infusing at the more precise rate noted on the PC unit.



Manual Programming—Secondary Infusion (Pump Module)



This mode is designed to support the delivery of secondary infusions ("piggybacking") in the same module. A secondary infusion can be programmed as a "Basic Infusion" or "Drug Library Infusion." When the secondary VTBI reaches zero, an audio tone sounds (if enabled) indicating completion of the secondary infusion. The primary infusion resumes automatically^①.

When the instrument is programmed and delivering in the secondary mode, the primary infusion is temporarily stopped and fluid is drawn from the secondary container. Delivery from the primary container resumes when the fluid level in the secondary line is level with the fluid in the primary container.

NOTE:

- ① When primary sets without a check valve are used, the clinician must manually clamp off the primary line during the secondary infusion and then manually unclamp the line once the secondary VTBI reaches zero.

Setup

1. Open secondary administration set package, remove set and close clamp.
2. Insert administration set spike into prepared fluid container and hang secondary container, following accepted hospital/facility procedure.
3. Fill drip chamber to $\frac{3}{4}$ full.
4. Open secondary administration set clamp and prime set. Close clamp.
5. Attach secondary administration set to upper injection site on primary set.
6. Using the hanger provided with secondary administration set, lower the primary fluid container to height indicated in following illustrations.

WARNING



Secondary applications require the use of a check valve or clamp on the primary IV line in order to prevent backflow of secondary medication into the primary line.

WARNING



The secondary administration set **must be primed** prior to beginning the secondary infusion.

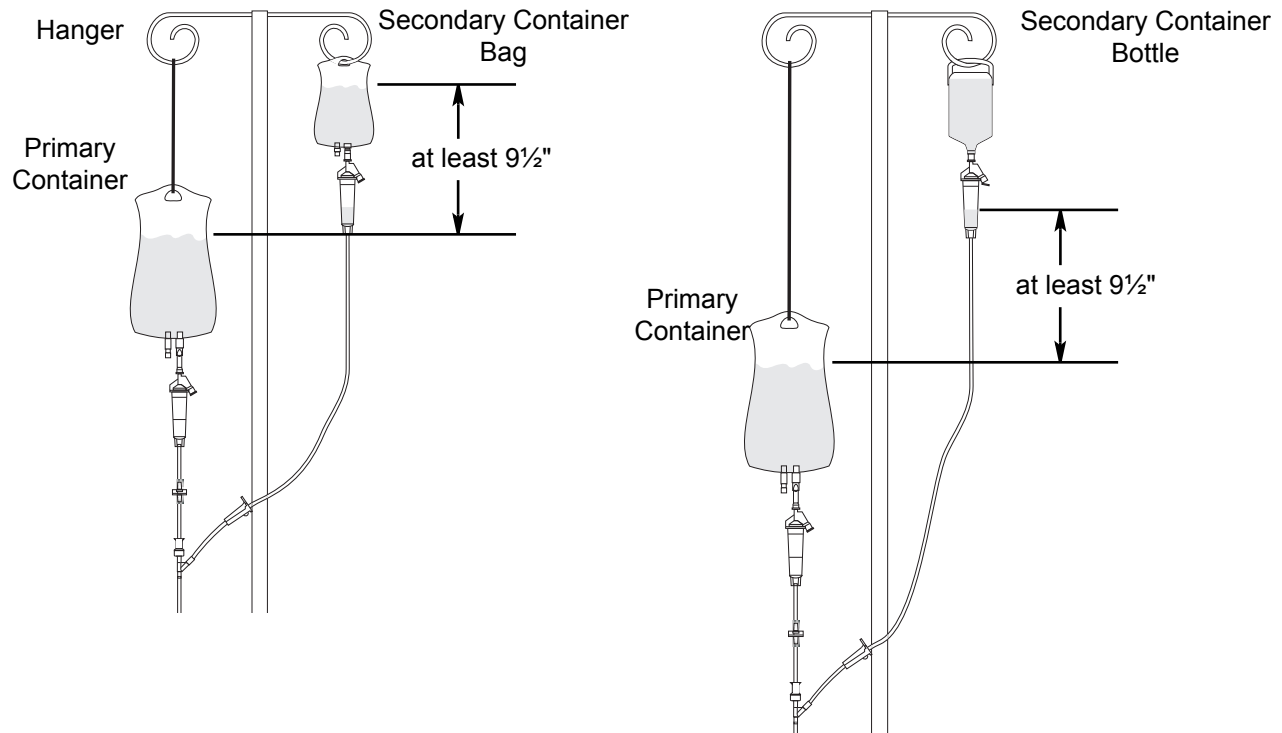
WARNING



The **secondary solution container** must be higher than the primary solution container.



Setup (Continued)



NOTE:

- ① The top of the fluid container should never be lower than the Y-site port to reduce the risk of air entering the primary set.

Infusion

The following procedure should be used only when:

- drug to be infused is listed in Drug Library,
- primary infusion is running, and
- a check valve administration set is being used.

To program a primary infusion, see "IV Fluid Infusion" procedure. To program a basic infusion, see "Infusion - NO Guardrails Suite MX Protection" procedure.

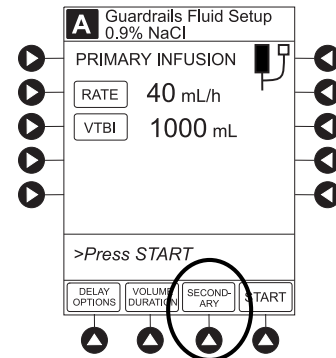
1. Press **CHANNEL SELECT** key.

Manual Programming—Secondary Infusion (Pump Module) (Continued)



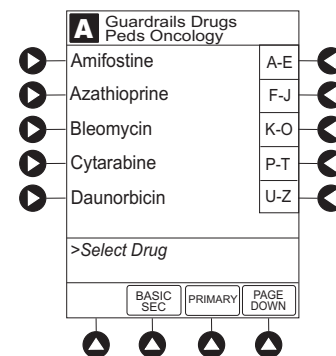
Infusion (Continued)

2. Press **SECONDARY** soft key.



3. Press soft key next to desired drug.

- To view additional drugs, press a soft key next to a letter group to navigate through alphabet, and/or **PAGE UP** and **PAGE DOWN** soft keys.
- If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion could appear. Different limits can be defined for same drug with different therapeutic indications.
- If applicable, a weight-based, non weight-based, or BSA-based option for delivery of this infusion could appear.
- If applicable, multiple concentration listings for delivery of this infusion could appear.

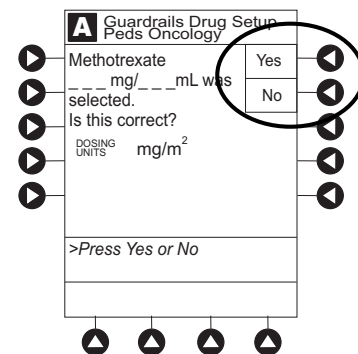


4. To continue programming, press **Yes** soft key. ^①

OR

To change selection, press **No** soft key.

- If **Yes** was selected and the facility has defined a Clinical Advisory for that drug, a message appears. To indicate information has been noted and continue programming, press **CONFIRM** soft key.
- If **Yes** was selected to continue programming, drug amount and diluent volume (if defined in Drug Library) are automatically entered for selected drug.

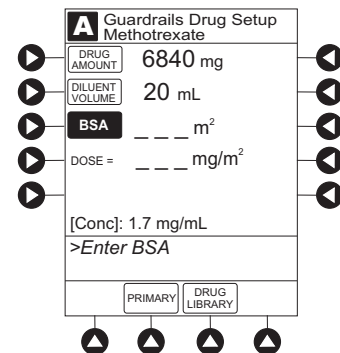


Manual Programming—Secondary Infusion (Pump Module) (Continued)



Infusion (Continued)

- If selected drug had "___ / ___ mL" concentration, drug amount and diluent volume need to be entered.
- If selected drug is not weight-based, **Not Used** is displayed in **PATIENT WEIGHT** field.
- If hospital/facility practice guidelines identify selected drug as weight-based, prompt for a patient weight in kilograms or BSA appear (as in illustrated example, which reflects use of Methotrexate).^②



5. Verify correct parameters and press **NEXT** soft key to confirm.
 - If the programmed total dose drug amount is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
 - If the programmed total dose drug amount is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
 - If a dose outside of Soft Limits has been entered and verified as correct, Message Display also shows either "LLL" for a low dose or "↑↑↑" for a high dose.
 - If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

Manual Programming—Secondary Infusion (Pump Module) (Continued)



Infusion (Continued)

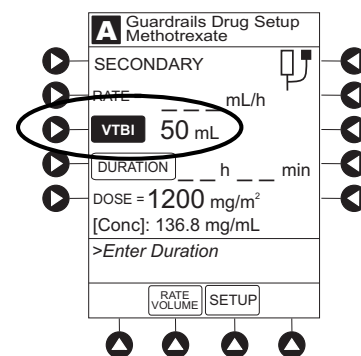
6. VTBI entry:

- When VTBI is less than 10 mL/h, entry can be to two decimal places (one-hundredth of a mL).
- VTBI is pre-populated with diluent volume of infusion. To change VTBI, press **VTBI** soft key and use numeric data entry keys.

WARNING

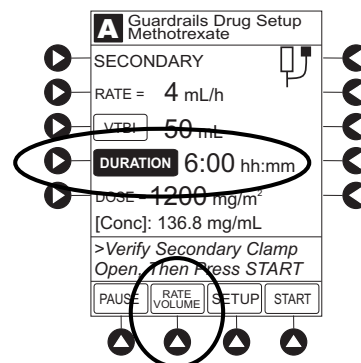


The **secondary VTBI settings** require consideration of such variables as factory overfill, medication additions. Underestimating the volume causes the remaining secondary solution to be infused at the primary rate; overestimating results in the primary solution being infused at the secondary rate. Multiple doses from a single container are not possible.



7. If an optional hospital-defined and editable starting value for intermittent duration is not already entered, enter duration or rate, as follows:

- To enter duration, press **DURATION** soft key and use numeric data entry keys (rate value is calculated and displayed).
- To enter rate, press **RATE VOLUME** soft key and use numeric data entry keys.



Manual Programming—Secondary Infusion (Pump Module) (Continued)



Infusion (Continued)

8. Open clamp on secondary administration set.
9. Verify correct parameters and press **START** soft key.
 - If the programmed duration is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
 - If the programmed duration is outside Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
 - If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
10. Verify drops are flowing from the secondary container drip chamber.

WARNING



The clamp on the secondary administration set must be opened. If the **clamp is not opened**, the fluid is delivered from the primary container.

NOTES:

- ① The facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (___ / ___ mL) and allow the clinician to enter the desired concentration.
- ② Patient weight or BSA is not editable during a Secondary Infusion.
- ③ Once a patient weight or BSA is entered and the infusion started, the patient weight or BSA is automatically entered for any additional weight-based or BSA calculation. Prior to the start of infusion, the patient weight or BSA key remains an editable field so that patient weight or BSA can be adjusted for any module. Changing the patient weight or BSA on one module will not affect the patient weight or BSA on any other module.



Infusion (Continued)

NOTE:

It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PC unit for the Pump module. However, due to space limitations on the Pump module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the Pump module. This value is only used for display purposes and the Pump module is actually infusing at the more precise rate noted on the PC unit.

Stop Secondary and Return to Primary

1. Press **CHANNEL SELECT** key.
2. Press **SETUP** soft key.
3. Press **PRIMARY** soft key.
4. Close clamp on secondary administration set.
OR
Disconnect secondary administration set from upper injection port.
5. Press **START** soft key.
6. To stop secondary infusion and begin infusing primary, press **Yes** soft key.^①
 - Secondary infusion stops and primary infusion begins.
 - Main screen appears.

NOTE:

- ① The SEC to PRI alert does not sound when the infusion is manually ended and returned to primary.

Programming with Interoperability and Guardrails Suite MX

Interoperability is designed to help automate existing manual workflows with regard to programming infusions on the Alaris Pump and Syringe modules.

Interoperability refers to the ability of the Alaris System Pump module and Syringe module to:

- Receive infusion order parameters from a third-party system for pre-population. This may be referred to as an automated programming request.
- Publish infusion status messages for consumption by third-party systems.

The following information on programming an infusion with interoperability does not include information regarding publishing infusion status messages from the Alaris System. For information on infusion status messages, refer to the following four guides:

- *Infusion Status Message Specification for CareFusion Coordination Engine—Regulated Infusion Adapter v1.3*
- *HL7 Order Message Specification for CareFusion Coordination Engine—Regulated Infusion Adapter v1.3*
- *Alaris System Interoperability Services User Reference Guide*
- *Alaris System Interoperability Services Guide for Clinical Workflow Testing*

The Alaris System with interoperability enables pre-population of infusion parameters from an infusion order in the hospital's electronic medical record/hospital information system (EMR/HIS) using the EMR/HIS vendor barcode medication administration (BCMA) system.

Pre-population of infusion parameters reduces the number of programming screens and key presses required with manual programming. There are no differences in programming screens, prompts or the user interface between an Alaris System with interoperability and an Alaris System without interoperability. The implementation of interoperability does not preclude a clinician from manually programming the Alaris System. Manual programming is required in the event of a failure in any component of the interfaced system.

Programming with Interoperability and Guardrails Suite MX (Continued)

Pre-population of infusion parameters applies to initial and subsequent infusions started in the Guardrails Library, as follows:

The following **primary** infusions can be pre-populated for both initial and subsequent infusion:

- Continuous
- Fluids
- Intermittent

The following **secondary** infusions can be pre-populated (Pump module only):

- Intermittent

The following infusions cannot be pre-populated and require manual programming:

- Titrations
- Bolus doses
- Basic Infusions (including Drug Calc infusions)

All Guardrail limits that apply to manual programming also apply to programming with interoperability. Additionally, infusions are protected by Guardrails limits with each rate change or titration.

The following procedures are to be used only when the drug to be infused is listed in the Drug Library. To access the Drug Library, a hospital-defined best-practice Data Set must be transferred using the Guardrails Editor Software and the Profiles feature must be enabled.

NOTE:

There is a potential for a discrepancy in precision between the numeric values displayed on the Alaris System (PC Unit, Pump module and Syringe module) and in the electronic medical record (EMR)/hospital information system (HIS) due to different rounding rules.

Programming with Interoperability and Guardrails Suite MX (Continued)

NOTE:

There is a potential that the concentration displayed on the Alaris System PC unit will use different units of measure than the concentration displayed in the EMR/HIS. The Alaris System PC unit displays the concentration (drug amount per 1 mL) using the dosing units assigned to that Guardrails drug entry. (Note: The Alaris System allows Continuous Infusions to be dosed in different units than the units used in the Drug Amount.) However, the Alaris System sends the concentration to the EMR/HIS using the units of the Drug Amount.

It is important to note that the concentration displayed on the Alaris System PC unit should be equivalent to the concentration displayed in the EMR/HIS even if different units of measure are used.

The following example is for a continuous drug that has a Drug Amount in grams, but is dosed in mg:

| Displayed on Alaris System PC unit | Infusion information sent to EMR/HIS |
|---|---|
| Drug Amount: 1 gram Diluent Volume: 100 mL [Conc]: 10 mg/mL | Drug Amount: 1 gram Diluent Volume: 100 mL [Conc]: 0.01 gram/mL |

NOTE:

It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PC unit for the Pump module. However, due to space limitations on the Pump module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the Pump module. This value is only used for display purposes and the Pump module is actually infusing at the more precise rate noted on the PC unit.

NOTE:

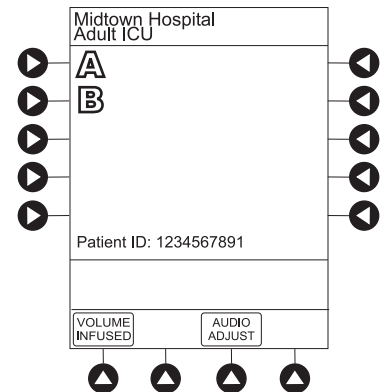
If the infusion order does not specify whether the infusion is to be pre-populated as a primary or secondary infusion, the Alaris System will determine whether to pre-populate the infusion as primary or secondary based on the state of the intended Module and on the Guardrails Drug Library configuration. For example: The infusion order will be pre-populated as a primary infusion on an idle Pump module if the configuration of the drug/fluid entry in the active Guardrails Profile supports it. The infusion order will be pre-populated as a secondary infusion on a Pump module that is programmed for or infusing a primary fluid if the configurations of both the primary and secondary entries in the active Guardrails Profile support it.

NOTE:

All fields that are editable with manual programming are editable when pre-populated with interoperability.

Programming with Interoperability—Initial Primary Infusion

1. Perform the following steps on the PC unit (see the PC unit section of "General Setup and Operation" and "Start-Up" beginning on page 1-3):
 - a. Power on system. (Scanning the module will not power on the device.)
 - b. Select **Yes** or **No to New Patient?**
 - c. Confirm current Profile or select a new Profile. This places the module in an *idle state* (not infusing or in the process of being programmed as illustrated Channels A and B).
2. Prepare the Administration Set for the Pump module, see *Prepare Administration Set (Pump Module)* on page 2-3.
3. Prime the Administration Set, see *Prepare Syringe and Administration Set (Syringe Module)* on page 2-7.



Programming with Interoperability—Initial Primary Infusion (Continued)

The generic workflow for pre-population of infusion parameters is as follows. Contact your EMR/HIS vendor for detailed instructions. Using the EMR/HIS system scanner used for barcode medication administration:

- Scan Patient's ID Band
- Scan fluid/medication barcode label
- Scan barcode label on the Pump or Syringe module
 - Pump module: The Pump module must be in an *idle* state or the clinician has pressed **CHANNEL SELECT**. Pre-population will fail if the module is scanned after the user has manually programmed the infusion beyond pressing **CHANNEL SELECT**.
 - Syringe module: Pre-population of infusion parameters for a Syringe module may occur when the module is already infusing, in an idle state, and/or the clinician has pressed **CHANNEL SELECT**. Pre-population will fail if the module is scanned after the user has manually programmed the infusion after pressing **CHANNEL SELECT**.

NOTE:

If the automated programming request is sent while the Syringe module is infusing, a prompt appears on the PC unit to install the scanned Syringe.

Programming with Interoperability—Initial Primary Infusion (Continued)

For the Pump module, proceed to step 6.

4. For the Syringe module, select the syringe type and size; otherwise proceed to step 5. If the installed syringe is loaded correctly, but not recognized, check the following:
 - a. If a label is between the syringe barrel and the barrel clamp, make sure that the label does not erroneously enlarge the barrel size of the syringe.
 - b. If a needle-free valve or other component is added to the syringe, ensure that it is no larger than the diameter of the syringe barrel.
- NOTE:**
- Thick labeling or adding a component to the syringe that is larger than the diameter of the syringe may prevent the device from correctly recognizing the installed syringe. If the issue continues despite the above troubleshooting, send the device to your facility's biomedical engineering department for servicing.
 - The capability of the Syringe module to recognize a new syringe and read the volume is unchanged from manual programming.
- c. Press the soft key next to the installed syringe type and size. If a default syringe list has been enabled and the correct syringe cannot be found, press the **ALL SYRINGES** soft key to select from a list of all compatible syringes.

WARNING



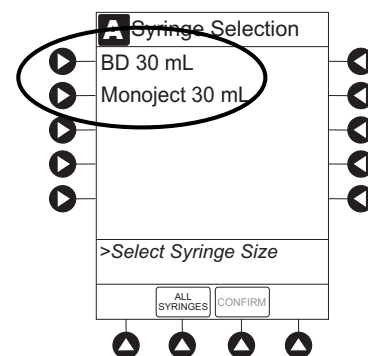
Ensure that the displayed **syringe manufacturer and syringe size** correctly identify the installed syringe. Mismatches might cause an under-infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page 2-136 and the *Alaris™ Syringe Module Set Compatibility Card*. If the installed syringe is displayed and selected but is not recognized, servicing is required. (see "Maintenance", "Service Information" in the "Appendix" section on this User Manual.)



WARNING

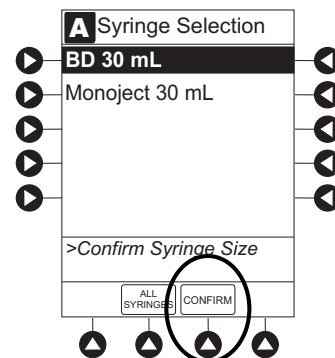


Selecting an incorrect syringe may cause an under or over infusion to the patient.

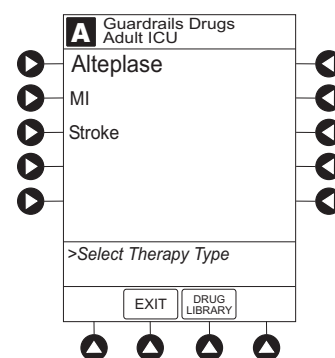


Programming with Interoperability—Initial Primary Infusion (Continued)

- d. To accept the Syringe type and size, press the **CONFIRM** soft key.



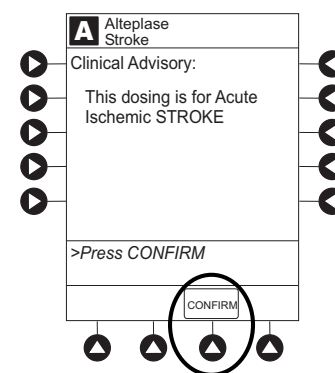
5. If applicable, select the Therapy on the PC unit.
- If a drug concentration or Guardrails Library selection has only one hospital-defined Therapy that matches the dosing units in the automated programming request, then the Therapy is automatically selected.
 - If a drug concentration or Guardrails Library selection has more than one hospital-defined Therapy, the Therapy screen appears. Select the Therapy indicated for the infusion.



NOTE:

Once the Therapy has been confirmed, the name is displayed in the title below the drug or fluid name on the infusion setup and programming screen of the PC unit.

6. If the hospital has defined a Clinical Advisory for the drug, a message appears. To indicate information has been noted and to continue programming, press the **CONFIRM** soft key on the PC unit.



Programming with Interoperability—Initial Primary Infusion (Continued)

The Patient ID and, depending on the infusion type, the following infusion parameters are pre-populated on the Alaris System from the automated programming request:

- Drug or Fluid name (alias or NDC)
 - Drug amount
 - Drug Amount units
 - Diluent Volume
 - Dose
 - Dosing units
 - Patient Weight or BSA (if used)
 - Rate
 - Volume to be infused (VTBI)
 - Duration
7. Review and verify that all parameters pre-populated on the Alaris System are correct prior to starting the infusion.

NOTE:

- If the infusion parameters are unable to be pre-populated on the Alaris System, error messages are displayed in the EMR/HIS. Error messages are not displayed on the PC unit. Consult the EMR/HIS for more information.
- Pre-population of infusion parameters on the Alaris System DOES NOT automatically start the infusion. As with any infusion, all infusion parameters need to be reviewed and confirmed by the clinician before pressing START.

8. Start applicable infusion as described in the following procedures:
- Continuous Infusion
 - Fluid Infusion
 - Intermittent Infusion

Programming with Interoperability—Initial Primary Infusion (Continued)

Continuous Infusion

The following workflow assumes that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Programming with Interoperability—Initial Primary Infusion* on page 2-62.

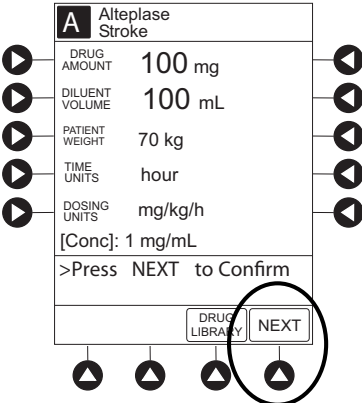
1. Review and verify that all parameters pre-populated on the Alaris System are correct prior to starting the infusion.

The drug amount, diluent volume, and patient weight (if continuous infusion is weight based) are pre-populated from the automated programming request.

2. Press **NEXT** to confirm.

NOTE:
Syringe module:

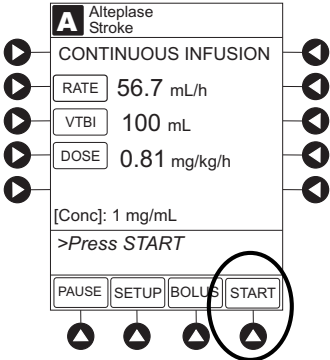
- ALL Mode can still be enabled with interoperability. However, the VTBI pre-populates with the volume to be infused from the automated programming request.
- If the VTBI in the automated programming request is greater than the actual volume in the syringe (for example, priming the IV disposable with the syringe would decrease the available volume in the syringe), the Alaris System will display the VTBI field as blank and the message in the prompt line on the Alaris PC unit would state: *Value x Exceeds MAX VTBI y*. The clinician can either manually program a value for the VTBI or use the **ALL** button if appropriate (and if the ALL Mode is enabled in the data set).



3. Review and verify that all parameters pre-populated on the Alaris System are correct prior to starting the infusion.

The rate, VTBI and dose are pre-populated from the automated programming request.

4. Press the **START** soft key.



Programming with Interoperability—Initial Primary Infusion (Continued)

Continuous Infusion (Continued)

5. For the Syringe module, unclamp tubing and attach administration set to patient.

NOTE:

Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

Programming with Interoperability—Initial Primary Infusion (Continued)

Fluid Infusion

The following workflow assumes that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Programming with Interoperability—Initial Primary Infusion* on page 2-62.

1. Review and verify that all parameters pre-populated on the Alaris System are correct prior to starting the infusion.

The rate and VTBI are pre-populated from the automated programming request.

2. Press the **START** soft key.

NOTE:

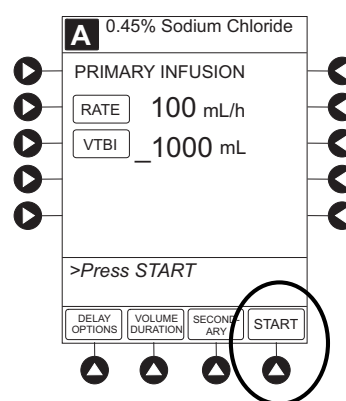
Syringe module:

- ALL Mode can still be enabled with interoperability. However, the VTBI will pre-populate with the volume to be infused from the automated programming request.
- If the VTBI in the automated programming request is larger than the actual volume in the syringe (for example, priming the IV disposable with the syringe would decrease the available volume in the syringe), the Alaris System will display the VTBI field as blank and the message in the prompt line on the Alaris PC unit would state: *Value x Exceeds MAX VTBI y*. The clinician can either manually program a value for the VTBI or use the **ALL** button if appropriate (and if the ALL Mode is enabled in the data set).

3. For the Syringe module, unclamp the tubing and attach the administration set to patient.

NOTE:

Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.



Programming with Interoperability—Initial Primary Infusion (Continued)

Intermittent Infusion

The following workflow assumes that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Programming with Interoperability—Initial Primary Infusion* on page 2-62.

NOTE:
Syringe Module: The KVO option is disabled when an intermittent infusion is programmed.

1. Review and verify that all parameters pre-populated on the Alaris System are correct prior to starting the infusion.

The drug amount, diluent volume, and patient weight (if intermittent infusion is weight based) or BSA (if intermittent infusion is BSA based) are pre-populated from the automated programming request.

2. Press **NEXT** to confirm.

NOTE:
Syringe module:

- ALL Mode can still be enabled with interoperability. However, the VTBI will pre-populate with the volume to be infused from the automated programming request.
- If the VTBI in the automated programming request is larger than the actual volume in the syringe (for example, priming the IV disposable with the syringe would decrease the available volume in the syringe), the Alaris System will display the VTBI field as blank and the message in the prompt line on the Alaris PC unit would state: *Value x Exceeds MAX VTBI y*. The clinician can either manually program a value for the VTBI or use the **ALL** button if appropriate (and if the ALL Mode is enabled in the data set).

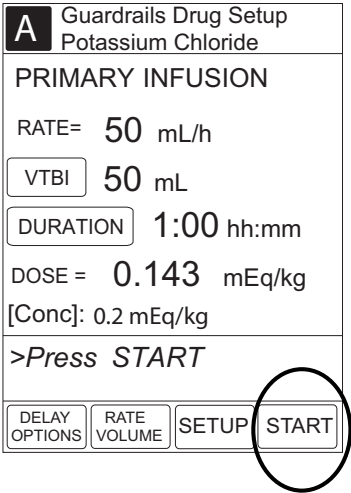
| | |
|-------------------------------------|--------------------|
| A | Potassium Chloride |
| DRUG AMOUNT | 10 mEq |
| DILUENT VOLUME | 50 mL |
| PATIENT WEIGHT | 70 kg |
| DOSE | 0.143 mEq/kg |
| [Conc]: 0.2 mEq/kg | |
| >Press NEXT to Confirm | |
| <input type="button" value="NEXT"/> | |

Programming with Interoperability—Initial Primary Infusion (Continued)

Intermittent Infusion (Continued)

- Review and verify that all parameters pre-populated on the Alaris System are correct prior to starting the infusion.

The rate, VTBI, and duration are pre-populated from the automated programming request.
- Press the **START** soft key.



- For the Syringe module, unclamp tubing and attach administration set to patient.

NOTE:
Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

Programming with Interoperability—Subsequent Primary Infusion (Pump Module)



Hospital policy should determine the preferred method for programming subsequent infusions.

Subsequent infusion for the Pump module refers to new bags, syringes, or containers used with the Pump module.

An automated programming request for a matching subsequent infusion can be sent to a Pump module that is infusing, paused, delayed, or alarming (including Infusion Complete - KVO).

Pre-populating an active Pump module is allowed if all of the following infusion parameters match between the subsequent infusion automated programming request and the running infusion:

- Drug or Fluid name (alias or NDC)
- Drug Amount (not applicable for fluids)
- Drug Amount units (not applicable for fluids)
- Diluent Volume (not applicable for fluids)
- Dosing units (not applicable for fluids)
- Patient Weight/BSA (if used)

NOTE:

If the infusion that is running on the Pump module is a custom concentration, the Drug Amount and Diluent Volume still must match between the incoming subsequent infusion automated programming request and the running infusion.

The pre-population of infusion parameters workflow for subsequent bags is unchanged from the initial bag; scan patient, scan medication label, scan Alaris Pump module, see *Programming with Interoperability—Initial Primary Infusion* on page 2-62. The infusion parameters for the subsequent bag must meet the required matching criteria. If the matching criteria are met, the infusion parameters are pre-populated on the PC unit without interruption of the currently running infusion.

Programming with Interoperability—Subsequent Primary Infusion (Pump Module) (Continued)

The following procedures assume that the Pump module has already been programmed with an Initial Primary Infusion.

NOTE:

If an infusion is in Delay when a subsequent automated programming request is sent and matching criteria:

- Are met, the Delay is canceled and the subsequent automated programming request infusion parameters are pre-populated on the PC unit. To add a Delay manually, refer to *Delay Options* on page 2-102.
- Are not met, the automated programming request is rejected and the infusion remains in Delay.

The generic workflow for pre-population of infusion parameters is as follows. Contact your EMR/HIS vendor for detailed instructions.

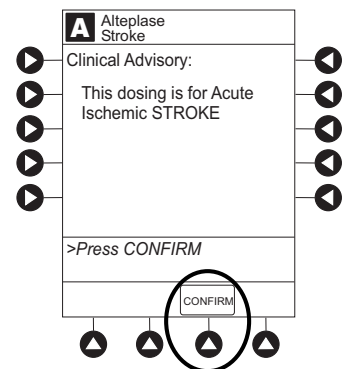
1. Using the EMR/HIS system scanner used for barcode medication administration:
 - Scan the Patient's ID Band
 - Scan the fluid/medication barcode label
 - Scan the barcode label on the Pump module
2. To indicate that information has been noted and to continue programming, press the **CONFIRM** soft key on the PC unit.

If the hospital has defined a Clinical Advisory for the drug, a message will appear.

NOTE:

If the infusion parameters are unable to be pre-populated on the Alaris System, error messages will be displayed in the EMR/HIS. Error messages will not be displayed on the PC unit. Consult the EMR/HIS.

3. Start the applicable infusion as described in the following procedures:
 - Continuous Infusion
 - Fluid Infusion
 - Intermittent Infusion



Programming with Interoperability—Subsequent Primary Infusion (Pump Module) (Continued)

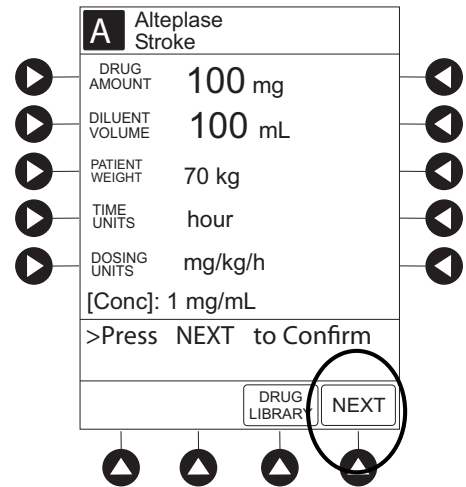
Continuous Infusion

The following workflow assumes that the Pump module has already been programmed with an Initial Primary Continuous Infusion and that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Programming with Interoperability—Initial Primary Infusion* on page 2-62.

1. Review and verify that all parameters pre-populated on the Alaris System are correct prior to starting the infusion.

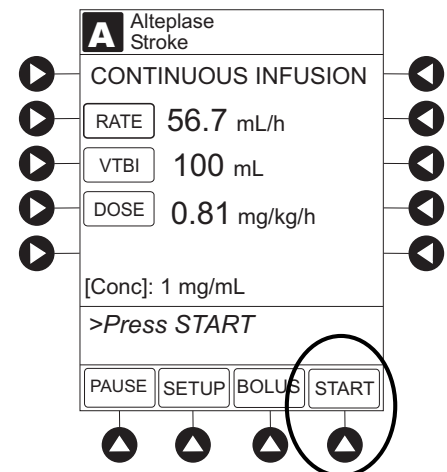
The drug amount, diluent volume, and patient weight (if continuous infusion is weight based) are pre-populated from the automated programming request.

2. Press **NEXT** to confirm.



3. After the parameters are confirmed, Press the **START** soft key.

The rate, VTBI and dose are pre-populated from the automated programming request.



Programming with Interoperability—Subsequent Primary Infusion (Pump Module) (Continued)

Continuous Infusion (Continued)

If the subsequent automated programming request contains an infusion parameter (rate or dose) that changes the current infusion rate, a message appears with a recalculation of the rate notification.

4. From the **Infusion Setup** screen:

- Select **YES** to accept the rate change and start the infusion.

OR

- Select **NO** to return the infusion to its current infusion rate and change the VTBI to the volume to be infused contained in the automated programming request.

| A Infusion Setup | |
|--|-----|
| New bag scan results in a recalculation of the rate to 45 mL/h | Yes |
| | No |
| Accept rate change? | |
| >Press Yes or No | |

5. Review and verify that all parameters pre-populated on the Alaris System are correct prior to starting the infusion

6. Press the **START** soft key.

| A Alteplase Stroke | |
|---------------------|--------------|
| CONTINUOUS INFUSION | |
| RATE | 56.7 mL/h |
| VTBI | 100 mL |
| DOSE | 0.81 mg/kg/h |
| [Conc]: 1 mg/mL | |
| >Press START | |
| PAUSE | SETUP |
| BOLUS | START |

Programming with Interoperability—Subsequent Primary Infusion (Pump Module) (Continued)

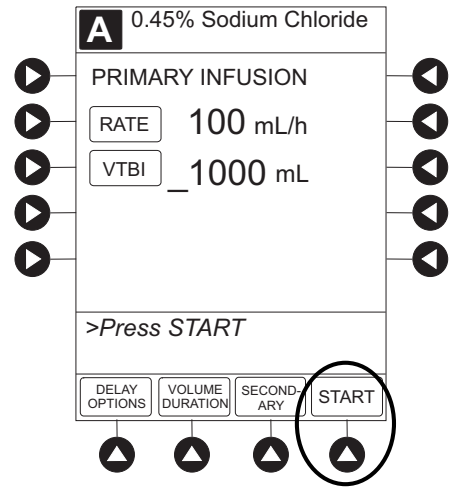
Fluid Infusion

The following workflow assumes that the Pump module has already been programmed with an Initial Primary Fluid Infusion and that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Programming with Interoperability—Initial Primary Infusion* on page 2-62.

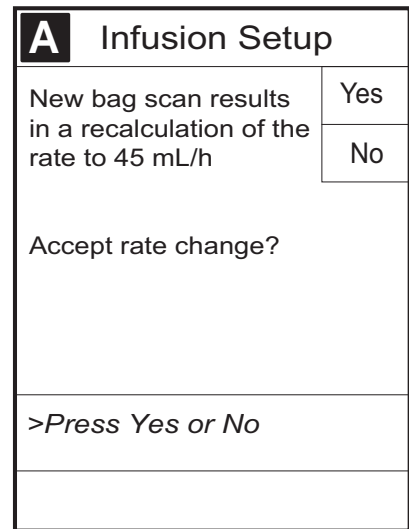
1. Review and verify that all parameters pre-populated on the Alaris System are correct.

The rate and VTBI are pre-populated from the automated programming request. If the subsequent automated programming request contains an infusion parameter (rate) that changes the current infusion rate, a message appears with a recalculation of the rate notification.

2. Press the **START** soft key.



3. From the **Infusion Setup** screen:
 - Select **YES** to accept the rate change and start the infusion.
 - OR**
 - Select **NO** to return the infusion its current infusion rate and change the VTBI to the volume to be infused contained in the automated programming request.

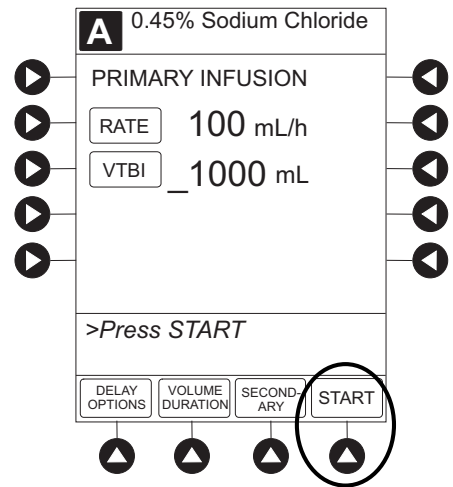


Programming with Interoperability—Subsequent Primary Infusion (Pump Module) (Continued)

Fluid Infusion (Continued)

4. Review and verify that all parameters pre-populated on the Alaris System are correct.

5. Press the **START** soft key.



Programming with Interoperability—Subsequent Primary Infusion (Pump Module) (Continued)

Intermittent Infusion

The following workflow assumes that the Pump module has already been programmed with an Initial Primary Intermittent Infusion and that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Programming with Interoperability—Initial Primary Infusion* on page 2-62.

1. Review and verify that all parameters pre-populated on the Alaris System are correct.

The drug amount, diluent volume, and patient weight (if intermittent infusion is weight based) or BSA (if intermittent infusion is BSA based) are pre-populated from the automated programming request.

2. Press **NEXT** to confirm.

| | |
|-------------------------------------|--------------------|
| A | Potassium Chloride |
| DRUG AMOUNT | 10 mEq |
| DILUENT VOLUME | 50 mL |
| PATIENT WEIGHT | 70 kg |
| DOSE | 0.143 mEq/kg |
| [Conc]: | 0.2 mEq/kg |
| >Press NEXT to Confirm | |
| <input type="button" value="NEXT"/> | |

3. Review and verify that all parameters pre-populated on the Alaris System are correct.

The rate, VTBI and duration are pre-populated from the automated programming request.

4. Press the **START** soft key.

| | | | |
|--|---|--------------------------------------|--------------------------------------|
| A | Guardrails Drug Setup Potassium Chloride | | |
| PRIMARY INFUSION | | | |
| RATE= | 50 mL/h | | |
| <input type="button" value="VTBI"/> | 50 mL | | |
| <input type="button" value="DURATION"/> | 1:00 hh:mm | | |
| DOSE = | 0.143 mEq/kg | | |
| [Conc]: | 0.2 mEq/kg | | |
| >Press START | | | |
| <input type="button" value="DELAY OPTIONS"/> | <input type="button" value="RATE VOLUME"/> | <input type="button" value="SETUP"/> | <input type="button" value="START"/> |

Programming with Interoperability—Subsequent Primary Infusion (Pump Module) (Continued)

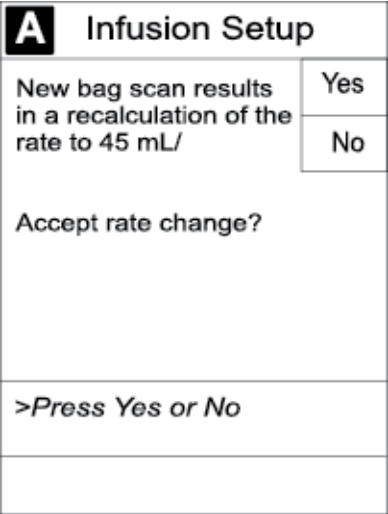
Intermittent Infusion (Continued)

If the subsequent automated programming request contains an infusion parameter (rate or dose) that affects or changes the current infusion rate, a message appears with a recalculation of the rate notification.

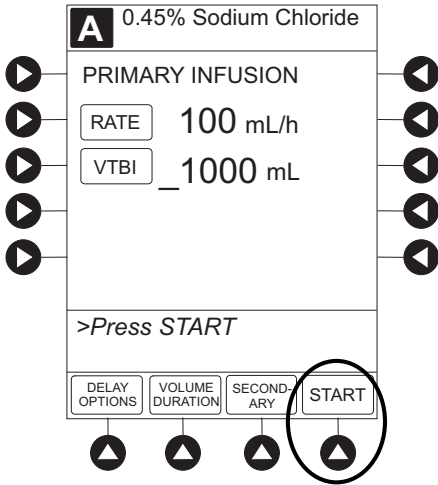
5. From the **Infusion Setup** screen:
 - Select **YES** to accept the rate change and start the infusion.

OR

 - Select **NO** to return the infusion its current infusion rate and change the VTBI to the volume to be infused contained in the automated programming request.



6. Review and verify that all parameters pre-populated on the Alaris System are correct.
7. Press the **START** soft key.



Programming with Interoperability—Subsequent Primary Infusion (Syringe Module)



Hospital policy should determine the preferred method for programming subsequent infusions.

Subsequent infusion for the Syringe module refers to new syringes used with the Syringe module.

An automated programming request for a subsequent infusion can be sent to a Syringe module when it is infusing or in an idle state.

NOTE:

If an infusion is in Delay when a subsequent automated programming request is sent, the Delay will be canceled and the subsequent automated programming request infusion parameters will be pre-populated on the PC unit. To add a delay manually, see *Delay Options* on page 2-102

Pre-population of infusion parameters for a subsequent syringe is the same workflow as an Initial Primary Infusion., see *Programming with Interoperability—Initial Primary Infusion* on page 2-62.

Programming with Interoperability—Secondary Infusion (Pump Module)

This mode is designed to support programming of secondary infusions ("piggybacking") on the same module as a primary fluid. When the secondary VTBI reaches zero, an audio tone sounds (if enabled) indicating completion of the secondary infusion. The primary infusion resumes automatically.

When the instrument is programmed and delivering in the secondary mode, the primary infusion is temporarily stopped and fluid is drawn from the secondary container. Delivery from the primary container resumes when the fluid level in the secondary line is level with the fluid in the primary container.

NOTE:

When primary sets without a check valve are used, the clinician must manually clamp off the primary line during the secondary infusion and then manually unclamp the line once the secondary VTBI reaches zero.

WARNING



Secondary applications require the use of a check valve or clamp on the primary IV line in order to prevent backflow of secondary medication into the primary line.

Infusion

In order to pre-populate infusion parameters for a secondary infusion, a primary fluid that supports a secondary must already be programmed or infusing. For more information, see *Programming with Interoperability—Initial Primary Infusion—Fluids* page 2-69 and *Manual Programming—Primary Infusion—IV Fluid Infusion* page 2-45.

Setup

1. Open a secondary administration set package, remove set, and close clamp.
2. Insert the administration set spike into the prepared fluid container and hang the secondary container, following accepted hospital/facility procedure.
3. Fill drip chamber to 2/3 full.
4. Open the secondary administration set clamp and prime the set. Close clamp.
5. Attach the secondary administration set to the upper injection site on primary set.

WARNING



The secondary administration set **must be primed** prior to beginning the secondary infusion.

Programming with Interoperability—Secondary Infusion (Pump Module) (Continued)

Infusion (Continued)

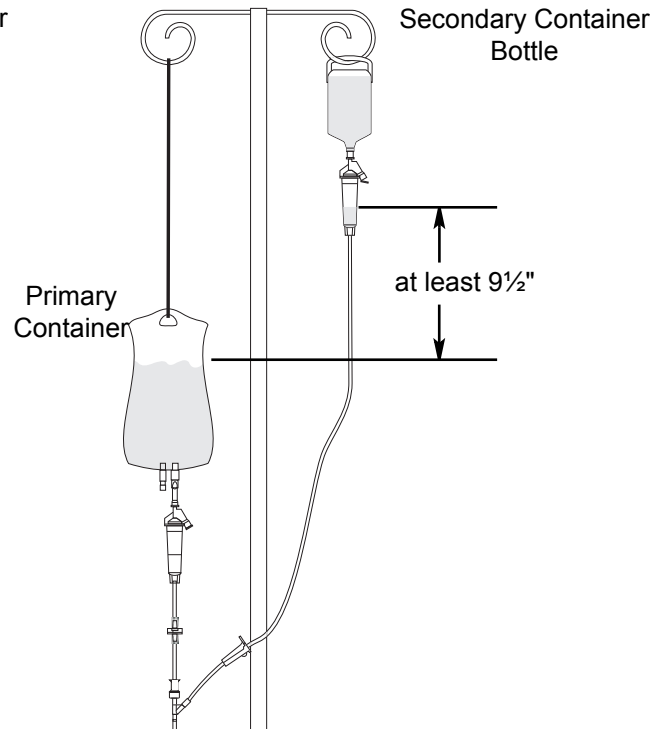
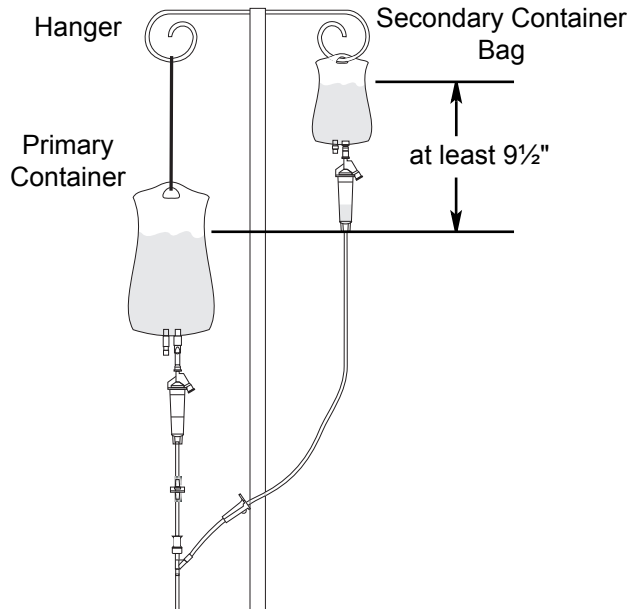
WARNING



The secondary solution container must be higher than the primary solution container.

Setup (Continued)

- Using the hanger provided with secondary administration set, lower the primary fluid container to the height indicated in following illustrations.



Programming with Interoperability—Secondary Infusion (Pump Module) (Continued)

Infusion (Continued)

Infusion

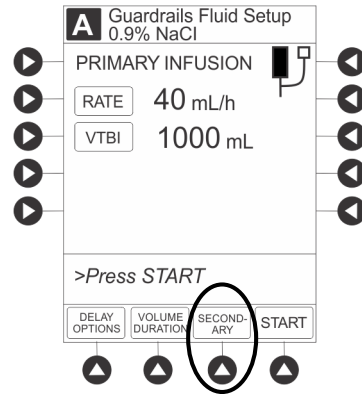
The generic workflow for pre-population of infusion parameters is as follows. Contact your EMR/HIS vendor for detailed instructions. Using the EMR/HIS system scanner used for barcode medication administration

- Scan Patient's ID Band
- Scan fluid/medication barcode label
- Scan barcode label on the Pump module

NOTE:

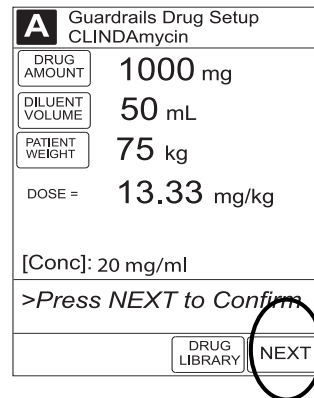
If the infusion parameters are unable to be pre-populated on the Alaris System, error messages are displayed in the EMR/HIS. Error messages are not displayed on the PC unit. Consult the EMR/HIS.

7. Press the **SECONDARY** soft key to continue with the pre-population of the infusion parameters for the secondary infusion.



The set-up page for the secondary infusion appears with the drug amount, diluent volume, and patient weight (if intermittent infusion is weight based) or BSA (if intermittent infusion is BSA based) pre-populated from the automated programming request.

8. Review and verify that all parameters pre-populated on the Alaris System are correct.
9. Press **NEXT** to confirm.



Programming with Interoperability—Secondary Infusion (Pump Module) (Continued)

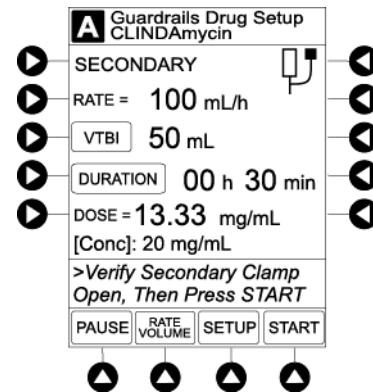
Infusion (Continued)

- Review and verify that all parameters pre-populated on the Alaris System are correct prior to starting the infusion.

The rate, VTBI, and duration are pre-populated from the automated programming request.

WARNING

The secondary VTBI settings require consideration of such variables as factory overfill and medication additions. Underestimating the volume causes the remaining secondary solution to be infused at the primary rate; overestimating results in the primary solution being infused at the secondary rate. Multiple doses from a single container are not possible.



- Open the clamp on secondary administration set.

WARNING

The clamp on the secondary administration set must be opened. If the **clamp is not opened**, the fluid is delivered from the primary container.

- Press the **START** soft key.

NOTE:

Pre-population of infusion parameters on the Alaris System **DOES NOT** automatically start the infusion. As with any infusion, all infusion parameters need to be reviewed and confirmed by the clinician before pressing **START**.

- Verify that drops are flowing from the secondary container drip chamber.

Programming with Interoperability—Secondary Infusion (Pump Module) (Continued)

Change Primary Infusion Parameter

1. Press **CHANNEL SELECT** key.
2. Press **SET UP** soft key.
3. Press **PRIMARY** soft key.
4. To change primary infusion parameter, press applicable soft key (**RATE** or **VTBI**) and use numeric data entry keys.
5. Verify correct primary infusion parameters and press **SECONDARY** soft key.
Secondary setup screen is displayed.
6. Press **NEXT** soft key.
7. To resume secondary infusion, press **START** soft key.
8. Verify that drops are flowing from the secondary container drip chamber.

Programming with Interoperability—Secondary Infusion (Pump Module) (Continued)

Stop Secondary and Return to Primary

1. Press the **CHANNEL SELECT** key.
2. Press the **SETUP** soft key.
3. Press the **PRIMARY** soft key.
4. Close the clamp on the secondary administration set.

-or-

Disconnect the secondary administration set from the upper injection port.

5. Press the **START** soft key.
6. To stop the secondary infusion and begin infusing the primary, press the **Yes** soft key.

The secondary infusion stops and primary infusion begins.
The main screen appears.

NOTE:

The SEC to PRI alert does not sound when the infusion is manually ended and returned to the primary.

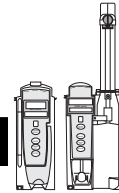
Programming—NO Guardrails Suite MX Protection

The following procedures should be used only when the drug to be infused is not listed in the Drug Library. When programming a drug not listed in the Drug Library, the drug calculation must be programmed using the **DRUG CALC** soft key within the Drug Library. There are no limits associated with any non-library drug calculation.

The illustrations in this procedure assume:

- ALL Mode (Syringe module), Drug Calculation, Dynamic Pressure Display, Profiles, and Volume Duration configurable settings are enabled.
- NEOI (Syringe module) and Delay Options configurable settings are disabled.

Manual Programming—NO Guardrails Suite MX Protection



If Delay Options is enabled, the **PAUSE** soft key becomes **DELAY OPTIONS**.

1. (see PC unit section of this User Manual, "General Setup and Operation," "Start-Up"):
 - a. Power on system.
 - b. Choose **Yes** or **No to New Patient?**
 - c. Confirm current Profile or select a new Profile.
 - d. Enter patient identifier, if required.
2. Prepare and load syringe/administration set (see "Getting Started").
3. Prime (see "Getting Started").
4. Start applicable infusion, as described in following procedures:
 - Basic Infusion without Drug Calculation
 - Basic Infusion with Drug Calculation
 - Bolus Dose

Basic Infusion without Drug Calculation

The following procedure should be used only to set up a **Basic Infusion**. To program an infusion using **Guardrails Drugs**, see "Primary Infusion - With Guardrails Suite MX Protection."

1. Press **CHANNEL SELECT** key.
2. Press **Basic Infusion** soft key.
Infusion Setup screen appears.
3. Start applicable infusion, as described in following procedures (see "Primary Infusion - With Guardrails Suite MX Protection," "IV Fluid Infusion" procedure).
 - Rate/Volume Infusion
 - Volume/Duration Infusion

WARNING

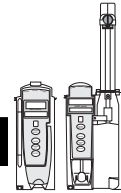


When addressing or clearing an occlusion:

Ensure that the fluid flow to the patient is OFF to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing or relieve the excess pressure through a stopcock, if present. The clinician should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.

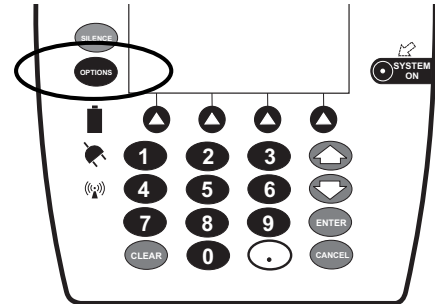
* Using a set with a pressure sensing

Manual Programming—NO Guardrails Suite MX Protection (Continued)



Promote Basic Infusion to Guardrails Software Protection Infusion

1. Press **CHANNEL SELECT** key on module running infusion to be promoted.
2. Press **OPTIONS** key.



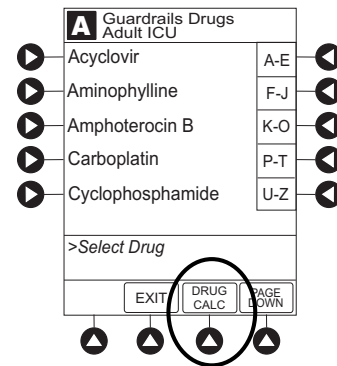
3. Press **Guardrails Drugs** soft key.
4. Continue programming (see "Primary Infusion - With Guardrails Suite MX Protection").

NOTE:

Basic infusions can only be promoted to Guardrails Continuous Infusion or Guardrails IV Fluids. A Basic Infusion cannot be promoted to a Guardrails intermittent drug.

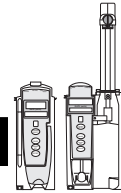
Basic Infusion with Drug Calculation

1. Press **Guardrails Drugs** soft key.
2. Press **DRUG CALC** soft key.



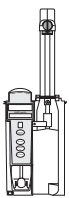
3. To enter **DRUG AMOUNT**, use numeric data entry keys.
4. Press soft key for appropriate unit of measure for drug amount.

Manual Programming—NO Guardrails Suite MX Protection (Continued)



Basic Infusion with Drug Calculation (Continued)

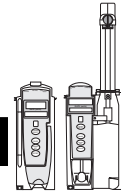
5. To enter diluent volume, use numeric data entry keys.
6. Press **PATIENT WEIGHT** soft key.
7. To indicate whether or not patient weight is to be used in Drug Calculation, press either **Yes** or **No** soft key.
8. To enter patient weight (if required) in kilograms, use numeric data entry keys.
9. Press **TIME UNITS** soft key.
10. To select time base for drug calculation, press either **Min**, **Hour**, or **Day** soft key.
11. Press soft key next to desired **DOSING UNITS**.
12. Verify correct infusion parameters and press **NEXT** soft key.



Syringe module: If ALL Mode is enabled, **VTBI ALL** is displayed.

13. To make a rate or dose entry, press applicable soft key, **RATE** or **DOSE**, and use numeric data entry keys (other value is calculated and displayed).
14. To enter volume to be infused, press **VTBI** soft key and use numeric data entry keys.

Manual Programming—NO Guardrails Suite MX Protection (Continued)



Basic Infusion with Drug Calculation (Continued)

- Pump module:

- When VTBI is less than 10 mL, entry can be to two decimal places (one-hundredth of a mL).
- In Drug Calculation mode, system infuses at calculated rate rounded to nearest one-hundredth of a mL per hour (as displayed on programming screen). Rate shown in Rate Display is rounded to nearest one-tenth of a mL per hour.

- Syringe module:

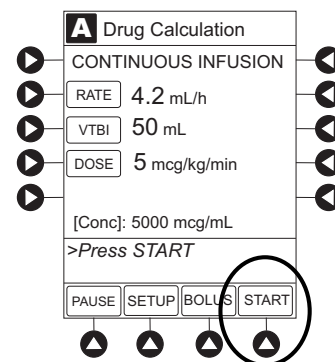
- If ALL Mode is enabled for syringe configuration in Data Set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

OR

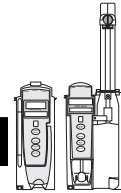
If ALL Mode is disabled for syringe configuration in Data Set, estimated available volume in syringe is displayed when **VTBI** soft key is pressed.

- To enter or change a numeric VTBI value, press **VTBI** soft key and use numeric data entry keys.
 - To deliver entire contents of syringe: Keep an **ALL VTBI** value, or press **ALL** soft key to change a numeric **VTBI** value to **ALL**.
- **BOLUS** soft key appears only if Bolus Dose is enabled within selected Profile, drug is bolusable, and a VTBI is entered.

15. Verify correct parameters and press **START** soft key.

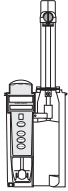


Manual Programming—NO Guardrails Suite MX Protection (Continued)



Basic Infusion with Drug Calculation (Continued)

16. Syringe module:



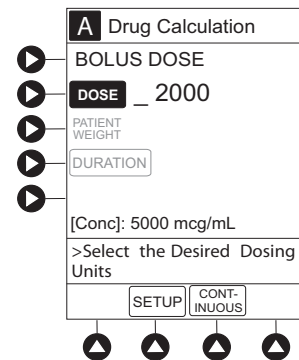
- Unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

NOTE:

Do not enter a patient weight if weight is not used in the calculation.

Bolus Dose

1. Set up infusion as described in "Continuous Infusion - Drug Calculation" procedure, but do not start infusion.
2. Press **BOLUS** soft key.
3. To enter Bolus Dose, use numeric data entry keys.
 - After a Bolus Dose and weight (if used) are entered, bolus VTBI and concentration [conc] alternate in Main Display.

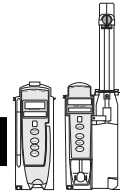


4. Press soft key next to appropriate unit of measure for dose.

If **mcg** or **mg** is selected as dosing unit, a **PATIENT WEIGHT** entry cannot be made. If **mcg/kg** or **mg/kg** is selected as dosing unit, a **PATIENT WEIGHT** entry is required.

5. To enter bolus duration, use numeric data entry keys.
TOTAL DOSE alternates with **INFUSE AT** rate.

Manual Programming—NO Guardrails Suite MX Protection (Continued)

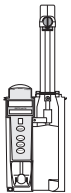


Bolus Dose (Continued)

6. Verify correct parameters and press **START** soft key.

To see details during bolus infusion, press **CHANNEL SELECT** key.

7. Syringe module:



- If Bolus Dose was programmed at beginning of infusion, unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

Stop and Restore Bolus Dose

See "Primary Infusion - With Guardrails Suite MX Protection," "Bolus Dose" procedure.



Secondary Infusion

See *Manual Programming—Secondary Infusion (Pump Module)* on page 2-51 for a description of the secondary infusion mode and for setup instructions.

Infusion

The following procedure should be used only when:

- drug to be infused is not listed in Drug Library,
- primary infusion is running, and
- a check valve administration set is being used.

To program a primary infusion, see *Manual Programming—Primary Infusion* on page 2-24. To program a basic infusion, see *Basic Infusion without Drug Calculation* on page 2-88.

1. Press **SECONDARY** soft key and then **BASIC SEC** soft key.



Infusion (Continued)

2. Enter secondary infusion rate or duration, as follows:
 - To enter secondary infusion rate, press **RATE** soft key and use numeric data entry keys.
 - To enter duration, press **DURATION** soft key and use numeric data entry keys.
3. To enter secondary volume to be infused, press **VTBI** soft key and use numeric data entry keys.
4. Open clamp on secondary administration set.
5. Verify correct infusion parameters and press **START** soft key.
6. Verify that drops are flowing from the secondary container drip chamber.

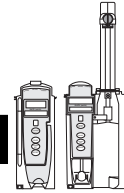
Change Primary Infusion Parameter

1. Press **CHANNEL SELECT** key.
2. Press **PRIMARY** soft key.
3. To change primary infusion parameter, press applicable soft key (**RATE** or **VTBI**) and use numeric data entry keys.
4. Verify correct primary infusion parameters and press **SECONDARY** soft key.
Secondary setup screen is displayed.
5. To resume secondary infusion, press **START** soft key.
6. Verify that drops are flowing from the secondary container drip chamber.

Stop Secondary and Return to Primary

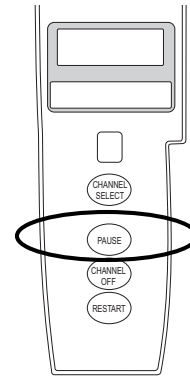
See *Manual Programming—Secondary Infusion (Pump Module)* on page 2-51.

Pause, Change, Restart Infusion

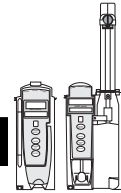


Pause and Restart Infusion

1. Press **PAUSE** key.^③
 - **PAUSE** scrolls in Message Display.
 - **PAUSED** appears on Main Display.
 - Yellow Standby Status Indicator illuminates.
 - After 2 minutes, **PAUSE-RESTART CHANNEL** visual and audio prompts begin, and yellow Standby Status Indicator flashes.



Pause, Change, Restart Infusion (Continued)



Pause and Restart Infusion (Continued)

- To reinitiate infusion:

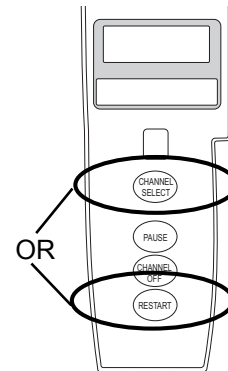
Press **RESTART** key.

OR

Press **CHANNEL SELECT** key and then press **START** soft key.

NOTES:

- To stop a Bolus Dose, see the "Bolus Dose" procedure.
- The Pump module keypad is used in the illustrations but the keys are the same for the Syringe module.
- An infusion can also be paused by pressing the **PAUSE** soft key (on PC unit), if the Delay Options are disabled. To pause an infusion programmed with Delay Options enabled, see "Delay Options," "Pause Infusion."



Change Rate or VTBI During Infusion

- Press **CHANNEL SELECT** key.
- Press either **RATE** or **VTBI** soft key.
- To enter desired parameter, use up/down arrows for rate titration, or numeric data entry keys.
- Verify correct infusion parameter entry and press **START** soft key.

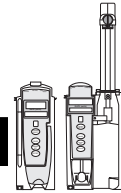
Restore Infusion

- To restart infusion using stored parameters, press **RESTORE** soft key.
- Verify correct parameters and press **START** soft key.

NOTE:

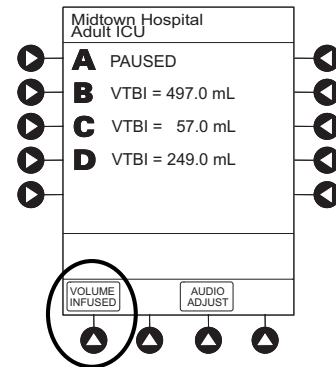
- To restore a Bolus Dose, see the "Bolus Dose" procedure.
- The restore option is only available if the system is powered up within 8 hours of the last use and when the prompt for **New Patient?** is selected as **No**.


View and Clear Volume Infused

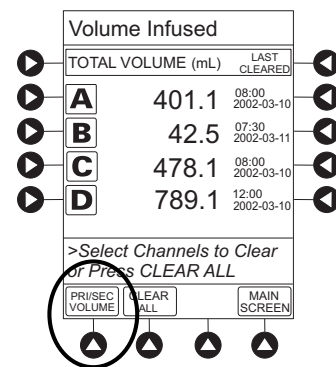


1. To view volume infused, press **VOLUME INFUSED** soft key.

- Total volume infused (primary + secondary), and time and date volume infused was last cleared, display for each module. ^{①②}

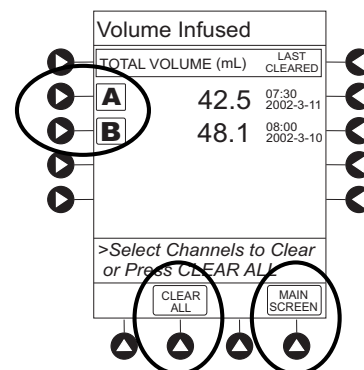


2.  Pump module: To view primary and secondary volume(s) infused, press **PRI/SEC VOLUME** soft key.

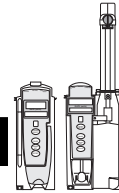


3. To clear volume infused:

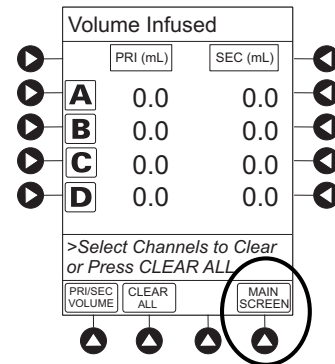
- If only selected module is to be cleared, press soft key next to applicable module and press **CLEAR CHANNEL** soft key.
Volume clears on selected module.
- If all modules are to be cleared, press **CLEAR ALL** soft key ^{③ ④}.



View and Clear Volume Infused (Continued)



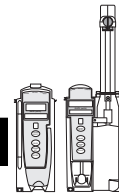
- To return to main screen, press **MAIN SCREEN** soft key.^③



NOTES:

- ① Date format is year-month-day.
- ② Pump module: A PRI/SEC VOLUME soft key is available to allow secondary volume infused to be displayed.
- ③ If no key is pressed, main screen appears after 30 seconds.
- ④ The illustrated example is a Syringe module display. A Pump module display has a PRI/SEC VOLUME soft key

Channel Labels

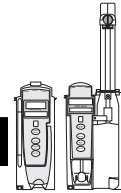


The **Channel Labels** option is not available if a **Guardrails IV fluids** or **Guardrails drugs** infusion is running on the module. A channel label is removed when the **Basic Infusion** is promoted to a **Guardrails IV fluids** or **Guardrails Drugs** infusion.

Select

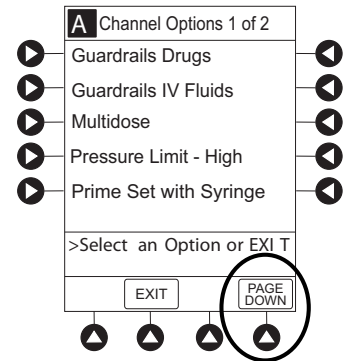
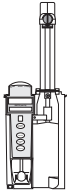
1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.

Channel Labels (Continued)

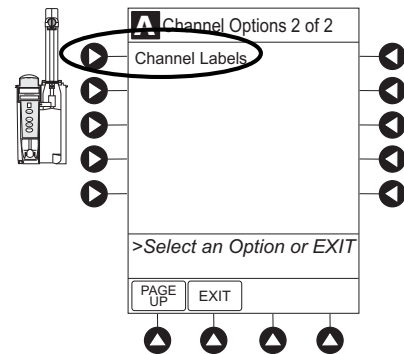
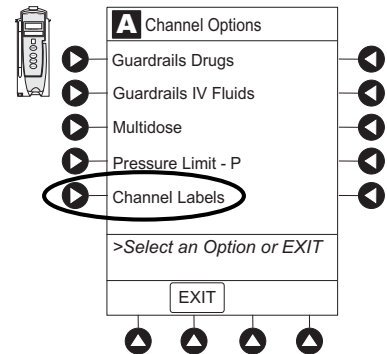


Select (Continued)

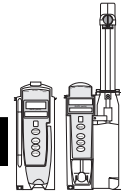
3. Syringe module: Press **PAGE DOWN** soft key.



4. Press Channel Labels soft key.

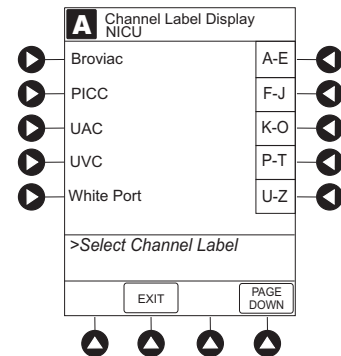


Channel Labels (Continued)



Select (Continued)

- Press soft key for desired label.^①
 - Selected label is highlighted and scrolls in Message Display.




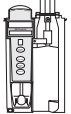
- To continue infusion, press **START** soft key.
OR
Program infusion as previously described.

NOTE:

- ^① To view additional labels, press a soft key next to a letter group to navigate through the alphabet, and/or **PAGE UP** and **PAGE DOWN** soft keys.

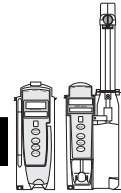
Remove

- Press **CHANNEL SELECT** key.
- Press **OPTIONS** key.
-  Syringe module: Press **PAGE DOWN** soft key.



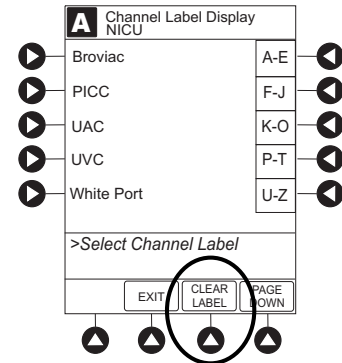
- Press **Channel Labels** soft key.

Channel Labels (Continued)

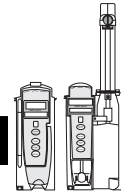


Remove (Continued)

- Press **CLEAR LABEL** soft key.
Label stops scrolling in Message Display.

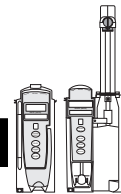


- To begin infusion, press **START** soft key.
OR
Program infusion as previously described.



Anesthesia Mode

See the PC unit section of this User Manual.

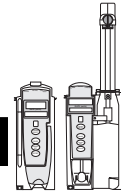


Delay Options

Delay Options can be enabled at the time the Alaris System is configured for use. If Delay Options is enabled, a primary infusion can be programmed to be delayed for a specified period of time and a callback can be scheduled, as described in the following procedures.

Since by definition, an infusion with Delay Options infuses for a programmed period of time, it is assumed that another infusing IV line keeps the vein open until the delayed infusion begins. When a delay is programmed, the infusion stops when complete and no KVO is delivered.

Delay Options (Continued)



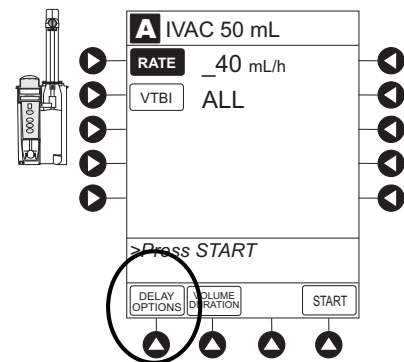
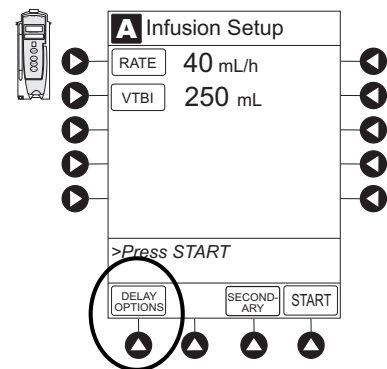
Delay Infusion

The delay period for an infusion can be programmed as a specific number of minutes or a time of day, as described in the following procedures. An infusion delay can be programmed prior to or after an infusion is initiated.

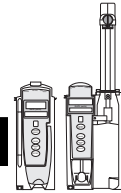
Specify by Minutes

The **Delay for** option is used to program an infusion delay for a minimum of 1 minute and up to 120 minutes.

1. Press **DELAY OPTIONS** soft key.



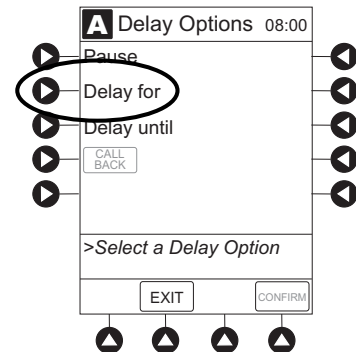
Delay Options (Continued)



Delay Infusion (Continued)

Specify by Minutes (Continued)

2. Press **Delay for** soft key.

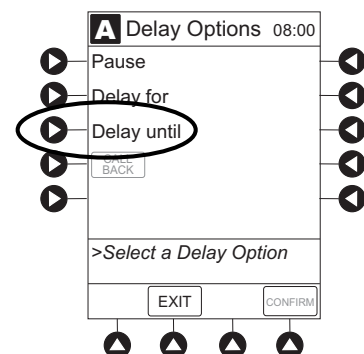


3. To enter number of minutes (up to 120) infusion is to be delayed for, use numeric data entry keys.
4. Press **CONFIRM** soft key.
 - Delay period counts down on Main Display.
 - If a **Before** callback has not been scheduled (see "Schedule a Callback" procedure), infusion automatically initiates at end of delay period.

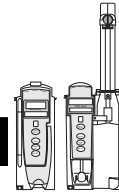
Specify by Time of Day

The **Delay until** option is used to program an infusion delay for a minimum of 1 minute and up to 23 hours 59 minutes.

1. Press **DELAY OPTIONS** soft key.
2. Press **Delay until** soft key.



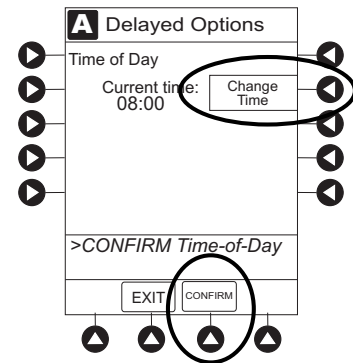
Delay Options (Continued)



Delay Infusion (Continued)

Specify by Time of Day (Continued)

3. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time. (See "System Options," "Time of Day" in PC unit section of this User Manual.)^①



4. To enter time of day infusion is to be initiated (up to 23 hours 59 minutes), use numeric data entry key.

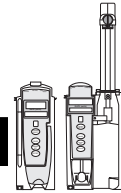
5. Press **CONFIRM** soft key.

- Time infusion is scheduled to start appears on Main Display.
- If a **Before** callback has not been scheduled (see "Schedule a Callback" procedure), infusion automatically initiates at end of delay period.

NOTE:

- ① If the current time has been previously confirmed, the **TIME OF DAY** screen does not display.
- ② If a delay is canceled before the delay ends, the Alaris System will alarm when the VTBI reaches zero and then changes to KVO rate.

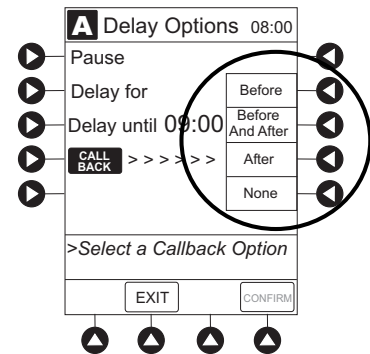
Delay Options (Continued)



Schedule a Callback

When programming a **Delay for** or **Delay until** infusion, a callback can be scheduled for that infusion. There are three types of callback:

- **Before**—gives an alert when delay period is completed and infusion needs to be initiated.
- **After**—gives an alert when delayed infusion has completed.
- **Before and After**—gives an alert when delay period is completed and infusion needs to be initiated and when delayed infusion has completed.



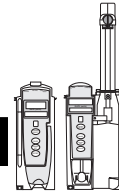
The default callback (After), or the callback for the current Profile, appears on the Main Display. To schedule a different callback:

1. Prior to pressing **CONFIRM** soft key to initiate delay during **Delay for** or **Delay until** programming process, press **CALL BACK** soft key.
2. Press soft key corresponding to desired callback option. Scheduled callback appears on Main Display.
3. To initiate delay, press **CONFIRM** soft key.
 - If **Delay until** programming, time infusion is scheduled to start appears on Main Display.

OR

If **Delay for** programming, delay period counts down on Main Display.

- If **Before** option was selected:
 - An audio prompt sounds when delay period has ended.
 - Yellow Standby Status Indicator flashes.
 - **DELAY COMPLETE** scrolls in Message Display and appears on Main Display.



Delay Options (Continued)

Schedule a Callback (Continued)

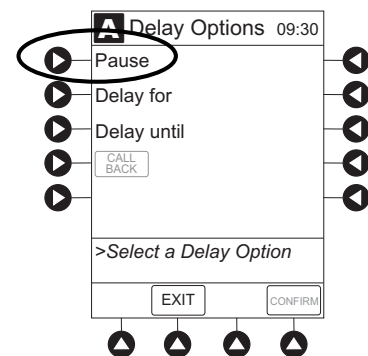
- If **After** option was selected:
 - An audio prompt sounds when delayed infusion completes, and continues to sound until responded to.
 - Yellow Standby Status Indicator flashes until audio is silenced.
 - Infusion completed message appears on Main Display.
 - **Infusion Complete** scrolls in Message Display.
 - If **Before and After** option was selected, same prompts and indicators mentioned above for both **Before** and **After** options are exhibited.
4. To respond to a callback:
- **Before** callback:
Press **CHANNEL SELECT** key and then **START** soft key.

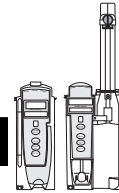
OR

 - Press **RESTART** key.
 - **After** callback: Press **CONFIRM** soft key.
 - **Before and After** callback: Respond as indicated above for both **Before** and **After**.

Pause Infusion

1. Press **DELAY OPTIONS** soft key.
2. Press **Pause** soft key.^①
 - If an alert has occurred, pause is not initiated by system until alert is addressed.





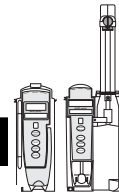
Delay Options (Continued)

Pause Infusion (Continued)

3. Press **CONFIRM** soft key.
 - **PAUSE** scrolls in Message Display.
 - **PAUSED** appears on Main Display.
 - Yellow Standby Status Indicator illuminates.
 - After 2 minutes: **PAUSE - RESTART CHANNEL** visual and audio prompts begin, and yellow Standby Status Indicator flashes.
4. To reinitiate infusion:
Press **RESTART** key.
OR
Press **CHANNEL SELECT** key and then **START** soft key.

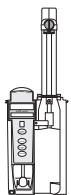
NOTE:

- ① The time displayed in the upper right corner of the screen is the time of day in a 24-hour clock format (military time).



Multidose Mode


Since, by definition, a multidose infusion does not infuse for a programmed period of time, it is assumed that another infusing IV line keeps the vein open until the beginning of the first dose and between subsequent doses. There is no keep vein open (KVO) infusion at the completion of a programmed **Delay until** infusion.



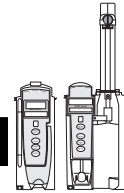
Syringe module: ALL Mode is not supported in Multidose Mode.

WARNING



- The Multidose feature is to be used only by **personnel properly trained** in using multidose infusions.
- **Caution labels**, which clearly differentiate single dose and multidose containers, must be utilized.
- Single dose piggybacking systems employing **check valve sets** are not designed for use with multidose 

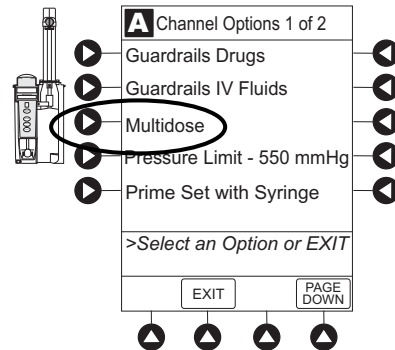
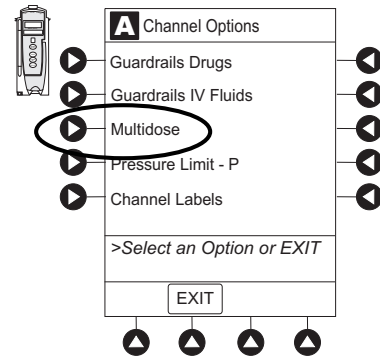
Multidose Mode (Continued)



The Delay Options function for multidose infusions is similar to Delay Options for continuous drug infusions, with the following differences:

- **Delay for** option (when scheduling a callback) is not available in Multidose Mode.
- Maximum allowable delay on a multidose infusion is 8 hours.

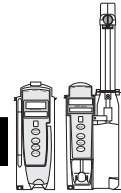
1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **Multidose** soft key.



4. Start applicable infusion, as described in following procedures:

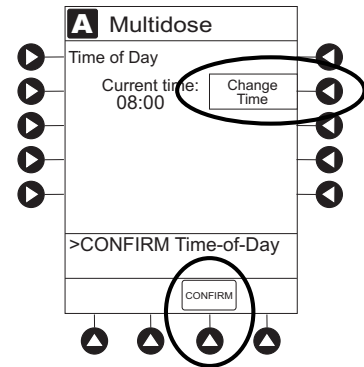
Volume/Duration Enabled
Volume/Duration Disabled

Multidose Mode (Continued)



Volume/Duration Enabled

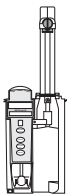
1. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time. (See *System Options, Time of Day* in the *Alaris PC Unit* section of this User Manual.)^①



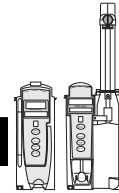
2. Press **VOLUME DURATION** soft key.
3. To enter volume to be infused for each dose, use numeric data entry keys.
4. To enter duration for each dose, press **DURATION** soft key and use numeric data entry keys.^②
5. To enter time interval (1 to 24 hours) between doses, press **DOSE INTERVAL** soft key and use numeric data entry keys.
6. To enter number of doses, press **# OF DOSES** soft key and use numeric data entry keys.
If Delay Options is enabled, **DELAY OPTIONS** soft key appears.^③

7. To begin multidose infusion, press **START** soft key.
 - Main Display shows remaining VTBI for that dose.
 - At completion of a multidose program, **MULTIDOSE COMPLETE** appears on Main Display.^④

8. Syringe module:



- Unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.



Multidose Mode (Continued)

Volume/Duration Enabled (Continued)

9. To see detail screen during or between infusions, press **CHANNEL SELECT** key.
 - During infusion, **Volume Remaining** is displayed.
 - Between infusions:
 - Number of doses completed and when next dose starts display.
 - Yellow Standby Status Indicator illuminates.

NOTES:

- ① If the current time has been previously confirmed, the **Time of Day** screen does not display.
- ② **RATE** is calculated with each keystroke for **DURATION**.
- ③ See "Delay Options" procedure to program an infusion delay. When delaying an infusion, a multidose cannot be delayed for more than 8 hours, and all doses in the multidose program must be completed within a 24-hour program.
- ④ Syringe module: If NEOI is enabled, the Near End of infusion message appears near the end of the last dose.

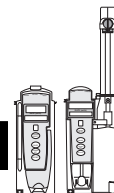
Volume/Duration Disabled

1. To enter rate, use numeric data entry keys.
2. To enter volume to be infused for each dose, press **VOLUME/DOSE** soft key and use numeric data entry keys.
3. To enter time interval (1 to 24 hours) between doses, press **DOSE INTERVAL** soft key and use numeric data entry keys.
4. To enter number of doses, press **# OF DOSES** soft key and use numeric data entry keys.

If Delay Options is enabled, DELAY OPTIONS soft key appears.^①

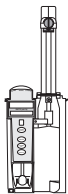
5. To begin multidose infusion, press **START** soft key.
 - Main Display shows remaining VTBI for that dose.
 - At completion of a multidose program, **MULTIDOSE COMPLETE** appears on Main Display.^②

Multidose Mode (Continued)



Volume/Duration Disabled (Continued)

6. Syringe module:



- Unclamp tubing and attach administration set to patient.
- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.

7. To see detail screen during or between infusions, press **CHANNEL SELECT** key.

- During infusion, **Volume Remaining** is displayed.
- Between infusions:
 - Number of doses completed and when next dose starts are displayed.
 - Yellow Standby Status Indicator illuminates.

NOTES:

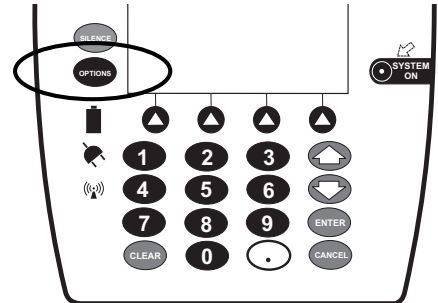
- ① See "Delay Options" procedure to program an infusion delay. When delaying an infusion, a multidose cannot be delayed for more than 8 hours, and all doses in the multidose program must be completed within a 24-hour program.
- ② Syringe module: If NEOI is enabled, the Near End of infusion message appears near the end of the last dose.

Select Pressure Limit

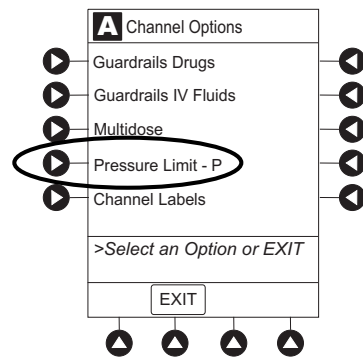
Pump Module



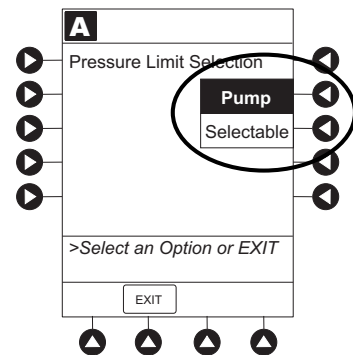
1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.



3. Press **Pressure Limit** soft key.



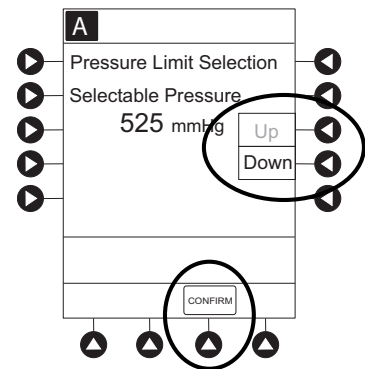
4. Press either **Pump** or **Selectable** pressure soft key. If **Selectable** is pressed, continue with next step; otherwise, proceed to last step.



Select Pressure Limit (Continued)

Pump Module (Continued)

- To select occlusion pressure limit, press either **Up** or **Down** soft key.
- Verify correct occlusion pressure limit input and press **CONFIRM** soft key.



- Press **START** soft key.

Syringe Module

Pressure Sensing Disc Installed

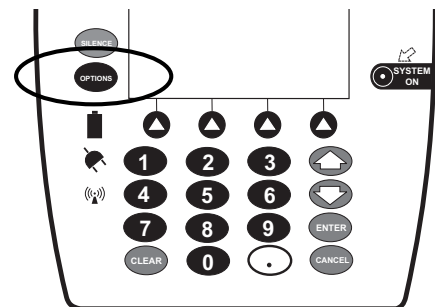
- Ensure that pressure sensing disc is installed correctly.
- Press **CHANNEL SELECT** key.
- Press **OPTIONS** key.



WARNING



Installing a pressure sensing disc after an infusion has started can result in a bolus to the patient.



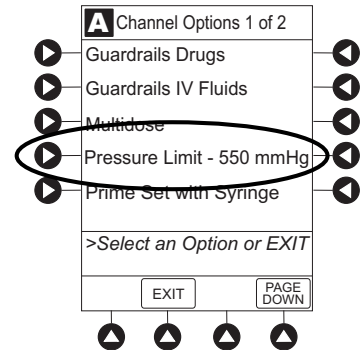
Select Pressure Limit (Continued)

Syringe Module (Continued)

Pressure Sensing Disc Installed (Continued)



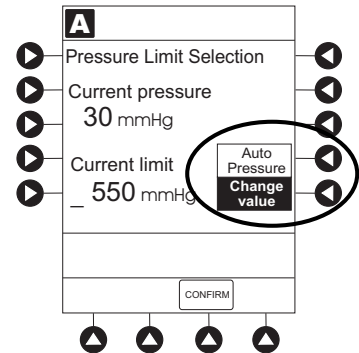
4. Press **Pressure Limit** soft key.



5. To enter a new pressure limit value, press **Change Value** soft key.^①

OR

If Auto Pressure feature is enabled, press **Auto Pressure** soft key.^②



Select Pressure Limit (Continued)

Syringe Module (Continued)

Pressure Sensing Disc Installed (Continued)



WARNING



To minimize the amount of time it takes the pump to recognize an occlusion (blockage) and generate an alarm while infusing at low rates (for example, < 5 mL/h and especially flow rates of < 0.5 mL/h):

- Consider the plunger force or occlusion pressure threshold setting and adjust it, as necessary. The lower the plunger force setting or occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (for example, lipids), the plunger force or occlusion pressure threshold setting may need to be adjusted to reduce false alarms.
 - Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance of the syringe stopper. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.
 - Use the Prime Set with Syringe feature on the pump when changing a syringe and/or tubing.
 - Use accessory devices, which have the smallest internal volume or deadspace (for example, use microbore tubing when infusing at low rates, shorter length of tubing, etc.).
6. Verify correct pressure limit input and press **CONFIRM** soft key.

Select Pressure Limit (Continued)

Syringe Module (Continued)



Pressure Sensing Disc Installed (Continued)

NOTES:

- ① The optimal occlusion alarm limit setting achieves a balance between the risk of false alarms and timely response to occlusions. To avoid interruptions in therapy, the limit should be set at a value higher than the expected actual "working" pressure, which will allow normal events such as patient movement and titrations to occur without alarms.
The "working" pressure presented to a pump by the IV cannula depends on several factors: combined rate of all infusions running into a single vascular access point, resistance of the fluid path, elevation differential, and vascular pressure dynamics. Resistance to flow is determined by the catheter's length and inner diameter, and the viscosity of the fluid. Kinking and clotting might also elevate the resistance to flow over time.
The Syringe module allows both fixed and customized approaches to pressure limits to be configured. Each Profile can be programmed with its own maximum pressure value, supporting a fixed limit approach. Customized limits can be set either manually, by reading the current pressure following stabilization and adding a margin, or by use of the Auto Pressure feature which, on activation, sets a margin of 30 mmHg for initial pressures under 100 mmHg or 30% of the initial pressure at higher initial values. The margin must be larger when variations in flow, resistance, and vascular pressure are anticipated. When pumping through high resistance access devices such as central line catheters, the Auto Pressure margin might be inadequate. With these devices, ten minutes or more might be required to allow the pressure to stabilize following flow rate changes, as required for the use of Auto Pressure. Therefore, caution should be used when using Auto Pressure for life sustaining fluids, to prevent unexpected interruptions of infusion due to occlusion alarms.
- ② If Auto Pressure is selected and current pressure is:
 - 100 mmHg or less – system adds 30 mmHg to current pressure to create a new alarm limit
 - greater than 100 mmHg – system adds 30% to current pressure

Select Pressure Limit (Continued)

Syringe Module (Continued)

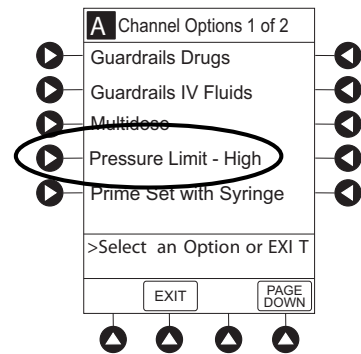
Pressure Sensing Disc NOT Installed

WARNING

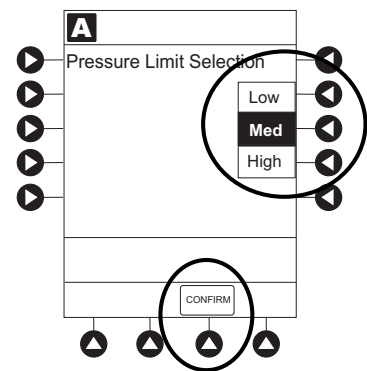


When the **pressure sensing disc is not being used** and an occlusion occurs, there is a risk of infusing pressurized buildup of infusates upon correction of the occlusion. To avoid an inadvertent bolus, relieve the pressure before restarting the infusion.

1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **Pressure Limit** soft key.



4. To select a pressure limit, press appropriate soft key.
5. Press **CONFIRM** soft key.



Select Pressure Limit (Continued)

Syringe Module (Continued)

Pressure Sensing Disc NOT Installed



WARNING



To minimize the amount of time it takes the pump to recognize an occlusion (blockage) and generate an alarm while infusing at low rates (for example, < 5 mL/h and especially flow rates of < 0.5 mL/h):

- Consider the plunger force or occlusion pressure threshold setting and adjust it, as necessary. The lower the plunger force setting or occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (for example, lipids), the plunger force or occlusion pressure threshold setting may need to be adjusted to reduce false alarms.
- Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance of the syringe stopper. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.
- Use the Prime Set with Syringe feature on the pump when changing a syringe and/or tubing.
- Use accessory devices, which have the smallest internal volume or deadspace (for example, use microbore tubing when infusing at low rates, shorter length of tubing, etc.).

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System Start-Up/Setup

See *Alaris Pump Module, Model 8100 Alaris Syringe Module, Model 8110, General Setup and Operation* on page 1-3, for various system start-up and setup procedures.

Set Up for Gravity Infusion (Pump Module)

1. Prime administration set (see "Getting Started," "Prime" procedure).
2. Adjust container to hang 20 inches above patient's vascular access device.
3. Attach administration set to patient's vascular access device.
4. Adjust flow rate with administration set roller clamp.



Change Solution Container (Pump Module)

1. To stop infusion, press **PAUSE** key.
2. Close roller clamp.
3. Remove empty solution container.
4. Insert administration set spike into prepared fluid container, following accepted hospital/facility procedure, and hang container 20 inches above Pump Module.
5. Press **CHANNEL SELECT** key.
6. To enter VTBI, press **VTBI** soft key and use numeric data entry keys.
7. Open roller clamp.
8. To resume infusion, press **START** soft key.



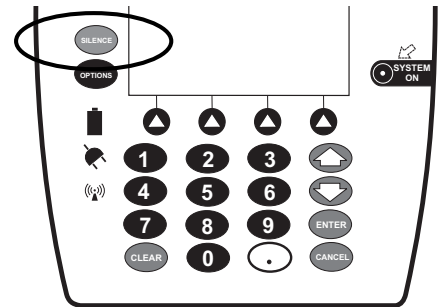
System Start-Up/Setup (Continued)

Change Syringe During Infusion (Syringe Module)

If a critical medication is being infused at a flow rate less than 1.0 mL/h and the patient is not stable enough to experience even a short period of time without the drug, it is recommended that the new syringe and administration set be installed as part of a second Alaris System setup. Before changing the infusion line at the patient end, start the infusion and wait for fluid to drip from the end of the tubing.

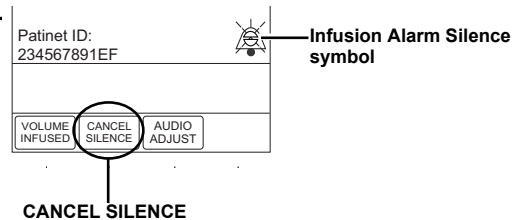


1. To stop infusion, press **PAUSE** key.
2. Open plunger grippers and syringe barrel clamp.
 - An audio alarm sounds—to silence, press **SILENCE** key.
 - Red Alarm Status Indicator flashes.
 - **CHECK SYRINGE** scrolls in Message Display.
 - The **CANCEL SILENCE** soft key is displayed and an Infusion Alarm Silence symbol appears in lower right of PC unit screen.



NOTE:

Press the CANCEL SILENCE soft key to reactivate a previously silenced alarm audio. If the alarm condition has not been resolved, the alarm audio will resume.



3. Remove syringe and separate administration set from syringe.
4. Reattach administration set to new syringe and load new syringe (see "Getting Started," "Prepare Syringe and Administration Set").
5. Select syringe type and size (see "Programming," "Primary Infusion - With Guardrails Suite MX Protection").
6. Press **CONFIRM** soft key.
7. Prime administration set using options menu or manually (see "Getting Started," "Prepare Syringe and Administration Set").

System Start-Up/Setup (Continued)

Change Syringe During Infusion (Syringe Module)



8. Press **RESTORE** soft key.

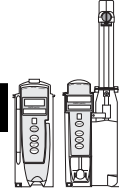
OR

To enter VTBI and rate, press **RATE** soft key and use numeric data entry keys, and then **VTBI** soft key and use numeric data entry keys.

9. To begin infusion, press **START** soft key.

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Warnings and Cautions



General

WARNINGS

- Ensure syringe sizes and models are compatible with the Syringe module. The use of any other syringe or administration set can cause improper pump operation, resulting in inaccurate fluid delivery, insufficient occlusion (blockage) sensing, or other potential hazards ^①
- Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h). Using a larger syringe when infusing at low rates can lead to inadequate syringe pump performance including delivery inaccuracies, delay of therapy, and delayed generation of occlusion alarms. This is due to the increased friction and compliance of the syringe stopper with larger syringes.
- Ideally, the Syringe module should be level with the patient's heart. If the Syringe module height is raised relative to the patient's heart level (for example, during patient transport), the increase in height of the Syringe module can result in a temporary increase in fluid delivery or bolus until the flow rate stabilizes. Alternatively, if the Syringe module is lowered relative to the patient's heart level, the decrease in the height of the Syringe module may result in a decrease in delivery or under-infusion until the flow rate stabilizes.
- Electronically prime the syringe pump system before starting an infusion or after replacing a near-empty syringe with a replacement syringe.
- During programming and prior to starting an infusion, verify that the syringe size and model on the PC unit display screen matches the syringe size and model loaded into the Syringe module.

Warnings and Cautions (continued)

General (continued)

WARNINGS



- The Pump and Syringe modules are designed to **stop fluid flow under alarm conditions**. Periodic patient monitoring must be performed to ensure that the infusion is proceeding as expected. It is a **positive displacement delivery system**, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters and intra-arterial infusion. It is neither designed nor intended to detect infiltrations and does not alarm under infiltration conditions.
- The use of positive displacement infusion devices ported together with **gravity flow infusion** systems into a common IV site can impede the flow of common "gravity only" systems, affecting their performance. Hospital/facility personnel must ensure that the performance of the common IV site is satisfactory under these circumstances.
- To prevent a **potential free-flow condition**, ensure that no extraneous object (for example, bedding, tubing, glove) is enclosed or caught in the Pump module door.

Warnings and Cautions (continued)

General (continued)

CAUTIONS



- Use compatible components which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (e.g., < 5 mL/h, and especially flow rates < 0.5 mL/h). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times.
- Minimize the height difference between the pump and the patient and avoid changes in the height of the Syringe module (for example, during transport of critically ill patients) to prevent unintended fluctuations in the flow rate.
- If using multiple syringe pumps and it is not clinically feasible to have all pumps level with the patient's heart, place the high risk or life-sustaining medications as close to the heart level as possible. When infusing multiple high risk or life-sustaining medications, consider placing the ones infusing at the lowest rates as close to the level of the patient's heart as possible.
- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (e.g., 50 - 200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (e.g., < 5 mL/h, and especially flow rates < 0.5 mL/h).

Warnings and Cautions (continued)

Administration Sets

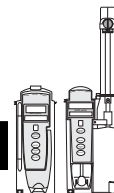
WARNINGS

- **When priming:**
 - Ensure that administration set is not connected to patient.
 - Ensure that air is expelled from line prior to beginning infusion (unexpelled air in line could have serious consequences).

Failure to prime correctly can delay infusion delivery and cause the total volume to be infused to read higher than the actual total delivered to the patient.

- **Discard if** packaging is not intact or protector caps are unattached.

Warnings and Cautions (Continued)

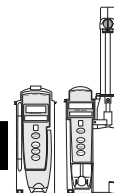


Administration Sets (Continued)

WARNINGS

- Use only **Alaris Pump module/GEMINI™ Infusion System administration sets** with the Pump module. The use of any other set can cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard. For a list of compatible sets, refer to the *Alaris™ Pump Module Set Compatibility Card* and the *Alaris™ Syringe Module Set Compatibility Card*.
- Use only standard, approved, single-use, disposable syringes with luer-lock connectors, and administration sets designed for use on syringe pumps. The use of any other syringe or administration set can cause improper instrument operation, resulting in an inaccurate fluid delivery or pressure sensing, or other potential hazards.^①
- **Before loading or unloading the syringe**, always turn off fluid flow to the patient, using the tubing clamp or stopcock. Uncontrolled fluid flow can occur when the administration set is not clamped or turned off, and can cause serious injury or death.
- When the **pressure sensing disc is not being used** and an occlusion occurs, there is a risk of infusing pressurized buildup of infusates upon correction of the occlusion. To avoid an inadvertent bolus, relieve the pressure before restarting the infusion.
- Ensure that the displayed **syringe manufacturer and syringe size** correctly identifies the installed syringe. Mismatches can cause an under-infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page 2-136 and the *Alaris™ Syringe Module Set Compatibility Card*.
- **Installing a pressure sensing disc** after an infusion has started can result in a bolus to the patient.

Warnings and Cautions (Continued)



Administration Sets (Continued)

NOTE:

- ① For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page 2-136 and the *Alaris™ Syringe Module Set Compatibility Card*. For a list of compatible administration sets, refer to the *Alaris™ Pump Module Set Compatibility Card*.

CAUTION



Before operating the instrument, verify that the administration set is **free from kinks and correctly installed**.

Occlusions

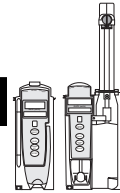
WARNINGS



To minimize the amount of time it takes the pump to recognize an occlusion (blockage) and generate an alarm while infusing at low rates (for example, < 5 mL/h and especially flow rates of < 0.5 mL/h):

- Consider the plunger force or occlusion pressure threshold setting and adjust it, as necessary. The lower the plunger force setting or occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (for example, lipids), the plunger force or occlusion pressure threshold setting may need to be adjusted to reduce false alarms.
- Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance of the syringe stopper. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.
- Use the Prime Set with Syringe feature on the pump when changing a syringe and/or tubing.
- Use accessory devices, which have the smallest internal volume or deadspace (for example, use microbore tubing when infusing at low rates, shorter length of tubing, etc.).

Warnings and Cautions (Continued)



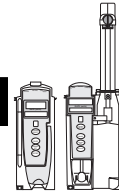
Occlusions (Continued)

WARNINGS

When addressing or clearing an occlusion:

- Ensure that the fluid flow to the patient is **OFF** to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing or relieve the excess pressure through a stopcock, if present. The clinician should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.
- Using a set with a pressure sensing disc and Back Off (after occlusion) enabled will cause the motor to reverse plunger movement during an occlusion until pressure returns to preocclusion levels, automatically reducing bolus flow.
- Being aware that using larger size syringes on a high plunger force setting may produce a larger post occlusion bolus due to excessive syringe stopper compliance.



Warnings and Cautions (Continued)

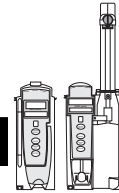


Epidural Administration

WARNING



- **Epidural administration** of drugs other than those indicated for epidural use could result in serious injury to the patient.
- It is strongly recommended that the source container, administration set, and Pump module used for **epidural drug delivery** be clearly differentiated from those used for other types of administration. 
- It is strongly recommended that the syringe, administration set, and Syringe module used for **epidural drug delivery** be clearly differentiated from those used for other types of administration. 
- The Alaris System can be used for epidural administration of **anesthetic and analgesic drugs**. This application is only appropriate when using anesthetics and analgesics labeled for continuous epidural administration and catheters intended specifically for epidural use. Use only an Alaris Pump module/GEMINI Infusion System administration set or syringe set, without a 'Y' connector or injection port, for epidural infusions.
 - Epidural administration of **anesthetic drugs**: Use indwelling catheters specifically indicated for short-term (96 hours or less) anesthetic epidural drug delivery.
 - Epidural administration of **analgesic drugs**: Use indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.



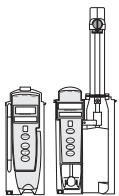
Warnings and Cautions (Continued)

Guardrails Suite MX

WARNINGS

- The **Guardrails Suite MX** incorporates dosing limits and instrument configuration parameters based on hospital/facility protocol. The software adds a **test of reasonableness** to drug programming based on the limits defined by the hospital/facility. Qualified personnel must ensure that the appropriateness of drug dosing limits, drug compatibility, and instrument performance, as part of the overall infusion. **Potential hazards** include drug interactions, inaccurate delivery rates and pressure alarms, and nuisance alarms.
- When loading a **Data Set** with the Guardrails Suite MX, **ensure that the correct** Profile (for patient care area) is selected prior to starting an infusion. Failure to use the appropriate Profile could cause serious consequences.

Administration Set/Syringe Information



Infusion modules:

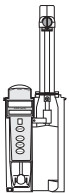
- For specific administration set instructions and replacement interval, refer to User Manual provided with set.
- For a listing of compatible administration sets, refer to the *Alaris™ Pump Module Set Compatibility Card* and the *Alaris™ Syringe Module Set Compatibility Card*.
- Use aseptic techniques when handling sets and syringes.
- Administration sets are supplied with a sterile and nonpyrogenic fluid path for one-time use. Do not resterilize.
- Discard administration set per facility protocol.
- For IV push medication (put instrument on hold), clamp tubing above port.
- Do not administer IV pushes through ports that are above the Alaris System.
- Flush port(s) per facility protocol.

Administration Set/Syringe Information (Continued)



The Pump module uses a wide variety of Alaris Pump module/GEMINI Infusion System administration sets. The sets are designed for use with the Pump module as well as for gravity-flow, stand-alone use.

- Primary set must be primed before use. It can be loaded into Pump module to deliver a large volume infusion or it can be set up to deliver a gravity infusion.
- Safety clamp fitment is a unique clamping device on the pumping segment that is part of all Alaris Pump module/GEMINI Infusion System sets (see "Safety Clamp Fitment").



The Syringe module uses standard, single-use, disposable syringes (with luer-lock connectors) and administration sets designed for use on syringe pumps. For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page 2-136 and the *Alaris™ Syringe Module Set Compatibility Card*.

SmartSite™ Infusion Set (Pump Module)



1. Prior to every access, swab top of Needle-Free Valve port with 70% isopropyl alcohol (1 - 2 seconds) and allow to dry (approximately 30 seconds).^①
2. Prime valve port. If applicable, attach syringe to Needle-Free Valve port and aspirate miniscule air bubbles.
3. Replace every 96 hours or after 100 activations, whichever occurs first. For infusions of blood, blood products or lipid emulsions, replace every 24 hours.

CAUTION



- If the Needle-Free Valve is **accessed by a needle** in an emergency, the valve will be damaged, causing leakage. Replace the Needle-Free Valve immediately.
- The Needle-Free Valve is **contraindicated** for blunt cannula systems.
- Do not leave **slip luer syringes** unattended.

NOTE:

Dry time is dependent on area temperature, humidity and ventilation.

Administration Set/Syringe Information (Continued)

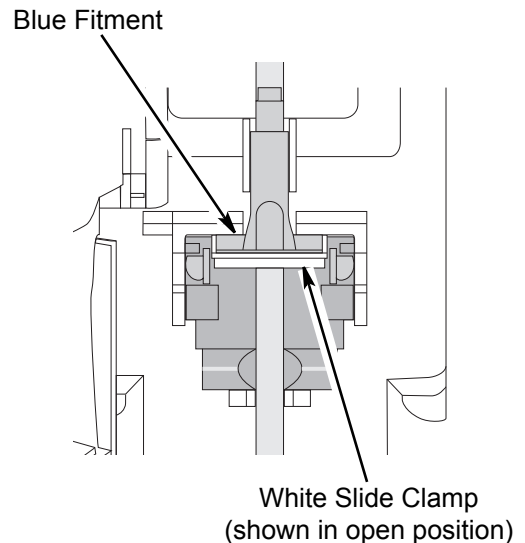
Safety Clamp Fitment (Pump Module)



The primary administration set's safety clamp fitment is a unique clamping device, on the pumping segment, that prevents inadvertent free-flow when the administration set is removed from the instrument.

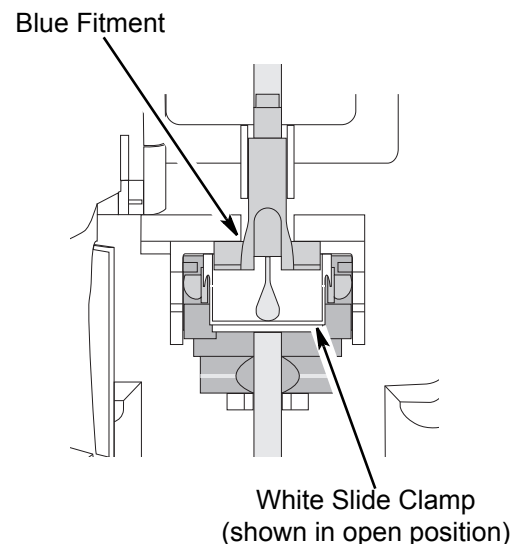
Safety Clamp Fitment in Open Position

When a new Alaris Pump module/GEMINI Infusion System administration set is removed from the package, the safety clamp fitment is in the open position (white slide clamp aligned with blue fitment). In this open position, flow is allowed as required for the priming process. The roller clamp is used to control flow during the priming process.



Safety Clamp Fitment in Closed Position

When an Alaris Pump module/GEMINI Infusion System administration set is removed from the Pump module, the instrument automatically engages the safety clamp fitment in the closed position (white slide clamp projects out from under blue fitment). In this closed position, flow is prevented.



Administration Set/Syringe Information (Continued)

Compatible Syringes (Syringe Module)

The Syringe module is calibrated and labeled for use with the following single-use disposable luer-lock syringes. Use only the syringe size and type specified on the Main Display. The full list of permitted syringe models is dependent on the software version of the Syringe module.



CAUTION



When using a **10 mL or smaller syringe**, CareFusion strongly recommends using an extension set with a pressure disc, for improved pressure monitoring and shorter times to occlusion alarm.

Compatible syringe availability and model numbers vary from country to country. The syringes listed in the table below may not be available in all countries, including the US and Canada. See the *Alaris Syringe module compatible syringes and flow rate ranges specification* for the country-specific syringe model numbers supported.

| Manufacturer | 1 mL | 3 mL | 5 mL | 6 mL | 10 mL | 12 mL | 20 mL | 30 mL | 35 mL | 50 mL | 60 mL |
|--------------|------|----------------|----------------|------|----------------|-------|-------|----------------|-------|-------|-------|
| BD Plastipak | x | x | x | | x | | x | x | | | x |
| IVAC | | | | | | | | | | x | |
| Monoject | | x ^① | | x | | x | x | | x | | x |
| Terumo | | x | x ^② | | x ^② | | x | x ^② | | | x |

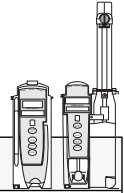
NOTES:

- ① The Monoject SoftPack Luer-Lock Syringe (blister pack) is the only currently supported Monoject 3 mL.
- ② The Terumo 5 mL can also be used as a 6 mL, the 10 mL as a 12 mL, and the 30 mL as a 35 mL.

Features and Displays

Features and Definitions

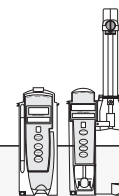
See the PC unit section of this User Manual for system features and definitions.



| Feature | Definition—Pump and Syringe Modules |
|-----------------------------|--|
| Anesthesia Mode | When operating in Anesthesia Mode, a module can be paused indefinitely without an alarm. Anesthesia Mode also makes it possible to have additional drugs in each Profile, which are only accessible when operating in that mode. |
| Bolus Dose | Allows a bolus infusion to be programmed using either Drug Library or drug calculation feature. It can be programmed with or without a Continuous Infusion following a bolus. |
| Callback | A callback for a programmed delay (see "Delay Options" definition) can be scheduled to give an alert Before an infusion is to be initiated, After an infusion is completed, Before and After an infusion, or no alert (None). |
| Channel Labels | Available when Profiles feature is enabled. It provides a hospital-defined list of labels, displayed in Channel (module) Message Display, and identifies module with catheter location or other helpful information. |
| Concentration Limits | Limits specified for range of concentrations allowed for a particular drug in a Profile. |
| Delay Options | Allows system to be programmed to delay start of an infusion a) for up to 120 minutes or b) for a specific time up to 23 hours 59 minutes. |
| Dose Checking | <p>Always Dose Checking option causes an Alert to occur each time a dose limit is exceeded. Drug label in Message Display provides an indicator ("↑↑↑" or "LLL") that dose is beyond current Soft Limit.</p> <p>Smart Dose Checking option causes an initial soft Alert to occur when a dose limit is exceeded. Subsequent programming beyond dose limit does not receive an Alert. Drug label in Message Display provides an indicator ("↑↑↑" or "LLL") that dose is beyond current Soft Limit.</p> |
| Drug Calculation | <p>Allows:</p> <ul style="list-style-type: none"> • entry of drug dose for a Continuous Infusion (Alaris System calculates correct flow rate to achieve desired dose), <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • entry of flow rate for a Continuous Infusion (Alaris System calculates corresponding drug dose). |

Features and Displays (Continued)

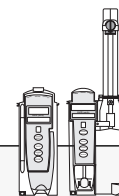
Features and Definitions (Continued)



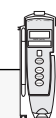
| Feature | Definition—Pump and Syringe Modules |
|---------------------------------|---|
| Drug Library | When Profiles feature is enabled, it provides a hospital-defined list of drugs and concentrations appropriate for use in as many as 30 Profiles. Drug Library use automates programming steps, including drug name, drug amount and diluent volume, and activates hospital-established best-practice limits. Drug Library entries can be delivered as a primary or secondary, or both, as determined by hospital-health system. |
| Duration Limits | Hospital-established limits around duration of an Intermittent Infusion. |
| Dynamic Pressure Display | Appears on Main Display. If enabled, it graphically displays current patient-side occlusion pressure set point and current patient-side operating pressure for that module. (See "Displays" for additional "Dynamic Pressure Display" information.) |
| Event Logging | Event Logging records instrument operations. |
| Initial Value | An optional and editable starting value for Continuous Infusion dose, duration, Bolus Dose, bolus rate of administration or Bolus Dose duration. |
| IV Fluid Library | An optional library consisting of IV Fluids (for example, TPN) and limits around rate of delivery. |
| Limit | <p>A programming Limit or best-practice guideline determined by hospital/health system and entered into system's Data Set. Supports concentration Limits for all infusions that utilize concentration. Profile-specific Limits can be defined for flow rate, patient weight, body surface area (BSA), maximum and minimum continuous dose, or total dose and duration for each drug in a Drug Library. Dose and duration Limits can be defined by hospital/health system as a Hard and/or Soft Limits.</p> <ul style="list-style-type: none"> • A Hard Limit is a programmed Limit that cannot be overridden, except in anesthesia mode. • A Soft Limit is a programmed Limit that can be overridden. |
| Multidose Mode | Allows 2 - 24 doses to be programmed at equally spaced intervals on the same module over a 24-hour period. This mode is designed to allow delivery of multiple, equal doses from the same IV container at regularly scheduled intervals. |
| Rapid Bolus | Fastest rate at which Bolus Dose should be delivered, as defined by facility's clinical best-practice guidelines. |
| Restore | To simplify programming, can be used to recall previous rate and volume settings for same patient. This option is only available if patient is not new and system is powered up within 8 hours of last usage. |

Features and Displays (Continued)

Features and Definitions (Continued)



| Feature | Definition—Pump and Syringe Modules |
|--------------------------|--|
| Therapies | An optional hospital-defined therapy or clinical indication for delivery of that infusion. Different Limits can be defined for same medication with different therapeutic indications. |
| Total Dose Limits | Hospital-established Limits around total dose of infusion. |
| Volume/Duration | Allows a volume-to-be-infused (VTBI) and duration (infusion time) to be programmed. Flow rate is automatically calculated. |



| Feature | Definition—Pump Module |
|-----------------------------------|---|
| Auto-Restart | <p>Part of Alaris System's Downstream Occlusion Detection system designed to minimize nuisance, patient-side occlusion alarms. Allows system to automatically continue an infusion following detection of a patient-side occlusion if downstream pressure falls to an acceptable level within a 15-second "Checking Line" period. If this feature is enabled, "Checking Line" function occurs when downstream pressure exceeds pressure limit.</p> <ul style="list-style-type: none"> • In Selectable Pressure Mode: Pressure limit is either user-adjustable or "locked" in system configuration. • In Pump Pressure Mode: Pressure limit is a function of flow rate and is automatically determined by device. <p>If downstream pressure decreases to a predetermined level, (below 50% pressure limit) during 15-second "Checking Line" period, infusion automatically continues. If condition is not cleared within 15 seconds, a "Partial Occlusion - Patient Side" alarm occurs.</p> <p>Using the Editor software, the system can be configured to allow 0 (zero) to 9 restart attempts within a rolling 10-minute period. If allowable number of restarts is exceeded or if feature is set to zero, an "Occluded - Patient Side" alarm occurs when system detects downstream pressure that exceeds pressure limit.</p> <p>NOTE: Auto-Restart for Anesthesia Mode is set to 9 and is not configurable.</p> |
| Default Occlusion Pressure | Starting occlusion pressure limit which can be configured by Profile in 25 mmHg increments. |

Features and Displays (Continued)

Features and Definitions (Continued)



| Feature | Definition—Pump Module |
|-----------------------------|---|
| Free Flow Protection | All Alaris Pump module/GEMINI Infusion System administration sets use a unique clamping device (safety clamp on the lower fitment) to prevent inadvertent free-flow when administration set is removed from instrument. |
| KVO Rate Adjust | Used to select KVO (Keep Vein Open) rate (0.1 to 20 mL/h allowed), which is rate of fluid flow after an "Infusion Complete" occurs. KVO rate never exceeds infusion rate. |
| Occlusion Pressure | <p>A complete range of downstream occlusion detection options is provided.</p> <ul style="list-style-type: none"> • Pump mode: Downstream occlusion alarm threshold is 525 mmHg at flow rates of 30 mL/h or greater. For rates less than 30 mL/h, occlusion pressure is rate-dependent to ensure rapid response to occlusions. • Selectable pressure mode: Downstream occlusion alarm threshold can be adjusted in 25 mmHg increments, from 50 mmHg up to maximum occlusion pressure of 525 mmHg. • Auto-Restart: (See "Auto-Restart" definition.) <p>In addition, Alaris System provides fluid-side occlusion detection.</p> |
| Secondary Infusions | Dual rate sequential piggyback (secondary) infusions can be infused, with limits, at delivery rates and volumes independent of primary infusion parameters. Automatic changeover occurs to primary infusion parameters when secondary infusion is complete if an Alaris Pump module/GEMINI Infusion System check valve administration set is used. |

Features and Displays (Continued)

Features and Definitions (Continued)



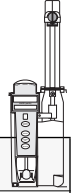
| Feature | Definition—Syringe Module |
|--|---|
| All Mode | When ALL is selected as the volume to be infused (VTBI), the entire contents of syringe is delivered. |
| Auto Pressure | When enabled and a pressure sensing disc is in use, Auto Pressure option is displayed in Pressure Limit screen. Auto Pressure automatically sets alarm limit for a shorter time to alarm, as follows: <ul style="list-style-type: none"> • If current pressure is 100 mmHg or less, system adds 30 mmHg to current pressure to create a new alarm limit. • If current pressure is greater than 100 mmHg, system adds 30% to current pressure to create a new alarm limit. |
| Auto Pressure Limit Adjustment | When a bolus is delivered, pressure alarm limits are temporarily raised to maximum limit. |
| Auto Syringe Size Identification | System automatically detects syringe size and narrows down syringe selection list. |
| Back Off | This feature is only available when administration set in use has a pressure sensing disc. When enabled, motor reverses plunger movement during an occlusion until pressure returns to preocclusion levels, automatically reducing bolus flow. |
| Fast Start | When Fast Start is enabled and an administration set having a pressure sensing disc is used, instrument runs at an increased rate when an infusion is first started, taking up any slack in drive mechanism. |
| Infusion Complete | An alert is given when current infusion is complete and VTBI has reached zero. |
| KVO | If enabled, allows continuous infusions to automatically switch into KVO mode upon completion. KVO option setting cannot be changed after instrument is powered on and a Profile selected. |
| Near End of Infusion (NEOI)^① | Allows an alarm to be configured to sound anywhere from 1 to 60 minutes prior to the end of the infusion. The NEOI alarm can be configured separately between continuous type infusions and intermittent infusions. A separate alert time can be set for continuous and intermittent infusions. |

NOTE:

- ① If the duration of the programmed infusion is less than or equal to the configured limit set in the Guardrail Editor, the NEOI alarm will occur at the start of the infusion.

Features and Displays (Continued)

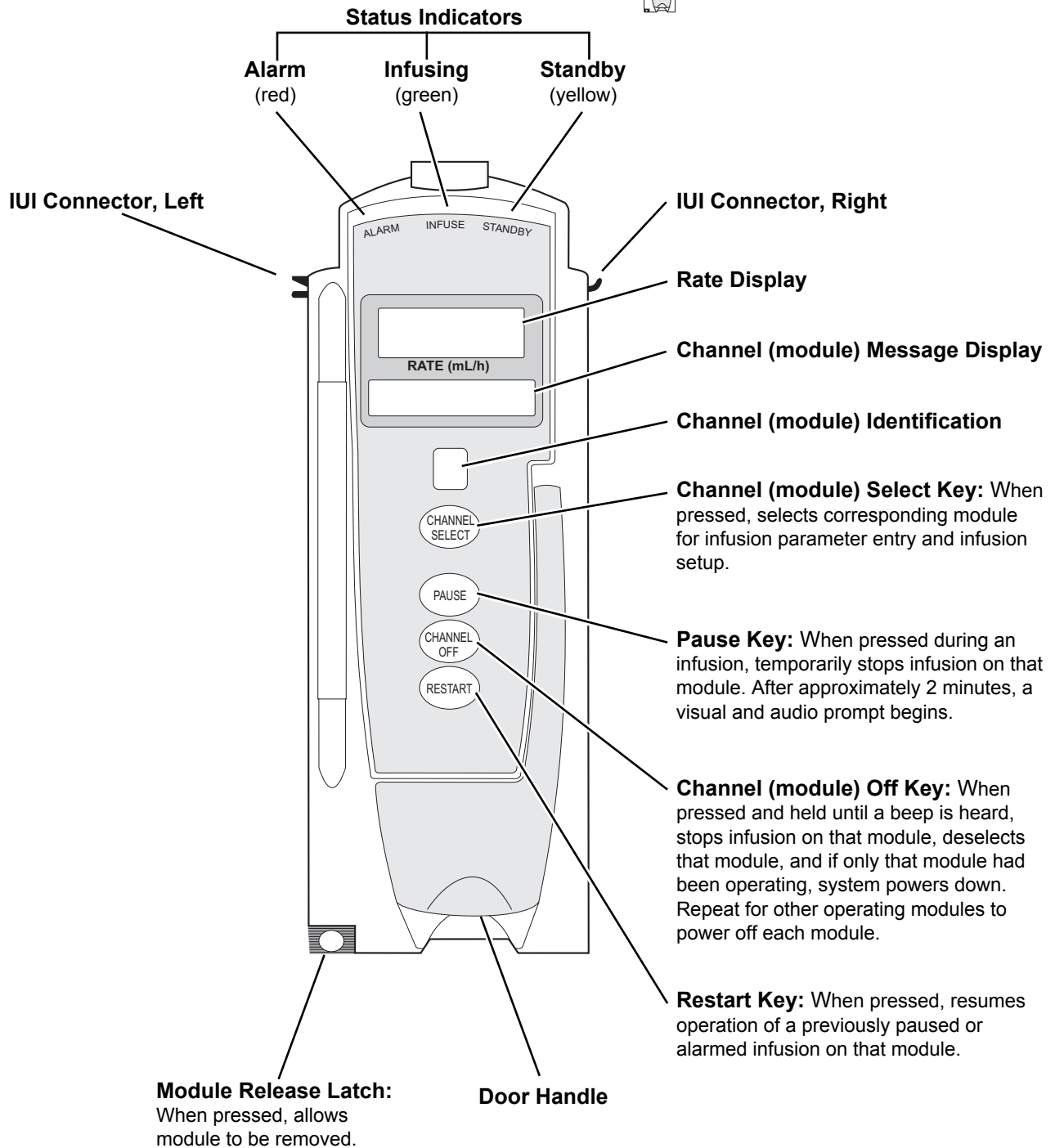
Features and Definitions (Continued)



| Feature | Definition—Syringe Module |
|---------------------------------|--|
| NEOI Snooze | Optional capability to remind users NEOI alarm has been silenced. This is shared Syringe and PCA setting. |
| Numeric Pressure Display | Dynamic pressure display is numerical and only available when pressure sensing disc is inserted. |
| Occlusion Pressure | <p>A complete range of downstream occlusion detection options is provided.</p> <ul style="list-style-type: none"> • With pressure sensing disc: Downstream occlusion alarm threshold is selectable between 25 and 1000 mmHg, in 1 mmHg increments. • Without pressure sensing disc: Downstream occlusion alarm threshold can be set to low, medium, or high. |
| Pressure Sensing Disc | <p>When installed, pressure sensing disc significantly improves instrument's pressure sensing capabilities for a faster occlusion detection time, and makes following features available:</p> <p>Auto Pressure Back-Off Customizable Pressure Alarm Settings (see "Occlusion Pressure") Fast Start Pressure Tracking</p> |
| Priming | Allows a limited volume of fluid to be delivered in order to prime administration set prior to being connected to a patient or after changing a syringe. When priming, a single continuous press of PRIME soft key delivers up to 2 mL of priming fluid. |
| Syringe Empty | Instrument gives an alert and stops when an empty syringe is detected. |
| Syringe Volume Detection | System automatically detects fluid volume in a syringe when it is inserted. |

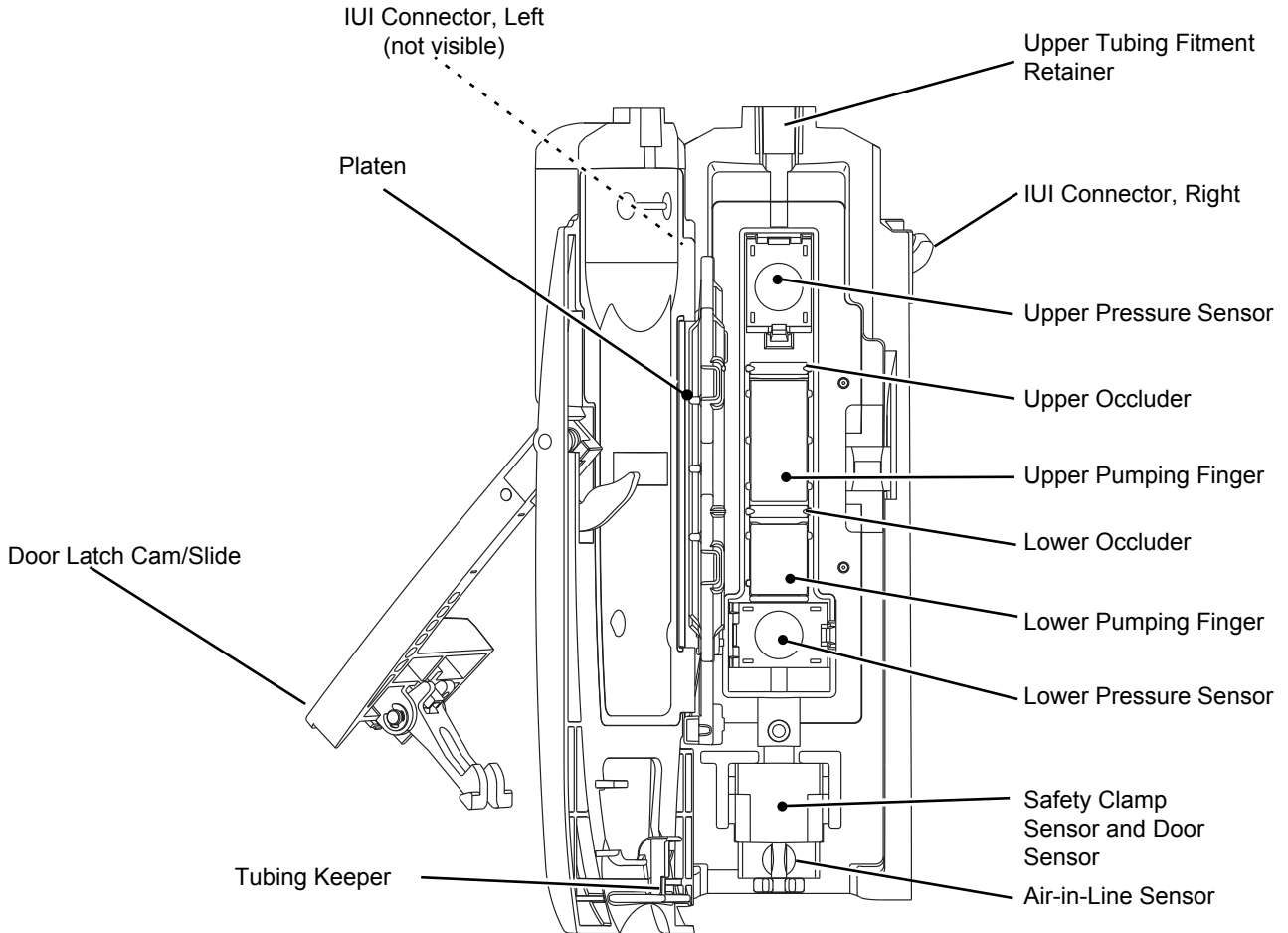
Features and Displays (Continued)

Operating Features, Controls, Indicators



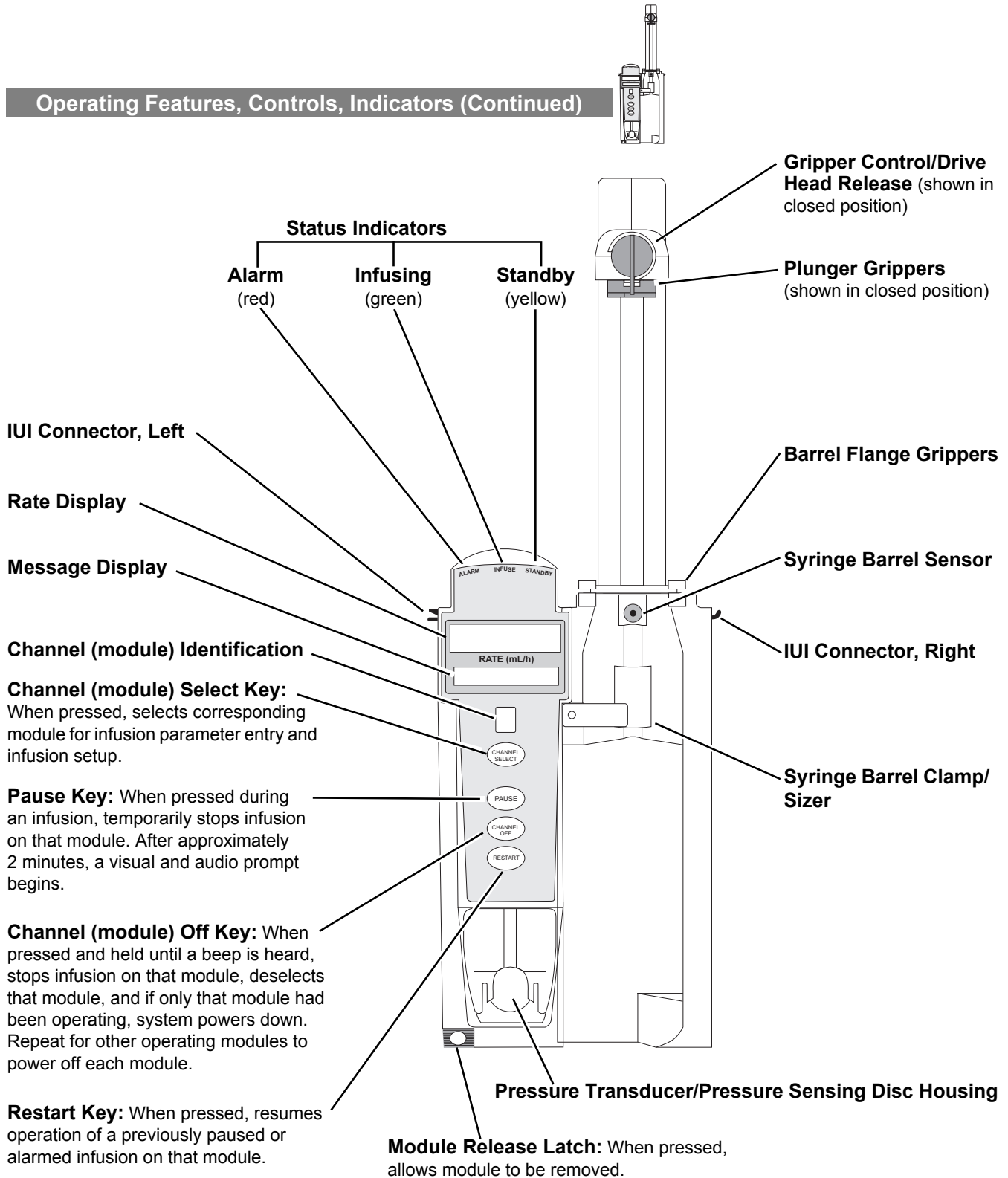
Features and Displays (Continued)

Operating Features, Controls, Indicators (Continued)



Features and Displays (Continued)

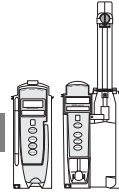
Operating Features, Controls, Indicators (Continued)



Features and Displays (Continued)

Displays

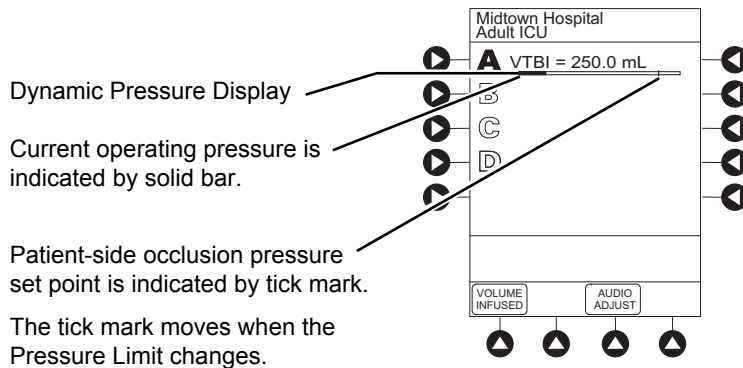
The displays illustrated throughout this document are for illustration purposes only. The display content varies, depending on configuration settings, type of administration set in use, hospital-defined Data Set uploaded using the Guardrails Suite MX, programmed drug calculation parameters, and many other variables. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.



Main Display

See the PC unit section of this User Manual.

Dynamic Pressure Display

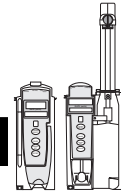


CAUTION



Although the dynamic pressure display bars for the Syringe module and Pump module both use the full width of the screen for display, they each **represent different ranges**. The Pump module's range is 50 to 525 mmHg and the Syringe module's range is 25 to 1000 mmHg.

Drug Calculation Definitions and Formulas



The Pump Module and Syringe module use the following parameters, entered during the drug calculation setup procedure:

- **Bolus Dose duration:** Time period over which Bolus Dose is to be administered.
- **Bolus Dose units:** Units used in calculating Bolus Dose. Bolus Dose units are selected from alternatives provided.
- **Diluent volume:** Volume of fluid used as diluent for drug (mL).
- **Dosing units:** Units used to calculate Continuous Infusion drug dose. Dosing Units are selected from alternatives provided.
- **Drug amount:** Amount of drug in IV container (gram, mg, mcg, mEq, or units).
- **Patient weight:** Weight of patient (kg); this is an optional parameter that is not needed unless drug dose is normalized for patient weight.
- **Time units:** Time base for all calculations (minute, hour, or day).

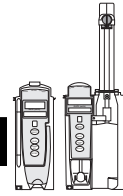
The Bolus Dose, drug dose, and flow rate parameters are calculated using the above parameters, as follows:

- Bolus Dose = Bolus Dose x patient weight (if used).
- Bolus Dose administration rate (**INFUSE AT:**):
When duration is entered = total dose / duration in minutes.
When Max Rate is used = Max Rate / 60 x concentration.
- Bolus Dose duration = bolus VTBI / bolus rate.
- Bolus Dose VTBI = bolus dose / drug concentration.
- Bolus rate = bolus VTBI / duration.
- Continuous drug dose = flow rate x drug concentration (normalized for patient weight if specified by entering a patient weight).
- Continuous flow rate = drug dose / drug concentration (normalized for patient weight if specified by entering a patient weight).
- Duration = VTBI / rate.
- Drug concentration = drug amount / diluent volume.
- Rate = VTBI / duration.

WARNING



The Drug Calculation feature is to be used only by **personnel properly trained** in the administration of continuously infused medications. Extreme caution should be exercised to ensure the correct entry of the drug calculation infusion parameters.



Drug Calculation Definitions and Formulas (Continued)

- Total Bolus Dose:
 - Bolus Dose not weight-based = Bolus Dose entered.
 - Bolus Dose weight-based = Bolus Dose x patient weight.
- Total dose:
 - Drug amount.
 - Drug amount / patient body surface area (BSA).
 - Drug amount / patient weight.

Configurable Settings

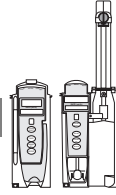
See the PC unit section of this User Manual for system configurable settings.

If the configuration settings need to be changed from the **Factory default** settings, refer to the applicable Technical Service Manual or contact CareFusion Technical Support, for technical, troubleshooting, and preventive maintenance information.

With the Profiles feature enabled, the settings are configured independently for each Profile. A hospital-defined, best-practice Data Set must be uploaded to enable the Profiles feature. Date and Time is a system setting and is the same in all Profiles.

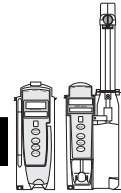
Configurable Settings (Continued)

Shared Infusion



| Feature | Default Setting | Options |
|--|----------------------|---|
| Delay Options • Callback | Disabled After | Enabled - Disabled None, Before, After, Before and After |
| Drug Calculation • Bolus Dose | Disabled Disabled | Enabled - Disabled Enabled - Disabled |
| Multidose • Callback | Disabled None | Enabled - Disabled None, Before, After, Before and After |
| Pressure Dynamic (Dynamic Pressure Display) | Disabled | Enabled - Disabled |
| Volume/Duration | Disabled | Enabled - Disabled |

Configurable Settings (Continued)



Pump Module



| Feature | Default Setting | Options |
|--|--|--|
| Accumulated Air | Enabled | Enabled - Disabled |
| Air-in-Line Settings (single bolus) | 75 mL | 50, 75, or 250 mL Anesthesia Mode only: 500 mL |
| Auto-Restart Attempts | 0 | 0 - 9 attempts Anesthesia Mode only: 9 attempts |
| KVO (Keep Vein Open) | 1 mL/h | 0.1 - 20 mL/h |
| Max Rate | 999 mL/h | 0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments |
| Max VTBI | 9999 mL | 0.1 - 9999 mL |
| Pressure Mode <ul style="list-style-type: none"> Mode Selection Lock Status Max Occlusion Pressure Default Starting Occlusion Pressure | Pump Unlocked 525 mmHg 525 mmHg | Pump, Selectable Locked, Unlocked 50 - 525 mmHg in 25 mmHg increments (adjustable only in Selectable Pressure Mode) 50 - 525 mmHg in 25 mmHg increments (configured by Profile and adjustable only in Selectable Pressure Mode) |
| SEC to PRI Alert | Enabled | Enabled - Disabled |
| Secondary (Dual Rate Sequential Piggybacking) | Disabled | Enabled - Disabled |

Configurable Settings (Continued)

Syringe Module



| Feature | Default Setting | Options |
|---|----------------------------------|---|
| ALL Mode | Disabled | Enabled - Disabled |
| Auto Pressure | Disabled | Enabled - Disabled |
| Back Off (after occlusion) | Enabled | Enabled - Disabled |
| Fast Start | Enabled | Enabled - Disabled |
| KVO (Keep Vein Open) <ul style="list-style-type: none"> Rate Adjust Volume Adjust | Disabled 1 mL/h 5% | Enabled - Disabled 0.01 - 2.5 mL/h (0.01 - 0.09 mL/h available for 1 mL and 3 mL syringes) 0.5 - 5% (Based on the total syringe size, not the volume of fluid in the syringe) |
| Max Rate | 999 mL/h | 0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments |
| Near End (NEOI) <ul style="list-style-type: none"> Continuous Alert Time Intermittent NEOI Intermittent Alert Time | Disabled 60 Disabled 15 | Enabled - Disabled 1 - 60 minutes Enabled - Disabled 1 - 60 minutes |
| NEOI Snooze (Shared Syringe and PCA setting) | Disabled | Enabled - Disabled 5, 10, or 15 minutes |
| Occlusion Pressure Set Point <ul style="list-style-type: none"> With Disc No Disc | 1000 mmHg High* | 25 - 1000 mmHg in 1 mmHg increments Low (200 mmHg) Medium (500 mmHg) High (800 mmHg) |
| Priming | Disabled | Enabled - Disabled |

NOTE:

*Occlusion Pressure Point cannot be set higher than the default setting.

Specifications

Pump Module



Accumulated Air Window:

| Single Bolus Setting (mcL) ^① | Volume Window (mL) | % Air that Causes Alarm | Volume (mL) that Causes Alarm |
|---|--------------------|-------------------------|-------------------------------|
| 50 | 2.8 | 10% | 0.28 |
| 75 | 8.0 | 20% | 1.6 |
| 250 | 8.0 | 30% | 2.4 |
| 500 ^② | 12.0 | 30% | 2.4 |

NOTE:

- ① In a standard bore tubing set:
 50 mcL is approximately 0.34 inches of air
 75 mcL is approximately 0.51 inches of air
 250 mcL is approximately 1.7 inches of air
- ② In Anesthesia Mode only.

Bolus Volume, Maximum after Occlusion:

| Pressure Limit (mmHg) | Rate (mL/h) | Bolus Volume (mL) |
|-----------------------|-------------|-------------------|
| 50 | 25 | ≤0.3 |
| 525 | 25 | ≤0.6 |

Critical Volume:

Maximum over-infusion that can occur in the event of a single fault condition is 0.6 mL.

Dimensions:

3.3" W x 8.9" H x 5.5" D

Environmental Conditions:

| | Operating | Storage/Transport |
|---|-------------------------------------|------------------------------------|
| Atmospheric Pressure | 525 - 4560 mmHg (700 - 6080 hPa) | 375 - 760 mmHg (500 - 1013 hPa) |
| Relative Humidity (Avoid prolonged exposure to relative humidity >85%) | 20 - 90% Noncondensing | 5 - 85% Noncondensing |
| Temperature Range | 41 - 104°F (5 - 40°C) | -4 - 140°F (-20 - 60°C) |

Equipment Orientation:

To ensure proper operation, Alaris System must remain in an upright position.

Specifications (Continued)

Pump Module (Continued)



Flow Rate Programming Increments:

| Rate Range (mL/h) | Increments (mL/h) | |
|-------------------|-------------------|-------------------------|
| | User Input Rates | Device Calculated Rates |
| 0.1 - 9.99 | 0.1 | 0.01 |
| 10 - 99.9 | | 0.1 |
| 100 - 999 | 1 | 1 |

Fluid Ingress Protection: IPX1, Drip Proof

Infusion of Air, Means to Protect Patient from:

Ultrasonic Air-in-Line Detection
 Maximum single bolus size = selectable 50, 75, or 250 microliters nominal (500 microliters in Anesthesia Mode)

Infusion Pressure, Maximum:

654 mmHg (Maximum Occlusion Alarm Threshold plus tolerance)

KVO (Keep Vein Open) Rate:

Factory default setting is 1 mL/h if set rate is 1 mL/h or above; or set rate, if rate is 0.9 mL/h or below.

KVO Selection Range:

KVO rate can be set in System Configuration from 0.1 - 20 mL/h in 0.1 mL/h increments.

Occlusion Alarm Thresholds:

Pump Mode: 525 mmHg at rates ≥ 30 mL/h
 Varying level based on rate and patient back-pressure at rates < 30 mL/h.
 Selectable Mode: User selected, 50 - 525 mmHg in 25 mmHg increments.

Operating Principle:

Positive displacement

Specifications (Continued)

Pump Module (Continued)

**Rate Accuracy:**

Rate accuracy of Alaris System is $\pm 5\%$ at rates between 1 and 999 mL/h and $\pm 5.5\%$ at rates < 1 mL/h, 95% of the time with 95% confidence, under conditions listed below.

Infusion Rate Range: 0.1 - 999 mL/h
Ambient Temperature: $68 \pm 4^\circ\text{F}$ ($20 \pm 2^\circ\text{C}$)
Source Container Height: 20 inches above top of Pump module
Test Solution: Distilled Water
Distal Back pressure: 0 mmHg (0 kPa)
Needle: 18 gauge
Administration Set Model: 2210

WARNING

Variations of head height, back pressure, or any combination of these **can affect rate accuracy**. Factors that can influence head height and back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure can also be affected by type of catheter. See “Trumpet and Start-Up Curves” for data on how these factors influence rate accuracy.

Shock Protection:

Type CF, Defibrillator Proof patient applied part.

Time to Alarm, Maximum:

| Pressure Limit (mmHg) | Rate (mL/h) | Time to Alarm |
|-----------------------|-------------|-------------------|
| 50 | 1 | ≤ 5 minutes |
| 50 | 25 | ≤ 15 seconds |
| 525 | 1 | ≤ 45 minutes |
| 525 | 25 | ≤ 2 minutes |

Volume to be Infused**Programming Increments:**

| Range (mL) | Increments (mL) |
|-------------|-----------------|
| 0.1 - 9.99 | 0.01 |
| 10 - 999.9 | 0.1 |
| 1000 - 9999 | 1 |

Weight:

2.6 lbs

NOTE:

The minimum Volume To Be Infused (VTBI) for both LVP and Syringe module (applicable to all syringe sizes) is 0.1mLs. This applies to Continuous Infusions, Bolus Dose, Intermittent Infusions, and IV Fluids.

Specifications (Continued)

Syringe Module



Bolus Volume, Maximum after Occlusion:

WARNING



Installing a pressure sensing disc after an infusion has started can result in a bolus to the patient.

Without Pressure Sensing Disc:

| Pressure Setting | Bolus Volume (mL) |
|------------------|-------------------|
| Low | 0.512 |
| Medium | 0.776 |
| High | 1.103 |

With Pressure Sensing Disc:

| Pressure Setting | Bolus Volume (mL) | |
|------------------|-------------------|------------------|
| | Back Off Disabled | Back Off Enabled |
| 300 mmHg | 0.462 | 0.126 |
| 500 mmHg | 0.575 | 0.331 |
| 1000 mmHg | 0.839 | 0.323 |

Alaris System has a back-off safety feature that, when enabled and a pressure sensing disc is in use, is designed to reduce bolus volume on occlusion release.

Specifications (Continued)



Syringe Module (Continued)

Bolus Volume, Maximum after Occlusion: (Continued)

Maximum Bolus Volume specifications are based on following standard operating conditions:

- Atmospheric Pressure: 645 - 795 mmHg
- Disposable Type:
 - No Pressure Disc: #30914
 - With Pressure Disc: #30920
- Humidity: 20 - 90%
- Rate: 5 mL/h
- Syringe Type: BD 50/60 mL
- Temperature: 68 ±4°F
- Volume Collection Time: approximately 2 minutes




Critical Volume:

Maximum over-infusion which can occur in the event of a single-fault condition will not exceed 2% of nominal syringe fill volume during loading and 1% of maximum syringe travel after syringe loading.

Dimensions:

4.5" W x 15.0" H x 7.5" D

Environmental Conditions:

| Symbol | Meaning | Operating | Storage/Transport |
|---|---|-------------------------------------|------------------------------------|
|  | Atmospheric Pressure | 525 - 4560 mmHg (700 - 6080 hPa) | 375 - 760 mmHg (500 - 1013 hPa) |
|  | Relative Humidity (Avoid prolonged exposure to relative humidity >85%) | 20 - 90% Noncondensing | 5 - 85% Noncondensing |
|  | Temperature Range | 41 - 104°F (5 - 40°C) | -4 - 140°F (-20 - 60°C) |

Equipment Orientation:

To ensure proper operation, Alaris System must remain in an upright position.

Specifications (Continued)

Syringe Module (Continued)



Flow Rate Programming: Flow rate range is from 0.01 to 999 mL/h and can be selected as follows:

| Flow Rates (mL) | Selectable Increments (mL/h) |
|-----------------|------------------------------|
| 0.01 - 9.99 | 0.01 |
| 10 - 99.9 | 0.1 |
| 100 - 999 | 1 |

Rate Restriction by Syringe Size:

| Syringe Size (mL) | Flow Rate Range (mL/h) |
|-------------------|------------------------|
| 50/60 | 0.1 - 999 |
| 30 | 0.1 - 650 |
| 20 | 0.1 - 500 |
| 10 | 0.1 - 250 |
| 5 | 0.1 - 150 |
| 3 | 0.01 - 100 |
| 1 | 0.01 - 30 |

Fluid Ingress Protection: IPX1, Drip Proof

Infusion Pressure, Maximum: Without Pressure Sensing Disc: approximately 800 mmHg (actual occlusion pressure varies based on syringe size and manufacturer)
With Pressure Sensing Disc: 1060 mmHg

KVO (Keep Vein Open) Rate: Factory default setting is 1 mL/h if set rate is 1 mL/h or above; or set rate, if rate is 0.9 mL/h or below.

KVO Rate Range: KVO rate can be set in System Configuration, in 0.01 mL/h increments, as follows:
0.01 - 2.5 mL/h (0.01 - 0.09 mL/h available for 1 mL and 3 mL syringes)

Occlusion Alarm Thresholds: Without Pressure Sensing Disc: Three settings—Low, Medium, High
With Pressure Sensing Disc: User selected, 25 - 1000 mmHg in 1 mmHg increments.

Operating Principle: Positive displacement

Specifications (Continued)

Syringe Module (Continued)



Rate Accuracy: $\pm 2\%$ of full scale plunger travel (not including syringe variation)

WARNING

Syringe size and running force, variations of back pressure, or any combination of these **can affect rate accuracy**. Factors that can influence back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure can also be affected by type of catheter. See “Trumpet and Start-Up Curves” for data on how these factors influence rate accuracy.

Shock Protection: Type CF, Defibrillator Proof

Time to Alarm, Maximum:

| Rate (mL/h) | Pressure Limit | |
|-------------|----------------------|---------------------------------------|
| | No Disc High Setting | With Disc Highest (1000 mmHg) Setting |
| 1 | 120 minutes | 105 minutes |
| 5 | 30 minutes | 30 minutes |

Maximum Time to Alarm specifications are based on following standard operating conditions:

Atmospheric Pressure: 645 - 795 mmHg
 Back Pressure: 0 mmHg before producing occlusion
 Disposable Type:
 No Pressure Disc: #30914
 With Pressure Disc: #30920
 Humidity: 20 - 90%
 Syringe Type: BD 50/60 mL
 Temperature: 68 $\pm 4^\circ$ F

Volume to be Infused Programming Increments:

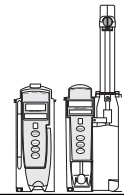
| Range (mL) | Increments (mL) |
|-------------|-----------------|
| 0.01 - 9.99 | 0.01 |
| 10 - 60 | 0.1 |

Weight: 4.5 lbs

NOTE:

The minimum Volume To Be Infused (VTBI) for both LVP and Syringe module (applicable to all syringe sizes) is 0.1mLs. This applies to Continuous Infusions, Bolus Dose, Intermittent Infusions, and IV Fluids.

Symbols



See the PC unit section of this User Manual for system symbols.

| Symbol | Meaning—Pump and Syringe Modules |
|----------------|---|
| | The Infusion Alarm Silence symbol indicates that infusion alarms have been acknowledged and silenced. Press the CANCEL SILENCE soft key to reactivate a previously silenced alarm audio. If the alarm condition has not been resolved, the alarm audio will resume. |
| | Type CF defibrillation-proof patient applied part. |
| Single-Use | Single-Use. Do not reuse. |
| | Product contains micron filter, where XX represents filter size. |
| | DEHP in fluid pathway. |
| | Non-DEHP plasticizer in fluid pathway. |
| | No DEHP in fluid pathway. |
| | Product is latex-free. |
| | Product incorporates Needle-Free Valve ports and should not be accessed by a needle. |
| | Approximate administration set priming volume. |
| | Expiration date for product is identified near hour glass symbol. |
| | Do not use if package is damaged. |
| | Manufacturer |

| Symbol | Meaning—Pump Module |
|--------|--|
| | Drops per milliliter specification for product is identified on drop symbol. |

Trumpet and Start-Up Curves

In this instrument, as with all infusion systems, the action of the pumping mechanism and variations in individual administration sets cause short-term fluctuations in rate accuracy. The following graphs show typical performance of the system, as follows:

- Accuracy during various time periods over which fluid delivery is measured (trumpet curves).
- Delay in onset of fluid flow when infusion commences (start-up curves).

Trumpet curves are named for their characteristic shape. They display discrete accuracy data averaged over particular time periods or "observation windows," not continuous data versus operating time.

Over long observation windows, short-term fluctuations have little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effect, as represented by the "mouth" of the trumpet. Knowledge of system accuracy over various observation windows might be of interest when certain drugs are being administered.

Because the clinical impact of short-term fluctuations on rate accuracy depends on the half-life of the drug being infused and on the degree of intravascular integration, the clinical effect cannot be determined from the trumpet curves alone. Knowledge of the start-up characteristics should also be considered.

The start-up curves represent continuous flow rate versus operating time for 2 hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data.

Pump Module

Effects of Pressure Variations



Under conditions of +100 mmHg pressure, the Pump module typically exhibits a long-term accuracy offset of approximately -3.5% from mean values.

Trumpet and Start-Up Curves (Continued)

Pump Module (Continued)



Under conditions of +300 mmHg pressure, the Pump module typically exhibits a long-term accuracy offset of approximately -6.2% from mean values.

Under conditions of -100 mmHg pressure, the Pump module typically exhibits a long-term accuracy offset of approximately +0.5% from mean values.

Resulting trumpet observation points typically track those of accuracy; therefore, no significant change in short-term variations result under these pressure conditions.

Effects of Negative Solution Container Heights

With a negative head height of -0.5 meters, the Pump module typically exhibits a long-term accuracy offset of approximately -2.8% from mean values.

Resulting trumpet observation points typically track those of accuracy; therefore, no significant change in short-term variations result under negative head height conditions.

Syringe Module



Trumpet and start-up curves have been provided for 1.0 mL/h and 5.0 mL/h. Measurements for trumpet curve rates below 1.0 mL/h are not provided because of the difficulty in measuring extremely small volumes over a large duration of time. In this case, the linear relationship of the plunger position and velocity to syringe volume and rate is verified, and is a function of the accuracy of the design.

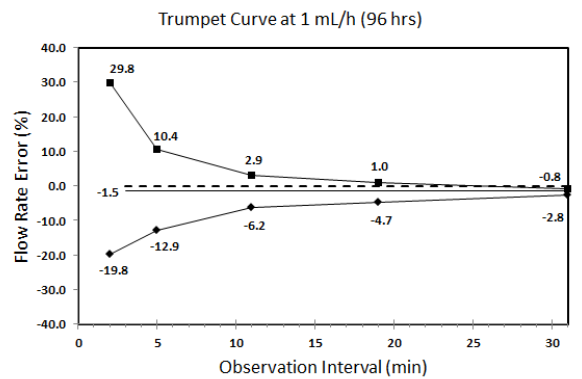
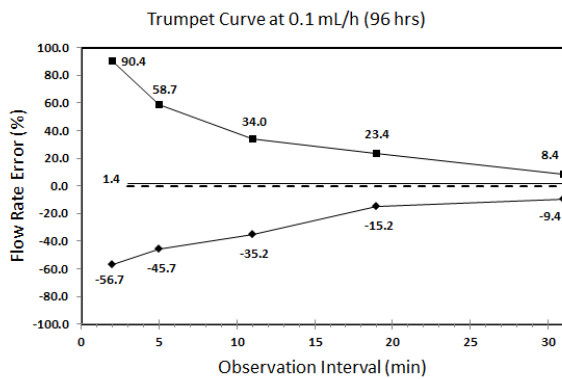
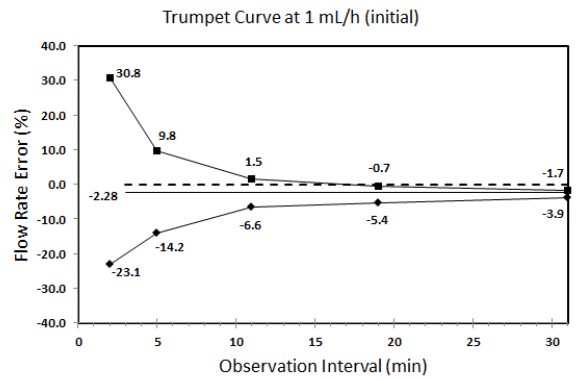
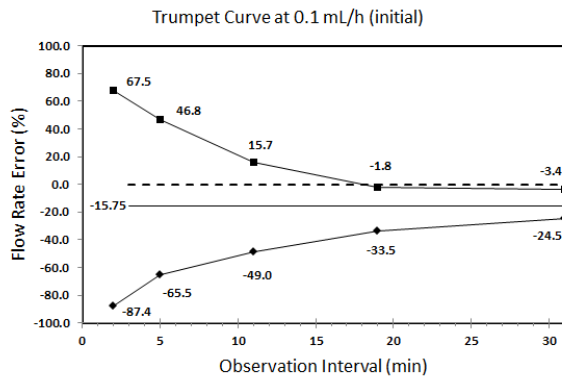
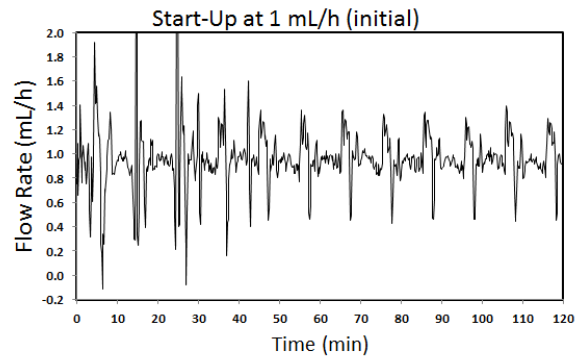
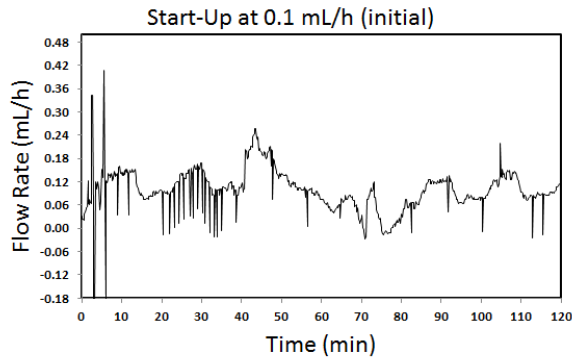
Measurements for trumpet curve rates above 5.0 mL/h are also not provided, as the syringe volume is displaced in a very short time with a rate up to 999 mL/h. Accuracy, however, is assured with the design implementation.

Under conditions of -100 mmHg, +100 mmHg, and +300 mmHg pressures, the Syringe module typically exhibits a long-term accuracy offset of approximately 0.2% or less from the mean value.

Trumpet and Start-Up Curves (Continued)

Graphs

Pump Module



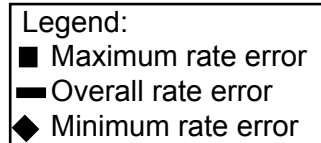
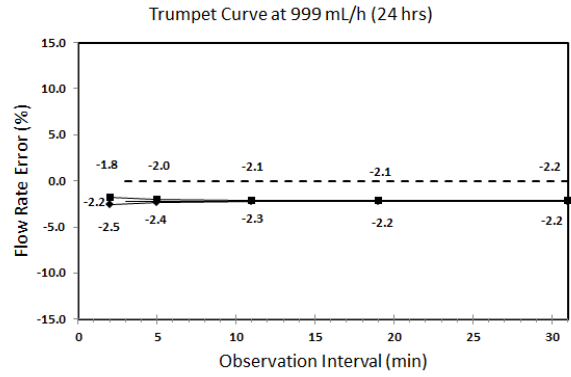
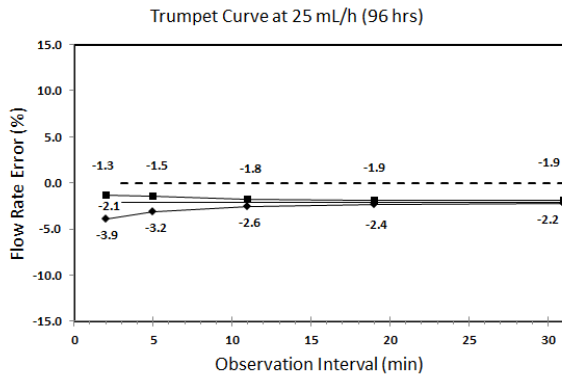
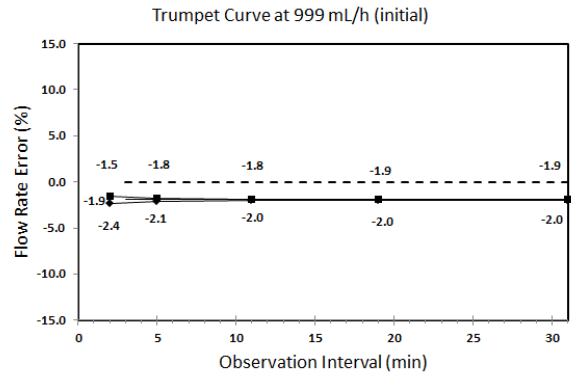
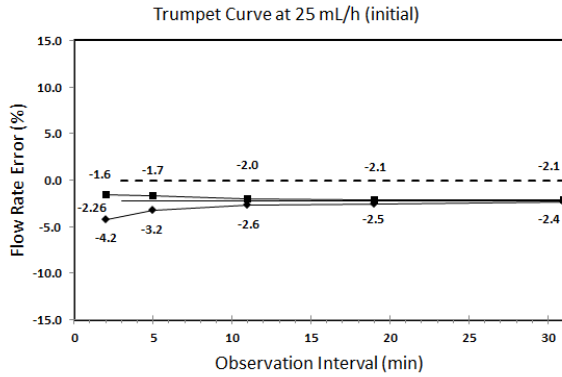
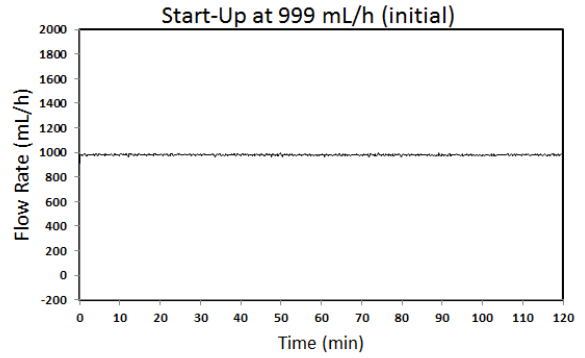
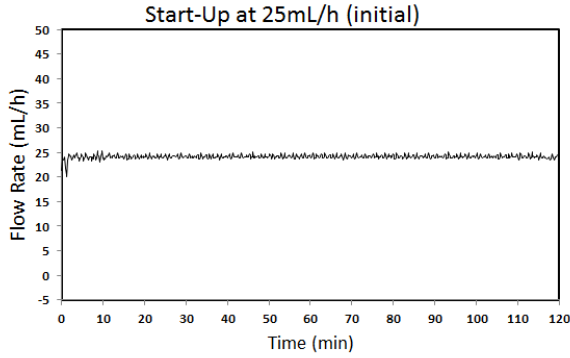
NOTE: The plot range has been increased to $\pm 100\%$ to allow visualization of the graph.

Legend:
 ■ Maximum rate error
 — Overall rate error
 ◆ Minimum rate error

Trumpet and Start-Up Curves (Continued)

Graphs—Pump Module (Continued)

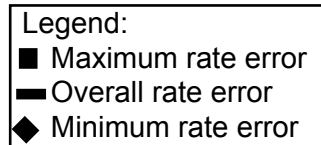
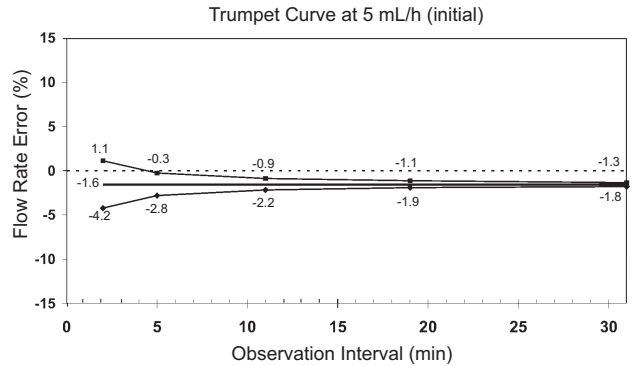
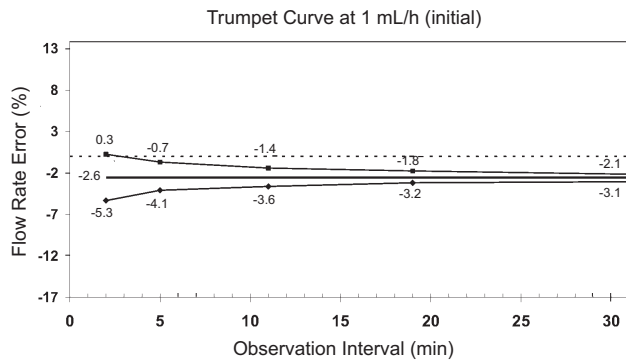
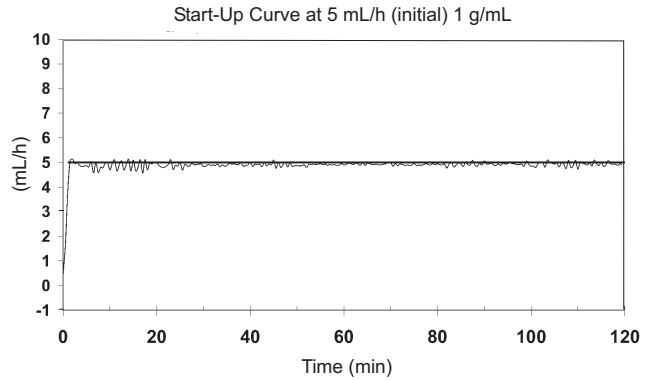
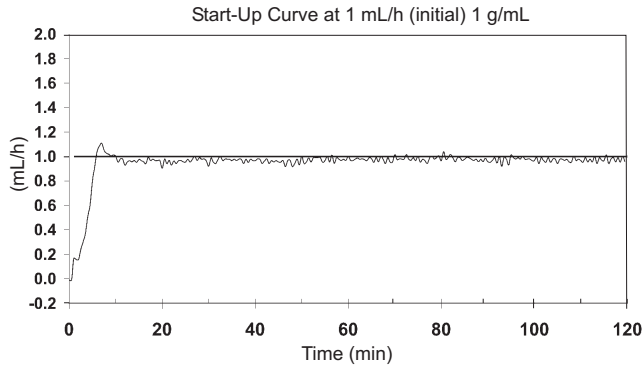
Pump Module



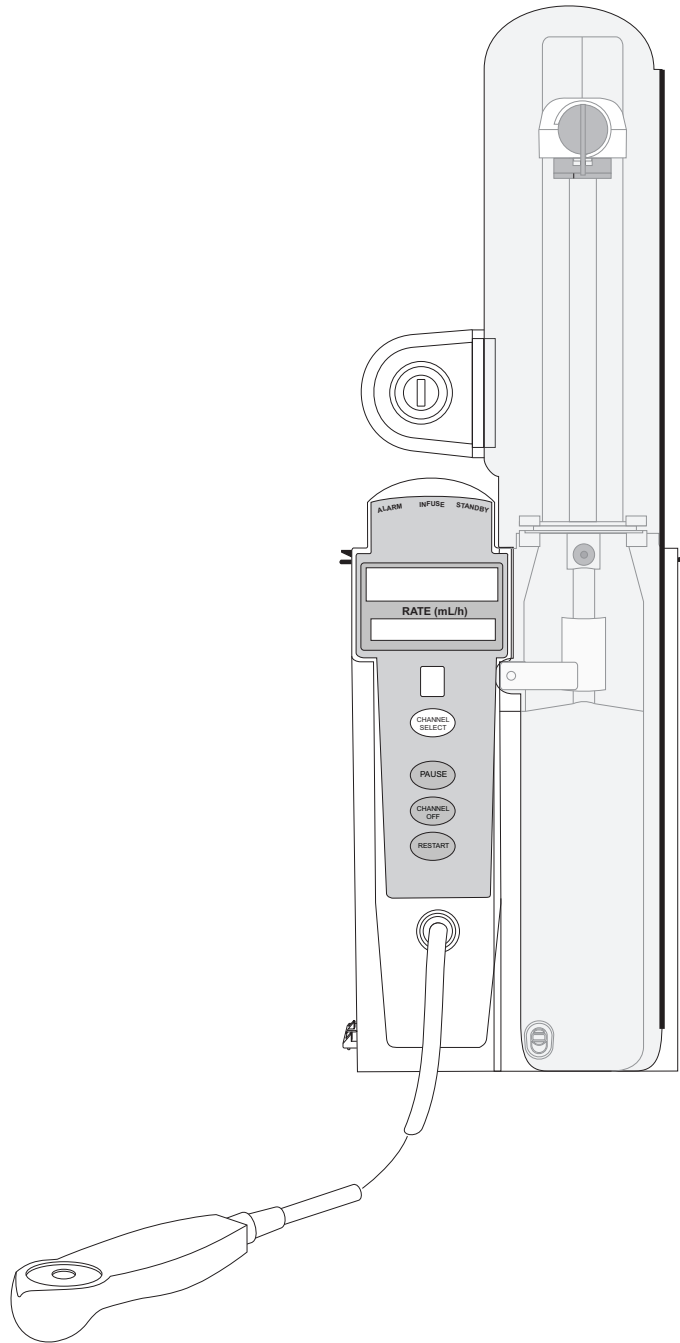
Trumpet and Start-Up Curves (Continued)

Graphs (Continued)

Syringe Module



Alaris PCA Module Model 8120



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Introduction

This section of the User Manual provides PCA module (Model 8120) instructions and information. It is used in conjunction with:

- Alaris product administration set instructions
- Drug product labeling
- *PCA Module Technical Service Manual*
- *PC unit chapter of this User Manual*
- System Maintenance software (and its instructions) for Alaris System check-in, maintenance, and wireless configuration

WARNING



Read all instructions, for both the PCA module and PC unit, before using the Alaris System.

The PCA module (Patient Controlled Analgesia) is intended for facilities that use syringe pumps for the delivery of medications or fluids. The PCA module is indicated for use on adults, pediatrics and neonates for continuous or intermittent delivery through clinically acceptable routes of administration; such as, intravenous (IV), subcutaneous or epidural. Only one PCA module can be connected to the Alaris System.

Administration Sets/Syringes: See "General Information" for specific administration set and syringe instructions.

- Administration Set Information
- Compatible Syringes

Alarms, Errors, Messages: See "Troubleshooting and Maintenance" for module-specific alarms, errors, and messages.

Contraindications: None known.

Electromagnetic Environment: See "Appendix" section of this User Manual ("Regulations and Standards," "Compliance").

Attach and Detach Dose Request Cord

The Dose Request Cord must be attached to the PCA module when delivering a PCA dose or PCA + continuous dose infusion.

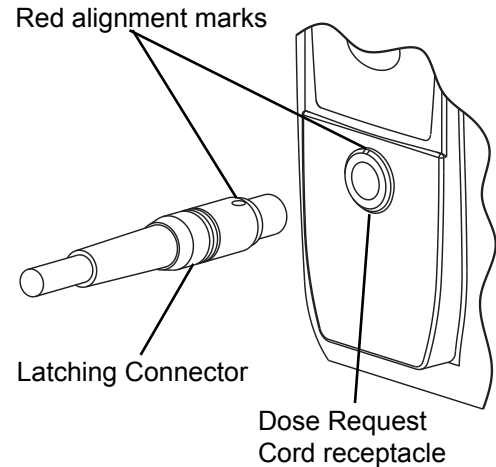
WARNING



Carefully locate the Dose Request Cord to reduce the possibility of patient entanglement or strangulation.

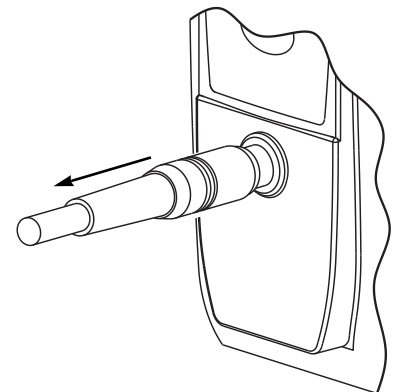
To attach Dose Request Cord:

Insert latching connector into Dose Request Cord attachment. Red marking on latching connector should be aligned with red marking on Dose Request Cord receptacle.



To detach Dose Request Cord:

Hold body of latching connector and pull straight out, without twisting or turning, from Dose Request Cord receptacle.



Prepare and Load Syringe and Administration Set

For instructions on how to go from checking in a PCA module to preparing it for an infusion setup, see "General Setup and Operation."

Prepare Syringe and Administration Set

1. Prepare syringe (see *Compatible Syringes* on page 3-49") in accordance with manufacturer's User Manual.
2. Prepare administration set in accordance with manufacturer's User Manual.
3. Attach upper fitting of administration set to syringe tip.

WARNING



Use only standard or pre-filled, single-use, disposable syringes (with luer-lock connectors) and nondedicated administration sets with integrated anti-siphon valves, designed for use on syringe-type PCA pumps. The use of any other **syringe or administration set** can cause improper instrument operation, resulting in inaccurate fluid delivery, pressure sensing, or other potential hazards. For a list of compatible syringes, refer to *Compatible Syringes* on page 3-49.

WARNING

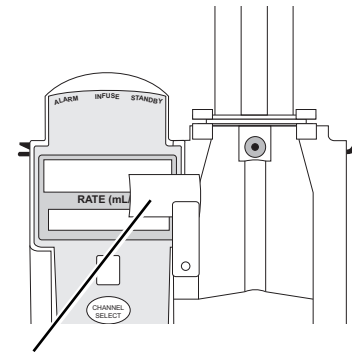


Before loading or unloading the syringe, always turn off fluid flow to the patient, using the tubing clamp or stopcock. Uncontrolled fluid flow can occur when the administration set is not clamped or turned off, and can cause serious injury or death.

Prepare and Load Syringe and Administration Set (Continued)

Load Syringe and Administration Set

1. Open syringe barrel clamp.
 - a. Pull syringe barrel clamp out and hold.
 - b. Rotate clamp to left (clockwise or counter clockwise) until it clears syringe chamber.
 - c. Gently release clamp.



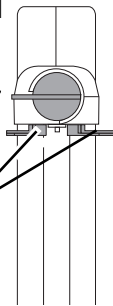
Syringe Barrel Clamp Open

2. Raise drive head to its fully extended position.
 - a. Twist gripper control clockwise and hold in position. ①
 - b. While holding gripper control in open position, raise drive head to full extension.
 - c. Gently release gripper control.

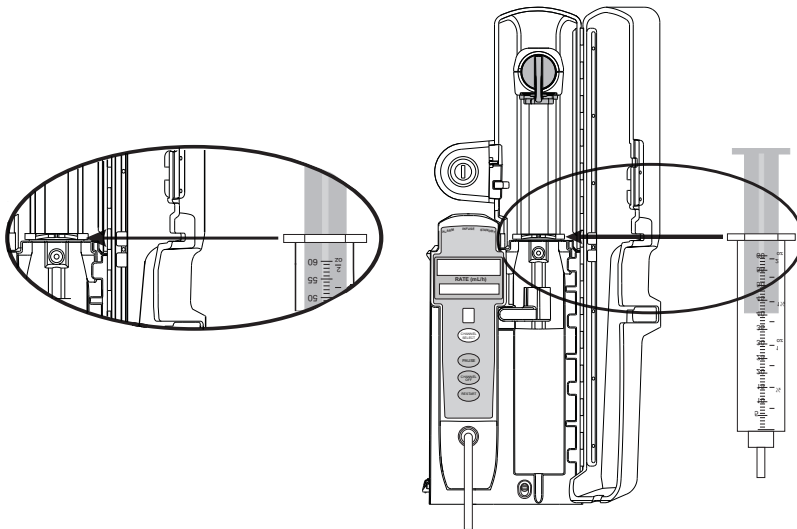
Drive Head Fully Extended

Gripper Control/Drive Head Release in Open Position

Plunger Grippers Open



3. Insert syringe (from front of instrument) by sliding flat edge of syringe barrel flange between barrel flange grippers.



WARNING

Before loading the syringe, check it for damage or defects.

CAUTION

When initially loading the syringe, allow for the volume of fluid contained in the administration set and retained in the syringe at the end of an infusion, as this "dead space" will not be infused.

Prepare and Load Syringe and Administration Set (Continued)

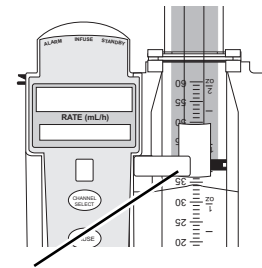
Load Syringe and Administration Set (Continued)

4. Lock syringe in place.
 - a. Pull syringe barrel clamp out and hold.
 - b. Rotate clamp to right (clockwise or counter clockwise) until it lines up with syringe.
 - c. Gently release clamp against syringe.

WARNING



Ensure that syringe barrel, flange, and plunger are installed and secured correctly. Failure to **install syringe correctly** can result in uncontrolled fluid flow to the patient, and can cause serious injury or death.



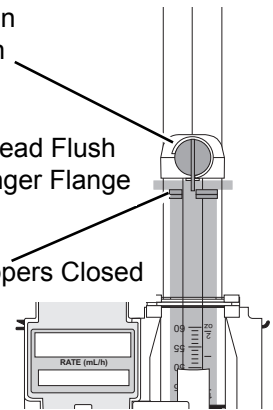
Syringe Barrel Clamp Closed

5. Lower drive head and lock plunger in place with plunger grippers.
 - a. Twist gripper control clockwise and hold in position. ①
 - b. While holding gripper control in open position, gently lower drive head until it makes contact with plunger flange.
 - c. Gently release gripper control.
 - d. Ensure that plunger grippers lock and hold plunger in place.

Gripper Control in Closed Position

Drive Head Flush with Plunger Flange

Plunger Grippers Closed



NOTE:

- ① The gripper control is spring loaded. When twisted to the open position and then released, it (and the plunger grippers) returns to the closed position.

Prepare and Load Syringe and Administration Set (Continued)

Security Lock Key Positions

There are three key positions associated with the security lock:

- UNLOCK unlocks security door. Key must be in this position when loading or changing a syringe.
- PROGRAM allows for initial programming or changes in programming without unlocking security door or interrupting current infusion.^①
- LOCK locks security door. Key must be in this position to start an infusion.

NOTE:

- ① See *Change Programming Parameters During an Infusion* on page 3-26.

References throughout this procedure to specific drugs and drug doses are for illustration purposes only. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

See "General Information," "Features and Displays" and the PC unit section of this User Manual for information about:

- Displays
- Operating Features, Controls, Indicators

Prepare Infusion

Select Syringe Type and Size

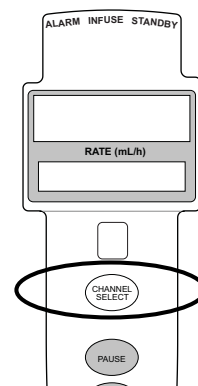
At the start of an infusion program, the system prompts the user to select and confirm the syringe type and size. The system automatically detects the syringe size, and lists syringe types and sizes that most closely match the installed syringe. If the syringe is not recognized, **Syringe not recognized** is displayed.

WARNING



- Ensure that the displayed **syringe manufacturer and size** correctly identifies the installed syringe. Mismatches can cause an under- infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, refer to *Compatible Syringes* on page 3-49.

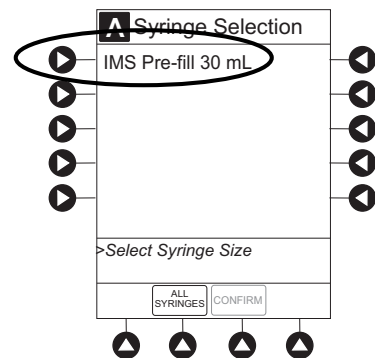
1. Press **CHANNEL SELECT** key. Key must be in **PROGRAM** position.



Prepare Infusion (Continued)

Select Syringe Type and Size (Continued)

- Press soft key next to installed syringe type and size. If installed syringe is not listed, press **ALL SYRINGES** soft key and select syringe from list.
 - Selection is highlighted.
 - CONFIRM** soft key is activated.
- To accept, press **CONFIRM** soft key.
Drug Library screen is displayed.



Prime

The Priming option can be enabled at the time the Alaris System is configured for use. The Priming selection (**PRIME** soft key) is available only after the syringe type and medication selection (prior to infusion mode selection).

WARNING

When priming:

- Ensure that patient is not connected.
- Ensure that air is expelled from line prior to beginning infusion (unexpelled air in line could have serious consequences).

Failure to prime correctly can delay infusion delivery and cause the total volume to be infused to read higher than the actual total delivered to the patient.

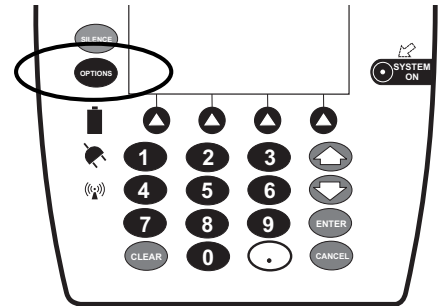
CAUTION

During priming, the pressure limit alarms are temporarily increased to their maximum level.

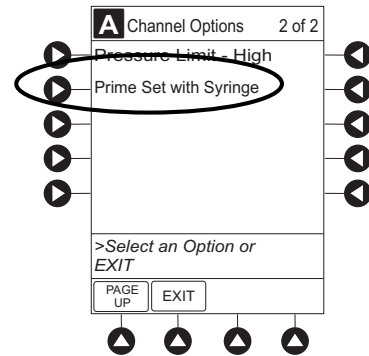
Prepare Infusion (Continued)

Prime (Continued)

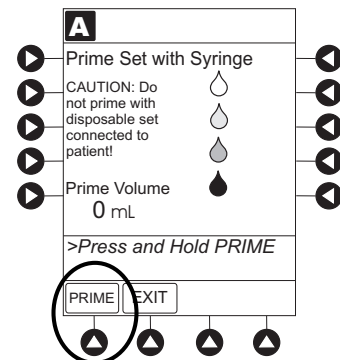
1. Press **OPTIONS** key.



2. Press **Prime Set with Syringe** soft key.



3. Press and hold **PRIME** soft key until fluid flows and priming of syringe administration set is complete.
 - Volume used during priming is displayed but is not added to **VTBI**.
 - Fluid is delivered during priming only while **PRIME** soft key is pressed. Each press of **PRIME** soft key delivers up to 2 mL at the maximum rate of the selected syringe. (see *Rate Restriction by Syringe Size*: on page 3-59) of priming/fluid per continuous press. To deliver additional amounts, press **PRIME** soft key again.

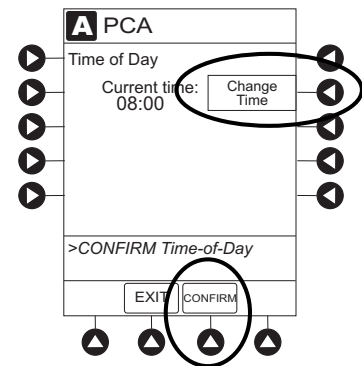


4. When priming is complete, release **PRIME** soft key.
5. To return to main screen, press **EXIT** soft key.
Guardrails Drug Setup screen is displayed.
6. Select infusion mode.

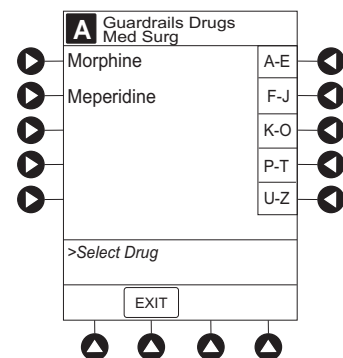
Prepare Infusion (Continued)

Program an Infusion

1. Perform steps in "Getting Started," "Prepare Syringe and Administration Set."
2. Perform following steps (see PC unit section of this User Manual, "General Setup and Operation," "Startup"):
 - a. Power on system.
 - b. Choose **Yes** or **No** to **New Patient?**
 - c. Select Profile, if required.
 - d. Enter patient identifier, if required.
3. Press **CHANNEL SELECT** key.
4. Unlock security door or set key to **PROGRAM** position.
5. Confirm time of day or change time if necessary.



6. Perform following steps:
 - a. Load syringe and administration set (see "Getting Started," "Load Syringe and Administration Set").
 - b. Select and confirm syringe type and size (see "Select Syringe Type and Size").
7. Press soft key next to desired drug.
Drug/Concentration screen appears.



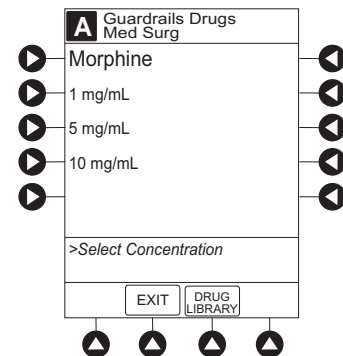
Prepare Infusion (Continued)

Program an Infusion (Continued)

8. Press soft key next to desired concentration.
 - Drug/Concentration confirmation screen appears.
 - To view additional drugs/concentrations, press **PAGE UP** and **PAGE DOWN** soft keys.
 - Facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (___ / ___ mL) and allow clinician to enter drug amount and diluent volume.
9. Confirm drug and concentration selection and press **Yes** soft key. To change selection, press **No** soft key.
 - If **Yes** was selected and facility has defined a Clinical Advisory for that drug, a message appears. To continue programming, press **CONFIRM** soft key.
 - If the programmed "___ / ___ mL" concentration is the outside the Soft Limit, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion must be reprogrammed.
 - If the programmed "___ / ___ mL" concentration is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Drug amount and diluent volume must be reprogrammed.
 - If there is a potential for a programmed "___ / ___ mL" parameter to result in an excessive volume or dose being delivered, following prompt appears:

"Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram."

The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:



Prepare Infusion (Continued)

Program an Infusion (Continued)

Drug Amount 1 mg
Diluent Volume 1 mL

OR

Drug Amount 30 mg
Diluent Volume 30 mL

- If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

10. Verify correct parameters and press **NEXT** soft key to confirm.
11. Prime syringe using Prime feature, if desired.

Infusion Modes

Programming Parameters

The PCA module uses the following programming parameters, depending on infusion mode selected. See "General Information," "Features and Definitions" for infusion mode definitions and features.

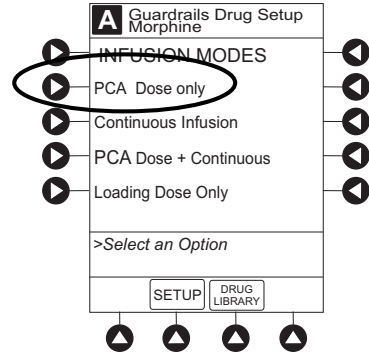
- **PCA Dose:** patient self-administered dose.
- **Lockout Interval:** programmed time elapse between availability of PCA doses.
- **Continuous Dose:** basal rate dose.
- **Max Limit:** (optional) total amount of drug which can be infused over a specified time period.
- **Loading Dose:** (optional) Bolus Dose infused prior to initiation of PCA infusion.
- **Bolus Dose:** (optional) additional dose programmed after initiation of PCA infusion.

When the PC unit is in the Infusion Mode Selection, Infusion Setup or Bolus Setup screens, a patient dose request from the Dose Request Cord is handled as an unmet demand.

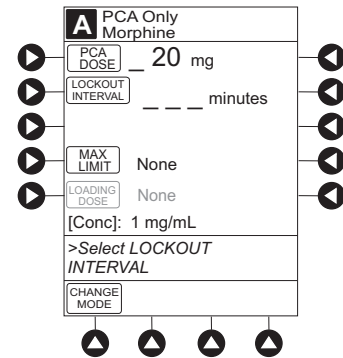
Infusion Modes (Continued)

Set Up PCA Dose Only

1. Perform steps in "Prepare Infusion."
2. Press **PCA Dose Only** soft key from Infusion Mode screen.

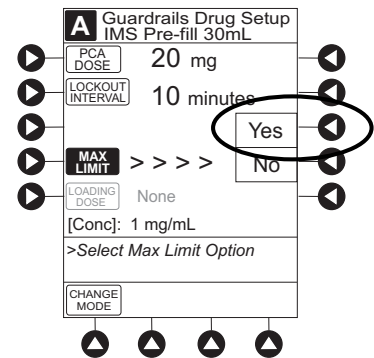


3. To enter PCA dose, use numeric data entry keys.



4. To enter lockout interval, press **LOCKOUT INTERVAL** soft key and use numeric data entry keys.
5. To enter maximum limit, press **MAX LIMIT** soft key and then **Yes** soft key.

If **No** is selected - then no MAX LIMITS will be available for this infusion.



6. Enter maximum limit using numeric data entry keys.
Time (in hours) associated with **Max Limit** is automatically entered based on setup in system configuration.

Infusion Modes (Continued)

Set Up PCA Dose Only (Continued)

- To enter loading dose, press **LOAD DOSE** soft key, press **Yes** soft key, and use numeric data entry keys.

Loading dose is included in volume infused but is not included in **Max Limit**.

- Verify correct parameters and press **CONFIRM** soft key.
 - If the programmed parameters are outside the Soft Limit, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion must be reprogrammed.
 - If the programmed parameters are outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
 - If there is a potential for a programmed "___ / ___ mL" parameter to result in an excessive volume or dose being delivered, following prompt appears:

"Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram."

The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:

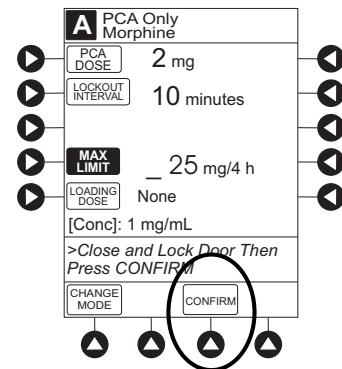
Drug Amount 1 mg
Diluent Volume 1 mL

OR

Drug Amount 30 mg
Diluent Volume 30 mL

- If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

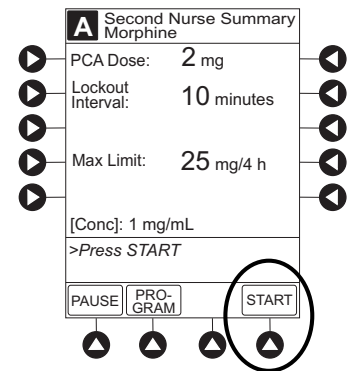
- Close and lock security door.



Infusion Modes (Continued)

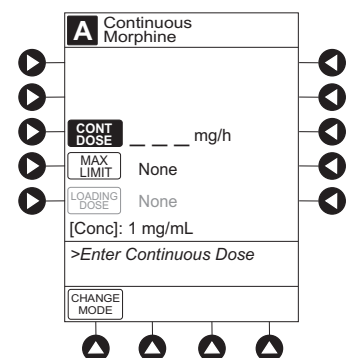
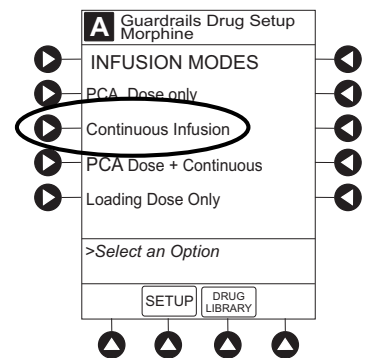
Set Up PCA Dose Only (Continued)

10. Verify correct parameters on second nurse summary screen and press **START** soft key.
 - Infusion mode and PCA drug name scroll in Channel Message Display. If a loading dose has been entered, scrolls **DELIVERING LOAD**.
 - Main Display alternates between volume remaining and PCA drug name with infusion mode.
 - When PCA dose is delivered:
 - Green Infusing Status Indicator illuminates.
 - Rate display flashes "_____".
 - **DELIVERING PCA** scrolls in Channel Message Display.
 - When PCA dose is complete, **PCA COMPLETE** scrolls in Channel Message Display.



Set Up Continuous Infusion Only

1. Perform steps in "Prepare Infusion."
2. Press **CONTINUOUS INFUSION** soft key from Infusion Mode screen.
3. To enter Continuous Infusion dose, press **CONT DOSE** soft key and use numeric data entry keys.



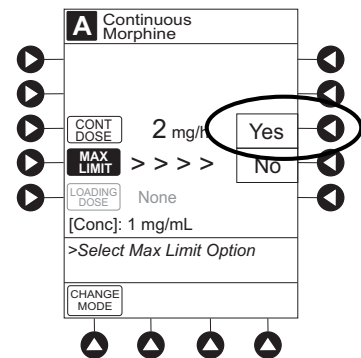
Infusion Modes (Continued)

Set Up Continuous Infusion Only (Continued)

4. To enter maximum limit, press **MAX LIMIT** soft key, press **Yes** soft key, and use numeric data entry keys.

Time (in hours) associated with **Max Limit** is automatically entered based on setup in system configuration.

If **No** is selected, no MAX LIMITS are available for this infusion.



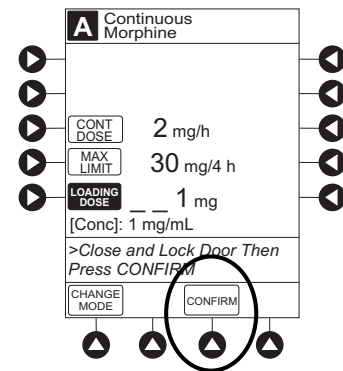
5. To enter loading dose, press **LOAD DOSE** soft key, press **Yes** soft key, and use numeric data entry keys.

Loading dose is included in volume infused but is not included in **Max Limit**.

6. Verify correct parameters and press **CONFIRM** soft key.
- If the programmed parameters are outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
 - If the programmed parameters are outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
 - If there is a potential for a programmed "___ / ___ mL" parameter to result in an excessive volume or dose being delivered, following prompt appears:

"Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram."

The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:



Infusion Modes (Continued)

Set Up Continuous Infusion Only (Continued)

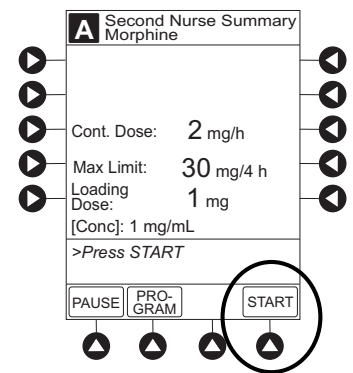
Drug Amount 1 mg
Diluent Volume 1 mL

OR

Drug Amount 30 mg
Diluent Volume 30 mL

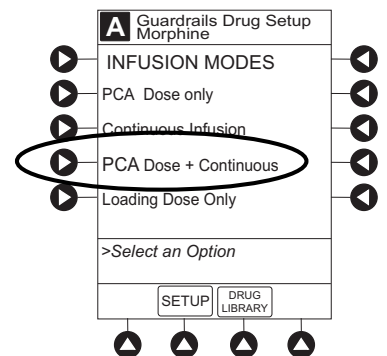
- If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

7. Close and lock security door.
8. Verify correct programming parameters and press **START** soft key.
 - Green Infusing Status Indicator illuminates.
 - Infusion mode and drug name scroll in Channel Message Display. If a loading dose has been entered, **DELIVERING LOAD** scrolls.
 - Volume infused in mL/h is displayed in Rate Display.
 - Main Display alternates between volume remaining and infusion mode with drug name.



Set Up PCA Dose and Continuous Infusion

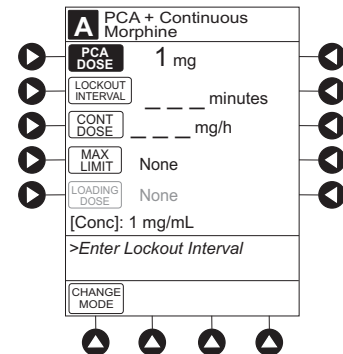
1. Perform steps in "Prepare Infusion."
2. Press **PCA DOSE + CONTINUOUS** soft key from Infusion Mode screen.



Infusion Modes (Continued)

Set Up PCA Dose and Continuous Infusion (Continued)

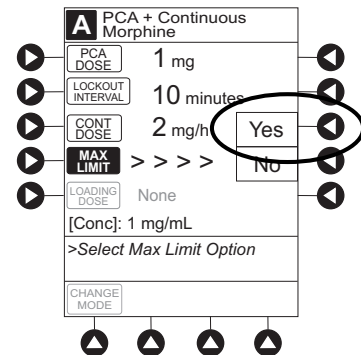
- To enter PCA dose, press **PCA DOSE** soft key and use numeric data entry keys.



- To enter lockout interval, press **LOCKOUT INTERVAL** soft key and use numeric data entry keys.
- To enter continuous dose, press **CONT DOSE** soft key and use numeric data entry keys.
- To enter maximum limit, press **MAX LIMIT** soft key, press **Yes** soft key, and use numeric data entry keys.

Time (in hours) associated with **Max Limit** is automatically entered based on setup in system configuration.

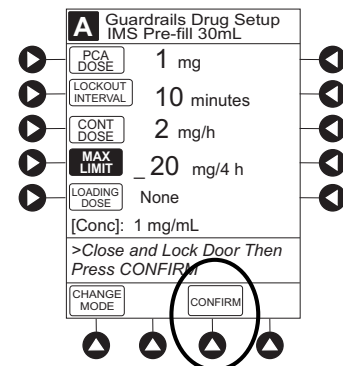
If **No** is selected - then no MAX LIMITS will be available for this infusion.



- To enter loading dose, press **LOAD DOSE** soft key, press **Yes** soft key and use numeric data entry keys.

Loading dose is included in VTBI but is not included in **Max Limit**.

- Verify correct parameters and press **CONFIRM** soft key.
 - If the programmed parameters are outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.



Infusion Modes (Continued)

Set Up PCA Dose and Continuous Infusion (Continued)

- If the programmed parameters are outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
- If there is a potential for a programmed "__ / __ mL" parameter to result in an excessive volume or dose being delivered, following prompt appears:

"Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram."

The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:

| | |
|----------------|------|
| Drug Amount | 1 mg |
| Diluent Volume | 1 mL |

OR

| | |
|----------------|-------|
| Drug Amount | 30 mg |
| Diluent Volume | 30 mL |

- If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

9. Close and lock security door.

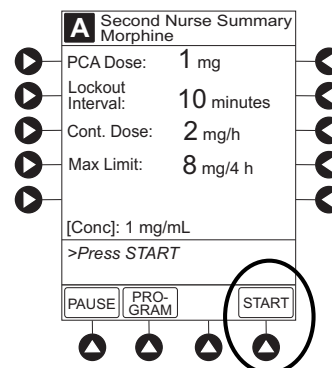
Infusion Modes (Continued)

Set Up PCA Dose and Continuous Infusion (Continued)

10. Verify correct parameters on second nurse summary screen and press **START** soft key.

During PCA dose + Continuous Infusion:

- Green Infusing Status Indicator illuminates.
- **DELIVERING PCA** scrolls in Channel Message Display when initiated. Continuous and PCA drug name scrolls in Channel Message Display between PCA doses.
- Volume infused for continuous dose is displayed in Rate Display.
- Main Display alternates between volume remaining and infusion mode with PCA drug name.
- When PCA dose is complete, **PCA COMPLETE** scrolls in Channel Message Display and resumes continuous dose.



Set Loading Dose Only

The following procedures should be used when setting a **LOADING DOSE ONLY** using the Drug Library.

1. Perform steps in "Prepare Infusion."
2. Press **LOADING DOSE ONLY** soft key from Infusion Mode screen.
3. To enter dose value, use numeric data entry keys.

Infusion Modes (Continued)

Set Loading Dose Only (Continued)

4. Verify correct dose value and then press **CONFIRM** soft key.
- Loading dose is included in VTBI but is not included in **Max Limit**.
 - If the programmed parameters are outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
 - If the programmed parameters are outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
 - If there is a potential for a programmed " __ / __ mL" parameter to result in an excessive volume or dose being delivered, following prompt appears:

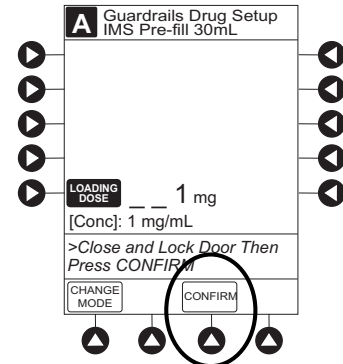
"Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram."

The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:

| | |
|----------------|------|
| Drug Amount | 1 mg |
| Diluent Volume | 1 mL |

OR

| | |
|----------------|-------|
| Drug Amount | 30 mg |
| Diluent Volume | 30 mL |

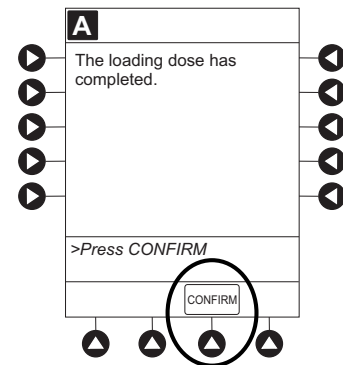
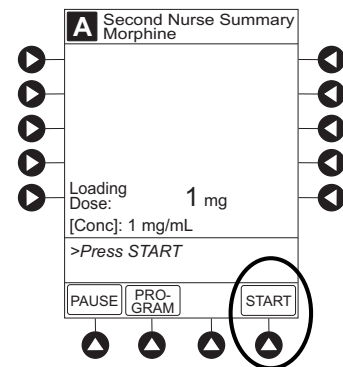


Infusion Modes (Continued)

Set Loading Dose Only (Continued)

- If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
5. Close and lock security door.
 6. Verify correct parameters on summary screen and press **START** soft key.
 - **DELIVERING LOAD** scrolls in Channel Message Display.
 - Infusion mode and drug name alternate with VTBI in Main Display.
 - When loading dose is complete, **The Loading Dose has Completed** appears on Main Display.
 7. Press **CONFIRM** soft key.

When **CHANNEL SELECT** key is pressed, Infusion Mode screen becomes available for selection of infusion mode.



Set Bolus Dose

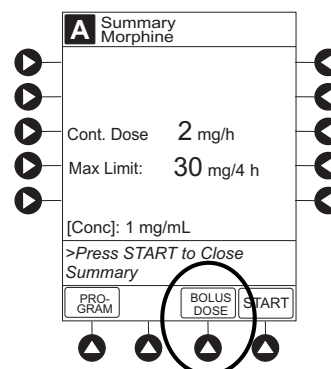
The following procedure should be used only when setting a **BOLUS DOSE** using the Drug Library. The **BOLUS DOSE** soft key is only available once an infusion has begun in PCA dose only, Continuous Infusion, or PCA + Continuous Infusion modes.

1. Press **CHANNEL SELECT** key.

Infusion Modes (Continued)

Set Bolus Dose (Continued)

2. Press **BOLUS DOSE** soft key.



3. Set key to **PROGRAM** position or enter 4-digit authorization code and press **CONFIRM** soft key.

4. To enter dose value, use numeric data entry keys.

5. Press **CONFIRM** soft key.

- If the programmed Bolus Dose is outside the Soft Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
- If the programmed Bolus Dose is outside the Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
- If there is a potential for a programmed " __ / __ mL" parameter to result in an excessive volume or dose being delivered, following prompt appears:

"Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram."

The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:

Infusion Modes (Continued)

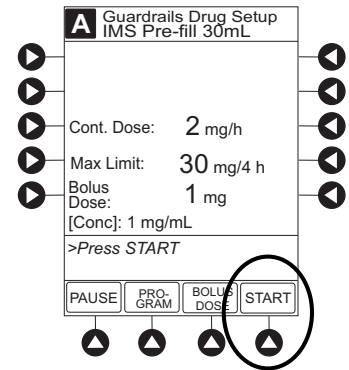
Set Bolus Dose (Continued)

Drug Amount 1 mg
Diluent Volume 1 mL

OR

Drug Amount 30 mg
Diluent Volume 30 mL

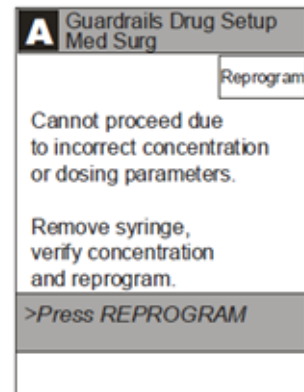
- If a Soft Limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
6. If Authorization Code is disabled, door must be locked before starting Bolus Dose.
 7. Verify correct dose value and then press **START** soft key:
 - **Delivering Bolus** scrolls in Channel Message Display.
 - Bolus and drug name alternate with VTBI in Main Display.
 - When Bolus Dose is complete, **BOLUS COMPLETE** scrolls in Channel Message Display.
 - Programmed infusion resumes.



PCA Volume Check

To reduce the instances of programming errors, the PCA checks the total volume of all programmed PCA parameters against a percentage (35%) of the capacity of the installed syringe. A PCA infusion can only be started when the total programmed volume is less than 35% of the syringe capacity.

The PCA volume check includes one hour of Continuous Dose, PCA Dose, Bolus Dose or Loading Dose. If the programmed volume is 35% or more of the capacity of the installed syringe during initial or subsequent programming, the clinician is presented with an alert which requires a reprogram.



Infusion Modes (Continued)

PCA syringe sizes and the correlating 35% of the syringe capacity

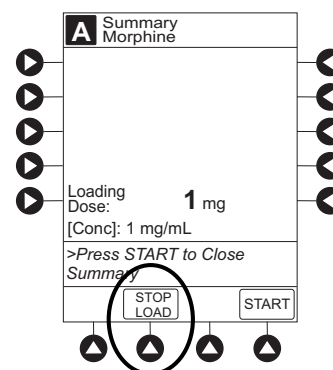
| Syringe Size | 35% of Syringe Capacity |
|--------------|-------------------------|
| 60mL | 21mL |
| 35mL | 12.25mL |
| 30mL | 10.5mL |
| 25mL | 8.75mL |
| 20mL | 7mL |

Stop a Loading, PCA, or Bolus Dose

1. Press **CHANNEL SELECT** key.
2. Press **STOP LOAD**, **STOP PCA**, or **STOP BOLUS** soft key as applicable.

Available soft key and stop confirmation screen are dependent on type of dose currently infusing and current infusion mode.

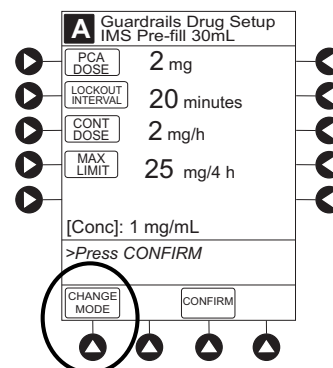
3. To stop dose and resume current program, press **Yes** soft key.



Infusion Modes (Continued)

Change Programming Parameters During an Infusion

1. Press **CHANNEL SELECT** key.
2. Press **PROGRAM** soft key.
3. Set key to program position, or if Authorization Code is enabled, enter 4-digit code.
4. Press **CHANGE MODE** soft key.



5. Select desired infusion mode.
6. Continue programming. See applicable procedure.^①
 - Set Up PCA Dose Only
 - Set Up Continuous Infusion Only
 - Set Up PCA + Continuous Infusion
7. Verify or change program settings and press **CONFIRM** soft key.
8. Close and lock door.
9. Verify correct programming parameters on summary screen and press **START** soft key.

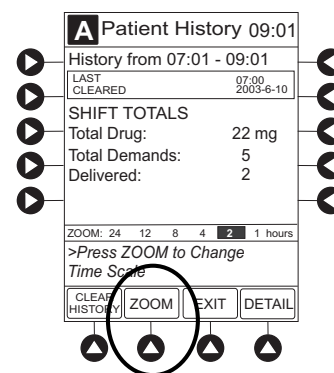
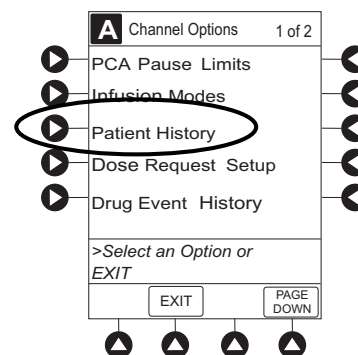
NOTE:

- ① Previously programmed values are carried over to new program.

Infusion Modes (Continued)

View Patient History

1. Press **CHANNEL SELECT** key.
2. From Main Display, press **OPTIONS** key.
3. Press **Patient History** soft key.
4. To select desired time period, press **ZOOM** soft key.^{①③}
5. To view detailed patient history, press **DETAIL** soft key.^②
6. To return to main patient history, press **MAIN HISTORY** soft key.



Infusion Modes (Continued)

View Patient History (Continued)

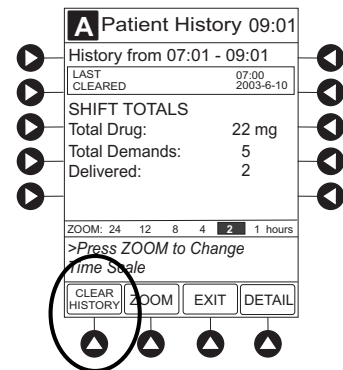
- To return to Main Display, press **EXIT** soft key.

NOTES:

- Total drug delivered includes applicable loading dose, PCA dose, continuous dose, and Bolus Dose. Total drug delivered does not include priming volume.
- Patient History** stores a rolling 24-hour log and is automatically cleared when selecting:
 - Yes to New Patient?** during startup.
 - A different drug from the Drug Library.
 - The same drug with different dosing units from the Drug Library.
 - A new **Therapy** for an mL-based drug.
 - Same patient with a new Profile.
- The Patient History defaults to the 8 hour view.

Clear Patient History

- Press **CHANNEL SELECT** key.
- From Main Display, press **OPTIONS** key.
- Press **Patient History** soft key.
- Press **CLEAR HISTORY** soft key.
A confirmation screen appears.
- To continue and clear patient history, press **Yes** soft key.
To cancel and return to patient history, press **No** soft key.



Infusion Modes (Continued)

Clear Patient History (Continued)

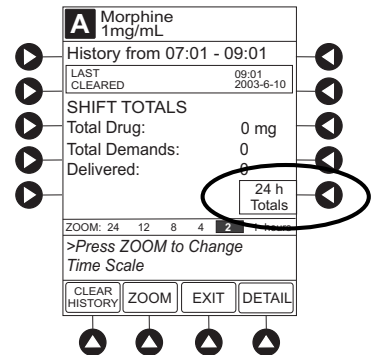
- Once patient history is cleared, the last 24 hours of patient history data can be retrieved and viewed. To retrieve last 24 hours, press **24 h Totals** soft key from **Patient History** screen.

24 h Totals soft key appears only if shift total is cleared and additional patient history information exists (up to previous 24 hours).

NOTE:

24 h Totals displays a rolling 24 hour history regardless of how many times the Patient History has been cleared.

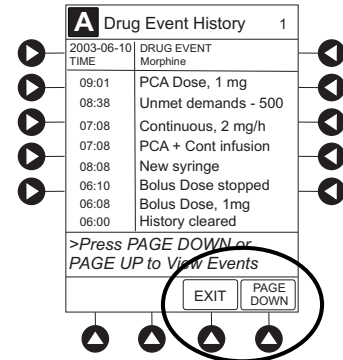
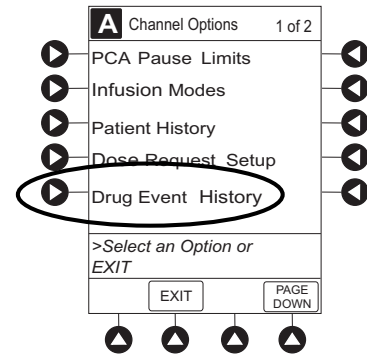
- To return to **Patient History** screen, press **SHIFT TOTALS** soft key.



Infusion Modes (Continued)

View Drug Event History

1. Press **CHANNEL SELECT** key.
2. From Main Display, press **OPTIONS** key.
3. Press **Drug Event History** soft key.
4. To scroll through history, press **PAGE DOWN** soft key. ①
5. To return to Main Display, press **EXIT** soft key.



NOTE:

- ① The **Drug Event History** stores approximately 12 hours of events and is automatically cleared upon selection of **New Patient?, Yes** during start-up or upon changing drug in Drug Library.

Configure Dose Request Cord

The Dose Request Cord can be configured to provide both audio and visual prompts to the patient. Visual prompts are provided through the LED indicator on the Dose Request Cord. Default configuration for the Dose Request Cord is established in the system configuration.

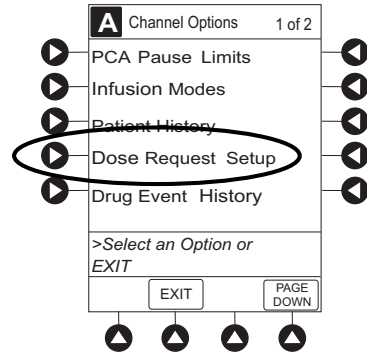
To change Dose Request Cord configuration:

1. Press **CHANNEL SELECT** key.

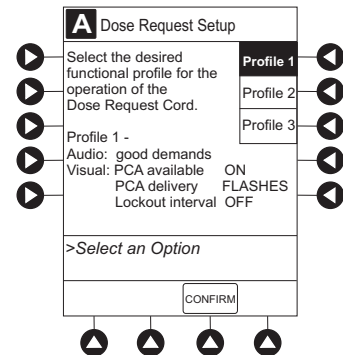
Infusion Modes (Continued)

Configure Dose Request Cord (Continued)

2. From Main Display, press **OPTIONS** key.
3. Press **DOSE REQUEST SETUP** soft key.



4. Review and select **Profile** soft key for desired operation of Dose Request Cord.



| | Profile 1 | Profile 2 | Profile 3 |
|---------------------------------------|------------------|-------------|-------------|
| Dose request cord audio - single beep | met demands only | all demands | all demands |
| Dose request cord led indicator: | | | |
| PCA available | On | On | Off |
| PCA delivery | Flashing | On | Off |
| Lockout interval | Off | On | Off |

5. Press **CONFIRM** soft key.

Infusion Modes (Continued)

Security Access Levels

The security access level can be configured to provide varying levels of access to the device. Security access is accomplished either through the use of the key or a 4-digit authorization code.

Default configuration for the security access level is established for each Profile or care area and can be changed in the system configuration. The 4-digit authorization code is established and can be changed in the system configuration.

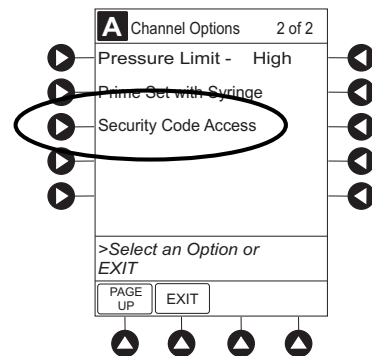
The 4-digit authorization code is configured for each Profile with Level 2 or Level 3 security access.

| Security Access Level | Initial Programming | Setting Bolus Dose | Subsequent Programming |
|-----------------------|---------------------|--------------------|------------------------|
| Level 1 | Key | Key | Key |
| Level 2 | Key | Code or Key | Key |
| Level 3 | Key | Code or Key | Code or Key |

Disable Security Access Code

The security code can be disabled for a specific infusion by using the following procedure:

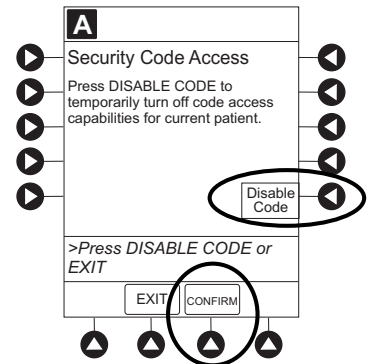
1. Press **CHANNEL SELECT** key.
2. From Main Display, press **OPTIONS** key.
3. Press **Security Code Access** soft key.



Infusion Modes (Continued)

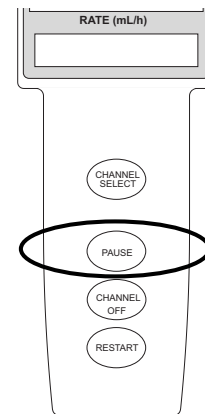
Disable Security Access Code (Continued)

4. Press **DISABLE CODE** soft key.
5. Press **CONFIRM** soft key.
Security access code remains disabled until **New Patient?**, **Yes** is selected in infusion startup or when instrument remains powered off for more than 8 hours.



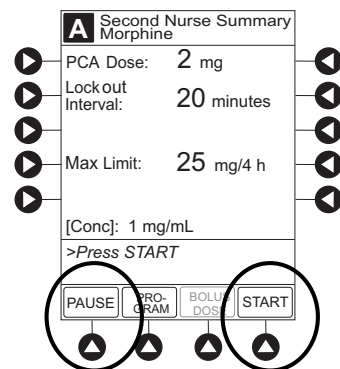
Pause Infusion

1. Press **PAUSE** key.
OR



From **Second Nurse Summary** screen, press **PAUSE** soft key.

- **PAUSE** scrolls in Channel Message Display.
- **PAUSED** appears on Main Display.
- Yellow Standby Status Indicator illuminates.
- After 2 minutes, **PAUSE-RESTART CHANNEL** visual and audio prompts begin, and yellow Standby Status Indicator flashes.



Infusion Modes (Continued)

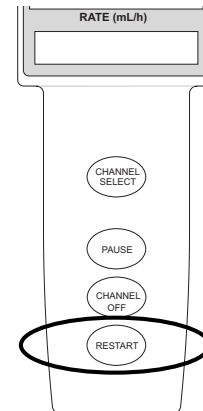
Pause Infusion (Continued)

- To reinitiate infusion:

Press **RESTART** key.

OR

Press **CHANNEL SELECT** key and then press **START** soft key on Main Display.



Change Syringe and Restore Infusion

- If syringe requires replacement:

- Unlock security door.
- Remove existing syringe and prepare new syringe (see "Getting Started," "Prepare and Load Syringe and Administration Set").

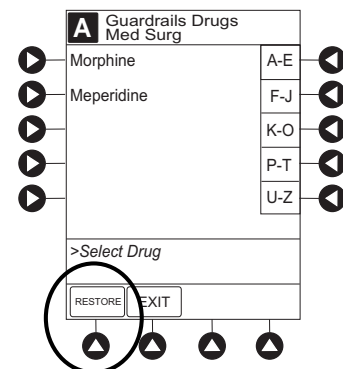
If drug and/or drug concentration is different from previous syringe, attach and prime new administration set.

- Load syringe and administration set (see "Getting Started," "Prepare and Load Syringe and Administration Set," "Load Syringe and Administration Set").
- Select syringe type and size (see "Prepare Infusion," "Select Syringe Type and Size").

- To restart infusion using restored parameters, press **RESTORE** soft key and continue with next step.

OR

To start a new infusion, select drug from Drug Library and follow steps for "Infusion Modes."



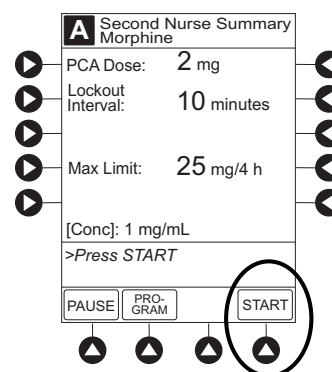
Infusion Modes (Continued)

Change Syringe and Restore Infusion (Continued)

3. Verify restored drug/concentration. Press **NEXT** soft key.
4. Prime administration set (see "Prepare Infusion," "Prime").
5. For restored parameters, verify valid parameters and press **CONFIRM** soft key.

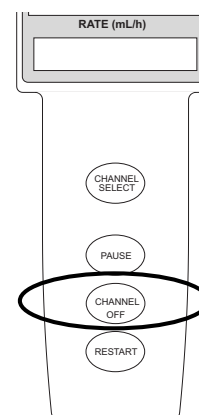
To change a restored parameter:

- a. Press applicable soft key.
 - b. Enter desired parameter using numeric data entry keys.
 - c. Press **CONFIRM** soft key.
6. Close and lock security door.
 7. Verify correct programming parameters on summary screen and press **START** soft key.



Stop Infusion

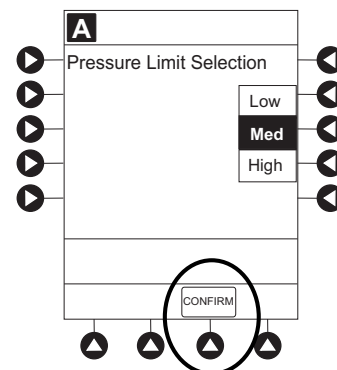
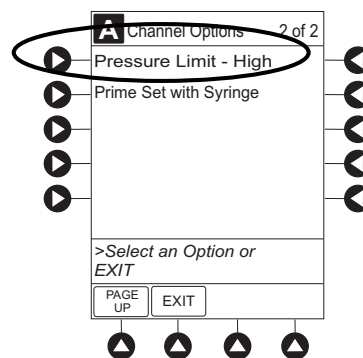
Press and hold **CHANNEL OFF** key until a beep is heard, approximately 1.5 seconds. If no other channel is active, the system powers down when the **CHANNEL OFF** key is released.



Infusion Modes (Continued)

Select Pressure Limit

1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **Pressure Limit** soft key.^①
4. To select a pressure limit, press appropriate soft key.
5. Press **CONFIRM** soft key.



NOTE:

- ① Option to change pressure limit can be selected:
- after drug is selected, and before infusion mode is selected and infusion starts, or
 - after infusion starts.

View and Clear Volume Infused

1. To view volume infused, press **VOLUME INFUSED** soft key from Main Display.
Total volume infused, and time and date volume infused was last cleared, is displayed for each channel.^①

Infusion Modes (Continued)

View and Clear Volume Infused (Continued)

- To clear volume infused:^{②③}
 - If only selected channels are to be cleared, press soft key next to applicable channel(s) and press **CLEAR CHANNEL** soft key.
 - If all channels are to be cleared, press **CLEAR ALL** soft key.
- To return to main screen, press **MAIN SCREEN** soft key.

NOTES:

- Date format is year-month-day.
- If no key is pressed, main screen appears after 30 seconds.
- Clearing volume infused on a PCA module does not clear patient history.

| | TOTAL VOLUME (mL) | LAST CLEARED |
|---|-------------------|--------------------|
| A | 401.10 | 08:00 1998-3-10 |
| B | 42.50 | 07:30 1998-3-11 |
| C | 478.10 | 08:00 1998-3-10 |
| D | 789.10 | 12:00 1998-3-10 |

>Select Channels to Clear
or Press CLEAR ALL

PRIME VOLUME CLEAR ALL MAIN SCREEN

PCA Pause Protocol Feature

The PCA Pause Protocol is an optional, hospital-configurable feature that is intended to align with the healthcare facility's current protocol for patient monitoring during PCA Therapy. All programming, data entry and validation of PCA Pause Protocol parameters are performed by a healthcare professional according to hospital-defined protocol/procedure or a physician's order.

If a monitoring module is not attached or started, the PCA Pause Protocol does not activate.

Program an Infusion

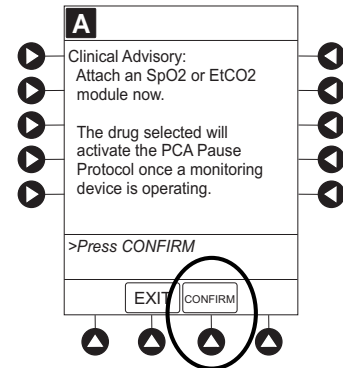
If the PCA Pause Protocol feature is enabled, perform the following procedure.

- Perform steps 1-8 in "Prepare Infusion," "Program an Infusion."
- Confirm drug and concentration selections and press **Yes** soft key.

Guardrails PCA Pause Protocol Feature (Continued)

Program an Infusion (Continued)

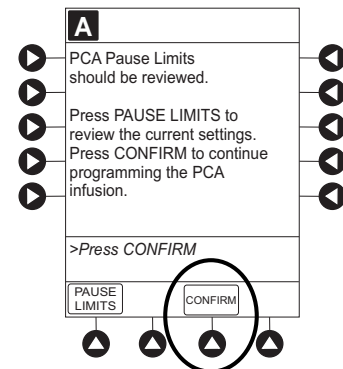
- Review Clinical Advisory.
 - To continue, press **CONFIRM** soft key.
 - To activate PCA Pause Protocol, attach and start an EtCO₂ module and/or SpO₂ module per facility protocol. To continue, press **CONFIRM** soft key.



- Verify correct parameters and press **NEXT** soft key to confirm.

Prompt appears.

- Press **CONFIRM** soft key.^①



- Start applicable infusion, as described in following procedures:^②

Set Up PCA Dose Only

Set Up Continuous Infusion Only

Set Up PCA Dose + Continuous Infusion

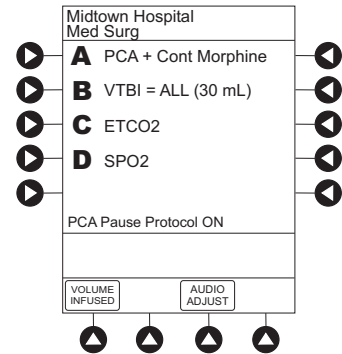
Set Loading Dose Only

Guardrails PCA Pause Protocol Feature (Continued)

Program an Infusion (Continued)

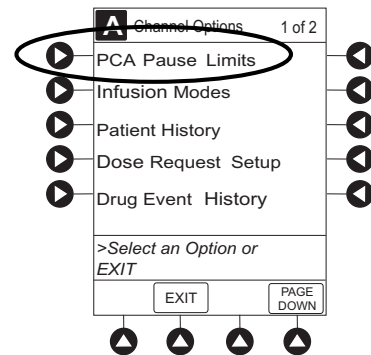
NOTES:

- ① To review PCA pause limits, see "Review or Change PCA Pause Alarm Limits."
- ② Once the **START** soft key is pressed, the Main Display screen alternates between volume remaining (VTBI - Volume to be Infused) and PCA drug name with the infusion code.
 - The Main Display displays **PCA Pause Protocol ON**.
 - If Patient ID is entered, **Patient ID** alternates with **PCA Pause Protocol ON**.

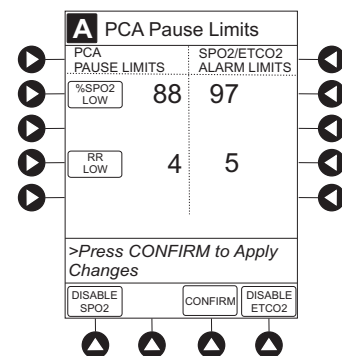


Review or Change PCA Pause Alarm Limits

1. From Main Display press **CHANNEL SELECT**.
2. Press **OPTIONS** key.
3. Press **PCA Pause Limits** soft key.



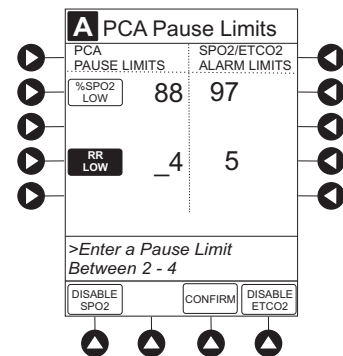
4. Verify that PCA pause limits as per facility protocol or physician order.



Guardrails PCA Pause Protocol Feature (Continued)

Review or Change PCA Pause Alarm Limits (Continued)

- To change PCA pause limits, press soft key that corresponds to alarm limit and enter a value within acceptable range.^①
- Press **CONFIRM** soft key.
- Press **START** soft key.

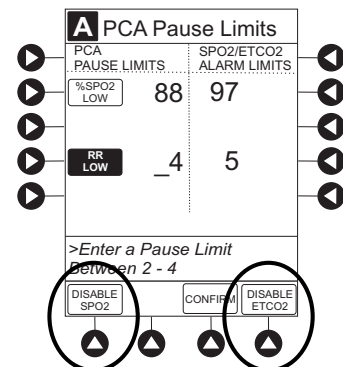


NOTE:

- ① The acceptable range for PCA Pause Protocol is configurable and defined by the hospital within the Data Set using the Guardrails Suite MX.
- The **PCA PAUSE LIMITS** must be lower than the **SPO2/ETCO2 ALARM LIMITS**. A prompt is provided if the **PCA PAUSE LIMITS** must be modified.

Disable PCA Pause Alarm

- From Main Display press **CHANNEL SELECT**.
- Press **OPTIONS** key.
- Press **PCA Pause Limits** soft key.
- Press **DISABLE SPO2** or **DISABLE ETCO2** soft key, as appropriate.
 - Disabling SpO₂ or EtCO₂ from this screen discontinues PCA Pause feature only, without interrupting monitoring functionality.
 - Once disabled, alarm limits are grayed out and are not editable.



Guardrails PCA Pause Protocol Feature (Continued)

Disable PCA Pause Alarm (Continued)

5. Press **CONFIRM** soft key.
6. Press **START** soft key.
7. To enable PCA Pause feature, follow steps 1-3 above and press **ENABLE SPO2** or **ENABLE ETCO2** soft key, as appropriate.

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System Start-Up/Setup

See the PC unit section of this User Manual, "General Setup and Operation" for various system start-up and setup procedures.

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Warnings and Cautions

General

WARNING



- The PCA module is designed to **stop fluid flow under alarm conditions**. Periodic patient monitoring must be performed to ensure that the infusion is proceeding as expected. It is a **positive displacement delivery system**, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters and intra-arterial infusion. It is neither designed nor intended to detect infiltrations and does not alarm under infiltration conditions.
- The use of positive displacement infusion devices ported together with **gravity flow infusion** systems into a common IV site can impede the flow of common "gravity only" systems, affecting their performance. Hospital/facility personnel must ensure that the performance of the common IV site is satisfactory under these circumstances.
- **Each time the Alaris System is turned on**, verify and/or set the monitoring mode, resistance alert, and/or pressure alarm limit. If the monitoring mode, resistance alert, and/or pressure alarm limit are not verified, the instrument might not operate within the desired occlusion detection parameter(s).

Administration Sets

WARNING



- Use only standard, single-use, disposable syringes (with luer-lock connectors) and non-dedicated administration sets with integrated anti-siphon valves, designed for use on syringe-type PCA pumps. The use of any other **syringe or administration set** can cause improper instrument operation, resulting in an inaccurate fluid delivery or pressure sensing, or other potential hazards. For a list of compatible syringes, refer to *Compatible Syringes* on page 3-49.

Warnings and Cautions (Continued)

Administration Sets (Continued)

WARNING



- **Before loading or unloading the syringe**, always turn off fluid flow to the patient, using the tubing clamp or stopcock. Uncontrolled fluid flow can occur when the administration set is not clamped or turned off, and can cause serious injury or death.
- When an occlusion occurs, there is a risk of infusing pressurized buildup of infusates upon correction of the occlusion. To **avoid an inadvertent bolus**, relieve the pressure before restarting the infusion.
- **When priming:**
 - Ensure that the patient is not connected.
 - Ensure that air is expelled from line prior to beginning infusion (unexpelled air in line could have serious consequences).

Failure to prime correctly can delay infusion delivery and cause the total volume to be infused to read higher than the actual total delivered to the patient.

- Ensure that the syringe manufacturer and syringe size displayed matches **syringe manufacturer and syringe size installed** in the PCA module. Mismatches can cause an under-infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, refer to *Compatible Syringes* on page 3-49.
- **Discard if** packaging is not intact or protector caps are unattached.

CAUTION



- Before operating instrument, verify that administration set is **free from kinks and installed correctly** in instrument.

Warnings and Cautions (Continued)

Epidural Administration

WARNING



- **Epidural administration** of drugs other than those indicated for epidural use could result in serious injury to the patient.
- It is strongly recommended that the syringe, administration set, and PCA module used for **epidural drug delivery** be clearly differentiated from those used for other types of administration.
- The Alaris System can be used for epidural administration of **anesthetic and analgesic drugs**. This application is only appropriate when using anesthetics and analgesics labeled for continuous epidural administration and catheters intended specifically for epidural use. Use only standard or pre-filled, single-use, disposable syringes (with luer-lock connectors) and non-dedicated administration sets with integrated anti-siphon valves, designed for use on syringe-type PCA devices without a 'Y' connector or injection port, for epidural infusions.
 - Epidural administration of **anesthetic drugs**: Use indwelling catheters specifically indicated for short-term (96 hours or less) anesthetic epidural drug delivery.
 - Epidural administration of **analgesic drugs**: Use indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.

Dose Request Cord

WARNING



- Only the **patient should press** the Dose Request Cord.
- **Carefully locate the Dose Request Cord** to reduce the possibility of patient entanglement or strangulation.

Warnings and Cautions (Continued)

Guardrails Software

WARNING



- The **Guardrails Suite MX** incorporates dosing limits and instrument configuration parameters based on hospital/facility protocol. The software adds a **test of reasonableness** to drug programming based on the limits defined by the hospital/facility. Qualified personnel must ensure the appropriateness of drug dosing limits, drug compatibility, and instrument performance, as part of the overall infusion. **Potential hazards** include drug interactions, inaccurate delivery rates and pressure alarms, and nuisance alarms.
- When loading a **Data Set** with the Guardrails Suite MX, **ensure that the correct Profile** (for patient care area) is selected prior to starting an infusion. Failure to use the appropriate Profile could cause serious consequences.

Administration Set/Syringe Information

The PCA module uses standard, single-use, disposable syringes (with luer-lock connectors) and administration sets with anti-siphon valves, designed for use on syringe-type PCA pumps.

- For specific administration set instructions and set replacement interval, refer to User Manual provided with set.
- For a list of compatible syringes, refer to *Compatible Syringes* on page 3-49.
- Use aseptic techniques when handling sets and syringes.
- Administration sets are supplied with a sterile and nonpyrogenic fluid path for one-time use. Do not resterilize.
- Discard administration set per facility protocol.
- For IV push medication (put instrument on hold), clamp tubing above port.
- Flush port(s) per facility protocol.

Compatible Syringes

The PCA module is calibrated and labeled for use with the following single-use disposable luer-lock syringes. Use only the syringe size and type specified on the Main Display. The full list of permitted syringe models is dependent on the PCA module's software version.

Syringe variability can impact occlusion pressure sensing. The variability can reduce the device's time to alarm and/or might require that a higher alarm pressure limit be programmed.

| Manufacturer | 20 mL | 30 mL | 35 mL | 60 mL |
|---------------|-------|----------------|-------|-------|
| B-D Plastipak | x | x | | x |
| IMS Pump Jet | | x ^① | | |
| Monoject | x | | x | x |
| Terumo | x | x | | x |

NOTE:

① Prefilled Morphine Sulfate 1 mg/mL.

Features and Displays

Features and Definitions

See the PC unit section of this User Manual for system features and definitions.

| Feature | Definition |
|---------------------------------------|--|
| Auto Pressure Limit Adjustment | When a bolus is delivered, pressure alarm limits are temporarily raised to maximum limit. |
| Auto Syringe Identification | System automatically detects syringe size and narrows down syringe selection list. |
| Bolus Delivery Rate | Rate at which PCA, bolus, and loading doses (boluses) are infused. |
| Bolus Dose | Allows an additional amount of medication to be programmed once PCA infusion has begun. Current PCA infusion resumes following delivery of a Bolus Dose. |

Features and Displays (Continued)

Features and Definitions (Continued)

| Feature | Definition |
|---------------------------|---|
| Concentration | <p>Drug amount per volume of fluid. For example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:</p> <p style="margin-left: 40px;">Drug Amount 1 mg Diluent Volume 1 mL</p> <p style="text-align: center;">OR</p> <p style="margin-left: 40px;">Drug Amount 30 mg Diluent Volume 30 mL</p> |
| Continuous Dose | Basal rate dose |
| Dose Request Cord | Allows a patient to self-administer a PCA dose, to be delivered according to programmed PCA parameters ("PATIENT USE ONLY" label is available for optional attachment to cord). Dose Request Cord features an indicator light that can be configured to provide feedback to patient on requested PCA doses. Dose Request Cord is enabled in PCA only and PCA + continuous modes. |
| Drug Event History | Records and displays sequential device events for a typical 12 hours, subject to change upon usage and number of modules. |
| Drug Library | When Profiles feature is enabled, it provides a hospital-defined list of drugs and concentrations appropriate for use in as many as ten Profiles. Drug Library use automates programming steps, including drug name, drug amount, and diluent volume, and activates hospital-established best-practice limits. A Data Set that includes a Drug Library is required prior to using PCA module. |
| Event Logging | Event Logging records instrument operations. |
| Initial Value | An optional and editable starting value for PCA dose, continuous dose, lockout interval, or maximum limit. |
| Limit | <p>A programming limit or best-practice guideline determined by hospital/health system and entered into system's Data Set. Dose limits can be defined by hospital/health system as Hard or Soft Limits.</p> <ul style="list-style-type: none"> • A Hard Limit is a programmed Limit that cannot be overridden. • A Soft Limit is a programmed Limit that can be overridden. |
| Loading Dose | Allows a bolus infusion to be programmed prior to initiation of PCA infusion. Can be programmed from Infusion Modes menu or applicable PCA, PCA + continuous, or continuous only programming screen prior to start of a new PCA infusion program. |

Features and Displays (Continued)

Features and Definitions (Continued)

| Feature | Definition |
|--|---|
| Lockout Interval | A configurable interval of time (1-99 minutes) that must pass between PCA Patient Doses. The lockout interval begins when the patient dose infusion starts. The Lockout Interval range is 1-99 minutes. |
| Max Dose Limit (Max Accumulated Dose Range) | Optional configuration that limits total amount of drug allowed to be delivered to patient in a defined period (1, 2, or 4 hours). <ul style="list-style-type: none"> • Should be configured in Data Set before Drug Library is developed. Once drugs are in Profile PCA Drug Library, Max Accumulated Dose Limit cannot be changed. • Applies to all drug setups within Profile PCA Drug Library. • Includes PCA Dose, Continuous Dose, and optional Bolus Dose if selected to be included. Loading Dose is not included. |
| Module Location Enforcement | Tamper resistant security feature that ensures PCA Module is in a tamper evident position. When enabled, PCA Module must be located to direct right of PC Unit to allow programming an infusion. |
| Near End of Infusion (NEOI) | The NEOI option allows an audio alarm to be configured based on a percentage of the syringe size. The alert time can be set to occur when 5-25% of the syringe size is remaining. |
| NEOI Snooze | Optional capability to remind users NEOI has been silenced. This is shared Syringe and PCA setting. |
| Occlusion Pressure | Downstream occlusion alarm threshold can be set to low, medium, or high. |

Features and Displays (Continued)

Features and Definitions (Continued)

| | |
|------------------------|--|
| Operating Modes | Four operating modes are available: <ul style="list-style-type: none">• PCA only• Continuous Infusion• PCA + Continuous Infusion• loading dose only All programming of infusions in each of four modes are completed using Drug Library as defined by hospital-established best-practice. |
| Patient History | PCA Module records and displays patient history for up to 24 hours, and can be trended to following intervals: 1-hr, 2-hr, 4-hr, 8-hr, 12-hr, 24-hr. Patient history includes following trending information: <ul style="list-style-type: none">• total demands• delivered demands• total drug delivered• time and date patient history last cleared• average drug per hour• default view is 8-hr• total amount of drug delivered via:<ul style="list-style-type: none">◦ PCA dose◦ Continuous Infusion◦ loading dose◦ Bolus Dose |

Features and Displays (Continued)

Features and Definitions (Continued)

| Feature | Definition |
|---------------------------------|---|
| PCA Dose | Enables a patient to self-administer a bolus infusion to be delivered at programmed lockout intervals through Dose Request Cord. When programmed in PCA+continuous mode, Continuous Infusion resumes following PCA dose. |
| PCA Pause Protocol | An optional and hospital-configurable feature intended to align with hospital/health system's current protocol for patient monitoring during PCA therapy. When enabled, PCA infusion pauses and alarms when defined monitoring values (% SpO ₂ and/or Respiratory Rate low) for SpO ₂ and/or EtCO ₂ module are exceeded and sustained. |
| Pressure Limit | Downstream occlusion alarm threshold can be set to low, medium, or high. Syringe variability might impact occlusion pressure sensing. Variability can reduce device's time to alarm and/or can require that a higher alarm pressure limit be programmed. |
| Priming | Allows a limited volume of fluid to be delivered in order to prime administration set prior to being connected to a patient or after changing a syringe. When priming, a single continuous press of PRIME soft key delivers up to 2 mL of priming/fluid. |
| Restore | To simplify programming, can be used to recall previous PCA programming parameters for same patient. This option is only available if patient is not new and system is powered up within 8 hours of last usage. |
| Security Access Level | Profile-specific security access level can be configured to provide varying levels of access to device. Security access is accomplished either through use of key or a 4-digit authorization code. For security level information, see "Programming," "Infusion Modes," "Security Access Levels." |
| Security Code | Four-character code assigned to allow access to PC unit for setting Bolus Doses and subsequent programming changes. Ability to use Profile-specific code is dependent upon configured Security Access Level. |
| Syringe Empty | Instrument gives an alert and stops when an empty syringe is detected. |
| Syringe Volume Detection | System automatically detects fluid volume in a syringe when it is inserted. |

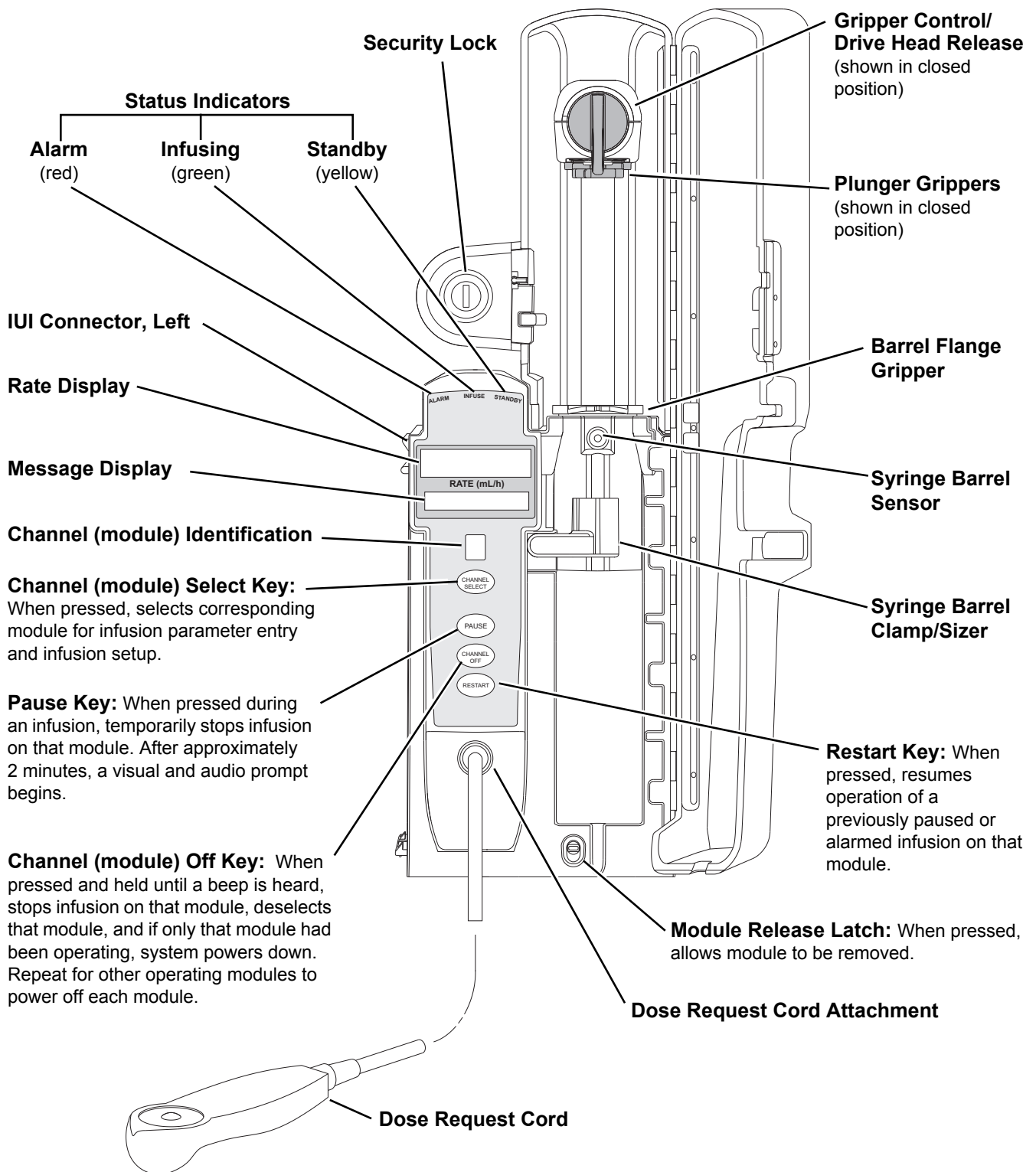
Features and Displays (Continued)

Features and Definitions (Continued)

| Feature | Definition |
|------------------------|--|
| Therapies | An optional hospital-defined therapy or clinical indication for delivery of that infusion. Different Limits can be defined for same medication with different therapeutic indications. |
| Time Window (h) | 1, 2, or 4 hours. |

Features and Displays (Continued)

Operating Features, Controls, Indicators



Features and Displays (Continued)

Displays

The displays illustrated throughout this document are for illustration purposes only. The display content varies, depending on configuration settings, type of administration set in use, hospital-defined Data Set uploaded using the Guardrails Suite MX, programmed drug calculation parameters, and many other variables. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

Configurable Settings

See the PC unit section of this User Manual for system configurable settings.

The configuration settings are selected during Data Set development and then uploaded to the Alaris System as part of the data.

With the Profiles feature enabled, the settings are configured independently for each Profile. A hospital-defined, best-practice Data Set must be uploaded to enable the Profiles feature. Date and Time is a system setting and is the same in all Profiles.

| Feature | Default Setting | Options |
|----------------------------------|---------------------------------------|--|
| Authorization Code | None | 4 digits (0 - 9) One code applies to all Profiles |
| Bolus Delivery Rate | 150 mL/h | 75 - 500 mL/h (limited by syringe size) |
| Bolus Dose | Disabled | Enabled - Disabled |
| Bolus Dose include in Max. Limit | Disabled | Enabled - Disabled |
| Dose Request Cord Configuration | Profile 2 | Profile 1, 2, 3 |
| Forced Module Location | Enabled | Enabled - Disabled |
| Loading Dose | Disabled | Enabled- Disabled |
| Lockout Interval | 1 - 99 minutes in 1-minute increments | Min/Max 1 - 99 minutes |

Specifications and Symbols (Continued)

| Feature | Default Setting | Options |
|--|--|--|
| Max Accumulated Dose Range | 4-hour limit | Disabled; 1, 2, or 4-hour limit |
| Max Rate (for Continuous Dose) ^① | 999 mL/h | 0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments |
| NEOI • Alert Time | Disabled | Enabled - Disabled 5 - 25% of syringe size |
| NEOI Snooze ^① | Disabled | 5, 10 or 15 minutes |
| Occlusion Pressure Set Point | High (800 mmHg) | Low (200 mmHg) Medium (500 mmHg) High (800 mmHg) |
| PCA Pause Protocol: • PCA Pause Protocol • Monitoring Module Attach Enforcement • PCA Pause Protocol Text • SpO ₂ Settings: ^② ◦ % SpO ₂ Low Limit ◦ Initial Value • EtCO ₂ Settings: ◦ Respiratory Rate Lower Limit (bpm) ◦ Initial Value | Disabled None PCA infusion has paused due to a decline in respiratory status. Check patient. None None None None | Enabled - Disabled Enabled - Disabled Editable per hospital protocol 20 - 99 20 - 99 0 - 149 0 - 149 |
| Priming | Enabled | Enabled- Disabled |
| Security Access Level | Level 1 | Level 1, 2, 3 |

NOTES:

- ① This configuration setting is a shared setting between the PCA module and the Syringe module.
- ② These values are configured in the SpO₂ module settings within the Editor Software and can be changed by the clinician by accessing Channel Options on the PCA module.
- ③ These values are configured in the EtCO₂ module settings within the Editor Software and can be changed by the clinician by accessing Channel Options on the PCA module.

Specifications and Symbols

Specifications

Bolus Dose Range: Configured according to hospital best-practice guidelines.

Bolus Volume, Maximum after Occlusion:

| Occlusion Pressure Limit | Bolus Volume (mL) |
|--------------------------|-------------------|
| Low | 0.994 |
| High | 0.396 |

Maximum Bolus Volume specifications are based on following standard operating conditions:




Atmospheric Pressure: 645 - 795 mmHg
 Disposable Type: #30883
 Humidity: 20 - 90%
 Rate: 5 mL/h
 Syringe Type: BD 50/60 mL
 Temperature: 68 ±4°F
 Volume Collection Time: approximately 2 minutes

Critical Volume: Maximum over-infusion which can occur in the event of a single-fault condition will not exceed 2% of nominal syringe fill volume during loading and 1% of maximum syringe travel after syringe loading.

Delivery Units: mcg, mcg/h, mg, mg/h, mL, mL/h

Dimensions: 4.5" W x 15.0" H x 7.5" D (exclusive of security door)

Environmental Conditions:

| Symbol | Meaning | Operating | Storage/Transport |
|---|---|-------------------------------------|------------------------------------|
|  | Atmospheric Pressure | 525 - 4560 mmHg (700 - 6080 hPa) | 375 - 760 mmHg (500 - 1013 hPa) |
|  | Relative Humidity (Avoid prolonged exposure to relative humidity >85%) | 20 - 90% Noncondensing | 5 - 85% Noncondensing |
|  | Temperature Range | 41 - 104°F (5 - 40°C) | -4 - 140°F (-20 - 60°C) |

Equipment Orientation: To ensure proper operation, Alaris System must remain in an upright position.

Specifications and Symbols (Continued)

Specifications (Continued)

Flow Rate Programming: Flow rate range is from 0.1 to 999 mL/h and can be selected as follows:

| Flow Rates (mL/h) | Selectable Increments (mL/h) |
|-------------------|------------------------------|
| 0.10 - 9.99 | 0.01 |
| 10 - 99.9 | 0.1 |
| 100 - 999 | 1.0 |

Rate Restriction by Syringe Size:

| Syringe Size (mL) | Flow Rate Range (mL/h) |
|-------------------|------------------------|
| 20 | 0.1 - 500 |
| 30/35 | 0.1 - 650 |
| 50/60 | 0.1 - 999 |

Fluid Ingress Protection: IPX1, Drip Proof

Loading Dose Range: Configured according to hospital best-practice guidelines.

Maximum Dose Range: Configured according to hospital best-practice guidelines.

Occlusion Alarm Thresholds: Three settings:
Low
Medium
High

Operating Principle: Positive displacement

PCA Dose Range: Configured according to hospital best-practice guidelines.

Rate Accuracy: $\pm 2\%$ of full scale plunger travel (not including syringe variation)

WARNING



Syringe size and running force, variations of back pressure, or any combination of these **can affect rate accuracy**. Factors that can influence back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure can also be affected by type of catheter. See "Trumpet and Start-Up Curves" for data on how these factors influence rate accuracy.

Shock Protection: Type CF, Defibrillator Proof patient applied part. (PCA module)
Type BF, Defibrillator Proof patient applied part. (Dose Request Cord)

Specifications and Symbols (Continued)

Specifications (Continued)

Time to Alarm, Maximum:

| Rate (mL) | High | Low |
|-----------|-------------|------------|
| 1 | 120 minutes | 37 minutes |
| 5 | 30 minutes | 7 minutes |

Maximum Time to Alarm specifications are based on following standard operating conditions:









Atmospheric Pressure: 645 - 795 mmHg
Back Pressure: 0 mmHg before producing occlusion
Disposable Type: #30883
Humidity: 20 - 90%
Syringe Type: BD 50/60 mL
Temperature: 68 ±4°F

Weight: 5.5 lbs

Specifications and Symbols (Continued)






Symbols

See the PC unit section of this User Manual for system symbols.

| Symbol | Meaning—Alaris Pump Module and Alaris Syringe Module |
|---|---|
|  | The Infusion Alarm Silence symbol indicates that infusion alarms have been acknowledged and silenced. Press the CANCEL SILENCE soft key to reactivate a previously silenced alarm audio. If the alarm condition has not been resolved, the alarm audio will resume. |
|  | Type CF defibrillation-proof patient applied part (PCA module). |
|  | Type BF defibrillation-proof patient applied part (Dose Request Cord). |
|  | Manufacturer |
| Single-Use  | Single-Use. Do not re-use. |
|  | DEHP in fluid pathway. |
|  | Non-DEHP plasticizer in fluid pathway. |
|  | No DEHP in fluid pathway. |

Specifications and Symbols (Continued)

Symbols (Continued)

| Symbol | Meaning—Alaris Pump Module and Alaris Syringe Module |
|---|--|
|  | Product is latex-free. |
|  | Approximate administration set priming volume. |
|  | Expiration date for product is identified near hourglass symbol. |
|  | Do not use if package is damaged. |
|  | Product contains micron filter, where xx represents filter size. |

Trumpet and Start-Up Curves

In this instrument, as with all infusion systems, the action of the pumping mechanism and variations in individual syringes and administration sets cause short-term fluctuations in rate accuracy. The following graphs show typical performance of the system, as follows:

- Accuracy during various time periods over which fluid delivery is measured (trumpet curves).
- Delay in onset of fluid flow when infusion commences (start-up curves).

Trumpet and start-up curves have been provided for 0.1 mL/h, 1.0 mL/h and 5.0 mL/h. Measurements for trumpet curve rates above 5.0 mL/h are also not provided, as the syringe volume is displaced in a very short time with a rate up to 999 mL/h. Accuracy, however, is assured with the design implementation.

Trumpet curves are named for their characteristic shape. They display discrete accuracy data averaged over particular time periods or "observation windows," not continuous data versus operating time.

Over long observation windows, short-term fluctuations have little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effect, as represented by the "mouth" of the trumpet. Knowledge of system accuracy over various observation windows might be of interest when certain drugs are being administered.

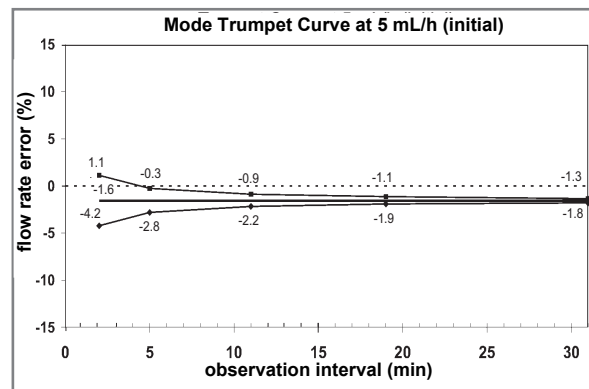
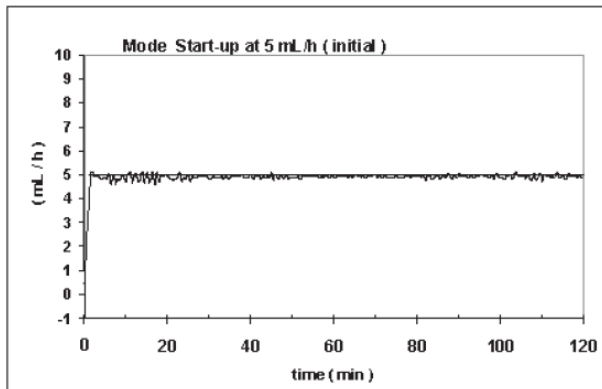
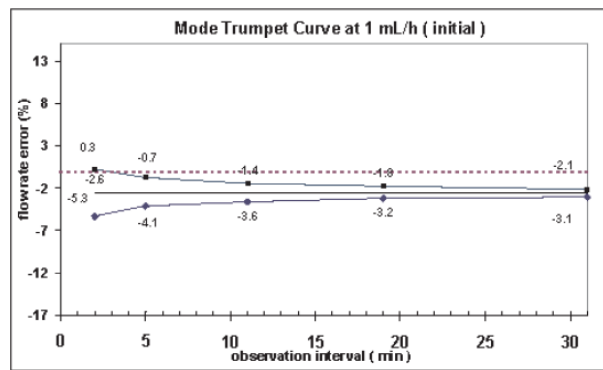
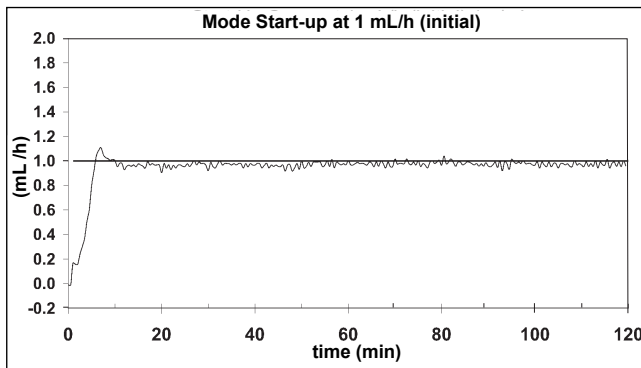
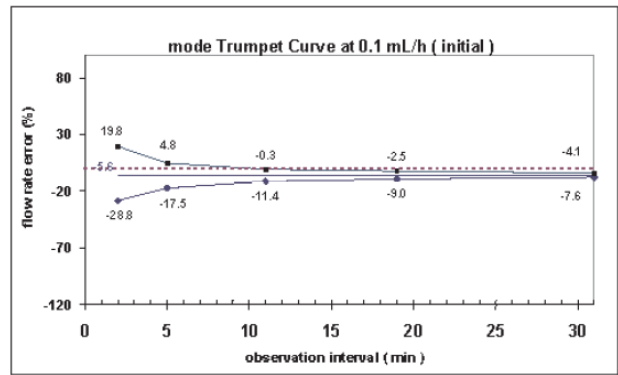
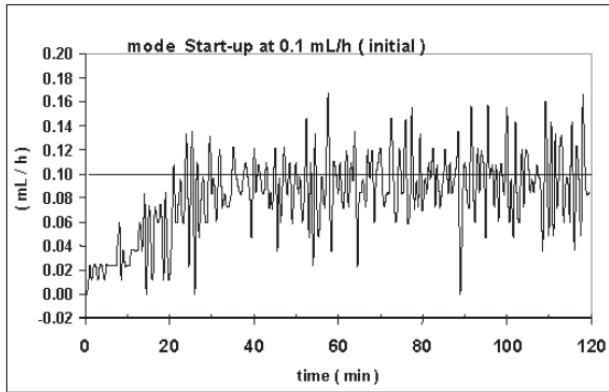
Because the clinical impact of short-term fluctuations on rate accuracy depends on the half-life of the drug being infused and on the degree of intravascular integration, the clinical effect cannot be determined from the trumpet curves alone. Knowledge of the start-up characteristics should also be considered.

Trumpet and Start-Up Curves (Continued)

The start-up curves represent continuous flow rate versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data.

Under conditions of -100 mmHg, +100 mmHg, and +300 mmHg pressures, the PCA module typically exhibits an accuracy of approximately 0.2% or less from the mean value.

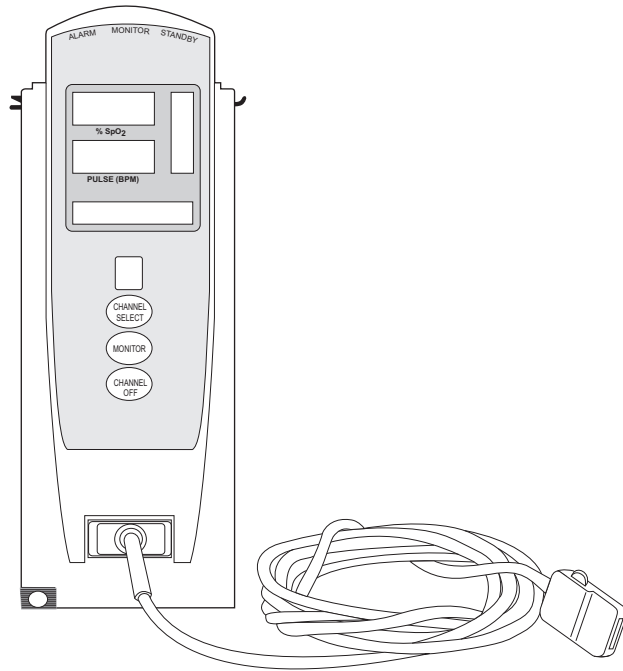
Trumpet and Start-Up Curves (Continued)



Legend:

- Maximum rate error
- Overall rate error
- ◆ Minimum rate error

Alaris SpO₂ Module Models 8210 and 8220



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Introduction

This section only applies to legacy SpO₂ users upgraded with v9.33 software.

This section of the User Manual provides SpO₂ module (Models 8210 and 8220) instructions and information. It is used in conjunction with:


- Nellcor™ and Masimo SET™ cable and sensor instructions
- PC unit section of this User Manual
- Nellcor™ Monitor Sensor Compatibility Card - Alaris™ SpO₂ Module Model 8210
- Masimo™ Monitor Sensor Compatibility Card - Alaris™ SpO₂ Module Model 8220
- *SpO₂ module Technical Service Manual*
- System Maintenance software (and its instructions) for Alaris System check-in, maintenance, and wireless configuration

The SpO₂ modules are indicated for continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate measured by an SpO₂ sensor. The SpO₂ modules and accessories are indicated for use with adult, pediatric, and neonatal patients, and for patients who are well or poorly perfused in hospitals and hospital-type facilities. The Model 8220 SpO₂ module is also indicated for use during motion and no motion conditions. Only one SpO₂ module can be connected to the Alaris System.

Please consult the facility's best practices guidelines on the preferred alarm settings for the monitoring of patients that are not continuously attended by a clinician.

The majority of user interface programming is identical for both SpO₂ modules. If a procedure/information applies to a specific module, the following identifiers indicate the applicable model.

Model 8210:  **NELLCOR**
(8210)

Model 8220:  **MASIMO SET**
(8220)

WARNING



Read all instructions for the SpO₂ module and PC unit, before using the Alaris System.

Introduction (continued)

Cables and Sensors: See "General Information" for "Cables and Sensors" information.

Alarms, and Messages: See "Troubleshooting and Maintenance" for module-specific "Alarms and Messages."

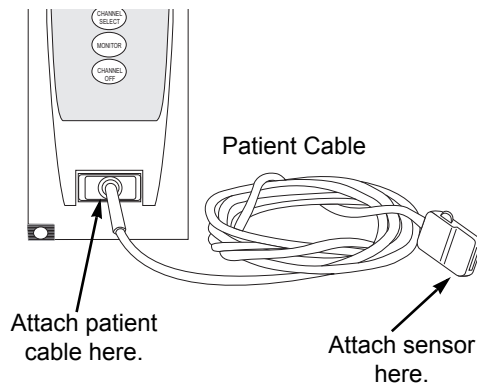
Contraindications: The SpO₂ modules are contraindicated for use as apnea monitors.

Electromagnetic Environment: See "Appendix" section of this User Manual ("Regulations and Standards," "Compliance").

Attach Cable and Sensor

The operator is responsible for checking the compatibility of the monitor, probe, and cable before use.

1. Attach applicable patient cable to SpO₂ module. Ensure a secure connection and that patient cable is not twisted, sliced or frayed.
2. Attach applicable sensor to patient cable. Refer to sensor's User Manual for detailed instructions.



3. Attach sensor to patient. Refer to sensor's User Manual for detailed instructions.

WARNING



The misapplication of sensors and patient cables with excessive pressure for prolonged periods can induce pressure injury.

WARNING



Model 8210:

Use only approved Nellcor sensors and pulse oximetry cables.

Model 8220:

Use only approved Masimo sensors and patient cables.

Use of sensors, transducers, cables, and accessories other than those specified can cause improper SpO₂ module performance resulting in inaccurate readings, increased emission, and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO₂ module. For a list of compatible sensors and cables, refer to the Monitor Sensor Compatibility Alaris™ SpO₂ Module 8220 Series.

Display references throughout this procedure are for illustration purposes only.

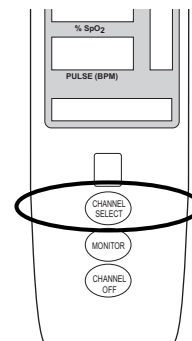
See "General Information," "Features and Displays" and the PC unit section of this User Manual for information about:

- Displays
- Operating Features, Controls, Indicators

The majority of user interface programming is identical for both SpO₂ modules.

Monitoring Mode

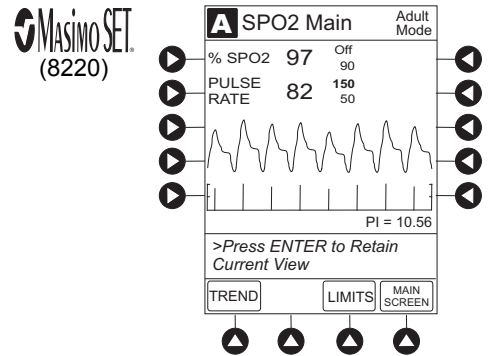
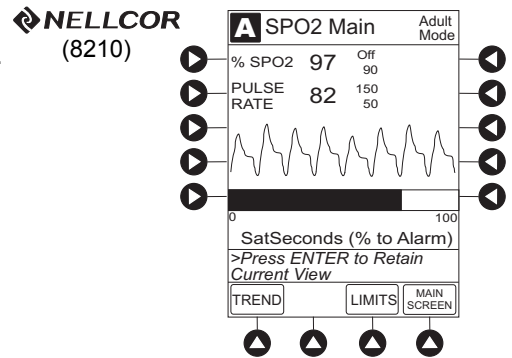
1. Perform following steps (see PC unit section of this User Manual, "General Setup and Operation," "Start-Up"):
 - a. Power on system.
 - b. Choose **Yes** or **No to New Patient?**
 - c. Confirm current Profile or select a new Profile.
 - d. Enter patient identifier, if required.
2. Attach patient cable and sensor (see "Getting Started").
3. Press **CHANNEL SELECT** key.
 - **SEARCHING** might appear in Channel Message display until SpO₂ and pulse readings stabilize (approximately 15 seconds).
 - If sensor is not attached to a site, **SENSOR OFF** is displayed.
 - To prevent screen from reverting to Main Display, press **ENTER** key within 30 seconds after **SPO2 Main** screen is displayed.
 - If sensor is not attached during message display, module goes into sleep mode. To begin monitoring once module is in this mode, press **MONITOR** key.
4. Ensure that sensor's red LED is on.



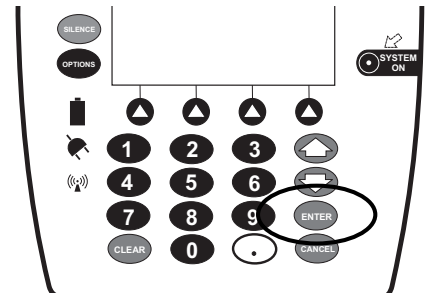
Monitoring Mode (Continued)

5. Alarm limits:

- To change settings, see "Set Alarm Limits" procedure.

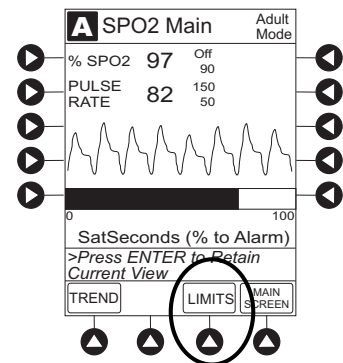


- To accept settings and begin monitoring, press **ENTER** key.



Set Alarm Limits

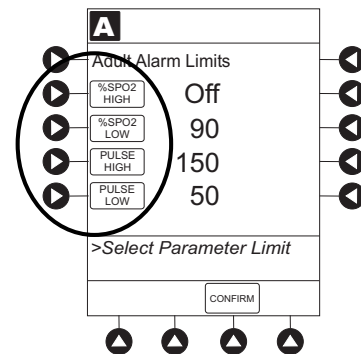
1. Press **LIMITS** soft key.



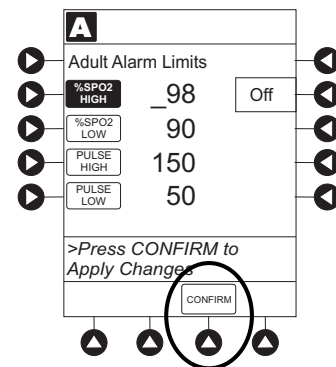
Monitoring Mode (Continued)

Set Alarm Limits (Continued)

- To change a limit setting, press soft key next to applicable parameter.



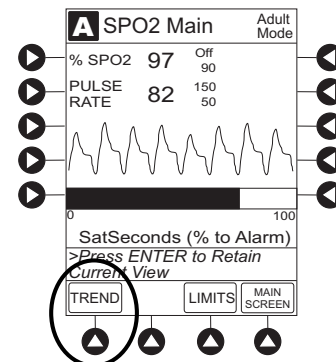
- Enter a numeric value for selected alarm limit.
%SPO2 HIGH limit can be **Off** or a numeric value.
- To move to next limit, press **ENTER** key.
- To confirm alarm settings and return to **SPO2 Main** display, press **CONFIRM** soft key.



- To return to Main Display, press **MAIN SCREEN** soft key.



Navigate Trend Data

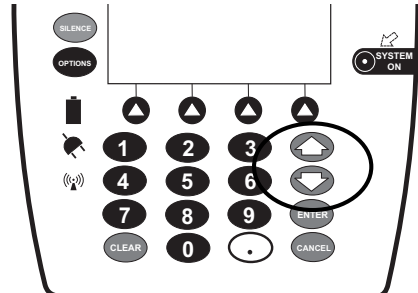
- To view **Trend Data**, press **TREND** soft key.
 - Tabular information is not updated while **Trend Data** view is displayed. Tabular data is updated, using new trend data stored in SpO₂ module, after leaving **Trend Data** view. To view latest data, return to **Trend Data** view.
 - is displayed if an alarm limit is reached.
 - If no **SPO2** or **PULSE** rate values are available for time period displayed, dashes (---) are displayed.
- To navigate from page to page, press **PAGE UP** and **PAGE DOWN** soft keys.



Monitoring Mode (Continued)

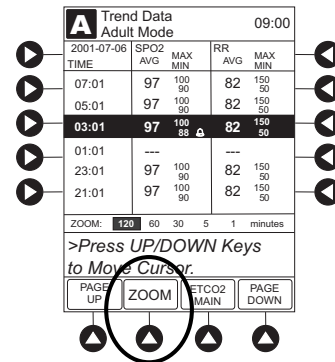
Navigate Trend Data (Continued)

3. To scroll data one row at a time, press  or  key.



4. To change **TIME** increments for data review, move cursor to desired time period and press **ZOOM** soft key.

- New time increments display.
- Each press of **ZOOM** soft key changes time increments.



5. To return to **SPO2 Main** display, press **SPO2 MAIN** soft key.


6. To return to Main Display, press **MAIN SCREEN** soft key.

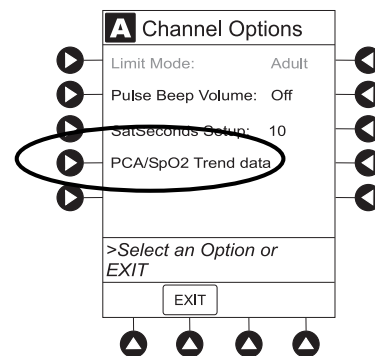
Navigate PCA/Alaris SpO₂ Module Trend Data

To access and view shared trend data when a PCA module is present, perform the following steps:

1. To access option to view trend data, press **OPTIONS** key while in **SPO2 Main** display.

2. To view **Trend Data**, press **PCA/SpO₂ Trend data** soft key.

- Tabular information is not updated while **Trend Data** view is displayed. Tabular data is updated, using new trend data stored in SpO₂ module, after leaving **Trend Data** view. To view latest data, return to **Trend Data** view.
-  is displayed if an alarm limit is reached.
- If no **SPO2** or **PULSE** rate values are available for time period displayed, dashes (---) display.



Monitoring Mode (Continued)

Navigate PCA/SpO₂ Trend Data (Continued)

- See "Navigate Trend Data" procedure for instructions on how to:
 - Navigate from page to page.
 - Change **TIME** increments.
 - Return to **SPO2 Main** display.
 - Return to Main Display.

| 2001-07-06 | | ETCO2 | | RR | | MAX | |
|------------|-----|-------|-----|-----|-----|-----|-----|
| TIME | AVG | MAX | MIN | AVG | MAX | MIN | MIN |
| 22:28 | 40 | 44 | 39 | 12 | 16 | 11 | 11 |
| 21:58 | 41 | 45 | 39 | 13 | 20 | 11 | 11 |
| 21:28 | 41 | 45 | 34 | 11 | 14 | 10 | 10 |
| 20:58 | --- | --- | --- | --- | --- | --- | --- |
| 20:28 | 39 | 44 | 37 | 12 | 14 | 11 | 11 |
| 19:58 | 39 | 44 | 37 | 12 | 14 | 11 | 11 |

ZOOM: 120 60 30 5 1 minutes

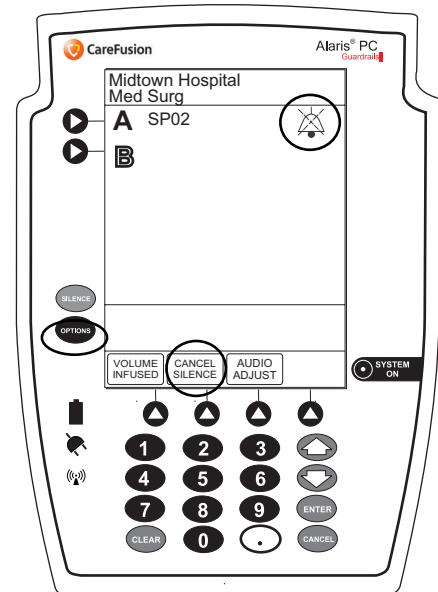
>Press UP/DOWN Keys to Move Cursor.

PAGE UP ZOOM ETCO2 MAIN PAGE DOWN

Presilence Alarm

- To presilence alarm, press **SILENCE** key.

All monitoring alarms are silenced for 120 seconds and a monitoring alarm silence symbol is displayed on the PC unit main screen. Subsequent infusion alarms are not silenced.
- To cancel presilence alarm and return to alarmable mode:
 - Press **CANCEL SILENCE** soft key.

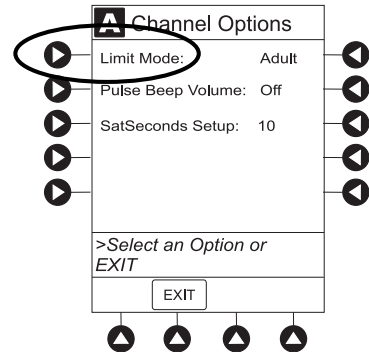


Channel Options

Change Limit Mode

The following procedure can be performed only when the Guardrails Suite MX is not enabled (Profile option not being used for programming).

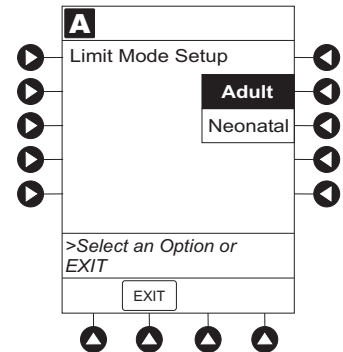
1. Press **Limit Mode** soft key.



2. To change **Limit Mode Setup**, press applicable soft key.

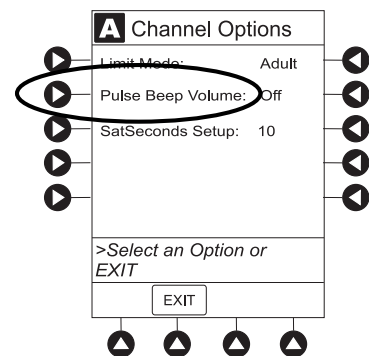
OR

To leave **Limit Mode Setup** unchanged and return to **SPO2 Main** display, press **EXIT** soft key.



Change Pulse Beep Volume

1. Press **Pulse Beep Volume** soft key.

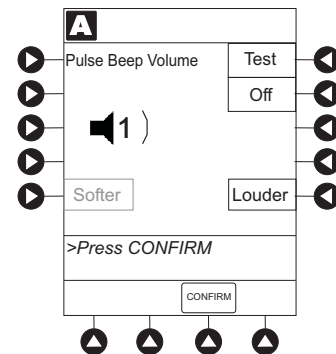


Channel Options (Continued)

Change Pulse Beep Volume (Continued)

2. To test or change:
 - a. To test volume level (when not attached to patient), press **Test** soft key.

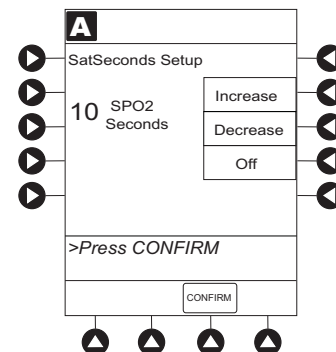
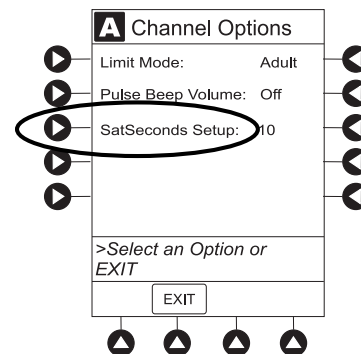
Pulse beep must be on to test volume level. To turn pulse beep on, press **Louder** soft key and adjust as needed.
 - b. To increase volume, press **Louder** soft key until desired volume level is attained (1, 2, or 3).
 - c. To decrease volume, press **Softer** soft key until desired volume level is attained.
 - d. To turn off pulse beep, press **Off** soft key.
3. To return to **SPO2 Main** display, press **CONFIRM** soft key.



Change SatSeconds Limit

NELLCOR
(8210)

1. Press **SatSeconds Setup** soft key.
2. To change SatSeconds™, press applicable soft key. Selectable **Increase** and **Decrease** options are **10**, **25**, **50**, and **100** seconds.
3. To return **SPO2 Main** display, press **CONFIRM** soft key.

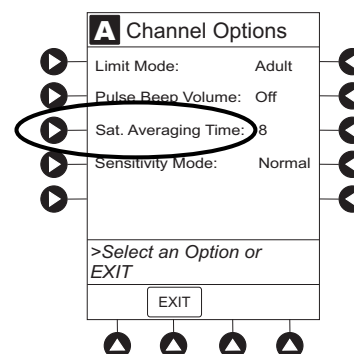


Channel Options (Continued)

Change Saturation Averaging Time

Masimo SET.
(8220)

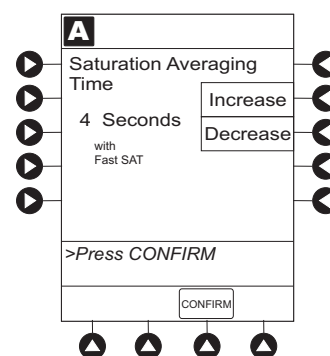
1. Press **Saturation Averaging Time** soft key.



2. To change **Saturation Averaging Time**, press applicable soft key. Selectable options are **2, 4, 8, 10, 12, 14,** and **16** seconds.

FAST SAT is enabled when **2** or **4** seconds is selected.

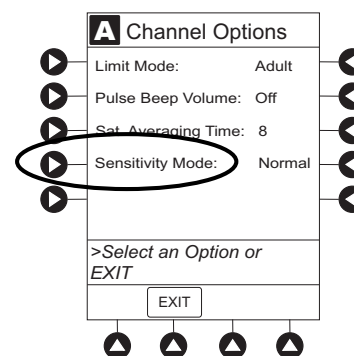
3. To return **SPO2 Main** display, press **CONFIRM** soft key.



Change Sensitivity Mode

Masimo SET.
(8220)

1. Press **Sensitivity Mode** soft key.

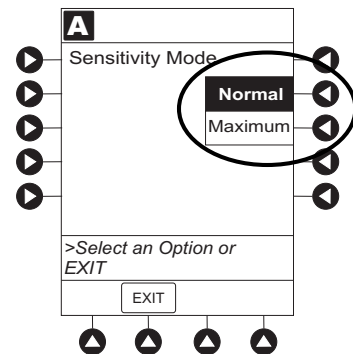


Channel Options (Continued)

Change Sensitivity Mode (Continued)

Masimo SET.
(8220)

2. To change **Sensitivity Mode**, press applicable soft key. ①
- **Normal:** Normal patient monitoring.
 - **Maximum:** Improved low perfusion performance.



NOTE:

- ① The sensitivity mode is displayed on the **SPO2 Main** display only when **Maximum** is selected.

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System Start-Up/Setup

See the PC unit section of this User Manual, "General Setup and Operation," for various system start-up and setup procedures.

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Warnings and Cautions

General

WARNINGS

- The SpO₂ module is **not to be used as an apnea monitor**.
- **Pulse oximetry readings and pulse signal** can be affected by certain ambient conditions, sensor application errors, and certain patient conditions.
- The SpO₂ module is intended only as an **adjunct in patient assessment**. It must be used in conjunction with clinical signs and symptoms.
- The SpO₂ module should be considered an **early warning device**. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-Oximeter to completely understand the patient's condition.
- **Interfering Substances:** Carboxyhemoglobin and methemoglobin can erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation can cause erroneous readings.
- The SpO₂ module is **not rated for defibrillation use**. Disconnect the sensor from the patient or patient cable from the module prior to defibrillation.
- **Do not lift** the SpO₂ module by the cable because it could disconnect from the instrument, causing it to drop on the patient. Do not place the SpO₂ module in any position that could cause it to fall onto the patient.
- **Respond immediately to system alarms;** patient monitoring can cease under certain alarm conditions.

Warnings and Cautions (Continued)

Sensors and Cables

WARNINGS



- **Inspect the SpO₂ sensor site regularly** to ensure correct sensor positioning, application, and site integrity. Tissue damage could occur over prolonged time periods, depending on the patient Profile (such as neonates) and method of application. Refer to the sensor instructions for additional information.
- Do not use a sensor, cable, or connector that **appears damaged**. Do not use a sensor with **exposed optical components**.
- The sensor **disconnect error message** and associated alarm indicate the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor.
- **Model 8210:**
 - Use only** approved Nellcor sensors and pulse oximetry cables.
- **Model 8220:**
 - Use only** approved Masimo sensors and patient cables.
 - Use of sensors, transducers, cables, and accessories other than those specified can cause improper SpO₂ module performance resulting in inaccurate readings, increased emission, and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO₂ module.
- **Carefully route patient cabling** to reduce the possibility of patient entanglement or strangulation.
- Before use, **read the sensor User Manual**, including all warnings, cautions, and instructions.

CAUTION



- **Do not immerse or dampen** the sensor or cable. Clean per manufacturer's instructions.

Cables and Sensors

Nellcor Patient Cables and Sensors



The Nellcor patient cables interface the SpO₂ module with the patient sensors.

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. Use only Nellcor sensors. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the User Manual accompanying the sensor.

For a list of compatible sensors and cables, refer to the Monitor Sensor Compatibility Alaris™ SpO₂ Module 8210 Series.

Masimo Patient Cables and Sensors





When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. Use only Masimo SET sensors. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the User Manual accompanying the sensor.

For a list of compatible sensors and cables, refer to the Monitor Sensor Compatibility Alaris™ SpO₂ Module 8220 Series.

Features and Displays


Features and Definitions

See the PC unit section of this User Manual for system features and definitions.

| Models 8210  and 8220  | |
|--|--|
| Feature | Definition |
| % SpO₂ Alarm Limits | Upper and lower saturation limits for %SpO ₂ alarm can be adjusted by clinician. |
| % SpO₂ Display | Functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO ₂ . |
| Limit Mode | Configurable mode that can be set to display either adult or neonatal monitoring mode. (See "Configurable Settings" for additional configurable features.) |
| Pleth Waveform | Plethysmographic (pleth) waveform is a graphic representation of changes in extremity blood volume during cardiac cycle events. Displayed waveform is a simulated signal (non-normalized). |
| Pulse Beat Volume | Sound of each pulse beep can be configured to be off or to a volume level of 1, 2, or 3. |
| Pulse Rate | Displayed in beats per minute (bpm). |
| Pulse Rate Alarm Limits | Upper and lower pulse rate alarm limits can be adjusted by clinician. |
| Trend Data | Tabular display of %SpO ₂ and pulse rate. Display shows average high and low values, and alarm conditions for time period displayed. Up to 24 hours of data is stored. |


Features and Displays (Continued)

Features and Definitions (Continued)

| Model 8210  NELLCOR | |
|--|---|
| Feature | Definition |
| SatSeconds™ | <p>SatSeconds™ limits controls time %SpO₂ level can fall outside the alarm limits before an audible alarm sounds. Method of calculation is as follows:</p> <p style="padding-left: 20px;">Number of percentage points %SpO₂ falls outside of the alarm limit is multiplied by number of seconds %SpO₂ level remains outside that limit.</p> <p style="padding-left: 20px;">Points x Seconds = SatSeconds™</p> <p style="padding-left: 20px;">Points = %SpO₂ percentage points outside of limit</p> <p style="padding-left: 20px;">Seconds = number of seconds %SpO₂ remains at that point outside of the limit</p> <p>Saturation levels might fluctuate rather than remain steady for a period of several seconds. %SpO₂ levels might fluctuate above and below alarm limit, reentering nonalarm range several times. During such fluctuations, %SpO₂ module integrates number of %SpO₂ points, both positive and negative, until either SatSeconds™ limit (SatSeconds™ time setting) is reached or %SpO₂ level returns to within a normal range and remains there.</p> <p>SatSeconds™ "Safety Net" is for patients with saturation levels having frequent excursions below limit but not staying below limit long enough for SatSeconds™ time setting to be reached. When three or more limit violations occur within 60 seconds, an alarm sounds, even if SatSeconds™ time setting has not been reached.</p> |
| SatSeconds™ alarm management | <p>With SatSeconds™ alarm management technology, upper and lower alarm limits are set in the same way as with traditional alarm management. A SatSeconds™ limit can be set to allow monitoring of %SpO₂ below selected low alarm limit for a period of time before an audible alarm sounds.</p> |

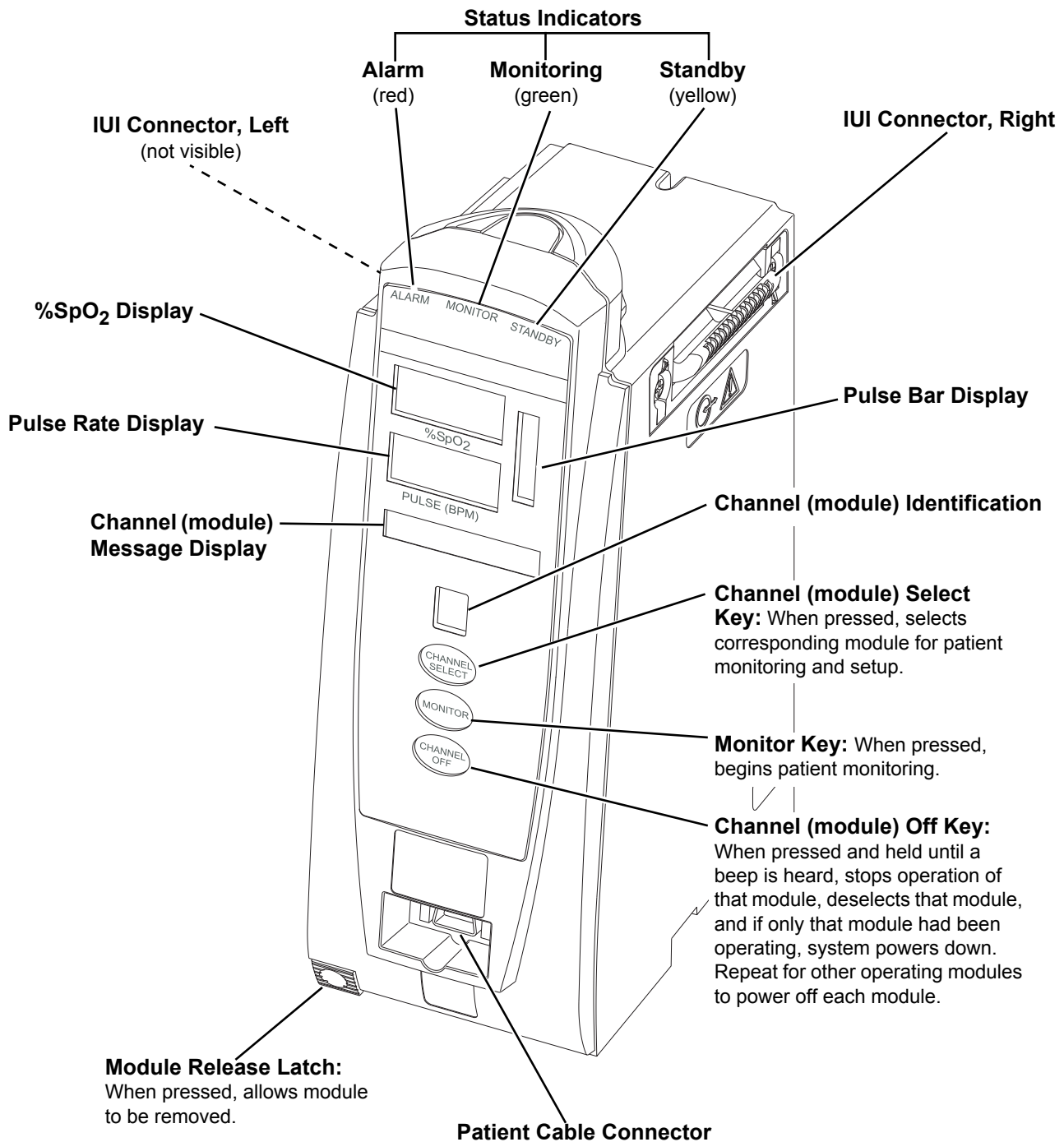
Features and Displays (Continued)

Features and Definitions (Continued)

| Model 8220  | |
|--|---|
| Feature | Definition |
| Fast SAT | When Fast SAT is enabled and there is one data point that is significantly different from a previous data point, averaging is disregarded and most recent data point is displayed. For example, if readings were 97%, 96%, 95%, and 85%, displayed saturation level would be 85%. |
| PI | Perfusion Index (PI) is a scaled numeric value derived from magnitude of pulsations displayed on plethysmographic (pleth) waveform. It is calculated as a percentage of pulsatile signal to nonpulsatile signal. PI is used to find best perfused site for sensor placement (larger the PI, stronger the perfusion). Operating range is 0.02 to 20. Desired number is greater than 1 or as large as possible. |
| Saturation Averaging Time | Averaging time can be set to 2, 4, 8, 10, 12, 14, or 16 seconds. |
| Sensitivity Mode | Sensitivity mode, normal or maximum, of current monitoring configuration is displayed in options mode. Normal setting is used for normal patient monitoring purposes. Maximum setting is used for improved low perfusion performance. |
| SET Technology | Signal Extraction Technology (SET) uses adaptive filters to separate arterial signal from nonarterial noise. SET provides for accurate readings under extreme conditions (such as low perfusion and motion). |
| Signal I.Q.[™] Feature | A visual indication of pulsation at sensor site. Vertical bar height indicates quality of measured signal. Signal I.Q. [™] feature is related to proper sensor application, adequate arterial signal, and intensity of motion. Use Signal I.Q. [™] feature to verify optimal sensor placement. |

Features and Displays (Continued)

Operating Features, Controls, Indicators



Features and Displays (Continued)

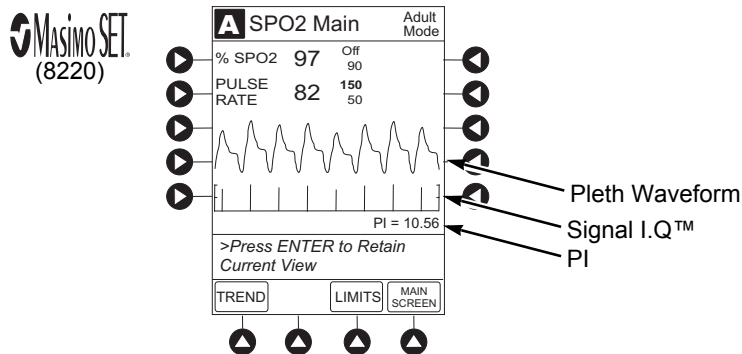
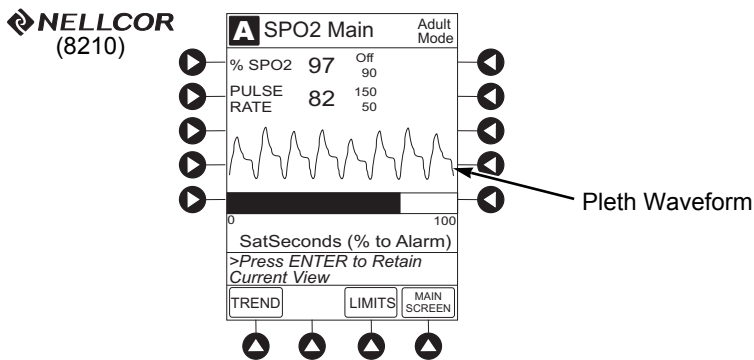
Displays

The displays illustrated throughout this document are for illustration purposes only. The display content varies, depending on configuration settings, hospital-defined Data Set uploaded using the Guardrails Suite MX, programmed parameters, and many other variables.

Main Display

See the PC unit section of this User Manual.

SPO2 Main Display






Configurable Settings

See the PC unit section of this User Manual for system configurable settings.

If the configuration settings need to be changed from the **Factory default** settings, refer to the applicable Technical Service Manual or contact CareFusion Technical Support for technical, troubleshooting, and preventive maintenance information.

With the Profiles feature enabled, the settings are configured independently for each Profile. A hospital-defined, best-practice Data Set must be uploaded to enable the Profiles feature. Date and Time is a system setting and is the same in all Profiles.

| Models 8210  NELLCOR and 8220  | | |
|---|---|-----------------|
| Feature | Default Setting | Options |
| Limit Mode | Adult | Adult, Neonatal |
| Pulse Beep Volume | 1 | 1, 2, 3, Off |
| Pulse Rate Alarm Limit, High | Adult Mode: 120 bpm Neonatal Mode: 200 bpm | 31 - 240 bpm |
| Pulse Rate Alarm Limit, Low | Adult Mode: 50 bpm Neonatal Mode: 100 bpm | 30 - 239 bpm |
| SpO ₂ Alarm Limit, High | Adult: Off Neonatal: 95% | 21 - 100%, Off |
| SpO ₂ Alarm Limit, Low | Adult: 90% Neonatal: 80% | 20 - 99% |

| Model 8210  NELLCOR | | |
|---|------------------------|------------------------------|
| Feature | Default Setting | Options |
| SatSeconds | Off | 10, 25, 50, 100 seconds; Off |

Configurable Settings (Continued)

| Model 8220 | | |
|---|-----------------|---------------------------------|
| Feature | Default Setting | Options |
| Saturation Averaging Time (display update period) | 8 seconds | 2, 4, 8, 10, 12, 14, 16 seconds |
| Sensitivity Mode | Normal | Normal, Maximum |

Specifications and Symbols

Specifications

Models 8210 and 8220

Alarms: Audible and visual alarms for high and low saturation and pulse rate, sensor condition, system failure, and low battery conditions.

Alarm Limits:

| | Low | High |
|------------------|--------------|--------------|
| Pulse Rate: | 30 - 239 bpm | 31 - 240 bpm |
| SpO ₂ | 20 - 99% | 21 - 100% |

Dimensions: 3.3" W x 8.9" H x 5.5" D
(8.4 cm W x 22.6 cm H x 14 cm D)

Environmental Conditions:

| Symbol | Meaning | Operating | Storage/Transport |
|--------|---|-------------------------------------|------------------------------------|
| | Atmospheric Pressure | 525 - 4560 mmHg (700 - 6080 hPa) | 375 - 760 mmHg (500 - 1013 hPa) |
| | Relative Humidity (Avoid prolonged exposure to relative humidity >85%) | 20 - 90% Noncondensing | 5 - 85% Noncondensing |
| | Temperature Range | 41 - 104°F (5 - 40°C) | -4 - 140°F (-20 - 60°C) |

Fluid Ingress Protection: IPX1, the SpO₂ module is protected against harmful effects of dripping water per IEC 60529

Specifications and Symbols (Continued)

Specifications (Continued)

Models 8210 NELLCOR and 8220

Mode of Operation: Continuous

Shock Protection: Type BF patient applied part

Weight: 2 lbs (0.91 kg)

Model 8210 NELLCOR

Accuracy Tolerance:

| | Low Perfusion ^① | Adult ^② | Neonate ^② |
|-----------------------|----------------------------|---------------------------|---------------------------|
| Pulse Rate | 20 - 250 bpm ±3 digits | 20 - 250 bpm ±3 digits | 20 - 250 bpm ±3 digits |
| Functional Saturation | 70 - 100% ±2 digits | 70 - 100% ±2 digits | 70 - 100% ±3 digits |

Display Update Period: 2.25 seconds

Measurement Range: Perfusion: 0.03 - 20%
Pulse Rate: 20 - 250 bpm
SpO₂: 1 - 100%

Pulse Amplitude Display: Visual indicators for pulse signals represent proportional pulse amplitude strength.

Sensor: Emitted light wavelength range is within 500 - 1000 nm. Output power does not exceed 15 mw.


Model 8220

Accuracy and Motion Tolerance:

| | Low Perfusion ^③ | Motion ^{④⑤} | No Motion ^⑥ | Resolution |
|------------|---|--|---|---------------------|
| Pulse Rate | 25 - 240 bpm Adults, Pediatrics, Neonates: ±3 digits | 25 - 240 bpm Adults, Pediatrics, Neonates: ±5 digits | 25 - 240 bpm Adults, Pediatrics, Neonates: ±3 digits | 1 bpm |
| Saturation | 70 - 100% Adults, Pediatrics: ±2 digits; Neonates: ±3 digits | 70 - 100% Adults, Pediatrics, Neonates: ±3 digits | 70 - 100% Adults, Pediatrics: ±2 digits; Neonates: ±3 digits | 1% SpO ₂ |

Specifications and Symbols (Continued)

Specifications (Continued)

Model 8220 

Display Update Period: Approximately 1 second.

Measurement Range: Perfusion: 0.02 - 20%
Pulse Rate: 25 - 240 bpm
SpO₂: 1 - 100%

Pulse Amplitude Display: Proportional to height of I.Q. signal.

Sensor: Emitted light wavelength range is within 500 - 1000 nm. Output power does not exceed 1 mw.

NOTE:

Wavelength range information can be especially useful to clinicians, for example, those performing photodynamic therapy.

Specifications and Symbols (Continued)

Specifications (Continued)




NOTES:

- ① Specification applies to monitor performance.
- ② Adult specifications are shown for OxIMAX MAX-A and MAX-N sensors. Neonate specifications are shown for OxIMAX MAX-N sensors. Saturation accuracy varies by sensor type.
- ③ Masimo Board performance has been validated for low perfusion accuracy in bench-top testing against a BIO-TEK simulator and a Masimo simulator.
- ④ Masimo Board performance has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies, while performing rubbing and tapping motions at 2 - 4 Hz at an amplitude of 1 - 2 cm and a nonrepetitive range of 70 - 100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
- ⑤ Masimo Board performance with Masimo LNOP™ Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates, while moving the neonate's foot at 2 - 4 Hz at an amplitude of 1 - 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
- ⑥ Masimo Board performance has been validated for no-motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies, in the range of 70 - 100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Specifications and Symbols (Continued)

Symbols

See the PC unit section of this User Manual for system symbols.

| Symbol | Meaning |
|---|--|
|  | Silenced alarm. Note: When displayed, the dashed lines through the symbol might appear as solid lines due to the small display size. |
|  | Is displayed in Trend Data screen to identify an exceeded alarm limit. |
|  | Type BF patient applied part. |

Measurement Accuracy

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the SpO₂ module to ensure that it is functioning properly.

NOTE:

Because the SpO₂ module's measurements are statistically distributed, only about two-thirds of the SpO₂ module measurements can be expected to fall within ± 1 Arms of the value measured by a co-oximeter.

An inaccurate measurement can be caused by:

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin).
- Intravascular dyes (such as indocyanine green or methylene blue).
- Exposure to excessive illumination; such as, a surgical lamp (especially one with a xenon light source), bilirubin lamp, fluorescent light, infrared heating lamp, or direct sunlight.^①
- Prolonged and/or excessive patient movement.
- Venous pulsations.

Measurement Accuracy (Continued)

- Sensor placed on an extremity with a blood pressure cuff, arterial catheter, intravascular line or other causes of insufficient perfusion.
- Nail irregularity, such as nail polish or fungus. Remove nail polish and/or move sensor to an unaffected site.
- Placement is too close to electrosurgery equipment.
- Defibrillation.

The loss of a pulse signal can occur in any of the following situations:

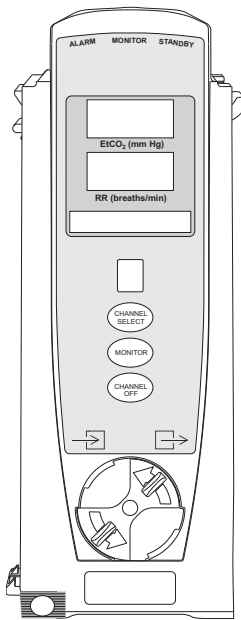
- The sensor is too tight.
- Exposure to excessive illumination; such as, a surgical lamp (especially one with a xenon light source), bilirubin lamp, fluorescent light, infrared heating lamp, or direct sunlight.
- The sensor placed on an extremity with a blood pressure cuff, arterial catheter, intravascular line, or other causes of insufficient perfusion.
- The patient has hypotension, severe vasoconstriction, severe anemia or hypothermia, is in cardiac arrest or is in shock.
- There is an arterial occlusion proximal to sensor.
- Placement is too close to electrosurgery equipment.

NOTE:

- ① Exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.

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Alaris EtCO₂ Module Model 8300



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Getting Started

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| Attach Gas Scavenging System..... | 5-4 |

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Introduction

This section of the User Manual provides EtCO₂ module (Model 8300) instructions and information. It is used in conjunction with:

- EtCO₂ module Technical Service Manual
- Monitor Accessory Compatibility Alaris™ EtCO₂ Module 8300 Series
- Covidien's Microstream™ disposable instructions
- PC unit section of this User Manual
- System Maintenance software (and its instructions) for Alaris System check-in, maintenance, and wireless configuration

The EtCO₂ module is a capnograph indicated for continuous, noninvasive monitoring of end tidal carbon dioxide (EtCO₂), fractional inspired carbon dioxide (FiCO₂) and respiratory rate (RR). The end-tidal gas reading is calculated as a maximum value. The recommended setting and factory default is a 20 second window. The window defines the maximum measured EtCO₂ and the minimum measure FiCO₂.

The EtCO₂ module and disposables are indicated for use with intubated and nonintubated adult, pediatric and neonatal patients. It is not intended for direct connection to ventilator or breathing systems. Only one EtCO₂ module can be connected to the Alaris System.

The EtCO₂ module is used with Covidien's patented Microstream Disposables/circuits for sidestream capnography. The Microstream EtCO₂ sampling lines deliver a sample of the inhaled and exhaled gases from direct contact to the patient via an oral/nasal cannula into the monitor for CO₂ measurement.

Microstream Disposable: See "General Information" for "Microstream Disposable" Information.

Alarms and Messages: See "Troubleshooting and Maintenance" for module-specific alarms and messages.

Contraindications: None known.

Electromagnetic Environment: See "Appendix" section of this User Manual ("Regulations and Standards," "Compliance").


WARNING

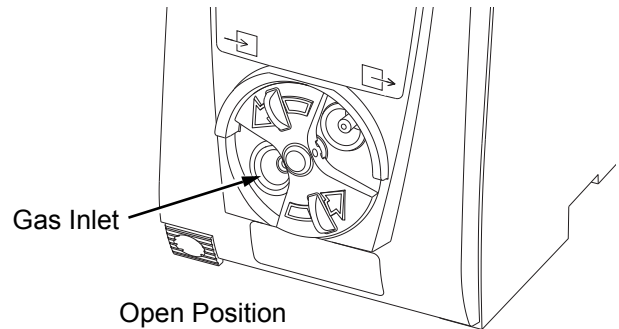
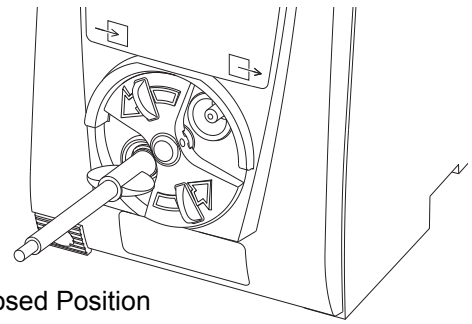


Read all instructions, for both the EtCO₂ module and PC unit, before using the Alaris System.

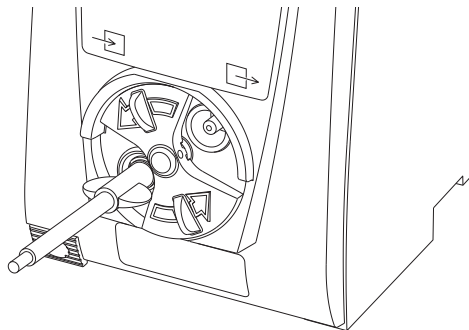
Connect Microstream™ Disposable

1. Open gas inlet/outlet door by turning door counterclockwise until gas inlet is clearly visible. Hold in open position.

Gas inlet is located on lower left corner of instrument and is marked with a gas inlet symbol ().



2. Connect Microstream Disposable:
 - a. Press brightly colored end of disposable into gas inlet.
 - b. Turn it clockwise until tightly secured to EtCO₂ module.



WARNING

Use only Microstream Disposables. Use of a disposable other than those specified can cause improper EtCO₂ module performance, resulting in inaccurate readings.

Connect Microstream Disposable (Continued)


3. Release door.
4. Connect Microstream Disposable to patient. Connection site and manner are dependent on patient intubation status and type of Microstream Disposable being used (refer to disposable's User Manual).

NOTE:

The Covidien Disposable may be used with 5 liters of oxygen with a nasal cannula. This disposable is not intended to be used with high flow oxygen through a nasal cannula. The use of a mask with high flow oxygen is recommended. Two nasal cannulas should not be used at one time.

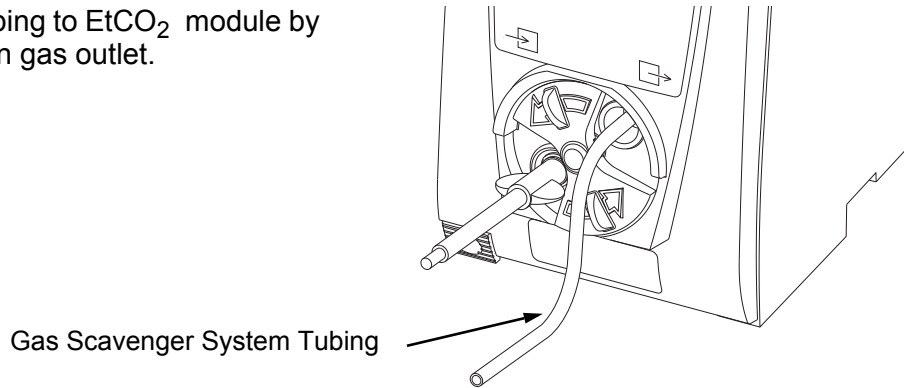
Attach Gas Scavenging System

In the presence of high oxygen or anesthesia concentrations, it might be necessary to connect a gas scavenging system to the EtCO₂ module.

1. Open gas inlet/outlet door by turning door counterclockwise until gas outlet is clearly visible. Hold in open position.
Gas outlet is located on lower right corner of instrument and is marked with a gas outlet symbol ().
2. Secure gas scavenger system tubing to EtCO₂ module by firmly pushing tubing into fitting on gas outlet.
3. Release door.

WARNING

There is a risk of patient cross-infection if the sampled gas is returned to the breathing system.



Display references throughout this procedure are for illustration purposes only.

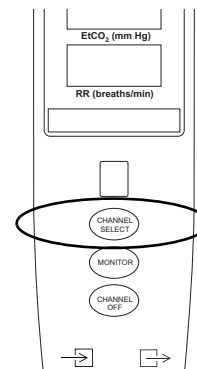
See "General Information," "Features and Displays" and PC unit section of this User Manual for information about:

- Displays
- Operating Features, Controls, Indicators

Monitoring Mode

1. Perform following steps (see PC unit section of this User Manual, "General Setup and Operation," "Start-Up"):
 - a. Power on system.
 - b. Choose **Yes** or **No** to **New Patient?**
 - c. Confirm current Profile or select a new Profile.
 - d. Enter patient identifier, if required.
2. Connect Microstream Disposable (see "Getting Started").
3. Press **CHANNEL SELECT** key.

SENSOR WARMING and then **SEARCHING** appear in Channel Message display until EtCO₂ and respiratory rate readings stabilize (up to 60 seconds).



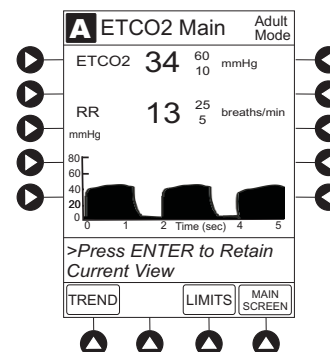
4. Alarm limits:
 - To change settings, see "Set Alarm Limits" procedure.

Monitoring Mode (Continued)

- To accept settings and begin monitoring, press **ENTER** key.

ETCO2 Main screen displays following information:^①

- Capnography waveform (scale adjustable).
- EtCO₂ value, as well as minimum and maximum EtCO₂ alarm limits.
- Limit Mode (Adult or Neonatal).
- Respiratory rate (RR, breaths/min), as well as minimum and maximum RR alarm limits.

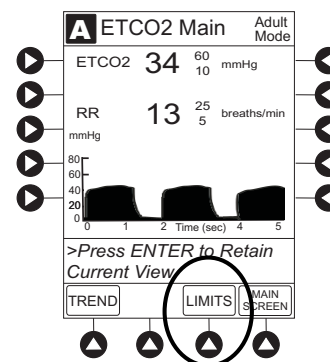


NOTE:

- ^① PC unit display response time is approximately ½ second longer than the EtCO₂ module response time.

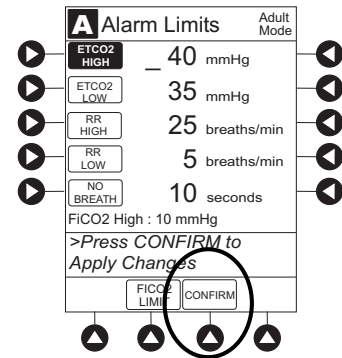
Set Alarm Limits

- Press **LIMITS** soft key.
- To change a limit setting, press soft key next to applicable parameter.
- Enter a numeric value for selected alarm limit.



Monitoring Mode (Continued)

- To move to next limit, press **ENTER** key.
- To confirm alarm settings and return to **ETCO2 Main** display, press **CONFIRM** soft key.







- To return to Main Display, press **MAIN SCREEN** soft key.

Monitoring Mode (Continued)

Navigate Trend Data



1. To view Trend Data, press **TREND** soft key.






Following information is displayed:

- **TIME** period for data review.
- Average **ETCO2** with high and low values.
- Average respiratory rate (**RR**) with high and low values.
- Alarm icon () with **Fi** in **TIME** column to indicate high FiCO₂ alarm limit has been exceeded.
- Alarm icon () to indicate an alarm limit has been exceeded.
- Alarm icon () in **RR** column to indicate a no breath () alarm limit has been triggered.
- Dashes (---), if no EtCO₂ or respiratory rate values are available for time period displayed.

Tabular information is not updated while **Trend Data** view is displayed. Tabular data is updated, using new trend data stored in EtCO₂ module, after leaving **Trend Data** view. To view latest data, return to **Trend Data** view.

2. To navigate from page to page, press **PAGE UP** and **PAGE DOWN** soft keys.

3. To scroll data one row at a time, press  or  key.

| A Trend Data Adult Mode 09:00 | | | | | |
|--|-------|---|-----|---------|---|
| 2001-07-06 | ETCO2 | | RR | | |
| TIME | AVG | MAX MIN | AVG | MAX MIN | |
| 22:58 Fi  | 40 | 47 38 | 13 | 26 11 |  |
| 22:28 Fi  | 40 | 44 39 | 12 | 19 11 |  |
| 21:58 | 41 | 45 39 | 13 | 29 11 | |
| 21:28 | 41 | 45 34  | 11 | 14 10 | |
| 20:58 | --- | | --- | | |
| 20:28 | 39 | 44 37 | 12 | 14 11 | |

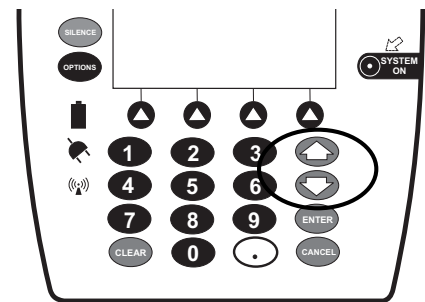
ZOOM: 120 60 **30** 5 1 minutes




>Press UP/DOWN Keys to Move Cursor.

| | | | |
|---------|------|------------|-----------|
| PAGE UP | ZOOM | ETCO2 MAIN | PAGE DOWN |
|---------|------|------------|-----------|

4. To change **TIME** increments for data review, move cursor to desired time period and press **ZOOM** soft key.

- New time increments display.
- Each press of **ZOOM** soft key changes time increments.



| A Trend Data Adult Mode 09:00 | | | | | |
|--|-------|---|-----|---------|--|
| 2001-07-06 | ETCO2 | | RR | | |
| TIME | AVG | MAX MIN | AVG | MAX MIN | |
| 22:28 Fi  | 40 | 44 39 | 12 | 16 11 | |
| 21:58 Fi  | 41 | 45 39 | 13 | 20 11 | |
| 21:28 | 41 | 45 34  | 11 | 14 10 | |
| 20:58 | --- | | --- | | |
| 20:28 | 39 | 44 37 | 12 | 14 11 | |
| 19:58 | 39 | 44 37 | 12 | 14 11 | |

ZOOM: 120 60 **30** 5 1 minutes

>Press UP/DOWN Keys to Move Cursor.

| | | | |
|---------|-------------|------------|-----------|
| PAGE UP | ZOOM | ETCO2 MAIN | PAGE DOWN |
|---------|-------------|------------|-----------|

Monitoring Mode (Continued)

Navigate Trend Data (Continued)

5. To return to **ETCO2 Main** display, press **ETCO2 MAIN** soft key.
6. To return to Main Display, press **MAIN SCREEN** soft key.

Navigate PCA/Alaris EtCO₂ Module Trend Data

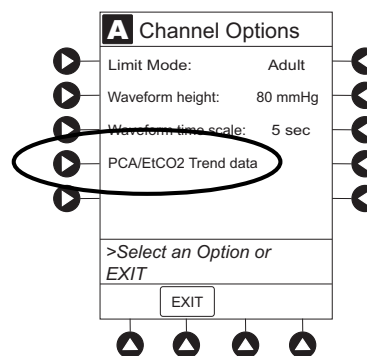
To access and view shared trend data when a PCA module is present, perform the following steps.

1. To view **ETCO2 Main** display, press **CHANNEL SELECT** key.
2. To access option to view trend data, press **OPTIONS** key.
3. To view **Trend Data**, press **PCA/EtCO2 Trend data** soft key.

Following information is displayed:

- **TIME** period for data review.
- Average **ETCO2**.
- Average respiratory rate (**RR**).
- Alarm icon ().
- **TOTAL DOSE** of medication infused through PCA module (includes Continuous Infusion, loading dose, bolus, and PCA dose).

4. See "Navigate Trend Data" procedure for instructions on how to:
 - Navigate from page to page.
 - Change **TIME** increments.
 - Return to **ETCO2 MAIN** display.
 - Return to Main Display.



| A Morphine 1mg/mL 09:00 | | | |
|-------------------------|-----------------|-----------|--------|
| 2003-06-06 | TOTAL DOSE (mg) | ETCO2 AVG | RR AVG |
| 08:01 | --- | 40 | 13 |
| 08:02 | 2.55 | 40 | 12 |
| 08:03 | 1.2 | 41 | 13 |
| 08:04 | 5.01 | 41 | 11 |
| 08:05 | --- | --- | --- |
| 08:06 | 2 | 39 | 12 |

ZOOM: 120 60 30 5 **1** minutes

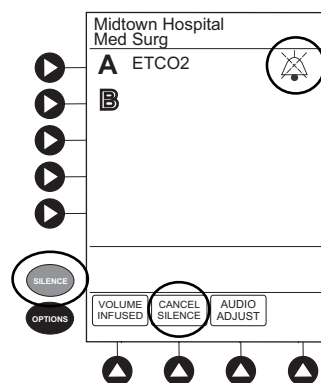
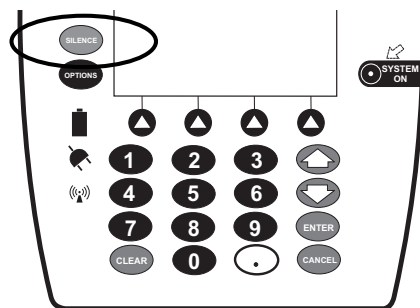
>Press UP/DOWN Keys to Move Cursor.

ZOOM
ETCO2 MAIN
PAGE DOWN

Monitoring Mode (Continued)

Presilence Alarm

1. To presilence alarm, press **SILENCE** key.
All monitoring alarms are silenced for 120 seconds and an Monitoring Alarm Silence symbol is displayed on the PC unit main screen. Subsequent infusion alarms are not silenced.
2. To cancel presilence alarm and return to alarmable mode:
 - Press **CANCEL SILENCE** soft key.

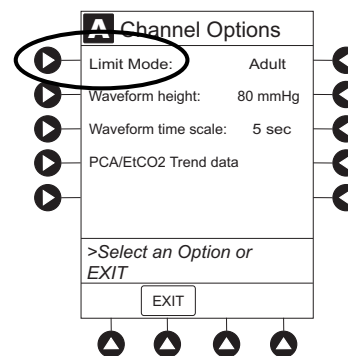


Channel Options

Change Limit Mode

The following procedure can be performed only when the Guardrails Suite MX is not enabled (Profile option not being used for programming).

1. Press **Limit Mode** soft key.



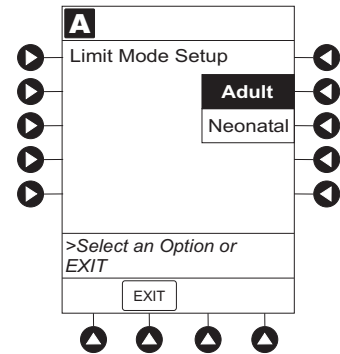
Channel Options (Continued)

Change Limit Mode (Continued)

- To change **Limit Mode Setup**, press applicable soft key.

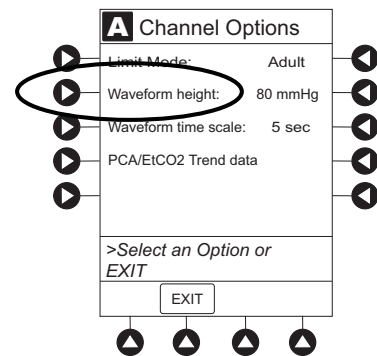
OR

To leave **Limit Mode Setup** unchanged and return to **ETCO2 Main** display, press **EXIT** soft key.



Change Waveform Height

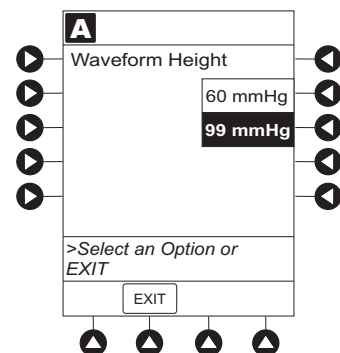
- Press **Waveform height** soft key.



- To change **Waveform Height**, select applicable range limit.

- 60 mmHg:** Displays a waveform for EtCO₂ values within 0 – 60 mmHg range. If EtCO₂ value exceeds that range, **Waveform Out of Range; Adjust Scaling** message is displayed until waveform falls back into range or 0 – 99 mmHg option is selected.
- 99 mmHg:** Displays a waveform for full EtCO₂ value range, 0 – 99 mmHg.

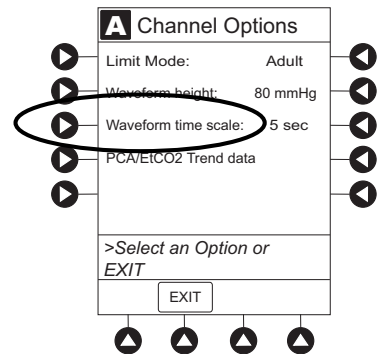
- To return to **ETCO2 Main** display, press **EXIT** soft key.



Channel Options (Continued)

Change Waveform Time Scale

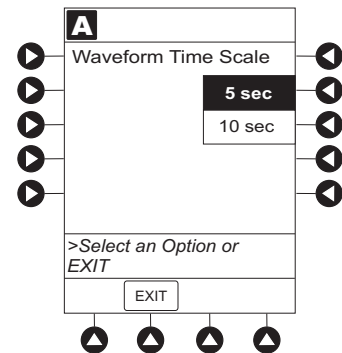
1. Press **Waveform time scale** soft key.



2. To change **Waveform Time Scale**, select applicable time scale.

OR

To leave **Waveform Time Scale** unchanged and return to **ETCO2 Main** display, press **EXIT** soft key.



System Start-Up/Setup

See the PC unit section of this User Manual, "General Setup and Operation," for various system start-up and setup procedures.

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Warnings and Cautions

General

WARNINGS

- **EtCO₂ and respiratory rate readings** can be affected by certain ambient environmental and patient conditions.
- The EtCO₂ module is **not to be used as an apnea monitor**.
- The EtCO₂ module is intended only as an **adjunct in patient assessment**. It must be used in conjunction with clinical signs and symptoms.
- If uncertain about **measurement accuracy**, assess patient's condition and vital signs by alternate means, then ensure that EtCO₂ module is functioning correctly.
- **Do not lift** the EtCO₂ module by Microstream Disposable because it could disconnect from the instrument, causing it to drop on the patient. Do not place the EtCO₂ module in any position that could cause it to fall onto the patient.
- Do not use the EtCO₂ module or Microstream Disposable inside a **hyperbaric chamber**.
- **Respond immediately to system alarms**; patient monitoring can cease under certain alarm conditions.

Microstream Disposable

WARNINGS

- Do not use a connector or Microstream Disposable that **appears damaged**.
- The Microstream Disposable **disconnect error message** and associated alarm indicate the Microstream Disposable is disconnected. Check the Microstream Disposable connection and, if necessary, replace the Microstream Disposable.
- **Use only Microstream Disposables**. Use of a disposable other than those specified can cause improper EtCO₂ module performance, resulting in inaccurate readings.

Warnings and Cautions (Continued)

Microstream Disposable (Continued)

WARNINGS

- Before use, **read Microstream Disposable User Manual**, including all warnings, cautions, and instructions.
- **Carefully locate the patient Microstream Disposable** to reduce the possibility of patient entanglement or strangulation.

CAUTIONS

- **Do not immerse or dampen** the Microstream Disposable.
- The Microstream Disposables are **designed for single patient use** and are not to be reprocessed. Do not attempt to disinfect or flush the disposable as the EtCO₂ module can be damaged.

Microstream Disposable

When selecting a Microstream Disposable, consider the patient's weight, condition, and intubation status. For more information on Microstream Disposables, contact Covidien at <http://www.covidien.com/rms> or 1-800-635-5267.

For a list of compatible disposables, refer to the Monitor Accessory Compatibility Alaris™ EtCO₂ Module 8300 Series (provided separately).

Features and Displays

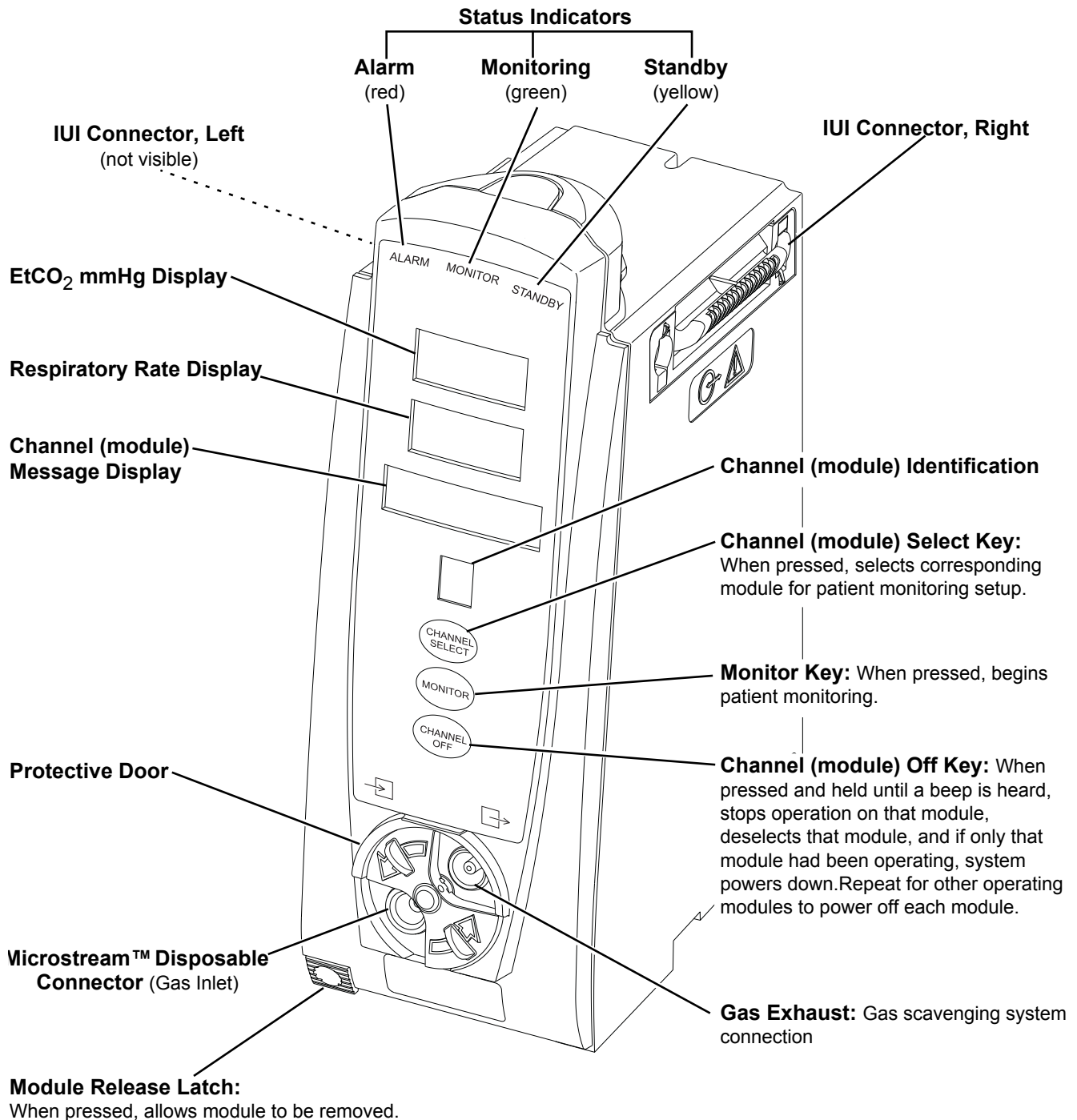
Features and Definitions

See the PC unit section of this User Manual for system features and definitions.

| Feature | Definition |
|----------------------------------|---|
| BPM | Breaths per minute. |
| Capnography Waveform | Real-time graphical display of CO ₂ concentration throughout respiration. |
| Data Display | Waveforms, trended data, and numerical values are displayed. |
| EtCO₂ | CO ₂ concentration in mmHg at end of exhalation. |
| FiCO₂ | Fractional-inspired CO ₂ ; CO ₂ concentration present during inhalation. |
| Limit Mode | Configurable mode that can be set to display either adult or neonatal monitoring mode. (See "Configurable Settings" for additional configurable features.) |
| Microstream Disposable | Covidien's line of Microstream Disposables are available for neonatal, pediatric, and adult patients. Patients can be intubated or nonintubated. |
| Programmable Alarm Limits | Alarm limits for EtCO ₂ , FiCO ₂ , respiration rates, and No Breath time periods are programmable. |
| Respiratory Rate | Patient's respiratory rate in breaths per minute (breaths/minute). |
| Trend Data | Tabular display of EtCO ₂ and respiratory rate. Display shows average, high, and low values, and alarm conditions for time period displayed. Up to 24 hours of data is stored. |

Features and Displays (Continued)

Operating Features, Controls, Indicators



Features and Displays (Continued)

Displays

The displays illustrated throughout this document are for illustration purposes only. The display content varies, depending on configuration settings, type of disposable in use, hospital-defined Data Set uploaded using the Guardrails Suite MX, programmed parameters, and many other variables.

Main Display

See the PC unit section of this User Manual.

Configurable Settings

See the PC unit section of this User Manual for system configurable settings.

If the configuration settings need to be changed from the **Factory default** settings, refer to the applicable Technical Service Manual or contact CareFusion Technical Support, for technical, troubleshooting, and preventive maintenance information. Please consult the facility's best practices guidelines on the preferred alarm settings for the monitoring of patients that are not continuously attended by a clinician.

With the Profiles feature enabled, the settings are configured independently for each Profile. A hospital-defined, best-practice Data Set must be uploaded to enable the Profiles feature. Date and Time is a system setting and is the same in all Profiles.

| Feature | Default Setting | Options |
|--|---|-------------------|
| EtCO ₂ Alarm Limit, High | Adult: 60 mmHg Neonatal: 60 mmHg | 5 - 99 mmHg |
| EtCO ₂ Alarm Limit, Low | Adult: 10 mmHg Neonatal: 10 mmHg | 0 - 98 mmHg |
| F _i CO ₂ Alarm Limit, High | Adult: 8 mmHg Neonatal: 8 mmHg | 2 - 99 mmHg |
| Limit Mode | Adult | Adult or Neonatal |
| No Breath Alarm | Adult: 30 seconds Neonatal: 20 seconds | 10 - 60 seconds |

Configurable Settings (Continued)

| Feature | Default Setting | Options |
|------------------------------------|---|-------------|
| Respiratory Rate Alarm Limit, High | Adult Mode: 35 bpm Neonatal Mode: 80 bpm | 1 - 150 bpm |
| Respiratory Rate Alarm Limit, Low | Adult Mode: 6 bpm Neonatal Mode: 12 bpm | 0 - 149 bpm |

Specifications and Symbols

Specifications

Accuracy:

EtCO₂ readings:

| CO ₂ Partial Pressure (at sea level) | Accuracy ^① |
|---|--|
| 0 - 38 mmHg | ±2 mmHg |
| 39 - 99 mmHg | ± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) |

NOTE:

- ① Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12 % of reading whichever is greater, for EtCO₂ values exceeding 18 mmHg. This is tested according to and is compliant with ISO 80601-2-55. To achieve the specified accuracies for breath rates above 60 breaths/minute, the Microstream FilterLine H Set for Infant/Neonatal must be used. Above 55°C module temperature, ± 1mmHg or ± 2.5%, whichever is greater, has to be added to the tolerance of the accuracy specifications.

The accuracy specification is maintained to within 4% of the values in the presence of interfering gases.

Above 55°C module temperature, ±1 mmHg or 2.5% (whichever is greater), has to be added to tolerance of accuracy specifications.

Respiration rate, measured in range of 0 - 150 bpm with following accuracy:

| | |
|----------------|--------|
| 0 - 70 bpm: | ±1 bpm |
| 71 - 120 bpm: | ±2 bpm |
| 121 - 150 bpm: | ±3 bpm |

Specifications and Symbols (Continued)

Specifications (Continued)

Alarm Limits:

| | Low | High |
|-------------------|---------------------|---------------------|
| EtCO ₂ | 0 - 98 mmHg | 5 - 99 mmHg |
| FiCO ₂ | Not Applicable | 2 - 99 mmHg |
| No Breath | 10 - 60 sec | Not Applicable |
| Respiration Rate | 0 - 149 breaths/min | 1 - 150 breaths/min |

Alarms:

Audible and visual alarms for high and low EtCO₂ and respiratory rate, high FiCO₂, Microstream Disposable condition, system failure, no breath, and low battery conditions.

Barometric Pressure:

EtCO₂ module is equipped with automatic barometric pressure compensation. There are no quantitative effects of barometric pressure for this device.




CO₂ Range:

Measures and reports partial pressures of CO₂ in the range of 0 - 99 mmHg at sea level. EtCO₂ and FiCO₂ values are calculated for all valid breaths.

Dimensions:

3.3" W x 8.9" H x 5.5" D
(8.4 cm W x 22.6 cm H x 14 cm D)

Environmental Conditions:

| Symbol | Meaning | Operating | Storage/Transport |
|---|---|--------------------------------------|--------------------------------------|
| | Altitude | -380 - 4570 m (-1250 - 15,000 ft) | -380 - 4570 m (-1250 - 15,000 ft) |
|  | Atmospheric Pressure | 525 - 4560 mmHg (700 - 6080 hPa) | 375 - 760 mmHg (500 - 1013 hPa) |
|  | Relative Humidity (Avoid prolonged exposure to relative humidity >85%) | 20 - 90% Noncondensing | 5 - 85% Noncondensing |
|  | Temperature Range | 41 - 104°F (5 - 40°C) | -4 - 140°F (-20 - 60°C) |

Fluid Ingress Protection: IPX1, Drip Proof

Specifications and Symbols (Continued)

Specifications (Continued)

| | |
|-------------------------------|--|
| Frequency Response: | EtCO ₂ accuracy applies for breath rates of up to 80 bpm. For maintaining accuracy for respiration rates above 80 bpm, accuracy is 4 mmHg or ±12% of reading, whichever is greater, for EtCO ₂ values exceeding 18 mmHg. To achieve specified accuracies for breath rates above 60 bpm, Microstream neonatal airway adapter M1996A must be used. |
| Gas Interference: | Following liquid anesthetics have been tested and were found to have no effect: Desflurane Enflurane Halothane Isoflurane Sevoflurane |
| Internal Power Source: | Operating time (fully charged): 5.5 hours |
| Measurement Range: | EtCO ₂ : 0 - 99 mmHg FiCO ₂ : 0 - 99 mmHg Respiratory Rate: 0 - 150 bpm |
| Mode of Operation: | Continuous |
| Sampling Gas Flowrate: | Nominally 50 mL/min -7.5 +15 mL/min |
| Shock Protection: | Type BF patient applied part |
| System Response Time: | EtCO ₂ module response: 2.9 seconds typical (includes rise time of 190 msec maximum and delay time of 2.7 seconds typical). PC unit display response: approximately ½ second longer than EtCO ₂ module response |
| Warm-Up Time: | 30 seconds typical |
| Waveform Sampling | 20 samples/s |
| Weight: | 2.5 lbs (0.91 kg) |








NOTE:

The periodic auto zero function compensates for drifts between components, changes in ambient temperature and barometric conditions. This automatic process eliminates variances that might otherwise cause measurement drift. Therefore the module does not exhibit drift.

Specifications and Symbols (Continued)

Symbols

See the PC unit section of this User Manual for system symbols.

| Symbol | Meaning |
|--|--|
|  | Type BF patient applied part. |
|  | Gas inlet. |
|  | Gas outlet. |
|  | Monitoring alarm or presence. Note: When displayed, the dashed lines through the symbol might appear as solid lines due to the small display size. |
|  | Is displayed in Trend Data screen to identify an exceeded alarm limit. |
|  | Is displayed in Trend Data screen to identify an exceeded no breath alarm limit. |
|  | Follow Instructions for Use |

Measurement Accuracy

The EtCO₂ module has been designed and manufactured to exacting standards and should perform well within given environmental and performance standards. There are certain conditions under which an inaccurate measurement or the loss of respiratory rate signal can occur.

An inaccurate EtCO₂ measurement can be caused by:

- Incorrect disposable application or use.
- Microstream Disposable disconnected or not securely connected to EtCO₂ module.
- Airway connection clogged, twisted, or leaking.
- Placement too close to electrosurgery equipment.
- Mechanically ventilated patient breathes spontaneously.

Loss of a respiratory rate signal can occur in any of the following situations:

- Incorrect disposable application or use.
- Microstream Disposable disconnected or not securely connected to EtCO₂ module.
- Airway connection clogged, twisted, or leaking.
- Patient not breathing.
- Placement too close to electrosurgery equipment.

WARNINGS

- If uncertain about **measurement accuracy**, assess patient's condition and vital signs by alternate means, then ensure that EtCO₂ module is functioning correctly.
- **Leaks or internal venting** of sampled gas can affect accuracy.

Measurement Accuracy (continued)

Respiration Rate Test

The following test method is used to determine the module's rated respiration rate range and the corresponding effects of end-tidal gas readings accuracy as a function of respiratory rate:

- The system is set for operation.
- The power connection is verified.
- The module is connected to the PC and power supply.
- A scope is connected to the digital/analog multifunction I/O.
- A digital output scheduler software is opened on the PC.
- Gas connections are checked.
- The power connection is verified.
- The gas mixes cylinders are open, set on the required pressure, and their condition is verified.
- A BPM setting is selected.
- The module is connected to the gas tube.
- The module is disconnected.

NOTE:

When CO₂ waveforms are generated the CO₂ reading line increases in height and then returns to the selected baseline rate (BPM).

Measurement Accuracy (continued)

Respiration Rate Test (continued)

| Test Action | Expected Results | |
|--|---|---|
| Measure Accuracy/RR Tolerance mmHg / bpm for Adult/Pediatric FilterLine Sets at respiration rates of 10, 40, and 60 bpm. | 10 bpm | ±2mmHg/±1bpm |
| | 40 bpm | ±2mmHg/±1bpm |
| | 60 bpm | ±2mmHg/±1bpm |
| Measure CO ₂ (mmHg) / RR (bpm) for Adult/Pediatric FilterLine Sets at respiration rates of 10, 40, and 60 bpm. | CO₂ Partial Pressure ^① | Accuracy ^② |
| | 0-38 mmHg | ± 2 mmHg |
| | 39-99 mmHg | ± (5% of reading + 0.08 for every 1 mmHg above 38 mmHg) |
| | 100-150 mmHg*** | ± (5% of reading + 0.08 for every 1 mmHg above 38 mmHg) |
| Measure Accuracy/RR Tolerance mmHg / bpm for Infant/Neonatal FilterLine H Sets at respiration rates of 60, 80, 120 and 150 bpm. | 60 bpm | ±2mmHg/±1bpm |
| | 80 bpm | ±2mmHg/±2bpm |
| | 120 bpm | ±4.1mmHg/±2bpm |
| | 150 bpm | ±4.1mmHg/±3bpm |
| Measure CO ₂ (mmHg) / RR (bpm) for Infant/Neonatal FilterLine H Sets at respiration rates of 60, 80, 120 and 150 bpm. | CO₂ Partial Pressure ^① | Accuracy ^② |
| | 0-38 mmHg | ± 2 mmHg |
| | 39-99 mmHg | ± (5% of reading + 0.08 for every 1 mmHg above 38 mmHg) |
| | 100-150 mmHg*** | ± (5% of reading + 0.08 for every 1 mmHg above 38 mmHg) |

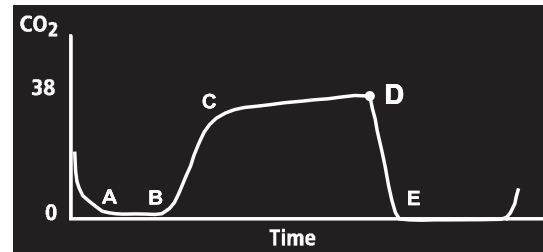
NOTE:

- ① At sea level.
- ② Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12 % of reading whichever is greater, for EtCO₂ values exceeding 18 mmHg. This is tested according to and is compliant with ISO 80601-2-55. To achieve the specified accuracies for breath rates above 60 breaths/minute, the Microstream FilterLine H Set for Infant/Neonatal must be used.

Waveform Analysis

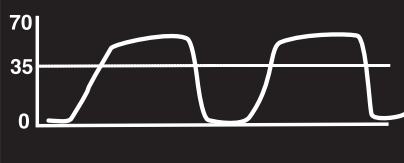
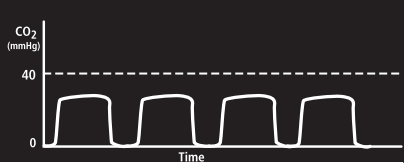

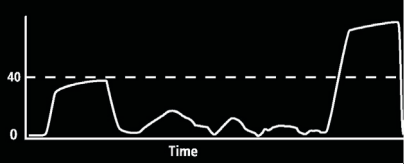
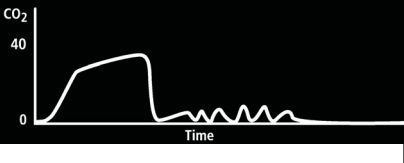
The EtCO₂ module provides the option to display EtCO₂ readings as a waveform. The following graph is an example of a normal waveform (normal ventilation, 35 - 45 mmHg). In the event the EtCO₂ value is above the waveform display range, the top of the waveform will be clipped. Numerical EtCO₂ values continue to be displayed on both the EtCO₂ module and PC unit.

- A - B:** baseline period of no CO₂; end of inhalation
- B - C:** rapid rise in CO₂
- C - D:** alveolar plateau
- D:** end of expiration; end tidal CO₂ (EtCO₂)
- D - E:** inhalation



Waveform Analysis (Continued)

Waveforms can be used to troubleshoot problems with equipment or monitor configuration, as well as to monitor a patient's clinical status. The following graphs are examples of common problems identifiable through waveform analysis. These are examples only and do not represent all potential abnormal waveforms. Abnormal waveforms are not always associated with alarms.

| Waveform | Possible Causes |
|---|--|
| <p>Hypoventilation</p>  | <ul style="list-style-type: none"> • overmedication |
| <p>Hyperventilation</p>  | <ul style="list-style-type: none"> • respiratory distress |
| <p>Partial Airway Obstruction</p>  | <ul style="list-style-type: none"> • relaxation of upper airway • head position |
| <p>Hypoventilation with Shallow Breathing</p>  | <ul style="list-style-type: none"> • medication effect • low tidal volume |
| <p>No Breath Detected</p>  | <ul style="list-style-type: none"> • apnea • very shallow breathing • overmedication • displaced cannula |

Principle of Operation

The EtCO₂ module uses Covidien's patented Microstream nondispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO₂ during every breath, the amount of CO₂ present at the end of exhalation (EtCO₂) and during inhalation (FiCO₂), and the Respiratory Rate. The EtCO₂ module is a side stream capnograph.

The Microstream Disposables deliver a sample of the inhaled and exhaled gases from the ventilator disposable or directly from the patient (via an oral/nasal cannula) into the monitor for CO₂ measurement. Moisture and patient secretions are extracted from the sample by the Microstream inline filter while maintaining the shape of the CO₂ waveform.

The 50 mL/min sampling gas flowrate reduces liquid and secretion accumulation, decreasing the risk of obstruction in the sample pathway in humid ICU environments. The small sample size eliminates the need for water traps and prevents excess fluid accumulation.

The EtCO₂ module draws a gas sample through a microsample cell (15 microliters). This extremely small volume is quickly flushed, allowing for a rise time of approximately 190 ms and accurate CO₂ readings, even at high respiration rates.

The Microbeam IR source illuminates the microsample cell and the reference channel. This proprietary IR light source generates only the specific wavelengths characteristic of the CO₂ absorption spectrum. The IR light that passes through the microsample cell and the IR light that passes through the reference channel are measured by IR detectors.

The microcomputer in the EtCO₂ module calculates the CO₂ concentration by comparing the signals from both channels.

No operator intervention is required for routine moisture or condensate.

All Microstream Disposables contain an inline hydrophobic filter to extract condensate and/or patient secretions while maintaining measurement and waveform integrity. For humid conditions within the operating parameters of the EtCO₂ module and Microstream Disposables, humidity has no quantitative effect on the CO₂ concentration, given the small 50 mL/min sample size rate. In high humidity environments or extended monitoring periods (24 - 72 hours), only Microstream Disposables designed for those instances should be

Principle of Operation (Continued)

used. In the event of humidity or condensate outside the EtCO₂ module's operating specifications, the EtCO₂ module will present a "Remove Blocked Disposable" message.

Due to the relatively small sampling size needed for EtCO₂ readings, partial pressure does not affect the ability of the EtCO₂ module to measure EtCO₂, as long as the 50 mL/min rate can be achieved.

Microstream Disposables are single-use, disposables which must be changed with each use. The manufacturer's sample flow, 50 mL/min, does not affect the disposable's life; however, humidity and specific patient conditions can shorten the effective life of the disposables. Microstream Disposables are rated for up to 24 hours and 72 hours use, depending on the specific Microstream Disposable.

The EtCO₂ module provides readings in compliance with BTPS (body temperature, pressure, saturation) standards.^① There is no affect on accuracy due to cyclic pressure up to 10 kPa.

NOTE:

- ① BTPS (body temperature, pressure, saturation assumed 37°C, 47 mmHg) calculations are made according to:

$$PCO_2 = FCO_2 \times (Pb - 47)$$

Where:

FCO₂ is fractional concentration of CO₂ in dry gas and

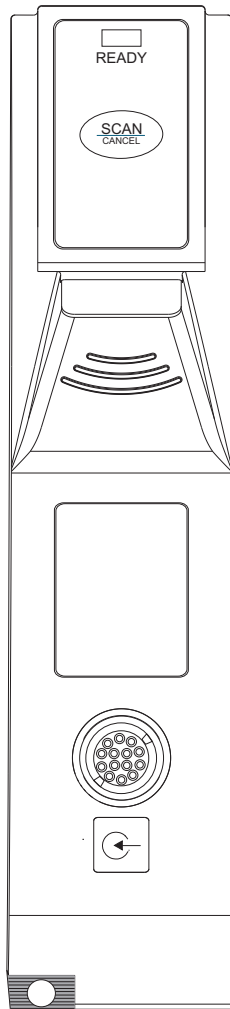
FCO₂ = % CO₂/100.

Pb is ambient pressure.

PCO₂ is partial pressure of CO₂ at BTPS.

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Alaris Auto-ID Module Model 8600



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Introduction

This section of the User Manual provides Auto-ID module (Model 8600) instructions and information. It is used in conjunction with:

- Auto-ID Label Specification
- *Auto-ID Module Technical Service Manual*
- Module-specific chapters of this User Manual
- PC unit section of this User Manual
- System Maintenance software (and its instructions) for Alaris System check-in, maintenance, and wireless configuration

The addition of the Auto-ID module to the Alaris System with Guardrails Suite MX combines dose limit technology and barcode technology to enhance medication safety. The Auto-ID module contains an internal barcode image scanner and supports an optional handheld scanner supplied by CareFusion. Scanning a barcoded clinician ID and/or a barcoded patient identification band supports verification of the correct patient and associates the CQI event logs with the clinician and/or patient. In addition, using the scanner allows an IV solution drug and concentration to be automatically selected from the Drug Library. Scanned solution containers can be used for Pump, Syringe and PCA infusions. Only one Auto-ID module can be connected to the Alaris System but it can be added as a fifth module.

The Alaris System with the Auto-ID module is intended to provide trained healthcare caregivers a way to automate infusion parameter input, thereby decreasing the number of manual steps necessary to enter infusion data. All data entry and infusion parameter validation is performed by the trained healthcare professional according to a physician's order.

Electromagnetic Environment: See "Appendix" section of this User Manual ("Regulations and Standards," "Compliance").

WARNING



Read all instructions, for both the Auto-ID module and PC unit, before using the Alaris System.

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Patient Identification

Associating the PC unit with a patient provides a means of identifying the module(s) that will deliver IV medications to that particular patient.

New Patient

To associate the PC unit with a new patient ID:

1. Attach handheld scanner to connection port on Auto-ID module. Ensure a secure circuit connection.
2. Power on PC unit.
3. To select **New Patient?**, press **Yes** soft key.
4. To accept current Profile, press **Yes** soft key.

OR

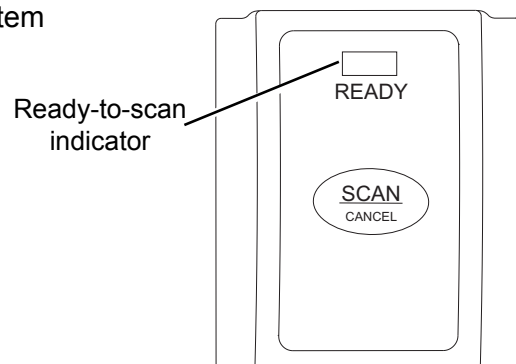
To proceed to Profile selection screen, press **No** soft key.

5. To accept Profile selection, press **CONFIRM** soft key.
 - **Patient ID Entry** screen appears. ①
 - Green **READY** indicator illuminates, indicating system is ready to scan.

WARNING



Use only the handheld external scanner supplied by CareFusion. Using other accessories can result in **increased emissions or decreased immunity** of the Alaris System.



Patient Identification (Continued)

New Patient (Continued)

6. To scan barcode on patient identification band, press scan trigger on handheld scanner. ②③
 - If scan is successful, an audible tone sounds and patient ID appears on Main Display.
 - If Profile is configured in Authorized User Mode, **PANEL LOCKED** screen appears.
 - When a questionable barcode is scanned at main screen and panel is unlocked, a prompt to confirm type of barcode scanned appears. This occurs whether Authorized User Mode is enabled or disabled.

To unlock panel, clinician's ID must be scanned.

NOTES:

- ① Automatic display of **Patient ID Entry** screen should be enabled in the System Configuration settings.
- ② If the patient ID is not entered at this time, it can still be entered later.
- ③ Patient ID can be entered manually using the PC unit keypad (see PC unit section of this User Manual).

NOTE:

There is a prompt to accept or decline the change of patient ID if it is different from the patient ID already associated to the PC unit.

While Infusion is in Progress

To associate the PC unit with a patient ID when patient ID screen is not shown:

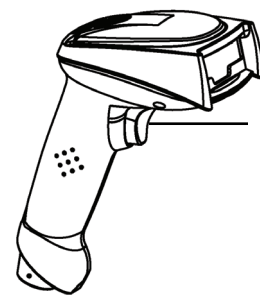
1. Attach handheld scanner to connection port on Auto-ID module. Ensure a secure circuit connection.

The green READY indicator illuminates, indicating the system is ready to scan.

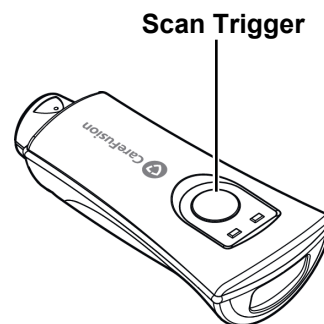
CAUTION



- **CLASS 1 LED PRODUCT:** Do not stare into the beam or allow beam to strike patient's face.
- **Always verify** that information displayed on the PC unit matches scanned data.



1st Generation Scanner



2nd Generation Scanner

Patient Identification (Continued)

New Patient (Continued)

- To scan barcode on patient identification band, press scan trigger on handheld scanner. ①

If scan is successful, an audible tone sounds and patient ID appears on Main Display.

NOTE:

- ① Patient ID can be entered manually using the PC unit keypad (see PC unit section of this User Manual).

CAUTIONS

- CLASS 1 LED PRODUCT:** Do not stare into the beam or allow beam to strike patient's face.
- Always verify** that information displayed on the PC unit matches scanned data.

NOTE:

There is a prompt to accept or decline the change of patient ID if it is different from the patient ID already associated to the PC unit.

Authorized User Mode*

Authorized User Mode is a feature that:

- Combines PC unit tamper resist feature with Auto-ID application.
- Is designed to ensure that only clinicians with a barcode on their ID badge can program Alaris System.
- Is available only if it is enabled in selected Profile and there is an Alaris Auto-ID module attached.

When this feature is enabled, the PC unit automatically enables the tamper resist mode upon power on and 5 minutes after programming is completed. If the system is configured to do so, the Authorized User Mode can be disabled without scanning a clinician's ID; press and hold the Tamper Resist Switch (on back of PC unit) for 3 - 4 seconds.

To unlock the keypad, the user must scan their ID badge or use the **OPTIONS** menu to manually input their ID number. When a questionable barcode is scanned at the main screen and the keypad is unlocked, a prompt to confirm the type of barcode scanned appears. This occurs whether the Authorized User Mode is enabled or disabled.

To use Alaris System with Authorized User Mode enabled:

1. Power on system and associate patient ID (see "Patient Identification" procedure).
Upon successful entry of patient ID, PC unit automatically enables tamper resist feature.
2. To disable tamper resist, press **SCAN/CANCEL** key on the Auto-ID module or the **SCAN** trigger on handheld scanner and scan clinician ID badge.

In a very low battery condition, with less than 5 minutes of battery time remaining, scanner is disabled. In this situation, disable tamper resist by pressing Tamper Resist Switch on back of PC unit for approximately 2 seconds.

Authorized User Mode* (Continued)

3. Program infusion.

When no keys have been pressed on PC unit for a 5-minute period, tamper resist mode is automatically enabled.

NOTE:

*There are three events that make the Authorized User Mode unavailable: a channel error, system error, or a discharged battery alarm.

Primary Infusion

Using the Auto-ID module to scan IV medication containers provides the ability to select the correct medication and Drug Amount/Diluent Volume from the drug library, and enhances safety through the use of the Guardrails Suite MX. It compares the medication identifier from the IV container barcode with the medication identifier from the Drug Library. If the patient ID is in the IV container barcode, the system also compares the patient identifier in the barcode with the patient identifier in the PC unit.^①

When the green **READY** indicator illuminates, the system is ready to scan.^②

NOTE:

- ① There is a prompt to accept or decline the change of patient ID if it is different from the patient ID already associated to the PC unit.
- ② **Auto-ID green READY scan** light on the Auto ID module illuminates, indicating the screens that allow scanning. The green ready scan light **does not illuminate** when the programming steps have passed the point of being able to scan the medication.

CAUTIONS



- **CLASS 1 LED PRODUCT:** Do not stare into the beam or allow beam to strike patient's face.
- **Always verify** that information displayed on the PC unit matches scanned data.

1. To scan barcode on IV container, press the **SCAN/CANCEL** key on Alaris Auto-ID module or scan trigger on handheld scanner.

The PC unit displays the scanned medication/fluid information.

2. Press **CHANNEL SELECT** key on appropriate module.

Alaris System determines if module selected is appropriate for scanned medication type. If selection is not appropriate, a pop-up message is displayed with a request to **CONFIRM** message, and scan is cancelled.

3. Program infusion (see applicable module-specific section of this User Manual).

Subsequent Primary Infusion

A subsequent primary infusion may be scanned with the Pump module running if the following criteria match between the scanned label and the running infusion:

- Drug or Fluid name (Alias or NDC)
- Drug Amount
- Drug Amount Units
- Diluent Volume

Secondary Infusion

To start a secondary infusion while a primary infusion is in progress:

1. To scan barcode on IV container, press **SCAN/CANCEL** key on Alaris Auto-ID module or scan trigger on handheld scanner.

The PC unit displays the scanned medication/fluid information.

2. Press **CHANNEL SELECT** key on appropriate module.
Primary infusion parameters display.
3. Press **SECONDARY** soft key.
4. Program secondary infusion (see Pump module section of this User Manual).

CAUTIONS

- **CLASS 1 LED PRODUCT:** Do not stare into the beam or allow beam to strike patient's face.
- **Always verify** that information displayed on the PC unit matches scanned data.

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System Start-Up/Setup

See the PC unit section of this User Manual, "*General Setup and Operation*", for various system start-up and setup procedures.

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Warnings and Cautions

WARNINGS

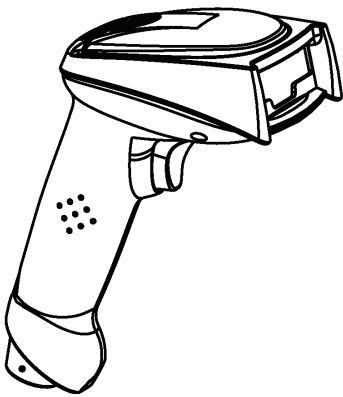
- Do not open the handheld scanner case. If the case is opened, an electrical shock hazard and possible exposure to **potentially hazardous LED light** exists which can result in serious personal injury and product damage.
- Carefully locate the handheld scanner to reduce the possibility of patient **entanglement or strangulation**.
- Use only the handheld external scanner supplied by CareFusion. Using other accessories can result in **increased emissions or decreased immunity** of the Alaris System.

CAUTION

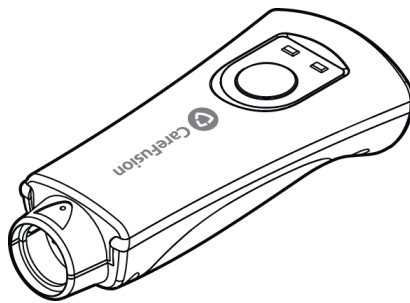
Class 1 LED devices are safe under reasonably foreseeable conditions of operation, including the use of optical instruments for intrabeam viewing. To **avoid potential harm**, avoid looking into the beam or allowing the beam to strike the patient's face.

Handheld Scanners

The handheld external scanners supplied by CareFusion are the only handheld scanners approved for use with the Auto-ID module.



1st Generation Scanner



2nd Generation Scanner

WARNINGS

- Do not open the handheld scanner case. If the case is opened, an electrical shock hazard and possible exposure to **potentially hazardous LED light** exists which can result in serious personal injury and product damage.
- Use only the handheld external scanner supplied by CareFusion. Using other accessories can result in **increased emissions or decreased immunity** of the Alaris System.

CAUTION

CLASS 1 LED PRODUCT: Do not stare into the beam or allow beam to strike patient's face.

Features

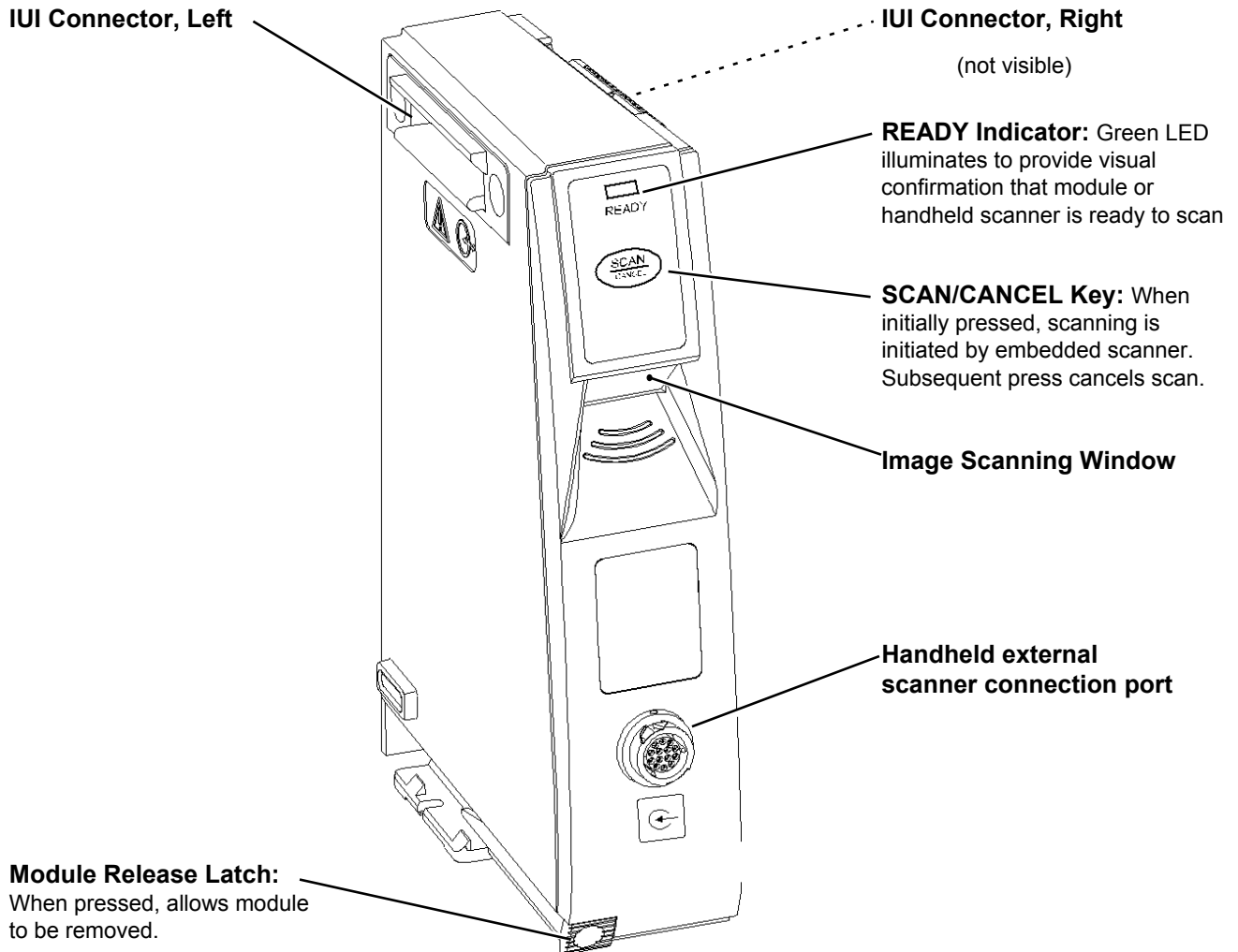
Features and Definitions

See the PC unit section of this User Manual for system features and definitions.

| Feature | Definition |
|--|---|
| Audible Scan Indicator | Provides audible confirmation of a successful scan. |
| Barcode | A machine-readable label used for automatic identification. Automatic identification (Auto-ID) is the broad term given to a host of technologies used to help machines identify objects and is often coupled with automatic data capture. These technologies include barcodes, smart cards, voice recognition, some biometric technologies (for example, retinal scans), optical character recognition, and others. |
| Built-In Optical Scan Engine | Employs technology similar to a digital camera to read barcodes. Allows use of two-dimensional barcodes. |
| Handheld Scanner with Optical Scan Engine | Allows scanning of patient ID, and of IV containers that have already been hung on IV pole. |
| Light Emitting Diode (LED) | Barcode scanner uses an array of high intensity LEDs to illuminate barcode image (see "Specifications"). |
| Two-Dimensional Barcode | Can contain more information and is more easily read by Auto-ID module; for example, patient ID and drug ID can be in same barcode. |

Features (Continued)

Operating Features, Controls, Indicators



Configurable Settings

See the PC unit section of this User Manual for system configurable settings

If the configuration settings need to be changed from the **Factory default** settings, refer to the applicable Technical Service Manual or contact CareFusion Technical Support, for technical, troubleshooting, and preventive maintenance information.




With the Profiles feature enabled, the settings are configured independently for each Profile. A hospital-defined, best-practice Data Set must be uploaded to enable the Profiles feature. Date and Time is a system setting and is the same in all Profiles.

Specifications and Symbols

Specifications

Auto-ID Module and Handheld Scanner

Environmental Conditions:

| Symbols | Meaning | Operating | Storage/Transport |
|---|---|-------------------------------------|------------------------------------|
|  | Atmospheric Pressure | 525 - 4560 mmHg (700 - 6080 hPa) | 375 - 760 mmHg (500 - 1013 hPa) |
|  | Relative Humidity (Avoid prolonged exposure to relative humidity >85%) | 20 - 90% Noncondensing | 5 - 85% Noncondensing |
|  | Temperature Range | 41 - 104°F (5 - 40°C) | -4 - 140°F (-20 - 60°C) |

LED Light:

Class 1 LED product.

Aiming LED: 523 nm, cw, 0.412 mW average radiant power

Illumination LED: 635 nm, cw, 2.226 mW average radiant power

Alaris Auto-ID Module

Dimensions:

2.0" W x 7.25" H x 5.0" D
(5.1 cm W x 19.8 cm H x 12.7 cm D)

Specifications and Symbols (Continued)

Specifications (Continued)

Alaris Auto-ID Module

| | |
|----------------------------------|-------------------------------|
| Fluid Ingress Protection: | IPX1, Drip Proof |
| Mode of Operation: | Continuous |
| Shock Protection: | Type BF patient applied part. |
| Weight: | 1 ±0.1 lbs (436.5 ±43.65 g) |

Handheld Scanner



| | |
|--------------------|---|
| Dimensions: | 3.25" W x 7.25" H x 4.25" L (8.3 cm W x 18.4 cm H x 10.8 cm L) |
| Housing: | UL 94V0 flammability rating |
| Weight: | 6.5 oz (178 g) |

Symbology

The Auto-ID module supports an optional handheld scanner that can be used to scan a patient's ID, medication labels and clinician badges. The Auto-ID module and handheld scanner read printed barcodes which are within the barcode print quality guidelines specified by ANSI X 3.182, CEN EN 1635, and ISO/IEC 15416 international standards. Some manufacturer-applied barcodes on IV bags are not compliant with these quality standards and might not be readable with the Auto-ID module and handheld scanner. Refer to the *Auto-ID Label Guidelines* for more detailed barcode label information.

Symbols

See the PC unit section of this User Manual for system symbols.

| Symbol | Meaning |
|---|-----------------------------------|
|  | Input. Handheld connection point. |
|  | Type BF patient applied part. |

Troubleshooting and Maintenance

Errors and Messages

Alarms and Alerts: See “Appendix A” *“Troubleshooting and Maintenance”* for the following system references:

Alarms and alerts
Audio Characteristics
Definitions
Display Color
Radio Frequency Note

Errors

| Error | Meaning | Response |
|-------------------------------------|---|---|
| Clinician ID is invalid | Clinician ID is not recognized. | Ensure that ID label is legible. Enter ID manually. |
| Patient ID is invalid | Patient ID is not recognized. | Ensure that ID label is legible. Enter ID manually. |
| Scanned label is invalid | Profile feature might be disabled. Barcode might not be readable or a supported symbology. | Ensure that Profile is enabled. Ensure that ID label is legible. Inform pharmacy of problem. |
| Scanned medication label is invalid | Barcode might not be readable or a supported symbology. | Ensure that ID label is legible. Inform pharmacy of problem. |

Errors and Messages (Continued)

Messages

| Message | Meaning | Response |
|--------------------------------------|---|--|
| Drug or Fluid not in current Profile | Drug and its concentration might not be in currently selected Profile. | Ensure that correct Profile is selected and that it has correct drug and concentration. |
| Channel Unavailable | Channel is currently infusing and cannot support scanned infusion. | If secondary infusion was scanned, select a channel with a primary infusion that supports the secondary. If primary infusion was scanned, select an idle channel to program. |
| Patient ID will be changed | The Patient ID is not the same Patient ID that is currently associated with the device. | If the Patient ID associated to the PC unit should be changed, press "Yes". If the Patient ID associated to the PC unit should not be changed, press "No". |

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Appendix A

Troubleshooting and Maintenance

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Troubleshooting and Maintenance

Troubleshooting and maintenance should be performed only by qualified personnel, using the applicable Technical Service Manual and the System Maintenance software.

| | |
|--|--|
| Alaris PC Unit, Model 8015 Alaris Pump Module, Model 8100 | Alaris PC Unit, Model 8015 and Alaris Pump Module, Model 8100 Technical Service Manual |
| Alaris Syringe Module, Model 8110 Alaris PCA Module, Model 8120 | Technical Service Manual Alaris Syringe Module, 8110 Series Alaris PCA Module, 8120 Series |
| Alaris SpO2 module Models 8210 and 8220 | Technical Service Manual Alaris SpO2 modules |
| Alaris EtCO2 module Model 8300 | Technical Service Manual Alaris EtCO2 Module, 8300 Series |
| Alaris Auto-ID Module, Model 8600 | Technical Service Manual Alaris Auto-ID Module, Model 8600 |

The Service Manuals and System Maintenance software are available from CareFusion. The Service Manuals includes routine service schedules, interconnect diagrams, component parts lists and descriptions, test procedures, and other technical information to assist qualified service personnel in repair and maintenance of the instrument's repairable components. The System Maintenance software is used to perform a new instrument check-in, preventive maintenance tests, calibration checks, calibration, and other maintenance functions.

Artifacts: It is normal for an infusion device to produce nonhazardous currents when infusing electrolytes. These currents vary proportional to the infusion device flowrate. When an ECG monitoring system is not functioning under optimal conditions, these currents might appear as artifacts, simulating actual ECG readings. To determine if ECG abnormalities are caused by patient condition or the ECG equipment, place the infusion device on hold. If the ECG readings become normal, the ECG equipment requires attention. Proper setup of the ECG equipment should eliminate these artifacts. Refer to the appropriate ECG monitoring system documentation for instructions on setup and maintenance.

Alaris Systems Manager Connections

When an Alaris Systems Manager connection is made, the Wireless Network Indicator on the PC unit illuminates. If connection to the Alaris Systems Manager is interrupted, the indicator light is extinguished. Some of the causes for a communications failure include:

- Alaris Systems Manager is not accessible in network, server services are not running, or server has been shut down.
- Wireless connection to access point is down due to wireless network changes.
- Local interference.
- PC unit has been moved outside the wireless coverage area.
- Wireless network card has been damaged.

If an interruption to the Alaris Systems Manager connection continues, contact the facility's information technology department.

Alarms and Alerts

Clinician's Position for Alarm Monitoring

CareFusion recommends that the clinician's position should be at a distance no greater than 1 meter to monitor visual alarm signals, four meters to monitor alarm condition and priority, and in proximity of the device so that any auditory alarm can be heard. The distance to monitor auditory alarms will vary depending upon your facility's acoustics and ambient sound. Auditory alarms signal sound pressure levels that are less than ambient levels can impede the clinician's recognition of an alarm condition and the alarm system.

Display Color

Color is used in the title and prompt bars to help communicate the following types of information.

| Communication | Color | Description |
|-------------------------|--------|---|
| Normal Operation | Blue | All messages other than noted below (normal operating displays). |
| Guardrails™ limit | Yellow | Visual message indicating a Limit was exceeded. |
| Pertinent message | Yellow | Visual message that calls attention to a programming parameter or to the infusion status. |
| Informational | Green | Visual message. |
| Alarms and malfunctions | Red | Visual message indicating an error or system inconsistency occurred. |

Definitions

Alerts and alarms are indicated by a combination of audible tones, visual flashing behavior, and a descriptive message on either the PC unit or scrolling module marquee.

Alarms notify the clinician of a potential or an actual hazardous condition.

Alarms and Alerts (continued)

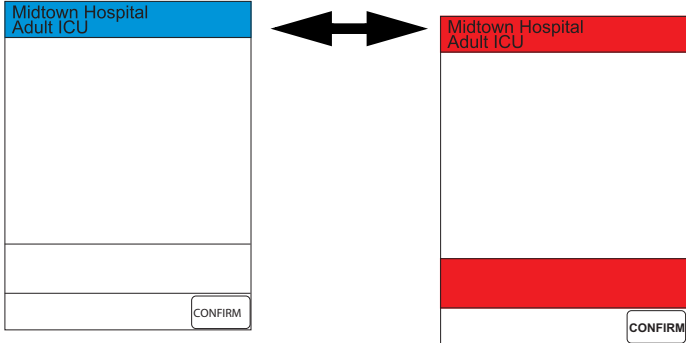
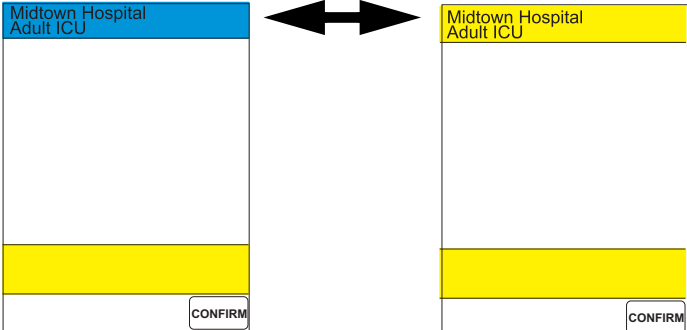

Definitions (continued)

| Terms | Definitions |
|-------------------------------|--|
| High Priority | A high-priority alarm is initiated by any alarm condition requiring immediate user response. |
| Medium Priority | A medium-priority alarm is initiated by any alarm condition requiring prompt user response. |
| Low Priority | A low-priority alarm is initiated by any condition requiring user awareness. |
| Informational Signal | A signal that provides information which may, or may not, require action to be taken by the clinician. |
| Reminder Signal (NEOI Snooze) | A periodic audible signal that reminds the user that a Near End of Infusion alert has been previously silenced. When enabled in the Dataset, this reminder signal can be configured in 5, 10, and 15 minute intervals. |

Alarms and Alerts (continued)

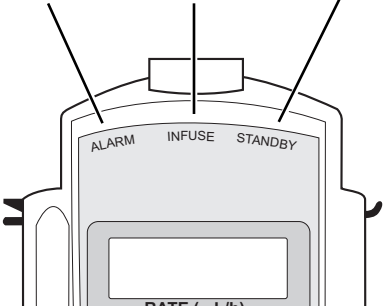
Definitions (continued)

The Alaris System alarms are further categorized by type:

| Terms | Definitions |
|-------------------------|--|
| <p>Technical Alarms</p> | <p>An alarm arising from a hardware or software failure condition. The signal priority is indicated by an audio tone and visually, by the color of the title bar on the PC unit screen, which may include flashing behavior.</p> |
| | <p>Technical High Priority—Title Bar flashes red</p>  |
| | <p>Technical Medium Priority—Title bar flashes yellow.</p>  |
| | <p>Technical Low Priority—Title bar appears in steady yellow</p>  |

Alarms and Alerts (continued)

Definitions (continued)

| Terms | Definitions |
|--|---|
| Infusion Alarms | An alarm arising from an infusion module (PCA, Syringe, Pump). |
| Monitoring Alarms | An alarm arising from a monitoring module. |
| <p style="text-align: center;">Status Indicators</p> <div style="display: flex; justify-content: space-around; font-weight: bold; font-size: 0.9em;"> Alarm (red) Infusing (green) Standby (yellow) </div>  | <p>Monitoring and Infusion high priority alarms—Module status indicator flashes red</p> <p>Monitoring and Infusion medium priority alarms—Module status indicator flashes yellow</p> <p>Infusion low priority alarms—Module status indicator appears in steady yellow</p> |

NOTE:

Monitoring alarms are either high or medium priority, there are no low priority Monitoring alarms.

NOTE:

The signal priority for both Monitoring and Infusion alarms is indicated by both an audio signal and by the color of the module status indicator, which may include a flashing behavior.

Alarms and Alerts (continued)

Definitions (continued)

| Terms | Definitions |
|-----------------------------|--|
| Advisory/Message | A sequence of audio and/or visual signals indicating the system operation status. |
| Alarm Signal | An audible and visual indicator of a potential or actual hazardous condition. |
| Alarm Silence | Alarms can be silence for up to 120 seconds by pressing the SILENCE key. The alarm indicator remains on and the alarm silence symbol is displayed. The silence period can be ended by pressing the CANCEL SILENCE soft key. An alarm can be silenced in the PANEL LOCKED condition. |
| Alert | A visual, audible, or visual and audible signal provided by the Alaris System. This includes alarms, informational, and reminder signals. |
| Calibration Check | A technical procedure, defined in the Technical Services Manual, to verify instrument calibration. |
| Cancel Silence ^① | An alarm may be canceled by pressing the cancel silence soft key. If the alarm condition has not been resolved, the alarm audio resumes. |
| Clinical Advisory | A visual message when a designated drug is selected to remind the clinician of specific hospital/facility standards of practice when programming an IV medication. A specific Clinical Advisory and/or message can be associated with a selected drug within any of the patient care Profiles. Clinical Advisories are not displayed in Anesthesia mode. |
| Control Unit | PC unit and Auto-ID (barcode) module |
| High Priority Alarm | A high-priority alarm is initiated by any alarm condition requiring immediate user response. |
| Information Signal | Any signal that is not an alarm signal or a reminder signal. |
| Infusion Alarm | An alarm arising from an infusion module (PCA, Syringe, Pump) |
| Low Priority Alarm | A low-priority alarm is initiated by any condition requiring user awareness. |

NOTE:

- ① A previously silenced alarm audio can be reactivated by pressing the **Cancel Silence**. If the alarm condition has not been resolved, the alarm audio will resume.

Alarms and Alerts (continued)

Definitions (continued)

| Terms | Definitions |
|-------------------------------|---|
| Maintenance Reminder | A visual message that when enabled appears at startup when a scheduled preventive maintenance is due/overdue for component of Alaris System (PC unit or attached module). |
| Medium Priority Alarm | A medium-priority alarm is initiated by any alarm condition requiring a prompt user response. |
| NEOI Snooze (Reminder signal) | Configurable alert, if enabled, provides an audio only tone when a Near End of Infusion alarm had been previously silenced. |
| Monitoring Alarm | An alarm arising from a monitoring module (SpO2 or EtCO2). |
| Presilence | Allows the user to silence a monitoring module for 2 minutes. Also known as Audio Pause, the duration of Presilence (Audio Pause) is not configurable.. |
| Prompt | An audio signal and/or a visual message appearing on bottom line of Main Display or in Message Display. Audio signal can be silenced for 12 seconds pressing the SILENCE key. |
| Technical Alarm | An alarm arising from a hardware or software failure condition. |

Alert Prioritization

All Alaris System Alerts are prioritized by type/source and the condition of the alert.

| ALERT Priority | ALERT Type/Source | Color Theme | Silenceable |
|-----------------|--------------------------|-----------------|-------------|
| HIGH Priority | Technical Software Fatal | N/A | NO |
| | Uncontrolled Infusion | Flashing Red | NO |
| | Technical Malfunction | Flashing Red | YES |
| | Monitoring | Flashing Red | YES |
| | Infusion/PC unit | Flashing Red | YES |
| MEDIUM Priority | Monitoring | Flashing Yellow | YES |
| | Infusion/PC unit | Flashing Yellow | YES |
| LOW Priority | Infusion/PC unit | Steady Yellow | YES |
| INFORMATIONAL | Informational | N/A | N/A |
| Reminder Signal | Reminder Signal | N/A | NO |

Alarms and Alerts (continued)

Audio Characteristics

| Profile | Priority | Audio Characteristics | Visual Indicator |
|-----------|----------|--|------------------|
| Profile 1 | High | Repeating sequence of 10 beeps followed by an approximate 7 second pause for a monitoring alarm Repeating sequence of 2 beeps followed by an approximate 1.5 second pause for an infusion alarm | Flashing Red |
| | Medium | Repeating sequence of 6 beeps followed by an approximate 4 second pause for a monitoring alarm Repeating sequence of 1 beep followed by an approximate 2 second pause for an infusion alarm | Flashing Yellow |
| | Low | Repeating sequence of 1 beep followed by an approximate 3.5 second pause. | Steady Yellow |
| Profile 2 | High | Repeating sequence of 10 beeps followed by an approximate 7 second pause for a monitoring alarm Repeating sequence of 2 beeps followed by an approximate 1 second pause for an infusion alarm | Flashing Red |
| | Medium | Repeating sequence of 6 beeps followed by an approximate 4 second pause for a monitoring alarm Repeating sequence of 1 beep followed by an approximate 2 second pause for an infusion alarm | Flashing Yellow |
| | Low | Repeating sequence of 1 beep followed by an approximate 3.5 second pause. | Steady Yellow |
| Profile 3 | High | Repeating sequence of 10 beeps followed by an approximate 7 second pause for a monitoring alarm Repeating sequence of 2 beeps followed by an approximate 0.5 second pause for an infusion alarm | Flashing Red |
| | Medium | Repeating sequence of 6 beeps followed by an approximate 4 second pause for a monitoring alarm Repeating sequence of 1 beep followed by an approximate 2 second pause for an infusion alarm | Flashing Yellow |
| | Low | Repeating sequence of 1 beep followed by an approximate 3.5 second pause. | Steady Yellow |

| | | | |
|-----------|--------|--|-----------------|
| Profile 4 | High | Repeating sequence of 10 beeps followed by an approximate 4 second pause | Flashing Red |
| | Medium | Repeating sequence of 3 beeps followed by an approximate 6 second pause | Flashing Yellow |
| | Low | Repeating sequence of 3 beeps followed by an approximate 15 second pause | Steady Yellow |

Alarms and Alerts (continued)

Audio Characteristics (continued)

Sound Pressure Level Ranges for Alarm Signals

| Alarm | Volume 5 (Max) | Volume 1 (Min) |
|------------------------|-------------------|-------------------|
| | Average SPL (dBA) | Average SPL (dBA) |
| HIGH - Malfunction | 68 | 60 |
| HIGH - Monitoring | | |
| HIGH - Infusion | | |
| MED - Monitoring | 68 | 55 |
| MED - Infusion | | |
| LOW - Infusion/PC unit | | |

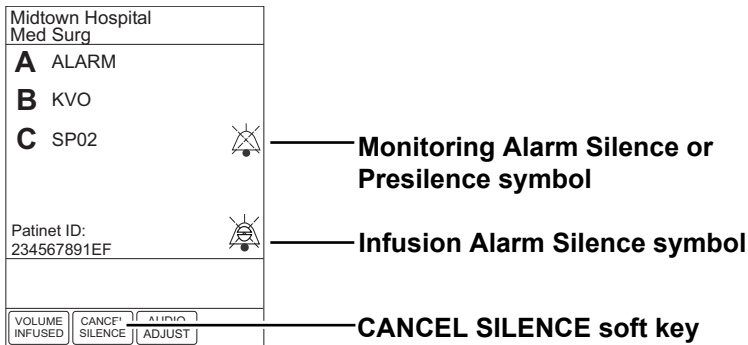
CAUTION



Profile 4 audio setting supports standards compliance. Setting the Alarm Audio Profile to Profile 4 could potentially result in the Alaris system alarms sounding similar to other medical devices, such as respirators and monitoring services that are compliant with the same safety standards.

Infusion Alarms:

Infusion alarms can be silenced for 120 seconds by pressing the **SILENCE** key. Visual alarm indicators remain on and an infusion alarm silence icon is displayed on the PC unit screen in the lower right corner. Silence period can be ended by pressing **CANCEL SILENCE** soft key. If the alarm condition still exists, the audible alarm tone will return.



Monitoring Alarm Silence or Presilence symbol

Infusion Alarm Silence symbol

CANCEL SILENCE soft key

Monitoring Alarms:

Monitoring alarms may be presilenced, or silenced in response to a monitoring alarm condition. All monitoring alarms are silenced for 120 seconds (subsequent infusion alarms are not silenced during this period). Alarm indicators remain on and a monitoring alarm silence icon is displayed. Silence period can be ended by pressing **CANCEL SILENCE** soft key.

Alarms and Alerts (continued)

Alarms

| Alarms | | | | |
|---------------------------------------|---------|---------------|---|--|
| Alarm Message | Device | Priority | Meaning | Response |
| ATTACH HANDSET | PCA | Low | The Dose Request Cord detached from the device during an active infusion. The Dose Request Cord is required only for PCA and PCA + Continuous Infusion modes. | Reattach the Dose Request Cord and press the RESTART key. |
| ACCUMULATED AIR-IN-LINE ALARM | Pump | High | A large number of air bubbles smaller than the current air-in-line limit has recently passed the air-in-line detector. | Clear air from the administration set. Press the RESTART key, or press the CHANNEL SELECT key and then the START soft key. |
| AIR-IN-LINE | Pump | High | Air has been detected in the administration set during an infusion. The infusion stops on affected channel. | Ensure that the tubing is properly installed in the Air-in-Line detector. If air is present, clear the air from administration set. Press the RESTART key, or press the CHANNEL SELECT key and then the START soft key. |
| ANESTHESIA MODE AC POWER CONNECTED | PC unit | Informational | The AC power cord is connected | Select Yes or No to continue in the anesthesia mode |
| ANESTHESIA MODE AC POWER DISCONNECTED | PC unit | Informational | The AC power cord is disconnected | The anesthesia mode was discontinued when the AC power cord was disconnected. |
| ATTACH MONITORING MODULE | PC unit | Informational | A Clinical Advisory is displayed for a PCA Infusion that contains PCA PAUSE PROTOCOL. | Attach the EtCO ₂ or SpO ₂ module. |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|-----------------------------|-------------------------------------|---------------|---|---|
| Alarm Message | Device | Priority | Meaning | Response |
| AUDIO SYSTEM ERROR | PC unit | Medium | The audio system has failed and the backup system is in use. The PC Unit currently in use may be continued temporarily with backup audio system. The audio notifications may sound altered. | Replace the PC unit as soon as possible. |
| AUTOZERO IN PROGRESS | EtCO ₂ | Informational | The EtCO ₂ module performs a baseline by sampling CO ₂ present in ambient air. | Wait for the device to complete its auto-zeroing function. After the autozero cycle is complete, the device begins measurement again. No user intervention is required. |
| BAD SENSOR | SpO ₂ | Medium | A broken or unknown SpO ₂ sensor or patient cable is attached. The device cannot monitor the patient's vital signs. | Check or replace the sensor and the patient cable. |
| BAR CODE MALFUNCTION | Auto-ID Displayed on the PC unit | Informational | A malfunction has occurred on the Auto-ID module disabling the barcode scanning functionality. The PC unit continues to operate. | The Auto-ID module should be serviced by qualified personnel or replaced as soon as possible. |
| BAR CODE SCANNING ERROR | PC unit | Informational | The Auto-ID scanner or handheld is not responding. | The Auto-ID module should be serviced by qualified personnel or replaced as soon as possible. |
| BAR CODE TRANSMISSION ERROR | PC unit | Informational | A communication error has occurred. | Reconnect the Auto-ID module. |
| BATTERY DISCHARGED | PC unit | High | All channels stopped. The device is in a low battery state where all channels are on standby to conserve battery life | To silence the alarm and restart the channels, plug in the power cord, or press SYSTEM OFF . Plug in or replace the device and restart the paused modules. |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|--|---|----------|--|---|
| Alarm Message | Device | Priority | Meaning | Response |
| BATTERY DISCHARGED POWERING DOWN | PC unit | High | The battery is completely discharged and the device is powering down. | Plug in or replace the device and restart the modules. |
| CHANNEL DISCONNECTED | Syringe PCA Pump SpO2 EtCO2 | High | Module(s) have either been disconnected while in operation, or have a non-recoverable error. | To silence the alarm and clear the message from screen, press the CONFIRM soft key. Reattach the module, if desired, ensuring it is securely "clicked" into place at Channel Release Latch. If the alarm is still present, replace the module. |
| CHANNEL ERROR | Syringe PCA Pump SpO2 EtCO2 | High | A malfunction is detected on the module. | Clear the channel error pop-up by pressing the CONFIRM softkey. Power down the system, or continue use of functional units, or replace the affected channel with an operable module. |
| CHECK IV SET | Pump | High | The administration set is not properly installed. Infusion stops on affected module. | Close the roller clamp, remove and reinstall the administration set, close the door, open the roller clamp, and then press the RESTART key. |
| CHECK SENSOR - ELECTRIC/ OPTIC INTERFERENCE | SpO2 | Medium | External interference on SpO2 sensor. | Check the sensor. Identify the source of external interference if it is other than sensor. |
| CHECK SENSOR - EXCESS AMBIENT LIGHT | SpO2 | Medium | SpO2 sensor is detecting excessive light. | Check the sensor. Remove or reduce the lighting. Cover or reposition the sensor. |
| CHECK SENSOR - HIGH PULSE AMPLITUDE | SpO2 | Medium | An artifact is interfering with the pulse reading. | Check the sensor. Relocate the sensor to a site with less artifact interference. |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|------------------------------------|---------------|-----------------|---|--|
| Alarm Message | Device | Priority | Meaning | Response |
| CHECK SENSOR - MOTION INTERFERENCE | SpO2 | Medium | The patient's motion has inhibited monitoring. | Check the sensor. Move the sensor to a site with less motion. |
| CHECK SENSOR - WEAK PULSE | SpO2 | Medium | The SpO2 sensor is receiving a weak pulse signal due to low perfusion. | Check the sensor. Confirm the correct sensor placement. Move the sensor to a better perfused site. |
| CHECK SENSOR - WEAK SIGNAL | SpO2 | Medium | The SpO2 sensor is receiving a low quality signal. | Check the sensor. Confirm the correct sensor placement. Move the sensor to a better perfused site. |
| CHECK SYRINGE | Syringe PCA | High | The lever, plunger, and/or barrel clamp is not engaged properly. | Inspect the Syringe/PCA module and adjust the appropriate sensor as needed. Reselect the syringe, restore or reprogram and start or restart the infusion. |
| CHECKING LINE | Pump | Informational | A patient-side occlusion has occurred; the Auto-Restart feature monitors downstream pressure to determine if infusion can continue. | No user response expected. |
| CLEARING DISPOSABLE | EtCO2 | Informational | The monitoring device is attempting to clear disposable of occlusion. | Wait for purging to complete. |
| CLOSE AND LOCK DOOR | PCA | High | The PCA door is unlocked/open during an active infusion. The infusion is stopped. | Lock the door and press the RESTART key. |
| CLOSE DOOR, then RESTART CHANNEL | Pump | High | The door was opened and closed during an infusion. The infusion stops on affected channel. | Close the door. Press RESTART , or press the CHANNEL SELECT key and then press the START soft key. |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|----------------------------------|---------------------------------------|-----------------|--|---|
| Alarm Message | Device | Priority | Meaning | Response |
| COMMUNICATION ERROR | All modules | High | The module has lost communication with the PC unit. | Replace module |
| DEFECTIVE BATTERY | PC unit | High | A battery failure is detected during normal operations. The active modules will continue as programmed. | Replace the device immediately. The settings are unrestoreable; <u>record the settings before powering down device.</u> |
| DELAY COMPLETE | Syringe Pump | Medium | Delay time complete. | To resume the infusion, press RESTART on the module or press CHANNEL SELECT and then the START soft key. |
| DELAYED STATUS | Syringe Pump | Informational | The infusion has been delayed for a defined period of time. | No user response is expected. |
| DISCONNECT OCCLUDED DISPOSABLE | EtCO ₂ | Medium | The disposable is occluded. | Check the disposable. Obtain a new disposable and attach it to patient. |
| DISPLAY FAILURE - REPLACE MODULE | SpO ₂ EtCO ₂ | High | There is a malfunction with the display on the SpO ₂ or EtCO ₂ modules. The device continues to monitor. | Replace the module. |
| DISPOSABLE DISCONNECTED | EtCO ₂ | Informational | No disposable is connected to the module while attempting to search for a patient. | Ensure disposable is attached to module. |
| DISPOSABLE DISCONNECTED | EtCO ₂ | Medium | No disposable is connected to the module during monitoring or after approximately 30 seconds of searching for a patient. | Ensure disposable is attached to module. |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|-------------------------------------|------------------------|---------------|---|---|
| Alarm Message | Device | Priority | Meaning | Response |
| HIGH ETCO2 | EtCO2 | High | The EtCO2 value is above the specified limit. | Assess the patient's condition. Confirm that the correct alarm limit values are selected. |
| HIGH FICO2 | EtCO2 | High | FiCO2 value is above the specified limit. | Assess the patient's condition. Confirm that the correct alarm limit values are selected. |
| HIGH RR | EtCO2 | High | The respiratory rate is above the specified limit. | Assess patient's the condition. Confirm that the correct alarm limit values are selected. |
| HIGH SATURATION | SpO2 | High | The high saturation alarm limits have been exceeded. | Assess the patient's condition. Confirm that the correct alarm limit values are selected. |
| HIGH_PULSE | SpO2 | High | The high pulse rate alarm limit has been exceeded. | Assess the patient's condition. Confirm that the correct alarm limit values are selected. |
| INCOMPATIBLE MODULE | PC unit | Informational | The PC unit is unable to recognize the attached MODULE because it is an unsupported module type | Remove the unsupported module. |
| INFUSION COMPLETE | Syringe PCA Pump | Medium | The current infusion is completed with no KVO. | Set up a new infusion or press the CHANNEL OFF key. |
| INFUSION COMPLETE - KVO | Pump Syringe | Medium | VTBI has been infused; the module is infusing at the KVO rate | Set up a new infusion, if required, and reinitiate the infusion |
| INSTALL PRESSURE DISC | Syringe | High | The Pressure Sensing Disc is removed. If an infusion is running, the infusion stops on affected module. | Reinstall the Pressure Sensing Disc and press the RESTART key |
| LOW BATTERY < 30 MIN PLUG IN NOW | PC unit | Low | Low battery threshold sensed; the remaining battery run time is limited. | Connect to a power source (alarm silenced). Low battery will continue to display after the AC is plugged in until the battery has built up sufficient charge to run the Alaris System for 30 minutes. To verify AC is charging, look at the AC LED on the front panel and verify that is is on. |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|----------------------|---------|---------------|--|---|
| Alarm Message | Device | Priority | Meaning | Response |
| LOW ETCO2 | EtCO2 | High | The EtCO2 value is below the specified limit. | Assess the patient's condition. Confirm that the correct alarm limit values are selected. |
| LOW RR | EtCO2 | High | The respiratory rate is below the specified limit. | Assess the patient's condition. Confirm that the correct alarm limit values are selected. |
| LOW SATURATION | SpO2 | High | The low saturation alarm limits have been exceeded. | Assess the patient's condition. Confirm that the correct alarm limit values are selected. |
| LOW_PULSE | SpO2 | High | The low pulse rate alarm limit has been exceeded. | Assess the patient's condition. Confirm that the correct alarm limit values are selected. |
| MAINTENANCE REMINDER | PC unit | Informational | The device is due for Preventative Maintenance | Notify the biomed that Preventative Maintenance of the device is due |
| MAX LIMIT REACHED | PCA | Low | This alarm occurs when an attempt is made that exceeds the maximum allowed drug amount for the patient. The PCA dose cannot be delivered until the configured time passes. | To silence the alarm, press the SILENCE key. To change the Max Limit, press CHANNEL SELECT , press the PROGRAM soft key, and unlock the door or enter the Authorization Code applicable for current Security Access Level. |
| MAX MODULES EXCEEDED | PC unit | Informational | The number of attached modules exceeds the maximum allowed. | Removed the unsupported module(s). |
| MISSING BATTERY | PC unit | High | Missing battery while operating. | Replace the device immediately. The settings are unrestoreable; record settings before powering down the device. |
| MULTIDOSE COMPLETE | PC unit | Medium | The Multidose infusion is complete. | Set up a new infusion or press the CHANNEL OFF key. |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|---------------------------------------|-------------------|-----------------|---|--|
| Alarm Message | Device | Priority | Meaning | Response |
| NEAR END OF INFUSION | Syringe, PCA | Low | The syringe is almost empty. This is a timed event that can be configured in the Data Set. To set or change this option, see "General Information" and "Configurable Settings". | To silence the alarm, press the SILENCE key. The module remains functional and continues the infusion. |
| NEOI Snooze | Syringe PCA | Reminder | A periodic audible signal that reminds the user that a Near End of Infusion alarm has been previously silenced. | None |
| NETWORK COMMUNICATION ERROR | PC unit | Informational | Wireless connections is lost. | The PC unit continues to operate without wireless functionality. |
| NO BREATH DETECTED | EtCO ₂ | High | No breath has been detected for a specified period of time. | Assess the patient's condition. Confirm that the correct alarm limit values are selected. Check the Microstream disposable to confirm that the correct disposable is chosen. Confirm the correct disposable placement. |
| NO SENSOR | SpO ₂ | Informational | No sensor is connected to the module while attempting to search for a patient. | Attach the sensor to the module. |
| NO SENSOR | SpO ₂ | Medium | No sensor is connected to the module during monitoring or after approximately 30 seconds of searching. | Check the patient. Attach the sensor to patient. |
| NO SIGNAL | SpO ₂ | Medium | Failure to find a patient signal | Check the sensor. Confirm the correct sensor placement. |
| OCCLUDED - FLUID SIDE/EMPTY CONTAINER | Pump | High | Indicates either an upstream occlusion or an empty container. The infusion stops on affected module. | Clear the occlusion on fluid side of the device. If necessary, refill the drip chamber. Press the RESTART key, or press the CHANNEL SELECT key and then the START soft key. |
| OCCLUDED - PATIENT SIDE | Pump | High | Increased back pressure sensed while infusing. The infusion stops on affected module. | Clear the occlusion. Press the RESTART key, or press the CHANNEL SELECT key and then the START soft key. |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|----------------------------------|--------------------|---------------|--|--|
| Alarm Message | Device | Priority | Meaning | Response |
| PARTIAL OCCLUSION - PATIENT SIDE | Pump | High | A partial occlusion of the patient side of the IV line detected by the Auto-Restart feature. | Clear the occlusion. Press the RESTART key, or press the CHANNEL SELECT key and then the START soft key. |
| PATIENT NOT DETECTED | EtCO2 | Medium | The patient is not detected. | Assess the patient condition. Check the disposable |
| PAUSED | Syringe, PCA, Pump | Informational | The pause control was pressed and the infusion stopped. | To resume the infusion press RESTART on module or press CHANNEL SELECT and then the START soft key. |
| PAUSE-RESTART CHANNEL | Syringe, PCA, Pump | Low | The module has been paused for 2 minutes. | To resume the infusion press RESTART on module or press CHANNEL SELECT and then the START soft key. |
| PCA HANDSET STUCK | PCA | Low | The PCA handset has been pressed too long. The infusion continues as programmed. | Replace the handset when the device is not in use. |
| PCA PAUSED - LOCKOUT | PCA | High | The PCA infusion has paused due to a decline in respiratory status | <p>Assess the patient status per hospital policy. Press CONFIRM once the patient's status and monitoring values have been addressed. Press the RESTART key per hospital policy.</p> <p>To view the trigger of the PCA Pause Alarm, press CHANNEL SELECT > OPTIONS > DRUG EVENT HISTORY, Press the Up/Down key to view the text for the monitoring value causing the PCA module to pause. Press EXIT and then START.</p> |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|--------------------------------|--------------------------------------|---------------|---|---|
| Alarm Message | Device | Priority | Meaning | Response |
| PRESSURE DISC INSERTED | Syringe | High | <p>The Pressure Sensing Disc was installed during a running infusion. The infusion stops on affected module.</p> <p>The Pressure Sensing Disc should not be installed during an infusion. Installing the disc delivers a bolus.</p> | Press the CONFIRM soft key and then the RESTART key. |
| PROGRAM STEP COMPLETE STATUS | Syringe, PCA, Pump | Informational | The Bolus/Loading dose has been delivered and the device is waiting for next programming instructions. | Program the next infusion step or turn the channel off. |
| PUMP CHAMBER BLOCKED | Pump | High | The tubing is blocked inside Pump module (pump chamber). | <ol style="list-style-type: none"> 1. Close the roller clamp and open the door. 2. Remove the tubing. 3. Massage the tubing from the top to the bottom to restore the flow. 4. Reload the set and close the door. 5. Press the NEXT soft key. 6. Press the CONFIRM soft key. 7. Open the roller clamp and press the RESTART key. 8. Verify the flow in the drip chamber after restarting the infusion. 9. Change the set if you are unable to establish flow. |
| REPLACE BATTERY | PC unit | Low | The battery has reduced runtime capacity. | Press CONFIRM to continue operation with reduced battery capacity or power down and replace the device. |
| SAFETY CLAMP OPEN / CLOSE DOOR | Pump | High | The safety clamp device is in open position while the door is open. | Close the roller clamp on administration set or close the door. |
| SEARCHING | SpO ₂ , EtCO ₂ | Informational | The monitoring device is attempting to start monitoring and is searching for patient vitals. Searching automatically follows initialization | N/A |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|------------------------------|--------------------|---------------|--|---|
| Alarm Message | Device | Priority | Meaning | Response |
| SENSOR OFF | SpO ₂ , | Medium | The sensor is not connected to the patient while monitoring or after approximately 30 seconds of searching for patient. | Check the patient. Attach the sensor to the patient. |
| SENSOR WARMING | EtCO ₂ | Informational | The monitoring device is preparing sensor mechanisms to search for and monitor the patient vitals. | N/A |
| SWITCHOVER STATUS | Syringe, PCA, Pump | Informational | The device is delivering medication/fluid. | No user response expected. |
| SYRINGE CALIBRATION REQUIRED | Syringe, PCA | Medium | The module needs calibration before use. CALIBRATE scrolls in the Message Display. Other modules currently infusing will continue to operate. | Replace the module with an operational device as soon as possible. Service by qualified personnel is required. Press the CONFIRM soft key to continue. |
| SYRINGE DRIVER HEAD ERROR | Syringe, PCA | High | A noninfusing module, with the plunger grippers open, senses that excessive pressure is being applied downward on the Drive Head. The word "OCCLUSION" scrolls in Message Display. | To silence the alarm and continue with normal operation, press the CONFIRM soft key. |
| SYRINGE EMPTY | Syringe, PCA | High | The syringe VTBI has completed and the syringe contains less than 2% total disposable volume. | Set up a new syringe infusion or press the CHANNEL OFF key. |
| SYSTEM ERROR | PC unit | High | A FATAL MALFUNCTION is detected on the PC unit | Replace the device immediately. The settings unrestorable; record the settings before powering down the device. |

Alarms and Alerts (continued)

Alarms (continued)

| Alarms | | | | |
|--|---------|---------------|---|---|
| Alarm Message | Device | Priority | Meaning | Response |
| VERY LOW BATTERY <5 MIN TO SHUTDOWN PLUG IN NOW | PC unit | High | The battery has an estimated run time of five minutes prior to infusion stopping. | Connect the AC power cord to the power source (alarm silenced). Very low battery will continue to display after the AC is plugged in until the battery has built up sufficient charge to run Alaris System for 5 minutes. To verify that AC is charging, look at the AC LED on the front panel. |
| WAIT STATUS | PCA | Informational | Device is waiting to deliver the next PCA dose. | No user response is expected |

Storage

Plug the PC unit into an AC outlet during storage to ensure a fully charged battery. The AC indicator light () is on when the PC unit is plugged in.

Battery Care and Maintenance

Battery Type and Charging

The PC unit is equipped with a 12 volt, 4000 mAh nickel metal hydride battery. The battery is charging whenever the instrument is plugged into an AC receptacle. The life expectancy of the battery is dependent on the amount of use, the depth of discharge, and the state of the charge that is maintained. Generally, the battery has the longest life if the instrument is plugged in and battery use is infrequent. Frequent use of battery power and insufficient battery charge cycles significantly decrease the life of the battery.

Normally a battery will last 2 years if used under proper maintenance. See *Proper Battery Maintenance* on page A-25.

Use only CareFusion batteries. The use of third party batteries could affect the safety and efficacy of Alaris products.

Battery Charging

The PC unit is shipped with the battery in a discharged condition. Before the PC unit is released for use, it should be plugged into a hospital grade AC outlet and the battery charged for at least 16 hours. This ensures proper battery operation when the Alaris System is first set up for patient use.

The battery is intended as a backup system. Leave the power cord connected to an external hospital grade AC power source whenever available.

If the device has been used on battery power, ensure that the battery is fully charged prior to using the device on battery power again. To fully charge a depleted battery connect the device to a hospital grade AC power source for 16 hours.

Battery Care and Maintenance (Continued)

Battery Storage and Use Conditions

If you plan to store the PC unit at temperatures in excess of 86°F (30°C) for one or more months, remove the battery from the PC unit and store the battery in an environment of 50 - 86°F (10 - 30°C).

If the batteries are to be stored for more than 1 year, they should be fully charged (16 hours) at least once per year to prevent leakage and deterioration in performance due to self-discharge.

When the battery has been out of use for one or more months, it will not have full capacity.

Some temporary reduction in capacity may occur if the battery is repeatedly partially discharged.

Battery Disposal

Battery replacement should be performed by qualified service personnel while the instrument is not in use.

Do not open, incinerate, or short circuit the battery. Worn-out batteries must be disposed of properly, according to local regulations.

CAUTION



Do not open, incinerate, or short circuit. Worn-out batteries must be disposed of properly, according to local regulations.

Proper Battery Maintenance

The battery should be conditioned every 12 months by qualified service personnel.

The battery should be replaced every 2 years by qualified service personnel.

Wireless Connection

Wireless Connection Soft Key

Send the PC unit to Biomed to resolve wireless connectivity issues.

The Wireless Connection soft key is inactive (grayed out) for one of the following reasons:

- The System Maintenance software was used to disable the wireless connection.
- The CF card flashing process was done without the programming of the proper AppConfig file (v9.12 or later).
- A valid network configuration has not been transferred.

To enable the wireless connection, consult the v9 or later System Maintenance software.

Wireless Connection Scenarios

At various locations, the PC unit may or may not be able to complete a wireless connection. When connected, the connection icon lights. If the PC unit cannot connect, the connection icon does not light, and device data is stored until a connection can be completed.

**NOTE:**

If there is no wireless connection, PC unit data (such as log information) is stored until a connection is re-established. System history and CQI logs are stored in non-volatile compact flash memory and are retained until memory is full and older items are purged.

The following table explains how the pump functions under various wireless scenarios.

| Full Connectivity | No Connectivity | Marginal Connectivity |
|---|---|--|
| <ul style="list-style-type: none">• Connectivity icon lighted• Near real-time full data transfer | <ul style="list-style-type: none">• Connectivity icon not lighted• Data stored until connection is reestablished | <ul style="list-style-type: none">• NA• Data stored and transferred as PC unit reestablishes connection |

Inspection Requirements

To ensure that the Alaris System remains in good operating condition, both regular and preventive maintenance inspections are required. Refer to the System Maintenance software for detailed instructions.

REGULAR INSPECTIONS

| PROCEDURE | FREQUENCY |
|---|--|
| INSPECT FOR DAMAGE <ul style="list-style-type: none"> • Exterior Surfaces • IUI Connector* • Keypad • Pole Clamp • Power Cord | <ul style="list-style-type: none"> • Each usage • Each usage • Each usage • Each usage • Each usage |
| CLEANING | As required |
| START-UP | Each usage |

NOTE:

* While visually inspecting the IUI connectors, look for fractures on the connectors black-colored plastic. If you see any damage, do not use an instrument with fractured IUI connectors. The IUI connector must be replaced before the instrument can be used again.

Inspect IUI Connectors

If any surface contaminants or blue or green deposits are visible, the connector must be replaced.

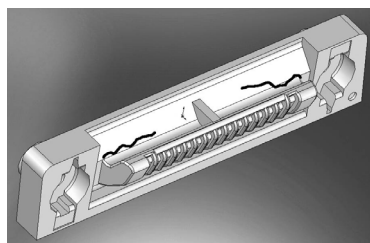


Figure 1: Male IUI Connector (right side)

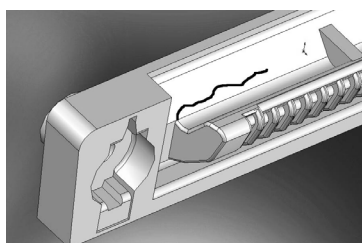


Figure 2: Male IUI Connector (right side)

1. Visually inspect the right side (male) IUI connector for cracks on the entire surface of the black colored plastic housing. See Figures 1 and 2 for the male IUI inspection area and typical cracks.
2. Visually inspect the left side (female) IUI connector for cracks on the edges of the black colored plastic housing.
3. If cracks are found, replace the IUI connector before use.

WARNING

Failure to perform these inspections can result in improper instrument operation.

CAUTION

Preventive maintenance inspections should only be performed by qualified service personnel.

WARNING

Failure to follow these instructions may result in potential hazards associated with damaged IUI connectors.

WARNING

Inserting a finger or other object into the IUI connector, when the module is attached to the PC unit, could result in electrical shock.

Cleaning

Inspect and clean the product per the following procedures. Read all warnings and cautions before continuing with this procedure.

Alaris System

Cleaning Products

Refer to the following website for cleaning product information: www.carefusion.com/alarissystemcleaning.

Procedure

Inspect IUI Connectors

1. Visually inspect the right side (male) IUI connector for cracks on the entire surface of the black colored plastic housing. See Figures 1 and 2 for the male IUI inspection area and typical cracks.

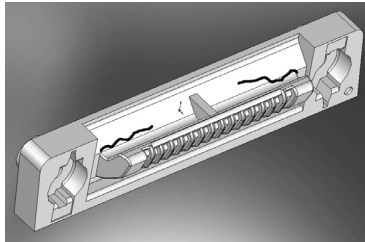


Figure 1: Male IUI Connector (right Side)

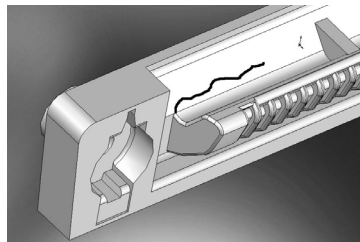


Figure 2: Male IUI Connector (right Side)

2. Visually inspect the left side (female) IUI connector for cracks on the edges of the black colored plastic housing.
3. If cracks are found, replace the IUI connector before use.

NOTE:

While visually inspecting the IUI connectors, look for fractures on the connectors black-colored plastic. If you see any damage, do not use an instrument with fractured IUI connectors. The IUI connector must be replaced before the instrument can be used again.

WARNING



- To prevent an **electrical hazard**:
 - Turn the instrument off and unplug the power cord from AC power before cleaning.
 - Do not spray fluids directly onto the instrument or into the IUI connectors.
 - Do not steam autoclave, EtO sterilize, immerse the instrument in fluids, or allow fluids to enter the instrument case.
 - Do not connect a module until the IUI connectors are thoroughly dry.
- **Do not use compressed air** to dry the instrument; this could force fluid into the instrument.

WARNING



Inserting a finger or other object into the IUI connector, when the module is attached to the PC unit, could result in electrical shock.

WARNING



Failure to perform these inspections can result in improper instrument operation.

CAUTION



Preventive maintenance inspections should only be performed by qualified service personnel.

Cleaning (Continued)

Alaris System (Continued)

Procedure (Continued)

NOTE:

Use the recommended healthcare-grade solutions and **DO NOT** use chemicals that can damage the surfaces of the instrument.

Cleaning the Case

1. Make sure the instrument is turned off, unplug the power cord and wipe all of the exposed device surfaces **EXCEPT** the inter-unit interface (UI) connectors.

DO NOT use an oversaturated cloth. Be sure to squeeze out excess liquid.



2. Use a dedicated soft-bristled brush to clean the case to remove any visible residue. The brush may also be used to clean narrow or hard-to-reach areas.

DO NOT use any hard, abrasive or pointed objects to clean any part of the instrument.

**CAUTION** 

- **The use of chemicals that can damage the surface of the instrument and failure to follow the Alaris product cleaning procedures and the cleaning solution manufacturer's recommended dilutions can result in an instrument malfunction or product damage, such as weakening and cracking of the case, and could void the warranty.**
- Do not allow the cleaning solution to contact the **UI connector** when cleaning the instrument.
- Do not use **hard, abrasive or pointed objects** to clean any part of the instrument.

CAUTION 

- Do not allow cleaning solutions to collect on the instrument. **Residue buildup** might cause the moving parts to become sticky and hinder their operation over time.
- Certain chemicals can damage the surfaces of the instrument. Refer to the following website for a list of **chemicals** that should **NOT** be used:

www.carefusion.com/alarissystemcleaning

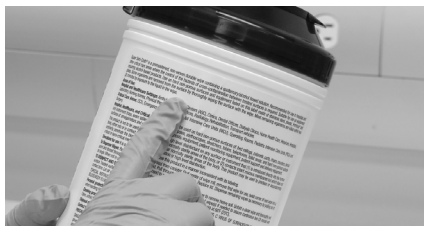
- Do not use chemicals that can damage the surface of the instrument. When possible use cleaning products that are recommended **for use** by CareFusion.

Cleaning (Continued)

Alaris System (Continued)

3. Follow the cleaner manufacturer's instructions on the time to leave it on the device surface. Then, remove the cleaner using a soft cloth dampened with water.

DO NOT allow the cleaner to collect on the instrument.



Cleaning the IUI

4. Apply 70% isopropyl alcohol directly to the dedicated IUI cleaning brush. To prevent cross-contamination, do not dip the brush into the IPA.

DO NOT use the same brush used on the case to clean the IUI connectors. Doing so could inadvertently transfer the cleaner or contaminants to the electrical contacts.



5. Clean both IUIs with the dedicated IUI cleaning brush.
To avoid accidentally depositing fluid on the connectors, DO NOT use any spray cleaners anywhere near the IUI connectors.

NEVER ALLOW ANY CLEANER OTHER THAN 70% IPA TO CONTACT THE IUI CONNECTORS.



Cleaning (Continued)

Alaris System (Continued)

Drying and Inspection

6. Confirm that the instruments and IUI connectors are thoroughly dry before using them again.

DO NOT attach devices that have not fully dried to one another. “Wet mating” can hinder proper instrument operation.



7. Fully inspect the instrument during each cleaning. Look for any visible external damage such as a cracked or broken door, handle, or latch. Open the door of each pump module and inspect the platen and hinge for cracks or other damage.

DO NOT use a device with any damage. Send it to Biomedical Engineering for repair.



WARNING



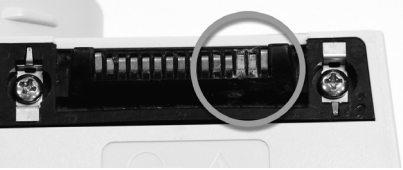
Inserting a finger or other object into the IUI connector, when the module is attached to the PC unit, could result in electrical shock.

Cleaning (Continued)

Alaris System (Continued)

8. Inspect the IUI connectors on each PC unit and module prior to use. Replace any IUI connector with surface contaminants, blue or green deposits, or cracks.

DO NOT use a device with any cracks or surface contaminants on the IUI connectors. Rather, send it to Biomedical Engineering for repair.



Service Information

Handheld Scanner

1. Use a clean soft cloth or lens tissue dampened with warm water or a mild nonabrasive detergent-water solution to clean all exposed surfaces.
2. Use a clean soft cloth or lens tissue dampened with water to rinse off cleaning solution.
3. Ensure that window is dry before returning to use.

If the instrument shows evidence of damage in transit, notify the carrier's agent immediately. Do not return damaged equipment to the factory before the carrier's agent has authorized repairs.

If the instrument fails to respond as described in this document and the cause cannot be determined, do not use the instrument. Contact qualified CareFusion service personnel.

If it is necessary to return the instrument for service, obtain a return authorization number prior to shipment. Carefully package the instrument (preferably in the original packaging), refer to the return authorization information, and return it to the appropriate service or distribution center. CareFusion does not assume any responsibility for loss of, or damage to, returned instruments while in transit.

Technical Support

Technical support, service information, applications, and manuals can be obtained by contacting a CareFusion representative. 888-812-3229.

When submitting any request for service, include:

- model number
- a description of difficulty experienced
- instrument settings
- administration set/lot number
- solution(s) used
- message displayed at time of difficulty

CAUTION



- Do not use **abrasive wipes or tissues** on the scanner's window.
- Do not use **solvents** (such as acetone, benzene, ether, phenol-based agents). These can damage the scanner's finish and window.
- **Do not immerse** in fluids.

WARNING



- The instrument case should only be opened by qualified personnel using **proper grounding techniques**. Prior to performing maintenance, disconnect attached module from the Alaris System and the PC unit from AC power.
- During servicing, an instrument's **configuration settings** might be reset to the factory defaults. Qualified hospital/facility personnel are responsible for checking in the instrument and ensuring the current hospital-approved Data Set is loaded.

WARRANTY

CareFusion warrants that:

- A. Each new Alaris System product is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by CareFusion to the original purchaser.
- B. The battery and each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by CareFusion to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with CareFusion to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at CareFusion's expense. The product requiring service should be returned promptly, properly packaged and postage prepaid by purchaser. Loss or damage in return shipment to the repair facility shall be at purchaser's risk.

In no event shall CareFusion be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Alaris System product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and CareFusion shall not be responsible for, any loss or damage arising in connection with the purchase or use of any Alaris System product which has been:

1. repaired by anyone other than an authorized CareFusion Service Representative;
2. altered in any way so as to affect, in CareFusion's judgment, the product's stability or reliability;
3. subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, effaced or removed; or
4. improperly maintained or used in any manner other than in accordance with the written instructions furnished by CareFusion.
5. Customer's use of repair or service parts or disposables that are not approved by CareFusion is at Customer's own risk and may void the product warranty provided by CareFusion.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of CareFusion, and CareFusion does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of CareFusion any other liability in connection with the sale or use of Alaris System products.

CAREFUSION DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

See packing inserts for international warranty, if applicable.

Compliance

Electromagnetic Environment

Alaris System

This system complies with part 18 of the FCC Rules (US version only). Operation is subject to the following two conditions:

- This system might not cause harmful interference.
- This system must accept any interference received, including interference that might cause undesired operation.

The digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus set out in the radio interference regulations of the Canadian Department of Communications (DOC).

Le present appareil numerique n'emet pas de bruits radioelectriques depassant les limites applicables aux appareils numeriques de la Classe B prescrites dans le reglement sur le brouillage radioelectrique edicte par le Ministere des Communications du Canada.

This system has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the system is operated in a commercial environment. This system generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the applicable user manual, it might cause harmful interference to radio communications. Operation of this system in a residential area is likely to cause harmful interference, in which case the user is required to correct the interference at their own expense.

The authority to operate this system is conditioned by the requirement that no modifications are made to the system unless the changes or modifications are expressly approved by CareFusion Corporation.

This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulation.

CAUTION



Any **changes or modifications** not expressly approved by the personnel responsible for compliance could void the user's authority to operate the system.

Compliance (Continued)

Electromagnetic Environment (Continued)

Cet appareil numérique de la Classe B respecte toutes les exigences du Règlement sur le matériel brouilleur du Canada.


The Alaris System includes an IEEE 802.11 RF transmitter, as designated by the icon on the rear of the system. It operates on the following frequencies with a maximum radiated power of 100 mW:

- **802.11a:** 5 GHz band, up to 54 Mbps physical RF specification.
- **802.11b:** 2.4 GHz band, up to 11 Mbps physical RF specification.
- **802.11g:** 2.4 GHz band, up to 54 Mbps physical RF specification.
- **802.11n:** 5 GHz or 2.4 GHz band, up to 72 Mbps physical RF specification.

The registration numbers are identified on the RF card installed in the rear of the PC unit.

Tables: The Alaris System is intended for use in the electromagnetic environments specified in the following tables.

Table 1
Electromagnetic Emissions


| Emissions Test | Compliance | Electromagnetic Environment—Guidance |
|--|------------|---|
| CISPR 11 RF Emissions | Group 1 | <p>Alaris System uses RF energy only for its internal function in normal product offering. Following icon appears on product. Refer to network card's user manual for further information.</p> <div style="text-align: center;">  </div> <p>RF emissions are very low and are not likely to cause interference with nearby electronic equipment.</p> |
| CISPR 11 RF Emissions | Class B | Alaris System is suitable for use in all establishments, including domestic establishments and those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes. |
| IEC 61000-3-2 Harmonic Emissions | Class A | |
| IEC 61000-3-3 Voltage Fluctuations Flicker Emissions | Complies | |

Compliance (Continued)

Electromagnetic Environment (Continued)

Alaris System (Continued)

Table 2
Electromagnetic Immunity

| Immunity Test | IEC 60601-1-2:2007 Test Level ^③ | Compliance Level ^③ | Electromagnetic Environment - Guidance |
|---|---|---|---|
| IEC 61000-4-2 Electrostatic Discharge (ESD) | For Model 8015, Infusion modules, and Auto-ID module: ±8 kV contact ±15 kV air For Model 8015 and monitoring modules: ±6 kV contact ±8 kV air | ±8 kV contact ^① ±15 kV air ^① For Model 8015, Infusion modules and Auto-ID module: ±8 kV contact ±15 kV air For Model 8015 and monitoring modules: ±6 kV contact ±8 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%. If connector testing exemption is used, following ESD sensitivity symbol appears adjacent to each connector. Alaris System User Manual – with v9.33 Model 8015" - Do Not Touch"  |
| IEC 61000-4-4 Electrical Fast Transient, Burst (EFT) ^② | ±2 kV for power supply lines ±1 kV for input/ output lines | ±2 kV for power supply lines ±1 kV for input/ output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-5 ^② Power Line Surge | ±1 kV differential mode ±2 kV common mode | ±1 kV differential mode ±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-8 Power Frequency Magnetic Field (50/60 Hz) | 3 A/m | 400 A/m 50 Hz ^① 400 A/m 60 Hz ^① | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

Compliance (Continued)

Electromagnetic Environment (Continued)

Alaris System (Continued)

Table 2 (Continued)
Electromagnetic Immunity


| Immunity Test | IEC 60601-1-2 Test Level ^③ | Compliance Level ^③ | Electromagnetic Environment - Guidance |
|--|--|--|--|
| IEC 61000-4-11 Voltage Dips, Short Interruptions, and Voltage Variations | <5% U_T (>95% dip in U_T) for 0.5 cycle | <5% U_T (>95% dip in U_T) for 0.5 cycle | Mains power quality should be that of a typical commercial or hospital environment. If continued operation of Alaris System is required during power mains interruptions, it is recommended that Alaris System be powered from an uninterruptible power supply or a battery. Alaris System does employ an internal short duration battery. |
| | 40% U_T (60% dip in U_T) for five cycles | 40% U_T (60% dip in U_T) for five cycles | |
| | 70% U_T (30% dip in U_T) for 25 cycles | 70% U_T (30% dip in U_T) for 25 cycles | |
| | <5% U_T (>95% dip in U_T) for 5 sec | <5% U_T (>95% dip in U_T) for 5 sec | |
| <p>Notes: At 80 MHz and 800 MHz, the higher frequency applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> | | | |
| <p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Alaris System is used exceeds the applicable RF compliance level above, the Alaris System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Alaris System.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.</p> | | | |

Compliance (Continued)

Electromagnetic Environment (Continued)

Alaris System (Continued)

Table 3
Electromagnetic Immunity - Life Support Equipment

| Immunity Test | IEC 60601-1-2 Test Level | Compliance Level ^① | Electromagnetic Environment - Guidance ^{④⑤} |
|-------------------------------|--------------------------------|-------------------------------|---|
| IEC 61000-4-6 Conducted RF | 10 Vrms 150 kHz - 80 MHz | 10 Vrms | Portable and mobile RF communications equipment should be used no closer to Alaris System (including cables) than recommended separation distance calculated from equation applicable to frequency of transmitter. Recommended Separation Distance: $d = \frac{12}{\sqrt{P}} \sqrt{P}$ $d = \frac{12}{E_1} \sqrt{P} \quad 80 \text{ MHz} - 800 \text{ MHz}$ $d = \frac{12}{E_1} \sqrt{P} \quad 80 \text{ MHz} - 2.5 \text{ GHz}$ <p style="margin-left: 40px;">d = recommended separation distance in meters (m).^⑥</p> <p style="margin-left: 40px;">P = maximum output power rating of transmitter in watts (W) according to transmitter manufacturer.</p> <p style="margin-left: 40px;">Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than compliance level in each frequency range.^{⑦⑧}</p> <p style="margin-left: 40px;">Interference might occur in vicinity of equipment marked with following symbol:</p> <div style="text-align: center;">  </div> |
| IEC 61000-4-3 Radiated RF | 10 V/m 80 MHz - 2.5 GHz | 10 V/m | |

Compliance (Continued)

Electromagnetic Environment (Continued)

Alaris System (Continued)

Table 4^{④⑤⑥⑨}
Recommended Separation Distances

Reduce the potential for electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters), and the Alaris System as recommended in this table, based on the maximum output power of the communications equipment.

For transmitters rated at a maximum output power not listed in this table, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) based on the transmitter manufacturer.

| Rated Maximum Output Power of Transmitter (W) | Separation Distance Based on Transmitter Frequency (m) | | | |
|---|--|-------------------------------|-------------------------------|-------------------------------|
| | 150 kHz - 80 MHz Outside ISM Bands | 150 kHz - 80 MHz In ISM Bands | 80 MHz - 800 MHz | 800 MHz - 2.5 GHz |
| | $d = \frac{3.5}{V_1} \sqrt{P}$ | $d = \frac{12}{V_2} \sqrt{P}$ | $d = \frac{12}{E_1} \sqrt{P}$ | $d = \frac{23}{E_1} \sqrt{P}$ |
| 0.01 | 0.02 | 0.06 | 0.06 | 0.12 |
| 0.1 | 0.06 | 0.19 | 0.19 | 0.36 |
| 1 | 0.18 | 0.6 | 0.6 | 1.15 |
| 10 | 0.55 | 1.9 | 1.9 | 3.64 |
| 100 | 1.75 | 6 | 6 | 11.5 |

Compliance (Continued)

Electromagnetic Environment (Continued)

Alaris System (Continued)

NOTES:

- ① Compliance levels raised by IEC 60601-2-24 (Edition 2.0 2012).
- ② Performed at the minimum and maximum rated input voltage.
- ③ U_T is the AC mains voltage prior to application of the test level.
- ④ At 80 MHz and 800 MHz, the higher frequency range applies.
- ⑤ These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- ⑥ The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz, and in the frequency range 80 MHz - 2.5 GHz, are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
- ⑦ Field strengths from fixed transmitters [such as base stations for radio (cellular/cordless) telephones and mobile radios, amateur radio, AM/FM radio broadcast, TV broadcast] cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Alaris System is used exceeds the applicable RF compliance level, the Alaris System should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating the Alaris System.
- ⑧ Over the frequency range 150 kHz - 80 MHz, field strengths should be less than $[V_1]$ V/m.
- ⑨ The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz, and 40.66 - 40.70 MHz.

Compact Flash Wireless Networking Module

The CF Wireless Module contains a radio frequency, wireless, local-area network interface (RF card). The RF card allows the Alaris System to communicate with the Alaris Systems Manager connected to the hospital information system. The RF card is compliant with the rules and regulations in the locations where the CF Wireless Module is sold, and is labeled as required.

The United States Federal Communications Commission (FCC) and Industry Canada (IC) identification numbers are visible through the CIB's clear plastic cover. If an international country approval stamp is required, it is placed adjacent to the identification numbers in the area provided. If the FCC identification number or country approval stamp is not easily visible, the RF card cover may be removed so that the information provided can be read. If the RF card cover is removed, ensure that it is reattached—using the screws that

Compliance (Continued)

Electromagnetic Environment (Continued)

Compact Flash Wireless Networking Module (Continued)

were removed, to ensure that the RF card is securely retained and protected against liquid ingress and damage.

The Class B digital device limits are designed to provide reasonable protection against harmful interference when the device is operated as intended. This device generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the applicable user manual, it might cause harmful interference to radio communications. Operation of this device in a residential area is likely to cause harmful interference, in which case the user is required to correct the interference at their own expense. There is, however, no guarantee that interference will not occur in a particular installation.

If the device does cause harmful interference to radio or television reception (determined by powering system off and on), one or more of the following corrective actions should be taken:

- Reorient or relocate receiving antenna.
- Increase separation distance between system and receiver.
- Connect system into an outlet on a circuit different from that to which receiver is connected.

This Class B digital device meets the requirements of the Canadian Interference Causing Equipment Regulations.

Cet appareil numérique de la Classe B respecte toutes les exigences du Règlement sur le Matériel Brouilleur du Canada.

This Class B digital device meets the requirements of the International community.

Australian Communications Authority
Applicant:



CareFusion Australia 316 Pty LTD
P.O. Box 355
Seven Hills West, NSW
Australia 2147

Phone: 02 9838 0255
Fax: 02 9674 4444

Compliance (Continued)

Standards

The Alaris System has been assessed and complies with the following standards:

PC unit and overall System: CAN/CSA C22.2 No. 60601-1-1 (3.0 Edition 2014), IEC 60601–1 (3.1 Edition 2012), 60601-1-2 (2007), 60601-1-8 (2012)

Auto-ID module: IEC 60825–1 (Edition 3.0 2014) (LEDs used in Auto-ID module are not regulated by FDA in the United States; however, they are classified as a CLASS 1 LED PRODUCT in other countries under this standard.)

Compact Flash Wireless Networking Module: Class B digital device limits pursuant to Parts 15 (RF Devices and Computing Devices 2015) and 18 (Medical Devices) of the FCC Rules and Regulations 2015. To comply with FCC and Industry Canada exposure requirements, the CF Wireless Module is approved for operation when there is more than 20 cm between the antenna and the user's or patient's body.

EtCO₂ module: ISO 80601-2-55 (2011), IEC 60601-2-49 (2011)

PCA, Pump and Syringe modules: IEC 60601-2-24 (Edition 2.0 2012), ANSI/ AAMI ID26 (2013)

Compliance (Continued)

Standards (Continued)

The Alaris System when upgraded to v9.33 software only has been assessed and complies with the following standards:

PC unit and overall System: UL 60601–1 (2003), CAN/CSA C22.2 No. 601.1-M90 (2.0 Edition 1990), IEC 60601–1 (2.0 Edition 1988)

Auto-ID module: IEC 60825–1 (2007) (LEDs used in Auto-ID module are not regulated by FDA in the United States; however, they are classified as a CLASS 1 LED PRODUCT in other countries under this standard.)

Compact Flash Wireless Networking Module: Class B digital device limits pursuant to Parts 15 (RF Devices and Computing Devices 2015) and 18 (Medical Devices) of the FCC Rules and Regulations 2015. To comply with FCC and Industry Canada exposure requirements, the CF Wireless Module is approved for operation when there is more than 20 cm between the antenna and the user's or patient's body.

EtCO₂ module: ISO 9918:1993, ASTM F 1456 (2001), ASTM F 1463 (1993), EN 475 (1995), EN 864 (1997)

PCA, Pump and Syringe modules: IEC 60601-2-24 (1.0 Edition (1998), ANSI/ AAMI ID26 (1998)

SpO₂ module: EN 865 (1997)

Compliance (Continued)

Hardware Dependencies

Additional test evidence is available for the EtCO₂ hardware included in devices manufactured with v9.33 software. This test evidence will not apply to devices upgraded to v9.33.

| EtCO₂ Hardware Dependencies | v9.33 Software Upgrade Only | Device Manufactured with v9.33 Software |
|---|------------------------------------|--|
| Note 1 for Accuracy of EtCO ₂ Readings (on page 5-20) | Does not apply | Applies |
| Accuracy Specification for Interfering Gases (on page 5-20) | Does not apply | Applies |
| Waveform Sampling (on page 5-22) | Does not apply | Applies |
| Respiration Rate Test Table (on page 5-26) | Does not apply | Applies |
| Note 2 for Accuracy in Respiration Rate Test Table (on page 5-26) | Does not apply | Applies |

Trademarks

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Alaris System User Manual –
with v9.33 Model 8015

