Directions for Use

Alaris™ System
(with Alaris™ PC Unit, Model 8015)

Supports Guardrails™ Suite MX with Guardrails™ Point-Of-Care software and up to v9.12 Operating System software.

December 2016
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General Contact Information

CareFusion
10020 Pacific Mesa Blvd  San Diego, California 92121
United States

Authorized European Representative
CareFusion UK 305 Ltd., The Crescent,
Jays Close, Basingstoke, Hampshire RG22 4BS, UK

Authorized Australian/New Zealand Representative
CareFusion Australia & New Zealand
Unit 3, 167 Prospect Highway
Seven Hills
NSW 2147
Australia
carefusion.com

Customer Advocacy - North America
(Clinical and technical feedback.)
Phone:  888.812.3266
E-mail: CustomerFeedback@carefusion.com

Technical Support - North America
(Maintenance and service information support; troubleshooting.)
Phone, United States:  888.812.3229
Phone, Canada:  800.387.8309

Technical Support - United Kingdom
(Maintenance and service information support; troubleshooting.)
Phone: 0800 389 6972
E-mail: GMB-INTL-Infusion-TechnicalSupport@carefusion.com

Customer Order Management - North America
(Product return, service assistance, and order placement.)
Phone, United States:  800.482.4822
Phone, Canada:  800.387.8309

Customer Care - United Kingdom
(Product return, service assistance, and order placement.)
Phone: 0800 917 8776
E-mail: UK-Customer-Service@carefusion.com

Technical Support and Customer Service - International
(Maintenance and service information support. Product return, service assistance, and order placement)
www.carefusion.com/customer-support/customer-service

Technical Support - Australia/New Zealand
(Maintenance and service information support. Troubleshooting, service assistance.)
Phone:  1300 729 258
E-mail: techservice-au@carefusion.com
General Contact Information (Continued)

Customer Care - Australia
(Product return and order placement.)
Phone: 1800 833 372
Email: au-customerservice@carefusion.com

Customer Care - New Zealand
(Product return and order placement.) Phone: 0508 422 734
Email: nz-customerservice@carefusion.com
Introduction

The Alaris™ PC Unit section of this Directions for Use (DFU) 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 in today’s growing professional healthcare environment. It consists of the PC Unit, the Guardrails™ Suite MX, and up to four detachable infusion and/or monitoring modules (channels). The Auto-ID Module can be included as a fifth module.

The Alaris System supported by this DFU uses a new generation PC Unit (Model 8015) which provides wireless connectivity right out of the box, and an enhanced display (including color) to clearly communicate critical programming, infusion, monitoring and hospital-defined policy information. Alaris System wireless communication makes it easier than ever to increase the safety of IV medication and continuously improve clinical best practices, regardless of existing wireless infrastructure.

The Model 8010 Nurse Call Accessory might not yet be available for use or compatible with the Model 8015.

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 15 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 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.

WARNING
Read all instructions before using the Alaris System.

CAUTION
Rx Only
Information about an Alert that occurs during use is stored within the PC Unit, and can be accessed using the CQI Reporter.

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.

**WARNINGS AND CAUTIONS:**

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

A \(\text{DANGER} \) is an alert to an imminent hazard which could result in serious personal injury and/or product damage if proper procedures are not followed.

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

A \(\text{CAUTION} \) is an alert to a potential hazard which could result in minor personal injury and/or product damage if proper procedures are not followed.

**DEFINED TERMS:**

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

<table>
<thead>
<tr>
<th>Product/Feature</th>
<th>Defined Term</th>
</tr>
</thead>
<tbody>
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<td>Alaris Auto-ID module</td>
<td>Auto-ID Module</td>
</tr>
<tr>
<td>Alaris EtCO₂ module</td>
<td>EtCO₂ Module</td>
</tr>
<tr>
<td>Alaris PCA module</td>
<td>PCA Module</td>
</tr>
<tr>
<td>Alaris PC unit</td>
<td>PC Unit</td>
</tr>
<tr>
<td>Alaris Pump module</td>
<td>Pump Module</td>
</tr>
</tbody>
</table>
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. Verify whether or not Profiles feature has been enabled.
Alaris™ PC Unit
Model 8015
# Troubleshooting and Maintenance

## General Information

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## Troubleshooting and Maintenance

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This section of the DFU 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 DFU
- 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, Alaris Server, and Mobile Server. The combined use of the Alaris System and Alaris Server:

- Reduces number of manual steps needed to program an infusion (by providing information obtained from Alaris Server). All data entry and validation of infusion parameters are performed, according to a physician's order, by a trained healthcare professional.
- Is integrated into a facility’s existing network infrastructure.

When enabled, the Alaris Server allows the exchange of information between the Alaris Server and the Alaris System. The PC Unit can be operated manually or in concert with the information exchanged with the Alaris Server. 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.

The Mobile Systems Manager does not utilize existing wireless infrastructure. It is intended to be used as a not-fully-functional substitution for the full Systems Manager in hospitals/facilities that do not have wireless communications installed. It can also be used in hospitals/facilities using the full Systems Manager but where wireless coverage is poor.
Alarms, Errors, Messages: See "Troubleshooting and Maintenance" for specific PC Unit alarms, errors and messages.

Contraindications: None known.

Electromagnetic Environment: See "Appendix" section of this DFU ("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.

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.
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.

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
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</table>

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.

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.
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 reidentification 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.

Secure to Pole Using Optional Locking Pole Clamp

1. Attach PC Unit to pole.
2. Insert PCA Module syringe door key into key lock on pole clamp knob.
3. To lock PC Unit to pole, turn key in direction of arrow (clockwise).
   Pole clamp knob spins in place, preventing PC Unit from being removed from pole.
4. To unlock PC Unit from pole, turn key in opposite direction of arrow (counter clockwise).
   Pole clamp knob no longer spins in place, allowing PC Unit to be removed from pole.
1. Connect PC Unit to an external AC power source. ①

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.
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)

2. To adjust display for optimum viewing, use **Lighter/Darker** soft keys.

3. To return to main screen, press **CONFIRM** soft key.

**Select New Patient and Profile Options**

The following procedures assume the Profiles feature is enabled.

1. 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.

2. 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)

3. To select a profile, press corresponding left soft key.
   To view additional choices, press PAGE DOWN soft key.

4. 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 bar code on patient identification band, see Auto-ID Module section of this DFU.
### Adjust Audio Volume

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.

### 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.

---

**CAUTION**

Setting the audio volume to the **lowest level** will lower all system alarms, including secondary alarms such as End of Infusion.
### Lock/Unlock Tamper Resist (Continued)

- 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.
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.
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 bar code on patient identification band, see AUTO-ID section of this DFU.

4. To verify correct entry, press CONFIRM soft key.
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.
6. 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**

1. Press **OPTIONS** key.

2. Press **Clinician ID** soft key.

3. 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.
To verify correct entry, press **CONFIRM** soft key.

1. Press **OPTIONS** key.

2. Press **Power Down All Channels** soft key.

3. Press **Yes** soft key.
   
   During power off sequence, Main Display flashes **POWERING DOWN**.
When the Anesthesia Mode is enabled while a module is paused, the module remains in an indefinite pause until restarted.

When Anesthesia Mode is enabled:

- All limits are set to **Soft**.
- Dose checking mode is set to **Smart**.
- Key-press audio is turned off.
- 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.

### Enable

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

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)

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

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

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**System Options** (Continued)

<table>
<thead>
<tr>
<th>System Configuration - Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factory Default: Yes</td>
</tr>
<tr>
<td>Shared Infusion Settings</td>
</tr>
<tr>
<td>PC Unit</td>
</tr>
<tr>
<td>Pump Module</td>
</tr>
<tr>
<td>SPO2 Module</td>
</tr>
</tbody>
</table>

**System Config - PCU 1 of 3**

- Alarm audio: Profile 1
- Anesthesia Mode: Disabled
- Battery meter: Disabled
- Clock setup: 09:00
- Limit Checking: ALWAYS

**System Config - PCU 2 of 3**

- Key click audio: Enabled
- Max Pt. BSA: 2 m²
- Max Pt. weight: 500 kg
- Patient ID Entry: Disabled
- Pending IV Orders: Enabled

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

NOTE:

1. The Profiles option is listed only if it is disabled.
2. The Limit Checking (or Dose Checking), Max Pt. BSA, and Pending IV orders options are listed only if the Profiles option is enabled and a valid Data Set is loaded.

Serial Numbers

1. Press OPTIONS key.
2. Press PAGE DOWN soft key.
3. Press Serial Numbers soft key.
   Serial numbers for PC Unit and all attached modules display. 

System Configurations (Continued)
4. To return to main screen, press EXIT soft key.

NOTE:

- "nnnn-nnnnnnnnn" in the illustrated display represents a serial number.

Software Versions

1. Press OPTIONS key.
2. Press PAGE DOWN soft key.
3. Press Software Versions soft key.
4. To review software version information, press View soft key next to applicable module.
   - OR
   - To return to main screen, press EXIT soft key.
5. To return to previous screen, press **EXIT** soft key.  

**NOTE:**  
① "nn.nn" in the illustrated display represents a software version.

### Time of Day

1. Press **OPTIONS** key.①  
2. Press **PAGE DOWN** soft key.  
   
   4. If time is correct, press **CONFIRM** soft key.  
      
      **OR**  
      To change time, press **Change Time** soft key.
5. Enter current Time of Day.

6. Press **CONFIRM** soft key.

**NOTE:**
- The format is a 24-hour clock (military time).

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**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.
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**, **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 54 Mbps for 802.11a/g and 11 Mbps for 802.11b.
     - **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**, or **CONNECTED** is displayed. A status of **INVALID CONFIG** is also displayed on a v9.5 and later PC Unit.
   - If status is **CONNECTED**:
     - PC Unit is connected to wireless network.
     - **Profile** being used for v9.5 and later PC Unit is displayed.
6. 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.

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

### Pre-v9.5 PC Unit:

![Pre-v9.5 Network Status](image)

- **Uptime**: 03:45:35
- **Bytes Sent**: 1,200,150
- **Bytes Received**: 13,890
- **Bytes Sent**: 13,890
- **Bytes Received**: 1,200,150

### v9.5 and later PC Unit:

![v9.5 Network Status](image)

- **Uptime**: 03:45:35
- **Bytes Sent**: 1,200,150
- **Bytes Received**: 13,890
- **Bytes Sent**: 13,890
- **Bytes Received**: 1,200,150
• Pre-v9.5 PC Unit: Information based on a status of DISABLED, SEARCHING, VERIFYING, CONNECTING, or CONNECTED is displayed.

• v9.5 and later PC Unit: Information based on a status of DISABLED, DISCONNECTED, CONNECTING, or CONNECTED, is displayed.

• If status is CONNECTED, PC Unit is connected to Alaris Server and the following information is displayed:
  - **Uptime**—length of time PC Unit has been connected.
  - **Server Address**—IP Address of Alaris Server.
  - **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** when v9.5 and later PC Unit is connected—first 20 characters of fully qualified domain name of Alaris Server.

### Wireless Connection

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

   v9.5 or later PC Unit: If **Wireless Connection** soft key is inactive (grayed out), System Maintenance software was used to disable wireless connection. To enable wireless connection, use v9.5 or later System Maintenance software.
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.
  - v9.5 System Maintenance software instructions also includes a procedure on how to disable a wireless RF card on a v9.0 or later 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 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.
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.

**NOTE:**

① PAGE DOWN soft key appears only if an Auto-ID module is attached.
**Explosion risk** if used in the presence of flammable anesthetic agents or gasses.

**WARNINGS**

- **DANGER**
- 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.
- 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 Server 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.
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.

---

### Electromagnetic Compatibility

- 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.
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 DFU (see "Regulations and Standards," "Compliance").

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician ID</td>
<td>An optional alphanumeric 16-character clinician identifier that can be entered and displayed.</td>
</tr>
<tr>
<td>Data Set</td>
<td>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.</td>
</tr>
</tbody>
</table>
### Features and Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
</table>
| **Guardrails™ Suite MX** | Designed to help prevent programming errors by:  
  • 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**        | An optional alphanumeric 16-character patient identifier that can be entered and displayed  
  • When enabled, ID entry defaults to Startup screen.  
  • When disabled, ID entry is only accessible from System Options screen. |
| **Profile**           | 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:  
  • 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).  
  
  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. |
| **System Configuration** | Allows system settings to be customized. If Profiles feature is enabled, system settings defined for selected profile are automatically activated. |
| **Tamper Resist**     | Provides a quick one-touch lockout of front panel keypad. |
Operating Features, Controls, Indicators

**Main Display**

**Soft Keys:** When pressed, allows selection of options or infusion parameters appearing on Main Display adjacent to soft key.

**Silence Key:** When pressed during an alarm, silences audio for 2 minutes.

**Options Key:** When pressed, allows access to available System or Channel Options.

**Battery Indicator:** When illuminated, indicates Alaris System is operating on battery power.

**Power Indicator:** When illuminated, indicates Alaris System is connected to an AC power source.

**Wireless Network Indicator:** When illuminated, indicates Alaris System is connected to Alaris Server or Mobile Systems Manager. When blinking, indicates data transfer.

**Clear Key:** When pressed, clears current selected parameter setting to "0".

**Module Release Latch:** When pressed, allows module to be removed.

**System On Key:** When pressed, changes Alaris System from standby to operating mode.

**Up Key:** When pressed, increases parameter with each key press or scrolls up when pressed and held.

**Down Key:** When pressed, decreases parameter with each key press or scrolls down when pressed and held.

**Enter Key:** When pressed, confirms current parameter entry.

**Cancel Key:** When pressed, sequentially backs out of current setup sequence.

**Decimal Key:** When pressed, inserts a decimal point in numeric data.

**Numeric Keypad**

**IUI Connector, Left**

(Not visible)

**IUI Connector, Right**
Use this bolt to reorient Pole Clamp 90° for attachment to a bed rail instead of a pole.

Primary Audio Speaker

Connector Plug over RJ45 Communication Data Port.

Tamper Resist Switch

Power Cord Strap

Wireless Network Card (see illustration below for LED location)

Wireless Network Card LED
Flashes green when Alaris System is powered up.

Optional Pole Locking Clamp:
PCA Module syringe door key locks and unlocks knob.
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

Nonhighlighted indicates a selected soft key.

"Active" Soft Key

Highlighted indicates a selected soft key.

Prompt Bar

Look here for user prompts.
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.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarm Audio</td>
<td>Profile 1</td>
<td>Profile 1, 2, or 3</td>
</tr>
<tr>
<td>Anesthesia Mode</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Battery Meter</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Clock Setup (Date and Time)</td>
<td>Not Applicable</td>
<td>Set date and time</td>
</tr>
<tr>
<td>Dose Checking</td>
<td>Always</td>
<td>Always, Smart</td>
</tr>
<tr>
<td>Key Click Audio</td>
<td>Enabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Max Patient Weight</td>
<td>500 kg</td>
<td>0.1 - 500 kg</td>
</tr>
<tr>
<td>Patient ID Entry</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>PM Reminder (Preventive Maintenance)</td>
<td>Enabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Profiles</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Tamper Resist</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
</tbody>
</table>
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:

- 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: System configuration parameters stored in volatile memory are retained for at least six months by internal backup lithium battery. 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.

Environmental Conditions:

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

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

Weight: 7.2 lbs
See the product-specific section of this DFU that applies to the attached module(s) for symbols specific to that module.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alternating Current:</td>
<td>Indicates device should be attached to alternating current source, 50/60 Hz only.</td>
</tr>
<tr>
<td>Caution:</td>
<td>Refer to accompanying documentation.</td>
</tr>
<tr>
<td>Canadian and U.S. Certification Mark:</td>
<td>Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety and performance standards.</td>
</tr>
<tr>
<td>Communications connector for RS-232 attachment.</td>
<td></td>
</tr>
<tr>
<td>Consult operating instructions.</td>
<td></td>
</tr>
<tr>
<td>Type CF defibrillation-proof equipment.</td>
<td></td>
</tr>
<tr>
<td>Electrostatic discharge (ESD).</td>
<td></td>
</tr>
<tr>
<td>Fuse Replacement:</td>
<td>Replace fuse only with same type and rating.</td>
</tr>
<tr>
<td>Protection against fluid ingress:</td>
<td>Drip Proof.</td>
</tr>
<tr>
<td>IUI Connector:</td>
<td>Inter-Unit Interface connector used to establish power and communications between PC Unit and attached modules.</td>
</tr>
<tr>
<td>Manufacturing Date:</td>
<td>Number adjacent to symbol indicates month and year of manufacture.</td>
</tr>
<tr>
<td>Potential Equalization Conductor (if so equipped).</td>
<td>Note: If integrity of PEC or Hospital Earth System is in question, operate instrument using internal battery power.</td>
</tr>
<tr>
<td>Radio frequency (RF) transmission.</td>
<td></td>
</tr>
</tbody>
</table>
### Specifications and Symbols (Continued)

#### Symbols (Continued)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="Rx_mark.png" alt="Rx" /> Only</td>
<td>Caution: Federal (U.S.A) law restricts this device to sale by or on order of a physician.</td>
</tr>
<tr>
<td><img src="lock.png" alt="Lock" /></td>
<td>Tamper Resist activate/deactivate switch.</td>
</tr>
<tr>
<td><img src="ce_mark.png" alt="CE" /></td>
<td>Conformité Européenne (CE marking) notified body 0086: British Standards Institution.</td>
</tr>
<tr>
<td><img src="n12875.png" alt="N12875" /></td>
<td>Australian Communications Authority.</td>
</tr>
<tr>
<td><img src="fcc.png" alt="FCC" /></td>
<td>Federal Communications Commission.</td>
</tr>
<tr>
<td><img src="ec_rep.png" alt="EC REP" /></td>
<td>Authorized representative in European Community.</td>
</tr>
</tbody>
</table>
General

Troubleshooting and maintenance are intended to be performed only by qualified personnel, using the Alaris System Technical Service Manuals and the System Maintenance software. The Service Manuals and System Maintenance software are available from CareFusion. The Service Manuals include 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.

Alaris Server Connections

When an Alaris Server or Mobile Systems Manager connection is made, the Wireless Network Indicator on the PC Unit lights up. If connection to the Alaris Server is interrupted, the indicator light is extinguished. Some of the causes for a communications failure include:

- Alaris Server 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 wireless coverage area.
- Wireless network card has been damaged.

If an interruption to the Alaris Server connection continues, the facility’s information technology department should be informed.
Alaris System DFU – up to v9.12 Model 8015
PC Unit Section

Alarms, Errors, Messages

To enhance safety and ease of operation, the Alaris System provides a full range of audio and visual alarms, errors, and messages.

Operating the system near equipment which radiates high-energy radio frequencies (such as electrosurgical/cauterizing equipment, portable radios, cellular telephones) might cause false alarm conditions. If this happens, reposition the Alaris System away from the source of interference or turn off the system and manually regulate the flow with the clamp and/or monitor the vital parameters using an appropriate clinical alternative.

Display Color

If the option to have a color display is enabled, color is used in the title and prompt bars to help communicate the following types of information.

<table>
<thead>
<tr>
<th>Communication</th>
<th>Color</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Operation</td>
<td>Blue</td>
<td>All messages other than noted above (normal operating displays).</td>
</tr>
<tr>
<td>Guardrails limit</td>
<td>Yellow</td>
<td>Visual message indicating a Limit was exceeded.</td>
</tr>
<tr>
<td>Informative</td>
<td>Green</td>
<td>Visual message requiring a response to clear message.</td>
</tr>
<tr>
<td>Alert and Standby</td>
<td>Red</td>
<td>Visual message indicating an error or system inconsistency occurred.</td>
</tr>
</tbody>
</table>

Definitions

See the product-specific section of this DFU that applies to the attached module(s) for alarm, error and message definitions specific to that module.

- **Advisory/Message**: A sequence of audio and/or visual signals indicating system operating status.
- **Alarm**: An audio and visual signal that a potentially unsafe condition is present. Immediate action is required.
- **Alarm Silence**: Alarms can be silenced for up to 120 seconds by pressing **SILENCE** key.
- **Error**: An audio and/or visual signal that a failure has been detected. Immediate action is required.


**Alarms, Errors, Messages** (Continued)

### Definitions (Continued)

**Maintenance Reminder**  A visual message that, when enabled, appears at startup when scheduled preventive maintenance is due/overdue for component of Alaris System (PC Unit or attached module).

**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 by pressing SILENCE key.

### Audio Characteristics

The Alaris System provides various types of alert information. See the product-specific section of this DFU that applies to the attached module(s) for audio characteristics specific to that module.

<table>
<thead>
<tr>
<th>Type</th>
<th>Sound</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advisory/Message</td>
<td>One short beep every 2 seconds.</td>
<td>Variable volume; can be silenced for 2 minutes.</td>
</tr>
<tr>
<td>Alarm</td>
<td>Choice of three alarm audio profiles, selectable in System Configuration.</td>
<td>Variable volume; can be silenced for 2 minutes.</td>
</tr>
<tr>
<td>Error (Hardware Detected)</td>
<td>Pairs of long beeps.</td>
<td>Fixed maximum decibel volume; cannot be silenced.</td>
</tr>
<tr>
<td>Error (Software Detected)</td>
<td>Pairs of long beeps.</td>
<td>Fixed maximum decibel volume; can be silenced for 2 minutes.</td>
</tr>
<tr>
<td>Illegal Key Press</td>
<td>Two short beeps.</td>
<td>Variable volume; cannot be silenced.</td>
</tr>
<tr>
<td>Key Click</td>
<td>One short beep.</td>
<td>Fixed minimum volume; can be silenced and disabled in System Configuration.</td>
</tr>
<tr>
<td>Prompt</td>
<td>One short beep every 2 seconds.</td>
<td>Variable volume; can be silenced.</td>
</tr>
</tbody>
</table>
## Alarms

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Discharged</td>
<td>Operation of all modules stopped due to insufficient battery charge.</td>
<td>Connect AC power cord to power source (alarm silenced). To continue operation of paused modules, press <strong>RESTART</strong> key on affected module.</td>
</tr>
<tr>
<td>Channel Disconnected</td>
<td>Module disconnected while in operation or have a communication problem.</td>
<td>To silence alarm and clear message from screen, press <strong>CONFIRM</strong> soft key. Reattach module, if needed, ensuring it is securely &quot;clicked&quot; into place at Module Release Latch. If alarm is still present, replace module.</td>
</tr>
<tr>
<td>Very Low Battery &lt;5 minutes to system shutdown</td>
<td>Battery has 5 minutes or less of power at current power consumption rate before operation stops.</td>
<td>Connect AC power cord to power source (alarm silenced).</td>
</tr>
</tbody>
</table>

## Errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audio System Error</td>
<td>Main speaker failure.</td>
<td>Visually check alarm status to determine whether or not an operational alarm also needs to be addressed (red Alarm Status Indicator lit). Replace PC Unit.</td>
</tr>
<tr>
<td>Channel Error</td>
<td>Error detected. Operation stops on affected module.</td>
<td>To silence alarm and continue operation of unaffected modules, press <strong>CONFIRM</strong> soft key. Replace module.</td>
</tr>
<tr>
<td>Defective Battery</td>
<td>Defective battery.</td>
<td>To continue temporary operation, press <strong>SILENCE</strong> key. Replace PC Unit.</td>
</tr>
<tr>
<td>Hardware Detected Error</td>
<td>Error detected on PC Unit. Operation stops on all modules.</td>
<td>Replace PC Unit.</td>
</tr>
<tr>
<td>Missing Battery</td>
<td>Battery not present or not connected.</td>
<td>To continue temporary operation, press <strong>SILENCE</strong> key. Replace PC Unit.</td>
</tr>
</tbody>
</table>
## Errors (Continued)

<table>
<thead>
<tr>
<th>Error</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Supply Error</td>
<td>Power supply system malfunction.</td>
<td>Disconnect AC power immediately. To continue operation under battery power, press SILENCE key. Replace PC Unit.</td>
</tr>
<tr>
<td>System Error</td>
<td>Error detected on PC Unit. Operation continues on all attached modules.</td>
<td>To continue temporary operation, press SILENCE key. Replace PC Unit.</td>
</tr>
</tbody>
</table>

## Messages

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Run Time = X.X hours</td>
<td>AC power cord is disconnected from power source. Approximate remaining battery run time under current power consumption rate is displayed.</td>
<td>Connect AC power cord to power source as soon as possible.</td>
</tr>
<tr>
<td>Low Battery</td>
<td>Low battery threshold sensed; remaining battery run time is limited.</td>
<td>Connect to power source (alarm silenced).</td>
</tr>
<tr>
<td>Panel Locked</td>
<td>Tamper Resist feature is active and key was pressed.</td>
<td>If appropriate, deactivate Tamper Resist feature using Tamper Resist Control on back of PC Unit.</td>
</tr>
<tr>
<td>Panel Unlocked</td>
<td>Tamper Resist feature deactivated.</td>
<td>None</td>
</tr>
<tr>
<td>Powering Down</td>
<td>Last module powering off. System shuts off in indicated number of seconds.</td>
<td>Press any key, except SYSTEM ON key, to cancel power down sequence.</td>
</tr>
<tr>
<td>Replace Battery</td>
<td>Occurs at System On. Battery has less than 50% of original capacity.</td>
<td>To continue normal operation with reduced battery capacity, press CONFIRM soft key. Replace PC Unit.</td>
</tr>
</tbody>
</table>
Plug the PC Unit into an AC outlet during storage to ensure a fully charged battery. The AC indicator light (_battery_icon_) 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 1-49.

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 a 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.

Proper Battery Maintenance

The battery should be replaced every 2 years by qualified service personnel.

The battery should be conditioned every 12 months by qualified service personnel. Refer to Alaris System Technical Service Manual for test and replacement procedures.

Battery Cautions and Disposal

CAUTION
Battery replacement should be performed by qualified service personnel while the instrument is not in use.

CAUTION
Do not open, incinerate, or short circuit the battery. Worn-out batteries must be disposed of properly, according to local regulations.
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

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**WARNING**

Failure to perform these inspections can result in improper instrument operation.

**CAUTION**

Preventive maintenance inspections should only be performed by qualified service personnel.
Alaris™ Pump Module, Model 8100
Alaris™ Syringe Module, Model 8110
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This section of the DFU 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 DFU
- Pump Module Set Compatibility Card
- Pump Module Technical Service Manual
- Syringe Module Set Compatibility Card
- Syringe Module Technical Service Manual
- System Maintenance software (and its instructions) for
  Alaris System check-in, maintenance, and wireless configuration

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.

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

Contraindications: None known.

Electromagnetic Environment: See "Appendix" section of this DFU ("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.

2. If a new set is being loaded, prime set (see "Prime" procedure).

3. Open 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.

WARNING

• 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.

• Administration Sets:
  ○ Use only 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 sets, refer to the Set Compatibility Card (provided separately).
  ○ Discard if packaging is not intact or protector caps are unattached.

CAUTION

• 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 fitment.

• When reloading an administration set, leave the safety clamp fitment in the closed position (see "General Information," "Safety Clamp Fitment").
c. Press safety clamp fitment into recess below mechanism. 


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.

6. Open roller clamp.

7. Verify that no fluid is flowing through drip chamber.

**NOTE:**

1. "Safety clamp" is referred to on a v9.0 PC Unit as "Flo-Stop."

---

**CAUTION**

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

---

**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.
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 blue ridged release tab on upper side of safety clamp device.
   b. Slide white slide clamp into blue fitment (open position).
   c. Adjust flow rate using set’s roller clamp.

   NOTE:
   ① "Safety clamp" is referred to on a v9.0 PC Unit as "Flo-Stop."

Prime

1. Prepare primary solution container in accordance with manufacturer’s directions for use

2. Open administration set package, remove set, and close roller clamp. (Refer to set’s directions for use.)

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 ⅔ full.
5. If container requires venting, open vent cap on administration set spike.

6. To prime tubing and clear air from injection sites and tubing fitments, slowly open roller clamp.

7. When priming is complete, close roller clamp.
To decrease start-up delays, delivery inaccuracies, and delayed generation of occlusion alarms when infusing at a rate less than 1.0 mL/h, the following actions are recommended:

- Use smallest syringe size possible (for example, if infusing 2.3 mL of fluid, use a 3 mL syringe).

**WARNING**

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.

**WARNING**

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

- Use compatible components which have the smallest internal volume or "deadspace." 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 (deadspace) 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

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 CHANNEL SELECT key.

WARNING

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.

CAUTION

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.

CAUTION

Minimize the height difference between the pump and the patient and avoid changes in the height of the Syringe module (for example, during the transport of critically ill patients), to prevent unintended fluctuations in the flow rate.
Prepare Syringe and Administration Set (Syringe Module) (Continued)

- 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.

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).

**WARNING**

Electronically prime the syringe pump system before starting an infusion or after replacing a near-empty syringe with a replacement syringe.

**WARNING**

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.

**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).
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 (see "General Information," "Compatible Syringes") in accordance with manufacturer's directions for use.

2. Prepare administration set (refer to Set Compatibility Card, provided separately) in accordance with manufacturer's directions for use.

3. Attach upper fitting of administration set to syringe tip.

**NOTE:**

① For a list of compatible syringes, see "Compatible Syringes."
   For a list of compatible administration sets, refer to the Set Compatibility Card (available separately).
Prepare Syringe and Administration Set (Syringe Module) (Continued)

Load

1. 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.

2. 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.

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

Load (Continued)

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

4. 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.
5. 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.

6. Lower drive head and lock plunger in place with plunger grippers.
   a. Twist gripper control clockwise and hold in position.
   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.

**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.

**CAUTION**
- To avoid an occlusion when loading a smaller 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).
7. Insert pressure sensing disc (if used), 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.

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

**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.
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: (See "General Information," "Features and Displays" for definitions.)
   - Auto Pressure
   - Back Off (upon occlusion)
   - Customizable Pressure Alarm Settings (see "Occlusion Pressure" feature definition)
   - Dynamic Pressure Display (see "Pressure Tracking" feature definition)
   - Fast Start

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.
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.

3. Press OPTIONS key.

4. Press Prime Set with Syringe soft key.

**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.
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 2 fingers.
7. Press and hold **PRIME** soft key.
8. Gently massage pressure sensing disc to ensure that all air is expelled. Disc must remain inverted only until 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 per continuous press. To deliver additional amounts, press PRIME soft key again.

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)

Administration Set With No Pressure Sensing Disc  (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.
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.

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. Disc must remain inverted only until 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).
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).
Programming

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 DFU 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.

Primary Infusion - With Guardrails™ Suite MX Protection

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 Editor Software and the Profiles feature must be enabled.

1. Perform following steps (see PC Unit section of this DFU, "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. Press CHANNEL SELECT key.

5. Syringe Module: Select syringe type and size, as follows; otherwise, proceed to step 6.

   a. 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 ALL SYRINGES soft key.

   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, see "General Information," "Compatible Syringes." If the installed syringe is displayed and selected, but is not recognized, servicing is required (see "Maintenance," "Service Information" in "Appendix" section of this DFU).
b. To accept, press CONFIRM soft key.

6. Start applicable infusion, as described in following procedures:
   - Continuous Infusion
   - Bolus Dose
   - Intermittent Infusion
   - IV Fluid Infusion

**NOTE:**

- 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.

**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.
• 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).

3. 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.
• 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).

4. Verify correct parameters and press NEXT soft key to confirm.
5. 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).

6. To enter volume to be infused, press VTBI soft key and use numeric data entry keys.

   • Pump Module:
     - When VTBI is less than 10 mL/h, 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.

   • BOLUS soft key appears only if Bolus Dose is enabled within selected profile, drug is bolusable, and a VTBI is entered.
Primary Infusion - With Guardrails Suite MX Protection  (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 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.

7. Verify correct parameters and press START soft key.
• If programmed continuous dose infusion is outside 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 programmed continuous dose infusion 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 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:

- 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 an open entry (_ _ / _ _ mL) and allow the clinician to enter the desired concentration.
2. Once a patient weight is entered, for any module, it is automatically entered for any subsequent weight-based calculation.

**Bolus Dose**

A bolus dose can be programmed at the beginning of, or during, an 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.

2. Press **BOLUS** soft key.

- If programmed continuous dose infusion is outside 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 programmed continuous dose infusion 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.
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 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.

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

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

  OR

• To change weight when continuous dose is weight-based:
  a. Press SETUP soft key.
  b. Press PATIENT WEIGHT soft key.
  c. To change patient weight, use numeric data entry keys.
d. Press NEXT soft key.
   If a continuous infusion is running, a prompt to confirm weight change appears.

e. Press BOLUS soft key.

f. To enter bolus dose, use numeric data entry keys.

5. Press DURATION soft key.

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.
   • If programmed bolus dose and/or bolus dose duration is outside 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 programmed bolus dose and/or bolus dose 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.
Primary Infusion - With Guardrails Suite MX Protection (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.

---

Press START to Continue Infusing Bolus Dose

PAUSE/STOP BOLUS

Infusing Bolus Dose

Pt. Weight: 70 kg

BOLUS VTBI = 6.3 mL

TOTAL DOSE = 6.3 mg

0.090 mg/kg

Alteplase

Stroke
3. To stop bolus and start continuous infusion, press Yes soft key.

4. To stop continuous infusion, press and hold CHANNEL OFF key until a beep is heard (approximately 1.5 seconds).®

### 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.

1. Bolus dose completed - module not turned off:
   a. Press CHANNEL SELECT key.
   b. Verify infusion parameters and press BOLUS 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, 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.
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.
   - OR
   - To change selection, press **No** soft key.
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, prompt for a patient weight in kilograms or BSA appears (as in illustrated example, which reflects use of Methotrexate).  

4. Verify correct parameters and press NEXT soft key to confirm.

- If programmed total dose drug amount is outside 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 programmed total dose drug amount 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.
5. VTBI entry:

- **Pump Module:**
  - When VTBI is less than 10 mL/h, entry can be to two decimal places (one-hundredth of a mL).
  - VTBI is prepopulated with diluent volume of infusion. To change 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, 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.
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 use numeric data entry keys.

7. Verify correct parameters and press START soft key.
   - If programmed duration is outside 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 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.

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 an open entry (___ / ___ mL) and allow the clinician to enter the desired concentration.
② Once a patient weight or BSA is entered, for any module, it is automatically entered for any subsequent weight-based calculation.
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.
2. 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.
3. Verify correct infusion parameter entry and press **START** soft key.\(^1\)
   - If programmed IV fluid is outside 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 programmed IV fluid 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.

4. **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**

1. Press **VOLUME DURATION** soft key.
Volume/Duration Infusion (Continued)

2. 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.
3. To enter volume duration, press DURATION soft key and use numeric data entry keys. Rate is automatically calculated.

4. Verify correct infusion parameter entry and press START soft key. If programmed IV Fluid is outside 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 programmed IV Fluid 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.

5. 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.
Primary Infusion - With Guardrails Suite MX Protection (Continued)

IV 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,
This mode is designed to support automatic secondary infusions ("piggybacking") in the same instrument. 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.

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.

**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 \( \frac{2}{3} \) full.


5. Attach secondary administration set to upper injection site on primary set.

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

**WARNING**

Secondary applications require the use of a **check valve set** on the primary IV 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.
Secondary Infusion - With Guardrails Suite MX Protection
(Pump Module) (Continued)

Setup (Continued)

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.
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.  
   OR
   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 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 or BSA appear (as in illustrated example, which reflects use of Methotrexate).

5. Verify correct parameters and press NEXT soft key to confirm.

   • If programmed total dose drug amount is outside 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 programmed total dose drug amount 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 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.
Secondary Infusion - With Guardrails Suite MX Protection
(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 prepopulated with diluent volume of infusion.
     To change VTBI, press VTBI soft key and use numeric
data entry keys.

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.

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.
8. Open clamp on secondary administration set.

   - If programmed duration is outside 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 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.

**NOTES:**
1. The facility can choose to prepopulate standard drug concentrations, or leave an open entry (_ _ / _ _ mL) and allow the clinician to enter the desired concentration.
2. Once a patient weight or BSA is entered, for any module, it is automatically entered for any subsequent weight-based calculation.

**Stop Secondary and Return to Primary**

1. Press CHANNEL SELECT key.
2. Press SETUP soft key.
3. Press PRIMARY soft key.

   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.
   
   • 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.

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### Infusion - 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.

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

1. Perform following steps (see PC Unit section of this DFU, "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
   - Continuous Infusion - Drug Calculation
   - Bolus Dose

---

**Basic Infusion**

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
Infusion - 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").

Continuous Infusion - 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.
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.¹
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.

   - **Pump Module**:
     - When VTBI is less than 10 mL/h, 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.
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.

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.
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.

   - 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.
Infusion - NO Guardrails Suite MX Protection (Continued)

Bolus Dose (Continued)

Stop and Restore Bolus Dose

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

Secondary Infusion - NO Guardrails Suite MX Protection (Pump Module)


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

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

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.
Secondary Infusion - NO Guardrails Suite MX Protection  
(Pump Module)  (Continued)

Infusion  (Continued)

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.
   Secondary setup screen is displayed.
5. To resume secondary infusion, press START soft key.

Stop Secondary and Return to Primary

See "Secondary Infusion - With Guardrails Suite MX Protection."

Pause, Change, Restart Infusion

Pause and Restart Infusion

1. Press PAUSE key.¹ ² 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.
2. To reinitiate infusion:
   Press **RESTART** key.

   OR

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

**NOTES:**

1. To stop a Bolus Dose, see the "Bolus Dose" procedure.
2. The Pump Module keypad is used in the illustrations but the keys are the same for the Syringe Module.
3. An infusion can also be paused by pressing the **PAUSE** soft key (on PC Unit), however, if an Alert has occurred, the system will not initiate the pause until the Alert has been addressed. To pause an infusion programmed with Delay Options, see "Delay Options," "Pause Infusion."

### Change Rate or VTBI During Infusion

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

### Restore Infusion

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

**NOTE:**

1. To restore a Bolus Dose, see the "Bolus Dose" procedure.
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.

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.
To return to main screen, press MAIN SCREEN soft key.

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.

4. Press Channel Labels soft key.
Channel Labels  (Continued)

Select  (Continued)

5. Press soft key for desired label. \(^\ddagger\)
   • Selected label is highlighted and scrolls in Message Display.

6. To continue infusion, press \textit{START} soft key.
   OR
   Program infusion as previously described.

\textbf{NOTE:}
\(^\ddagger\) To view additional labels, press a soft key next to a letter group to navigate through the alphabet, and/or \textit{PAGE UP} and \textit{PAGE DOWN} soft keys.

Remove

1. Press \textit{CHANNEL SELECT} key.
2. Press \textit{OPTIONS} key.
4. Press \textit{Channel Labels} soft key.
5. Press CLEAR LABEL soft key.
   Label stops scrolling in Message Display.

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

**Anesthesia Mode**

See the PC Unit section of this DFU.

**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.
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.
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.
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 DFU.)

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:
If the current time has been previously confirmed, the TIME OF DAY screen does not display.
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 (None), 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.
• 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.
   • If an alert has occurred, pause is **not** initiated by system until alert is addressed.
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
② The Multidose feature is to be used only by personnel properly trained in using multidose infusions.
③ Caution labels, which clearly differentiate single dose and multidose containers, must be utilized.
④ Single dose piggybacking systems employing check valve sets are not designed for use with multidose containers.
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 PC Unit section of this DFU.)

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.

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.

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.

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.
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.

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.
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.
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.
5. To select occlusion pressure limit, press either **Up** or **Down** soft key.

6. Verify correct occlusion pressure limit input and press **CONFIRM** soft key.

7. Press **START** soft key.

---

**Syringe Module**

**Pressure Sensing Disc Installed**

1. Ensure that pressure sensing disc is installed correctly.

2. Press **CHANNEL SELECT** key.

3. Press **OPTIONS** key.

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**WARNING**

Installing a pressure sensing disc after an infusion has started can result in a bolus to the patient.
4. Press **Pressure Limit** soft key.

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

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

**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.).

NOTE:

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.

2. 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.

3. 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, 10 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.

4. 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 to create a new alarm limit
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.
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.).
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 causes the motor to reverse the plunger movement during an occlusion until the pressure returns to preocclusion levels, which automatically reduces 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.
General Setup and Operation

System Start-Up/Setup

See the PC Unit section of this DFU, "General Setup and Operation," 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.
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 prompt sounds—to silence, press **SILENCE** key.
   - Red Alarm Status Indicator flashes.
   - **CHECK SYRINGE** scrolls in Message Display.

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").

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.
• Ensure syringe sizes and models are compatible with 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.

• 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.
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).
• 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**

- 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**

• **Use only 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 Set Compatibility Card (provided separately).

• Use only standard, single-use, approved, 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, see "Compatible Syringes."

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

\(^1\) For a list of compatible syringes, see "Compatible Syringes." For a list of compatible administration sets, refer to the Set Compatibility Card (available separately).
Before operating the instrument, verify that the administration set is **free from kinks and correctly installed**.

### Occlusion

**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.).
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.
• 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 a 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**

- 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 DFU provided with set.
  - For a list of compatible administration sets, refer to Set Compatibility Card (provided separately).
  - 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.
The Pump Module uses a wide variety of 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 (referred to on v9.0 PC Unit as Flo-Stop) is a unique clamping device on the pumping segment that is part of all 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, see "Compatible Syringes."

### Administration Set/Syringe Information (Continued)

#### 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).

2. Prime valve port. If applicable, attach syringe to Needle-Free Valve port and aspirate miniscule air bubbles.

3. Replace every 72 hours or after 100 activations, whichever occurs first. For infusions of blood, blood products or lipid emulsions, replace every 24 hours.

**NOTE:**

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

**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.
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 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 not occluded but 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 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 occluded.

NOTE:

1. “Safety clamp” is referred to on a v9.0 PC Unit as “Flo-Stop.”
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.

Compatible syringe availability and model numbers vary from country to country. See supplemental tip sheet for country-specific syringe model numbers supported.

### Compatible Syringes (Syringe Module)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>1 mL</th>
<th>3 mL</th>
<th>5 mL</th>
<th>6 mL</th>
<th>10 mL</th>
<th>12 mL</th>
<th>20 mL</th>
<th>30 mL</th>
<th>35 mL</th>
<th>50 mL</th>
<th>60 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Plastipak</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>IVAC</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monoject</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terumo</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTES:**

1. The Monoject SoftPack Luer-Lock Syringe (blister pack) is the only currently supported Monoject 3 mL.

**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.
# Features and Displays

## Features and Definitions

See the PC Unit section of this DFU for system features and definitions.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition—Pump and Syringe Modules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anesthesia Mode</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Bolus Dose</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Callback</strong></td>
<td>A callback for a programmed delay (see &quot;Delay Options&quot; definition) can be scheduled to give an alert <strong>Before</strong> an infusion is to be initiated, <strong>After</strong> an infusion is completed, <strong>Before and After</strong> an infusion, or no alert (<strong>None</strong>).</td>
</tr>
<tr>
<td><strong>Channel Labels</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Concentration Limits</strong></td>
<td>Limits specified for range of concentrations allowed for a particular drug in a profile.</td>
</tr>
<tr>
<td><strong>Delay Options</strong></td>
<td>Allows system to be programmed to delay start of an infusion <strong>a)</strong> for up to 120 minutes or <strong>b)</strong> for a specific time up to 23 hours 59 minutes.</td>
</tr>
</tbody>
</table>
| **Dose Checking**   | 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.  
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. |
| **Drug Calculation**| Allows:  
• entry of drug dose for a continuous infusion (Alaris System calculates correct flow rate to achieve desired dose),  
**OR**  
• entry of flow rate for a continuous infusion (Alaris System calculates corresponding drug dose).                                                                                   |
<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition—Pump and Syringe Modules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Library</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Duration Limits</strong></td>
<td>Hospital-established limits around duration of infusion.</td>
</tr>
<tr>
<td><strong>Dynamic Pressure Display</strong></td>
<td>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 &quot;Displays&quot; for additional &quot;Dynamic Pressure Display&quot; information.)</td>
</tr>
<tr>
<td><strong>Event Logging</strong></td>
<td>Event Logging records instrument operations.</td>
</tr>
<tr>
<td><strong>Initial Value</strong></td>
<td>An optional and editable starting value for continuous infusion dose, duration, bolus dose, bolus rate of administration or bolus dose duration.</td>
</tr>
<tr>
<td><strong>IV Fluid Library</strong></td>
<td>An optional library consisting of IV Fluids (for example, TPN) and limits around rate of delivery.</td>
</tr>
</tbody>
</table>
| **Limit**            | 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.  
  • 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 Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition—Pump and Syringe Modules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapies</td>
<td>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.</td>
</tr>
<tr>
<td>Total DoseLimits</td>
<td>Hospital-established Limits around total dose of infusion.</td>
</tr>
<tr>
<td>Volume/Duration</td>
<td>Allows a volume-to-be-infused (VTBI) and duration (infusion time) to be programmed. Flow rate is automatically calculated.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition—Pump Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-Restart</td>
<td>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 &quot;Checking Line&quot; period. If this feature is enabled, &quot;Checking Line&quot; function occurs when downstream pressure exceeds pressure limit.</td>
</tr>
<tr>
<td></td>
<td>• In Selectable Pressure Mode: Pressure limit is either user-adjustable or &quot;locked&quot; in system configuration.</td>
</tr>
<tr>
<td></td>
<td>• In Pump Pressure Mode: Pressure limit is a function of flow rate and is automatically determined by device.</td>
</tr>
<tr>
<td></td>
<td>If downstream pressure decreases to a predetermined level, (below 50% of pressure limit) during 15-second &quot;Checking Line&quot; period, infusion automatically continues. If condition is not cleared within 15 seconds, a &quot;Partial Occlusion - Patient Side&quot; alarm occurs.</td>
</tr>
<tr>
<td></td>
<td>Using Editor software, 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 &quot;Occluded - Patient Side&quot; alarm occurs when system detects downstream pressure that exceeds pressure limit.</td>
</tr>
<tr>
<td>Default Occlusion</td>
<td>Starting occlusion pressure limit which can be configured by profile in 25 mmHg increments.</td>
</tr>
</tbody>
</table>
Features and Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition—Pump Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free Flow Protection</td>
<td>All Pump Module/Gemini Infusion System administration sets utilize a unique clamping device (safety clamp on pumping mechanism) to prevent inadvertent free-flow when administration set is removed from instrument.</td>
</tr>
</tbody>
</table>
|                         | **NOTE:**  
|                         | ⚫ "Safety clamp" is referred to on a v9.0 PC Unit as "Flo-Stop."                                                                                                                                                    |
| 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      | A complete range of downstream occlusion detection options is provided.  
|                         | ⚫ **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, up to maximum occlusion pressure of 525 mmHg.  
|                         | ⚫ **Auto-Restart:** (See "Auto-Restart" definition.)  
|                         | In addition, Alaris System provides fluid-side occlusion detection.                                                                                                                                                    |
| 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 Pump Module/Gemini Infusion System check valve administration set is used. |
## Features and Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition—Syringe Module</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Mode</strong></td>
<td>When <strong>ALL</strong> is selected as volume to be infused (VTBI), entire contents of syringe is delivered.</td>
</tr>
</tbody>
</table>
| **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:  
• 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. |
| **Near End of Infusion (NEOI)** | Allows an alert to be configured to sound anywhere from 1 to 60 minutes before infusion is complete. Alert occurs at configured time or when 25% of VTBI remains, whichever comes later. |
| **Occlusion Pressure**         | A complete range of downstream occlusion detection options is provided.  
• 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. |
### Features and Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition—Syringe Module</th>
</tr>
</thead>
</table>
| **Pressure Sensing Disc** | When installed, pressure sensing disc significantly improves instrument’s pressure sensing capabilities for a faster occlusion detection time, and makes following features available:  
  - Auto Pressure  
  - Back-Off  
  - Customizable Pressure Alarm Settings (see "Occlusion Pressure")  
  - Fast Start  
  - Pressure Tracking |
| **Pressure Tracking**     | Dynamic current pressure display is only available when pressure sensing disc is inserted.                                                                  |
| **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. |
| **Selectable KVO**       | Allows some infusions to automatically switch into KVO mode upon completion. KVO option setting cannot be changed after instrument is powered on and a profile selected. |
| **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.                                                                               |
Operating Features, Controls, Indicators

- **Channel Select Key:** When pressed, selects corresponding module for infusion parameter entry and infusion setup.
- **Pause Key:** When pressed during an infusion, temporarily stops infusion on that module. After approximately 2 minutes, a visual and audio prompt begins.
- **Channel Off Key:** When pressed and held until a beep is heard, stops infusion on that module, deselects that module, and if only that module had been operating, system powers down. Repeat for other operating modules to power off each module.
- **Restart Key:** When pressed, resumes operation of a previously paused or alarmed infusion on that module.

**Status Indicators**
- Alarm (red)
- Infusing (green)
- Standby (yellow)

**IUI Connector, Left**
- Module Release Latch: When pressed, allows module to be removed.

**IUI Connector, Right**
- Door Handle

**Rate Display**

**Channel (module) Message Display**

**Channel (module) Identification**

**Channel (module) Select Key**
- When pressed, selects corresponding module for infusion parameter entry and infusion setup.
NOTE:

○ "Safety clamp" is referred to on a v9.0 PC Unit as "Flo-Stop."
Features and Displays (Continued)

Channel (module) Identification

Channel (module) Select Key:
When pressed, selects corresponding module for infusion parameter entry and infusion setup.

Pause Key: When pressed during an infusion, temporarily stops infusion on that module. After approximately 2 minutes, a visual and audio prompt begins.

Channel (module) Off Key: When pressed and held until a beep is heard, stops infusion on that module, deselects that module, and if only that module had been operating, system powers down. Repeat for other operating modules to power off each module.

Restart Key: When pressed, resumes operation of a previously paused or alarmed infusion on that module.

Status Indicators

Alarm
Infusing
Standby
(red)
(green)
(yellow)

IUI Connector, Left

Rate Display

Message Display

Channel (module) Identification

Gripper Control/Drive Head Release (shown in closed position)

Plunger Grippers (shown in closed position)

Barrel Flange Grippers

Syringe Barrel Sensor

IUI Connector, Right

Syringe Barrel Clamp/Sizer

Gripper Control/Drive Head Release (shown in closed position)

Pressure Transducer/Pressure Sensing Disc Housing

Module Release Latch: When pressed, allows module to be removed.
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 DFU.

**Dynamic Pressure Display**

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.
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.
• 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.

Convertible Settings

See the PC Unit section of this DFU 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.

### Shared Infusion

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delay Options</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• Callback</td>
<td>None</td>
<td>None, Before, After, Before and After</td>
</tr>
<tr>
<td>Drug Calculation</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• Bolus Dose</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Multidose</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• Callback</td>
<td>None</td>
<td>None, Before, After, Before and After</td>
</tr>
<tr>
<td>Pressure Dynamic</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>(Dynamic Pressure Display)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume/Duration</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
</tbody>
</table>
### Configurable Settings (Continued)

#### Pump Module

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accumulated Air</td>
<td>Enabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Air-in-Line Settings (single bolus)</td>
<td>75 mcL</td>
<td>50, 75, or 250 mcL Anesthesia Mode only: 500 mcL</td>
</tr>
<tr>
<td>Auto-Restart Attempts</td>
<td>0</td>
<td>0 - 9 attempts Anesthesia Mode only: 9 attempts</td>
</tr>
<tr>
<td>KVO (Keep Vein Open)</td>
<td>1 mL/h</td>
<td>0.1 - 20 mL/h</td>
</tr>
<tr>
<td>Max Rate</td>
<td>999 mL/h</td>
<td>0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments</td>
</tr>
<tr>
<td>Max VTBI</td>
<td>9999 mL/h</td>
<td>0.1 - 9999 mL</td>
</tr>
<tr>
<td>Pressure Mode</td>
<td>Pump</td>
<td>Pump, Selectable</td>
</tr>
<tr>
<td>• Mode Selection</td>
<td>Unlocked</td>
<td>Locked, Unlocked</td>
</tr>
<tr>
<td>• Lock Status</td>
<td>525 mmHg</td>
<td>50 - 525 mmHg in 25 mmHg increments (adjustable only in Selectable Pressure Mode)</td>
</tr>
<tr>
<td>• Default Starting Occlusion Pressure</td>
<td>525 mmHg</td>
<td>50 - 525 mmHg in 25 mmHg increments (configured by profile and adjustable only in Selectable Pressure Mode)</td>
</tr>
<tr>
<td>SEC to PRI Alert</td>
<td>Enabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Secondary (Dual Rate Sequential Piggybacking)</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
</tbody>
</table>
### Syringe Module

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL Mode</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Auto Pressure</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Back Off (after occlusion)</td>
<td>Enabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Fast Start</td>
<td>Enabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>KVO (Keep Vein Open)</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• Rate Adjust</td>
<td>1 mL/h</td>
<td>0.01 - 2.5 mL/h (0.01 - 0.09 mL/h available for 1 mL and 3 mL syringes)</td>
</tr>
<tr>
<td>• Volume Adjust</td>
<td>5%</td>
<td>0.5 - 5%</td>
</tr>
<tr>
<td>Max Rate</td>
<td>999 mL/h</td>
<td>0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments</td>
</tr>
<tr>
<td>Near End (NEOI)</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• Alert Time</td>
<td>60</td>
<td>1 - 60 minutes or 25% of remaining infusion time, whichever comes later</td>
</tr>
<tr>
<td>Occlusion Pressure Set Point</td>
<td>1000 mmHg High</td>
<td>25 - 1000 mmHg in 1 mmHg increments Low, Medium, High</td>
</tr>
<tr>
<td>Priming</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
</tbody>
</table>
Specifications

Pump Module

Accumulated Air Window:

<table>
<thead>
<tr>
<th>Single Bolus Setting (mcL)</th>
<th>Volume Window (mL)</th>
<th>% Air that Causes Alarm</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>2.8</td>
<td>10%</td>
</tr>
<tr>
<td>75</td>
<td>8.0</td>
<td>20%</td>
</tr>
<tr>
<td>250</td>
<td>8.0</td>
<td>30%</td>
</tr>
<tr>
<td>500*</td>
<td>12.0</td>
<td>30%</td>
</tr>
</tbody>
</table>

* In Anesthesia Mode only.

Bolus Volume, Maximum after Occlusion:

<table>
<thead>
<tr>
<th>Pressure Limit (mmHg)</th>
<th>Rate (mL/h)</th>
<th>Bolus Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>25</td>
<td>≤0.3</td>
</tr>
<tr>
<td>525</td>
<td>25</td>
<td>≤0.6</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th></th>
<th>Operating</th>
<th>Storage/Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atmospheric Pressure</td>
<td>525 - 4560 mmHg (700 - 6080 hPa)</td>
<td>375 - 760 mmHg (500 - 1013 hPa)</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>20 - 90% Noncondensing</td>
<td>5 - 85% Noncondensing</td>
</tr>
<tr>
<td>Temperature Range</td>
<td>41 - 104°F (5 - 40°C)</td>
<td>-4 - 140°F (-20 - 60°C)</td>
</tr>
</tbody>
</table>

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

Flow Rate Programming Increments:

<table>
<thead>
<tr>
<th>Rate Range (mL/h)</th>
<th>Increments (mL/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>User Input Rates</td>
</tr>
<tr>
<td>0.1 - 9.99</td>
<td>0.1</td>
</tr>
<tr>
<td>10 - 99.9</td>
<td>0.1</td>
</tr>
<tr>
<td>100 - 999</td>
<td>1</td>
</tr>
</tbody>
</table>

Fluid Ingress Protection: IPX1, Drip Proof
### Specifications (Continued)

#### Pump Module (Continued)

<table>
<thead>
<tr>
<th><strong>Infusion of Air, Means to Protect Patient from:</strong></th>
<th>Ultrasonic Air-in-Line Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum single bolus size = selectable 50, 75, or 250 microliters nominal (500 microliters in Anesthesia Mode)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Infusion Pressure, Maximum:</strong></th>
<th>654 mmHg (Maximum Occlusion Alarm Threshold plus tolerance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>KVO (Keep Vein Open) Rate:</td>
<td>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.</td>
</tr>
<tr>
<td>KVO Selection Range:</td>
<td>KVO rate can be set in System Configuration from 0.1 - 20 mL/h in 0.1 mL/h increments.</td>
</tr>
<tr>
<td>Occlusion Alarm Thresholds:</td>
<td>Pump Mode: 525 mmHg at rates ≥30 mL/h Varying level based on rate and patient back–pressure at rates &lt;30 mL/h. Selectable Mode: User selected, 50 - 525 mmHg in 25 mmHg increments.</td>
</tr>
<tr>
<td>Operating Principle:</td>
<td>Positive displacement</td>
</tr>
<tr>
<td>Rate Accuracy:</td>
<td>Rate accuracy of Alaris System is ±5% at rates between 1 and 999 mL/h and ±5.5% at rates &lt;1 mL/h, 95% of the time with 95% confidence, under conditions listed below.</td>
</tr>
<tr>
<td>Infusion Rate Range:</td>
<td>0.1 - 999 mL/h</td>
</tr>
<tr>
<td>Ambient Temperature:</td>
<td>68 ±4°F (20 ±2°C)</td>
</tr>
<tr>
<td>Source Container Height:</td>
<td>20 inches above top of Pump Module</td>
</tr>
<tr>
<td>Test Solution:</td>
<td>Distilled Water</td>
</tr>
<tr>
<td>Distal Back pressure:</td>
<td>0 mmHg (0 kPa)</td>
</tr>
<tr>
<td>Needle:</td>
<td>18 gauge</td>
</tr>
<tr>
<td>Administration Set Model:</td>
<td>2210</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th><strong>Shock Protection:</strong></th>
<th>Type CF, Defibrillator Proof</th>
</tr>
</thead>
</table>
Specifications (Continued)

**Pump Module (Continued)**

Time to Alarm, Maximum:

<table>
<thead>
<tr>
<th>Pressure Limit (mmHg)</th>
<th>Rate (mL/h)</th>
<th>Time to Alarm</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>1</td>
<td>≤5 minutes</td>
</tr>
<tr>
<td>50</td>
<td>25</td>
<td>≤15 seconds</td>
</tr>
<tr>
<td>525</td>
<td>1</td>
<td>≤45 minutes</td>
</tr>
<tr>
<td>525</td>
<td>25</td>
<td>≤2 minutes</td>
</tr>
</tbody>
</table>

Volume to be Infused Programming Increments:

<table>
<thead>
<tr>
<th>Range (mL)</th>
<th>Increments (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 - 9.99</td>
<td>0.01</td>
</tr>
<tr>
<td>10 - 999.9</td>
<td>0.1</td>
</tr>
<tr>
<td>1000 - 9999</td>
<td>1</td>
</tr>
</tbody>
</table>

Weight: 2.6 lbs

**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:

<table>
<thead>
<tr>
<th>Pressure Setting</th>
<th>Bolus Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>0.512</td>
</tr>
<tr>
<td>Medium</td>
<td>0.776</td>
</tr>
<tr>
<td>High</td>
<td>1.103</td>
</tr>
</tbody>
</table>

With Pressure Sensing Disc:

<table>
<thead>
<tr>
<th>Pressure Setting</th>
<th>Back Off Disabled</th>
<th>Back Off Enabled</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mmHg</td>
<td>0.462</td>
<td>0.126</td>
</tr>
<tr>
<td>500 mmHg</td>
<td>0.575</td>
<td>0.331</td>
</tr>
<tr>
<td>1000 mmHg</td>
<td>0.839</td>
<td>0.323</td>
</tr>
</tbody>
</table>

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

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

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:

<table>
<thead>
<tr>
<th>Flow Rates (mL)</th>
<th>Selectable Increments (mL/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01 - 9.99</td>
<td>0.01</td>
</tr>
<tr>
<td>10 - 99.9</td>
<td>0.1</td>
</tr>
<tr>
<td>100 - 999</td>
<td>1</td>
</tr>
</tbody>
</table>

**Rate Restriction by Syringe Size:**

<table>
<thead>
<tr>
<th>Syringe Size (mL)</th>
<th>Flow Rate Range (mL/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50/60</td>
<td>0.1 - 999</td>
</tr>
<tr>
<td>30</td>
<td>0.1 - 650</td>
</tr>
<tr>
<td>20</td>
<td>0.1 - 500</td>
</tr>
<tr>
<td>10</td>
<td>0.1 - 250</td>
</tr>
<tr>
<td>5</td>
<td>0.1 - 150</td>
</tr>
<tr>
<td>3</td>
<td>0.01 - 100</td>
</tr>
<tr>
<td>1</td>
<td>0.01 - 30</td>
</tr>
</tbody>
</table>

**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 Selection 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: ±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:

<table>
<thead>
<tr>
<th>Rate (mL/h)</th>
<th>No Disc High Setting</th>
<th>With Disc Highest (1000 mmHg) Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>120 minutes</td>
<td>105 minutes</td>
</tr>
<tr>
<td>5</td>
<td>30 minutes</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

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 ±4°F

Volume to be Infused

<table>
<thead>
<tr>
<th>Range (mL)</th>
<th>Increments (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01 - 9.99</td>
<td>0.01</td>
</tr>
<tr>
<td>10 - 60</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Weight: 4.5 lbs
## Symbols

See the PC Unit section of this DFU for system symbols.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning—Pump and Syringe Modules</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Heart]</td>
<td>Type CF defibrillation-proof equipment.</td>
</tr>
<tr>
<td>![Micron Filter]</td>
<td>Product contains micron filter, where XX represents filter size.</td>
</tr>
<tr>
<td>![DEHP]</td>
<td>DEHP in fluid pathway.</td>
</tr>
<tr>
<td>![Non-DEHP]</td>
<td>Non-DEHP plasticizer in fluid pathway.</td>
</tr>
<tr>
<td>![DEHP-Free]</td>
<td>No DEHP in fluid pathway.</td>
</tr>
<tr>
<td>![Latex-Free]</td>
<td>Product is latex-free.</td>
</tr>
<tr>
<td>![Needle-Free]</td>
<td>Product incorporates Needle-Free Valve ports and should not be accessed by a needle.</td>
</tr>
<tr>
<td>![Priming Volume]</td>
<td>Approximate administration set priming volume.</td>
</tr>
<tr>
<td>![Expiration Date]</td>
<td>Expiration date for product is identified near hour glass symbol.</td>
</tr>
<tr>
<td>![Do Not Use]</td>
<td>Do not use if package is damaged.</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

### Pump Module

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning—Pump Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Drops per Milliliter]</td>
<td>Drops per milliliter specification for product is identified on drop symbol.</td>
</tr>
</tbody>
</table>
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.

**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.
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 ±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

Start-Up at 25 mL/h (initial)

Start-Up at 999 mL/h (initial)

Trumpet Curve at 25 mL/h (initial)

Trumpet Curve at 999 mL/h (initial)

Trumpet Curve at 25 mL/h (96 hrs)

Trumpet Curve at 999 mL/h (24 hrs)

Legend:
- Maximum rate error
- Overall rate error
- Minimum rate error
Trumpet and Start-Up Curves (Continued)

Graphs (Continued)

Syringe Module

Start-Up Curve at 1 mL/h (initial) 1 g/mL

Start-Up Curve at 5 mL/h (initial) 1 g/mL

Trumpet Curve at 1 mL/h (initial)

Trumpet Curve at 5 mL/h (initial)

Legend:
- Maximum rate error
- Overall rate error
- Minimum rate error

Alaris System DFU – up to v9.12 Model 8015
Pump and Syringe Modules Section
General Information 2-127
Troubleshooting and Maintenance

General

Troubleshooting and maintenance are intended to be performed only by qualified personnel, using the Pump Module and Syringe Module Technical Service Manuals, and the System Maintenance software. The Service Manuals and System Maintenance software are available from CareFusion. The Service Manuals include 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 flow rate. 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.

Alarms, Errors, Messages

See the PC Unit section of this DFU for the following system references:

Alarms, Errors, Messages
Audio Characteristics
Definitions
Display Color
Radio Frequency Note
Alarms, Errors, Messages (Continued)

Definitions

Alert
A visual message to help reduce programming errors by indicating a Limit (Soft or Hard) has been exceeded. A response is required before programming can continue.

Clinical Advisory
A visual message when a designated drug is selected to remind 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.

Audio Characteristics

<table>
<thead>
<tr>
<th>Type</th>
<th>Sound</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switchover</td>
<td>Six short beeps: secondary switching to primary. Two short beeps: bolus switching to continuous.</td>
<td>Variable volume; can be silenced and disabled in System Configuration.</td>
</tr>
</tbody>
</table>

Alarms

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Channel Disconnected</td>
<td>Module disconnected while in operation or have a communication problem.</td>
<td>To silence alarm and clear message from screen, press CONFIRM soft key. Reattach module if desired, ensuring it is securely “clicked” into place at Module Release Latch. If alarm is still present, replace module.</td>
</tr>
</tbody>
</table>
### Alarms (Continued)

#### Pump Module

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accumulated Air-in-Line</td>
<td>A large number of air bubbles smaller than current air-in-line limit has recently passed detector.</td>
<td>Clear air from line. To continue infusion, press <strong>RESET</strong> soft key and then <strong>RESTART</strong> key.</td>
</tr>
<tr>
<td>Air-in-Line</td>
<td>Air has been detected in administration set during an infusion. Infusion stops on affected module.</td>
<td>Ensure that tubing is properly installed in Air-in-Line Detector. If air is present, clear air from administration set. Press <strong>RESTART</strong> key, or press <strong>CHANNEL SELECT</strong> key and then <strong>START</strong> soft key.</td>
</tr>
<tr>
<td>Check IV Set</td>
<td>Administration set is not properly installed. Infusion stops on affected module.</td>
<td>Close roller clamp, remove and reinstall administration set, close door, open roller clamp, and then press <strong>RESTART</strong> key.</td>
</tr>
<tr>
<td>Close Door</td>
<td>Door opened during an infusion. Infusion stops on affected module.</td>
<td>Close door. Press <strong>RESTART</strong> key, or press <strong>CHANNEL SELECT</strong> key and then <strong>START</strong> soft key.</td>
</tr>
<tr>
<td>Flo-Stop Open - Close Door</td>
<td>Safety clamp device is in open position while door is open.</td>
<td>Close roller clamp on administration set or close door.</td>
</tr>
<tr>
<td>Occluded - Fluid Side/Empty Container</td>
<td>Indicates either upstream occlusion or empty container. Infusion stops on affected module.</td>
<td>Clear occlusion on fluid side of instrument. If necessary, refill drip chamber. Press <strong>RESTART</strong> key, or press <strong>CHANNEL SELECT</strong> key and then <strong>START</strong> soft key.</td>
</tr>
<tr>
<td>Occluded - Patient Side</td>
<td>Increased back pressure sensed while infusing in pump delivery mode. Infusion stops on affected module.</td>
<td>Clear occlusion. Press <strong>RESTART</strong> key, or press <strong>CHANNEL SELECT</strong> key and then <strong>START</strong> soft key.</td>
</tr>
<tr>
<td>Partial Occlusion - Patient Side</td>
<td>Partial occlusion of patient side of IV line detected by Auto-Restart feature.</td>
<td>Clear occlusion. Press <strong>RESTART</strong> key, or press <strong>CHANNEL SELECT</strong> key and then <strong>START</strong> soft key.</td>
</tr>
</tbody>
</table>
### Alarms, Errors, Messages (Continued)

#### Alarms (Continued)

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<tr>
<th>Pump Module</th>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
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</thead>
</table>
2. Remove tubing.  
3. Massage tubing from top to bottom to restore flow.  
4. Reload set and close door.  
5. Press NEXT soft key.  
6. Press CONFIRM soft key.  
7. Open roller clamp and press NEXT key.  
8. Verify flow in drip chamber after restarting infusion.  
9. Change set if not able to establish flow. |
| Restart Channel | Door opened and closed during an infusion. Infusion stops on affected module. Module paused for 2 minutes. | Close door. Press Restart key, or press CHANNEL SELECT key and then START soft key.  
Press RESTART key, or press CHANNEL SELECT key and then START soft key. |
| Safety Clamp Open - Close Door (v9.1 and later PC Unit only) | Safety clamp device is in open position while door is open. | Close roller clamp on administration set or close door |

<table>
<thead>
<tr>
<th>Syringe Module</th>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occlusion</td>
<td>Increased back pressure sensed while infusing. Infusion stops on affected module.</td>
<td>Clear occlusion. Press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
<td></td>
</tr>
<tr>
<td>Pressure Disc Installed</td>
<td>Pressure sensing disc installed during an infusion. Infusion stops on affected module.</td>
<td>Press CONFIRM soft key and RESTART key.</td>
<td></td>
</tr>
</tbody>
</table>
## Syringe Module

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure Disc Removed</td>
<td>Pressure sensing disc removed. Infusion stops on affected module.</td>
<td>Reinsert pressure sensing disc and press <strong>RESTART</strong> key.</td>
</tr>
<tr>
<td>Syringe Empty</td>
<td>Syringe is empty. If syringe is not empty, other possibilities are:</td>
<td>Set up new infusion or press <strong>CHANNEL OFF</strong> key.</td>
</tr>
<tr>
<td></td>
<td>• Pressure sensing disc inappropriate/defective.</td>
<td>Verify that appropriate pressure sensing disc is in use and functioning properly.</td>
</tr>
<tr>
<td></td>
<td>• Syringe plunger travel impeded.</td>
<td>Verify that syringe plunger movement is unimpeded.</td>
</tr>
<tr>
<td></td>
<td>• Pressure transducer defective.</td>
<td>If syringe is not empty and above actions do not correct alarm, replace module.</td>
</tr>
</tbody>
</table>

### Syringe Adjustment Alarms

When a syringe installation problem is detected, a visual signal is displayed. Text in the display blinks to indicate the location of the problem.

---

Press or Adjust Syringe

**CANCEL**

**CONFIRM**

Syringe Installation

 lever

 flange

 clamp

> Press **CANCEL** or Adjust Syringe
## Alarms, Errors, Messages (Continued)

### Alarms (Continued)

**Syringe Adjustment Alarms (Continued)**

When problem is corrected, press **CONFIRM** soft key.

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check Syringe</td>
<td>Plunger grippers opened during infusion and then closed. Infusion stops on affected module. Syringe barrel clamp opened during infusion and then closed. Infusion stops on affected module. Syringe plunger not captured while in idle state. System alarms after 30 seconds to indicate potential siphoning condition.</td>
<td>Securely lock plunger grippers, press <strong>CHANNEL SELECT</strong> key, and reselect syringe. Securely lock syringe barrel clamp and press <strong>RESTART</strong> key. Check for potential siphoning. Ensure that administration set clamp (roller/slide) is in closed position. Securely lock plunger grippers over syringe plunger.</td>
</tr>
<tr>
<td>Drive Not Engaged</td>
<td>Drive system disengaged during operation.</td>
<td>Open and close plunger grippers and syringe barrel clamp. Ensure that syringe is properly installed.</td>
</tr>
</tbody>
</table>
### Errors

**Pump Module and Syringe Modules**

<table>
<thead>
<tr>
<th>Error</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Channel Error</td>
<td>Error detected. Operation stops on affected module.</td>
<td>To silence alarm and continue operation of unaffected module(s), press CONFIRM soft key. Replace module, as needed.</td>
</tr>
</tbody>
</table>

**Syringe Module**

<table>
<thead>
<tr>
<th>Error</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe Calibration Required</td>
<td>Error on infusing module indicating calibration is required. Infusion stops on affected module. CALIBRATE scrolls in Message Display.</td>
<td>To silence alarm and continue operation of unaffected module(s), press CONFIRM soft key. Replace module, as needed.</td>
</tr>
<tr>
<td>Syringe Driver Head Error</td>
<td>Noninfusing module, with plunger grippers open, senses excessive pressure being applied downward on Drive Head. OCCLUSION scrolls in Message Display.</td>
<td>To silence alarm and continue normal operation, press CONFIRM soft key.</td>
</tr>
</tbody>
</table>

### Messages

**Pump and Syringe Modules**

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia Mode</td>
<td>Anesthesia Mode discontinued when disconnected from AC.</td>
<td>Press CONFIRM soft key.</td>
</tr>
<tr>
<td>Bolus Dose Complete</td>
<td>Module running in continuous infusion mode if programmed.</td>
<td>None</td>
</tr>
<tr>
<td>Delay Complete</td>
<td>Delay time completed.</td>
<td>Press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>Infusion Complete</td>
<td>Current infusion completed.</td>
<td>Set up a new infusion or press CHANNEL OFF key.</td>
</tr>
</tbody>
</table>
### Alarms, Errors, Messages (Continued)

#### Messages (Continued)

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion Complete - KVO</td>
<td>Programmed volume-to-be-infused delivered; module running at KVO rate.</td>
<td>Set up a new infusion or press CHANNEL OFF key.</td>
</tr>
<tr>
<td>Panel Locked</td>
<td>Tamper Resist feature is active and a key was pressed.</td>
<td>If appropriate, deactivate Tamper Resist feature using Tamper Resist Control on back of PC Unit.</td>
</tr>
<tr>
<td>Panel Unlocked</td>
<td>Tamper Resist feature deactivated.</td>
<td>None</td>
</tr>
<tr>
<td>Pause</td>
<td>Pause control pressed; infusion stopped.</td>
<td>To resume infusion, press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>Start time for next dose has passed.</td>
<td>Start of next dose passed.</td>
<td>Press CONFIRM soft key.</td>
</tr>
</tbody>
</table>

#### Pump Module

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checking Line</td>
<td>Patient-side occlusion occurred; Auto-Restart feature monitoring downstream pressure to determine if infusion can continue.</td>
<td>None</td>
</tr>
<tr>
<td>Secondary</td>
<td>Secondary infusion in progress on indicated module.</td>
<td>None. When secondary VTBI=&quot;0&quot;, infusion reverts to programmed primary parameters.</td>
</tr>
</tbody>
</table>
### Messages (Continued)

#### Syringe Module

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>After Call Back</td>
<td>Infusion completed.</td>
<td>Press CONFIRM soft key.</td>
</tr>
<tr>
<td>NEOI (Near End of Infusion)</td>
<td>Syringe almost empty.</td>
<td>None.  This is a timed event that can be set.  To set or change this option, see &quot;General Information,&quot; &quot;Configurable Settings.&quot;</td>
</tr>
<tr>
<td>Syringe Not Recognized</td>
<td>Installed syringe of unknown type and size.</td>
<td>Select and confirm correct syringe type and size, and then press CONFIRM; or use a syringe type and size that system can automatically and correctly identify.</td>
</tr>
</tbody>
</table>

#### Possible End of Infusion Messages and Alerts (Syringe Module)

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<th>Module Display</th>
<th>Audio/Visual Alert</th>
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</thead>
<tbody>
<tr>
<td>NA</td>
<td>All</td>
<td>Yes</td>
<td>Syringe Empty</td>
<td>Syringe Empty</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>On</td>
<td>All</td>
<td>No</td>
<td>Syringe Empty</td>
<td>Syringe Empty</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>Off</td>
<td>All</td>
<td>No</td>
<td>Syringe Empty</td>
<td>Syringe Empty</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>NA</td>
<td>Numeric</td>
<td>Yes</td>
<td>Complete</td>
<td>Infusion complete</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>NA</td>
<td>Numeric</td>
<td>Yes</td>
<td>Syringe Empty</td>
<td>Syringe Empty</td>
<td>Yes/Yes (If an After callback is scheduled)</td>
</tr>
<tr>
<td>Off</td>
<td>Numeric</td>
<td>No</td>
<td>Complete</td>
<td>Infusion complete</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>Off</td>
<td>Numeric</td>
<td>No</td>
<td>Syringe Empty</td>
<td>Syringe Empty</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>On</td>
<td>Numeric</td>
<td>No</td>
<td>Syringe Empty</td>
<td>Syringe Empty</td>
<td>Yes/Yes</td>
</tr>
</tbody>
</table>
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**

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<td>• Keypad</td>
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<tr>
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</table>

**WARNING**

Failure to perform these inspections can result in improper instrument operation.

**CAUTION**

Preventive maintenance inspections should only be performed by qualified service personnel.
Alaris™ PCA Module
Model 8120
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Introduction

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

- Alaris™ product administration set instructions
- Drug product labeling
- PCA Module Set Compatibility Card
- PCA Module Technical Service Manual
- PC Unit chapter of this DFU
- System Maintenance software (and its instructions) for Alaris System check-in, maintenance, and wireless configuration

The PCA Module is intended for facilities that utilize 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 DFU ("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 "General Information," "Compatible Syringes") in accordance with manufacturer's directions for use.

2. Prepare administration set (refer to Set Compatibility Card, provided separately) in accordance with manufacturer's directions for use.

3. Attach upper fitting of administration set to syringe tip.

Load Syringe and Administration Set

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, see "General Information," "Compatible Syringes." For a list of compatible administration sets, refer to the Set Compatibility Card (provided separately).

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.
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.

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

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.
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.

5. Lower drive head and lock plunger in place with plunger grippers.
   a. Twist gripper control clockwise and hold in position.⁠
   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.

**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.

**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.
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 changes in programming without unlocking security door or interrupting current infusion.
- **LOCK** locks security door. Key must be in this position to start an infusion.
Programming

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 DFU 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.

1. Press CHANNEL SELECT key. Key must be in PROGRAM position.

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, see "General Information," "Compatible Syringes." If the installed syringe is displayed and selected, but is not recognized, servicing is required (see "Service Information" in "Appendix" section of this DFU).
2. 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.

3. 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 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 DFU, "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.
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 prepopulate standard drug concentrations, or leave an open entry (___/___mL) and allow clinician to enter drug amount and diluent volume.

   • 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 programmed "___/___mL" concentration is outside 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 programmed "___/___mL" concentration is outside 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.


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.
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.

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.
7. 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**.

8. Verify correct parameters and press **CONFIRM** soft key.

- If programmed parameters are outside 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 programmed parameters are outside 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 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 PCA Dose 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.

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.
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.

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 programmed parameters are outside 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 programmed parameters are outside 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:
Set Up Continuous Infusion Only (Continued)

<table>
<thead>
<tr>
<th>Drug Amount</th>
<th>1 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluent Volume</td>
<td>1 mL</td>
</tr>
</tbody>
</table>

OR

<table>
<thead>
<tr>
<th>Drug Amount</th>
<th>30 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluent Volume</td>
<td>30 mL</td>
</tr>
</tbody>
</table>

- 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 + Continuous Infusion

1. Perform steps in "Prepare Infusion."

2. Press PCA DOSE + CONTINUOUS soft key from Infusion Mode screen.
3. To enter PCA dose, press **PCA DOSE** soft key and use numeric data entry keys.

4. To enter lockout interval, press **LOCKOUT INTERVAL** soft key and use numeric data entry keys.

5. To enter continuous dose, press **CONT DOSE** soft key and use numeric data entry keys.

6. 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.

7. 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**.

8. Verify correct parameters and press **CONFIRM** soft key.

   - If programmed parameters are outside 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 programmed parameters are outside Hard Limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
Infusion Modes (Continued)

Set Up PCA Dose + Continuous Infusion (Continued)

• 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:

\[
\begin{align*}
\text{Drug Amount} & \quad 1 \text{ mg} \\
\text{Diluent Volume} & \quad 1 \text{ mL} \\
\text{OR} \\
\text{Drug Amount} & \quad 30 \text{ mg} \\
\text{Diluent Volume} & \quad 30 \text{ mL}
\end{align*}
\]

• 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.


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.

![Second Nurse Summary Morphine](image-url)
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.

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 programmed parameters are outside 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 programmed parameters are outside 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.

   - 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 programmed bolus dose is outside 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 programmed bolus dose is outside 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:

<table>
<thead>
<tr>
<th>Cont. Dose</th>
<th>Max Limit</th>
<th>Conc:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mg/h</td>
<td>30 mg/4 h</td>
<td>1 mg/mL</td>
</tr>
</tbody>
</table>

Press START to Close Summary.
Infusion Modes (Continued)

Set Bolus Dose (Continued)

<table>
<thead>
<tr>
<th>Drug Amount</th>
<th>1 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluent Volume</td>
<td>1 mL</td>
</tr>
</tbody>
</table>

OR

<table>
<thead>
<tr>
<th>Drug Amount</th>
<th>30 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluent Volume</td>
<td>30 mL</td>
</tr>
</tbody>
</table>

- 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.

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.

**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.①

5. To view detailed patient history, press DETAIL soft key.②

6. To return to main patient history, press MAIN HISTORY soft key.

7. To return to Main Display, press EXIT soft key.

NOTES:

① Total drug delivered includes applicable loading dose, PCA dose, continuous dose, and bolus dose. Total drug delivered does not include priming volume.

② 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.
Clear Patient History

1. Press CHANNEL SELECT key.

2. From Main Display, press OPTIONS key.

3. Press Patient History soft key.

4. Press CLEAR HISTORY soft key.
   A confirmation screen appears.

5. To continue and clear patient history, press Yes soft key. To cancel and return to patient history, press No soft key.

6. Once patient history is cleared, 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).

7. To return to Patient History screen, press SHIFT TOTALS soft key.
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.  

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.
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.

5. Press **CONFIRM** soft key.

### 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
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.

<table>
<thead>
<tr>
<th>Security Access Level</th>
<th>Initial Programming</th>
<th>Setting Bolus Dose</th>
<th>Subsequent Programming</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Key</td>
<td>Key</td>
<td>Key</td>
</tr>
<tr>
<td>Level 2</td>
<td>Key</td>
<td>Code or Key</td>
<td>Key</td>
</tr>
<tr>
<td>Level 3</td>
<td>Key</td>
<td>Code or Key</td>
<td>Code or Key</td>
</tr>
</tbody>
</table>

**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.
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.
2. 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**

1. If syringe requires replacement:
   a. Unlock security door.
   b. 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.

   c. Load syringe and administration set (see "Getting Started," "Prepare and Load Syringe and Administration Set," "Load Syringe and Administration Set").

   d. Select syringe type and size (see "Prepare Infusion," "Select Syringe Type and Size").

2. 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."

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.


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.
## Select Pressure Limit

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.

## 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.

### NOTE:

- 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.
2. To clear volume infused:
   - 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.

3. 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.

## 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.

1. Perform steps 1-8 in "Prepare Infusion," "Program an Infusion."

2. Confirm drug and concentration selections and press **Yes** soft key.
3. 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.

4. Verify correct parameters and press **NEXT** soft key to confirm.
   Prompt appears.

5. Press **CONFIRM** soft key. 

6. Start applicable infusion, as described in following procedures:
   - Set Up PCA Dose Only
   - Set Up Continuous Infusion Only
   - Set Up PCA Dose + Continuous Infusion
   - Set Loading Dose Only
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.
Review or Change PCA Pause Alarm Limits (Continued)

5. To change PCA pause limits, press soft key that corresponds to alarm limit and enter a value within acceptable range.\(^1\)

6. Press CONFIRM soft key.

7. 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

1. From Main Display press **CHANNEL SELECT**.

2. Press **OPTIONS** key.

3. Press **PCA Pause Limits** soft key.

4. Press **DISABLE SPO2** or **DISABLE ETCO2** soft key, as appropriate.

   - Disabling SpO\(_2\) or ETCO\(_2\) from this screen discontinues PCA Pause feature only, without interrupting monitoring functionality.
   - Once disabled, alarm limits are grayed out and are not editable.
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.
Secure to Pole Using Optional Locking Pole Clamp

See the PC Unit section of this DFU if a locking pole clamp is in use and the locking feature is to be used.

System Start-Up/Setup

See the PC Unit section of this DFU, "General Setup and Operation," for various system start-up and setup procedures.
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).

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, see "Compatible Syringes." For a list of compatible sets, refer to the Set Compatibility Card (provided separately).
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 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, see "Compatible Syringes."

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

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

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 directions for use provided with set.
- For a list of compatible syringes, see "Compatible Syringes."
- For a list of compatible administration sets, refer to Set Compatibility Card (provided separately).
- 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.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>20 mL</th>
<th>30 mL</th>
<th>35 mL</th>
<th>50 mL</th>
<th>60 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-D Plastipak</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>IMS Pump Jet</td>
<td>✗</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MonoJect</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terumo</td>
<td>✗</td>
<td>✗</td>
<td></td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

**NOTE:**

① Prefilled Morphine Sulfate 1 mg/mL.

Features and Displays

See the PC Unit section of this DFU for system features and definitions.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto Pressure Limit</td>
<td>When a bolus is delivered, pressure alarm limits are temporarily raised to</td>
</tr>
<tr>
<td>Adjustment</td>
<td>maximum limit.</td>
</tr>
<tr>
<td>Auto Syringe Identification</td>
<td>System automatically detects syringe size and narrows down syringe</td>
</tr>
<tr>
<td></td>
<td>selection list.</td>
</tr>
<tr>
<td>Bolus Delivery Rate</td>
<td>Rate at which PCA, bolus, and loading doses (boluses) are infused.</td>
</tr>
<tr>
<td>Bolus Dose</td>
<td>Allows an additional amount of medication to be programmed once PCA</td>
</tr>
<tr>
<td></td>
<td>infusion has begun. Current PCA infusion resumes following delivery of a</td>
</tr>
<tr>
<td></td>
<td>bolus dose.</td>
</tr>
</tbody>
</table>
### Features and Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Concentration</strong></td>
<td>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:</td>
</tr>
</tbody>
</table>
|                       | Drug Amount 1 mg  
|                       | Diluent Volume 1 mL  
|                       | OR  
|                       | Drug Amount 30 mg  
|                       | Diluent Volume 30 mL |
| **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 internal, or maximum limit.                                  |
| **Limit**             | 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.  
|                       | • A Hard Limit is a programmed Limit that cannot be overridden.  
<p>|                       | • A Soft Limit is a programmed Limit that can be overridden. |
| <strong>Loading Dose</strong>      | 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. |</p>
<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lockout Interval</td>
<td>Allows programming of a predetermined interval of time that must elapse between delivery of PCA doses.</td>
</tr>
</tbody>
</table>
| Max Dose Limit (Max Accumulated Dose Limit) | Optional configuration that limits total amount of drug allowed to be delivered to patient in a defined period (1, 2, or 4 hours).  
• 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. |
| 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) | Allows an alert to be configured to sound anywhere between 5 – 25% volume remaining. |
| NEOI Alert | Alert Time can be set to occur when 5 – 25% of VTBI remains. |
| Occlusion Pressure | Downstream occlusion alarm threshold can be set to low, medium, or high. |
| Operating Modes | Four operating modes are available:  
• 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:  
• total demands  
• delivered demands  
• total drug delivered  
• time and date patient history last cleared  
• average drug per hour  
• total amount of drug delivered via:  
  ◦ PCA dose  
  ◦ continuous infusion  
  ◦ loading dose  
  ◦ bolus dose |
### Features and Displays (Continued)

#### Features and Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PCA Dose</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>PCA Pause Protocol</strong></td>
<td>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 (% SpO₂ and/or Respiratory Rate low) for SpO₂ and/or EtCO₂ Module are reached.</td>
</tr>
<tr>
<td><strong>Pressure Limit</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Priming</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Restore</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Security Access Level</strong></td>
<td>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 &quot;Programming,&quot; &quot;Infusion Modes,&quot; &quot;Security Access Levels.&quot;</td>
</tr>
<tr>
<td><strong>Security Code</strong></td>
<td>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 Access Level.</td>
</tr>
<tr>
<td><strong>Syringe Empty</strong></td>
<td>Instrument gives an alert and stops when an empty syringe is detected.</td>
</tr>
<tr>
<td><strong>Syringe Volume Detection</strong></td>
<td>System automatically detects fluid volume in a syringe when it is inserted.</td>
</tr>
</tbody>
</table>
### Features and Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapies</td>
<td>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.</td>
</tr>
<tr>
<td>Time Window (h)</td>
<td>1, 2, or 4 hours.</td>
</tr>
</tbody>
</table>
### Operating Features, Controls, Indicators

#### Features and Displays (Continued)

**Status Indicators**
- **Alarm** (red)
- **Infusing** (green)
- **Standby** (yellow)

**IUI Connector, Left**

**Rate Display**

**Message Display**

**Channel (module) Identification**

**Channel (module) Select Key:**
When pressed, selects corresponding module for infusion parameter entry and infusion setup.

**Pause Key:** When pressed during an infusion, temporarily stops infusion on that module. After approximately 2 minutes, a visual and audio prompt begins.

**Channel (module) Off Key:** When pressed and held until a beep is heard, stops infusion on that module, deselects that module, and if only that module had been operating, system powers down. Repeat for other operating modules to power off each module.

**Restart Key:** When pressed, resumes operation of a previously paused or alarmed infusion on that module.

**Module Release Latch:** When pressed, allows module to be removed.

**Dose Request Cord Attachment**

**Gripper Control/Drive Head Release** (shown in closed position)

**Plunger Grippers** (shown in closed position)

**Barrel Flange Gripper**

**Syringe Barrel Sensor**

**Syringe Barrel Clamp/Sizer**

**Dose Request Cord**
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.

See the PC Unit section of this DFU 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.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
</table>
| 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                    | Enabled         | 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                  | Enabled         | Enabled - Disabled                                                      |
| Lockout Interval              | 1 - 99 minutes in 1-minute increments | Min/Max 1 - 99 minutes |
### Specifications and Symbols (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Accumulated Dose Range</td>
<td>1-hour limit</td>
<td>Disabled; 1, 2, or 4-hour limit</td>
</tr>
<tr>
<td>Max Rate (for Continuous Dose)</td>
<td>999 mL/h</td>
<td>0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments</td>
</tr>
<tr>
<td>NEOI</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Alert Time</td>
<td></td>
<td>5 - 25% of remaining infusion</td>
</tr>
<tr>
<td>Occlusion Pressure Set Point</td>
<td>High (800 mmHg)</td>
<td>Low (200 mmHg) Medium (500 mmHg) High (800 mmHg)</td>
</tr>
<tr>
<td>PCA Pause Protocol:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• PCA Pause Protocol</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• Monitoring Module Attach</td>
<td>None</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• PCA Pause Protocol Text</td>
<td>PCA infusion has paused due to a decline in respiratory status. Check patient.</td>
<td>Editable per hospital protocol</td>
</tr>
<tr>
<td>• SpO2 Settings:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>① % SpO2 Low Limit</td>
<td>None</td>
<td>20 - 99</td>
</tr>
<tr>
<td>① Initial Value</td>
<td>None</td>
<td>20 - 99</td>
</tr>
<tr>
<td>• EtCO2 Settings:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>② Respiratory Rate Lower Limit</td>
<td>None</td>
<td>0 - 149</td>
</tr>
<tr>
<td>(bpm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>② Initial Value</td>
<td>None</td>
<td>0 - 149</td>
</tr>
<tr>
<td>Priming</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Security Access Level</td>
<td>Level 1</td>
<td>Level 1, 2, 3</td>
</tr>
</tbody>
</table>

**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

### Specifications

**Bolus Dose Range:** Configured according to hospital best-practice guidelines.

**Bolus Volume, Maximum after Occlusion:**

<table>
<thead>
<tr>
<th>Occlusion Pressure Limit</th>
<th>Bolus Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>0.994</td>
</tr>
<tr>
<td>High</td>
<td>0.396</td>
</tr>
</tbody>
</table>

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:**

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

**Equipment Orientation:** To ensure proper operation, Alaris System must remain in an upright position.
Flow Rate Programming: Flow rate range is from 0.01 to 999 mL/h and can be selected as follows:

<table>
<thead>
<tr>
<th>Flow Rates (mL)</th>
<th>Selectable Increments (mL/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.10 - 9.99</td>
<td>0.01</td>
</tr>
<tr>
<td>10 - 99.9</td>
<td>0.1</td>
</tr>
<tr>
<td>100 - 999</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Rate Restriction by Syringe Size:

<table>
<thead>
<tr>
<th>Syringe Size (mL)</th>
<th>Flow Rate Range (mL/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>0.1 - 500</td>
</tr>
<tr>
<td>30/35</td>
<td>0.1 - 650</td>
</tr>
<tr>
<td>50/60</td>
<td>0.1 - 999</td>
</tr>
</tbody>
</table>

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: ±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 (PCA Module)
Type BF, Defibrillator Proof (Dose Request Cord)
Specifications and Symbols (Continued)

Specifications (Continued)

Time to Alarm, Maximum:

<table>
<thead>
<tr>
<th>Rate (mL)</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>120 minutes</td>
<td>37 minutes</td>
</tr>
<tr>
<td>5</td>
<td>30 minutes</td>
<td>7 minutes</td>
</tr>
</tbody>
</table>

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

Symbols

See the PC Unit section of this DFU for system symbols.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning—Alaris Pump Module and Alaris Syringe Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Heart]</td>
<td>Type CF defibrillation-proof (PCA Module).</td>
</tr>
<tr>
<td>![Person]</td>
<td>Type BF defibrillation-proof (Dose Request Cord).</td>
</tr>
<tr>
<td>![Manufacturer]</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>![Single-Use]</td>
<td>Single-Use. Do not re-use.</td>
</tr>
<tr>
<td>![DEHP]</td>
<td>DEHP in fluid pathway.</td>
</tr>
<tr>
<td>![Non-DEHP]</td>
<td>Non-DEHP plasticizer in fluid pathway.</td>
</tr>
<tr>
<td>![No DEHP]</td>
<td>No DEHP in fluid pathway.</td>
</tr>
</tbody>
</table>
Specifications and Symbols  (Continued)

Symbols  (Continued)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning—Alaris Pump Module and Alaris Syringe Module</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="LaTex Symbol" /></td>
<td>Product is latex-free.</td>
</tr>
<tr>
<td><img src="image" alt="Priming Volume Symbol" /></td>
<td>Approximate administration set priming volume.</td>
</tr>
<tr>
<td><img src="image" alt="Expiration Date Symbol" /></td>
<td>Expiration date for product is identified near hourglass symbol.</td>
</tr>
<tr>
<td><img src="image" alt="Warning Symbol" /></td>
<td>Do not use if package is damaged.</td>
</tr>
<tr>
<td><img src="image" alt="Micron Filter Symbol" /></td>
<td>Product contains micron filter, where xx represents filter size.</td>
</tr>
</tbody>
</table>

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.
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 a long-term accuracy offset 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
Troubleshooting and maintenance are intended to be performed only by qualified personnel, using the PCA Module Technical Service Manual, and the System Maintenance software. The Service Manual and System Maintenance software are available from CareFusion. The Service Manual 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 proportionally to the infusion device flow rate. 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.

**Alarms, Errors, Messages**

See the PC Unit section of this DFU for the following system references:

- Alarms, Errors, Messages
- Audio Characteristics
- Definitions
- Display Color
- Radio Frequency Note
**Alarms, Errors, Messages** (Continued)

### Definitions

**Alert**
A visual message to help reduce programming errors by indicating a Limit (Soft or Hard) has been exceeded. A response is required before programming can continue.

**Clinical Advisory**
A visual message defined by the facility for a designated drug and displayed when that drug is selected for an infusion. The message provides instructions related to specific drug use and/or 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.

### Alarms

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attach Dose Request Cord</td>
<td>Dose Request Cord detached from device. Dose Request Cord required for PCA only and PCA + continuous infusion modes.</td>
<td>Reattach Dose Request Cord and press <strong>RESTART</strong> key.</td>
</tr>
<tr>
<td>Channel Disconnected</td>
<td>Module disconnected while in operation or have a communication problem.</td>
<td>To silence alarm and clear message from screen, press <strong>CONFIRM</strong> soft key. Reattach module, if desired, ensuring it is securely &quot;clicked&quot; into place at Channel Release Latch. If alarm is still present, replace module.</td>
</tr>
<tr>
<td>Lock Door</td>
<td>Door unlocked during infusion (system does not infuse with door unlocked).</td>
<td>Lock door and press <strong>RESTART</strong> key.</td>
</tr>
<tr>
<td>Occlusion</td>
<td>Increased back pressure sensed while infusing. Infusion stops on affected module.</td>
<td>Clear occlusion. Press <strong>RESTART</strong> key, or press <strong>CHANNEL SELECT</strong> key and then <strong>START</strong> soft key.</td>
</tr>
<tr>
<td>PCA Pause Alarm</td>
<td>PCA infusion has paused due to a decline in respiratory status.</td>
<td>Assess patient status per hospital policy. Press <strong>CONFIRM</strong> once patient status and monitoring values have been addressed. Press <strong>RESTART</strong> key per hospital policy.</td>
</tr>
</tbody>
</table>
Alarms, Errors, Messages (Continued)

Alarms (Continued)

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe Empty</td>
<td>Syringe is empty.</td>
<td>Set up new infusion or press CHANNEL OFF key.</td>
</tr>
<tr>
<td></td>
<td>If syringe is not empty, other possibility is: Syringe plunger travel</td>
<td>Verify that syringe plunger movement is unimpeded.</td>
</tr>
<tr>
<td></td>
<td>impeded.</td>
<td>If syringe is not empty and above actions do not correct alarm, replace</td>
</tr>
<tr>
<td></td>
<td></td>
<td>module.</td>
</tr>
</tbody>
</table>

**Syringe Adjustment Alarms**

When a syringe installation problem is detected, a visual signal is displayed. Text in the display blinks to indicate the location of the problem.

When problem is corrected, press CONFIRM soft key.

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe Adjustment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check Syringe</td>
<td>Plunger grippers opened during infusion and then closed. Infusion stops</td>
<td>Securely lock plunger grippers, press CHANNEL SELECT key, and reselect</td>
</tr>
<tr>
<td></td>
<td>on affected module.</td>
<td>syringe.</td>
</tr>
<tr>
<td></td>
<td>Syringe barrel clamp opened during infusion and then closed. Infusion</td>
<td>Securely lock syringe barrel clamp and press RESTART key.</td>
</tr>
<tr>
<td></td>
<td>stops on affected module.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Syringe plunger not captured while in idle state. System alarms after</td>
<td>Check for potential siphoning. Ensure that administration set clamp</td>
</tr>
<tr>
<td></td>
<td>30 seconds to indicate potential siphoning condition.</td>
<td>(roller/slide) is in closed position. Securely lock plunger grippers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>over syringe plunger.</td>
</tr>
<tr>
<td>Drive Not Engaged</td>
<td>Drive system disengaged during operation.</td>
<td>Open and close plunger grippers and syringe barrel clamp. Ensure that</td>
</tr>
<tr>
<td></td>
<td></td>
<td>syringe is properly installed.</td>
</tr>
</tbody>
</table>
# Alarms, Errors, Messages

## Errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Channel Error</td>
<td>Error detected. Operation stops on affected module.</td>
<td>To silence alarm and continue operation of unaffected module(s), press <strong>CONFIRM</strong> soft key. Replace module, as needed.</td>
</tr>
<tr>
<td>Syringe Calibration Required</td>
<td>Error on infusing module indicating calibration is required. Infusion stops on affected module. <strong>CALIBRATE</strong> scrolls in Message Display.</td>
<td>To silence alarm and continue operation of unaffected module(s), press <strong>CONFIRM</strong> soft key. Replace module, as needed.</td>
</tr>
<tr>
<td>Syringe Driver Head Error</td>
<td>Noninfusing module, with plunger grippers open, senses excessive pressure being applied downward on Drive Head. <strong>OCCLUSION</strong> scrolls in Message Display.</td>
<td>To silence alarm and continue normal operation, press <strong>CONFIRM</strong> soft key.</td>
</tr>
</tbody>
</table>

## Messages

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolus Complete</td>
<td>Current bolus dose completed. Channel running in continuous dose if programmed.</td>
<td>None</td>
</tr>
</tbody>
</table>
| Incorrect concentration or dosing | An incorrect concentration or dose parameter is programmed. | 1. Remove syringe.  
2. Verify that concentration listed on syringe matches concentration (DRUG AMOUNT and DILUENT VOLUME) programmed into PCA Module.  
3. Reprogram. |
| Infusion Complete      | Current infusion completed.                                              | Set up a new infusion or press **CHANNEL OFF** key.                      |
| Load Complete          | Current loading dose completed. Infusion mode menu available or programmed infusion running. | None                                                                     |
### Alarms, Errors, Messages (Continued)

# Messages (Continued)

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Limit Reached</td>
<td>Programmed maximum limit has been reached over time period specified. Infusion paused until time limit has expired.</td>
<td>To silence alarm, press SILENCE key. To change Max Limit, press CHANNEL SELECT, press PROGRAM soft key, and unlock door or enter Authorization Code applicable for current Security Access Level.</td>
</tr>
<tr>
<td>NEOI (Near End of Infusion)</td>
<td>Syringe almost empty.</td>
<td>This is a timed event that can be set or changed (see &quot;General Information,&quot; &quot;Configurable Settings&quot;). To silence alarm, press SILENCE key. PCA Module remains functional and continues infusion. Green indicator light is lit (when programmed in PCA Dose plus continuous mode) or flashes (when programmed in PCA Dose only), and yellow light flashes. PCA Module is silent until Syringe Empty alarm sounds (see Syringe Empty alarm response)</td>
</tr>
<tr>
<td>Panel Locked</td>
<td>Tamper Resist feature is active and a key was pressed.</td>
<td>If appropriate, deactivate Tamper Resist feature using Tamper Resist Control on back of PC Unit.</td>
</tr>
<tr>
<td>Panel Unlocked</td>
<td>Tamper Resist feature deactivated.</td>
<td>None</td>
</tr>
<tr>
<td>Pause</td>
<td>Pause control pressed; infusion stopped.</td>
<td>To resume infusion, press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>PCA Complete</td>
<td>Current PCA dose complete. Channel running in continuous dose if programmed.</td>
<td>None</td>
</tr>
<tr>
<td>PCA Not In Secure Location</td>
<td>PCA Module is not in preferable location to allow locking to PC Unit. Device is not in a tamper evident position.</td>
<td>Detach PCA Module from current position and reattach to immediate right of PC Unit.</td>
</tr>
<tr>
<td>Syringe Not Recognized</td>
<td>Installed syringe of unknown type and size.</td>
<td>Select and confirm correct syringe type and size, and then press CONFIRM soft key, or use a syringe type and size that system can automatically and correctly identify.</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSPECT FOR DAMAGE</td>
<td></td>
</tr>
<tr>
<td>• Exterior Surfaces</td>
<td>Each usage</td>
</tr>
<tr>
<td>• IUI Connector</td>
<td>Each usage</td>
</tr>
<tr>
<td>• Keypad</td>
<td>Each usage</td>
</tr>
<tr>
<td>• Mechanical Parts</td>
<td>Each usage</td>
</tr>
<tr>
<td>CLEANING</td>
<td>As required</td>
</tr>
<tr>
<td>START-UP</td>
<td>Each usage</td>
</tr>
</tbody>
</table>

**WARNING**

Failure to perform these inspections can result in improper instrument operation.

**CAUTION**

Preventive maintenance inspections should only be performed by qualified service personnel.
Alaris™ SpO₂ Module
Models 8210 and 8220
This section of the DFU provides SpO2 Module (Models 8210 and 8220) instructions and information. It is used in conjunction with:

- Nellcor™ and Masimo™ cable and sensor instructions
- PC Unit section of this DFU
- SpO2 Module sensor and cable Compatibility Cards
- 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.

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)

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 DFU ("Regulations and Standards," "Compliance").
Attach Cable and Sensor

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 directions for use for detailed instructions.

3. Attach sensor to patient. Refer to sensor’s directions for use for detailed instructions.

**WARNING**

Model 8210:

Use only approved OxiMax™ sensors, and DOC–10 and OC–3 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 Sensor and Cable Compatibility Card (provided separately).
Display references throughout this procedure are for illustration purposes only.

See "General Information," "Features and Displays" and the PC Unit section of this DFU 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 DFU, "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.
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.
Set Alarm Limits  (Continued)

2. To change a limit setting, press soft key next to applicable parameter.

3. Enter a numeric value for selected alarm limit.
   \%SPO2 HIGH limit can be Off or a numeric value.

4. To move to next limit, press ENTER key.

5. To confirm alarm settings and return to SPO2 Main display, press CONFIRM soft key.

6. To return to Main Display, press MAIN SCREEN soft key.

Navigate Trend Data

1. 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 (---) display.

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.

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/SpO2 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)

3. 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.

Presilence Alarm

1. To presilence alarm, press SILENCE key.
   All monitoring alarms are silenced for 120 seconds. Subsequent infusion alarms are not silenced.

2. To cancel presilence alarm and return to alarmable mode:
   • Press CHANNEL SELECT key.
   • Press CANCEL SILENCE soft key.
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.
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

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.
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**

1. Press **Sensitivity Mode** soft key.

---
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.
See the PC Unit section of this DFU, "General Setup and Operation," for various system start-up and setup procedures.
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.
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 OxiMax™ sensors, and DOC–10 and OC–3 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 Sensor and Cable Compatibility Card (provided separately).

- Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

- Before use, read the sensor directions for use, including all warnings, cautions, and instructions.

Do not immerse or dampen the sensor or cable. Clean per manufacturer’s instructions.
The Nellcor DOC-10 and OC-3 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 OxiMax sensors. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor.

For a list of compatible sensors and cables, refer to the Sensor and Cable Compatibility Card (provided separately).

Reusable patient cables of various lengths are available. All cables that display the Masimo SET™ logo are designed to work with an SpO₂ Module displaying the Masimo SET logo.

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 directions for use accompanying the sensor.

For a list of compatible sensors and cables, refer to the Sensor and Cable Compatibility Card (provided separately).
See the PC Unit section of this DFU for system features and definitions.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>% SpO₂ Alarm Limits</td>
<td>Upper and lower saturation limits for %SpO₂ alarm can be adjusted by clinician.</td>
</tr>
<tr>
<td>% SpO₂ Display</td>
<td>Functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO₂.</td>
</tr>
<tr>
<td>Limit Mode</td>
<td>Configurable mode that can be set to display either adult or neonatal monitoring mode. (See &quot;Configurable Settings&quot; for additional configurable features.)</td>
</tr>
<tr>
<td>Pleth Waveform</td>
<td>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).</td>
</tr>
<tr>
<td>Pulse Beat Volume</td>
<td>Sound of each pulse beep can be configured to be off or to a volume level of 1, 2, or 3.</td>
</tr>
<tr>
<td>Pulse Rate</td>
<td>Displayed in beats per minute (bpm).</td>
</tr>
<tr>
<td>Pulse Rate Alarm Limits</td>
<td>Upper and lower pulse rate alarm limits can be adjusted by clinician.</td>
</tr>
<tr>
<td>Trend Data</td>
<td>Tabular display of %SpO₂ 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.</td>
</tr>
</tbody>
</table>
### Features and Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
</table>
| **SatSeconds**           | SatSecond limits controls time %SpO₂ level can fall outside alarm limits before an audible alarm sounds. Method of calculation is as follows:  
                         | Number of percentage points %SpO₂ falls outside of alarm limit is multiplied by number of seconds %SpO₂ level remains outside that limit.  
                         | Points x Seconds = SatSeconds  
                         | Points = %SpO₂ percentage points outside of limit  
                         | Seconds = number of seconds %SpO₂ remains at that point outside of limit  
                         | 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.  
                         | 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. |
| **SatSeconds alarm management** | 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.                                                                |

---

Alaris System DFU – up to v9.12 Model 8015

SpO₂ Module Section

General Information 4-19
### Features and Definitions (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fast SAT</strong></td>
<td>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%.</td>
</tr>
<tr>
<td><strong>PI</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Saturation Averaging Time</strong></td>
<td>Averaging time can be set to 2, 4, 8, 10, 12, 14, or 16 seconds.</td>
</tr>
<tr>
<td><strong>Sensitivity Mode</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>SET™ Technology</strong></td>
<td>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).</td>
</tr>
<tr>
<td><strong>Signal I.Q.™ Feature</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
Features and Displays  (Continued)

Operating Features, Controls, Indicators

**Status Indicators**
- **Alarm** (red)
- **Monitoring** (green)
- **Standby** (yellow)

**%SpO2 Display**

**Pulse Rate Display**

**Channel (module) Identification**

**Channel (module) Select Key:** When pressed, selects corresponding module for patient monitoring and setup.

**Monitor Key:** When pressed, begins patient monitoring.

**Channel (module) Off Key:** When pressed and held until a beep is heard, stops operation of that module, deselects that module, and if only that module had been operating, system powers down. Repeat for other operating modules to power off each module.

**Module Release Latch:** When pressed, allows module to be removed.

**Patient Cable Connector**

**IUI Connector, Left** (not visible)

**IUI Connector, Right**

**Pulse Bar Display**

**Channel (module) Message Display**

**Message Display**

**Channel (module) Identification**
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 DFU.

**SPO2 Main Display**

![SPO2 Main Display Diagram]

**Features and Displays**

**Displays**

![SPO2 Main Display Diagram]

*Pleth Waveform

*Signal I.Q.

*PI*
Configurable Settings

See the PC Unit section of this DFU 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.

<table>
<thead>
<tr>
<th>Models 8210 and 8220 Masimo SET.</th>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit Mode</td>
<td>Adult</td>
<td>Adult, Neonatal</td>
<td></td>
</tr>
<tr>
<td>Pulse Beep Volume</td>
<td>1</td>
<td>1, 2, 3, Off</td>
<td></td>
</tr>
<tr>
<td>Pulse Rate Alarm Limit, High</td>
<td>Adult Mode: 120 bpm Neonatal Mode: 200 bpm</td>
<td>31 - 240 bpm</td>
<td></td>
</tr>
<tr>
<td>Pulse Rate Alarm Limit, Low</td>
<td>Adult Mode: 50 bpm Neonatal Mode: 100 bpm</td>
<td>30 - 239 bpm</td>
<td></td>
</tr>
<tr>
<td>SpO2 Alarm Limit, High</td>
<td>Adult: Off Neonatal: 95%</td>
<td>21 - 100%, Off</td>
<td></td>
</tr>
<tr>
<td>SpO2 Alarm Limit, Low</td>
<td>Adult: 90% Neonatal: 80%</td>
<td>20 - 99%</td>
<td></td>
</tr>
</tbody>
</table>

| Model 8210 Nellcor               |
|----------------------------------|---------|---------|
| Feature                          | Default Setting | Options |
| SatSeconds                       | Off     | 10, 25, 50, 100 seconds; Off |
**Configurable Settings** (Continued)

<table>
<thead>
<tr>
<th>Model 8220</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feature</td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>Saturation Averaging Time (display update period)</td>
</tr>
<tr>
<td>Sensitivity Mode</td>
</tr>
</tbody>
</table>

**Specifications and Symbols**

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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Dimensions:</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Environmental Conditions:</td>
</tr>
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<td></td>
</tr>
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<td></td>
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<td></td>
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<tr>
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<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td>Fluid Ingress Protection:</td>
</tr>
<tr>
<td>Mode of Operation:</td>
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<tr>
<td>Shock Protection:</td>
</tr>
<tr>
<td>Weight:</td>
</tr>
</tbody>
</table>
Specifications and Symbols

Specifications (Continued)

Model 8210 NELLCOR

Accuracy Tolerance:

<table>
<thead>
<tr>
<th></th>
<th>Low Perfusion</th>
<th>Adult</th>
<th>Neonate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Rate</td>
<td>20 - 250 bpm</td>
<td>20 - 250 bpm</td>
<td>20 - 250 bpm</td>
</tr>
<tr>
<td></td>
<td>±3 digits</td>
<td>±3 digits</td>
<td>±3 digits</td>
</tr>
<tr>
<td>Functional Saturation</td>
<td>70 - 100%</td>
<td>70 - 100%</td>
<td>70 - 100%</td>
</tr>
<tr>
<td></td>
<td>±2 digits</td>
<td>±2 digits</td>
<td>±3 digits</td>
</tr>
</tbody>
</table>

Display Update Period: 2.25 seconds

Measurement Range:
- Perfusion: 0.03 - 20%
- Pulse Rate: 20 - 250 bpm
- SpO\(_2\): 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 Masimo SET

Accuracy and Motion Tolerance:

<table>
<thead>
<tr>
<th></th>
<th>Low Perfusion</th>
<th>Motion</th>
<th>No Motion</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Rate</td>
<td>25 - 240 bpm</td>
<td>25 - 240 bpm</td>
<td>25 - 240 bpm</td>
<td>1 bpm</td>
</tr>
<tr>
<td></td>
<td>Adults, Pediatrics, Neonates: ±3 digits</td>
<td>Adults, Pediatrics, Neonates: ±5 digits</td>
<td>Adults, Pediatrics, Neonates: ±3 digits</td>
<td></td>
</tr>
<tr>
<td>Saturation</td>
<td>70 - 100%</td>
<td>70 - 100%</td>
<td>70 - 100%</td>
<td>1% SpO(_2)</td>
</tr>
<tr>
<td></td>
<td>±2 digits; Neonates: ±3 digits</td>
<td>Adults, Pediatrics: ±2 digits; Neonates: ±3 digits</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Neonates: ±3 digits</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Display Update Period: Approximately 1 second.

Measurement Range:
- Perfusion: 0.02 - 20%
- Pulse Rate: 25 - 240 bpm
- SpO\(_2\): 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.
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.
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.

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.
- 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.

### Specifications and Symbols (Continued)

#### Symbols

See the PC Unit section of this DFU for system symbols.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>🔔</td>
<td>Silenced alarm. Note: When displayed, the dashed lines through the symbol might appear as solid lines due to the small display size.</td>
</tr>
<tr>
<td>🔔</td>
<td>Is displayed in Trend Data screen to identify an exceeded alarm limit.</td>
</tr>
<tr>
<td>⚠️</td>
<td>Type BF equipment.</td>
</tr>
</tbody>
</table>

### 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.

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.
- 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.
Measurement Accuracy (Continued)

- Placement is too close to electrosurgery equipment.
- Defibrillation.

The loss of a pulse signal can occur in any of the following situations:

- 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.
- Sensor placed on an extremity with a blood pressure cuff, arterial catheter, intravascular line, or other causes of insufficient perfusion.
- 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:
- Exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.
Troubleshooting and Maintenance

General

Troubleshooting and maintenance are intended to be performed only by qualified personnel, using the SpO₂ Module Technical Service Manual, and the System Maintenance software. The Service Manual and System Maintenance software are available from CareFusion. The Service Manual 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 and preventive maintenance tests.

Alarms and Messages

See the PC Unit section of this DFU for the following system references:
- Alarms, Errors, Messages
- Audio Characteristics
- Definitions
- Display Color
- Radio Frequency Note

Definition

**Alarm Silence**

Alarms can be silenced for up to 120 seconds by pressing SILENCE key. Alarm indicators remain on and alarm silence symbol is displayed. Silence period can be ended by pressing CANCEL SILENCE soft key.

Alarms

<table>
<thead>
<tr>
<th>Models 8210 NELLCOR and 8220 MASIMO SET.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alarm</strong></td>
</tr>
<tr>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Bad Sensor</td>
</tr>
</tbody>
</table>
### Alarms and Messages (Continued)

#### Alarms (Continued)

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check Sensor - Electrical or Optical Interference</td>
<td>External interference on sensor.</td>
<td>Check sensor. Identify source of external interference if other than sensor.</td>
</tr>
<tr>
<td>High Pulse Rate Alarm</td>
<td>High pulse rate alarm limit has been exceeded.</td>
<td>Assess patient’s condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>High SpO2 Alarm</td>
<td>High SpO2 alarm limit has been exceeded.</td>
<td>Assess patient’s condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>Low Pulse Rate Alarm</td>
<td>Low pulse rate alarm limit has been exceeded.</td>
<td>Assess patient’s condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>Low SpO2 Alarm</td>
<td>Low SpO2 alarm limit has been exceeded.</td>
<td>Assess patient’s condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>No Sensor</td>
<td>Sensor not properly attached to patient cable or patient cable not properly attached to SpO2 Module.</td>
<td>Attach sensor to patient cable or attach patient cable to SpO2 Module.</td>
</tr>
<tr>
<td>No Signal</td>
<td>Failure to find a patient signal after 30 seconds of searching.</td>
<td>Check sensor. Confirm correct sensor placement.</td>
</tr>
<tr>
<td>Remove Module (Max=1)</td>
<td>More than one SpO2 Module attached.</td>
<td>Remove additional SpO2 Module.</td>
</tr>
<tr>
<td>Sensor Off</td>
<td>Sensor not properly attached to patient.</td>
<td>Reattach sensor to patient.</td>
</tr>
</tbody>
</table>

### Model 8210 NELLCOR

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check Sensor - High Pulse Amplitude</td>
<td>Artifact interfering with pulse reading.</td>
<td>Check sensor. Relocate sensor to a site with less artifact interference.</td>
</tr>
<tr>
<td>Check Sensor - Excessive Ambient Light</td>
<td>Light interference on sensor.</td>
<td>Check sensor. Remove or reduce lighting. Cover or reposition sensor.</td>
</tr>
</tbody>
</table>
### Alarms and Messages (Continued)

#### Alarms (Continued)

<table>
<thead>
<tr>
<th>Model 8210 NELLCOR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alarm</strong></td>
</tr>
<tr>
<td>Check Sensor - Motion Interference</td>
</tr>
<tr>
<td>Check Sensor - No signal</td>
</tr>
<tr>
<td>Check Sensor - Weak Pulse</td>
</tr>
<tr>
<td>Check Sensor - Weak Signal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model 8220 Masimo SET</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alarm</strong></td>
</tr>
<tr>
<td>Check Sensor - Light</td>
</tr>
<tr>
<td>Check Sensor - Low Perfusion</td>
</tr>
<tr>
<td>Check Sensor - Low Signal I.Q.</td>
</tr>
</tbody>
</table>
### Alarms and Messages (Continued)

#### Messages

<table>
<thead>
<tr>
<th>Model 8210 NELLCOR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Message</strong></td>
</tr>
<tr>
<td>Check Sensor - Electrical or Optical Interference</td>
</tr>
<tr>
<td>Check Sensor - High Pulse Amplitude</td>
</tr>
<tr>
<td>Check Sensor - Excessive Ambient Light</td>
</tr>
<tr>
<td>Check Sensor - Motion Interference</td>
</tr>
<tr>
<td>Check Sensor - Weak Pulse</td>
</tr>
<tr>
<td>Check Sensor - Weak Signal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model 8220 MASIMO SET</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Message</strong></td>
</tr>
<tr>
<td>Check Sensor - Low Perfusion</td>
</tr>
<tr>
<td>Check Sensor - Low Signal I.Q.</td>
</tr>
</tbody>
</table>
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

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<td></td>
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<tr>
<td>• Exterior Surfaces</td>
<td>Each usage</td>
</tr>
<tr>
<td>• IUI Connector</td>
<td>Each usage</td>
</tr>
<tr>
<td>• Keypad</td>
<td>Each usage</td>
</tr>
<tr>
<td>CLEANING</td>
<td>As required</td>
</tr>
<tr>
<td>START-UP</td>
<td>Each usage</td>
</tr>
</tbody>
</table>

**WARNING**

Failure to perform these inspections can result in improper instrument operation.

**CAUTION**

Preventive maintenance inspections should only be performed by qualified service personnel.
Alaris™ EtCO₂ Module
Model 8300
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This section of the DFU provides EtCO₂ Module (Model 8300) instructions and information. It is used in conjunction with:

- EtCO₂ Module Technical Service Manual
- Microstream™ Disposable Compatibility Card
- Origion’s Microstream disposable instructions
- PC Unit section of this DFU
- 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 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 Origion’s patented Microstream Disposables/circuits for sidestream capnography.

**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 DFU ("Regulations and Standards," "Compliance").
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.

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 directions for use).

**WARNING**

Use only Microstream Disposables. Use of a disposable other than those specified can cause improper EtCO₂ Module performance, resulting in inaccurate readings. For a list of compatible disposables, refer to the Microstream Disposable Compatibility Card (provided separately).
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.
Display references throughout this procedure are for illustration purposes only.

See "General Information," "Features and Displays" and PC Unit section of this DFU for information about:

- Displays
- Operating Features, Controls, Indicators

## Monitoring Mode

1. Perform following steps (see PC Unit section of this DFU, "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:

- 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

1. Press LIMITS soft key.

2. To change a limit setting, press soft key next to applicable parameter.

3. Enter a numeric value for selected alarm limit.

4. To move to next limit, press ENTER key.

5. To confirm alarm settings and return to ETCO2 Main display, press CONFIRM soft key.

6. 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 ø 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 ETCO2 Main display, press ETCO2 MAIN soft key.

6. To return to Main Display, press MAIN SCREEN soft key.

**Navigate PCA/EtCO2 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.
Monitoring Mode (Continued)

Presilence Alarm

1. To presilence alarm, press SILENCE key.
   All monitoring alarms are silenced for 120 seconds. Subsequent infusion alarms are not silenced.

2. To cancel presilence alarm and return to alarmable mode:
   - Press CHANNEL SELECT key.
   - 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 ETCO2 Main display, press EXIT soft key.

Change Waveform Height

1. Press Waveform height soft key.

2. 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.

3. To return to ETCO2 Main display, press EXIT soft key.
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 DFU, "General Setup and Operation," for various system start-up and setup procedures.
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.

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. For a list of compatible disposables, refer to the Microstream Disposable Compatibility Card (provided separately).
Before use, read Microstream Disposable directions for use, including all warnings, cautions, and instructions.

Carefully locate the patient Microstream Disposable to reduce the possibility of patient entanglement or strangulation.

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.

When selecting a Microstream Disposable, consider the patient’s weight, condition, and intubation status. For more information on Microstream Disposables, contact Oridion at http://www.oridaon.com or 1-888-ORIDION.

For a list of compatible disposables, refer to the Sensor and Cable Compatibility Card (provided separately).
### Features and Definitions

See the PC Unit section of this DFU for system features and definitions.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPM</td>
<td>Breaths per minute.</td>
</tr>
<tr>
<td>Capnography Waveform</td>
<td>Real-time graphical display of CO₂ concentration throughout respiration.</td>
</tr>
<tr>
<td>Data Display</td>
<td>Waveforms, trended data, and numerical values are displayed.</td>
</tr>
<tr>
<td>EtCO₂</td>
<td>CO₂ concentration in mmHg at end of exhalation.</td>
</tr>
<tr>
<td>FiCO₂</td>
<td>Fractional-inspired CO₂; CO₂ concentration present during inhalation.</td>
</tr>
<tr>
<td>Limit Mode</td>
<td>Configurable mode that can be set to display either adult or neonatal monitoring mode. (See &quot;Configurable Settings&quot; for additional configurable features.)</td>
</tr>
<tr>
<td>Microstream Disposable</td>
<td>Oridion’s line of Microstream Disposables are available for neonatal, pediatric, and adult patients. Patients can be intubated or nonintubated.</td>
</tr>
<tr>
<td>Programmable Alarm Limits</td>
<td>Alarm limits for EtCO₂, FiCO₂, respiration rates, and No Breath time periods are programmable.</td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td>Patient’s respiratory rate in breaths per minute (breaths/minute).</td>
</tr>
<tr>
<td>Trend Data</td>
<td>Tabular display of EtCO₂ 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.</td>
</tr>
</tbody>
</table>
Features and Displays (Continued)

Operating Features, Controls, Indicators

<table>
<thead>
<tr>
<th>Status Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarm (red)</td>
</tr>
<tr>
<td>Monitoring (green)</td>
</tr>
<tr>
<td>Standby (yellow)</td>
</tr>
</tbody>
</table>

- **IUI Connector, Left** (not visible)
- **EtCO₂ mmHg Display**
- **Respiratory Rate Display**
- **Channel (module) Message Display**
- **Channel (module) Identification**
  - **Channel (module) Select Key:** When pressed, selects corresponding module for patient monitoring setup.
  - **Monitor Key:** When pressed, begins patient monitoring.
  - **Channel (module) Off Key:** When pressed and held until a beep is heard, stops operation on that module, deselects that module, and if only that module had been operating, system powers down. Repeat for other operating modules to power off each module.
- **Protective Door**
- **Microstream Disposable Connector** (Gas Inlet)
- **Module Release Latch:** When pressed, allows module to be removed.
- **Gas Exhaust:** Gas scavenging system connection
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 DFU.

**Configurable Settings**

See the PC Unit section of this DFU 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.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>EtCO₂ Alarm Limit, High</td>
<td>Adult: 60 mmHg</td>
<td>5 - 99 mmHg</td>
</tr>
<tr>
<td></td>
<td>Neonatal: 60 mmHg</td>
<td></td>
</tr>
<tr>
<td>EtCO₂ Alarm Limit, Low</td>
<td>Adult: 10 mmHg</td>
<td>0 - 98 mmHg</td>
</tr>
<tr>
<td></td>
<td>Neonatal: 10 mmHg</td>
<td></td>
</tr>
<tr>
<td>FICO₂ Alarm Limit, High</td>
<td>Adult: 8 mmHg</td>
<td>2 - 99 mmHg</td>
</tr>
<tr>
<td></td>
<td>Neonatal: 8 mmHg</td>
<td></td>
</tr>
<tr>
<td>Limit Mode</td>
<td>Adult</td>
<td>Adult or Neonatal</td>
</tr>
<tr>
<td>No Breath Alarm</td>
<td>Adult: 30 seconds</td>
<td>10 - 60 seconds</td>
</tr>
<tr>
<td></td>
<td>Neonatal: 20 seconds</td>
<td></td>
</tr>
</tbody>
</table>
### Configurable Settings (Continued)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Rate Alarm</td>
<td>Adult Mode: 35 bpm</td>
<td>1 - 150 bpm</td>
</tr>
<tr>
<td>Limit, High</td>
<td>Neonatal Mode: 150 bpm</td>
<td></td>
</tr>
<tr>
<td>Respiratory Rate Alarm</td>
<td>Adult Mode: 6 bpm</td>
<td>0 - 149 bpm</td>
</tr>
<tr>
<td>Limit, Low</td>
<td>Neonatal Mode: 12 bpm</td>
<td></td>
</tr>
</tbody>
</table>

### Specifications and Symbols

#### Specifications

**Accuracy:**

EtCO₂ readings:

<table>
<thead>
<tr>
<th>CO₂ Partial Pressure (at sea level)</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 38 mmHg</td>
<td>±2 mmHg</td>
</tr>
<tr>
<td>39 - 99 mmHg</td>
<td>± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg)</td>
</tr>
</tbody>
</table>

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

**Alarm Limits:**

<table>
<thead>
<tr>
<th>Low</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>EtCO₂</td>
<td>0 - 98 mmHg</td>
</tr>
<tr>
<td>FiCO₂</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>No Breath</td>
<td>10 - 60 sec</td>
</tr>
<tr>
<td>Respiration Rate</td>
<td>0 - 149 breaths/min</td>
</tr>
</tbody>
</table>

**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.
Specifications and Symbols (Continued)

Specifications (Continued)

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:

<table>
<thead>
<tr>
<th></th>
<th>Operating</th>
<th>Storage/Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altitude</td>
<td>-380 - 4570 m (-1250 - 15,000 ft)</td>
<td>-380 - 4570 m (-1250 - 15,000 ft)</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>525 - 795 mmHg (700 - 1060 hPa)</td>
<td>375 - 760 mmHg (500 - 1013 hPa)</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>20 - 90% Noncondensing</td>
<td>5 - 85% Noncondensing</td>
</tr>
<tr>
<td>Sound Pressure</td>
<td>34.9 db</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Temperature Range</td>
<td>41 - 104°F (5 - 40°C)</td>
<td>-4 - 140°F (-20 - 60°C)</td>
</tr>
</tbody>
</table>

Flow Rate: Nominally 50 mL/min -7.5 +15 mL/min

Fluid Ingress Protection: IPX1, Drip Proof

Frequency Response: 
EtCO₂ 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 EtCO₂ 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:
- EtCO₂: 0 - 99 mmHg
- FiCO₂: 0 - 99 mmHg
- Respiratory Rate: 0 - 150 bpm

Mode of Operation: Continuous

Shock Protection: Type BF, Defibrillator Proof
Specifications and Symbols (Continued)

Specifications (Continued)

System Response Time: EtCO₂ 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 EtCO₂ Module response

Warm-Up Time: 30 seconds typical

Weight: 2.5 lbs (0.91 kg)

Symbols

See the PC Unit section of this DFU for system symbols.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Type BF defibrillation-proof equipment." /></td>
<td>Type BF defibrillation-proof equipment.</td>
</tr>
<tr>
<td><img src="image" alt="Gas inlet." /></td>
<td>Gas inlet.</td>
</tr>
<tr>
<td><img src="image" alt="Gas outlet." /></td>
<td>Gas outlet.</td>
</tr>
<tr>
<td><img src="image" alt="Silenced alarm. Note: When displayed, the dashed lines through the symbol might appear as solid lines due to the small display size." /></td>
<td>Silenced alarm. Note: When displayed, the dashed lines through the symbol might appear as solid lines due to the small display size.</td>
</tr>
<tr>
<td><img src="image" alt="Is displayed in Trend Data screen to identify an exceeded alarm limit." /></td>
<td>Is displayed in Trend Data screen to identify an exceeded alarm limit.</td>
</tr>
<tr>
<td><img src="image" alt="Is displayed in Trend Data screen to identify an exceeded no breath alarm limit." /></td>
<td>Is displayed in Trend Data screen to identify an exceeded no breath alarm limit.</td>
</tr>
</tbody>
</table>
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.

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

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.
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.

<table>
<thead>
<tr>
<th>Waveform</th>
<th>Possible Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoventilation</td>
<td>• overmedication</td>
</tr>
<tr>
<td>Hyperventilation</td>
<td>• respiratory distress</td>
</tr>
<tr>
<td>Partial Airway Obstruction</td>
<td>• relaxation of upper airway</td>
</tr>
<tr>
<td></td>
<td>• head position</td>
</tr>
<tr>
<td>Hypoventilation with Shallow Breathing</td>
<td>• medication effect</td>
</tr>
<tr>
<td></td>
<td>• low tidal volume</td>
</tr>
<tr>
<td>No Breath Detected</td>
<td>• apnea</td>
</tr>
<tr>
<td></td>
<td>• very shallow breathing</td>
</tr>
<tr>
<td></td>
<td>• overmedication</td>
</tr>
<tr>
<td></td>
<td>• displaced cannula</td>
</tr>
</tbody>
</table>
The EtCO₂ Module uses Oridion’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 flow rate 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
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. There is 
no effect 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:

PCO₂ = FCO₂ x (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.
**General**

Troubleshooting and maintenance are intended to be performed only by qualified personnel, using the EtCO$_2$ Module Technical Service Manual, and the System Maintenance software. The Service Manual and System Maintenance software are available from CareFusion. The Service Manual 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.

**Alarms and Messages**

See the PC Unit section of this DFU for the following system references:

Alarms, Errors, Messages
Audio Characteristics
Definitions
Display Color
Radio Frequency Note

**Definitions**

- **Alarm Silence**: Alarms can be silenced for up to 120 seconds by pressing SILENCE key. Alarm indicators remain on and alarm silence symbol is displayed. Silence period can be ended by pressing CANCEL SILENCE soft key.

- **Calibration Check**: A technical procedure, outlined in Technical Service Manual to verify instrument calibration.
### Audio Characteristics

<table>
<thead>
<tr>
<th>Type</th>
<th>Sound</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>EtCO₂ Alarm (HIGH PRIORITY)</td>
<td>A sequence of five beeps.</td>
<td>Variable volume; can be silenced for 2 minutes.</td>
</tr>
<tr>
<td>EtCO₂ Alarm (LOW PRIORITY)</td>
<td>One long beep approximately every 4 seconds.</td>
<td>Variable volume; can be silenced for 2 minutes.</td>
</tr>
<tr>
<td>EtCO₂ Error (Hardware Detected)</td>
<td>A single alarm tone volume.</td>
<td>Fixed maximum decibel volume; cannot be silenced.</td>
</tr>
<tr>
<td>EtCO₂ Error (Software Detected)</td>
<td>Pairs of long beeps.</td>
<td>Fixed maximum decibel volume; can be silenced for 2 minutes.</td>
</tr>
</tbody>
</table>

### Alarms

<table>
<thead>
<tr>
<th>High Priority Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHANNEL ERROR</td>
<td>Hardware failure detected by software.</td>
<td>To silence alarm and continue operation of unaffected instrument, press CONFIRM soft key. Replace module, as needed.</td>
</tr>
<tr>
<td>DISPOSABLE DISCONNECTED</td>
<td>Microstream Disposable removed from instrument during monitoring mode.</td>
<td>Attach Microstream Disposable to instrument.</td>
</tr>
<tr>
<td>HIGH ETCO₂</td>
<td>EtCO₂ value is above specified limit.</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>HIGH FICO₂</td>
<td>FiCO₂ value is above specified limit</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>HIGH RR</td>
<td>Respiratory rate is above specified limit.</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>LOW ETCO₂</td>
<td>EtCO₂ value is below specified limit</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
</tbody>
</table>
### Alarms (Continued)

<table>
<thead>
<tr>
<th>High Priority Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW RR</td>
<td>Respiratory rate is below specified limit.</td>
<td>Assess patient condition. Confirm correct alarm limit values are selected.</td>
</tr>
<tr>
<td>NO BREATH DETECTED</td>
<td>No breath detected for a specified period of time.</td>
<td>Assess patient condition. Check Microstream Disposable. Confirm correct disposable is chosen and correct disposable placement.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Low Priority Alarm</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Disconnect Occluded Disposable</td>
<td>Purging operation failed.</td>
<td>Check Microstream Disposable. Obtain a new Microstream Disposable. Attach Microstream Disposable to patient and module.</td>
</tr>
</tbody>
</table>

### Messages

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autozero (in progress)</td>
<td>EtCO₂ Module performs a baseline by sampling CO₂ present in ambient air.</td>
<td>Wait for instrument to complete its auto-zeroing function. After auto-zero cycle is complete, instrument begins measurement again. No user intervention is required.</td>
</tr>
<tr>
<td>Clearing Disposable</td>
<td>Microstream Disposable blocked.</td>
<td>Check Microstream Disposable. Wait for purging to complete.</td>
</tr>
<tr>
<td>Disposable Disconnected</td>
<td>No Microstream Disposable present and instrument not in monitoring mode.</td>
<td>Attach Microstream Disposable to patient and instrument to begin monitoring.</td>
</tr>
<tr>
<td>Patient Not Detected</td>
<td>Monitor or Channel Select key pressed and patient not detected.</td>
<td>Assess patient condition. Check disposable.</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSPECT FOR DAMAGE</td>
<td></td>
</tr>
<tr>
<td>• Exterior Surfaces</td>
<td>• Each usage</td>
</tr>
<tr>
<td>• IUI Connector</td>
<td>• Each usage</td>
</tr>
<tr>
<td>• Keypad</td>
<td>• Each usage</td>
</tr>
<tr>
<td>CLEANING</td>
<td>As required</td>
</tr>
<tr>
<td>START-UP</td>
<td>Each usage</td>
</tr>
</tbody>
</table>

**WARNING**

Failure to perform these inspections can result in improper instrument operation.

**CAUTION**

Preventive maintenance inspections should only be performed by qualified service personnel.
Alaris™ Auto-ID Module
Model 8600
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This section of the DFU provides Auto-ID Module (Model 8600) instructions and information. It is used in conjunction with:

- Auto-ID Label Specification
- Module-specific chapters of this DFU
- PC Unit section of this DFU
- 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 combines Guardrails™ Suite MX with dose limit technology and bar code technology to provide a new level of medication safety. The Auto-ID Module contains an internal bar code image scanner and supports an optional handheld scanner supplied by CareFusion. Scanning a bar-coded clinician ID and/or a bar-coded 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 DFU ("Regulations and Standards," "Compliance").
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.
   - 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.
6. To scan bar code on patient identification band, press scan trigger on handheld scanner. 

- 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 bar code is scanned at main screen and panel is unlocked, a prompt to confirm type of bar code scanned appears. This occurs whether Authorized User Mode is enabled or disabled.

7. 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 DFU).

---

**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.

2. To scan bar code on patient identification band, press scan trigger on handheld scanner. 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 DFU).

---

**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.
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 bar code on their ID badge can program Alaris System.
- Is available only if it is enabled in selected profile and there is an 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 bar code is scanned at the main screen and the keypad is unlocked, a prompt to confirm the type of bar code 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 key 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.

3. Program infusion.
   When no keys have been pressed on PC Unit for a 5-minute period, tamper resist mode is automatically enabled.
Primary Infusion

Utilizing the Auto-ID Module to scan IV medication containers provides the ability to support verification of the right medication and concentration, and enhances safety through the use of the Guardrails Suite MX. It compares the medication identifier from the IV container bar code with the medication identifier from the Drug Library. If the patient ID is in the IV container bar code, the system also compares the patient identifier in the barcode with the patient identifier in the PC Unit.

When the green READY indicator illuminates, the system is ready to scan.

1. To scan bar code on IV container, press SCAN/CANCEL key on 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 DFU).

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.
To start a secondary infusion while a primary infusion is in progress:

1. To scan bar code on IV container, press SCAN/CANCEL key on 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 DFU).

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 DFU, "General Setup and Operation," for various system start-up and setup procedures.


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 Scanner

The handheld external scanner supplied by CareFusion is the only handheld scanner approved for use with the Auto-ID Module.

**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 and Definitions

See the PC Unit section of this DFU for system features and definitions.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audible Scan Indicator</td>
<td>Provides audible confirmation of a successful scan.</td>
</tr>
<tr>
<td>Bar Code</td>
<td>A machine-readable label used for automatic identification. Automatic identification (Auto-ID) is the broad term given to a host of technologies</td>
</tr>
<tr>
<td></td>
<td>used to help machines identify objects and is often coupled with automatic data capture. These technologies include bar codes, smart cards, voice</td>
</tr>
<tr>
<td></td>
<td>recognition, some biometric technologies (for example, retinal scans), optical character recognition, and others.</td>
</tr>
<tr>
<td>Built-In Optical Scan Engine</td>
<td>Employs technology similar to a digital camera to read bar codes. Allows use of two-dimensional bar codes.</td>
</tr>
<tr>
<td>Handheld Scanner with Optical</td>
<td>Allows scanning of patient ID, and of IV containers that have already been hung on IV pole.</td>
</tr>
<tr>
<td>Scan Engine</td>
<td></td>
</tr>
<tr>
<td>Light Emitting Diode (LED)</td>
<td>Bar code scanner uses an array of high intensity LEDs to illuminate bar code image (see &quot;Specifications&quot;).</td>
</tr>
<tr>
<td>Two-Dimensional Bar Code</td>
<td>Can contain more information and is more easily read by Auto-ID Module; for example, patient ID and drug ID can be in same bar code.</td>
</tr>
</tbody>
</table>
Features (Continued)

Operating Features, Controls, Indicators

**IUI Connector, Left**

**IUI Connector, Right** (not visible)

**READY Indicator:** Green LED illuminates to provide visual confirmation that module or handheld scanner is ready to scan.

**SCAN/CANCEL Key:** When initially pressed, scanning is initiated by embedded scanner. Subsequent press cancels scan.

**Image Scanning Window**

**Handheld external scanner connection port**

**Module Release Latch:** When pressed, allows module to be removed.
Configurable Settings

See the PC Unit section of this DFU 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:

<table>
<thead>
<tr>
<th>Environmental Condition</th>
<th>Operating</th>
<th>Storage/Transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atmospheric Pressure</td>
<td>525 - 4560 mmHg (700 - 6080 hPa)</td>
<td>375 - 760 mmHg (500 - 1013 hPa)</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>20 - 90% Noncondensing</td>
<td>5 - 85% Noncondensing</td>
</tr>
<tr>
<td>Temperature Range</td>
<td>41 - 104°F (5 - 40°C)</td>
<td>-4 - 140°F (-20 - 60°C)</td>
</tr>
</tbody>
</table>

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)

Electronic Memory:

System configuration parameters stored in volatile memory are retained for at least 6 months by PC Unit internal backup lithium battery. Module-specific Auto-ID parameters are stored for 8 hours by PC Unit when system is turned off. After 8 hours of continuous off time, or if module is changed, system automatically purges module-specific information.
Specifications and Symbols  (Continued)

Specifications (Continued)

<table>
<thead>
<tr>
<th>Alaris Auto-ID Module</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fluid Ingress Protection:</strong></td>
</tr>
<tr>
<td><strong>Mode of Operation:</strong></td>
</tr>
<tr>
<td><strong>Shock Protection:</strong></td>
</tr>
<tr>
<td><strong>Weight:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Handheld Scanner</th>
</tr>
</thead>
</table>
| **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 bar codes which are within the bar code print quality guidelines specified by ANSI X 3.182, CEN EN 1635, and ISO/IEC 15416 international standards. Some manufacturer-applied bar codes 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 bar code label information.

Symbols

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Input Symbol]</td>
<td>Input. Handheld connection point.</td>
</tr>
</tbody>
</table>
Troubleshooting and Maintenance

General

Troubleshooting and maintenance are intended to be performed only by qualified personnel, using the Auto-ID Module Technical Service Manual and the System Maintenance software. The Service Manual and System Maintenance software are available from CareFusion. The Service Manual 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, and other maintenance functions.

Errors and Messages

See the PC Unit section of this User Manual for the following system references:

Alarms, Errors, Messages
Audio Characteristics
Definitions
Display Color
Radio Frequency Note

Errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician ID is invalid</td>
<td>Clinician ID is not recognized.</td>
<td>Ensure that ID label is legible. Enter ID manually.</td>
</tr>
<tr>
<td>Patient ID is invalid</td>
<td>Patient ID is not recognized.</td>
<td>Ensure that ID label is legible. Enter ID manually.</td>
</tr>
<tr>
<td>Scanned label is invalid</td>
<td>Profile feature might be disabled. Bar code might not be readable or a supported symbology.</td>
<td>Ensure that Profile is enabled. Ensure that ID label is legible. Inform pharmacy of problem.</td>
</tr>
<tr>
<td>Scanned medication label is invalid</td>
<td>Bar code might not be readable or a supported symbology.</td>
<td>Ensure that ID label is legible. Inform pharmacy of problem.</td>
</tr>
</tbody>
</table>
Errors and Messages (Continued)

Messages

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug or Fluid not in current profile</td>
<td>Drug and its concentration might not be in currently selected profile.</td>
<td>Ensure that correct profile is selected and that it has correct drug and concentration.</td>
</tr>
<tr>
<td>Channel unavailable</td>
<td>Channel is currently infusing and cannot support scanned infusion.</td>
<td>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.</td>
</tr>
</tbody>
</table>

Inspection Requirements

To ensure that the 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

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSPECT FOR DAMAGE</td>
<td></td>
</tr>
<tr>
<td>• Exterior Surfaces</td>
<td>• Each usage</td>
</tr>
<tr>
<td>• IUI Connector</td>
<td>• Each usage</td>
</tr>
<tr>
<td>• Keypad</td>
<td>• Each usage</td>
</tr>
<tr>
<td>• Mechanical Parts</td>
<td>• Each usage</td>
</tr>
<tr>
<td>CLEANING</td>
<td>As required</td>
</tr>
<tr>
<td>START-UP</td>
<td>Each usage</td>
</tr>
</tbody>
</table>

WARNING

Failure to perform these inspections can result in improper instrument operation.

CAUTION

Preventive maintenance inspections should only be performed by qualified service personnel.
Appendix

Maintenance
Regulations and Standards
Inspect and clean the product per the following procedures. Read all warnings and cautions before continuing with this procedure.

**Alaris™ System**

### Cleaning Products

The following basic cleaners are approved for use on the Alaris System:

<table>
<thead>
<tr>
<th>Cleaner</th>
<th>Dilution</th>
</tr>
</thead>
<tbody>
<tr>
<td>10% bleach</td>
<td>1 part bleach to 9 parts water</td>
</tr>
<tr>
<td>70% isopropyl alcohol (IPA)</td>
<td>not applicable</td>
</tr>
<tr>
<td>mild detergent</td>
<td>per manufacturer’s recommendation, as needed</td>
</tr>
<tr>
<td>warm water</td>
<td>not applicable</td>
</tr>
</tbody>
</table>


### Procedure

1. Inspect instrument for damage.
   - a. Inspect instrument for visible external damage, such as a cracked or broken door, case, handle, or latch, or a damaged IUI connector.
   - b. All damages must be repaired prior to placing the instrument back in use.

2. Clean instrument.
   - Do not allow a cleaning solution other than 70% IPA to contact the IUI connectors. See step 3 for IUI connector cleaning instructions.
   - a. Keep instrument upright and do not allow any part of instrument to become saturated with or submerged in fluid during cleaning operation.

### WARNINGS

- 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.

### CAUTIONS

- The use of **unapproved cleaners 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 **IUI connector** when cleaning the instrument.
- **Do not use hard, abrasive or pointed objects** to clean any part of the instrument.
b. Clean all exposed surfaces using a disposable wipe or a clean soft cloth dampened with cleaning solution. A soft-bristled brush can be used to clean hard to reach and narrow areas, and to remove hardened organic deposits.

c. Remove adhesive residue using 70% IPA.

d. Thoroughly remove cleaning solution using a clean soft cloth dampened with water.

3. Clean IUI connectors.
   a. If surface contaminants, or blue or green deposits, are visible, connector must be replaced.
   b. Apply 70% IPA to surface of IUI connectors using a soft-bristled brush.

4. Ensure that instrument, and IUI connectors, are thoroughly dry (dry to the touch) before returning to use. Dry time is dependent on temperature, humidity and area ventilation.

**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.

**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.
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.

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

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.

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.
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 directions for use, 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.

Cet appareil numerique de la Classe B respecte toutes les exigences du Reglement sur le materiel 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 Mbits/s physical RF specification.
- **802.11b**: 2.4 GHz band, up to 11 Mbits/s physical RF specification.
- **802.11g**: 2.4 GHz band, up to 54 Mbits/s 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**

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment—Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>CISPR 11 RF Emissions</td>
<td>Group 1</td>
<td>Alaris System uses RF energy only for its internal function in normal product offering. Following icon appears on product. Refer to network card's directions for use for further information.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RF emissions are very low and are not likely to cause interference with nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11 RF Emissions</td>
<td>Class B</td>
<td>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.</td>
</tr>
<tr>
<td>IEC 61000-3-2 Harmonic Emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2 Voltage Fluctuations Flicker Emissions</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2
Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>IEC 60601-1-2 Test Level&lt;sup&gt;®&lt;/sup&gt;</th>
<th>Compliance Level&lt;sup&gt;®&lt;/sup&gt;</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
</table>
| IEC 61000-4-2 Electrostatic Discharge (ESD)         | ±6 kV contact ±8 kV air              | ±8 kV contact<sup>®</sup>  ±15 kV air<sup>®</sup> | 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. “- Do Not Touch” |
| IEC 61000-4-4 Electrical Fast Transient, Burst (EFT)<sup>®</sup> | ±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 Power Line Surge<sup>®</sup>         | ±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<sup>®</sup> 400 A/m 60 Hz<sup>®</sup> | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
### Table 2 (Continued)
**Electromagnetic Immunity**

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>IEC 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-11 Voltage Dips, Short Interruptions, and Voltage Variations</td>
<td>&lt;5% (U_T) (&lt;95% dip in (U_T)) for 0.5 cycle</td>
<td>&lt;5% (U_T) (&lt;95% dip in (U_T)) for 0.5 cycle</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>40% (U_T) (60% dip in (U_T)) for five cycles</td>
<td>40% (U_T) (60% dip in (U_T)) for five cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% (U_T) (30% dip in (U_T)) for 25 cycles</td>
<td>70% (U_T) (30% dip in (U_T)) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5% (U_T) (&gt;95% dip in (U_T)) for 5 sec</td>
<td>&lt;5% (U_T) (&gt;95% dip in (U_T)) for 5 sec</td>
<td></td>
</tr>
</tbody>
</table>
### Electromagnetic Environment (Continued)

#### Compliance (Continued)

**Table 3**
Electromagnetic Immunity - Life Support Equipment

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-6 Conducted RF</td>
<td>10 Vrms 150 kHz - 80 MHz</td>
<td>20 Vrms</td>
<td>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: $rac{12}{\sqrt{P}}$</td>
</tr>
<tr>
<td>IEC 61000-4-3 Radiated RF</td>
<td>10 V/m 80 MHz - 2.5 GHz</td>
<td>20 V/m</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than compliance level in each frequency range.</td>
</tr>
</tbody>
</table>

Interference might occur in vicinity of equipment marked with following symbol:

![Interference Symbol]
**Electromagnetic Environment (Continued)**

Table 4

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.

<table>
<thead>
<tr>
<th>Rated Maximum Output Power of Transmitter (W)</th>
<th>Separation Distance Based on Transmitter Frequency (m)</th>
<th>150 kHz - 80 MHz Outside ISM Bands</th>
<th>150 kHz - 80 MHz In ISM Bands</th>
<th>80 MHz - 800 MHz</th>
<th>800 MHz - 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5 ( \frac{\sqrt{P}}{V_1} )</td>
<td>12 ( \frac{\sqrt{P}}{V_2} )</td>
<td>12 ( \frac{\sqrt{P}}{E_1} )</td>
<td>23 ( \frac{\sqrt{P}}{E_1} )</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.01</td>
<td>0.02</td>
<td>0.06</td>
<td>0.06</td>
<td>0.12</td>
<td></td>
</tr>
<tr>
<td>0.1</td>
<td>0.06</td>
<td>0.19</td>
<td>0.19</td>
<td>0.36</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.18</td>
<td>0.6</td>
<td>0.6</td>
<td>1.15</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>0.55</td>
<td>1.9</td>
<td>1.9</td>
<td>3.64</td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>1.75</td>
<td>6</td>
<td>6</td>
<td>11.5</td>
<td></td>
</tr>
</tbody>
</table>
NOTE:
① Compliance levels raised by IEC 60601-2-24.
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 $[V_T] \text{ V/m}$.
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 Server 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
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 directions for use, 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 Reglement sur le Matériel Brouilleur du Canada.

This Class B digital device meets the requirements of the International community.

Australian Communications Authority C-Tick mark N12875.

Applicant:

CareFusion Australia 316 Pty LTD
P.O. Box 355
Seven Hills West, NSW
Australia 2147

Phone: 02 9838 0255
Fax: 02 9674 4444
The Alaris System has been assessed and complies with the following standards:

**PC Unit and overall System:** UL 60601–1, CAN/CSA C22.2 No. 601.1–M90, IEC 60601–1

**Auto-ID Module:** IEC 60825–1 (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) and 18 (Medical Devices) of the FCC Rules and Regulations. 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, ASTM F 1456-01, ASTM F 1463, EN 475, EN 864

**PCA, Pump and Syringe Modules:** IEC 60601-2-24, ANSI/AAMI ID:26

**SpO₂ Module:** EN 865
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