BD Alaris™ System with Guardrails™ Suite MX

For BD Alaris™ PCU Model 8015 and
Alaris™ PCU Model 8015
Software Version 12.1.2 and Supported Modules

User Manual

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BD Alaris™ System with Guardrails™ Suite MX User Manual

The information in this document is subject to change and does not represent a commitment on the part of BD to provide additional services or enhancements. The screens illustrated in the document are for reference purposes only and might be different than the screens displayed on your computer. Documentation provided with this product might reference product not present in your facility or not yet available for sale in your area.

If difficulties are encountered while using this software, refer to the user manual, service manual, or related service bulletin(s) before contacting BD. Provide a description of the difficulty experienced, any messages that were displayed at the time of the difficulty, and the software version. Before you return the software to BD, contact BD to get a return authorization number. Put the software in its original packaging (if available), write the return authorization number on the package, and return to the nearest facility.

To request a printed copy of this document, contact BD at 800.482.4822, or contact your local BD representative. Provide the document's part number listed on the cover page. Allow approximately two weeks for shipment to a location within the United States. Shipments to locations outside the United States may take longer.

Report any serious incident that has occurred in relation to this product to your BD representative (or manufacturer).

Caution: Federal law restricts this device to sale by or on the order of a physician or other licensed healthcare professional.

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DME: 10000384478-01

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About this Guide

This chapter contains the following topics:

Intended Use and Indications for Use

BD Alaris™ System with Guardrails™ Suite MX

Intended Use

The BD Alaris™ System with Guardrails™ Suite MX is intended for use by healthcare professionals for the monitoring and controlled delivery of fluids, medications, blood and blood products into patients.

Indications for Use

The BD Alaris™ System with Guardrails™ Suite MX is a modular infusion pump and monitoring system for the continuous or intermittent administration of fluids to adult, pediatric and neonatal patients through clinically accepted routes of administration: intravenous (IV), intra-arterial (IA), subcutaneous, epidural, or irrigation of fluid spaces. Administered fluids include pharmaceutical drugs, blood and blood components as required for patient therapy. The BD Alaris™ System with Guardrails™ Suite MX is an interoperable system capable of communicating and exchanging data with compatible information technology systems.

The BD Alaris™ System with Guardrails™ Suite MX includes the PC Unit (PCU) and one or more of the following: Pump Module, Syringe Module, end-tidal CO_2 ($EtCO_2$) Module, Auto-ID Module, patient controlled analgesia (PCA) Module, and associated software applications. $EtCO_2$ Module is a capnograph that continuously monitors end tidal carbon dioxide ($EtCO_2$), fractional inspired carbon dioxide ($FiCO_2$), and respiratory rate (RR).

BD Alaris™ Pump Module, Alaris™ Syringe Module, and Alaris™ PCA Module are indicated for varying patient populations, routes of administration, and infusates. Refer to the table below for the module-specific variations.

Module	Route of Administration	Infusates	Patient Populations
BD Alaris™ Pump Module	Intravenous	Fluids, pharmaceutical drugs, blood and blood products	Adult Pediatric Neonatal
	Subcutaneous	Fluids and pharmaceutical drugs	
	Epidural	Pain management medications	
	Intra-arterial	Pharmaceutical drugs	
	Irrigation of fluid spaces	Irrigation solutions	
Alaris™ Syringe Module	Intravenous	Fluids, pharmaceutical drugs, blood and blood products	
	Subcutaneous	Pharmaceutical drugs	
	Epidural	Pain management medications	
	Intra-arterial	Pharmaceutical drugs	
Alaris™ PCA Module	Intravenous	Pain management medications	
	Subcutaneous		
	Epidural		

Contraindications

Situations in which the device should not be used because the risk of use clearly outweighs the benefits.

BD Alaris™ System Contraindications

- The BD Alaris™ System is contraindicated for enteral route of administration.

Summary of Warnings and Cautions

WARNING

- **Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System (see *Introduction* on page *xvi*).**
- **Use only BD manufactured parts in the operation and maintenance of your BD equipment. Use of repair or service parts, accessories, or syringes, dedicated infusion sets, or disposables that are not approved by BD is at customer's own risk and could expose patients to risk of device failure, injury, or even death. In addition, use of such parts, accessories, or disposables may void the product warranty provided by BD.**
- **Use only BD approved parts when performing corrective maintenance or repairs. Use of third party parts can affect the safety and efficacy of the BD Alaris™ and Alaris™ devices, leading to risk of device failure, patient injury, or even death (see *Approved Parts Recommendation* on page *xix*).**
- **If it becomes necessary to replace the following cables or accessories, use only approved parts that are listed in the technical service manual. Use of other parts may affect the safety and efficacy of the BD Alaris™ System, leading to risk of device failure, patient injury, or even death.**
  - **PCU Power Cord**
  - **PCU Serial Cable**
  - **PCA Dose Request Cord**
  - **Auto-ID Handheld Scanner**

CAUTION

- Rx Only: Prescription use only (see *Introduction* on page *xvi*).

Introduction

WARNING

Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System.

CAUTION

Rx Only: Prescription use only.

The BD Alaris™ PCU section of this user manual provides procedures and information applicable to the BD Alaris™ System and the PCU. Each of the other major sections provides product-specific procedures and information.

The system is a portable modular system intended for adult, pediatric, and neonatal care. The system consists of the PCU, the Guardrails™ Suite MX, and up to four detachable infusion and/or monitoring modules (channels). An Alaris™ Auto-ID Module may be added to the system with any combination of one to four other modules. The use of the system is restricted to one patient at a time.

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

BD Alaris™ Guardrails™ Suite MX

Guardrails™ Suite MX for the system brings a new level of medication error prevention to the point of patient care. The Guardrails™ Suite MX features medication dosing, concentration delivery rate, and optional initial programming guidelines for up to 30 patient-specific care areas, referred to as profiles.

A total of up to 10,000 unique drug/concentration or fluid entries (setups) can be created and distributed between profiles with a maximum of 1,500 setups per profile. 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™ Suite MX 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 BD Alaris™ Guardrails™ Editor software, the PC-based authoring tool. A data set is then transferred to the system by qualified personnel and then activated by the clinical staff. The approved data sets are maintained by the Guardrails™ Editor software for future updates and reference.

Information about alerts that occur during use are stored within the PCU, and can be accessed using the Guardrails™ CQI Reporter software.

Warnings, Cautions, and Notes

Product-specific warnings and cautions, covered in the applicable sections of this user manual, provide information needed to safely and effectively use the system.

WARNING

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

CAUTION

A statement that alerts the user of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

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

Essential Performance

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

The BD Alaris™ System is designed to provide an accurate measurement of a patient's end-tidal CO_2 levels and will detect and alarm for physiological conditions that are out of range.

Defined Terms

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

Product/Feature	Defined Term
Alaris™ Auto-ID Module	Auto-ID Module
Alaris™ $EtCO_2$ Module	$EtCO_2$ Module
Alaris™ PCA Module	PCA Module
Alaris™ PCU	PCU
Alaris™ Pump Module	Pump Module
Alaris™ Syringe Module	Syringe Module
BD Alaris™ PCU	PCU
BD Alaris™ Pump Module	Pump Module
BD Alaris™ System or Alaris™ System (includes PCU and one or more modules, such as Pump Module, Syringe Module, PCA Module, $EtCO_2$ Module, or Auto-ID Module)	system
BD Alaris™ System Maintenance	System Maintenance
BD Alaris™ Systems Manager	Systems Manager
Guardrails™ alert	alert
Guardrails™ clinical advisory	clinical advisory
Guardrails™ CQI Reporter	CQI Reporter
Guardrails™ data set	data set
Guardrails™ drug library	drug library
BD Alaris™ Guardrails™ Editor	Guardrails™ Editor
Guardrails™ hard limit	hard limit
Guardrails™ IV fluid	IV fluid
Guardrails™ limit	limit
Guardrails™ PCA pause protocol	PCA pause protocol
Guardrails™ soft limit	soft limit
Infusion set	IV set administration set
SmartSite™ needle-free valve	needle-free valve

Approved Parts Recommendation

WARNING

Use BD manufactured parts in the operation and maintenance of your BD equipment. Use of repair or service parts, accessories, or syringes, dedicated infusion sets, or disposables that are not approved by BD is at customer's own risk and could expose patients to risk of device failure, injury, or even death. In addition, use of such parts, accessories, or disposables may void the product warranty provided by BD.

Any 510(k) clearance from the Food and Drug Administration (FDA) or regulatory approval secured by BD to market the BD Alaris™ System was based on use of BD manufactured parts and equipment and BD validated and authorized disposables. A list of BD approved disposables that are validated to be compatible with the BD Alaris™ System is provided in the BD Alaris™ System user manual. BD has not validated any non-BD parts or accessories for the maintenance, repair or operation of the BD Alaris™ System and Alaris™ System products. Because unauthorized parts and accessories were not included in the review and approval/clearance of the products, their use may adulterate and misbrand the product in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §302 et seq or other laws.

WARNING

Use only BD approved parts when performing corrective maintenance or repairs. Use of third party parts can affect the safety and efficacy of the BD Alaris™ and Alaris™ devices, leading to risk of device failure, patient injury, or even death.

WARNING

If it becomes necessary to replace the following cables or accessories, use only approved parts that are listed in the technical service manual. Use of other parts may affect the safety and efficacy of the BD Alaris™ System, leading to risk of device failure, patient injury, or even death.

- **PCU Power Cord**
- **PCU Serial Cable**
- **PCA Dose Request Cord**
- **Auto-ID Handheld Scanner**

Product Compatibility

The following tables list the compatibility of the v12.1.2 products.

BD Alaris™ System Device Compatibility

PCU	Pump Module	Syringe Module	PCA Module	$EtCO_2$ Module	Auto-ID Module	Wireless Card
12.1.2	12.1.2	12.1.2	12.1.2	12.1.2	8.5.26	b/g a/b/g a/b/g/n

BD Alaris ™ PCU and Alaris™ PCU with BD Alaris™ Systems Manager

PCU	Systems Manager	System Maintenance	Guardrails™ Editor	CQI Reporter	EMR Interoperability	Asset Management
12.1.2	12.3. x	12.3. x	12.1.2	10.17	Yes	Yes

BD Alaris ™ PCU and Alaris™ PCU without BD Alaris™ Systems Manager

PCU	System Maintenance	Guardrails™ Editor	CQI Reporter
12.1.2	12.3. x	12.1.2	10.17

NOTE:
The Alaris™ SpO_2 models 8210 and 8220 are not supported or compatible with the BD Alaris™ PCU and Alaris™ PCU model 8015, version 12.1.2.

If an SpO_2 Module is attached to a PCU version 12.1.2, a channel error message with error code 400.5040 will appear on the PCU display.

Installation

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

Prior to Placing the System in Use

1. Perform the check-in procedure using System Maintenance software (see *BD Alaris™ System Maintenance User Manual, Chapter 3 Preventive Maintenance*).
2. Load the hospital-defined best-practice data set using one of the following methods:
   - If using Systems Manager, transfer the data set wirelessly to the PCU (see *BD Alaris™ Systems Manager User Manual).*
   - If not using Systems Manager, use the System Maintenance or the Guardrails™ Editor transfer tool to transfer the data set to the PCU (see *BD Alaris™ System Maintenance User Manual* or *BD Alaris™ Guardrails™ Editor User Manual).*
3. Power cycle the PCU.
4. Press **Yes** on the New Patient message to activate the data set and select the desired profile (see *Selecting New Patient and Profile Options* on page *20*).

   NOTE:
   To enable the profiles feature, a hospital-defined best-practice data set must be uploaded to the PCU.
5. Clean PCUs and all modules before placing the instruments in clinical use. See *Cleaning* on page *449*.

Symbols Glossary

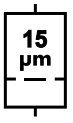
The following table shows the symbols and the applicable standards used in this user manual.

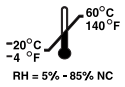
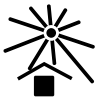
Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	The infusion alarm silence symbol indicates that infusion alarms have been acknowledged and silenced. Press the CANCEL SILENCE soft key to reactivate a previously silenced alarm audio. If the alarm condition has not been resolved, the alarm audio will resume.	Bell Canceled Acknowledge (Alarm Cancel)	PCU Interface	Ref 5576-1 IEC 60417-1 Graphical Symbols for use on equipment. Part 1: Overview and Application
	The infusion alarm silence symbol indicates the module that has been acknowledged and silenced.	Bell Cancel (Alarm Cancel)	PCU Interface	Ref 5576-1 IEC 60417-1 Graphical Symbols for use on equipment. Part 1: Overview and Application
	Type CF defibrillation-proof patient applied part.	Defibrillation-proof Type CF Applied Part.	PCU, Pump Module, Syringe Module, PCA Module device labels	Ref 5336 IEC 60417-1 Graphical Symbols for use on equipment. Part 1: Overview and Application
	Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety and performance standards.	Canadian and U.S. Certification Mark	PCU and all modules device labels	NA
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	Follow instructions for use	PCU and all modules device labels	Ref. 10: IEC 60601-1, Table D.2, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
	Alternating Current: Indicates device should be attached to alternating current source, 50/60 Hz only.	Alternating Current	PCU device label	Ref 5032 IEC 60417-1 Graphical Symbols for use on equipment. Part 1: Overview and Application
	Warning: Refer to accompanying documentation.	Warning	PCU, all modules, and PCA handset device labels, user manuals, CD and box labels, and quick reference guides	ISO 7010 Symbol Ref: Symbol- W001 Per. IEC 60601-1:2012 Clause 7.5

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	Caution: Refer to accompanying documentation.	Caution	User manuals and quick reference guides	Ref 0434A IEC-TR-60878 Graphic symbols for electrical equipment used in a medical practice
IPX2	Degree of particle and water ingress protection.	Degrees of ingress protection provided by enclosure	PCU, all modules, and PCA handset device labels	Ref. 2: IEC 60601-1, Table D.3, General requirements for basic safety and essential performance
	IUI Connector: Inter-Unit Interface connector used to establish power and communications between PCU and attached modules.	Input-output	PCU and all modules side panel	Ref. 5448 IEC-TR-6078 Graphic symbols for electrical equipment in a medical practice
	Indicates the date on which a product was manufactured.	Date of manufacturer	Unique device identification (UDI) label for PCU, and all modules	Ref. 2497 IEC-TR-6078 Graphic symbols for electrical equipment in a medical practice
	Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	Non-ionizing electromagnetic radiation	PCU front panel and user manual	Ref. 5140 IEC-TR-6078 Graphic symbols for electrical equipment in medical practice
	Federal Law restricts device to sale by or on the order of a licensed health provider.	Prescription use only	User manual, CD and box labels, and external packaging	21 CFR 801.109
	Complies with Australian Communications Requirements.	Australian Communications Authority	PCU device label and user manual	NA
	Meets FCC requirements per 21 CFR Part 15.	Federal Communication Authority	PCU and all modules device labels	Meets FCC requirements per 21 CFR Part 15
	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment.	Magnetic resonance (MR) unsafe	PCU device label	ASTM F2503 Reference no. Table 2, symbol 7.3.3; 7.4.9: Fig 9
	Plug the PCU into an AC outlet during storage to ensure a fully charged battery. The AC indicator light is on when the PCU is plugged in.	Power plug	PCU front panel	Ref 5334 IEC-TR-60878: Graphical symbols for electrical equipment in a medical practice

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.	Atmospheric pressure limitation	User manual and shipping label	Ref 2621 IEC-TR-60878 Graphical symbols for electrical equipment in a medical practice
	Indicates the acceptable upper and lower limits of Relative humidity for transport and storage.	Humidity limitation	User manual and external packaging	Ref 2620 IEC-TR-60878 Graphical symbols for electrical equipment in a medical practice
	Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.	Temperature limitation	User manual	Ref 5.3.6 ISO 15223-1 Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Consult Instructions for Use	Consult instructions for use symbol	PCU and all modules device labels	Ref 5.4.3 ISO 15223-1 Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirements
	Protective earth (ground)	Protective earth (ground)	PCU back panel	Ref 5019 IEC-TR-60878 Graphic symbols for use on electrical equipment in medical practice
	Identifies a connector for a serial data connection.	Serial interface	PCU back panel	Ref 5850 IEC 60417 Graphic symbols for use on electrical equipment
	Indicates that a control function is locked or to show the locked status.	Locking, general	PCU back panel	Ref 5569 IEC 60417 Graphic symbols for use on electrical equipment
	Indicates that a function is not locked or to show the unlocked status.	Unlocking	PCU back panel	Ref 5570 IEC 60417 Graphic symbols for use on electrical equipment
	Identifies the manufacturer of a product.	Manufacturer	PCU and all modules device labels, user manual, and external packaging	Ref. 3082 IEC-TR-6078 Graphic symbols for electrical equipment in a medical practice
	Defibrillation-proof type BF applied part complying with IEC 60601-1.	Defibrillation-proof Type BF applied part	PCA handset	Ref. 5334 IEC-TR-6078 Graphic symbols for electrical equipment in a medical practice

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	Type BF applied part complying with IEC 60601-1.	Type BF applied part	$EtCO_2$ Module, Auto-ID Module device labels	Ref. 0795 IEC-TR-6078 Graphic symbols for electrical equipment in a medical practice
	Gas inlet	Input; entrance	$EtCO_2$ Module front panel	Ref. 0794 IEC-TR-6078 Graphic symbols for electrical equipment in a medical practice
	Gas outlet	Output; exit	$EtCO_2$ Module front panel	Ref. 0795 IEC-TR-6078 Graphic symbols for electrical equipment in a medical practice
	This symbol is accompanied by a date to indicate that the device should not be used after the end of the year, month or day shown.	Use by date	Disposable packaging	Ref 5.1.4 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied
	Indicates the manufacturer's catalogue number so that the medical device can be identified.	Catalogue number	Disposable packaging, PCU and all modules device labels, CD and box labels, and shipping labels	Ref 5.1.6 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	Do not re-use	Disposable packaging	Ref 5.4.2 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile. The method of sterilization shall be indicated in the empty box, as appropriate.	Sterile fluid path	Disposable packaging	Ref 5.2.3 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied.

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	Indicates a medical device that has been sterilized using irradiation.	Sterilized using irradiation	Disposable packaging	Ref 5.2.4 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates a medical device that is not to be resterilized.	Do not resterilize	Disposable packaging	Ref 5.2.6 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates a medical device that has not been subjected to a sterilization process.	Non-sterile	Disposable packaging	Ref 5.2.7 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates a medical device that is non-pyrogenic.	Non-pyrogenic	Disposable packaging	Ref 5.6.3 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates the number of drops per milliliter.	Drops per milliliter	Disposable packaging	Ref 5.6.4 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size.	Liquid filter with pore size	Disposable packaging	5.6.5 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	Contains or presence of natural rubber latex	Disposable packaging	Ref 5.4.5 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	Medical device is derived from or manufactured from products that contain bis (ethylhexyl) phthalate (DEHP).	Contains or presence of bis (ethylhexyl) phthalate (DEHP)	Disposable packaging	Ref A.1 BS EN 15986 Symbols for use in the labeling of medical devices - Requirements for labeling of medical devices containing phthalates
	Indicates a medical device that should not be used if the package has been damaged or opened.	Do not use if package is damaged	External packaging	Ref 5.2.8 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates that the marked item or its materials is part of a recovery or recycling process.	General symbol for recover/ recyclable	External packaging	Ref 1135 IEC-TR-60878 Graphical symbols for electrical equipment in a medical practice
	Indicates that the items are not to be vertically stacked higher than the specified number of items.	Stacking limits by number	External packaging	Ref 2403 IEC-TR-60878 Graphical symbols for electrical equipment in a medical practice
	Indicates the temperature limits to which the medical device can be safely exposed.	Temperature limit	External packaging	Ref 5.3.7 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates a medical device that needs to be protected from moisture.	Keep dry	External packaging	Ref 5.3.4 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	This side up.	This way up	External packaging	Ref No. 13 ISO 780 Packaging Distribution Packaging-Graphical Symbols for handling and storage of packages
	Indicates a medical device that needs protection from light sources.	Keep away from sunlight	External packaging	Ref 5.3.2 ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	Indicates a medical device that can be broken or damaged if not handled carefully.	Fragile, handle with care	External packaging	Ref: 5.2.9 ISO 15223-1 Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Authorized EC Representative.	Authorized representative in the European Community	PCU and all modules device labels, shipping label (International only), and user manual	Ref 5.1.2 ISO 15223-1 Medical devices-symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirement
	Indicates a medical device that has been sterilized using ethylene oxide.	Sterilized using ethylene oxide	Disposable packaging	Ref 5.2.3 ISO 15223-1 Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates packages contain electrostatic sensitive devices.	Electrostatic sensitive devices	User manual	Ref. 5134 IEC-TR-6078 Graphic symbols for electrical equipment in a medical practice

Chapter 1
BD Alaris™ PCU Model 8015

This chapter contains the following topics:

Summary of Warnings and Cautions

General

WARNING

- **Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System (see *About this Chapter* on page *8*).**
- **Explosion risk if used in the presence of flammable anesthetic agents or gases.**
- **The BD Alaris™ System is not intended to replace supervision by medical personnel.**
- **Do not modify the device. Modifying the device could affect the safety and efficacy of the BD Alaris™ System.**
- **Do not use the BD Alaris™ System in extracorporeal oxygenation (ECMO) as it has not been tested or evaluated for use in this application. Use in ECMO could adversely affect the performance of the BD Alaris™ System.**
- **The BD Alaris™ System has not been tested or evaluated for use in motor vehicles or aircraft.**
- **Do not use in hyperbaric chamber to ensure patient and operator safety. The BD Alaris™ System is not certified for use in oxygen-enriched environments.**

CAUTION

- Rx only: prescription use only.
- If a device or accessory is dropped or severely jarred, take the device out of use immediately. Send the device to biomedical engineering for inspection to ensure the device is functioning properly before reuse.
- Do not use a device that appears to be damaged. Send the device to biomedical engineering for repair.
- Do not use sharp objects such as pens or pencils to press buttons on the keypad as they could cause damage.

Before Each Use

WARNING

- **Securely attach modules as instructed to prevent damage to IUI connectors and potential interruption of therapy (see *Attaching and Detaching a Module* on page *15*).**
- **The system performs a self-check during power up. The PCU should beep, no errors should occur, and if a module is connected, all LED segments should flash. If the system fails the self-check, remove the failing PCU or module from use (see *Powering On the System* on page *17*).**
- **Before each use, verify that all alarm limits, such as occlusion alarm limits, are appropriate for the patient to ensure that alarms occur as intended.**

CAUTION

- When attaching the BD Alaris™ System to an IV pole, ensure the pole clamp is tightened securely to prevent the system from slipping (see *Attaching the System to an IV Pole* on page *14*).
- Setting the audio volume to the lowest level will lower the volume of all system alarms (see *Adjusting Audio Volume* on page *23*).
- Ensure that the device is as close to level with patient's heart as possible. Patient's heart level should be in line with the CHANNEL SELECT key (see *Attaching the System to an IV Pole* on page *14*).

Alarms and Audio Volume

WARNING

- **Ensure that the audio volume (loudness) is set appropriately for each patient prior to using the device (see *Adjusting Audio Volume* on page *23*).**
- **Do not silence an alarm without assessing the patient's condition to avoid compromising patient safety.**

Anesthesia Mode

WARNING

- **Select the profile (care area) where the patient will be taken following anesthesia to prevent an incorrect profile from being used (see *Anesthesia Mode* on page *31*).**
- **Do not enable anesthesia mode except in an OR or critical care setting where a trained and qualified anesthesia provider or critical care clinician is in constant attendance (see *Anesthesia Mode* on page *31*).**
- **Disable anesthesia mode once the patient is stable and is transferred to a setting where they will no longer be attended by a trained and qualified anesthesia provider or critical care clinician (see *Anesthesia Mode* on page *31*).**

Battery

WARNING

- **Keep the power cord connected to a hospital grade AC power source whenever available. The battery is intended as a backup system (see *Powering On the System* on page *17*).**
- **Disconnect from main (AC) and battery power when performing maintenance.**
- **Use only BD batteries. The use of third party batteries could affect the safety and efficacy of BD Alaris™ System and Alaris™ System products, leading to risk of device failure, patient injury, or even death.**
- **The battery cannot be repaired and should not be opened.**
- **Battery replacement should be performed by biomedical engineering while the device is not in use.**

Electrical Shock Hazard

WARNING

- **Do not open case. Refer to biomedical engineering.**
- **Always plug into a grounded, hospital grade three-wire receptacle to prevent electrical shock.**
- **Inserting a finger or other object into the inter-unit interface (IUI) connector when the module is attached to the PCU could result in electrical shock.**

Magnetic Resonance Imaging (MRI) Safety Information and Electromagnetic Compatibility

WARNING

- **Do not use the BD Alaris™ System near magnetic resonance imaging (MRI) equipment or any other magnetic equipment. Keep the BD Alaris™ System outside the MRI scanner room.**
- **Do not use the BD Alaris™ System near therapeutic radiation equipment.**
- **To avoid improper device operation due to electromagnetic incompatibility, do not use any accessory or cable other than those specified.**
- **This device uses a wireless radio card. The FCC requires the following warnings about radio interference:**
  - **Per FCC regulations, maintain a distance of at least 7.8 inches/20 cm between the radio card on the PCU and a human body.**
  - **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BD Alaris™ System, including cables. Otherwise, degradation of the performance of this equipment could result.**
  - **The system is intended for use by healthcare professionals only. This is a CISPR 11 Class B Group 1 medical system. The BD Alaris™ System can cause radio interference. Reorienting, relocating or shielding the system, or filtering the connection to the mains network, are examples of steps that can be taken to reduce or eliminate interference.**
- **The BD Alaris™ System should not be used in close proximity with other electronic equipment. If adjacent or stacked use is necessary, monitor the BD Alaris™ System to verify that it is operating normally in that setup (See *Recommended Separation Distances* on page *379.*).**

CAUTION

- Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and used according to the EMC information provided in Appendix A (see *Regulations and Standards* on page *373*).

About this Chapter

WARNING

Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System.

CAUTION

Rx Only: Prescription use only.

This section of the user manual provides PCU (model 8015) and system instructions and information. It is used in conjunction with:

- *BD Alaris™ PCU Model 8015, Alaris™ PCU Model 8015, BD Alaris™ Pump Module Model 8100, and Alaris™ Pump Module Model 8100 Technical Service Manual*
- Product-specific sections of this user manual
- System maintenance software (and its instructions) for system check-in, maintenance, and configurations for connecting PCUs to the wireless network

The PCU is the core of the 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 system and systems manager. The combined use of the system and systems manager is integrated into a facility's existing network infrastructure.

When enabled, the systems manager allows the exchange of information between the systems manager and the PCU. The PCU can be operated manually or together with the information exchanged with the systems manager. If communication with the wireless network is interrupted (for example, out of range), the PCU can be used, as intended, by programming infusions manually.

BD Alaris™ and Alaris™ PCU

The BD Alaris™ PCU is the core of the BD Alaris™ System and provides a common user interface for programming infusions and continuous $EtCO_2$ monitoring.

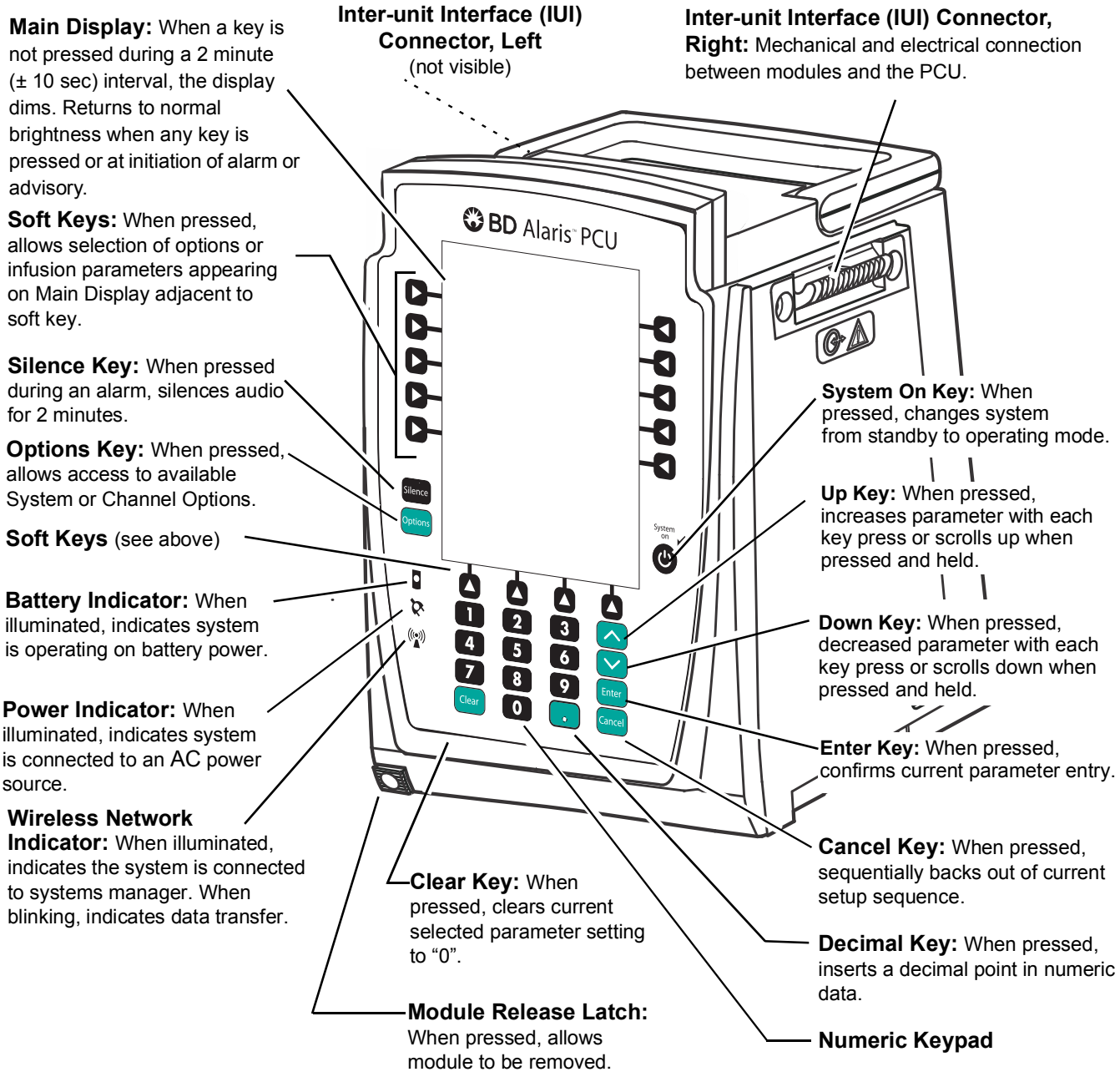
The BD Alaris™ PCU and Alaris™ PCU are shown below.

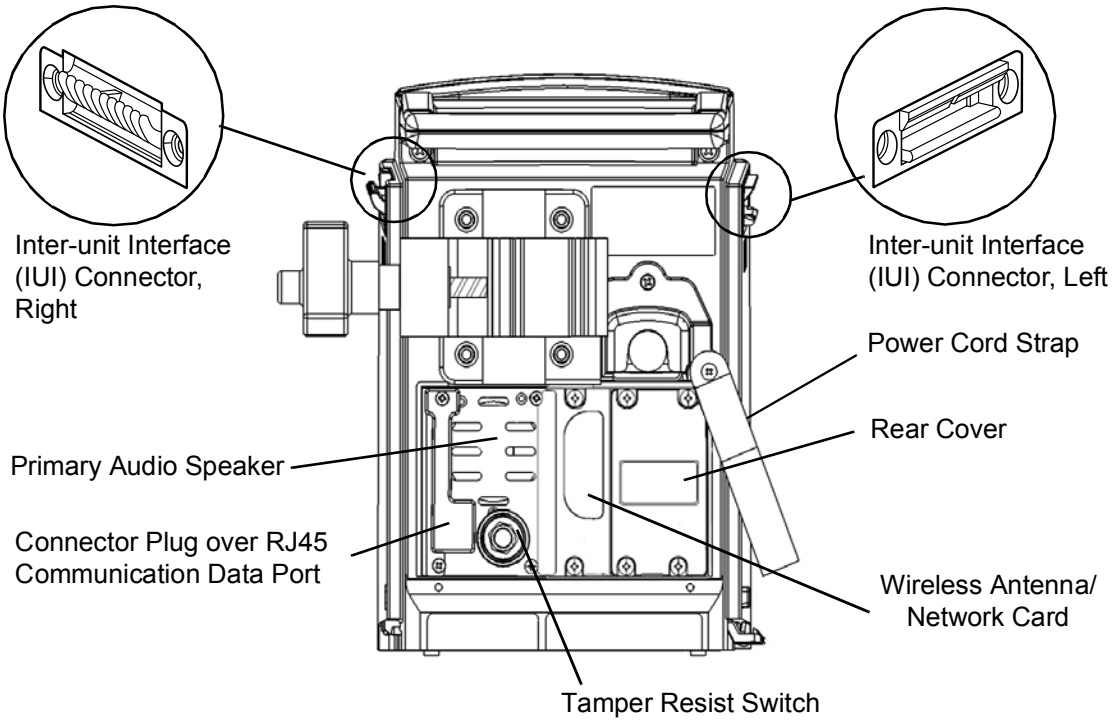
BD Alaris™ PCU

Alaris™ PCU

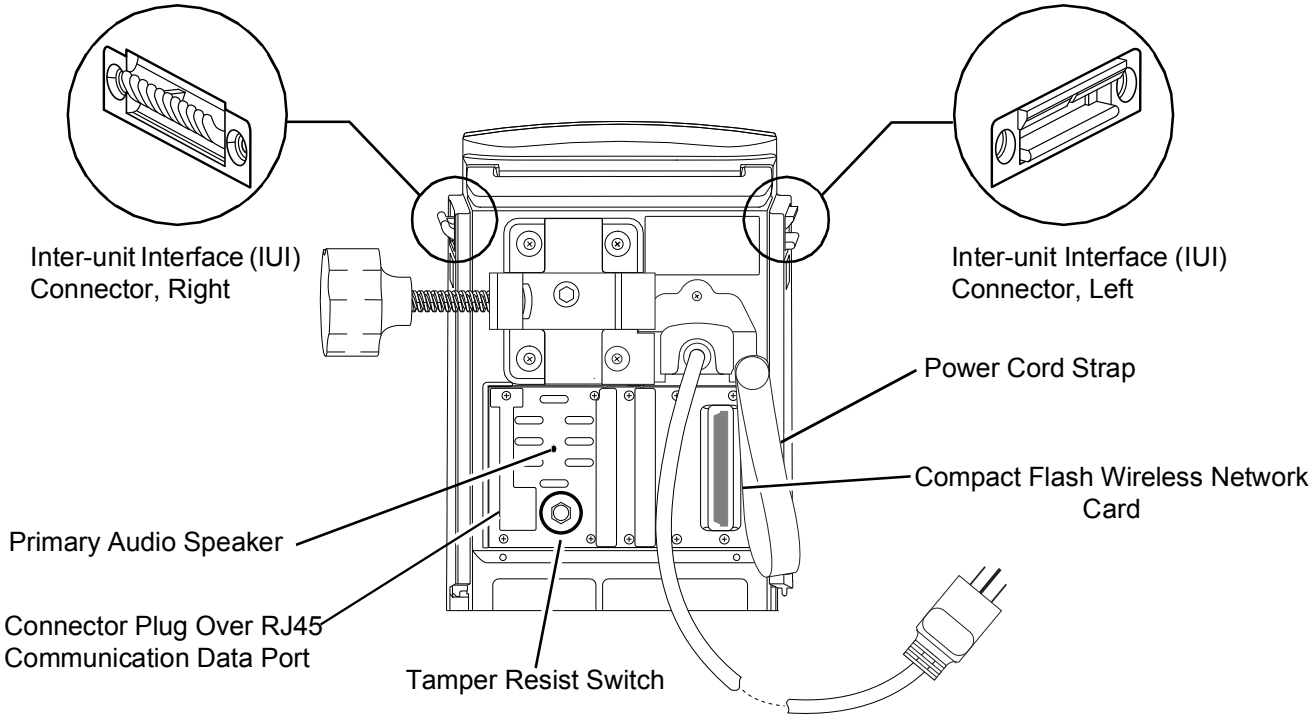
NOTE:
In this document, all references to the PCU refer to both BD Alaris™ PCU and Alaris™ PCU.

Operating Features, Controls, and Indicators





BD Alaris™ PCU Rear Panel - IEC 802.11 a/b/g/n Wireless Network Card



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

Features and Definitions

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

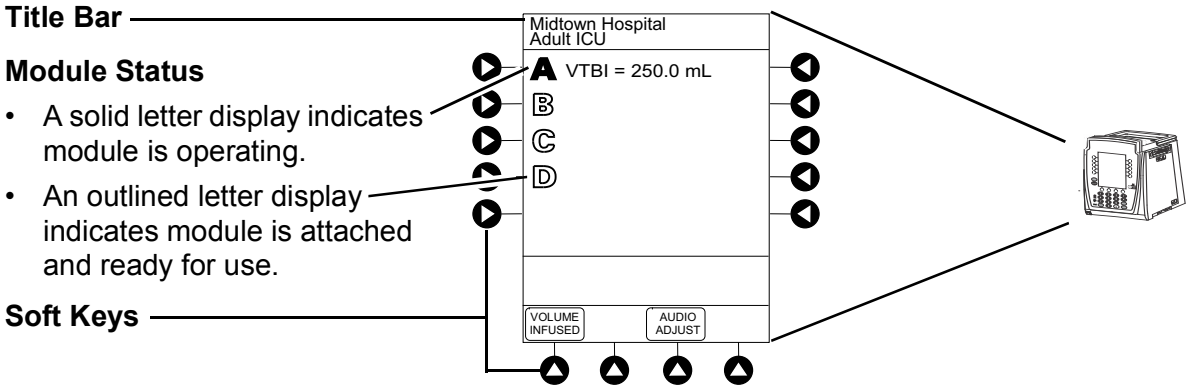
Feature	Definition
Clinician ID	An optional alphanumeric 16-character clinician identifier that can be entered.
Guardrails™ Data Set	Created using Guardrails™ Editor software authoring tool and then transferred to the PCU. A data set reflects hospital/facility's best practice guidelines for IV drug administration and IV fluid administration. The data set includes: profile drug and fluid libraries, clinical advisories, device configurations, therapies, and channel labels.
Guardrails™ Suite MX	Software designed to help prevent programming errors by: • Customizing device configurable settings to meet the needs of selected hospital/facility area/unit (profile). • Checking user-programming against hospital-defined best practice guidelines. • Providing a visual and audio prompt if a programmed entry is outside of the hospital/facility established limits.
No Guardrails™ - Basic Infusion	No Guardrails™ - Basic Infusion is a mode in which there are no Guardrails™ Suite MX safety software protection limits. No Guardrails™ - Basic Infusion is typically used for medications and fluids not found in the drug library, investigational medications, and in emergency situations. No Guardrails™ - Basic Infusion may include primary, secondary, or drug calculation infusions.
No Guardrails™ - Basic Infusion Clinical Advisory	When enabled, reinforces the hospital/facility best practice guidelines regarding the utilization of Guardrails™ Suite MX by providing a clinical advisory notifying the clinician that there is no Guardrails™ Suite MX protection for the selection made. This applies to basic infusion, basic secondary, and drug calculation. This clinical advisory text can be customized within the Guardrails™ Editor and will appear in all profiles where this feature is enabled.
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 Guardrails™ Suite MX drug library parameters limits (best practice guidelines) for a specific patient population or patient type, that can consist of the following components: • Device 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 PCU.
System Configuration	Allows system settings to be customized. If profiles feature is enabled, the system settings defined for selected profile are automatically activated.
Tamper Resist	Provides a quick one-touch lockout of the front panel keypad when the infusion is running, during a delay, or an $EtCO_2$ Module is actively monitoring. You cannot lock out the front panel keypad during keep vein open (KVO). An alarm can be silenced even though the panel is locked.

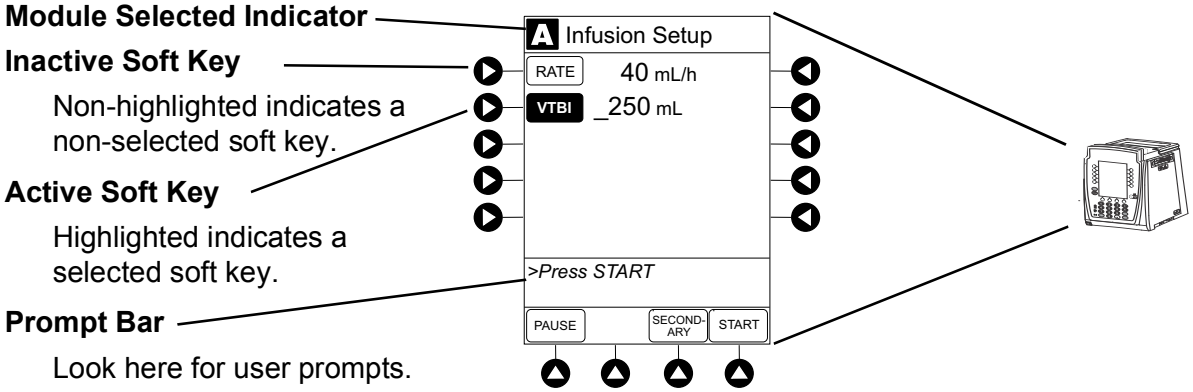
Displays

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. The display dims after 2-minutes (± 10 sec) if no keys are pressed during that interval. The display returns to normal brightness when any key is pressed or at the initiation of any alarm or advisory. See *Alarms and Alerts* on page *349* for additional color categories.

Main Display





Initial Setup

The PCU initial setup section includes the following procedures:

Attaching the System to an IV Pole on page *14*

Attaching and Detaching a Module on page *15*

Attaching the System to an IV Pole

The pole clamp is located on the back of the PCU.

CAUTION

When attaching the BD Alaris™ System to an IV pole, ensure the pole clamp is tightened securely to prevent the system from slipping.

CAUTION

Ensure that the device is as close to level with patient's heart as possible. Patient's heart level should be in line with the CHANNEL SELECT key.

1. To attach the device to an IV pole, turn the knob counter clockwise to open the clamp, position the clamp on the pole, and turn the knob clockwise to tighten securely.
2. Position the BD Alaris™ System vertically during operation.

Attaching and Detaching a Module

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

An individual hospital or facility can choose to permanently attach modules. To remove permanently attached modules, contact biomedical engineering.

Attaching a Module

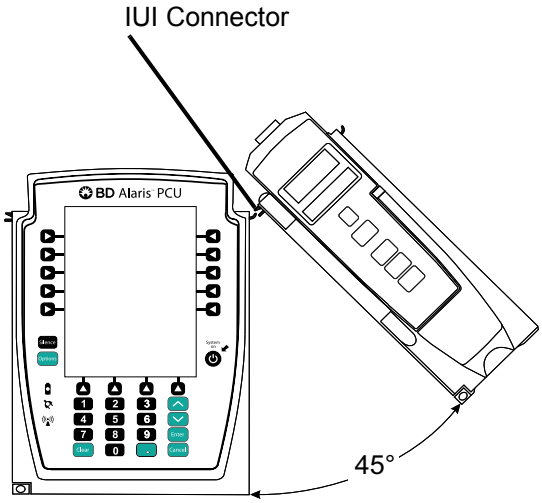
The system is designed to operate a maximum of four infusion or monitoring modules. Modules added in excess of four are not recognized by the system. Auto-ID may be added to the PCU with any combination of one to four other modules. A module can be attached in any position; however, when mounted on an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

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

WARNING

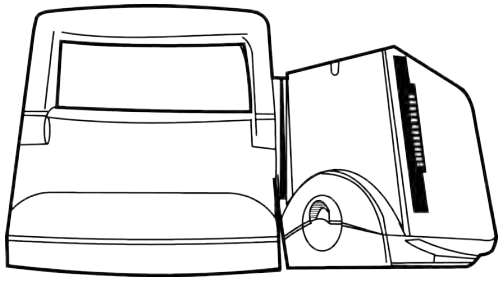
Securely attach modules as instructed to prevent damage to IUI connectors and potential interruption of therapy.

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



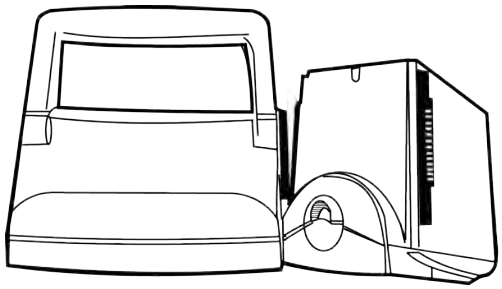
Front View

Aligned IUI Connectors



Top View

IUI Connectors Not Aligned



Top View

2. Rotate free module down against PCU or attached module until release latch snaps in place.
   - The system tests the module, causing all LED segments and indicator lights of displays to illuminate briefly.
   - The appropriate module identification display (A, B, C, or D) illuminates. Modules are always labeled left to right, so if a module is added to the 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 the main display.

   NOTE:
   If any of the following conditions are observed, the affected module must be removed from use and inspected by qualified personnel:

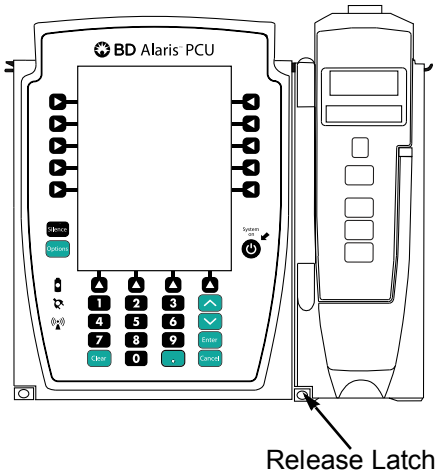
   •LED segments are not illuminated on displays during power-on test.

   •Indicator lights do not illuminate.

   •Appropriate module identification does not appear.

Detaching a Module

1. Ensure that the module is powered off before detaching.
2. Push the module release latch, and then rotate the module up and away from the PCU or other attached module (opposite to motion shown in the *Attaching a Module* on page *15* procedure) to disengage connectors.
   - The system re-identifies 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 the main display.



Powering On the System

WARNING

The system performs a self-check during power up. The PCU should beep, no errors should occur, and if a module is connected, all LED segments should flash. If the system fails the self-check, remove the failing PCU or module from use.

WARNING

Keep the power cord connected to a hospital grade AC power source whenever available. The battery is intended as a backup system.

1. Connect the PCU to an external AC power source.
2. Press the **SYSTEM ON** key.

   NOTE:

   •Previous infusion parameters are automatically cleared after 8 hours.

   •The self-test provides the clinician with verification of the operational safety and correct functioning of alarms for the system.

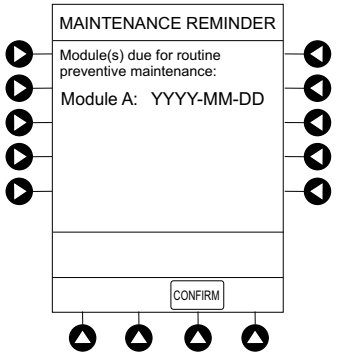
   System self-test begins:

   - 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 the preventive maintenance (PM) reminder option is enabled and scheduled preventive maintenance is due, the **MAINTENANCE REMINDER** screen appears.
   - At completion of the system-on test, the **New Patient?** screen appears.
   - If either of the following conditions is observed, the PCU 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.

Responding to Maintenance Reminder

If the PM reminder option is enabled and the PCU 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.

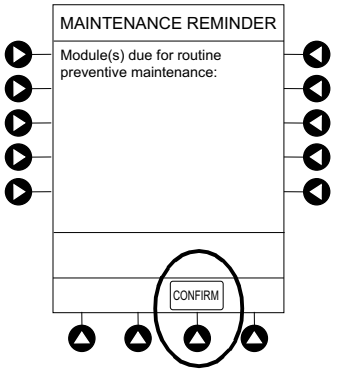
1. Notify the appropriate facility personnel when a **MAINTENANCE REMINDER** occurs and remove the instrument requiring maintenance (see *Attaching and Detaching a Module* on page *15*).



2. If the system was powered off to replace the PCU, restart the process.

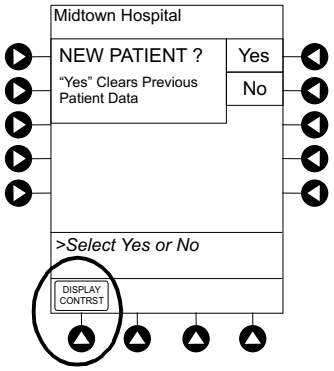
   or

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

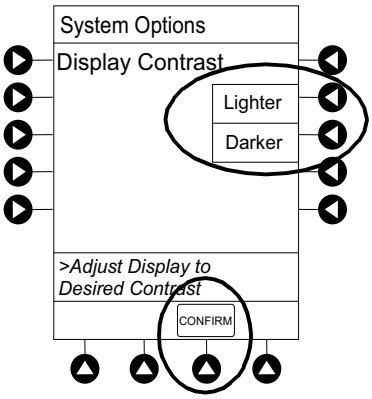


Adjusting Display Contrast

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



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



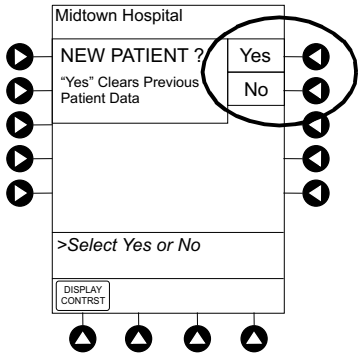
3. To return to main screen, press the **CONFIRM** soft key.

Selecting New Patient and Profile Options

A profile is a subset of the drug library that is intended to meet the needs of a specific group of patients. Each profile contains drugs, fluids, limits, and device configuration settings that are appropriate for use in that particular patient population. Profiles are created by your facility as a part of the drug library.

The following procedures assume the profiles feature is enabled.

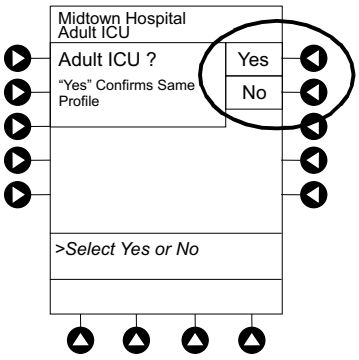
1. Select required **NEW PATIENT?** option.
   - To indicate programming is for a new patient and clear all stored patient parameters from memory, press the **Yes** soft key.
   - To confirm programming is for same patient and retain all stored patient parameters, press the **No** soft key.
     - Last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



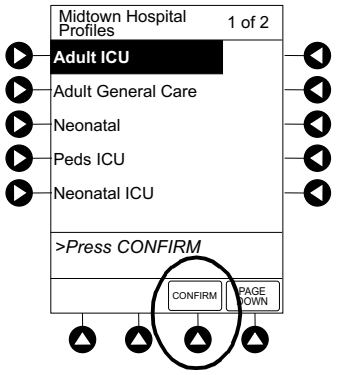
2. Accept or change current profile:
   - To accept current profile, press the **Yes** soft key.

     Main screen appears.
   - To change profile, press the **No** soft key and continue with next step.

     Profile selection screen appears.



3. To select a profile, press the corresponding left soft key. To view additional choices, press the **PAGE DOWN** soft key.
4. To confirm profile selection, press the **CONFIRM** soft key.



Main screen appears.

Activating the Data Set

The data set (drug library) is the set of information that defines the behavior of the system, including both the drug and fluid libraries (with associated dosing limits) and the configuration settings for each profile. The data set is developed by each facility to provide a comprehensive infusion safety system that supports hospital-established best practices. The data set is transferred wirelessly (or with a cable) to each PCU.

It is important to ensure that the latest data set is loaded into the PCU. To check the status of the data set, see *Viewing Data Set Status* on page *44*. If the data set status is **Pending**, use the following steps to update the data set.

1. Power off the PCU (also referred to as power-cycling).
   a. Press the **OPTIONS** key.
   b. Press the **Power Down All Channels** soft key.
   c. Press **Yes** at the confirmation prompt.
2. Power on the PCU.
3. Press the **Yes** soft key at the **New Patient** screen. Doing this clears all stored patient parameters from the memory and activates the pending data set.
4. Review the data set status. It should now display **Current**.
5. To confirm data set status:
   a. Press the **OPTIONS** key.
   b. Press the **Page Down** soft key, and select **Data Set Status**.

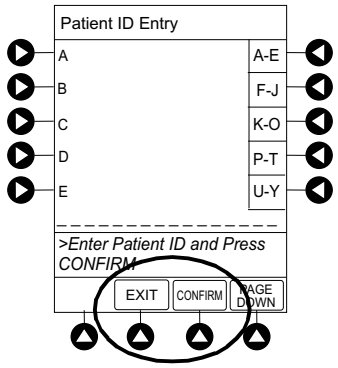
      Data set status should display **Current**.

      If data set status is **Pending**, repeat step 1.

Adding Patient Identifier (ID)

The option to enter and display a 16-character alphanumeric patient ID is always available. The device 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* on page *26*).

1. If **Yes** was selected to indicate programming for a new patient, perform one of following steps:
   - If patient ID is not required, press the **CONFIRM** or **EXIT** soft key.



   - To manually enter patient ID, use numeric data entry keys and/or alpha speed keys.
     a. An alphanumeric ID, of up to 16 characters, can be entered.
     b. 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.
     c. To access letter "Z" and special characters (hyphen, underscore, space), press the **PAGE DOWN** soft key.
     d. To clear an entire entry, press the **CLEAR** key.
     e. To back up a single character at a time, press the **CANCEL** key.
   - To scan barcode on patient identification band, see *Alaris™ Auto-ID Module Model 8600* on page *327*.

NOTE:
It is recommended that protected health information (PHI) (for example, patient name or social security number) not be used for Patient ID entries.

Adjusting Audio Volume

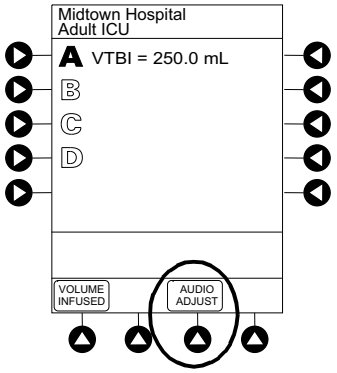
WARNING

Ensure that the audio volume (loudness) is set appropriately for each patient prior to using the device.

CAUTION

Setting the audio volume to the lowest level will lower the volume of all system alarms.

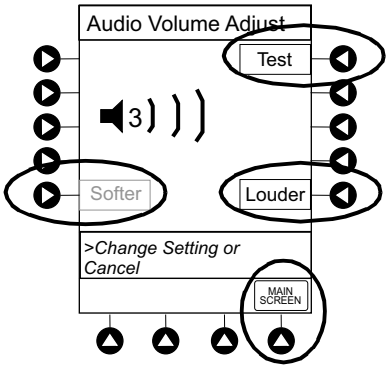
1. Press the **AUDIO ADJUST** soft key.



2. To change volume to the desired level, press either the **Louder** or the **Softer** soft key. To sample alarm loudness level, press the **Test** soft key.
3. To return to the main screen, press the **MAIN SCREEN** soft key.

   After 30 seconds without a key press, the main display appears.

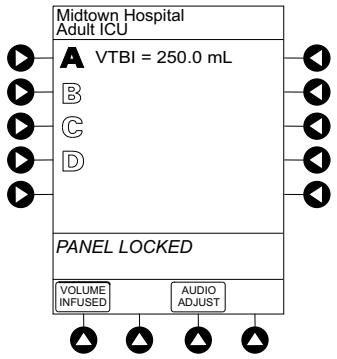
NOTE:
The minimum audio volume defaults to level 1. Levels 1–5 may be set per profile. The user is able to lower the device audio volume to the minimum limit set. When the minimum audio volume level limit has been reached, the Softer soft key is unavailable and the PCU emits an illegal key press audio (two beeps).



Locking and Unlocking Tamper Resist

1. Start operation of applicable module.
2. Press and hold the tamper resist switch on the back of the PCU for 3 to 4 seconds (see *Operating Features, Controls, and Indicators* on page *10* for more information).

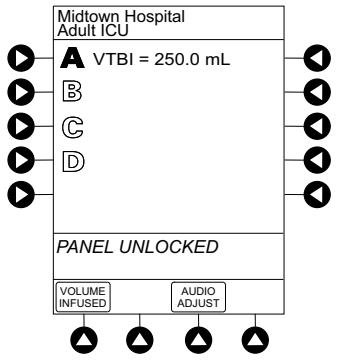
   NOTE:
   The PCU exits the tamper resist mode when a channel error, system error, or the discharge battery screen is displayed.



   - An advisory tone (if **Key Click Audio** is enabled) and a 3-second **Panel Locked** prompt on the main display confirms activation.
   - When tamper resist is active, the keypad panel is locked; however, the 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 (two beeps) audio advisory.
3. To unlock the keypad panel, press and hold the tamper resist switch for 3 to 4 seconds.

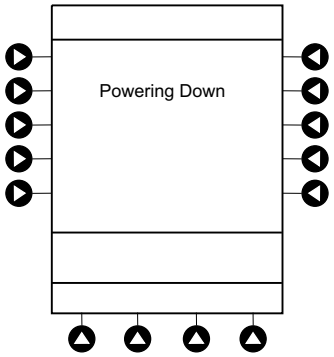
   An advisory tone (if **Key Click Audio** is enabled) and a 3-second **Panel Unlocked** prompt on the main display confirm activation.



Powering Off the System

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

- During power off sequence, the main display flashes **Powering Down.**

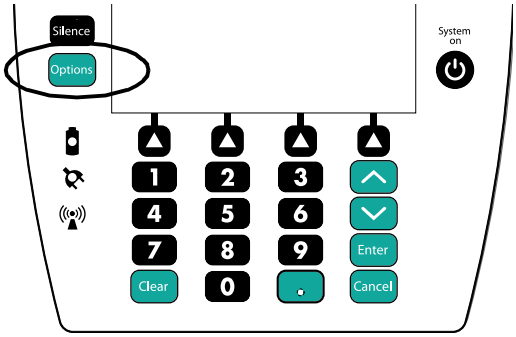


- To interrupt the power down sequence, quickly press any key (except **SYSTEM ON**) on the PCU. If a device needs to be used on a new patient, the system should be completely powered down and then restarted with the **SYSTEM ON** key. When all attached modules are powered off, the PCU automatically powers down.

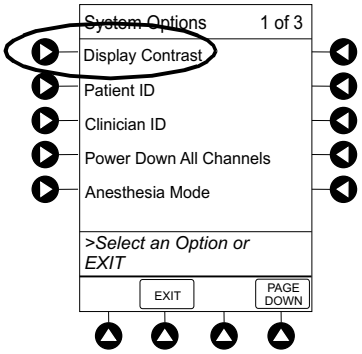
System Options

Adjusting Display Contrast

1. Press the **OPTIONS** key.



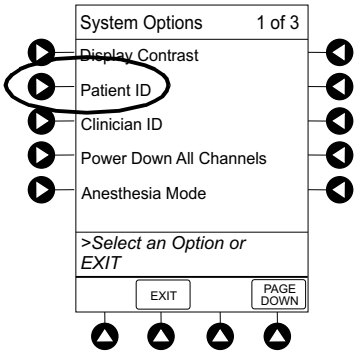
2. Press the **Display Contrast** soft key.



3. Adjust the display and return to the main screen (see *Adjusting Display Contrast* on page *19* for the procedure).

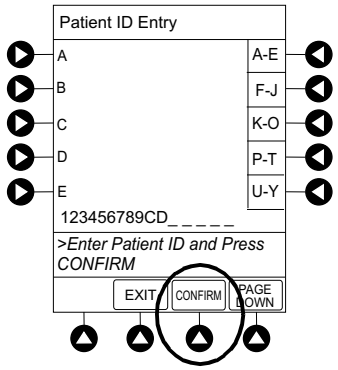
Entering Patient ID

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



NOTE:
It is recommended that protected health information (PHI) (for example, patient name or social security number) not be used for Patient ID entries.

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 the **PAGE DOWN** soft key.
     - To clear an entire entry, press the **CLEAR** key.
     - To back up a single character at a time, press the **CANCEL** key.
   - To scan the barcode on the patient identification band, see *Alaris™ Auto-ID Module Model 8600* on page *327* for more information.
4. To verify correct entry, press the **CONFIRM** soft key.

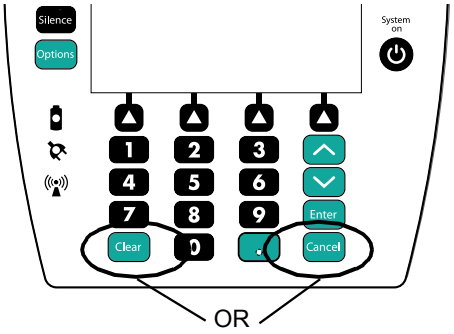


Modifying Patient ID

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

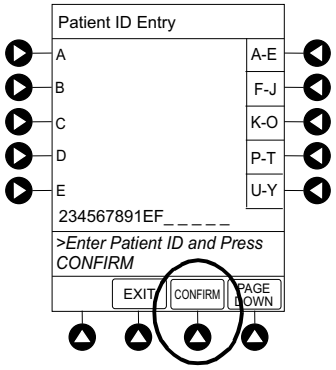
   or

   To back up a single character at a time, press the **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 the **PAGE DOWN** soft key.
5. To verify correct entry, press the **CONFIRM** soft key.

   New Patient ID Entry verification screen appears.



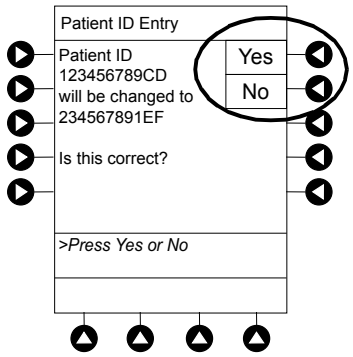
6. To accept modified patient ID, press the **Yes** soft key.

   Main screen appears with new patient ID.

   or

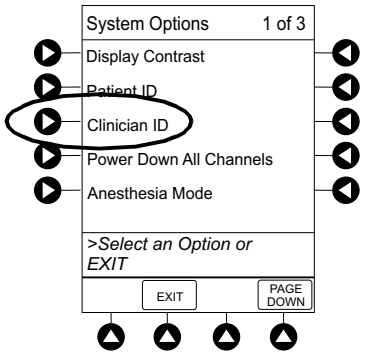
   To retain original (old) patient ID, press the **No** soft key.

   Main screen appears with old Patient ID.



Entering Clinician ID

1. Press the **OPTIONS** key.
2. Press the **Clinician ID** soft key.

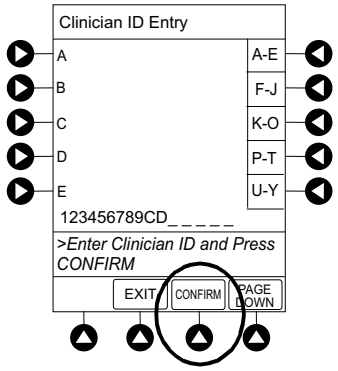


3. Scan or manually enter clinician identifier:

   To manually enter clinician identifier, use numeric data entry keys and/or alpha speed keys.

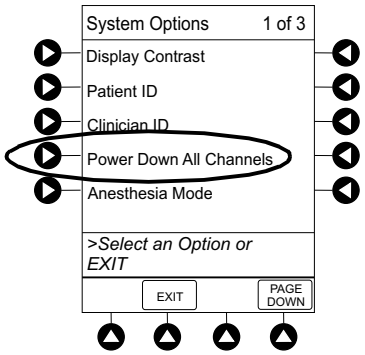
   - An alphanumeric identifier, of up to 16 characters, can be entered.
   - Press soft key next to a letter group to list letters in that group. Press soft key next to an individual letter to enter that letter.
   - To access letter "Z" and special characters (hyphen, underscore, space), press the **PAGE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

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



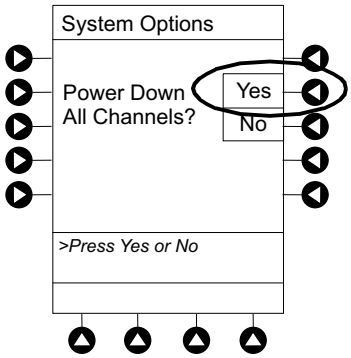
Powering Down All Channels

1. Press the **OPTIONS** key.
2. Press the **Power Down All Channels** soft key.



3. Press the **Yes** soft key.

   During power off sequence, the main display flashes **POWERING DOWN**.



Anesthesia Mode

WARNING

Do not enable anesthesia mode except in an OR or critical care setting where a trained and qualified anesthesia provider or critical care clinician is in constant attendance.

WARNING

Disable anesthesia mode once the patient is stable and is transferred to a setting where they will no longer be attended by a trained and qualified anesthesia provider or critical care clinician.

WARNING

Select the profile (care area) where the patient will be taken following anesthesia to prevent an incorrect profile from being used.

When the anesthesia mode is enabled and then the pause feature is used, the module remains in an indefinite pause until restarted.

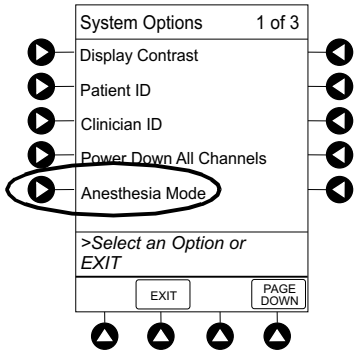
When anesthesia mode is enabled:

- A channel can be paused indefinitely without an alarm.
- The air-in-line associated with the profile can be set to one of the following settings: 50, 75, 125, 175, 250, or 500 microliters.
- All limits are set to **Soft**.
- Limit checking mode is set to **Smart**.
- Key-press audio is turned off.
- Auto-restart for anesthesia mode is set to 9 and is not configurable.
- Panel lock through tamper resist mode or authorized user mode is not available.
- Guardrails™ drug list defaults to drugs designated by editor software as anesthesia only. All Guardrails™ drugs in a profile can be viewed by pressing the **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.
- Clinical advisories are not displayed.

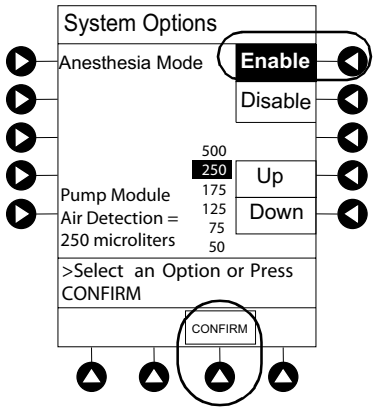
NOTE:
If an infusion is paused in regular mode and then the anesthesia mode is enabled, the device will alarm at the 2 minute warning.

Enabling Anesthesia Mode

1. Press the **OPTIONS** key.
2. Press the **Anesthesia Mode** soft key.



3. Press the **Enable** soft key.



4. Press the **Up** or **Down** soft key to set the Pump Module air detection to 50, 75, 125, 175, 250, or 500 microliters.
5. Press the **CONFIRM** soft key.

Disabling Anesthesia Mode

The anesthesia mode can be disabled, and normal operation resumed, using one of the following three methods:

- Disabling through System Options.
- Disconnecting from AC power.
- Connecting to AC power.

NOTE:
Hard Guardrails™ limits are re-established when anesthesia mode is disabled, both for existing infusions and new infusions.

From System Options Menu

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

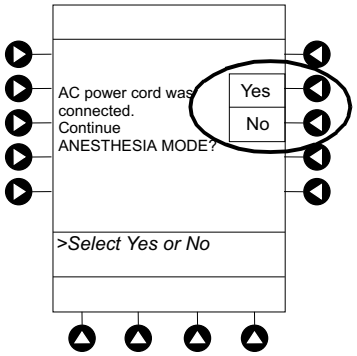
   Anesthesia mode no longer appears on main display, indicating it has been disabled.

Connecting to AC Power

1. Connect system to AC power.
2. To continue using anesthesia mode, press the **Yes** soft key.

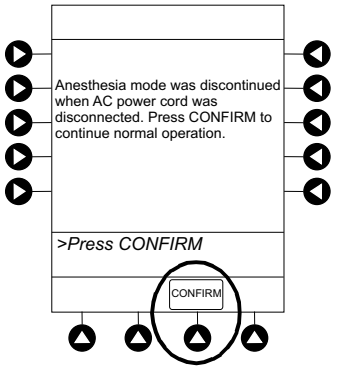
   or

   To discontinue anesthesia mode, press the **No** soft key.



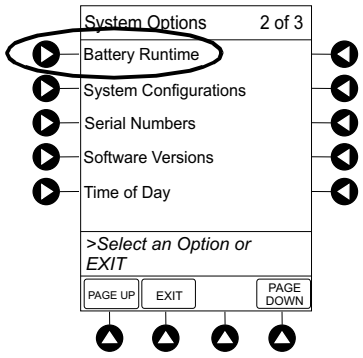
Disconnecting from AC Power

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 the **CONFIRM** soft key.

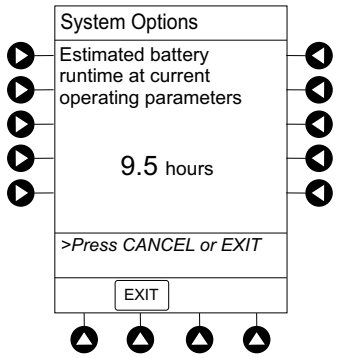


Displaying Battery Runtime

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

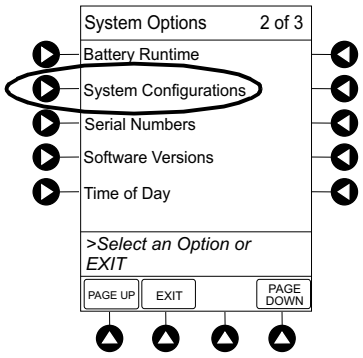


4. To return to main screen, press the **CANCEL** key or the **EXIT** soft key.

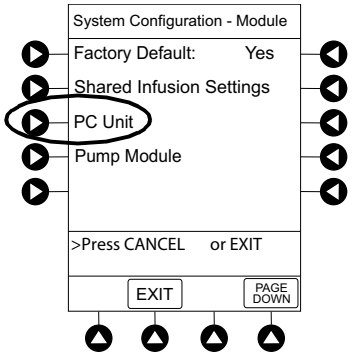


System Configuration

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



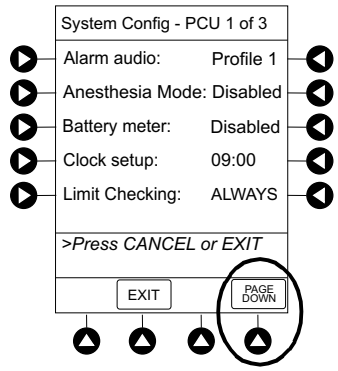
4. Press the **PC Unit** soft key.

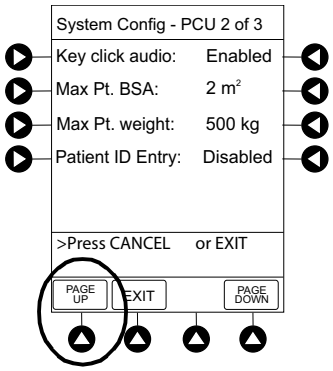


5. To review various system configuration settings, press the **PAGE DOWN** and **PAGE UP** soft keys.

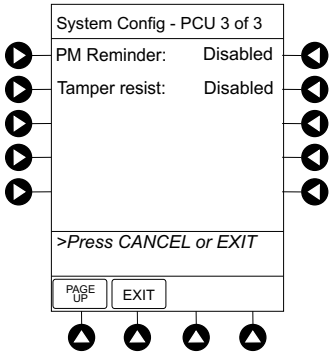
NOTE:

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





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

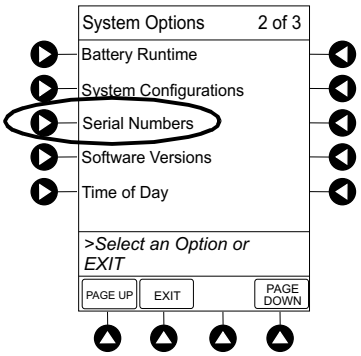


Displaying Serial Numbers

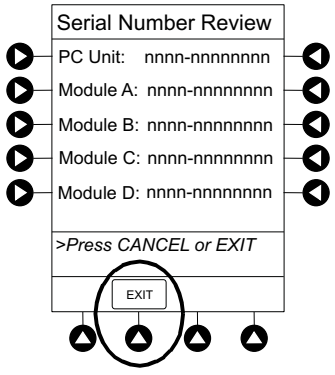
1. Press the **OPTIONS** key.
2. Press the **PAGE DOWN** soft key.
3. Press the **Serial Numbers** soft key.

   Serial numbers for PCU and all attached modules appear.

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



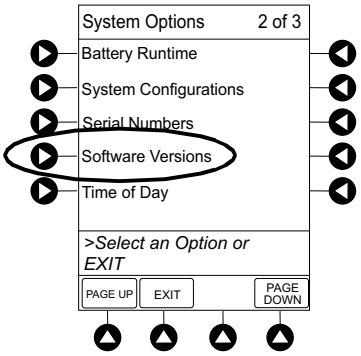
4. To return to main screen, press the **EXIT** soft key.



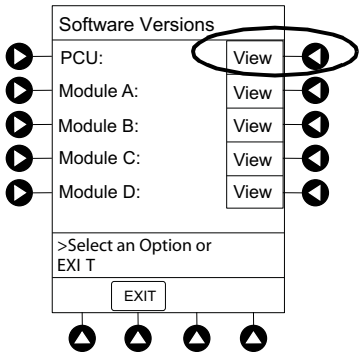
Viewing Software Versions

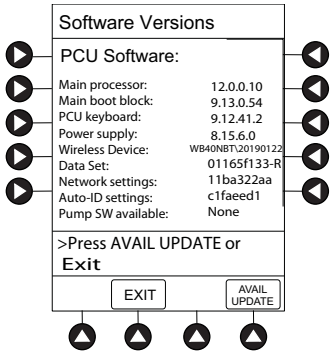
The software versions screens display the active running software components on the PCU and the attached modules that are available on the PCU.

1. Press the **OPTIONS** key.
2. Press the **PAGE DOWN** soft key.
3. Press the **Software Versions** soft key to display the Software Versions menu.



4. Do one of the following:
   - To view software components and configurations on the PCU, press the **View** soft key for the PCU.

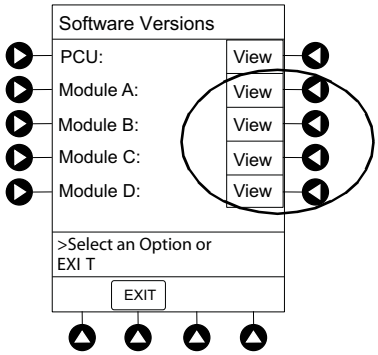


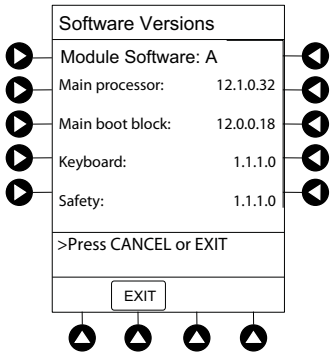


   The PCU Software screen appears.

NOTE:
The illustrations shown are examples and may not reflect the software versions or configuration IDs on your device.

- To view the active software components for the desired module, press the **View** soft key for the module.





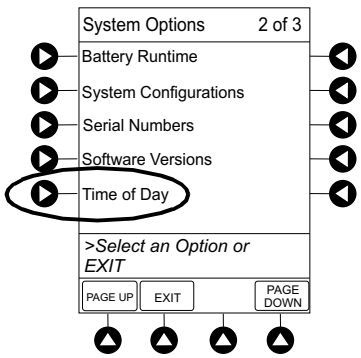
The Module Software screen appears.

NOTE:
The illustrations shown are examples and may not reflect the software versions or configuration IDs on your device.

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

Setting Time of Day

1. Press the **OPTIONS** key.
2. Press the **PAGE DOWN** soft key.
3. Press the **Time Of Day** soft key.

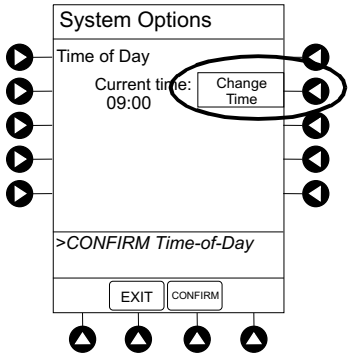


4. If time is correct, press the **CONFIRM** soft key.

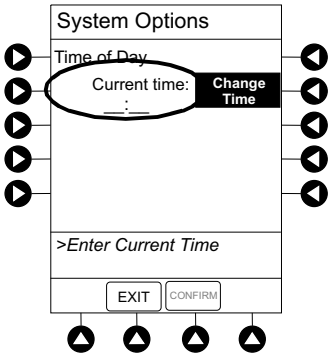
   or

   To change time, press the **Change Time** soft key.

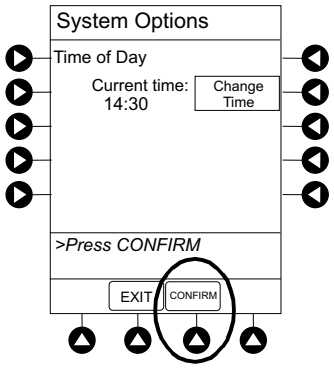
   NOTE:
   The format is a 24-hour clock (military time).



5. Enter the current time of day.



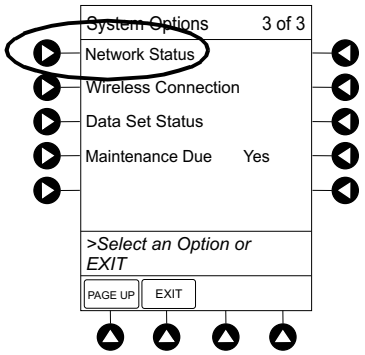
6. Press the **CONFIRM** soft key.



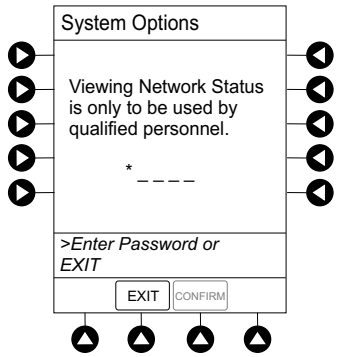
Viewing Network Status

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

1. Press the **OPTIONS** key.
2. Press the **PAGE DOWN** soft key two times.
3. To view network status and wireless status information, press the **Network Status** soft key.

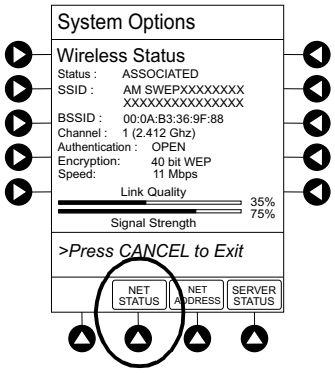


4. Enter the password (refer to *BD Alaris™ System Maintenance Software User Manual*) and press the **CONFIRM** soft key.

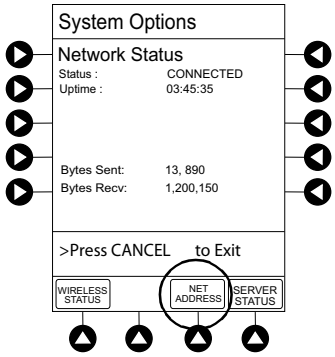


- Information based on a wireless status of **DISABLED**, **DISASSOCIATED**, **CONFIGURING**, **ASSOCIATING**, **ASSOCIATED**, or **AUTHENTICATING** is displayed.
- If wireless status is **ASSOCIATED**, the following information is displayed:
  - Wireless connectivity: **SSID**, **Channel**, **Authentication**,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

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

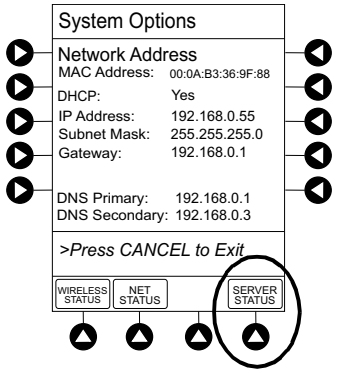


6. To view network address information, press the **NET ADDRESS** soft key.

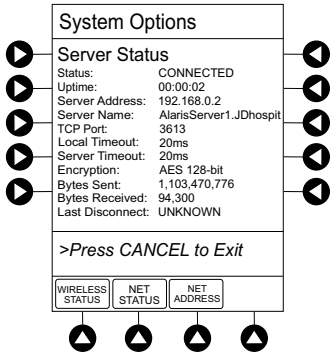


   - The **MAC Address** of the wireless RF card attached to the PCU is displayed.
   - If **DHCP** displays **NO**, the PCU is set to use a static IP address.
   - When the PCU is connected to the wireless network, the **IP Address, Subnet Mask, Gateway**, and **DNS** information are displayed.

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

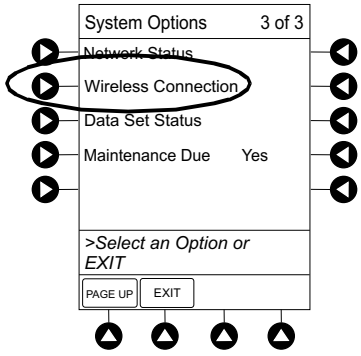


- Information based on a status of **DISABLED**, **DISCONNECTED**, **CONNECTING**, or **CONNECTED** is displayed.
- If the status is **CONNECTED**, the PCU is connected to the systems manager and the following information is displayed:
  - **Uptime**—length of time PCU has been connected.
  - **Server Address**—IP Address of systems manager.
  - **Server Name**—first 20 characters of fully qualified domain name of systems manager.
  - **TCP Port**—the systems manager TCP port that connects to the PCU.
  - **Encryption**—the 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.



Wireless Connection

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

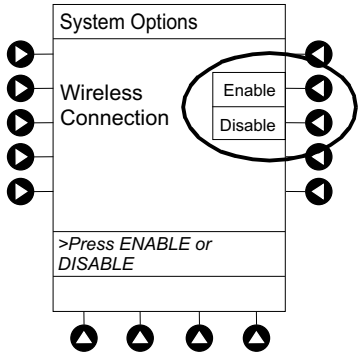


If the **Wireless Connection** soft key is inactive (grayed out), the PCU has the following configuration:

- The system maintenance software was used to disable wireless connection.
- The CF card flashing process was done without the programming of the proper AppConfig file (v9.12 or later). For more information, refer to the *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015 Software and Hardware Upgrade Instructions*.
- A network configuration was never transferred.

To enable wireless connection, use system maintenance software. Send the PCU to the biomedical department to resolve wireless connectivity issues.

4. Wireless connection can be disabled or enabled:
   - To disable wireless communication, press the **Disable** soft key.
     - If wireless connection is disabled, it remains disabled until PCU is powered off. The setting defaults to **Enable** when the PCU is powered back on.
     - System maintenance software instructions also include a procedure on how to disable a wireless RF card on a PCU being used in a non-wireless environment. Wireless connection remains disabled until system maintenance is used to enable it.
   - To enable wireless connection, press the **Enable** soft key.



Activating a New Data Set

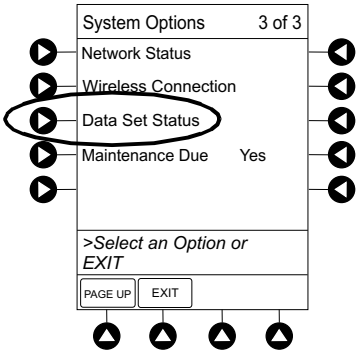
1. Power down by pressing **CHANNEL OFF** on each module or by pressing **OPTIONS** and **Power Down All Channels**.
2. Power on by pressing **SYSTEM ON**.
3. At **NEW PATIENT** prompt, select **YES**.

   The new data set name will appear in the title bar.

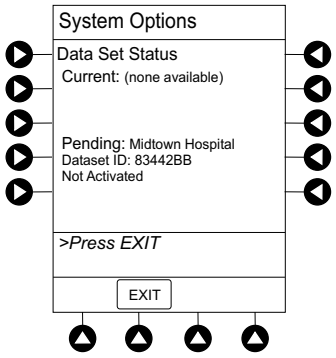
   NOTE:
   If the new data set name does not appear in the title bar, check that the system is connected to the wireless network.

Viewing Data Set Status

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

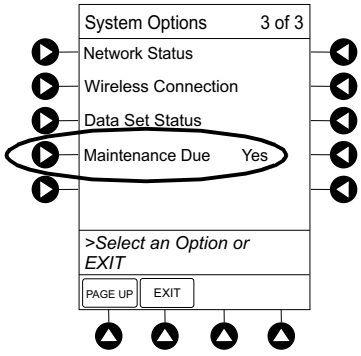


A status of **Current** or **Pending** is displayed. A **Pending** status also notes that the data set is **Transferring** or **Not Activated**.



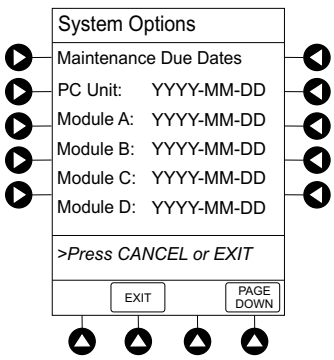
Viewing Maintenance Due

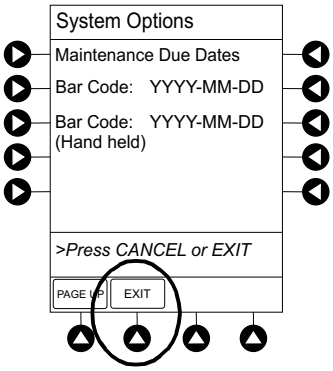
1. Press the **OPTIONS** key.
2. Press the **PAGE DOWN** soft key two times.
3. Press the **Maintenance Due** soft key.



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

NOTE:
The **PAGE DOWN** soft key appears only if an Auto-ID Module is attached.





System Configuration Settings

If the configuration settings need to be changed from the **Factory default** settings, refer to the applicable technical service manual or contact BD technical support for technical, troubleshooting, and preventive maintenance information.

NOTE:
When a Guardrails™ data set is enabled in the PCU the data set overrides all configuration settings.

With the profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best practice data set must be uploaded to the PCU to enable the profiles feature. Date and time is a system setting and is the same in all profiles. Before selecting settings, it is recommended that the hospital conduct a risk assessment or other hospital-defined best practice.

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

Specifications and Symbols

Battery Operation:

Battery run time is a function of the number of modules attached and module activity. With a new, fully charged battery, the system operates as follows before a BATTERY DISCHARGED message occurs:

- 1 hour with four Pump Modules infusion at 999 mL/h and one Auto-ID Module
- 6 hours with one Pump Module infusing at 25 mL/h
- 6 hours with one Pump Module infusing at 25 mL/h and one Auto-ID Module
- 3 hours with four Pump Modules infusing at 25 mL/h
- 3 hours with four Pump Modules infusing at 25 mL/h and one Auto-ID Module
- 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 $EtCO_2$ Module

The device is equipped with a secondary battery that automatically switches over when there is an interruption of the supply mains.

Communication Data Port:

RS-232 with an RJ45 connector.

Dimensions:

8.1" W x 8.8" H x 8.8" D (including pole clamp)

Electric Classification:

Class 1, Internally Powered Equipment

Electronic Memory:

The system configuration/data set is stored in compact flash memory along with operating software.

The events and error logs, CQI, and historical reporting logs, and the system alarm settings are stored in the on-board flash memory in the PCU and modules. This is nonvolatile memory and can be held indefinitely or until replaced with new data. Logs and alarm settings are maintained even during a total loss of power to the system. The date and time of system power down is captured in the event log. The older log entries are purged as the log file reaches capacity. 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 or $EtCO_2$ Module is detached and replaced with another PCA or $EtCO_2$ Module, its module-specific trend data is purged.

Memory will not be lost due to a weak/discharged battery as data is stored on flash memory as noted.

Compact flash memory: Stores application software, audio wave files, data set, and hex files data for operating system software, all needed to operate the system.

On-board flash memory: Contains software needed to initially turn on system. Stores boot software application, and events, errors and battery logs.

Environmental Conditions:

Symbol	Meaning	Operating	Storage/ Transport
	Atmospheric Pressure	525 - 795 mmHg (70 - 106 kPa)	375 - 760 mmHg (50 - 101 kPa)
	Relative Humidity (Avoid prolonged exposure to relative humidity >90%)	20 - 90% Noncondensing	5 - 90% Noncondensing
	Temperature Range	41 - 104°F (5 - 40°C)	-4 - 140°F (-20 - 60°C)

NOTE:
The storage/transport relative humidity value does not apply to small screen PCU models (4.7 inches diagonally). The relative humidity value for the small screen PCU is 85%.

Equipment Orientation: To ensure proper operation, the system must remain in an upright position.

Fluid Ingress Protection: IPX2, Drip Proof

Mode of Operation: Continuous

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

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

NOTE:
The defibrillation marking on the PCU is to indicate defibrillation classification of systems when modules (pump, PCA, and syringe) that are classified as defibrillation proof are connected to the PCU. The defibrillation marking on the PCU is to indicate the classification for the modules that are rated for this classification. This defibrillation marking is not intended for the PCU alone.

Weight: 8.2 lbs (includes pole clamp and power cord)

Max System Weight: 28.3 lbs; Max System Weight includes 1 PCU (with power cord), 3 Syringe Modules, 1 PCA Module, and 1 Auto-ID Module.

Chapter 2
BD Alaris™ Pump Module Model 8100 and Alaris™ Syringe Module Model 8110

This chapter contains the following topics:

Summary of Warnings and Cautions

BD Alaris™ Pump Module General

WARNING

- **Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System (see *About This Chapter* on page *66*).**
- **The BD Alaris™ System is not intended to replace supervision by medical personnel.**
- **Discard infusion set if packaging is not intact or protector caps are unattached (see *Preparing for an Infusion (BD Alaris™ Pump Module)* on page *78*).**
- **If the patient is receiving a gravity infusion using the same IV site as an infusion on the pump, monitor the infusion to be sure it is flowing as intended.**

CAUTION

- Rx Only: Prescription use only.

BD Alaris™ Pump Module Free-Flow Prevention

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 (see *BD Alaris™ Pump Module Set Loading* on page *87*).**
- **To prevent a potential free-flow condition, do not use a Pump Module if it is damaged in any way or does not appear to be functioning as expected. Free-flow can result in patient harm (see *BD Alaris™ Pump Module Set Loading* on page *87*).**

CAUTION

- Keep the Pump Module door closed when the device is not in use to avoid damage to door components.

BD Alaris™ Pump Module Rate Accuracy

WARNING

- **Rate accuracy can be affected by:**
  - **Temperature and viscosity of the IV solution**
  - **Height of the pump in relation to the patient**
  - **Height of the solution container in relation to the pump**
  - **Back pressure related to the infusion set and the IV catheter**
- **When infusing at rates less than 1 mL/h, ensure that the pump is not placed higher than the patient's heart level. Placing the pump higher than the patient can result in infusion delivery faster than the intended flow rate. Adjust the pump height if the patient is moved to a position lower than the pump, for instance when moving to a chair.**
- **Use only BD Alaris™ Pump infusion sets with the Pump Module. The use of any other set can cause improper device operation, resulting in an inaccurate fluid delivery or other potential hazard (see *BD Alaris™ Pump Module Infusion Set Compatibility* on page *80*).**
- **Follow proper infusion set loading instructions and ensure the set is free of kinks and that all clamps are open before starting an infusion. Improperly loaded sets or failing to open clamps can result in delayed start of infusion or inaccurate fluid delivery (see *BD Alaris™ Pump Module Set Loading* on page *87*).**
- **Ensure the upper fitment is not elevated above the fitment recess on the pump. Do not stretch or twist the set while loading or when closing the door (see *BD Alaris™ Pump Module Set Loading* on page *87*).**
- **Insert upper tubing fitment into the upper fitment recess before installing the safety clamp into the lower recess to help prevent stretching or twisting of the tubing during loading (see *BD Alaris™ Pump Module Set Loading* on page *87*).**
- **Avoid delivering small bolus or loading dose volumes (< 0.5 mL) at high flow rates (≥ 500 mL/h) because they may not be delivered accurately.**

CAUTION

- Ensure that the device is as close to level with patient's heart as possible. Patient's heart level should be in line with the CHANNEL SELECT key.
- Minimize the height difference between the Pump Module and the patient and avoid changes in the height of the BD Alaris™ System to prevent unintended fluctuations in the flow rate.
- If using multiple PCUs 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 components with one-way valves (also known as pressure-activated valves), especially when infusing at low or very low flow rates because infusion start may be delayed, and unintended boluses may occur. This is because flow cannot start until the valve opens and may start suddenly when it does open. An example of a low flow rate is < 5 mL/h or very low rate is < 0.5 mL/h.
- Use compatible sets with a small priming volume to minimize the time it takes for medication to reach the patient. This is particularly important when infusing at low rates (for example, < 5 mL/h) or very low flow rates (< 0.5 mL/h). It also helps to maintain delivery accuracy and reduces the time to alarm for an occlusion.

BD Alaris™ Pump Module Occlusion Detection

WARNING

- **When programming an infusion 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 can cause serious consequences.**
- **Before each use, verify that all alarm limits, such as occlusion alarm limits, are appropriate for the patient to ensure that alarms occur as intended.**
- **The BD Alaris™ System is capable of infusing during various conditions encountered in clinical practice, for instance through small gauge catheters, filters, and other components. The system is designed to alarm and stop based on pressure limit settings, but you must monitor the infusion to ensure that it is proceeding as expected.**
- **Time-to-alarm for occlusion can be affected by:**
  - **Occlusion pressure setting**
  - **Flow rate**
  - **Location of the occlusion**
  - **Infusion set and components**
  - **Fluid viscosity**
- **To minimize the amount of time for the pump to generate an occlusion alarm while infusing at low rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h), do the following:**
  - **Consider the occlusion pressure limit setting and adjust it, as necessary. The lower the setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (for example, lipids), the occlusion pressure limit setting may need to be increased to reduce false alarms.**
  - **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, and so on).**
- **Use lowest occlusion pressure settings when infusing at low or very low flow rates. High occlusion pressure settings result in longer time to alarm when an occlusion occurs.**
- **Follow proper infusion set loading instructions and ensure the set is free of kinks and that all clamps are open before starting an infusion. Improper set loading or failing to open clamps can result in delayed start of infusion or inaccurate fluid delivery.**

WARNING

- **Ensure the upper fitment is not elevated above the fitment recess on the pump. Do not stretch or twist the set while loading or when closing the door (see *BD Alaris™ Pump Module Set Loading* on page *87*).**
- **Ensure tubing is correctly placed over pressure sensors (see *BD Alaris™ Pump Module Set Loading* on page *87*).**
- **The BD Alaris™ System is neither designed nor intended to detect infiltrations and does not alarm under infiltration conditions.**
- **Ensure the vent is open, if applicable. Rigid containers, glass bottles, and burettes used with unvented sets or with vent closed can cause upstream occlusions.**
- **When infusing at flow rates below 5 mL/h, the pump may take an extended period of time to detect an upstream occlusion and sound an alarm. Ensure that the fluid path is free of kinks or obstructions and observe for several minutes to verify that drops are falling.**

BD Alaris™ Pump Module Post-Occlusion Bolus

WARNING

- **An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus when the occlusion is cleared. The volume of this post-occlusion bolus can be affected by:**
  - **Height of the pump in relation to the patient**
  - **Increase in infusion set distal length**
  - **Increase in infusate temperature**
- **To prevent a bolus after release of an occlusion, 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.**

BD Alaris™ Pump Module Air-in-Line Detection

WARNING

- **When programming an infusion 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 can cause serious consequences.**
- **Ensure that patient is not connected when priming.**
- **Ensure that air is expelled from line prior to beginning infusion when priming (unexpelled air in line could have serious consequences) (see *Priming the BD Alaris™ Pump Module Infusion Set* on page *86* and *Using Priming Options* on page *103*).**
- **For BD Alaris™ Pump Module, ensure that the tubing guide arm is not missing and that it opens when the Pump Module door opens. The tubing guide arm is a small component inside the door that helps guide the tubing into the air-in-line sensor. If the tubing guide arm is missing or broken a nuisance air-in-line alarm can occur. If there is a failure, send the Pump Module to BD for repair (see *BD Alaris™ Pump Module Set Loading* on page *87*).**
- **The secondary infusion set must be primed prior to beginning the secondary infusion (see *Preparing a Secondary Infusion* on page *140* and *Setup* on page *167*).**
- **When clinically appropriate, consider use of 0.2 micron in-line air eliminating filters to prevent downstream infusion of air for high-risk patients for example, neonates.**

CAUTION

- Ensure that tubing is fully inserted in the air-in-line detector to reduce the potential for nuisance air-in-line alarms (see *BD Alaris™ Pump Module Set Loading* on page *87*).

BD Alaris™ Pump Module Secondary Infusion

WARNING

- **Secondary applications require the use of a check valve or clamp on the primary IV line to prevent backflow of secondary medication into the primary line (see *Preparing a Secondary Infusion* on page *140* and *Secondary Infusion (Pump Module)* on page *167*).**
- **The secondary infusion set must be primed prior to beginning the secondary infusion (see *Secondary Infusion* on page *140* and *Setup* on page *167*).**
- **The secondary solution container must be higher than the primary solution container (see *Preparing a Secondary Infusion* on page *140* and *Setup* on page *167*).**
- **When programming a secondary piggyback infusion, confirm that the programmed secondary VTBI matches the actual volume of the bag (including any additives or overfill). This ensures that the entire secondary volume infuses at the correct rate (see *Programming a Secondary Infusion* on page *142*).**
- **The clamp on the secondary infusion set must be opened. If the clamp is closed, the fluid is delivered from the primary container (see *Programming a Secondary Infusion* on page *142* and *Programming a No Guardrails™ Secondary Infusion* on page *178*).**

Alaris™ Syringe Module General

WARNING

- **Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System (see *About This Chapter* on page *66*).**
- **The BD Alaris™ System is not intended to replace supervision by medical personnel.**
- **Discard infusion set if packaging is not intact or protector caps are unattached.**
- **Before loading the syringe, check for damage or defects (see *Alaris™ Syringe Module Loading* on page *97*).**
- **When loading a small size syringe, use extra care to avoid loss of medication and ensure correct loading:**
  - **Clamp tubing before loading.**
  - **Stabilize the syringe plunger while gently lowering the drive head.**
  - **Ensure that the plunger head makes contact with the small black sensor, located on the bottom of the drive head (between the plunger grippers) (see *Alaris™ Syringe Module Loading* on page *97*).**
- **If the patient is receiving a gravity infusion using the same IV site as an infusion on the pump, monitor the infusion to be sure it is flowing as intended.**

CAUTION

- Rx Only: Prescription use only.
- If pre-running infusions to allow medications to reach a steady state prior to connection to the patient, ensure the distal end of the tubing is level with or higher than the device. Failure to do so can create negative pressure resulting in siphoning or delayed start of infusion (see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*).

Alaris™ Syringe Module Free-Flow Prevention

WARNING

- **Ensure that the syringe barrel, flange, and plunger are installed and secured correctly. Failure to install the syringe correctly can result in uncontrolled fluid flow to the patient (see *Alaris™ Syringe Module Loading* on page *97*).**
- **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 infusion set is not clamped or turned off, and can cause serious injury or death (see *Alaris™ Syringe Module Loading* on page *97*).**

Alaris™ Syringe Module Rate Accuracy

WARNING

- **Do not use incompatible syringe sizes and models with the Syringe Module. Use of incompatible syringes can impact pump operation resulting in inaccurate fluid delivery, delayed generation of occlusion alarms, and other potential problems (see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*).**
- **Ensure that the displayed syringe manufacturer and syringe size match the installed syringe. Mismatches can impact flow rate accuracy (see *Manual Programming with Guardrails™ Suite MX* on page *110* and *Initial Primary Infusion* on page *151*).**
- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe can impact pump performance including delivery accuracy and startup time, and generation of occlusion alarms and bolus volume after occlusion. This is due to the increased friction and compliance of the syringe stopper with larger syringes. It is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h) (see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*).**
- **When using the pressure sensing disc feature, only use sets labeled for use with Alaris™ Syringe Module. Use of any other pressure sensing disc sets can cause improper device operation.**
- **Rate accuracy can be affected by:**
  - **Temperature and viscosity of the IV solution**
  - **Height of the pump in relation to the patient**
  - **Back pressure related to the infusion set and the IV catheter**
- **Avoid raising or lowering the syringe pump during an infusion. Raising or lowering the syringe pump during an infusion can result in a bolus of medication or fluid or a delay in the infusion or under infusion due to changes in hydrostatic pressure.**
- **Use the Prime Set with Syringe feature in the Channel Options menu, when starting an infusion or changing the syringe and tubing. Failure to do so can delay the infusion delivery startup time and lead to delivery inaccuracies (see *Using Priming Options* on page *103* and *Selecting Syringe Module Pressure Limit with Pressure Sensing Disc NOT Installed* on page *194*).**
- **Avoid delivering small bolus or loading dose volumes (< 0.5 mL) at high flow rates (≥ 500 mL/h) because they may not be delivered accurately.**

CAUTION

- Ensure that the device is as close to level with patient's heart as possible. Patient's heart level should be in line with the CHANNEL SELECT key.
- Minimize the height difference between the Syringe Module and the patient and avoid changes in the height of the BD Alaris™ System to prevent unintended fluctuations in the flow rate.
- If using multiple PCUs 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 components with one-way valves (also known as pressure-activated valves), especially when infusing at low or very low flow rates because infusion start may be delayed, and unintended boluses may occur. This is because flow cannot start until the valve opens and may start suddenly when it does open. An example of a low flow rate is < 5 mL/h or very low rate is < 0.5 mL/h (see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*).
- Use compatible sets with a small priming volume to minimize the time it takes for medication to reach the patient. This is particularly important when infusing at low rates (for example, < 5 mL/h) or very low flow rates (< 0.5 mL/h). It also helps to maintain delivery accuracy and reduces the time to alarm for an occlusion.

Alaris™ Syringe Module Occlusion Detection

WARNING

- **When programming an infusion 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 can cause serious consequences.**
- **Before each use, verify that all alarm limits, such as occlusion alarm limits, are appropriate for the patient to ensure that alarms occur as intended.**
- **The BD Alaris™ System is capable of infusing during various conditions encountered in clinical practice, for instance through small gauge catheters, filters, and other components. The system is designed to alarm and stop based on pressure limit settings, but you must monitor the infusion to ensure that it is proceeding as expected.**
- **Do not use incompatible syringe sizes and models with the Syringe Module. Use of incompatible syringes can impact pump operation resulting in inaccurate fluid delivery, delayed generation of occlusion alarms, and other potential problems (see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*).**
- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe can impact pump performance including delivery accuracy and startup time, generation of occlusion alarms and bolus volume after occlusion. This is due to the increased friction and compliance of the syringe stopper with larger syringes. It is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h).**
- **To minimize the amount of time for the pump to generate an occlusion alarm while infusing at low rates (for example, < 5 mL/h) and especially very low flow rates (< 0.5 mL/h), do the following:**
  - **Consider the occlusion pressure limit setting and adjust it, as necessary. The lower the setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (for example, lipids), the occlusion pressure limit setting may need to be adjusted to reduce false alarms.**
  - **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe when infusing at low rates can lead to delayed generation of occlusion alarms. This is due to the higher compliance of the syringe stopper and increased friction between the plunger and the walls of the syringe with larger syringes.**
  - **Use the Prime Set with Syringe feature in the Channel Options menu, when starting an infusion or changing the syringe and tubing. Failure to do so can delay the infusion delivery startup time and lead to delivery inaccuracies.**

WARNING

- **Use compatible components that have the smallest internal volume or deadspace to minimize the residual volumes between the syringe and the patient.**
- **Use accessory devices that have the smallest internal volume or deadspace (for example, use microbore tubing when infusing at low rates, shorter length of tubing, and so on).**
- **Time-to-alarm for occlusion can be affected by:**
  - **Occlusion pressure setting**
  - **Flow rate**
  - **Location of the occlusion**
  - **Infusion set and components**
  - **Fluid viscosity**
- **When loading a small size syringe, use extra care to avoid loss of medication and ensure correct loading:**
  - **Clamp tubing before loading.**
  - **Stabilize the syringe plunger while gently lowering the drive head.**
  - **Ensure that the plunger head makes contact with the small black sensor, located on the bottom of the drive head (between the plunger grippers) (see *Alaris™ Syringe Module Loading* on page *97*).**
- **The BD Alaris™ System is neither designed nor intended to detect infiltrations and does not alarm under infiltration conditions.**
- **Use lowest occlusion pressure settings when infusing at low or very low flow rates. High occlusion pressure settings result in longer time to alarm when an occlusion occurs.**

CAUTION

- When infusing high risk or life-sustaining medications at low flow rates, consider using an extension set with a pressure sensing disc for improved pressure monitoring and shorter times to occlusion alarm (see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*).
- Installing a pressure sensing disc after an infusion has started can result in a bolus to the patient (see *Selecting Syringe Module Pressure Limit with Pressure Sensing Disc Installed* on page *192*).

Alaris™ Syringe Module Post-Occlusion Bolus

WARNING

- **An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus when the occlusion is cleared. The volume of this post-occlusion bolus can be affected by:**
  - **Height of the pump in relation to the patient**
  - **Increase in infusion set distal length**
  - **Increase in infusate temperature**
- **To prevent a bolus after release of an occlusion, 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.**
- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe can impact pump performance including delivery accuracy and startup time, generation of occlusion alarms and bolus volume after occlusion. This is due to the increased friction and compliance of the syringe stopper with larger syringes. It is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h).**

CAUTION

- Use a set with a pressure sensing disc with back off feature enabled to reduce bolus volume after an occlusion.

Alaris™ Syringe Module Priming

WARNING

- **Ensure that patient is not connected when priming.**
- **Ensure that air is expelled from line prior to beginning infusion (unexpelled air-in-line could have serious consequences) (see *Priming Infusion Set With Pressure Sensing Disc* on page *96* and *Using Priming Options* on page *103*).**
- **Do not prime with the pressure sensing disc installed. Doing so can result in air being trapped in the disc. To ensure that all air is expelled, gently massage the disc during priming (see *Priming Infusion Set With Pressure Sensing Disc* on page *96* and *Using Priming Options* on page *103*).**
- **When clinically appropriate, consider use of 0.2 micron in-line air eliminating filters to prevent downstream infusion of air for high-risk patients for example, neonates.**

BD Alaris™ Pump Module and Alaris™ Syringe Module Programming

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 (see *Drug Calculation Definitions and Formulas* on page *201*).**
- **If an error is made when entering DRUG AMOUNT or DILUENT VOLUME, it may result in an over- or under-infusion. If a lower concentration is entered in error, this may result in a higher than intended delivery (over-infusion) (see *Programming an Infusion with a Custom Concentration Entry* on page *120*).**

CAUTION

- When you have primed the tubing with the medication syringe, consider the volume that will remain in the tubing when programming rate/duration. This ensures the entire drug dose will infuse over the intended duration (see *Intermittent Infusion* on page *129*).

BD Alaris™ Pump Module and Alaris™ Syringe Module Epidural

WARNING

- **Follow epidural precautions:**
  - **Administer only anesthetics/analgesics that are approved and labeled for epidural administration (as indicated by the drug's package insert). Epidural administration of drugs other than those indicated can result in serious patient injury.**
  - **Use only catheters, inserted by a qualified clinician, that are specifically labeled for epidural drug delivery.**
  - **Use infusion sets with NO injection sites (also known as Y-sites or ports).**
  - **Label the container and the infusion set to indicate that they are For Epidural Use Only.**
  - **Clearly identify infusion pumps used for epidural infusions.**
  - **Patients receiving epidural infusions should be closely monitored by clinicians who are trained and qualified to manage such infusions.**

About This Chapter

WARNING

Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System.

CAUTION

Rx Only: Prescription use only.

This section of the user manual provides Pump Module (model 8100) and Syringe Module (model 8110) instructions and information. It is used in conjunction with:

- BD Alaris™ infusion set instructions
- Drug product labeling
- PCU chapter of this manual (see *About this Chapter* on page *8*)
- *BD Alaris™ PCU Model 8015, Alaris™ PCU Model 8015, BD Alaris™ Pump Module Model 8100, and Alaris™ Pump Module Model 8100 Technical Service Manual*
- *Alaris™ Syringe Module Model 8110 and Alaris™ PCA Module Model 8120 Technical Service Manual*
- System maintenance software (and its instructions) for system check-in, maintenance, and configurations for connecting the PCUs to the wireless network

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

Some functionality described in this chapter may not be available to all customers.

BD Alaris™ and Alaris™ Pump Module

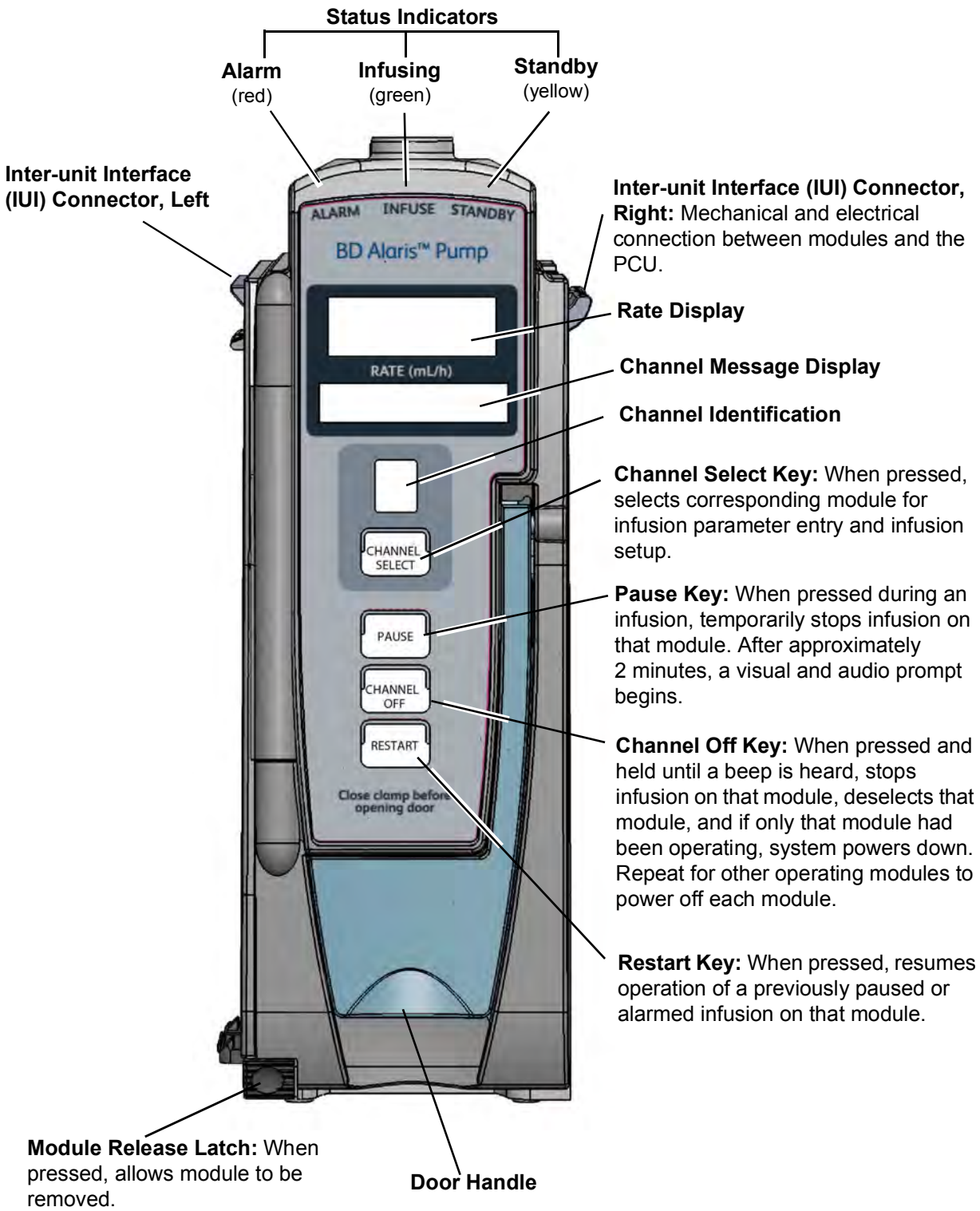
The BD Alaris™ Pump Module is designed for delivery of fluids, medications, and blood products for adult, pediatric, and neonatal patients.

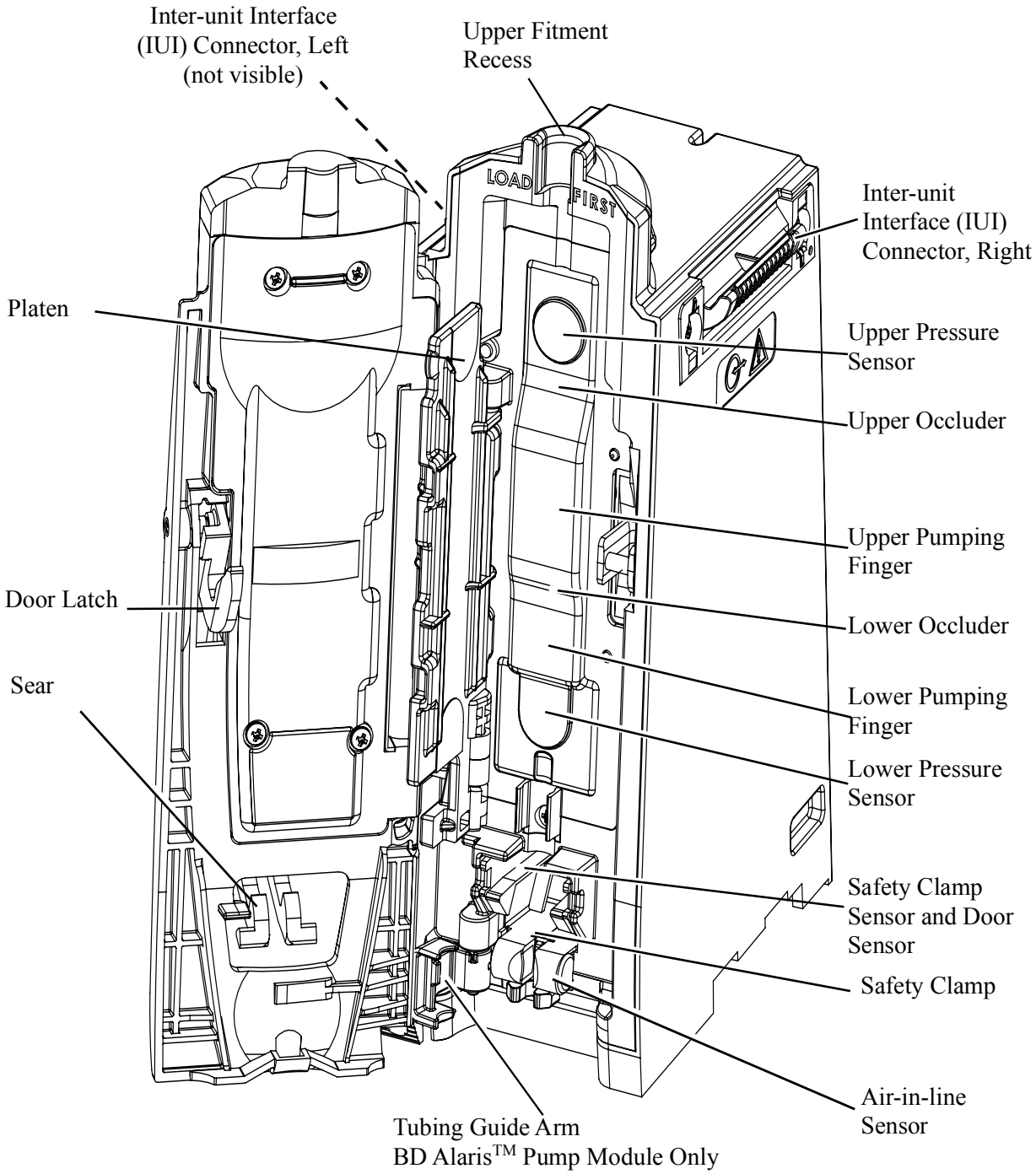
The BD Alaris™ and Alaris™ Pump modules are shown below.

BD Alaris™ Pump Module

Alaris™ Pump Module

Operating Features, Controls, and Indicators





BD Alaris™ Pump Module

Alaris™ Syringe Module

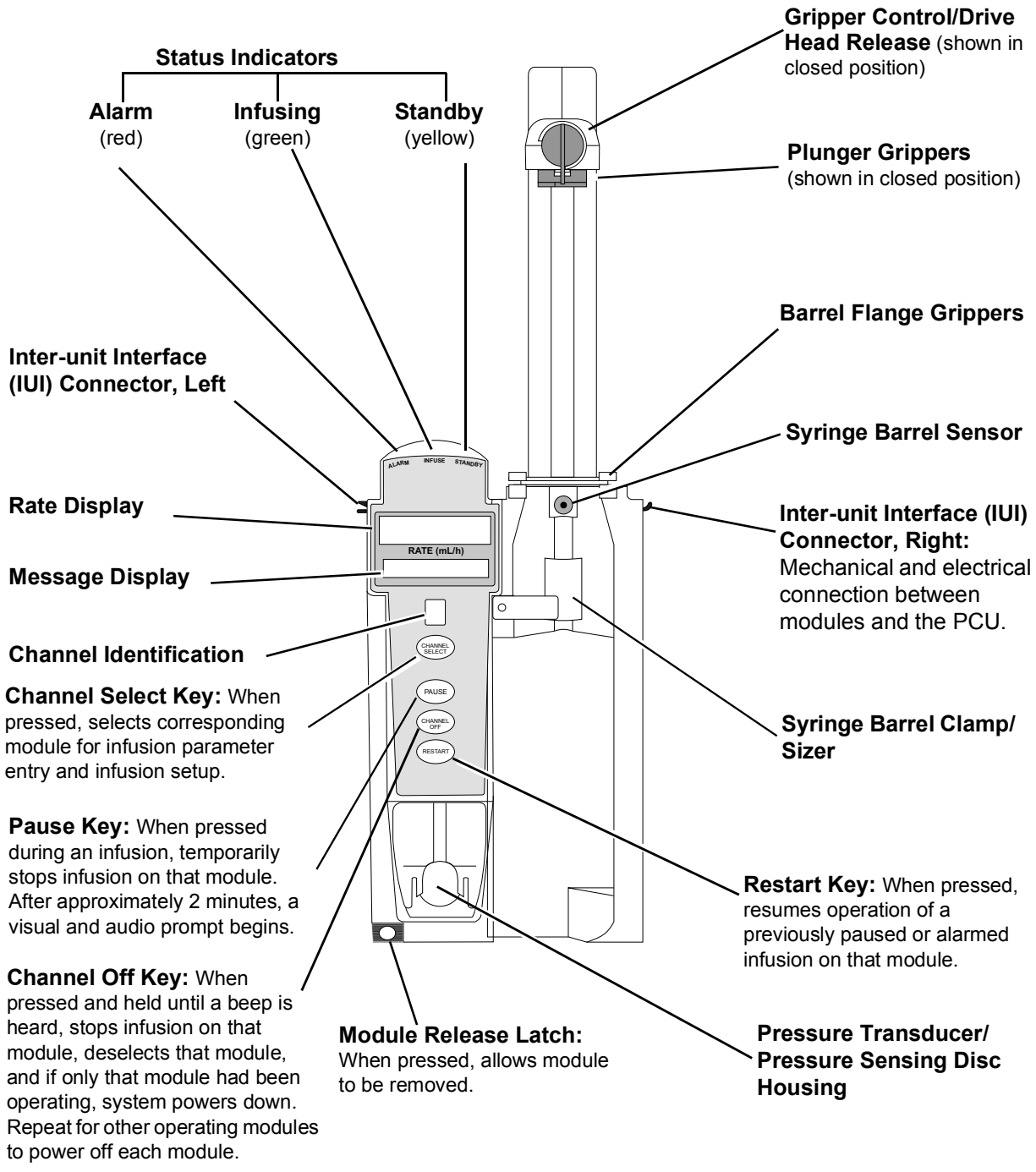
The Alaris™ Syringe Module is designed for syringe delivery of medications, fluids, and blood products for adult, pediatric, and neonatal patients.

The Alaris™ Syringe Module is shown below.

Alaris™ Syringe Module

NOTE:
In this document, Pump or Syringe Module refers to BD Alaris™ Pump and Alaris™ Pump or Alaris™ Syringe Module.

Operating Features, Controls, and Indicators



Alaris™ Syringe Module

Features and Definitions

See *System Configuration Settings* on page *46* for system features and definitions.

Feature	Definition—Pump and Syringe Modules
Anesthesia Mode	When operating in anesthesia mode, a module can be paused indefinitely without an alarm. Anesthesia mode also makes it possible to have additional drugs in each profile, which are only accessible when operating in that mode. Air-in-line settings can also be adjusted to 50, 75, 125, 175, 250, and 500 microliters (500 microliters - anesthesia mode only).
Bolus Dose	Allows a bolus infusion to be programmed using either drug library or drug calculation feature. It can be programmed with or without a continuous infusion following a bolus.
Callback	A callback for a programmed delay (see *Delay Options* on page *184* for a definition) can be scheduled to give an alert **Before** an infusion is to be started, **After** an infusion is completed, **Before and After** an infusion, or no alert (**None**).
Channel Labels	Available when profiles feature is enabled. Provides a hospital-defined list of labels, displayed in channel (module) message display, and identifies module with catheter location or other helpful information.
Concentration Limits	Limits specified for range of concentrations allowed for a particular drug in a profile.
Delay Options	Allows system to be programmed to delay start of an infusion for 1 minute to 11 hours 59 minutes
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 (the system calculates correct flow rate to achieve desired dose), or Entry of flow rate for a continuous infusion (the system calculates corresponding drug dose).
Drug Library	When profiles feature is enabled, it provides a hospital-defined list of drugs and concentrations appropriate for use in as many as 30 profiles. Drug library use automates programming steps, including drug name, drug amount and diluent volume, and activates hospital-established best-practice limits. Drug library entries can be delivered as a primary or secondary, or both, as determined by hospital-health system.
Duration Limits	Hospital-established limits around duration of an intermittent infusion.
Dynamic Pressure Display	Appears on Main Display. If enabled, it graphically displays current patient-side occlusion pressure set point and current patient-side operating pressure for that module (see *Dynamic Pressure Display* on page *77*).

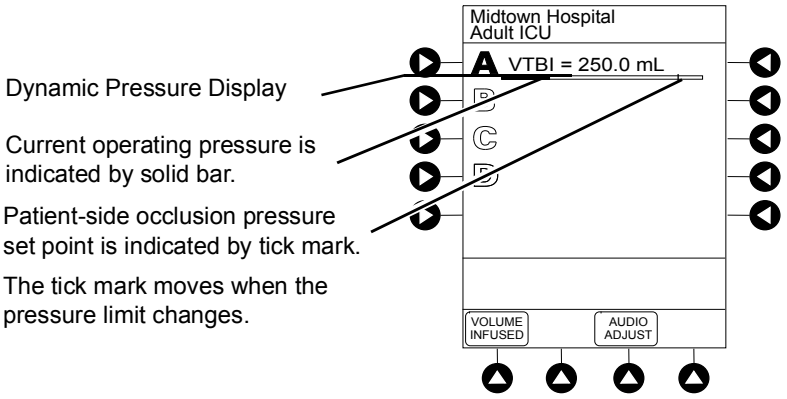
Feature	Definition—Pump and Syringe Modules
Event Logging	Event logging records device operations.
Initial Value	An optional and editable starting value for continuous infusion dose, duration, bolus dose, bolus rate of administration, or bolus dose duration.
IV Fluid Library	An optional library consisting of IV fluids (for example, total parenteral nutrition) and limits around rate of delivery (mL/h).
Limit	A programming limit or best-practice guideline determined by hospital or 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 or health system as hard 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.
No Guardrails™ - Basic Infusion	No Guardrails™ - Basic Infusion is a mode in which there are no Guardrails™ Suite MX safety software protection limits. No Guardrails™ - Basic Infusion is typically used for medications and fluids not found in the drug library, investigational medications, and in emergency situations. No Guardrails™ - Basic Infusion may include primary, secondary, or drug calculation infusions.
No Guardrails™ - Basic Infusion Clinical Advisory	When enabled, reinforces the hospital/facility best-practice guidelines regarding the utilization of Guardrails™ by providing a clinical advisory notifying the clinician that there are No Guardrails™ protections for the selection made. This clinical advisory can be customized by the facility/hospital within the Guardrails™ Editor and will appear in all profiles, where enabled.
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. The restore option is available for infusions on the same module and PCU if the system is powered up within 8 hours of last use and the user answers No to the New Patient prompt.
Therapies	An optional hospital-defined therapy or clinical indication for delivery of that infusion. Different limits can be defined for same medication with different therapeutic indications.
Total Dose Limits	Hospital-established limits around total dose of infusion.
Volume/Duration	Allows a volume-to-be-infused (VTBI) and duration (infusion time) to be programmed. Flow rate is automatically calculated.

Feature	Definition—Pump Module
Auto-Restart	Part of the system's downstream occlusion detection system designed to minimize nuisance, patient-side occlusion alarms. Allows system to automatically continue an infusion following detection of a patient-side occlusion if downstream pressure falls to an acceptable level within a 15-second checking line period. If this feature is enabled, checking line function occurs when downstream pressure exceeds pressure limit. • In selectable pressure mode: Pressure limit is either user-adjustable or locked in system configuration. • In pump pressure mode: Pressure limit is a function of flow rate and is automatically determined by device. If downstream pressure decreases to a predetermined level (below 50% pressure limit) during 15-second checking line period, infusion automatically continues. If condition is not cleared within 15 seconds, a partial occlusion - patient side alarm occurs. Using the Guardrails™ Editor software, the system can be configured to allow 0 (zero) to 9 restart attempts within a rolling 10-minute period. If allowable number of restarts is exceeded or if feature is set to zero, an occluded - patient side alarm occurs when system detects downstream pressure that exceeds pressure limit. **NOTE:** Auto-restart for anesthesia mode is set to 9 and is not configurable.
Default Occlusion Pressure	Starting occlusion pressure limit that can be configured by profile in 25 mmHg increments.
Free Flow Protection	All BD Alaris™ Pump infusion sets use a unique clamping device (safety clamp on the lower fitment) to prevent inadvertent free-flow when infusion set is removed from device.
KVO Rate Adjust	Used to select keep vein open (KVO) 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, from 50 mmHg up to maximum occlusion pressure of 525 mmHg. • **Auto-Restart:** (See *Auto-Restart* on page *74*.) In addition, the 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 a BD Alaris™ Pump Module infusion set with a check valve is used.

Feature	Definition—Syringe Module
All Mode	When **ALL** is selected as the volume to be infused (VTBI), the entire contents of syringe is delivered.
Auto Pressure	When enabled and a pressure sensing disc is in use, auto pressure option is displayed in pressure limit screen. Auto pressure automatically sets alarm limit for a shorter time to alarm, as follows: • 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 available only when infusion 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 infusion set having a pressure sensing disc is used, device runs at an increased rate when an infusion is first started, taking up any slack in drive mechanism.
Infusion Complete	An alert is given when current infusion is complete and VTBI has reached zero.
KVO	If enabled, allows continuous infusions to automatically switch into KVO mode upon completion. KVO option setting cannot be changed after device is powered on and a profile selected.
Near End of Infusion (NEOI)	Allows an alarm to be configured to sound anywhere from 1 to 60 minutes prior to the end of the infusion. The NEOI alarm can be configured separately between continuous type infusions and intermittent infusions. A separate alert time can be set for continuous and intermittent infusions. **NOTE:** If the duration of the programmed infusion is less than or equal to the configured limit set in the Guardrails™ Editor, the NEOI alarm will occur at the start of the infusion.

Feature	Definition—Syringe Module
NEOI Snooze	Optional capability to remind users NEOI alarm has been silenced. This is a shared syringe and PCA setting.
Numeric Pressure Display	Dynamic pressure display is numerical and available only when pressure sensing disc is inserted.
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.
Pressure Sensing Disc	When installed, pressure sensing disc significantly improves device's pressure sensing capabilities for a faster occlusion detection time, and makes the following features available: • Auto Pressure • Back-Off • Customizable Pressure Alarm Settings (see *Occlusion Pressure* on page *74*) • Fast Start • Pressure Tracking
Priming	Allows a limited volume of fluid to be delivered to prime infusion set prior to being connected to a patient or after changing a syringe. When priming, a single continuous press of **PRIME** soft key delivers up to 2 mL of priming fluid.
Syringe Empty	Device generates 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.

Dynamic Pressure Display



NOTE:
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.

Preparing for an Infusion (BD Alaris™ Pump Module)

WARNING

Infusion sets:

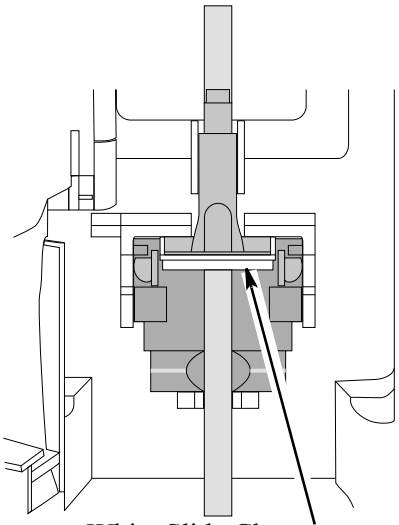
- **Use only BD Alaris™ Pump infusion sets with the Pump Module. The use of any other set can cause improper device operation, resulting in inaccurate fluid delivery or other potential hazard.**
- **Discard infusion set if packaging is not intact or protector caps are unattached.**

Safety Clamp (BD Alaris™ Pump Module)

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

Safety Clamp in Open Position

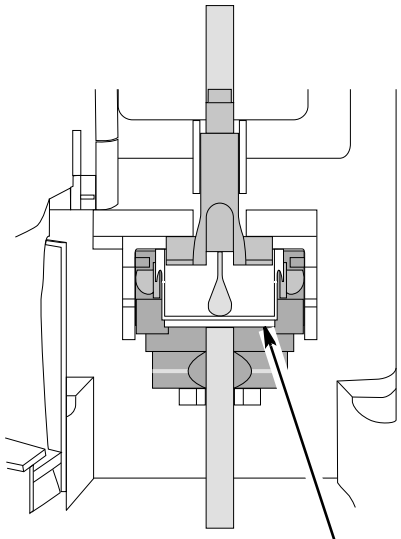
When a new BD Alaris™ Pump infusion set is removed from the package, the safety clamp is in the open position (white slide clamp aligned with blue housing). In this open position, flow is allowed as required for the priming process. The roller clamp is used to control flow during the priming process.



White Slide Clamp
(shown in open position)

Safety Clamp in Closed Position

When an infusion set is removed from the Pump Module, the device automatically engages the safety clamp in the closed position (white slide clamp projects out from under blue housing). In this closed position, flow is prevented.



White Slide Clamp
(shown in closed position)

BD Alaris™ Pump Module Infusion Set Compatibility

Compatible infusion sets for the BD Alaris™ Pump Module are shown in the tables below. For the updated list, refer to the BD website: bd.com/Infusionlibrary. To locate the compatibility list on the BD website, enter **compatible disposables** in the search field.

For additional information including priming volume, see https://www.bd.com/en-us/offerings/capabilities/infusion-therapy/infusion-therapy-resource-library?contenttype=962.

WARNING

Use only BD Alaris™ Pump infusion sets with the Pump Module. The use of any other set can cause improper device operation, resulting in an inaccurate fluid delivery or other potential hazard.

Description Keys

Defines the keys shown in the compatibility table descriptions that follow. For example, 20D 2SS CV describes a 20 drop/mL infusion set with 2 SmartSite™ Y-sites and a check valve.

Key	Description
AMBER	Amber colored tubing
BAG	Bag access device
BLD	Blood set
BUR	Burette
CV	Check valve
D	Drop count
DEHP	DEHP is part of the material formulation
G	Ganged manifold (2 or 3 gang)
HALF	Half set
INJ	Y injection port
LOW SORB	Low sorbing (polyethylene) lined tubing
M	Filter size measured in microns (0.2 M, 1.2 M, 15 M, 180 M, 200 M)
MANI	Manifold
MICROBORE	Micro bore tubing
SC	Slide clamp
SMBORE	Small bore tubing
SS	SmartSite™ Y connector
TEX	Texium™ connector
VSA	Vented syringe adapter

Key	Description
VS	VersaSafe™ Y connector
WSPK	Stopcock (3 or 4 way)
YELLOW	Yellow-striped tubing

NOTE:
DEHP-free sets do not contain DEHP in the description.

Primary Pump Sets

Model Number	Description
2420-0007	20D 2SS CV
2420-0500	20D DEHP 2SS CV
2426-0007	20D 3SS CV
2426-0500	20D DEHP 3SS CV
10015861A	SS BAG 20D LOW SORB 3SS CV
10942011	20D
11171447	20D 3SS 2CV
11426965	20D CV
2120-0500	20D DEHP 2VS CV
2260-0500	20D LOW SORB
2452-0007	10D 3SS 2CV
24600-0007	20D LOW SORB 3SS CV
10012645	20D DEHP SS CV
10013186	60D DEHP 3SS CV
11404930	10D 3SS CV
24001-0007	20D SS CV
24201-0007	20D 2 SS
2455-0500	20D DEHP SS
10013072	20D LOW SORB 2SS CV
10013361	SS BAG 20D 2SS CV
10321213	SS BAG 20D
11287205	20D 4SS 4SS
11590100	60D 2SS CV
2466-0007	SS BAG 20D LOW SORB
2207-0007	20D
2419-0007	20D 3SS CV
2424-0007	20D 4SS 4SS
2428-0007	20D 4SS 2CV
2429-0007	20D 4SS CV
2433-0007	20D 2SS CV
2435-0007	20D 4SS CV
2451-0007	20D 3CV

Model Number	Description
2461-0007	20D LOW SORB 3SS CV
C24117	20D LOW SORB
10014855A	SS BAG 20D LOW SORB 2SS CV
10061661A	SS BAG 20D LOW SORB 4SS CV
10404198	20D 3SS CV
10879047	10D 2SS CV
11484001	20D SS CV
24200-0007	20D SC 2 SS
24260-0007	20D SC 3 SS

Blood Sets

Model Number	Description
2278-0500	BLD200M 20D DEHP SMBORE
2477-0007	BLD180M 15D SS
10015414	BLD180M 15D DEHP
10062818	BLD180M 15D

Specialty Sets

Model Number	Description
22603-B007T	SS BAG 20D LOW SORB TEX
24010-0007T	20D 3SS TEX CV
24301-0007T	SS BAG 20D LOW SORB SS TEX 0.2M
24601-B007T	SS BAG 20D LOW SORB 2SS TEX CV
10013361T	SS BAG 20D 2SS TEX CV
10321213T	SS BAG 20D TEX
22000-B007T	SS BAG 20D TEX
22600-0007T	20D LOW SORB TEX
22602-B007T	SS BAG 20D LOW SORB TEX
22601-B007T	SS BAG 20D LOW SORB TEX
11522558	20D 3SS CV BV
2403-0007	HALF SS
2206-0007	20D YELLOW MICROBORE
10011301	20D DEHP YELLOW MICROBORE CV
11426964	20D LOW SORB

Model Number	Description
2204-0007	20D
10013890	20D LOW SORB
10015862	SS BAG 20D LOW SORB
11419365	20D MANI 3WSPK CV
2423-0007	10D 4SS 2G-4WSPK CV
10015896	10D 3SS 2G-4WSPK CV
10813621	20D 4SS 3G-4WSPK CV
24008-0007	20D 2SS MANI CV
2413-0007	20D 5SS 4G-4WSPKCV
2422-0007	10D 4SS 4WSPK CV
2450-0500	10D 3SS 2G-3WSPK CV
10010483	VSA SMBORE

In-line Filter Sets

Model Number	Description
10010453	20D LOW SORB SS 1.2M
10561554	20D DEHP 3SS 15M CV
11532269	20D LOW SORB 2SS 0.2M CV
2202-0007	20D 1.2M
2203-0500	20D DEHP AMBER 15M
2432-0007	20D 3SS 0.2M CV
10010454	20D LOW SORB SS 0.2M
2434-0007	20D SS 0.2M CV
2465-0007	SS BAG 20D LOW SORB SS 0.2M
10406194	20D LOW SORB SMBORE 3SS 0.2M CV
10863358	20D DEHP 15M
2232-0007	20D 0.2M

Burettes

Model Number	Description
10015012	BUR 20D LOW SORB SMBORE SS 0.2M
2441-0007	BUR 60D SMBORE 3SS
2447-0007	BUR 60D 2SS BV
11613191	BUR 60D LOW SORB 2SS 0.2M BV
10821753	BUR 20D 3SS
2443-0600	BUR 60D DEHP SMBORE 3SS 0.2M

Priming the BD Alaris™ Pump Module Infusion Set

WARNING

Ensure that patient is not connected when priming.

WARNING

Ensure that air is expelled from line prior to beginning infusion when priming (unexpelled air-in-line could have serious consequences).

WARNING

Ensure the vent is open, if applicable. Rigid containers, glass bottles, and burettes used with unvented sets or with vent closed can cause upstream occlusions.

WARNING

When clinically appropriate, consider use of 0.2 micron in-line air eliminating filters to prevent downstream infusion of air for high-risk patients for example, neonates.

1. Prepare primary solution container in accordance with manufacturer's user manual. Allow solutions to warm to room temperature, if possible. When infusing a chilled solution, air bubbles may form as cold solutions begin to warm.
2. Open infusion set package, remove set, and close roller clamp. (Refer to set's user manual.)
3. Insert infusion set spike into prepared fluid container, following accepted hospital/facility procedure, and hang the solution container at the height required to achieve the desired flow rate.
4. Fill drip chamber to ⅔ full. Hang drip chamber vertically.
5. If container requires venting, open vent cap on infusion set spike.
6. Priming tubing should be done slowly to help prevent turbulence. Slowly open roller clamp to prime tubing.
7. When priming is complete, close roller clamp.
8. Verify no fluid flow.

BD Alaris™ Pump Module Set Loading

WARNING

- **Follow proper infusion set loading instructions and ensure the set is free of kinks before starting an infusion. Improperly loaded sets can impact pump operation resulting in inaccurate fluid delivery.**
- **Ensure the upper fitment is not elevated above the fitment recess on the pump. Do not stretch or twist the set while loading or when closing the door.**
- **Ensure tubing is correctly placed over pressure sensors.**
- **For BD Alaris™ Pump Module, ensure that the tubing guide arm is not missing and that it opens when the Pump Module door opens. The tubing guide arm is a small component inside the door that helps guide the tubing into the air-in-line sensor. If the tubing guide arm is missing or broken a nuisance air-in-line alarm can occur. If there is a failure, send the Pump Module to BD for repair.**

WARNING

To prevent a potential free-flow condition, do not use a Pump Module if it is damaged in any way or does not appear to be functioning as expected. Free-flow can result in patient harm.

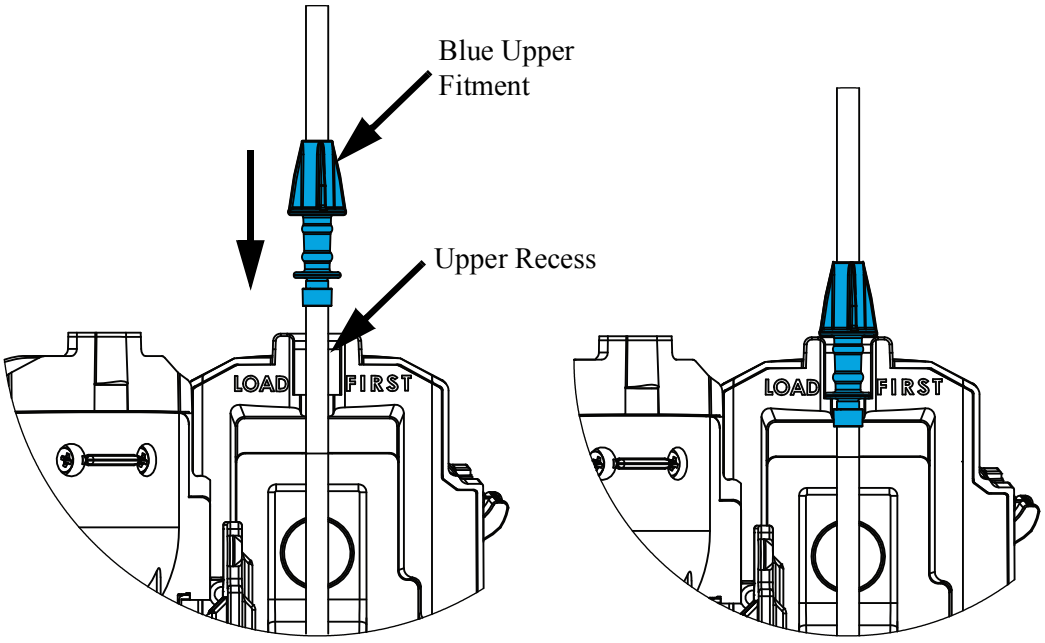
CAUTION

Insert upper tubing fitment into the upper fitment recess before installing the safety clamp into the lower recess to help prevent stretching or twisting of the tubing during loading.

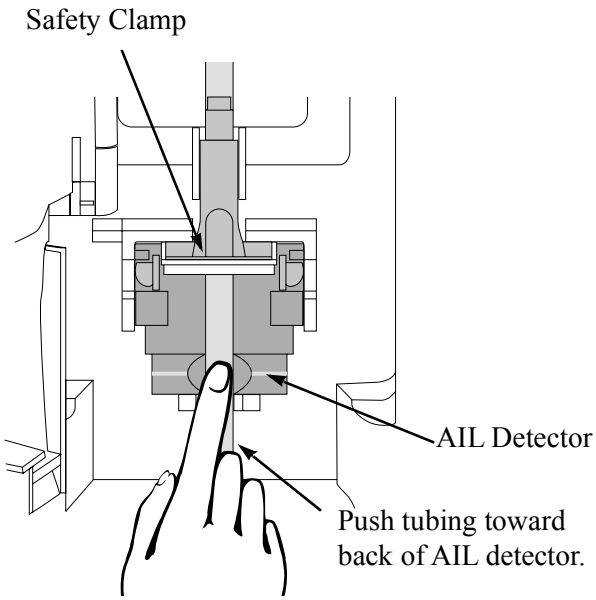
NOTE:
Leave the safety clamp in the closed position when reloading an infusion set to prevent unintended flow.

1. Open the Pump Module door.
2. Look at all visible surfaces and moving parts for any signs of damage, including cracks and loose parts.
3. If a new set is being loaded, prime the set. See *Priming the BD Alaris™ Pump Module Infusion Set* on page *86* for more information.

4. Load the infusion set, as follows:
   a. Hold blue upper fitment above fitment recess and lower into recess. The blue upper fitment fits loosely in the recess.
   b. Ensure that tubing is not twisted or stretched.



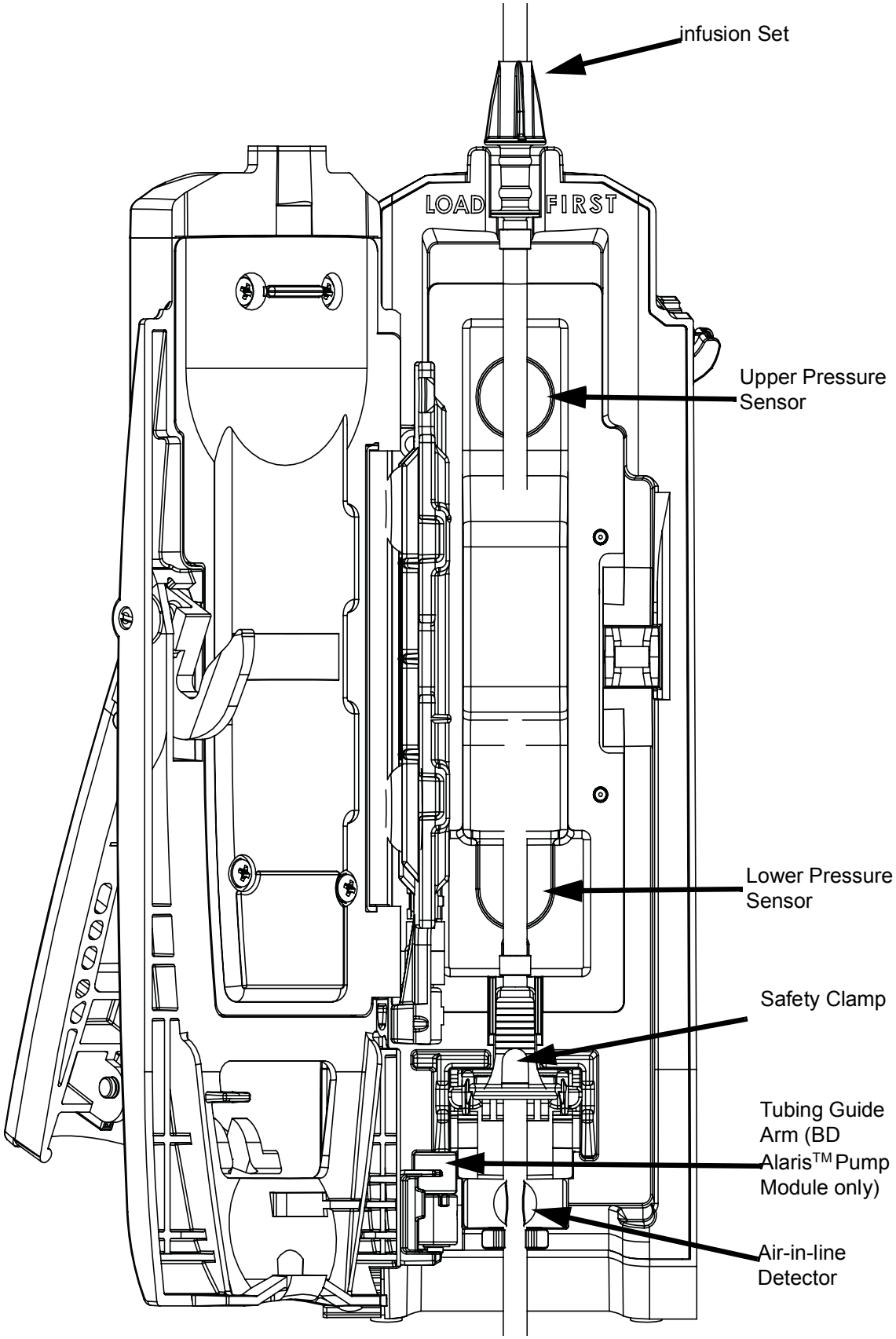
c. Press the safety clamp into recess below mechanism.



CAUTION

Ensure that tubing is fully inserted in the air-in-line detector to reduce the potential for nuisance air-in-line alarms.

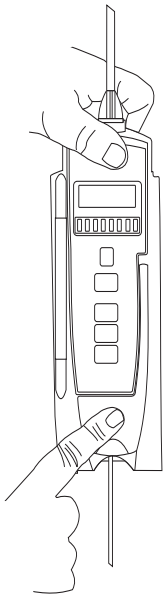
d. Using a finger tip, firmly push tubing toward back of air-in-line (AIL) detector.


infusion Set
LOAD
FIRST
Upper Pressure Sensor
Lower Pressure Sensor
Safety Clamp
Tubing Guide Arm (BD Alaris™ Pump Module only)
Air-in-line Detector

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.

5. Close the door and latch, as follows:
   a. Close the door and hold it in a closed position by grasping both the door and the device case with one hand.
   b. Gently lower the latch. The safety clamp is automatically disengaged.

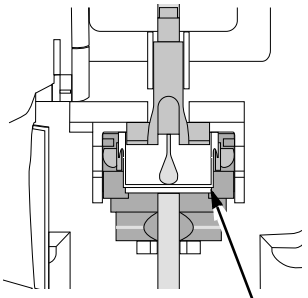


6. Open the roller clamp.
7. Verify that no fluid is flowing through the drip chamber.

Removing the Infusion Set

1. Close the roller clamp.
2. Open the Pump Module door.

   The set's safety clamp fitment automatically closes to prevent accidental free-flow.



3. Remove set, as follows:
   a. Gently pull tubing below air-in-line detector forward and out.
   b. Lift upper fitment from upper fitment receptacle.
4. If set is being removed to begin a gravity flow:
   a. Depress the blue ridged release tab on upper side of safety clamp device.
   b. Slide the white slide clamp into blue fitment (open position).
   c. Adjust the flow rate using set's roller clamp.

Preparing for an Infusion (Alaris™ Syringe Module)

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

- Use smallest syringe size possible (for example, if infusing 2.3 mL of fluid, use a 3 mL syringe).
- Use compatible components which have the smallest internal volume or deadspace. For example:
  - Tubing internal diameter: Smallbore or microbore tubing is recommended when infusing at low rates or small volumes.
  - 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.

WARNING

Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe can impact pump performance including delivery accuracy and startup time, generation of occlusion alarms and bolus volume after occlusion. This is due to the increased friction and compliance of the syringe stopper with larger syringes. It is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h).

WARNING

When clinically appropriate, consider use of 0.2 micron in-line air eliminating filters to prevent downstream infusion of air for high-risk patients for example, neonates.

CAUTION

When infusing high risk or life-sustaining medications at low flow rates, consider using an extension set with a pressure sensing disc for improved pressure monitoring and shorter times to occlusion alarm.

CAUTION

- Use compatible sets with a small priming volume to minimize the time for medication to reach the patient. This is particularly important when infusing at low rates (for example, < 5 mL/h) or very low flow rates (< 0.5 mL/h). It also helps to maintain delivery accuracy and reduces the time to alarm for an occlusion.
- If pre-running infusions to allow medications to reach a steady state prior to connection to the patient, ensure the distal end of the tubing is level with or higher than the device. Failure to do so can create negative pressure resulting in siphoning or delayed start of infusion.
- Avoid use of components with one-way valves (also known as pressure-activated valves), especially when infusing at low or very low flow rates because infusion start may be delayed, and unintended boluses may occur. This is because flow cannot start until the valve opens and may start suddenly when it does open. An example of a low flow rate is < 5 mL/h or very low rate is < 0.5 mL/h.

1. Prepare syringe (for a list of compatible syringes, refer to *Alaris™ Syringe Module Infusion Set Compatibility* on page *94*) in accordance with manufacturer's user manual.
2. Prepare infusion set in accordance with manufacturer's user manual.
3. Attach upper fitting of infusion set to syringe tip.

Alaris™ Syringe Module Infusion Set Compatibility

WARNING

When using the pressure sensing disc feature, only use Alaris™ Syringe Module sets. Use of any other pressure sensing disc sets can cause improper device operation.

Compatible infusion sets for the Alaris™ Syringe Module are shown in the tables below. Other non-dedicated extension sets appropriate for the syringe pump use can also be utilized. For the updated list, refer to the BD website: bd.com/Infusionlibrary. To locate the compatibility list on the BD website, enter **compatible disposables** in the search field.

Compatible Infusion Sets with Pressure Sensing Disc

Model Number	Description
10014914	Microbore tubing, 60", 0.7 mL, non-DEHP
10014916	Microbore tubing, 0.2 micron filter, 60", 1 mL, non-DEHP
10014918	Low sorbing tubing, 60", 1.2 mL, non-DEHP
10798703	Microbore tubing, 20 drop, check valve, SmartSite™ needle-free valve, Y-extension, anti-siphon valve, 96", 11 mL, non-DEHP
10798697	Microbore amber tubing, spin male luer lock, 63", 0.8 mL non-DEHP
30916-07	Microbore tubing, SmartSite™ needle-free connector, fixed male luer lock, 60", 0.8 mL, non-DEHP
10014917	Smallbore tubing, 60", 1.7 mL, non-DEHP

Model Number	Description
10798696	Microbore tubing, 20 drop drip chamber, check valve SmartSite™ needle-free valve, Y-extension, anti-siphon valve, 0.2 micron filter, 96", 10.5 mL, non-DEHP
10014913	Microbore tubing 36", 0.5mL, non-DEHP
10015612	Microbore tubing, 78", 1 mL, non-DEHP
10321214	Microbore tubing, spin male luer Lock, 79", 1 mL, non-DEHP
30920-07	Smallbore tubing, SmartSite™ needle-free connector, fixed male luer lock, 60", 1.5 mL, non-DEHP
10014915	Microbore tubing, 0.2micron filter, 36", 08 mL, non-DEHP
10912433	Microbore tubing, fixed male luer lock, 48", 0.7 mL, non-DEHP

Compatible Infusion Sets without Pressure Sensing Disc

Model Number	Description
10689602	Microbore tubing, 20 drop drip-chamber, anti-siphon valve, check valve, 1 SmartSite™ Y-site, 95", 13 mL, non-DEHP

Priming Infusion Set With Pressure Sensing Disc

The following steps apply to manual priming.To prime using the Prime Set with Syringe feature in the Channel Options menu see *Using Priming Options* on page *103*.

WARNING

Ensure that patient is not connected when priming.

WARNING

Ensure that air is expelled from line prior to beginning infusion (unexpelled air-in-line could have serious consequences).

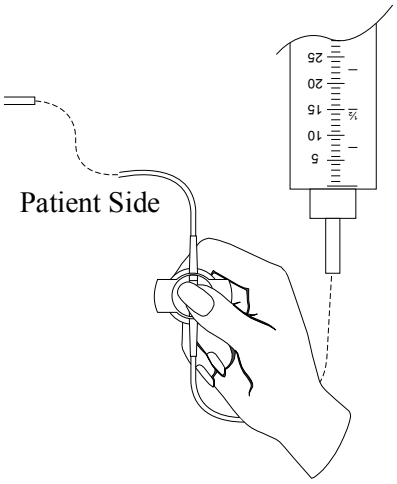
1. Ensure that infusion set is not connected to patient.

WARNING

Do not prime with the pressure sensing disc installed. Doing so can result in air being trapped in the disc. To ensure that all air is expelled, gently massage the disc during priming.

2. If installed, remove pressure sensing disc from device.

   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 two fingers.



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

Priming Infusion Set With No Pressure Sensing Disc

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

Alaris™ Syringe Module Loading

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 infusion set is not clamped or turned off, and can cause serious injury or death.

WARNING

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

WARNING

When loading a small size syringe, use extra care to avoid loss of medication and ensure correct loading:

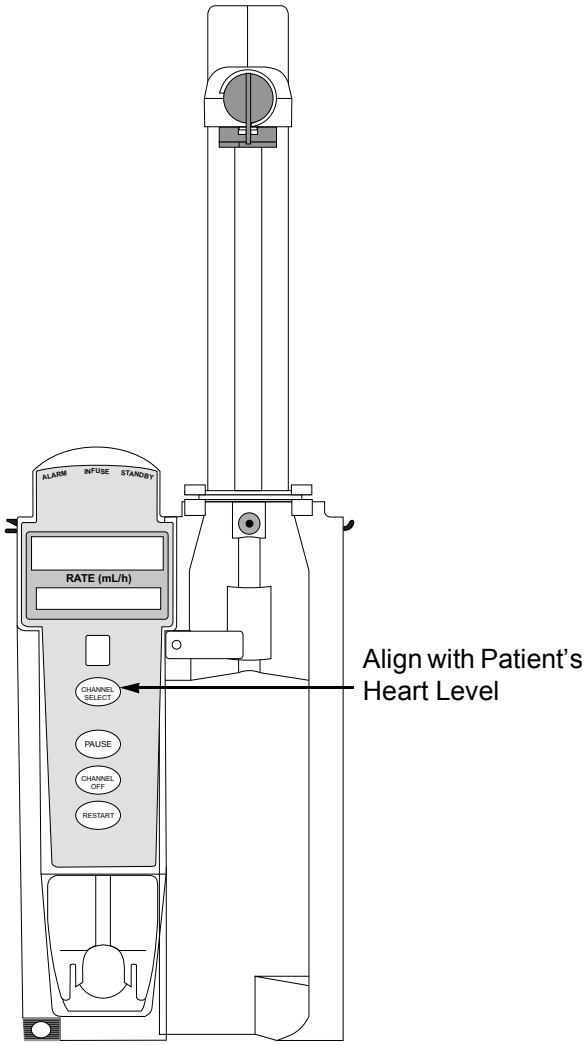
- **Clamp tubing before loading.**
- **Stabilize the syringe plunger while gently lowering the drive head.**
- **Ensure that the plunger head makes contact with the small black sensor, located on the bottom of the drive head (between the plunger grippers).**

CAUTION

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

CAUTION

Ensure that the device is as close to level with patient's heart as possible. Patient's heart level should be in line with the **CHANNEL SELECT** key.

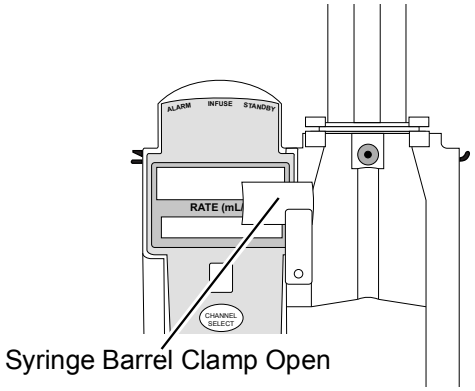


1. Position the device as close to level of patient's heart as possible—patient's heart level should be in line with **CHANNEL SELECT** key.
   - Keep the system level with the patient's heart to maintain positive pressure.
   - If using a pre-run infusion practice (to allow for medication equilibration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

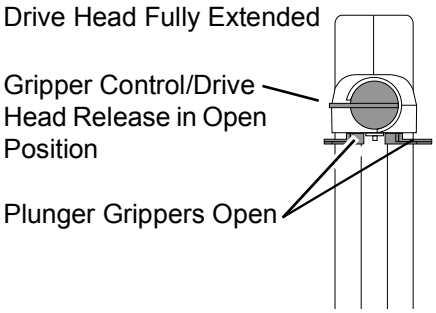
WARNING

Before loading the syringe, check for damage or defects.

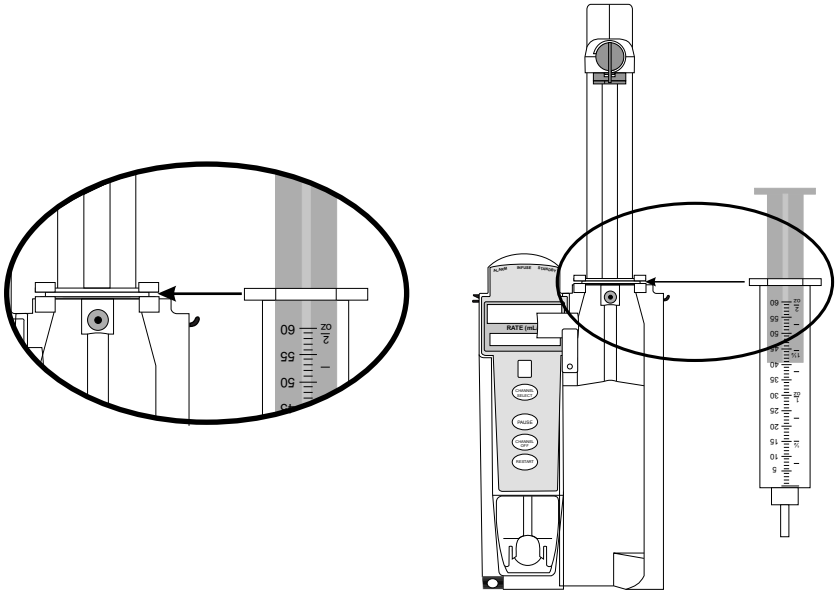
2. Open syringe barrel clamp.
   a. Pull syringe barrel clamp out and hold.
   b. Rotate clamp to left (clockwise or counter clockwise) until it clears syringe chamber.
   c. Gently release clamp.



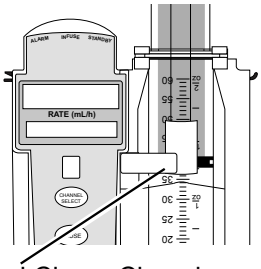
3. Raise the drive head to its fully extended position.
   a. Twist gripper control clockwise and hold in position.
   b. While holding gripper control in open position, raise the drive head to full extension.
   c. Gently release gripper control.



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



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.

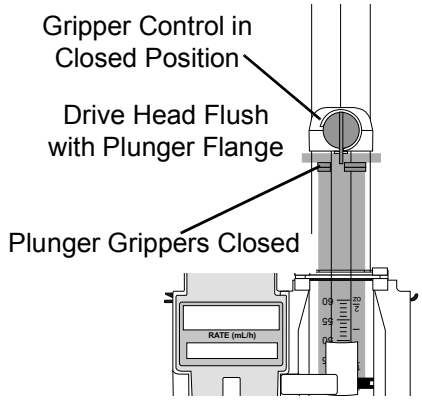


Syringe Barrel Clamp Closed

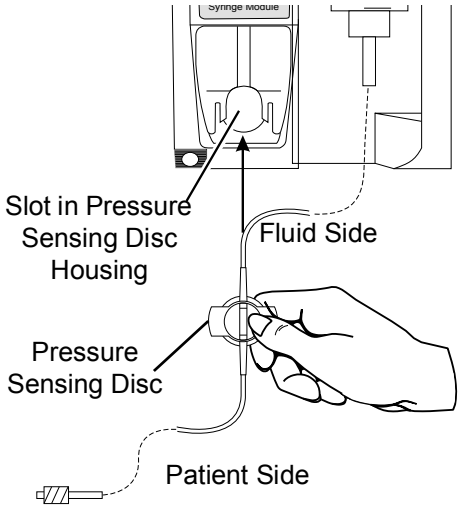
6. Lower the drive head and lock plunger in place with plunger grippers.
   a. Twist gripper control clockwise and hold in position.

   NOTE:
   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.

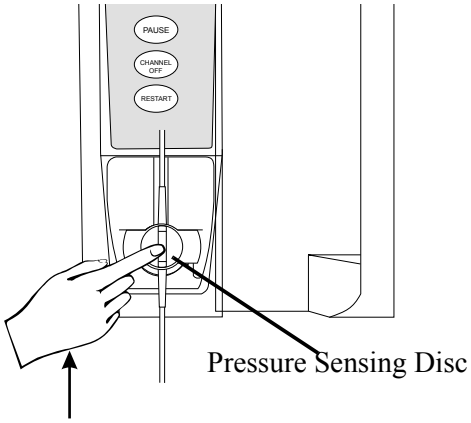
   b. While holding gripper control in open position, gently lower the drive head until it makes contact with plunger flange.
   c. Gently release gripper control.
   d. Ensure that plunger grippers lock and hold plunger in place.



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 device)



   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.



NOTE:
The following Syringe Module features are available only with extension sets fitted with a pressure sensing disc:

- Auto Pressure
- Back Off (upon occlusion)
- Customized Pressure Alarm Settings (see *Occlusion Pressure* on page *74* for the feature definition)
- Dynamic Pressure Display
- Numeric Pressure Display
- Fast Start
  (See *Features and Definitions* on page *72* for definitions.)

Eliminating Mechanical Slack

To minimize mechanical slack, and minimize startup 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 *Alaris™ Syringe Module Loading* on page *97*). If a pressure sensing disc is being used, do not install disc until priming is complete.
2. Select syringe and infusion type (see *Programming Infusions* on page *109* for more information).
3. Open infusion set clamp.
4. Prime, as follows, using the Priming option (see *Using Priming Options* on page *103* for more information):
   a. Follow applicable procedure (based on whether or not pressure sensing disc is installed) through step to press and hold the **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).

Using Priming Options

The priming option can be enabled when the 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 device before priming. See the applicable procedure (as follows) depending on whether or not a pressure sensing disc is used.

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

WARNING

Ensure that air is expelled from line prior to beginning infusion (unexpelled air-in-line could have serious consequences).

WARNING

Ensure that patient is not connected when priming.

WARNING

- **Use the Prime Set with Syringe feature in the Channel Options menu, when starting an infusion or changing the syringe and tubing. Failure to do so can delay the infusion delivery startup time and lead to delivery inaccuracies.**

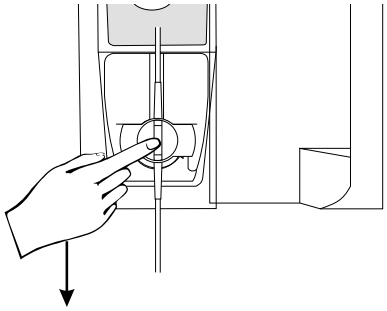
Priming Infusion Set With Pressure Sensing Disc

WARNING

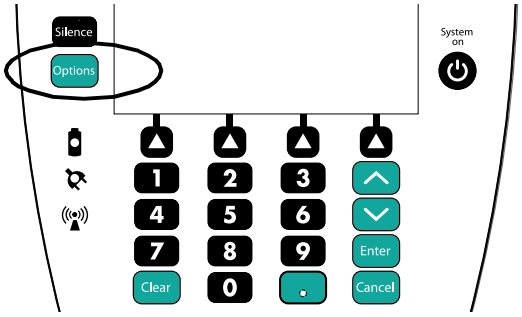
Do not prime with the pressure sensing disc installed. Doing so can result in air being trapped in the disc. To ensure that all air is expelled, gently massage the disc during priming.

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

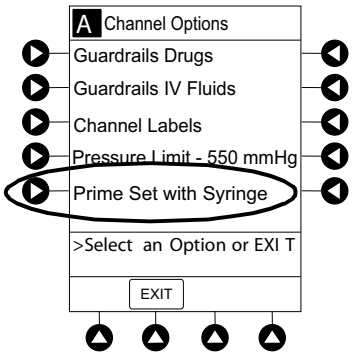
   Using a finger, apply firm downward pressure on pressure sensing disc (not tubing) until disc snaps loose from slot in pressure sensing disc housing.



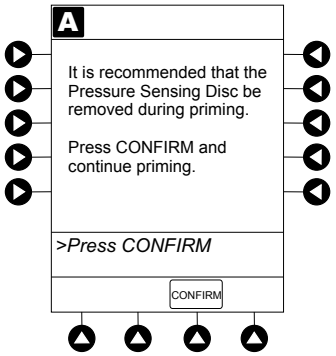
3. Press the **OPTIONS** key.



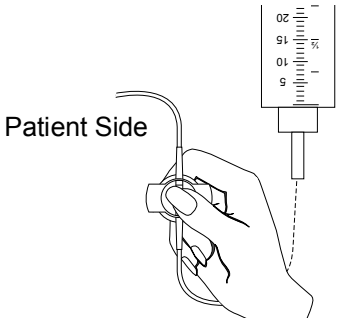
4. Press the **Prime Set with Syringe** soft key.



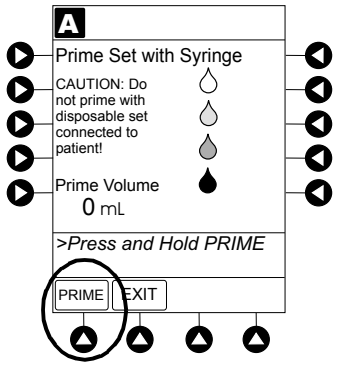
If pressure sensing disc was not removed prior to pressing **Prime Set with Syringe** soft key, a pressure sensing disc removal prompt is displayed.



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



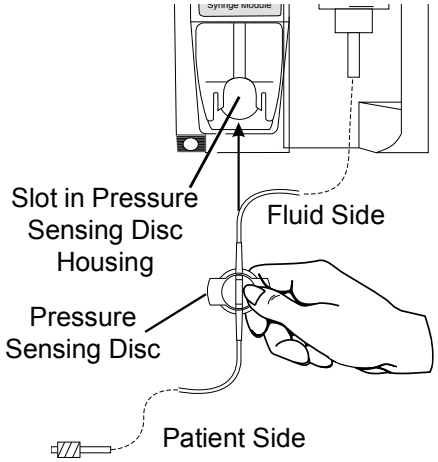
7. Press and hold **PRIME** soft key.



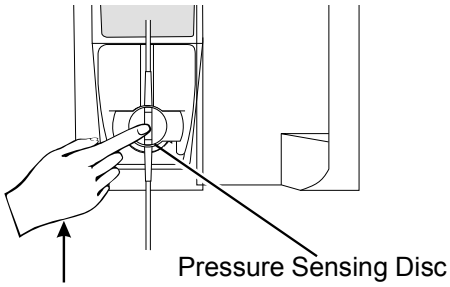
8. Gently massage pressure sensing disc to ensure that all air is expelled. The disc must remain inverted only until the air is expelled. Continue to gently massage disc throughout priming to ensure that it does not become under- or over-filled.
9. Continue to prime until the fluid flows and priming is complete.

   Fluid is delivered during priming only while the **PRIME** soft key is pressed. Each press of the **PRIME** soft key delivers up to 2 mL of priming fluid at the maximum rate of the selected syringe per continuous press. To deliver additional amounts, press the **PRIME** soft key again. (See *Rate restriction by syringe size:* on page *229*).
10. When priming is complete, release pressure sensing disc and the **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 device)
    b. Gently slide pressure sensing disc up into slot in pressure sensing disc housing.

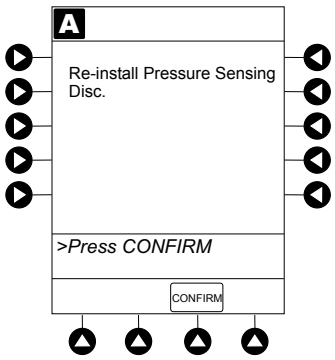


c. Apply firm upward pressure on pressure sensing disc (not tubing) until disc snaps into place.



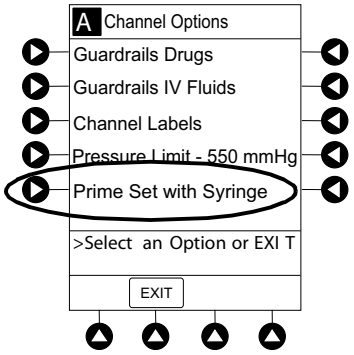
12. To return to main screen, press the **EXIT** soft key.

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



Priming Infusion Set With No Pressure Sensing Disc

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



3. Press and hold the **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 the **PRIME** soft key.

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

Programming Infusions

The system can be programmed with Guardrails™ protection or with no Guardrails™ protection:

- Guardrails™ protection
  - Manual Programming *(*see *Manual Programming with Guardrails™ Suite MX* on page *110)*
  - Programming with Interoperability (see *Programming with Interoperability and Guardrails™ Suite MX* on page *147*)
  - Auto-ID (Refer to *Alaris™ Auto-ID Module Model 8600* on page *327*)
- No Guardrails™ protection
  - *Preparing for a No Guardrails Basic Infusion* on page *172*
  - *Programming a No Guardrails™ Basic Infusion with Drug Calculation* on page *174*

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.

Manual Programming with Guardrails™ Suite MX

The following procedures are to be used only when the drug to be infused is listed in the drug library. To access the drug library, a hospital-defined best practice data set must be transferred to the system and the profile feature must be enabled.

1. Perform the following steps:
   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/infusion set (see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*).
3. Prime (see *Priming Infusion Set With Pressure Sensing Disc* on page *104*).
4. Press the **CHANNEL SELECT** key.

WARNING

Ensure that the displayed syringe manufacturer and syringe size match the installed syringe. Mismatches can impact flow rate accuracy.

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

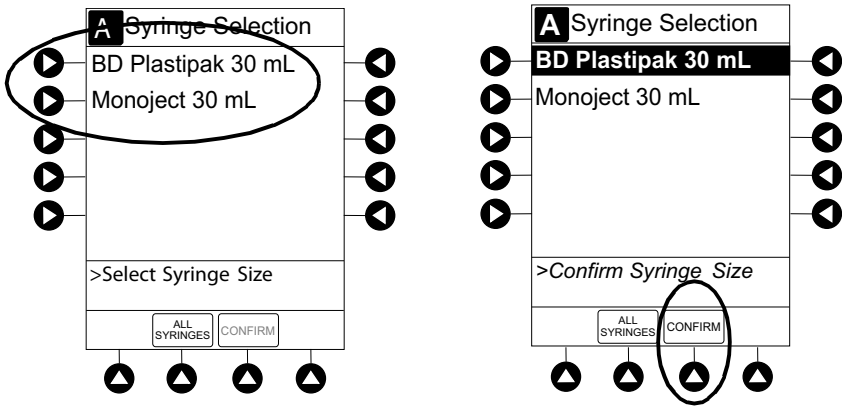
   NOTE:
   At the start of a Syringe Module infusion program, the system prompts to select and confirm the syringe type and size. The system automatically detects the syringe size, and lists syringe types and sizes that most closely match the installed syringe. If the syringe is not recognized, **Syringe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

   If the installed syringe is loaded correctly, but not recognized, check for the following:

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

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

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



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

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

   Programming a Continuous Infusion on page *112*

   Programming a No Guardrails™ Basic Bolus Dose on page *177*

   Intermittent Infusion on page *158*

   Fluid Infusion on page *157*

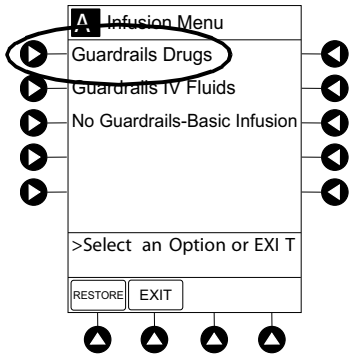
NOTE:
It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PCU for the Pump Module. However, due to space limitations on the Pump Module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the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

Programming a Continuous Infusion

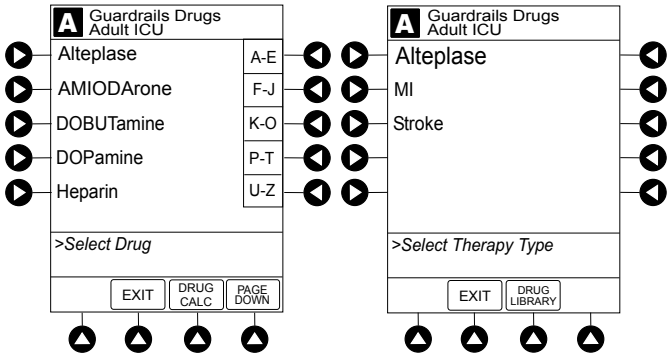
When using a drug listed in the drug library, the drug parameters are automatically calculated, based on:

- Drug selected
- Concentration
- Weight entry (if required)
- Rate or dose entry
- VTBI entry (Syringe Module—if other than All)

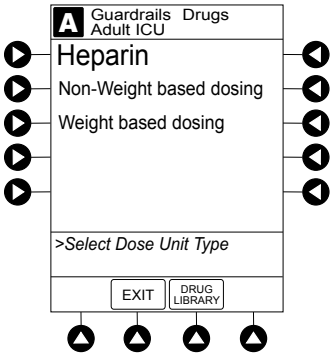
1. Press the **GUARDRAILS DRUGS** soft key.



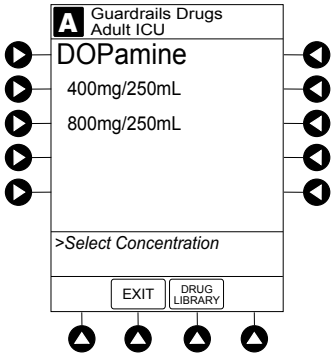
2. Press the soft key next to desired drug.
   - To view additional drugs/concentrations, press a soft key next to a letter group to navigate through alphabet, and/or **PAGE UP** and **PAGE DOWN** soft keys.



   - 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).

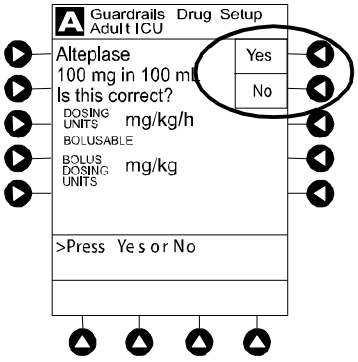
NOTE:
The facility can choose to pre-populate standard drug concentrations or leave a custom concentration (_ _ / _ _ mL) and allow the clinician to enter the desired concentration.

3. To continue programming, press the **Yes** soft key.

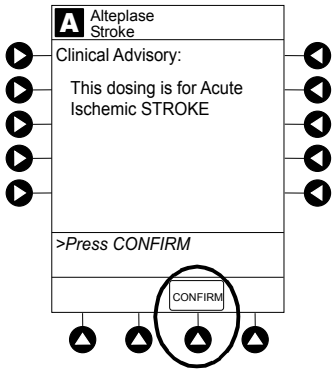
   Bolus dose units appear if bolus dose is enabled.

   or

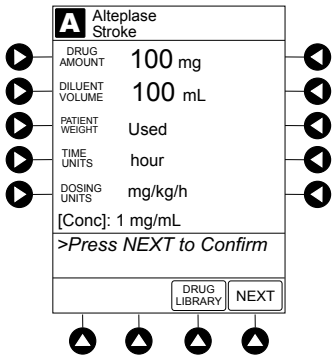
   To change selection, press the **No** soft key.



- 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 the **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.

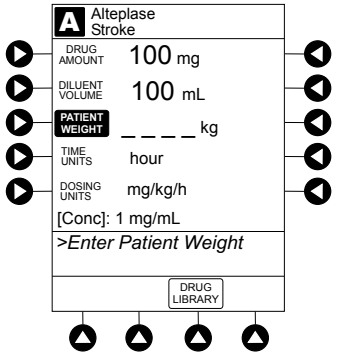


If the selected drug had "_ _ / _ _ mL" concentration, the drug amount and diluent volume need to be entered. See *Programming an Infusion with a Custom Concentration Entry* on page *120*.

- If the 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, a prompt for a patient weight in kilograms appears (as in illustrated example, which reflects use of Alteplase).

NOTE:

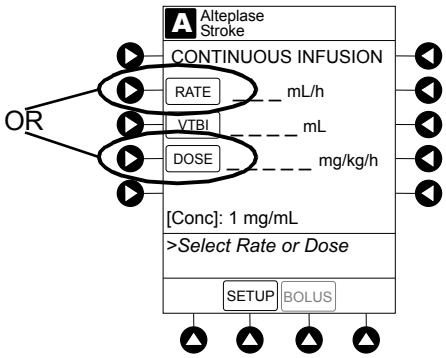
- Patient weight can be edited during a continuous infusion.
- After a patient weight is entered and an infusion is started for any module, the patient weight is automatically entered for any additional weight-based calculation. The patient weight remains an editable field; therefore, patient weight can be adjusted for any module. Changing the patient weight on one module does not affect the patient weight on any other module.



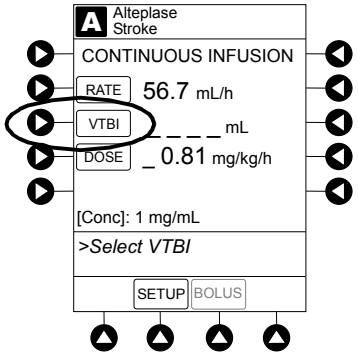
4. Verify correct parameters and press the **Next** soft key to confirm.
5. An optional hospital-defined and editable starting value for continuous infusion dose might already be entered.

   or

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



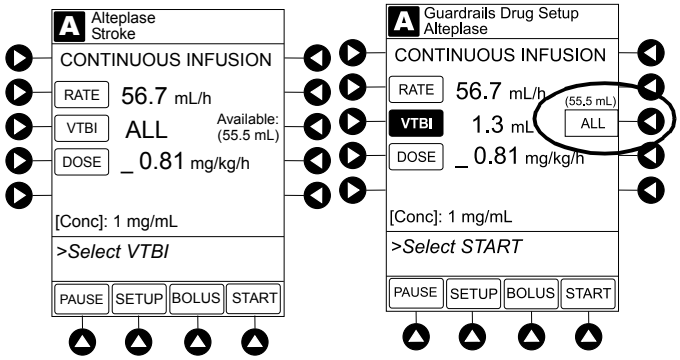
6. To enter the volume to be infused, press the **VTBI** soft key and enter value.
   - Pump Module:
     - When VTBI is less than 10 mL, the entry can be to two decimal places (one-hundredth of a mL).
     - In drug calculation mode, system infuses at calculated rate rounded to nearest one-hundredth of a mL per hour (as displayed on the programming screen on the PCU). The rate shown in rate display on the Pump Module is rounded to nearest one-tenth of a mL per hour.
   - The **Bolus** soft key appears only if bolus dose is enabled within the selected profile, the drug is bolusable, and a VTBI is entered.



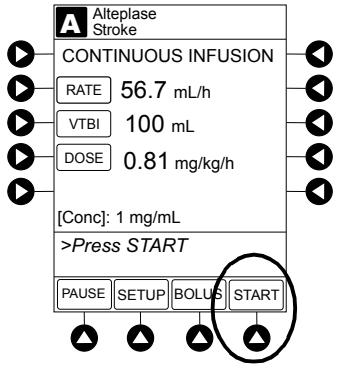
- Syringe Module:
  - If **ALL Mode** is enabled for syringe configuration in data set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

  or

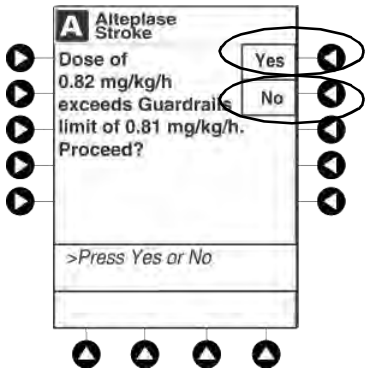
  - If **ALL Mode** is disabled for syringe configuration in data set, estimated available volume in syringe is displayed when **VTBI** soft key is pressed.
  - To enter or change a numeric VTBI value, press the **VTBI** soft key and enter value.
- To deliver entire contents of syringe: Keep an **ALL VTBI** value, or press the **ALL** soft key to change a numeric VTBI value to **ALL**.



7. Verify the correct parameters and press the **START** soft key.
   - The drug name and dose will scroll on the module message display.
   - For the Pump Module, when beginning an infusion and periodically during the infusion, check the drip chamber to ensure that the drip rate correlates to the intended infusion rate.

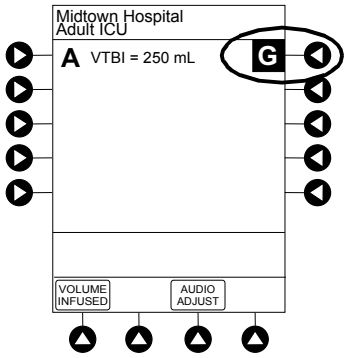


   - If the programmed continuous dose infusion is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.



   - If the programmed continuous dose infusion is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.

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



8. For the Syringe Module, unclamp tubing and attach infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

   NOTE:
   In some situations it may be necessary to attach the infusion set to the patient's access before opening the clamp (for example, hazardous drugs or extremely small volume infusions).

Programming an Infusion with a Custom Concentration Entry

A custom concentration is a drug entry with an unspecified concentration entry in the drug library that requires the **DRUG AMOUNT** and **DILUENT VOLUME** to be entered manually.

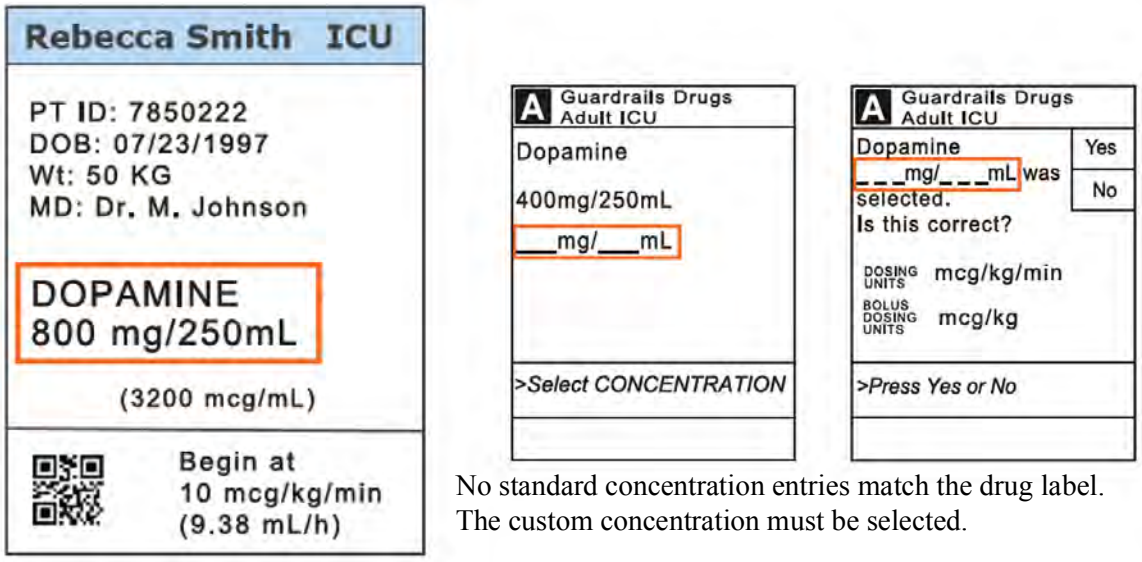
WARNING

If an error is made when entering DRUG AMOUNT or DILUENT VOLUME, it may result in an over- or under-infusion. If a lower concentration is entered in error, this may result in a higher than intended delivery (over-infusion).

1. After selecting a medication, select the concentration **__mg/__mL**.

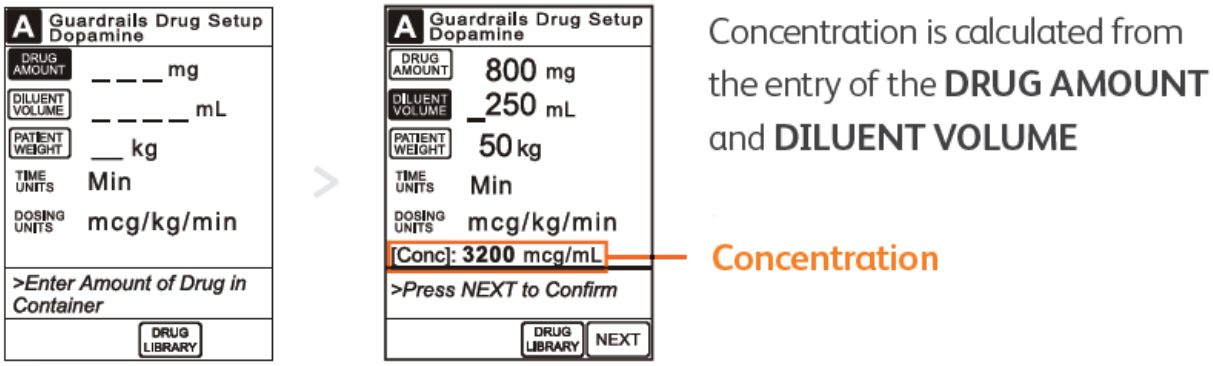
   Custom concentration should only be used when the medication label does not match any of the drug concentration selections on the programming screen as shown in the following example.

Sample Drug Label

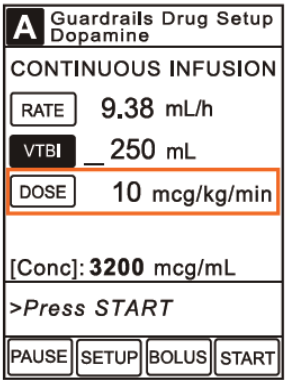


No standard concentration entries match the drug label. The custom concentration must be selected.

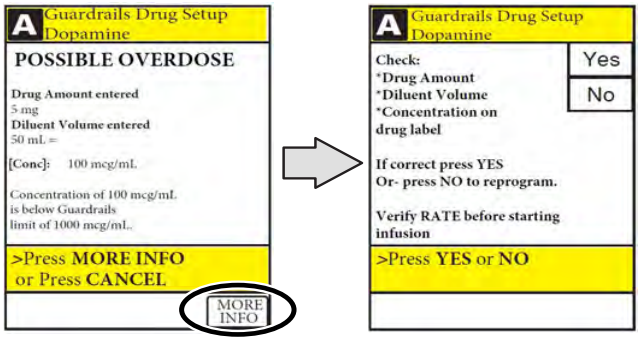
2. Enter the **DRUG AMOUNT** and **DILUENT VOLUME**.
   Confirm that the concentration on the display matches the drug label.



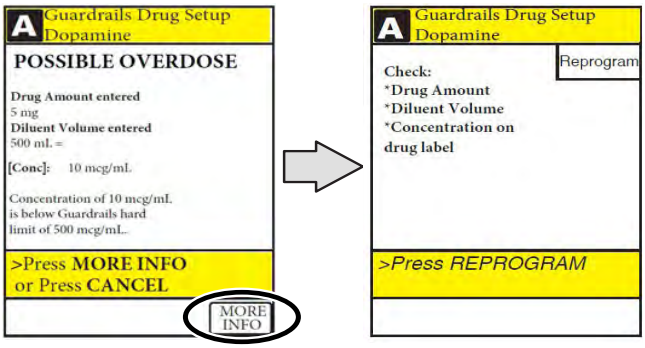
NOTE:
The **DRUG AMOUNT** is not the dose. The dose is entered on the next screen.



3. If the programmed _ _ / _ _ mL concentration is outside the hospital-established Guardrails™ limit, an audio alert sounds and a visual Guardrails™ concentration alert appears, notifying the user that a potential over or under dose condition may be present.
   - The Guardrails™ alert screen displays the entered **DRUG AMOUNT**, **DILUENT VOLUME**, calculated concentration, and Guardrails™ concentration limit allowing the user to verify the parameters against the infusion order.
   - Press **CANCEL** to return to the programming screen to reenter the **DRUG AMOUNT** and **DILUENT VOLUME.**
   - Press **MORE INFO** to further verify the entered infusion parameters.
   - If the Guardrails™ alert is outside the soft limit and the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, the infusion must be reprogrammed.



   - If the programmed _ _ mg/ _ _ mL concentration is outside the hard limit for that care area. **MORE INFO** or **CANCEL** can be pressed but the **DRUG AMOUNT** and **DILUENT VOLUME** must be reprogrammed.



For customers with electronic health record (EHR) interoperability, when programming a custom concentration using pre-population of infusion parameters, the **DRUG AMOUNT** and **DILUENT VOLUME** are included in the automated programming request.

Bolus Dose

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

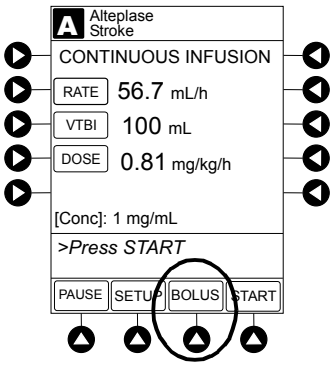
NOTE:

- 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.
- The bolus VTBI cannot exceed the programmed continuous infusion VTBI.
- Programming and starting a bolus dose deletes any programmed delay.
- If no continuous rate is entered or if the bolus dose VTBI equals the continuous infusion VTBI, the infusion ends when the bolus has been delivered. No KVO infusion follows.

WARNING

Avoid delivering small bolus or loading dose volumes (< 0.5 mL) at high flow rates (≥ 500 mL/h) because they may not be delivered accurately.

1. Set up infusion as described in *Programming a Continuous Infusion* on page *112*, but do not start infusion.
2. Press the **BOLUS** soft key.
   - If the programmed continuous dose infusion is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
   - If the programmed continuous dose infusion is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. The infusion needs to be reprogrammed.

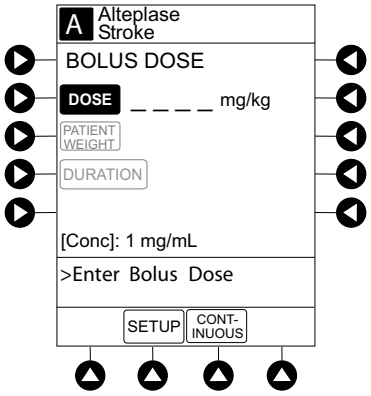


3. An optional hospital-defined and editable starting value for bolus dose and/or bolus rate duration might already be entered.

   or

   To enter bolus dose, use numeric data entry keys.

   - A bolus dose can be either weight-based or non weight-based independent of whether the continuous infusion is weight-based or non weight-based.
   - If no weight has previously been programmed in system and bolus dose is weight-based, weight must be entered.
   - If the continuous dose is weight-based, the programmed weight is displayed. The same weight value will be used for both the continuous dose and the bolus dose.
   - If bolus dose is not weight-based, **Not Used** is displayed in **PATIENT WEIGHT** field.



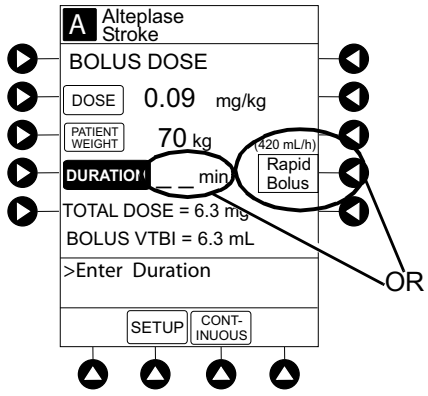
4. Press the **DURATION** soft key.

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

   or

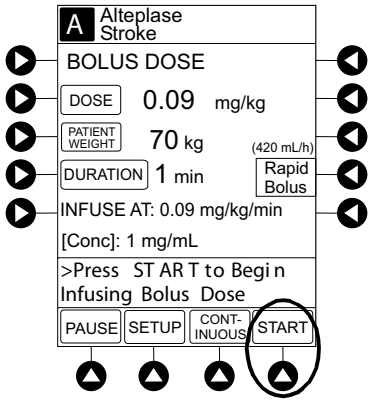
   To deliver bolus dose at maximum safe rate possible for selected drug and setup, and automatically calculate a bolus duration, press the **Rapid Bolus** soft key.

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



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

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



   - 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.

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

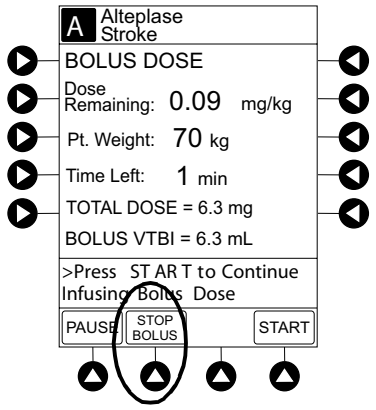
7. For the Syringe Module, if bolus dose was programmed at beginning of infusion, unclamp tubing and attach infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

   NOTE:
   In some situations it may be necessary to attach the infusion set to the patient's access before opening the clamp (for example, hazardous drugs or extremely small volume infusions).

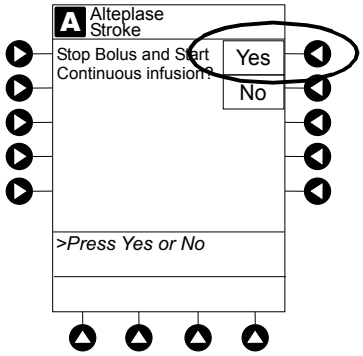
Stopping a Bolus Dose

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



3. To stop bolus and start a Continuous Infusion, press the **Yes** soft key.



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

   NOTE:
   The Pump Module keypad is used in the illustration but the key is the same for the Syringe Module.

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

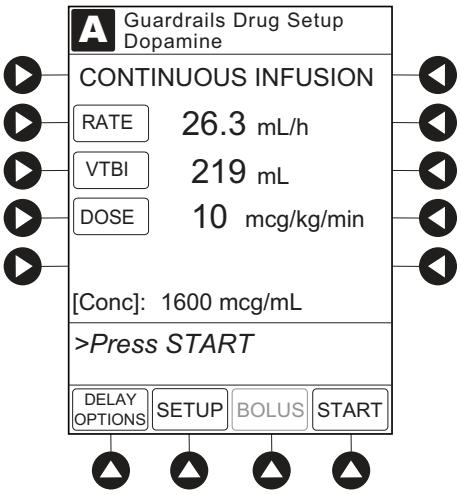
Weight Change During a Continuous Infusion

It is not necessary to interrupt an infusion to make a change to patient weight. If a weight-based continuous infusion is running and the weight is changed, the system will initially preserve the infusion rate. When an infusion has been titrated to effect, the patient will continue to receive the same amount of medication, to ensure that the desired physiologic effect is maintained.

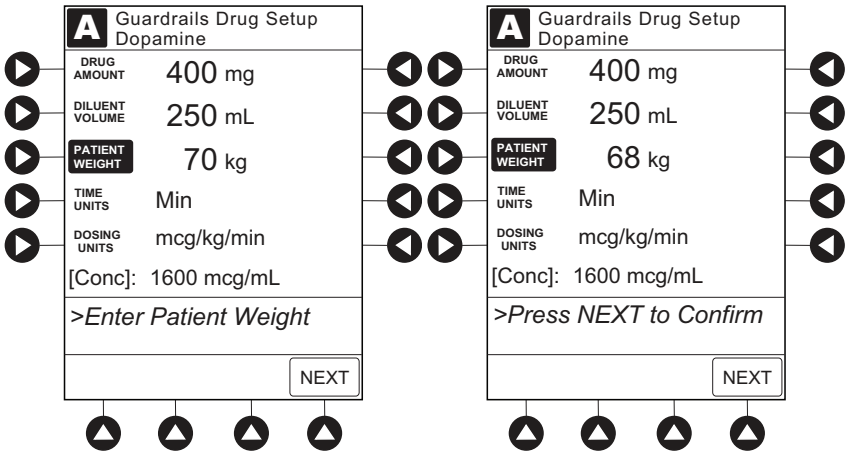
NOTE:
If necessary, adjust the dose after accepting the weight change and rate will automatically be adjusted.

1. Press the **CHANNEL SELECT** key.

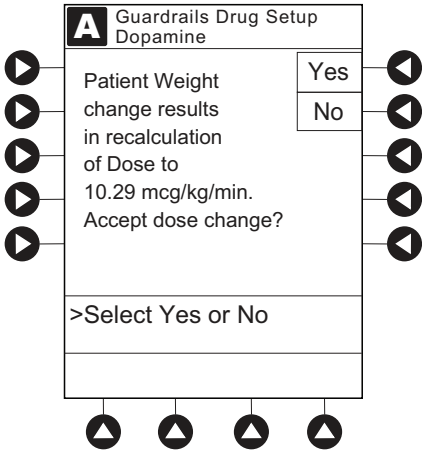
   The Continuous Infusion programming page displays.



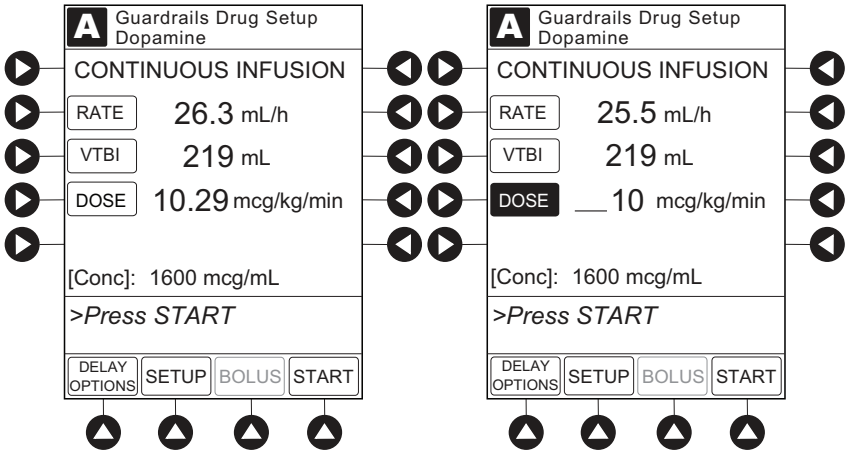
2. Press the **SETUP** soft key.
3. Press the **PATIENT WEIGHT** soft key. To change patient weight, use numeric data entry keys.



4. Press the **NEXT** soft key. The dose will be recalculated, and a dose change notification appears.



5. Press **YES** to accept the changes.
6. If the infusion is not a titratable drip and the original dose was correct, press the **DOSE** soft key and use the numeric data entry keys to enter the desired dose. The rate is automatically adjusted.



7. Verify correct parameters and press the **START** soft key.
8. For the Pump Module, when beginning an infusion and periodically during the infusion, check the drip chamber to ensure that the drip rate correlates to the intended infusion rate.

Intermittent Infusion

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

- Drug selected
- Weight or body surface area (BSA) entry (if required)
- Dose entry
- Rate or duration dose entry
- VTBI entry

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

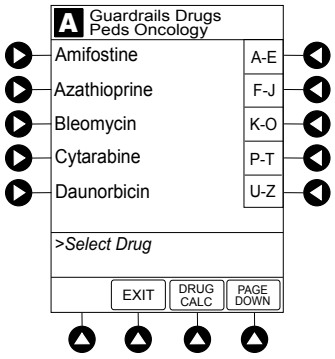
NOTE:
Patient weight or BSA is not editable during an intermittent infusion.

CAUTION

When you have primed the tubing with the medication syringe, consider the volume that will remain in the tubing when programming rate/duration. This ensures the entire drug dose will infuse over the intended duration.

1. Press the **Guardrails Drugs** soft key.
2. Press soft key next to desired drug.
    - To view additional drugs, press the 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.

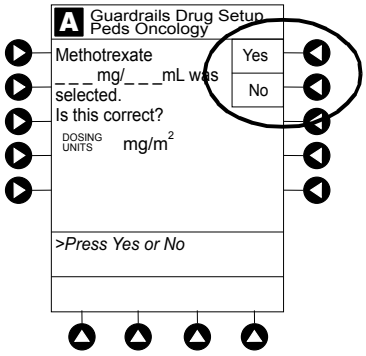
    NOTE:
    The facility can choose to pre-populate standard drug concentrations or leave a custom concentration (_ _ / _ _ mL) and allow the clinician to enter the desired concentration.



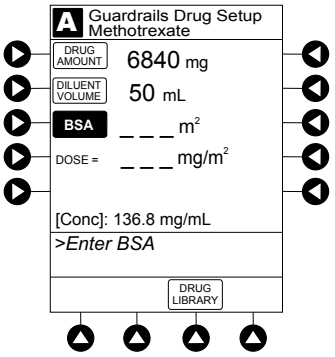
3. To continue programming, press the **Yes** soft key.

   or

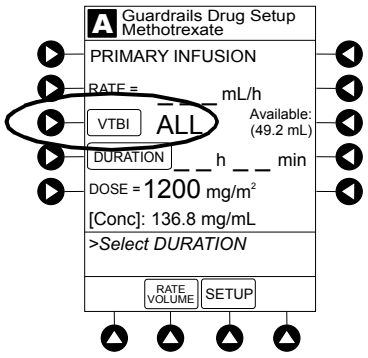
   To change selection, press the **No** soft key.



- 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 the **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. See *Programming an Infusion with a Custom Concentration Entry* on page *120*.
- If selected drug is not weight-based, **NOT USED** is displayed in **PATIENT WEIGHT** field.
- If hospital/facility practice guidelines identify selected drug as weight-based or by BSA, a prompt for a patient weight in kilograms or BSA appears (as in illustrated example, which reflects the use of Methotrexate).



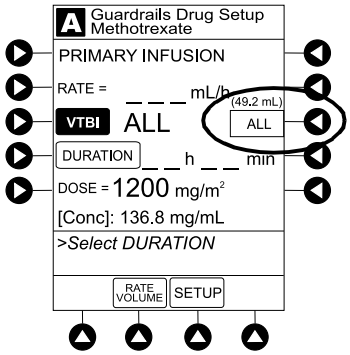
4. Verify correct parameters and press the **NEXT** soft key to confirm.
   - If the programmed total dose drug amount is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
   - If the programmed total dose drug amount is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
   - If a dose outside of soft limits has been entered and verified as correct, Message Display also shows either LLL for a low dose or ↑↑↑ for a high dose.
   - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
5. VTBI entry:
   - Pump Module:
     - When VTBI is less than 10 mL, entry can be to two decimal places (one-hundredth of a mL).
     - VTBI is pre-populated with diluent volume of infusion. To change VTBI, press the **VTBI** soft key and enter new value.



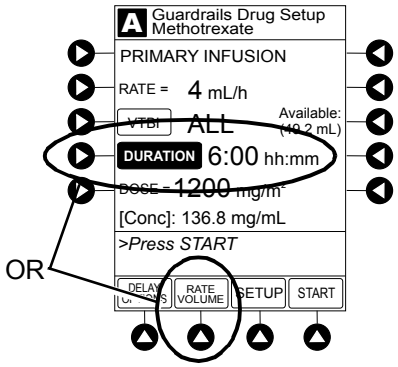
- Syringe Module:
  - If **ALL Mode** is enabled for syringe configuration in data set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

  or

  - If **ALL Mode** is disabled for syringe configuration in data set, estimated available volume in syringe is displayed when **VTBI** soft key is pressed.
  - To enter or change a numeric **VTBI** value, press the **VTBI** soft key and enter value.
  - To deliver entire contents of syringe: Keep an **ALL VTBI** value, or press the **ALL** soft key to change a numeric **VTBI** value to **ALL**.



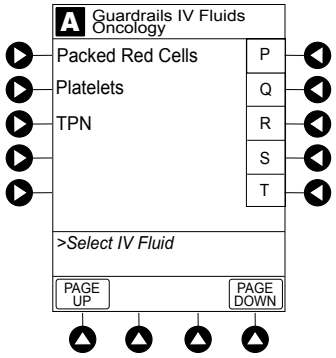
6. If an optional hospital-defined and editable starting value for intermittent duration is not already entered, enter duration or rate, as follows:
   - To enter duration, press the **DURATION** soft key and use numeric data entry keys (rate value is calculated and displayed).
   - To enter rate, press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



7. Verify correct parameters and press the **START** soft key.
   - For the Pump Module, when beginning an infusion and periodically during the infusion, check the drip chamber to ensure that the drip rate correlates to the intended infusion rate.
   - If the programmed duration is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Press the **Yes** soft key to accept the programmed duration and continue programming, or press the **No** soft key to reprogram the duration.
   - If the programmed duration is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
   - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
   - The drug name and dose will scroll on the module Message Display.
8. For the Syringe Module, unclamp tubing and attach infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

Fluid Infusion

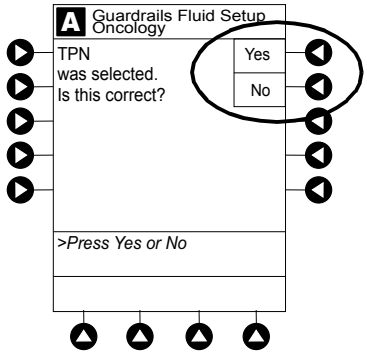
1. Press the **Guardrails IV Fluids** soft key.
2. Press the soft key next to IV fluid to be delivered.



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

   or

   To return to list, press the **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 the **CONFIRM** soft key.

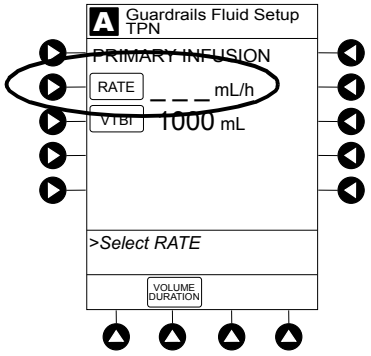
4. Start applicable infusion, as described in following procedures:

   Rate/Volume Infusion on page *135*

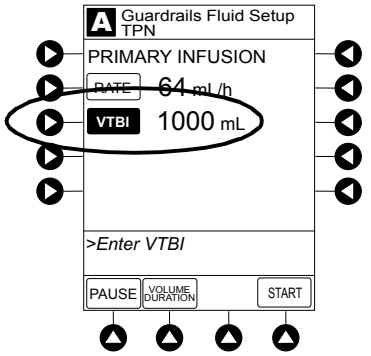
   Volume/Duration Infusion on page *137*

Rate/Volume Infusion

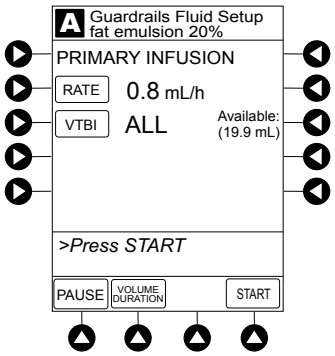
1. To enter flow rate, press the **RATE** soft key and use numeric data entry keys.



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

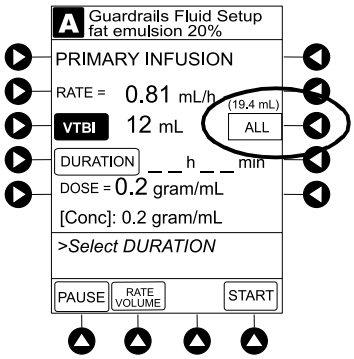


- Syringe Module:
  - If **ALL Mode** is enabled for syringe configuration in data set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.



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



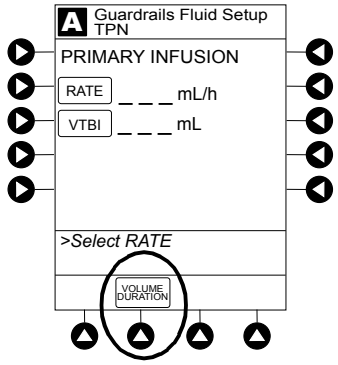
3. Verify correct infusion parameter entry and press the **START** soft key.
   - For Pump Module, when beginning an infusion and periodically during the infusion, check the drip chamber to ensure that the drip rate correlates to the intended infusion rate.
   - If the programmed IV fluid is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, infusion needs to be reprogrammed.
   - If the programmed IV fluid is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
   - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

4. For the Syringe Module, unclamp tubing and attach infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

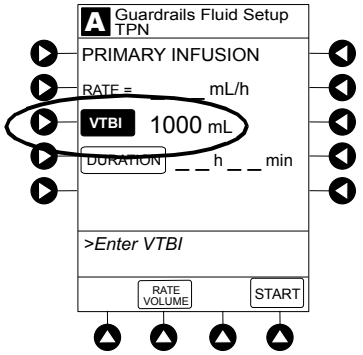
   NOTE:
   In some situations it may be necessary to attach the infusion set to the patient's access before opening the clamp (for example, hazardous drugs or extremely small volume infusions).

Volume/Duration Infusion

1. Press the **VOLUME DURATION** soft key.



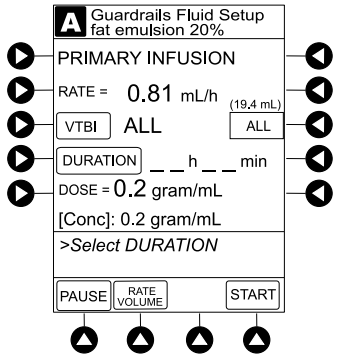
2. To enter **VTBI**, press the **VTBI** soft key and use numeric data entry keys.



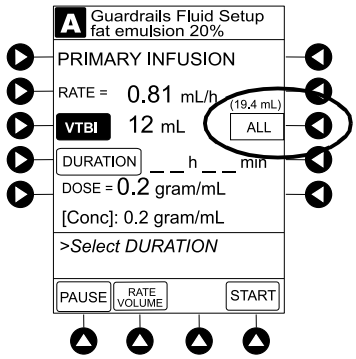
- Syringe Module:
  - If **ALL Mode** is enabled for syringe configuration in data set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

  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.

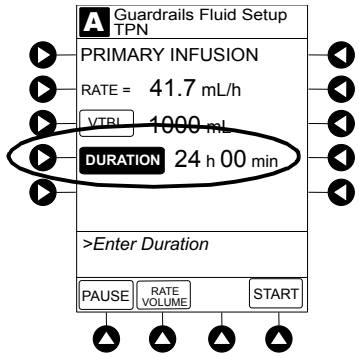


  - To enter or change a numeric **VTBI** value, press the **VTBI** soft key and use numeric data entry keys.
  - To deliver entire contents of syringe: Keep an **ALL VTBI** value, or press the **ALL** soft key to change a numeric **VTBI** value to **ALL**.



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

   Rate is automatically calculated.

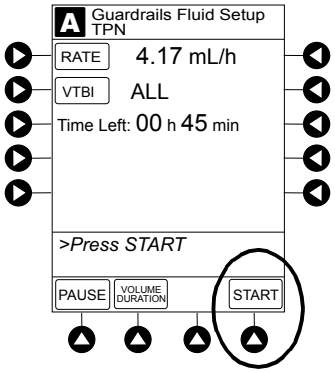


4. Verify correct infusion parameter entry and press the **START** soft key.
   - For Pump Module, when beginning an infusion and periodically during the infusion, check the drip chamber to ensure that the drip rate correlates to the intended infusion rate.
   - If the programmed IV fluid is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
   - If the programmed IV fluid is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
   - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

   NOTE:
   To view infusion **Time Left** during a volume/duration infusion, press the **CHANNEL SELECT** key. To return to previous screen, press the **START** soft key.

5. For the Syringe Module, unclamp tubing and attach infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

   NOTE:
   In some situations it may be necessary to attach the infusion set to the patient's access before opening the clamp (for example, hazardous drugs or extremely small volume infusions).



Secondary Infusion

This mode is designed to support the delivery of secondary infusions (piggybacking) in the same module. A secondary infusion can be programmed as a No Guardrails™ - 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 device 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.

Preparing a Secondary Infusion

WARNING

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

WARNING

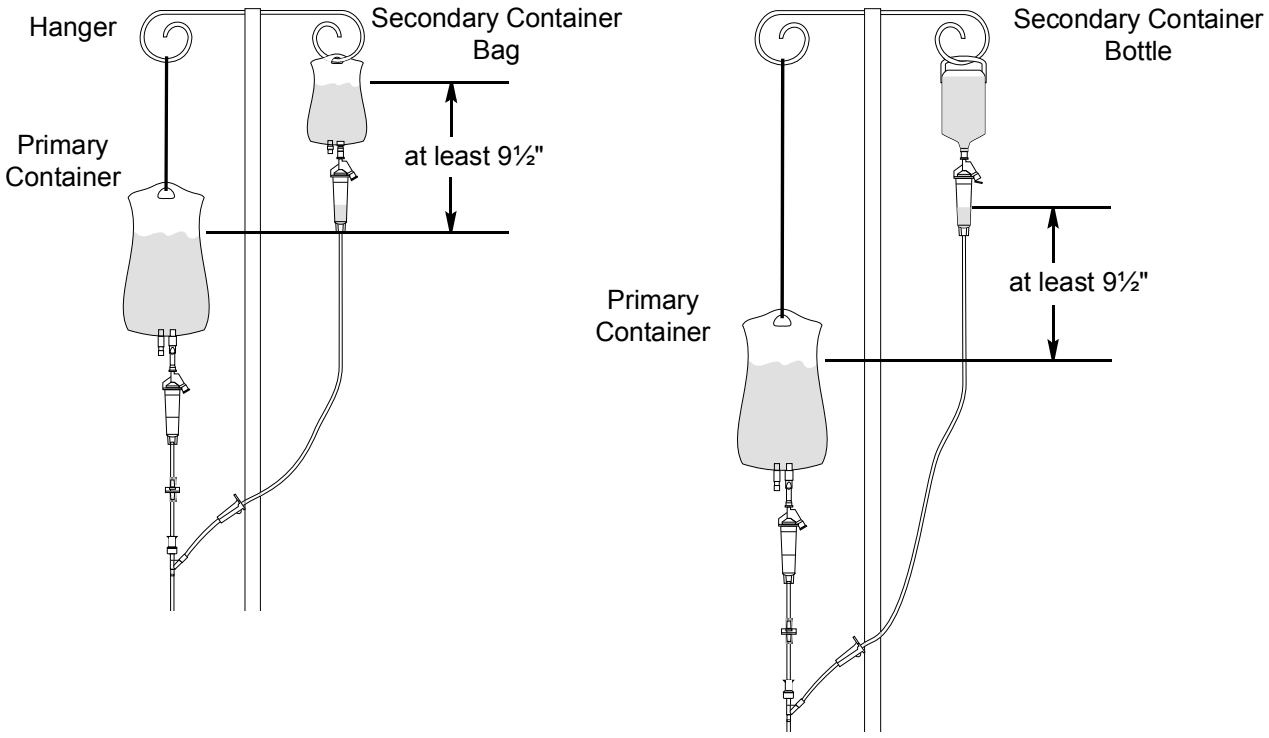
The secondary infusion set must be primed prior to beginning the secondary infusion.

WARNING

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

1. Open secondary infusion set package, remove set and close clamp.
2. Insert infusion set spike into prepared fluid container and hang secondary container, following accepted hospital/facility procedure.
3. Fill drip chamber to ⅔ full.
4. Open secondary infusion set clamp and prime set. Close clamp.

5. Attach secondary infusion set to upper injection site on primary set.
6. Using the hanger provided with secondary infusion set, lower the primary fluid container to height indicated in following illustrations.



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

If necessary, use additional hangers to lower the primary container to achieve the minimum 9 1/2" head height differential between the primary and secondary fluids.

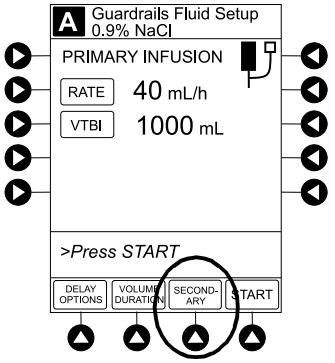
Programming a Secondary Infusion

The following procedure should be used only when:

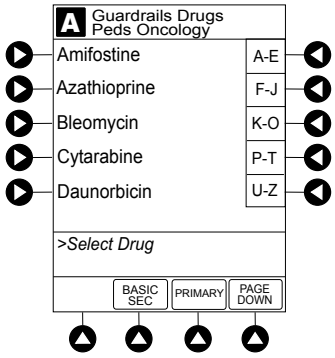
- Drug to be infused is listed in drug library
- Primary infusion is running
- Set with a check valve or clamp on the primary IV line is being used

To program a primary infusion, see *Fluid Infusion* on page *134*. To program a No Guardrails™ - Basic Infusion, see *Preparing for a No Guardrails Basic Infusion* on page *172*.

1. Press the **CHANNEL SELECT** key.
2. Press the **SECONDARY** soft key.



3. Press soft key next to desired drug.
   - To view additional drugs, press the 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.

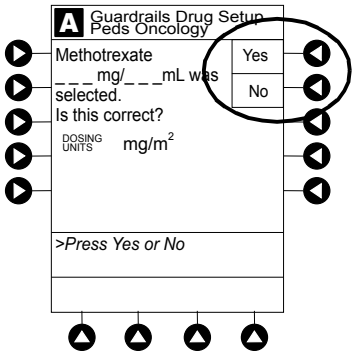


4. To continue programming, press the **Yes** soft key.

   or

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

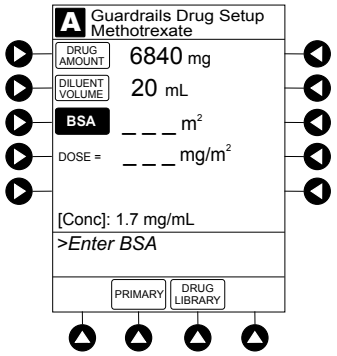
   NOTE:
   The facility can choose to pre-populate standard drug concentrations or leave a custom concentration (_ _ / _ _ mL) and allow the clinician to enter the desired concentration.



- If **Yes** was selected and the facility has defined a clinical advisory for that drug, a message appears. To indicate information has been noted and continue programming, press the **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. See *Programming an Infusion with a Custom Concentration Entry* on page *120*.
- 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).

NOTE:

- Patient weight or BSA is not editable during a secondary infusion.
- After a patient weight or BSA is entered and the infusion started, the patient weight or BSA is automatically entered for any additional weight-based or BSA calculation. Prior to the start of infusion, the patient weight or BSA key remains an editable field so that patient weight or BSA can be adjusted for any module. Changing the patient weight or BSA on one module will not affect the patient weight or BSA on any other module.

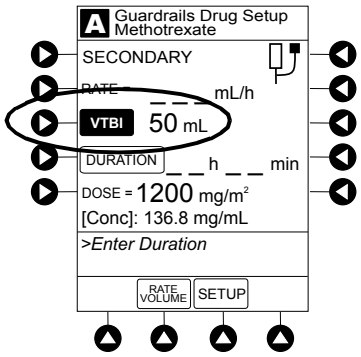


5. Verify correct parameters and press the **NEXT** soft key to confirm.
   - If the programmed total dose drug amount is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If the **Yes** soft key is pressed, programming continues;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

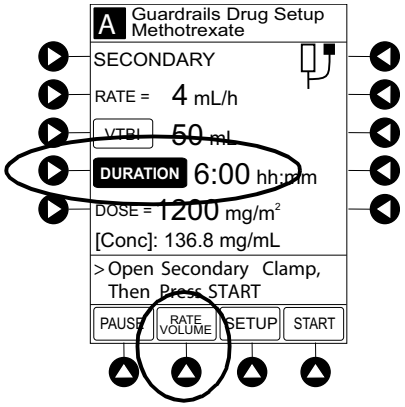
WARNING

When programming a secondary piggyback infusion, confirm that the programmed secondary VTBI matches the actual volume of the bag (including any additives or overfill). This ensures the entire secondary volume infuses at the correct rate.

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



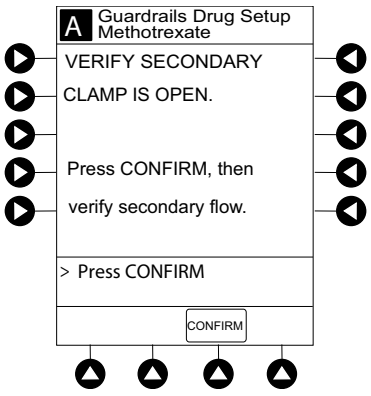
7. If an optional hospital-defined and editable starting value for intermittent duration is not already entered, enter duration or rate, as follows:
   - To enter duration, press the **DURATION** soft key and use numeric data entry keys (rate value is calculated and displayed).
   - To enter rate, press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



WARNING

The clamp on the secondary infusion set must be opened. If the clamp is closed, the fluid is delivered from the primary container.

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



12. Observe the secondary drip chamber to verify that drops are falling and that flow does not appear to be too fast or too slow. Do this periodically throughout the infusion. No drops should be falling in the primary drip chamber.

NOTE:
Programming the secondary rate over 500 mL/h may result in concurrent flow with the primary container.

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

Stopping Secondary and Returning to Primary

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

   or

   Disconnect secondary infusion set from upper injection port.
5. Press the **START** soft key.
6. To stop secondary infusion and begin infusing primary, press the **Yes** soft key.
   - Secondary infusion stops and primary infusion begins.
   - Main screen appears.

Programming with Interoperability and Guardrails™ Suite MX

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

Interoperability refers to the ability of the system Pump Module and Syringe Module to:

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

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

- *Infusion Adapter HL7 Infusion Status PCD-10/PCD-01 Message Specification for BD Care Coordination Engine-Regulated*
- *Infusion Adapter HL7 Infusion Order Message PCD-03 Specification for BD Care Coordination Engine-Regulated*
- *BD Alaris™ Interoperability User Reference Guide*
- *BD Alaris™ Interoperability Clinical Workflow Testing User Guide*

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

NOTE:
Due to the intermittent nature of a wireless environment, some data can be lost if a connection cannot be established or is lost. The Systems Manager and wireless network card are designed to minimize these incidents but cannot eliminate them.

Calculation Services

Calculation services is a set of predefined rules that are performed only when the following parameters are not sent from the EMR when programming with interoperability:

- Infusion duration (VTBI divided by rate)
- Body surface area (BSA) (total dose divided by modified dose)
- Weight-based dose (total dose divided by patient weight)
- Flow rate (weight-based rate multiplied by patient weight)
- Reduced concentration values (drug amount divided by diluent amount)

No additional calculations are performed beyond what is described above. The rules are defined by calculation services through BD's internal design controls. The specific EMR interface determines which predefined rules are used.

Calculation services also validates the following infusion fields and sends the values in outbound data:

- Duration
- Rate
- GiveAmount
- DoseTimeUnit
- PatientBSA
- Patient Weight
- GiveDoseRateAmount
- DoseAmount
- GiveStrength
- GiveStrengthUnit
- DoseDriveUnit
- DoseModifierUnit
- GiveStrengthVolume
- WeightBasedRate
- ReducedConcentration

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

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

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

- Continuous
- Fluids
- Intermittent

The following **secondary** infusion can be pre-populated (Pump Module only):

- Intermittent

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

- Titrations
- Bolus doses
- No Guardrails™ - Basic Infusions (including drug calculation infusions)

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

The following procedures are to be used only when the drug to be infused is listed in the drug library. To access the drug library, a hospital-defined best-practice data set must be transferred using the Guardrails™ Editor software and the profiles feature must be enabled.

NOTE:
There is a potential for a discrepancy in precision between the numeric values displayed on the system (PCU, Pump Module and Syringe Module) and in the electronic medical record (EMR)/hospital information system (HIS) due to different rounding rules. The device accepts a limited set of precision values for manual input and display, however, all program values are calculated and reported to 4 decimal places of precision.

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

It is important to note that the concentration displayed on the PCU should be equivalent to the concentration displayed in the EMR/HIS even if different units of measure are used.
The following example is for a continuous drug that has a Drug Amount in grams, but is dosed in mg:

Displayed on PCU	Infusion information sent to EMR/HIS
Drug Amount: 1 gram Diluent Volume: 100 mL [Conc]: 10 mg/mL	Drug Amount: 1 gram Diluent Volume: 100 mL [Conc]: 0.01 gram/mL

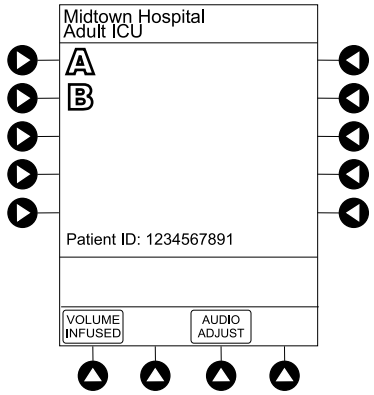
NOTE:
It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the PCU for the Pump Module. However, due to space limitations on the Pump Module rate display, the rate is displayed to the nearest one-tenth of a mL per hour on the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

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

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

Initial Primary Infusion

1. Perform the following steps on the PCU (see *Initial Setup* on page *14 and Powering On the System* on page *17*):
   a. Power on system. (Scanning the module will not power on the device.)
   b. Select **Yes** or **No** to **New Patient?**
   c. Confirm current profile or select a new profile. This places the module in an *idle state* (not infusing or in the process of being programmed as illustrated Channels A and B).
2. Prepare the infusion set for the Pump Module, see *Preparing for an Infusion (BD Alaris™ Pump Module)* on page *78*.
3. Prime the infusion set, see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*.



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

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

NOTE:
If the automated programming request is sent while the Syringe Module is infusing, a prompt appears on the PCU to install the scanned syringe.

For the Pump Module, proceed to step 6.

4. For the Syringe Module, select the syringe type and size; otherwise proceed to step 7. If the installed syringe is loaded correctly, but not recognized, check the following:
   a. If a label is between the syringe barrel and the barrel clamp, make sure that the label does not erroneously enlarge the barrel size of the syringe.
   b. If a needle-free valve or other component is added to the syringe, ensure that it is no larger than the diameter of the syringe barrel.

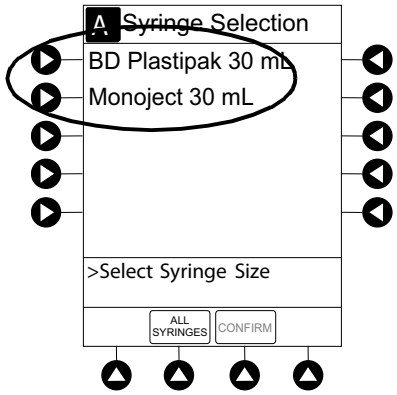
NOTE:

- Thick labeling or adding a component to the syringe that is larger than the diameter of the syringe may prevent the device from correctly recognizing the installed syringe. If the issue continues despite the above troubleshooting, send the device to your facility's biomedical engineering department for servicing.
- The capability of the Syringe Module to recognize a new syringe and read the volume is unchanged from manual programming.

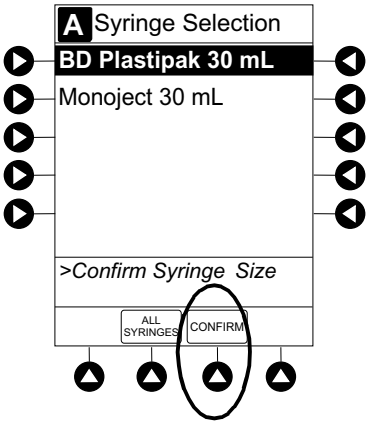
WARNING

Ensure that the displayed syringe manufacturer and syringe size match the installed syringe. Mismatches can impact flow rate accuracy.

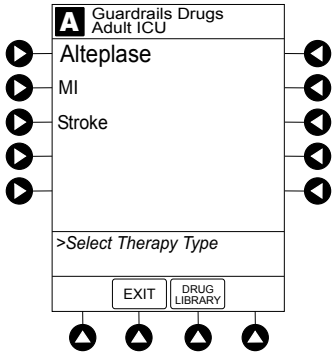
   c. Press the soft key next to the installed syringe type and size. If a default syringe list has been enabled and the correct syringe cannot be found, press the **ALL SYRINGES** soft key to select from a list of all compatible syringes.



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

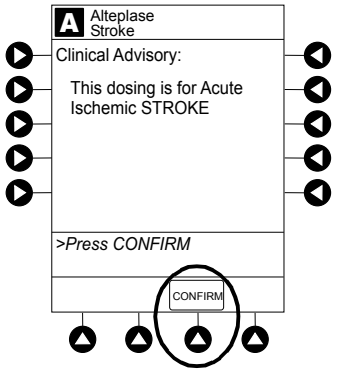


5. If applicable, select the therapy on the PCU.
   - If a drug concentration or Guardrails™ library selection has only one hospital-defined therapy that matches the dosing units in the automated programming request, then the therapy is automatically selected.
   - If a drug concentration or Guardrails™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



NOTE:
Once the therapy has been confirmed, the name is displayed in the title below the drug or fluid name on the infusion setup and programming screen of the PCU.

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



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

- Drug or Fluid name (alias or NDC)
- Drug amount
- Drug Amount units
- Diluent Volume
- Dose
- Dosing units
- Patient Weight or BSA (if used)
- Rate
- Volume to be infused (VTBI)
- Duration

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

NOTE:

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

8. Start applicable infusion as described in the following procedures:

Programming a Continuous Infusion on page *112*

Fluid Infusion on page *157*

Intermittent Infusion on page *158*

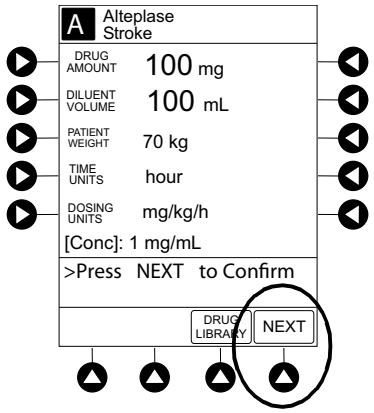
Continuous Infusion

The following workflow assumes that the patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Initial Primary Infusion* on page *151*.

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

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

2. Press the **NEXT** to confirm.



NOTE:

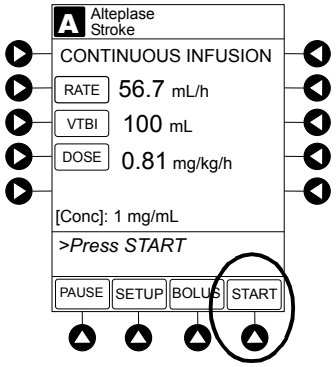
Syringe Module:

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

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

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

4. Press the **START** soft key.
   - For the Pump Module, when beginning an infusion and periodically during the infusion, check the drip chamber to ensure that the drip rate correlates to the intended infusion rate.



5. For the Syringe Module, unclamp tubing and attach infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

   NOTE:
   In some situations it may be necessary to attach the infusion set to the patient's access before opening the clamp (for example, hazardous drugs or extremely small volume infusions).

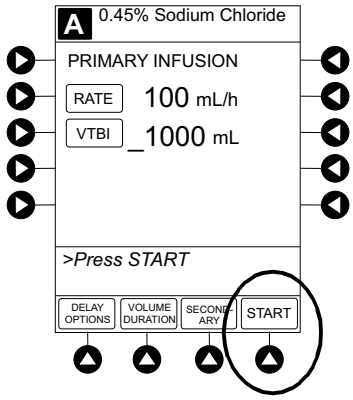
Fluid Infusion

The following workflow assumes that the patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned. See *Initial Primary Infusion* on page *151*.

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

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

2. Press the **START** soft key.
   - For the Pump Module, when beginning an infusion and periodically during the infusion, check the drip chamber to ensure that the drip rate correlates to the intended infusion rate.



NOTE:

Syringe Module:

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

3. For the Syringe Module, unclamp the tubing and attach the infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

   NOTE:
   In some situations it may be necessary to attach the infusion set to the patient's access before opening the clamp (for example, hazardous drugs or extremely small volume infusions).

Intermittent Infusion

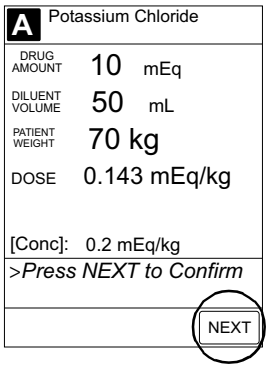
The following workflow assumes that the patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Initial Primary Infusion* on page *151*.

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

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

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

2. Press the **NEXT** to confirm.



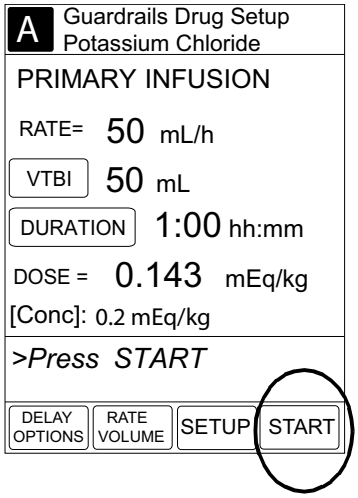
NOTE:
Syringe Module:

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

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

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

4. Press the **START** soft key.
   - For the Pump Module, when beginning an infusion and periodically during the infusion, check the drip chamber to ensure that the drip rate correlates to the intended infusion rate.



5. For the Syringe Module, unclamp tubing and attach infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

   NOTE:
   In some situations it may be necessary to attach the infusion set to the patient's access before opening the clamp (for example, hazardous drugs or extremely small volume infusions).

Subsequent Primary Infusion (Pump Module)

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

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

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

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

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

NOTE:
When the infusion that is running on the Pump Module was programmed using a custom concentration, the Drug Amount and Diluent Volume of the subsequent infusion automated programming request must match the running infusion.

The pre-population of infusion parameters workflow for subsequent bags is unchanged from the initial bag; scan patient, scan medication label, scan Pump Module, see *Initial Primary Infusion* on page *151*. The infusion parameters for the subsequent bag must meet the required matching criteria. If the matching criteria are met, the infusion parameters are pre-populated on the PCU without interruption of the currently running infusion.

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

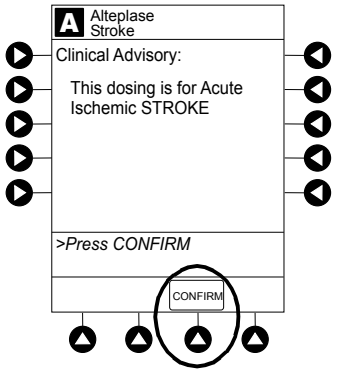
NOTE:
If an infusion is in Delay when a subsequent automated programming request is sent and matching criteria:

- Are met, the Delay is canceled and the subsequent automated programming request infusion parameters are pre-populated on the PCU. To add a Delay manually, refer to *Delay Options* on page *184*.
- Are not met, the automated programming request is rejected and the infusion remains in Delay.

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

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

   If the hospital has defined a clinical advisory for the drug, a message will appear.



NOTE:
If the infusion parameters cannot be pre-populated on the system, error messages will be displayed in the EMR/HIS. Error messages will not be displayed on the PCU. Consult the EMR/HIS.

3. Start the applicable infusion as described in the following procedures:

   Programming a Continuous Infusion on page *112*

   Programming a Secondary Infusion on page *142*

   Intermittent Infusion on page *158*

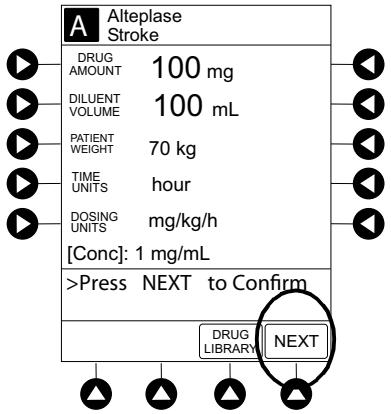
Subsequent Continuous Infusion

The following workflow assumes that the Pump Module has already been programmed with an initial primary continuous infusion and that the patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, *see Initial Primary Infusion* on page *151*.

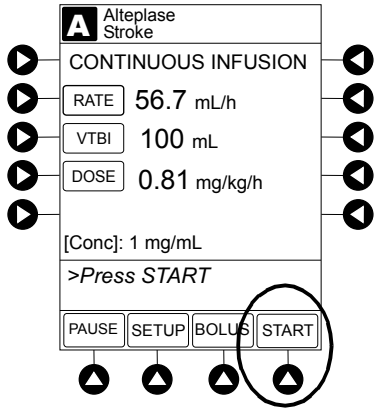
1. Review and verify that all parameters pre-populated on the system are correct prior to starting the infusion.

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

2. Press the **NEXT** to confirm.



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

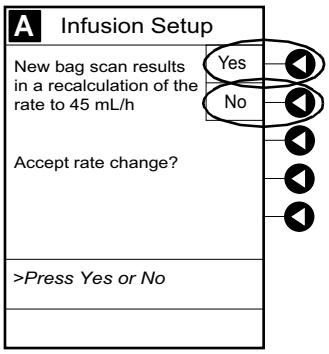


   The rate, VTBI, and dose are pre-populated from the automated programming request.

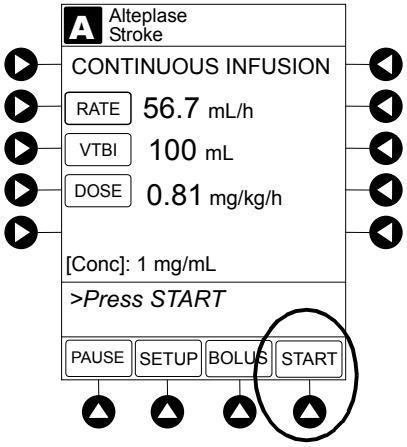
   If the subsequent automated programming request contains an infusion parameter (rate or dose) that changes the current infusion rate, a message appears with a recalculation of the rate notification.

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

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



5. Review and verify that all parameters pre-populated on the system are correct prior to starting the infusion.
6. Press the **START** soft key.



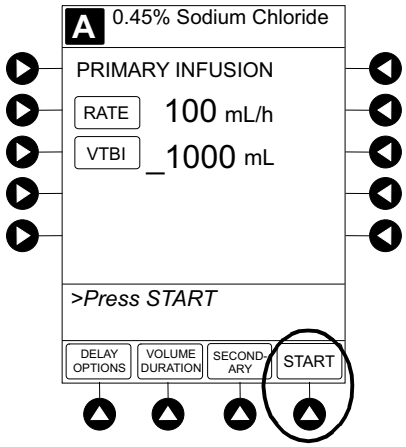
Subsequent Fluid Infusion

The following workflow assumes that the Pump Module has already been programmed with an initial primary fluid infusion and that the patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Initial Primary Infusion* on page *151*.

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

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

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

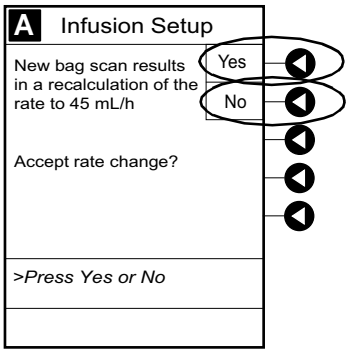


3. From the **Infusion Setup** screen:

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

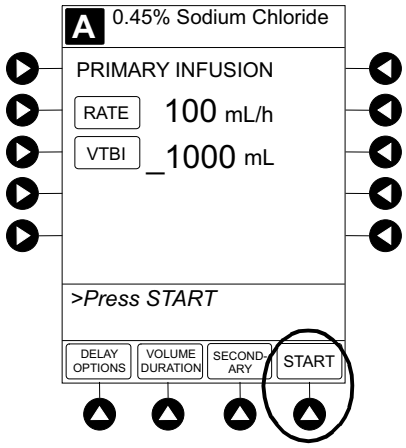
     or

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



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

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



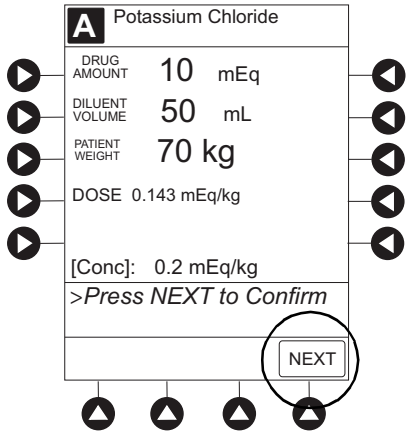
Subsequent Intermittent Infusion

The following workflow assumes that the Pump Module has already been programmed with an initial primary intermittent infusion and that the patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned. *See Initial Primary Infusion* on page *151* for more information.

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

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

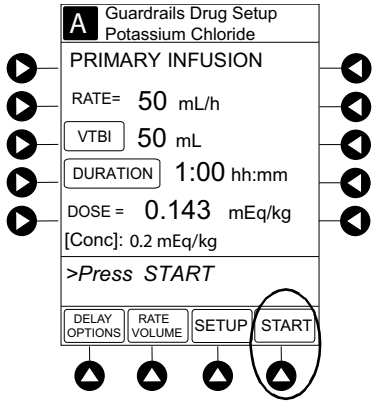
2. Press the **NEXT** to confirm.



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

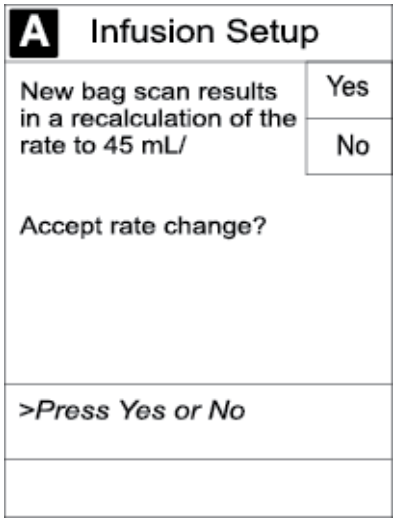
   The rate, VTBI, and duration are pre-populated from the automated programming request.

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



5. If the subsequent automated programming request contains an infusion parameter (rate or duration) that affects or changes the current infusion rate, a message appears with a recalculation of the rate notification.
6. From the **Infusion Setup** screen:
   - Select **Yes** to accept the rate change and start the infusion.

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



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

Subsequent Primary Infusion (Syringe Module)

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

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

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

NOTE:
If an infusion is in Delay when a subsequent automated programming request is sent, the Delay will be canceled and the subsequent automated programming request infusion parameters will be pre-populated on the PCU. To add a delay manually, see *Delay Options* on page *184*.

Pre-population of infusion parameters for a subsequent syringe is the same workflow as an initial primary infusion. See *Initial Primary Infusion* on page *151* for more information.

Secondary Infusion (Pump Module)

WARNING

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

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

When the device 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.

Infusion

In order to pre-populate infusion parameters for a secondary infusion, a primary fluid that supports a secondary must already be programmed or infusing. For more information, see *Initial Primary Infusion, Fluid Infusion* on page *157* and *Secondary Infusion.*

Setup

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

WARNING

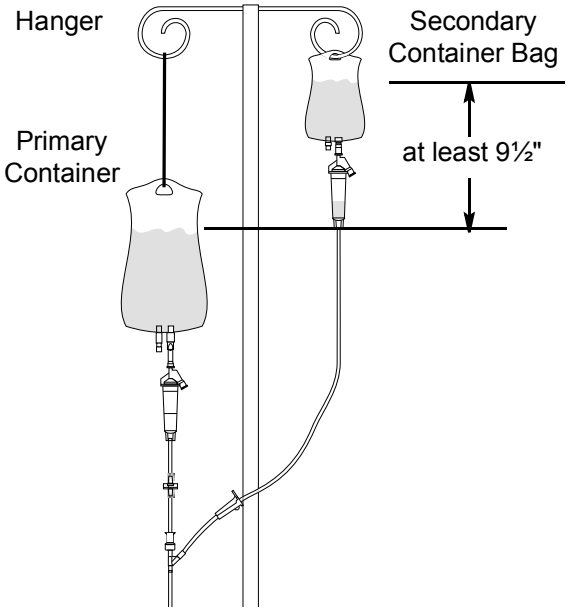
The secondary infusion set must be primed prior to beginning the secondary infusion.

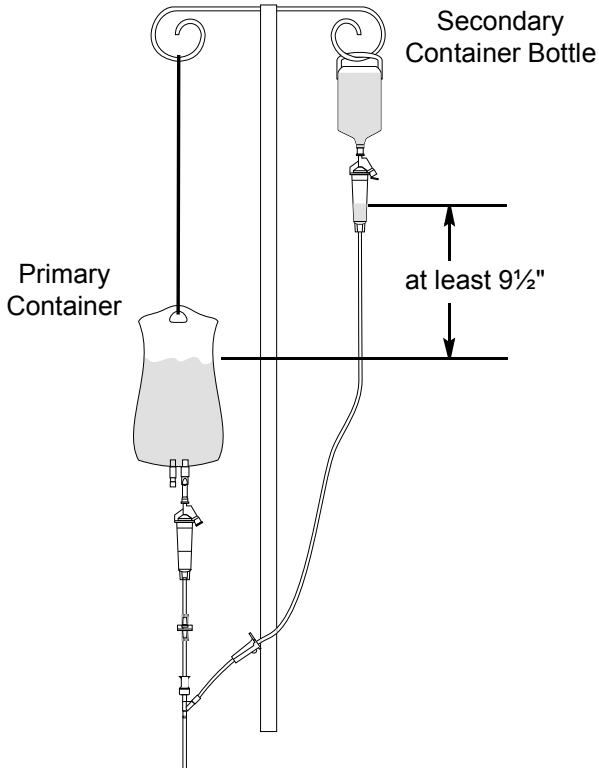
5. Attach the secondary infusion set to the upper injection site on primary set.

WARNING

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

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

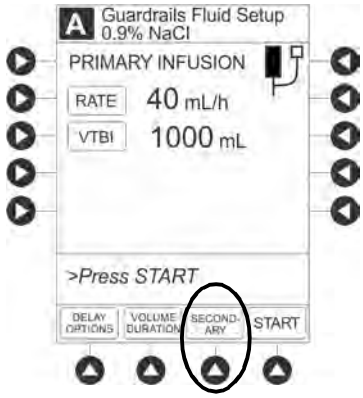




The generic workflow for pre-population of infusion parameters is as follows. Contact your EMR/HIS vendor for detailed instructions. Using the EMR/HIS system scanner used for barcode medication administration:

- Scan patient's ID band.
- Scan fluid/medication barcode label.
- Scan barcode label on the Pump Module.

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

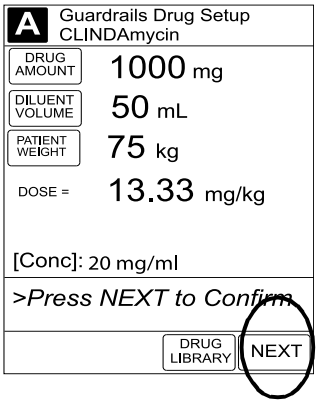


The set-up page for the secondary infusion appears with the drug amount, diluent volume, and patient weight (if intermittent infusion is weight-based) or BSA (if intermittent infusion is BSA-based) pre-populated from the automated programming request.

8. Review and verify that all parameters pre-populated on the system are correct.

NOTE:
If the infusion parameters cannot be pre-populated on the system, error messages are displayed in the EMR/HIS. Error messages are not displayed on the PCU. Refer to the EMR/HIS for more information.

9. Press the **NEXT** to confirm.

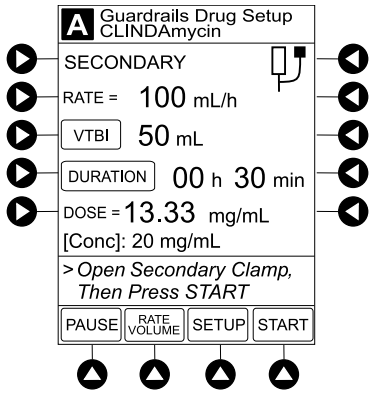


WARNING

When programming a secondary piggyback infusion, confirm that the programmed secondary VTBI matches the actual volume of the bag (including any additives or overfill). This ensures the entire secondary volume infuses at the correct rate.

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

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



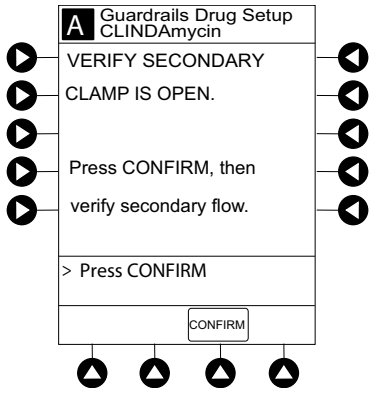
WARNING

The clamp on the secondary infusion set must be opened. If the clamp is closed, the fluid is delivered from the primary container.

11. Open the clamp on secondary infusion set.
12. Press the **START** soft key.

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

13. Verify secondary clamp is open.
14. Press the **CONFIRM** soft key.



15. Observe the secondary drip chamber to verify that drops are falling and that flow does not appear to be too fast or too slow. Do this periodically throughout the infusion. No drops should be falling in the primary drip chamber.

Changing Primary Infusion Parameter

1. Press the **CHANNEL SELECT** key.
2. Press the **SET UP** soft key.
3. Press the **PRIMARY** soft key.
4. To change primary infusion parameter, press the applicable soft key (**RATE** or **VTBI**) and use numeric data entry keys.
5. Verify correct primary infusion parameters and press the **SECONDARY** soft key.

   Secondary setup screen is displayed.
6. Press the **NEXT** soft key.
7. To resume secondary infusion, press the **START** soft key.
8. Verify that drops are flowing from the secondary container drip chamber.

Stopping Secondary and Returning to Primary

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

   or

   Disconnect the secondary infusion set from the upper injection port.
5. Press the **START** soft key.
6. To stop the secondary infusion and begin infusing the primary, press the **Yes** soft key.

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

No Guardrails™ Basic Infusion

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 can be programmed using the **DRUG CALC** soft key within the drug library. There are no Guardrails™ limits protections 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.

Preparing for a No Guardrails Basic Infusion

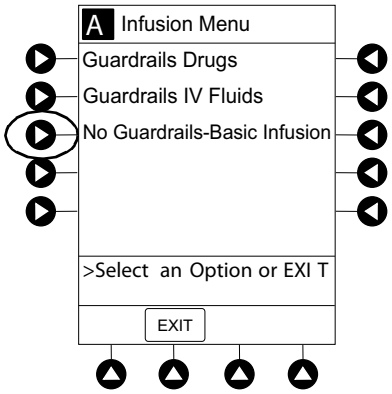
If Delay Options is enabled, the **PAUSE** soft key becomes **DELAY OPTIONS.**

1. Perform the following steps (see *Initial Setup* on page *14* for specific steps):
   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/infusion set (see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*).
3. Prime (see *Priming Infusion Set With Pressure Sensing Disc* on page *96*).
4. Start applicable infusion, as described in following procedures:
   - *Rate/Volume Infusion* on page *135*
   - *Programming a No Guardrails™ Basic Infusion* on page *173*

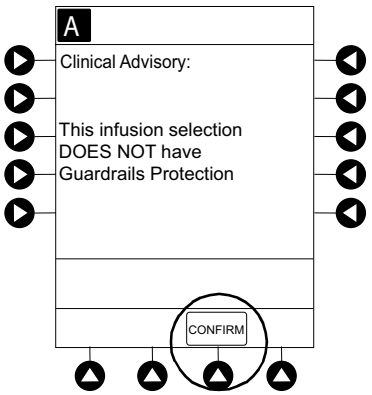
Programming a No Guardrails™ Basic Infusion

The following procedure should only be used to set up a No Guardrails™ - Basic Infusion. To program an infusion using **Guardrails Drugs**, see *Initial Primary Infusion* on page *151*.

1. Press the **CHANNEL SELECT** key.
2. Press the **No Guardrails-Basic Infusion** soft key.



- An optional hospital-defined clinical advisory message may appear reminding the clinician that No Guardrails™ - Basic Infusion feature does not have limits. Press **CONFIRM** soft key to continue programming.

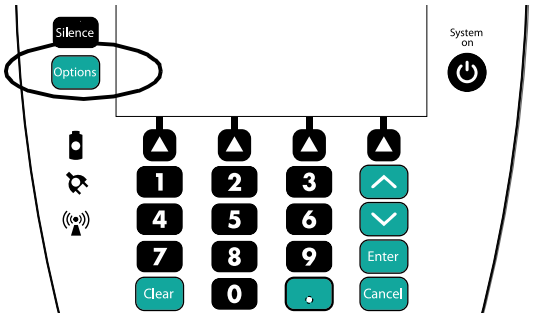


Infusion Setup screen appears.

3. Start applicable infusion as described in the following procedures (see *Initial Primary Infusion*):
   - *Fluid Infusion* on page *134*
   - *Rate/Volume Infusion* on page *135*
   - *Volume/Duration Infusion* on page *137*

Changing a No Guardrails™ Basic Infusion to Guardrails™ Primary Infusion

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

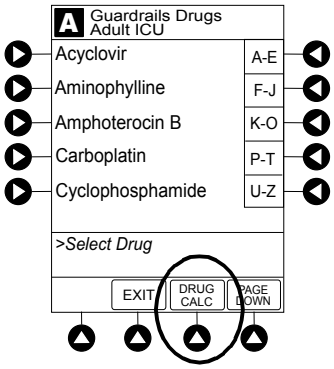


3. Press the **Guardrails Drugs** soft key.
4. Continue programming (see *Initial Primary Infusion* on page *151*).

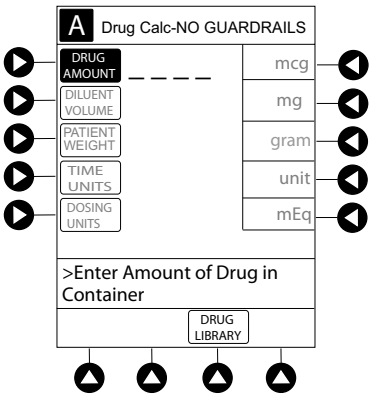
NOTE:
No Guardrails™ - Basic Infusions can only be promoted to Guardrails™ Continuous Infusion or Guardrails™ IV Fluids. A No Guardrails™ - Basic Infusion cannot be promoted to a Guardrails™ intermittent drug.

Programming a No Guardrails™ Basic Infusion with Drug Calculation

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



3. To enter **DRUG AMOUNT**, use numeric data entry keys.

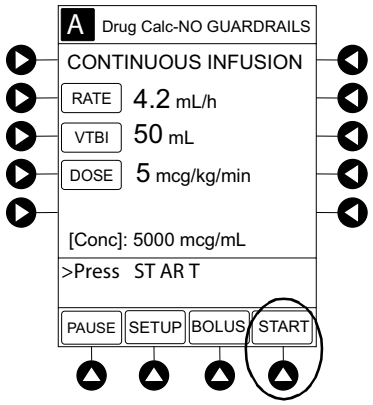


4. Press soft key for appropriate unit of measure for drug amount.
5. To enter diluent volume, use numeric data entry keys.
6. Press the **PATIENT WEIGHT** soft key.
7. To indicate whether or not patient weight is to be used in Drug Calculation, press the either **Yes** or **No** soft key.
8. To enter patient weight (if required) in kilograms, use numeric data entry keys.
9. Press the **TIME UNITS** soft key.
10. To select time base for drug calculation, press the either **Min, Hour**, or **Day** soft key.
11. Press the soft key next to desired **DOSING UNITS**.
12. Verify correct infusion parameters and press the **NEXT** soft key.
    - Syringe Module: If ALL Mode is enabled, **VTBI ALL** is displayed.
13. To make a rate or dose entry, press the 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 the **VTBI** soft key and use numeric data entry keys.
    - Pump Module:
        - When VTBI is less than 10 mL, entry can be to two decimal places (one-hundredth of a mL).
        - In Drug Calculation mode, system infuses at calculated rate rounded to nearest one-hundredth of a mL per hour (as displayed on programming screen). Rate shown in Rate Display is rounded to nearest one-tenth of a mL per hour.
    - Syringe Module:
        - If ALL Mode is enabled for syringe configuration in data set, **ALL** is displayed in **VTBI** field and estimated available volume in syringe is displayed.

        or

        - If ALL Mode is disabled for syringe configuration in data set, estimated available volume in syringe is displayed when **VTBI** soft key is pressed.
        - To enter or change a numeric VTBI value, press the **VTBI** soft key and use numeric data entry keys.
        - To deliver entire contents of syringe: Keep an **ALL VTBI** value, or press the **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 the **START** soft key.
    - For the Pump Module, when beginning an infusion and periodically during the infusion, check the drip chamber to ensure that the drip rate correlates to the intended infusion rate.



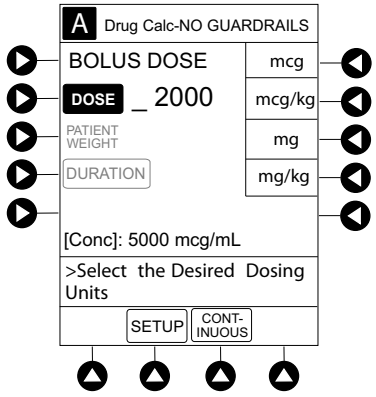
16. For the Syringe Module, unclamp tubing and attach infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

NOTE:

- In some situations it may be necessary to attach the infusion set to the patient's access before opening the clamp (for example, hazardous drugs or extremely small volume infusions).
- Do not enter a patient weight if weight is not used in the calculation.

Programming a No Guardrails™ Basic Bolus Dose

1. Set up infusion as described in *Programming a No Guardrails™ Basic Infusion with Drug Calculation* on page *174*, but do not start infusion.
2. Press the **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 the 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.
6. Verify correct parameters and press the **START** soft key.

   To see details during bolus infusion, press the **CHANNEL SELECT** key.
7. For the Syringe Module, if bolus dose was programmed at beginning of infusion, unclamp tubing and attach infusion set to patient. Unclamping before attaching to the patient minimizes any potential bolus from pressure buildup during syringe loading that could be delivered when the clamp is released.

Programming a No Guardrails™ Secondary Infusion

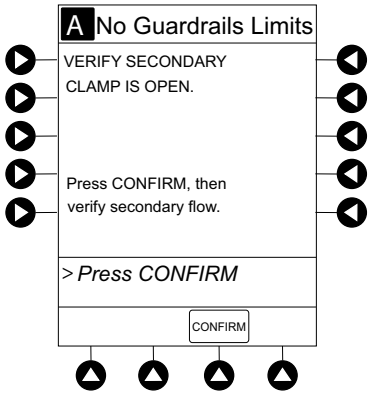
See *Secondary Infusion* on page *140* for a description of the secondary infusion mode and for setup instructions.

The following procedure should be used only when:

- Drug to be infused is not listed in drug library
- Primary infusion is running

To program a primary infusion, see *Manual Programming with Guardrails™ Suite MX* on page *110*. To program a No Guardrails™ - Basic Infusion, see *Programming a No Guardrails™ Basic Infusion* on page *173*.

1. Press the **SECONDARY** soft key and then **BASIC SEC** soft key.
2. Enter secondary infusion rate or duration, as follows:
   - To enter secondary infusion rate, press the **RATE** soft key and use numeric data entry keys.
   - To enter duration, press the **DURATION** soft key and use numeric data entry keys.
3. To enter secondary volume to be infused, press the **VTBI** soft key and use numeric data entry keys.
4. Open clamp on secondary infusion set.
5. Verify correct infusion parameters and press the **START** soft key.
6. Verify secondary clamp is open.
7. Press the **CONFIRM** soft key.



WARNING

The clamp on the secondary infusion set must be opened. If the clamp is closed, the fluid is delivered from the primary container.

8. Observe the secondary drip chamber to verify that drops are falling and that flow does not appear to be too fast or too slow. Do this periodically throughout the infusion. No drops should be falling in the primary drip chamber.

Changing Primary Infusion Parameters

1. Press the **CHANNEL SELECT** key.
2. Press the **PRIMARY** soft key.
3. To change primary infusion parameter, press the applicable soft key (**RATE** or **VTBI**) and use numeric data entry keys.
4. Verify correct primary infusion parameters and press the **SECONDARY** soft key.

   Secondary setup screen is displayed.
5. To resume secondary infusion, press the **START** soft key.
6. Verify that drops are flowing from the secondary container drip chamber.

Stopping Secondary and Returning to Primary

See *Secondary Infusion* on page *140*.

General Programming

The following sections describe additional features and functionality.

Pausing and Restarting an Infusion

1. Press the **PAUSE** 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.

NOTE:

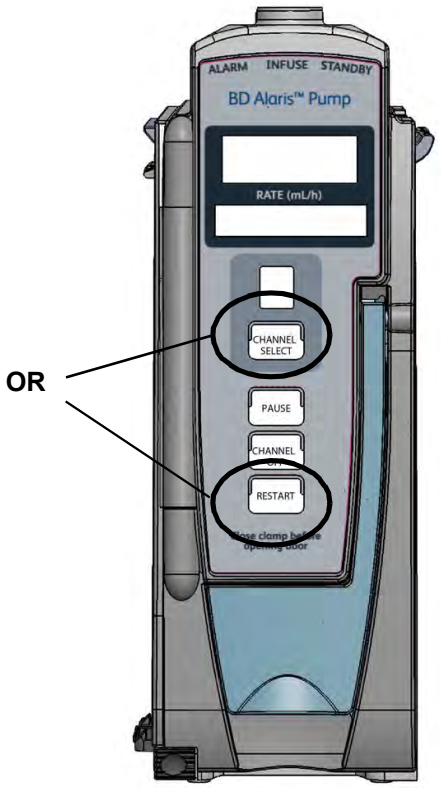
- The Pump Module keypad is used in the illustrations but the keys are the same for the Syringe Module.
- An infusion can also be paused by pressing the **PAUSE** soft key (on PCU), if the Delay Options are disabled. To pause an infusion programmed with Delay Options enabled, see *Delay Options* on page *184* and *Pausing an Infusion* on page *187*.

2. To restart infusion:

   Press the **RESTART** key.

   or

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



Changing Rate or VTBI During an Infusion

1. Press the **CHANNEL SELECT** key.
2. Press either the **RATE** or the **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 the **START** soft key.

NOTE:
The up/down arrows default to the **RATE** field when **CHANNEL SELECT** is pressed during an infusion.

Restoring an Infusion

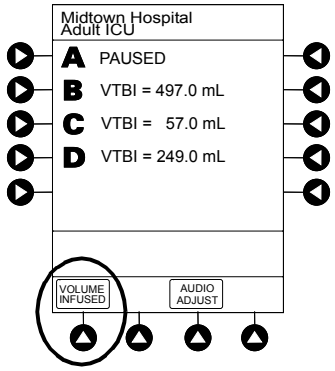
1. To restart infusion using stored parameters, press the **RESTORE** soft key.
2. Verify correct parameters and press the **START** soft key.

NOTE:

- The restore option is available for infusions on the same module and PCU if the system is powered up within 8 hours of last use and the user answers **No** to the **New Patient** prompt.
- To restore a bolus dose, see *Stopping a Bolus Dose* on page *126* and *Restoring a Bolus Dose* on page *127*.

Viewing and Clearing Volume Infused

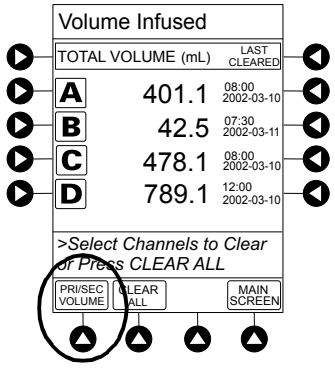
1. To view volume infused, press the **VOLUME INFUSED** soft key.
   - Total volume infused (primary + secondary), and time and date volume infused was last cleared, display for each module.



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

   NOTE:

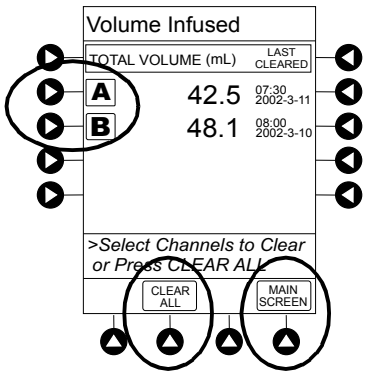
   - Date format is year-month-day.
   - Pump Module: A **PRI/SEC VOLUME** soft key is available to allow secondary volume infused to be displayed.



3. To clear volume infused:
   - If only selected module is to be cleared, press the soft key next to applicable module and press the **CLEAR CHANNEL** soft key.
   - Volume clears on selected module.
   - If all modules are to be cleared, press the **CLEAR ALL** soft key.

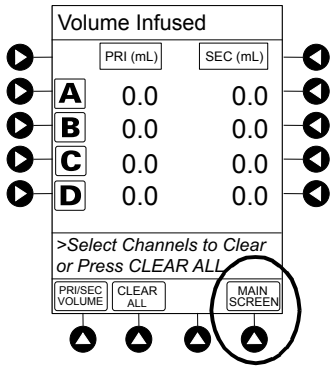
NOTE:

- If no key is pressed, main screen appears after 30 seconds.
- The illustrated example is a Syringe Module display. A Pump Module display has a **PRI/SEC VOLUME** soft key.



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

NOTE:
If no key is pressed, main screen appears after 30 seconds.



Delay Options

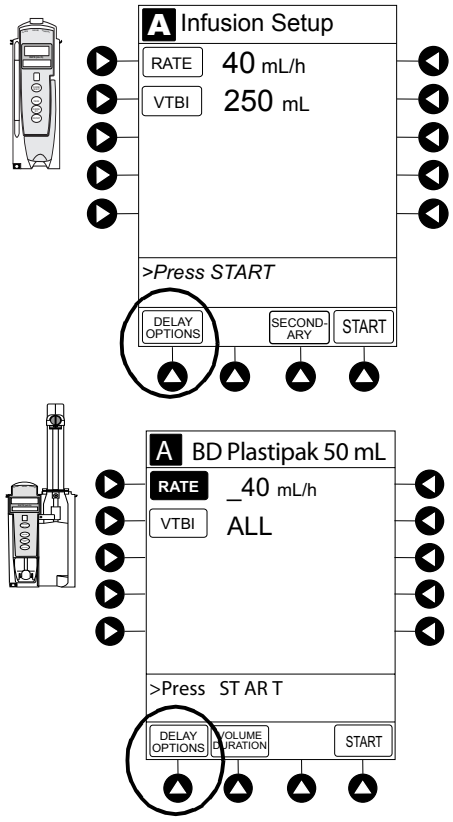
Delay options can be enabled at the time the system is configured for use. If delay options is enabled, a primary infusion can be programmed to be delayed for a specified period of time and a callback can be scheduled, as described in the following procedures.

Infusions programmed using delay options will transition to infusion complete-KVO when enabled.

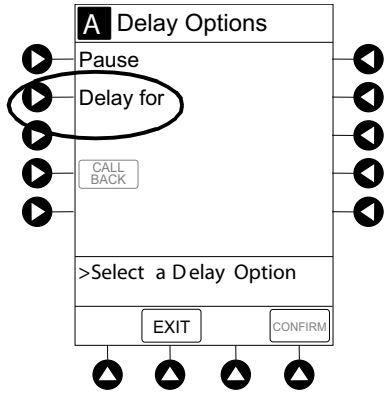
Delaying an Infusion

An infusion can be paused for 2 minutes or it can be delayed for a specific duration from 1 minute to 11 hours and 59 minutes in the future. An infusion delay can be programmed prior to or after an infusion is started.

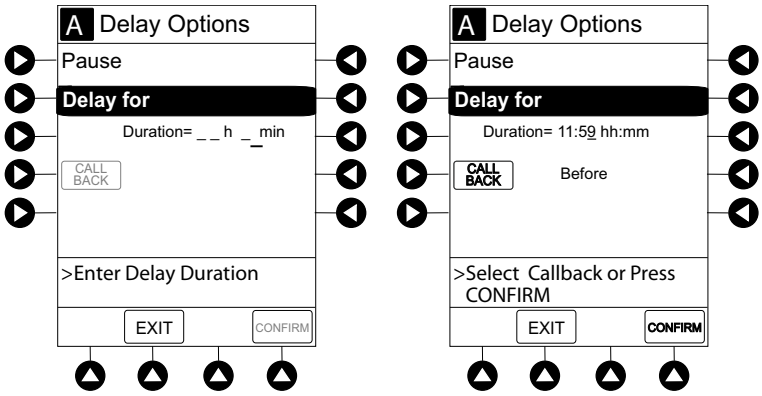
1. Press the **DELAY OPTIONS** soft key.



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



3. To enter the duration of the delay in hours or minutes, use the numeric data entry keys.

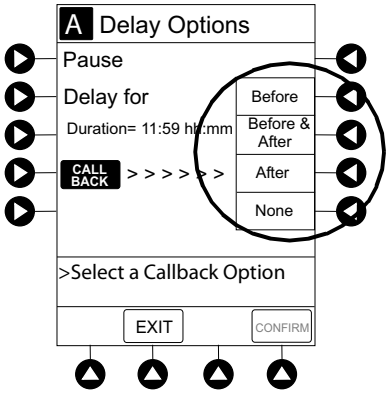


4. Press the **Confirm** soft key.
   - Delay period counts down on Main Display.
   - If a **Before** callback has not been scheduled (see *Scheduling a Callback* on page *186*), infusion automatically starts at end of delay period.

Scheduling a Callback

When programming a delay for an infusion, a callback can be scheduled. There are three types of callbacks:

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



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

1. Press the **CALL BACK** soft key.
2. Press the soft key corresponding to desired callback option.

   Scheduled callback appears on Main Display.
3. To start delay, press the **CONFIRM** soft key.
   - 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 and message appears, which requires confirmation when delayed infusion completes. The infusion will continue in Infusion Complete-KVO status on the Pump Module and, if enabled, on the Syringe Module.
     - Status Indicator displays flashing red and solid green lights.
     - **KVO or Complete** message appears on Main Display.
     - **Infusion Complete-KVO** 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 the **CHANNEL SELECT** key and then **START** soft key.

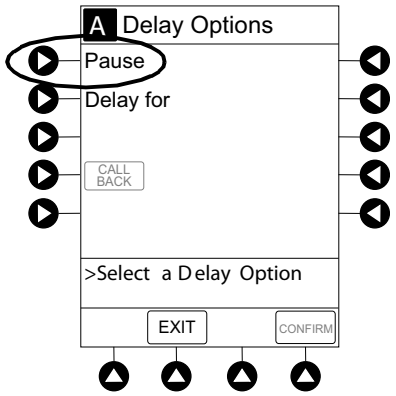
     or

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

Pausing an Infusion

1. Press the **DELAY OPTIONS** soft key.
2. Press the **Pause** soft key.

   If an alert has occurred, pause is not started by system until alert is addressed.



3. Press the **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 restart infusion:
   - Press the **RESTART** key.

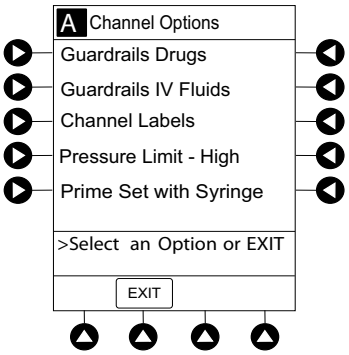
   or
   - Press the **CHANNEL SELECT** key and then the **START** soft key.

Channel Labels

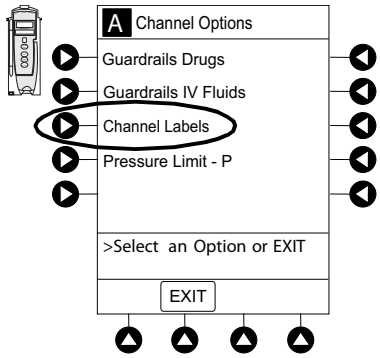
The channel labels option is not available if a Guardrails™ IV fluids or Guardrails™ drug infusion is running on the module. A channel label is removed when the No Guardrails™ - Basic Infusion is promoted to a Guardrails™ IV fluids or Guardrails™ drugs infusion.

Selecting a Channel Label

1. Press the **CHANNEL SELECT** key.
2. Press the **OPTIONS** key.
3. Syringe Module: Press the **PAGE DOWN** soft key.

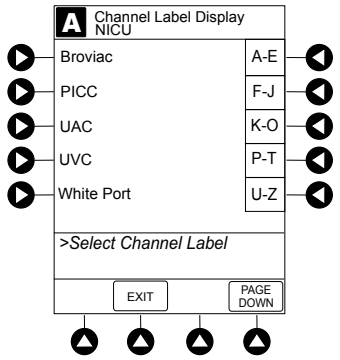


4. Press the **Channel Labels** soft key.



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

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



6. To continue infusion, press the **START** soft key.

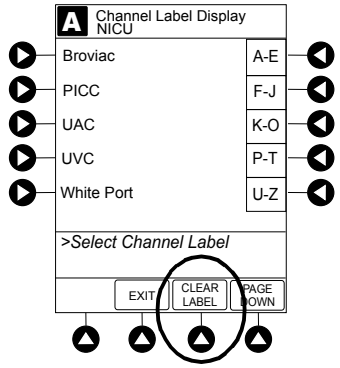
   or

   Program infusion as previously described.

Removing a Channel Label

1. Press the **CHANNEL SELECT** key.
2. Press the **OPTIONS** key.
3. Syringe Module: Press the **PAGE DOWN** soft key.
4. Press the **CHANNEL LABELS** soft key.
5. Press the **CLEAR LABEL** soft key.

   Label stops scrolling in Message Display.



6. To begin infusion, press the **START** soft key.

   or

   Program infusion as previously described.

Pressure Limit

WARNING

Time-to-alarm for occlusion can be affected by:

- **Occlusion pressure setting**
- **Flow rate**
- **Location of the occlusion**
- **Infusion set and components**
- **Fluid viscosity**

WARNING

Use lowest occlusion pressure settings when infusing at low or very low flow rates. High occlusion pressure settings result in longer time to alarm when an occlusion occurs.

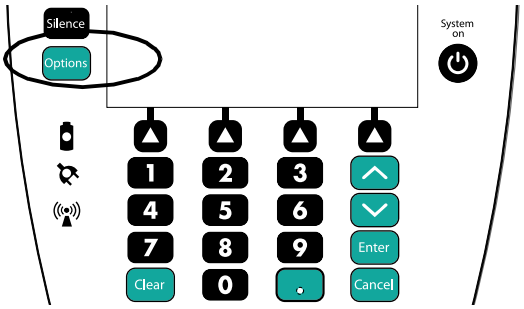
The optimal occlusion alarm limit setting achieves a balance between the risk of false alarms and timely response to occlusions. To avoid interruptions in therapy, the limit should be set at a value higher than the expected actual working pressure, which will allow normal events such as patient movement and titrations to occur without alarms.

The working pressure presented to a pump by the IV cannula depends on several factors: combined rate of all infusions running into a single vascular access point, resistance of the fluid path, elevation differential, and vascular pressure dynamics. Resistance to flow is determined by the catheter's length and inner diameter, and the viscosity of the fluid. Kinking and clotting might also elevate the resistance to flow over time.

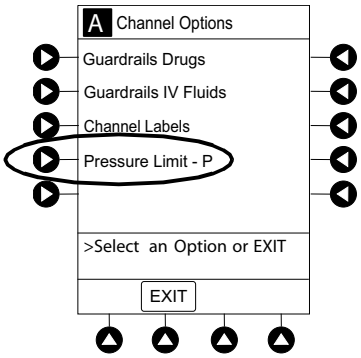
The Syringe Module allows both fixed and customized approaches to pressure limits to be configured. Each profile can be programmed with its own maximum pressure value, supporting a fixed limit approach. Customized limits can be set either manually, by reading the current pressure following stabilization and adding a margin, or by use of the auto pressure feature which, on activation, sets a margin of 30 mmHg for initial pressures under 100 mmHg or 30% of the initial pressure at higher initial values. The margin must be larger when variations in flow, resistance, and vascular pressure are anticipated. When pumping through high resistance access devices such as central line catheters, the auto pressure margin might be inadequate. With these devices, ten minutes or more might be required to allow the pressure to stabilize following flow rate changes, as required for the use of auto pressure. Therefore, caution should be used when using auto pressure for life sustaining fluids, to prevent unexpected interruptions of infusion due to occlusion alarms.

Selecting Pump Module Pressure Limit

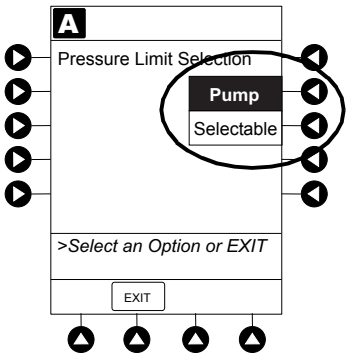
1. Press the **CHANNEL SELECT** key.
2. Press the **OPTIONS** key.



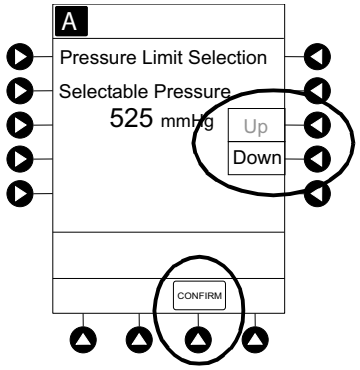
3. Press the **PRESSURE LIMIT** soft key.



4. Press either the **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 the **Up** or **Down** soft key.



6. Verify correct occlusion pressure limit input and press the **CONFIRM** soft key.
7. Press the **START** soft key.

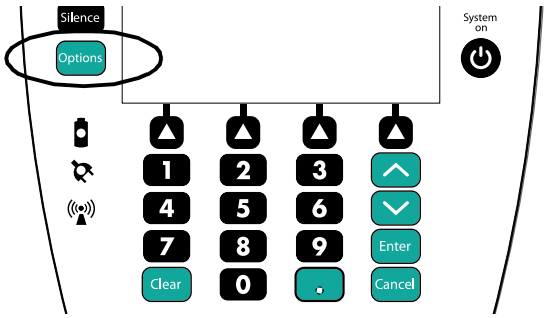
Selecting Syringe Module Pressure Limit with Pressure Sensing Disc Installed

WARNING

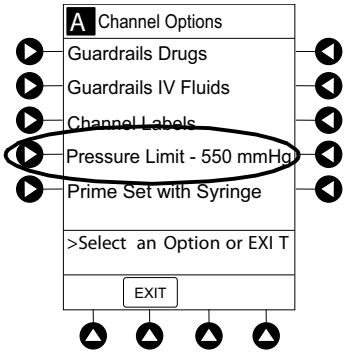
To minimize the amount of time for the pump to generate an occlusion alarm while infusing at low rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h), do the following:

- **Consider the occlusion pressure limit setting and adjust it, as necessary. The lower the setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (for example, lipids), the occlusion pressure limit setting may need to be increased to reduce false alarms.**

1. Ensure that pressure sensing disc is installed correctly.
2. Press the **CHANNEL SELECT** key.
3. Press the **OPTIONS** key.



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



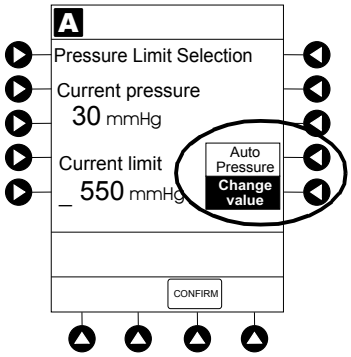
5. To enter a new pressure limit value, press the **Change Value** soft key.

   or

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

   NOTE:
   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



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

Selecting Syringe Module Pressure Limit with Pressure Sensing Disc NOT Installed

WARNING

When an occlusion occurs, pressurized fluid builds up that can be infused upon release of the occlusion. To avoid an unintentional bolus, relieve the pressure before restarting the infusion.

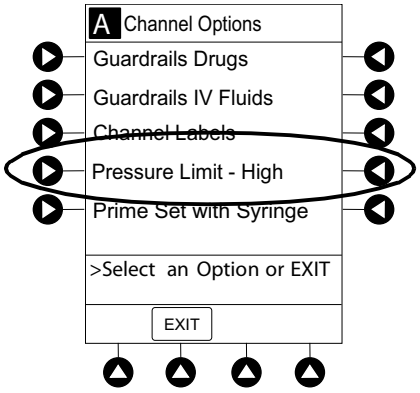
WARNING

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

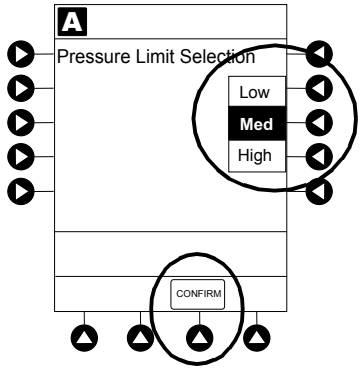
- **Consider the occlusion pressure limit setting and adjust it, as necessary. The lower the setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (for example, lipids), the occlusion pressure limit setting may need to be adjusted to reduce false alarms.**
- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe when infusing at low rates can lead to delayed generation of occlusion alarms. This is due to the higher compliance of the syringe stopper and increased friction between the plunger and the walls of the syringe with larger syringes.**
- **Use the Prime Set with Syringe feature in the Channel Options menu, when starting an infusion or changing the syringe and tubing. Failure to do so can delay the infusion delivery startup time and lead to delivery inaccuracies.**
- **Use compatible components that have the smallest internal volume or deadspace to minimize the residual volumes between the syringe and the patient.**
- **Use accessory devices that have the smallest internal volume or deadspace (for example, use microbore tubing when infusing at low rates, shorter length of tubing, and so on).**

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

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



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



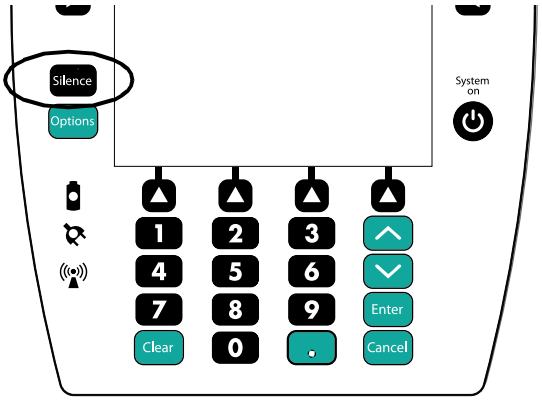
Changing a Solution Container (Pump Module)

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

Changing a Syringe During an Infusion

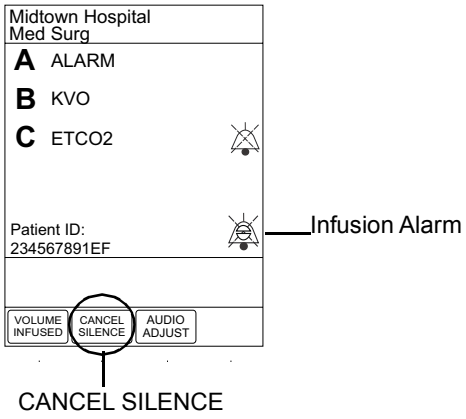
If a critical medication is being infused at a flow rate less than 1.0 mL/h and the patient is not stable enough to experience even a short period of time without the drug, it is recommended that the new syringe and infusion set be installed as part of a second system setup. Before changing the infusion 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 the **PAUSE** key.
2. Open plunger grippers and syringe barrel clamp.
   - An audio alarm sounds—to silence, press the **SILENCE** key.



   - Red Alarm Status Indicator flashes.
   - **CHECK SYRINGE** scrolls in Message Display.
   - The **CANCEL SILENCE** soft key is displayed and an Infusion Alarm Silence symbol appears in lower right of PCU screen.

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



3. Remove syringe and separate infusion set from syringe.
4. Reattach infusion set to new syringe and load new syringe (see *Preparing for an Infusion (Alaris™ Syringe Module)* on page *93*).

5. Select syringe type and size (see *Manual Programming with Guardrails™ Suite MX* on page *110*).
6. Press the **CONFIRM** soft key.
7. Prime infusion set using options menu or manually (see *Using Priming Options* on page *103* and *Priming Infusion Set With No Pressure Sensing Disc* on page *108*).
8. Press the **RESTORE** soft key.

   or

   To enter VTBI and rate, press the **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 the **START** soft key.

Infusion Set/Syringe Information

- For specific infusion set instructions and replacement interval, refer to packaging label provided with set.
- For a listing of commonly used Pump Module and Syringe Module infusion sets refer to bd.com/Infusionlibrary.
- Use aseptic techniques when handling sets and syringes.
- Infusion sets are supplied with a sterile and nonpyrogenic fluid path for one-time use. Do not resterilize.
- Discard infusion set per facility protocol.
- For IV push medication (put device on hold), and clamp tubing above port.
- Do not administer IV pushes through ports that are above the system.
- Flush port(s) per facility protocol.

The Pump Module uses a wide variety of BD Alaris™ Pump infusion 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 is a unique clamping device on the pumping segment that is part of all BD Alaris™ Pump infusion sets (see *Setting Up a Gravity Infusion* on page *199*).

The Syringe Module uses standard, single-use, disposable syringes (with luer-lock connectors) and infusion sets designed for use on syringe pumps. For a list of compatible syringes, refer to *Alaris™ Syringe Module Compatible Syringes* on page *200*.

NOTE:
Refer to the infusion set instructions.

Setting Up a Gravity Infusion

1. Prime infusion set (see *About This Chapter*, *Priming the BD Alaris™ Pump Module Infusion Set* on page *86* for the procedure).
2. Adjust container to hang at least 20 inches above patient's vascular access device (see *Safety Clamp (BD Alaris™ Pump Module)* on page *78*).
3. Attach infusion set to patient's vascular access device.
4. Adjust flow rate with infusion set roller clamp.

Alaris™ Syringe Module Compatible Syringes

WARNING

Do not use incompatible syringe sizes and models with the Syringe Module. Use of incompatible syringes can impact pump operation resulting in inaccurate fluid delivery, delayed generation of occlusion alarms, and other potential problems.

Medications delivered on the Syringe Module must be prepared in a syringe that accommodates the desired flow rate. The following table shows the flow rate ranges for each syringe size and the reorder numbers. For the updated list, refer to the BD website: bd.com/Infusionlibrary. To locate the compatibility list on the BD website, enter **compatible syringe list** in the search field.

The Syringe Module is calibrated and labeled for use with the syringe models listed in the table. Use only the syringe size and type specified on the main display.

Compatible Syringes for the Syringe Module

Size	BD	Monoject™	Terumo™	Flow Rate Range
1 mL	309628	N/A	N/A	0.01-30 mL/h
3 mL	309657	Soft pack only 1180300777	SS-03L*	0.01-100 mL/h
5 mL	309646	N/A	SS-05L (6 mL total)*	0.1-150 mL/h
6 mL	N/A	Soft pack 1180600777 Rigid pack 8881516937	N/A	0.1-150 mL/h
10 mL	300912	N/A	SS-10L (12 mL total)*	0.1-250 mL/h
12 mL	N/A	Soft pack 1181200777 Soft pack 1181200777T Rigid pack 8881512878	N/A	0.1-250 mL/h
20 mL	302830	Soft pack 1182000777 Rigid pack 8881520657	SS-20L2 (25 mL total)*	0.1-500 mL/h
30 mL	302832	N/A	SS-30L (35 mL total)*	0.1-650 mL/h
35 mL	N/A	Soft pack 1183500777 Rigid pack 8881535762	N/A	0.1-650 mL/h
50 mL	309653	N/A	N/A	0.1-999 mL/h
60 mL	N/A	Soft pack 1186000777 Soft pack 1186000777T Rigid pack 8881560125	SS-60L	0.1-999 mL/h

*Only available in Canada.

Drug Calculation Definitions and Formulas

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.

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.

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

Configurable Settings

If the configuration settings need to be changed from the factory default settings, refer to the applicable Technical Service Manual or contact BD technical support, for technical, troubleshooting, and preventive maintenance information.

NOTE:
When a Guardrails™ data set is enabled in the PCU the Guardrails™ data set overrides all configuration settings.

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 Pump and Syringe Settings

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

BD Alaris™ Pump Module Settings

Feature	Default Setting	Options
Accumulated Air	Enabled	Enabled - Disabled
Air-in-Line Settings (single bolus)	75 mcL	50, 75, 125, 175, or 250 mcL Anesthesia Mode only: 500 mcL
Auto-Restart Attempts	0	0 - 9 attempts Anesthesia Mode only: 9 attempts
KVO (Keep Vein Open)	1 mL/h	0.1 - 20 mL/h
Max Rate	999 mL/h	0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments
Max VTBI	9999 mL	0.1 - 9999 mL
Pressure Mode • Mode Selection • Lock Status • Max Occlusion Pressure • Default Starting Occlusion Pressure	 Pump Unlocked 525 mmHg 525 mmHg	 Pump, Selectable Locked, Unlocked 50–525 mmHg in 25 mmHg increments (adjustable only in Selectable Pressure Mode) 50–525 mmHg in 25 mmHg increments (configured by profile and adjustable only in Selectable Pressure Mode)
SEC to PRI Alert	Enabled	Enabled - Disabled
Secondary (Dual Rate Sequential Piggybacking)	Disabled	Enabled - Disabled

Alaris™ Syringe Module Settings

Feature	Default Setting	Options
ALL Mode	Disabled	Enabled - Disabled
Auto Pressure	Disabled	Enabled - Disabled
Back Off (after occlusion)	Enabled	Enabled - Disabled
Fast Start	Enabled	Enabled - Disabled
KVO (Keep Vein Open) • Rate Adjust • Volume Adjust	Disabled 1 mL/h 5%	Enabled - Disabled 0.01–2.5 mL/h (0.01 - 0.09 mL/h available for 1 mL and 3 mL syringes) 0.5–5% (Based on the total syringe size, not the volume of fluid in the syringe)
Max Rate	999 mL/h	0.1–99.9 mL/h in 0.1 mL/h increments; 100–999 mL/h in 1 mL/h increments
Near End (NEOI) • Continuous Alert Time • Intermittent NEOI • Intermittent Alert Time	Disabled 60 Disabled 15	Enabled - Disabled 1–60 minutes Enabled - Disabled 1–60 minutes
NEOI Snooze (Shared syringe and PCA setting)	Disabled	Enabled - Disabled 5, 10, or 15 minutes
Occlusion Pressure Set Point • With Disc • No Disc	 1000 mmHg High*	 25–1000 mmHg in 1 mmHg increments Low (200 mmHg) Medium (500 mmHg) High (800 mmHg)
Priming	Disabled	Enabled - Disabled

NOTE:
*Occlusion pressure limit cannot be set higher than the default setting.

BD Alaris™ Pump Module Specifications

Pump Module specifications are provided in the following sections.

Standard Operating Conditions

Standard operating conditions is a term used to describe the conditions under which testing was performed for the BD Alaris™ System in the specifications section of this manual. They are listed below.

Performance test results vary when testing is performed in conditions other than standard operating conditions. For results from testing performed in non-standard operating conditions, refer to Appendix C – Non-Standard Performance.

- Temperature: 20 °C ± 2 °C
- Atmospheric Pressure: 645 mmHg to 795 mmHg
- Relative Humidity: 20% - 90% noncondensing
- Infusion Rate Range: 0.1 to 999 mL/h
- Fluid Head Height: 20 ± 1 inch from top of the Pump Module
- Back Pressure: 0 mmHg ± 2 mmHg
- Solution Type: Distilled water
- Needle: 18 gauge, 40 mm, 1.5 inch length
- Infusion Set: Not expired, ≤ 3 years shelf life, ≤ 96 hours of usage

Pump Module Performance Topic	Infusion Set Under Standard Operating Conditions
Rate Accuracy Bolus Accuracy	**For flow rate ≥ 100 mL/h:** 115 inch - 130 inch set with ≥ 0.100 inch tubing inner diameter, ≤ 20 drops per mL drip chamber, ≥ 1 SmartSite™ Y-Site above and/or below pumping segment and no flow restricting components (for example, check valve, anti-siphon valve, filters, stopcocks, or manifolds) Example: 24200-0007 no check valve, standard bore **For flow rate < 100 mL/h:** 115 inch - 130 inch set with < 0.100 inch tubing inner diameter, ≥ 20 drops per mL drip chamber, ≥ 1 SmartSite™ Y-Site above and/or below pumping segment and no flow restricting components (for example, check valve, anti-siphon valve, filters, stopcocks, or manifolds) Example: 2411-0500 no check valve, small bore
Upstream Occlusion Downstream Occlusion Post-Occlusion Bolus Volume Air-in-line Alarm	115 inch - 130 inch set with ≥ 0.100 inch tubing inner diameter, ≤ 20 drops per mL drip chamber, ≥ 1 SmartSite™ Y-Site above and/or below pumping segment and no flow restricting components (for example, check valve, anti-siphon valve, filters, stopcocks, or manifolds) Example: 24200-0007 no check valve, standard bore

Pump Module Flow Rate Accuracy

Flow rate accuracy is ± 5% at flow rates ≥ 1 mL/h and from - 8% to + 5 % at flow rates < 1 mL/h under standard operating conditions, with 95% confidence and 95% reliability.

Verification studies demonstrate that flow rate accuracy under standard operating conditions are as shown in the table.

Flow Rate (mL/h)	Average Flow Rate Accuracy[1]
0.1	-1.81%
1	-1.63%
10	-1.33%
100	-1.42%
999	0.56%

1.Flow rate accuracy measured at steady-state

Pump Module Upstream Occlusion Time-to-Alarm

Upstream occlusion time-to-alarm is ≤ 5 minutes at flow rates of ≥ 5 mL/h, under standard operating conditions, with 95% confidence and 99% reliability.

Verification studies demonstrate that upstream occlusion time-to-alarm under standard operating conditions are as shown in the table.

Flow Rate (mL/h)	Time-to-Alarm Average	Time-to-Alarm Upper Bound[1]
5	1 min 22 sec	≤ 1 min 58 sec
125	5 sec	≤ 21 sec
999	2 sec	≤ 3 sec

1.Upper bound with 95% confidence and 99% reliability

NOTE:
Verification studies demonstrate that upstream occlusion time-to-alarm increases as flow rates decrease.

Characterization studies demonstrate that Pump Module upstream occlusion time-to-alarm increases at flow rates < 5 mL/h under standard operating conditions, and may result in time-to-alarm as follows:

- 1 mL/h: 2 min 50 sec (average) and 12 min 44 sec (upper bound[1])
- 0.1 mL/h: 31 min 9 sec (average) and 2 hr 21 min 44 sec (upper bound[1])

Pump Module Downstream Occlusion Pressure Limit Modes

Downstream occlusion settings are determined for each profile in your facility's data set. The default setting is pump mode, which sets the limit at 525 mmHg when infusing at rates ≥ 30 mL/h. If a selectable pressure limit is desired, selectable mode can be used. A pressure limit and a maximum pressure limit is determined by your facility for each profile.

Pressure Limit Mode	Flow Rate (mL/h)	Downstream Occlusion Pressure Limit
Pump	≤ 1	50 mmHg
	> 1 to < 30	Increases linearly from 50 to 525 mmHg
	≥ 30	525 mmHg
Selectable	Any	50 to 525 mmHg in increments of 25 mmHg

Pump Module Downstream Occlusion Time-to-Alarm

Downstream occlusion time-to-alarm is ≤ 5 minutes at flow rates of ≥ 1 mL/h, under standard operating conditions, with 95% confidence and 99% reliability.

Verification studies demonstrate that downstream occlusion time-to-alarm in pump mode under standard operating conditions are as shown in the table.

Pump Mode (Default)

Flow Rate (mL/h)	Time-to-Alarm Average	Time-to-Alarm Upper Bound[1]
1	1 min 51sec	≤ 2 min 47sec
25	41 sec	≤ 52 sec
125	29 sec	≤ 50 sec
999	28 sec	≤ 58 sec

1.Upper bound with 95% confidence and 99% reliability

NOTE:
Verification studies demonstrate that downstream occlusion time-to-alarm increases as flow rates decrease.

Characterization studies demonstrate an average time-to-alarm at a flow rate of 0.1 mL/h under standard operating conditions of 32 min 55 sec, with an upper bound of 58 min 35 sec.

Pump Module Downstream Occlusion Time-to-Alarm

If the factory default downstream occlusion pressure mode (pump mode) is changed to selectable mode, characterization studies demonstrate that downstream occlusion time-to-alarm may increase.

Selectable Mode

Selectable Mode Pressure Limit	Flow Rate (mL/h)	Time-to-Alarm Average	Time-to-Alarm Upper Bound[1]
50 mmHg Lowest selectable setting	0.1	32 min 55 sec	≤ 58 min 35 sec
	1	1 min 37 sec	≤ 3 min 13 sec
	10	23 sec	≤ 36 sec
525 mmHg Highest selectable setting	0.1	3 hr 17 min 24 sec	≤ 3 hr 54 min 40 sec
	1	13 min 13 sec	≤ 19 min 25 sec
	10	1 min 11 sec	≤ 1 min 31 sec

1.Upper bound with 95 % confidence and 99 % reliability

Pump Module Infusion Pressure Maximum

654 mmHg (Maximum occlusion alarm threshold 525 mmHg, plus tolerance 129 mmHg)

Pump Module Post-Occlusion Bolus Volume

When an occlusion occurs, pressurized fluid builds up that can be infused upon release of the occlusion. The Pump Module post-occlusion bolus volume is ≤ 0.3 mL throughout the flow rate range and under standard operating conditions, with 95% confidence and 99% reliability.

Verification studies demonstrate that post-occlusion bolus volume at standard operating conditions are as shown in the table.

Downstream Occlusion Pressure Limit (mmHg)	Post-Occlusion Bolus Volume Average[1] (mL)	Post-Occlusion Bolus Volume Upper Bound[1,2] (mL)
50	0.019	≤ 0.079
525	0.146	≤ 0.232

1.Bolus volume tested throughout the Pump Module flow rate range
2.Upper bound with 95% confidence and 99% reliability

Pump Module Bolus Volume Accuracy

Bolus volume accuracy is ± 5% for bolus volume of 5 mL at the maximum settable flow rate[1], under standard operating conditions, with 95% confidence and 97% reliability.

Verification studies demonstrate that bolus volume accuracy at standard operating conditions are as shown in the table.

Bolus Volume (mL)	Flow Rate[1,2] (mL/h)	Average Bolus Volume Accuracy[3]
5	300	-1.14%
5	999	0.46%

1. The Pump Module minimum programmable bolus duration is 1 minute, resulting in a maximum flow rate of 300 mL/h for a 5 mL bolus. The rapid bolus feature maximum rate is limited by the settings in the Guardrails™ data set. If the user selects the rapid bolus feature, the maximum flow rate could increase to 999 mL/h, depending on the settings in the Guardrails™ data set.
2. If configured with a Guardrails™ data set, the bolus dose and duration is limited by the Guardrails™ data set. Therefore, the Guardrails™ data set can limit the Pump Module maximum flow rate by bolus volume.
3. Bolus volume accuracy is measured at steady-state.

Pump Module Air-in-line Alarm - Single Bolus

Air detection algorithms aim to detect bubbles of approximately the setting size. Not all bubbles are exactly that size. Some bubbles smaller than the setting may trigger an alarm. Some slightly larger bubbles may not cause an alarm.

The tolerance range is shown in the table. The smallest bubble that can cause an alarm at each configurable setting is shown in the No Alarm if Smaller Than column while the bubble size when an alarm is certain is in the Will Alarm if Larger Than column. If the bubble size is between the two values, the Pump Module may or may not alarm.

Air-in-line Alarm Setting Single Bolus (mcL)	No Alarm if Smaller Than (mcL)	Will Alarm if Larger Than (mcL)
50[1]	50	80
75[1]	45	105
125	75	175
175	105	245
250	150	350
500[2]	400	600

1. Results for lipid solutions differ from the table at the lowest air-in-line settings (50 and 75 mcL). Lipids may contain trapped or dissolved air. During testing, alarms occurred when a very small bubble of an exact size was introduced into lipid solutions. Because of the accrual of the trapped air with the bubble, causing it to grow, the tolerance range for lipids is wider.
   - At the 50 mcL setting the tolerance range is 15 mcL to 85 mcL
   - At the 75 mcL setting the tolerance range is 30 mcL to 120 mcL
2. The 500 mcL setting is available for anesthesia mode only.

NOTE:

In a standard bore tubing set:
50 mcL is approximately 0.34 inches of air
75 mcL is approximately 0.51 inches of air
125 mcL is approximately 0.85 inches of air
175 mcL is approximately 1.19 inches of air
250 mcL is approximately 1.7 inches of air

Pump Module Air-in-Line Alarm

Accumulated Air-in-Line Alarm

The accumulated air-in-line alarm is designed to notify the user when many small bubbles pass the air sensor. Single bubbles that are too small to meet the single bolus air-in-line alarm threshold can pass the air sensor without causing a single bolus air-in-line alarm. The Pump Module monitors the amount of air that passes the air sensor. An accumulated air-in-line alarm occurs when the percentage of air in a specific volume that passes the sensor is greater than or equal to the values listed in the table.

Depending on the air-in-line setting, the Pump Module monitors the percentage of air in a specific window of volume that passes the air sensor. Lower air-in-line settings cause the Pump Module to evaluate the amount of air in smaller volumes.

Air-in-Line Alarm Single Bolus Setting (mcL)	Volume Infused Past the Sensor[1,2] (mL)	Percent of Air in the Volume Infused that Causes Alarm[1,2]	Air Volume that Causes Alarm[1,2] (mL)
50	1.2	15%	0.18
75 125 175	4.4	25%	1.10
250	5.2	35%	1.82
500[3]	7.8	35%	2.73

1. Assumes constant percentage of air infused for every 200 mcL of volume infused.
2. As the percentage of air in the volume infused increases above the percent values listed in the table, the accumulated air-in-line alarm occurs at lower volumes infused and air volumes than shown.
3. The 500 mcL setting is available in anesthesia mode only.

NOTE:
Lipids may contain trapped air bubbles, causing the Pump Module to alarm at lower air volume percentages than shown in the table.

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

Dimensions: 3" W x 8.8" H x 5.5" D

Environmental Conditions:

Symbols	Meaning	Operating	Storage/Transport
	Atmospheric Pressure	525–795 mmHg (70–106 kPa)	375–760 mmHg (50–101 kPa)
	Relative Humidity (Avoid prolonged exposure to relative humidity >90%)	20–90% Noncondensing	5–90% Noncondensing
	Temperature Range	41–104°F (5–40°C)	-4–140°F (-20–60°C)

Equipment Orientation: To ensure proper operation, the system must remain in an upright position.

Flow Rate Programming Increments:

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

Fluid Ingress Protection: IPX2, Drip Proof

Infusion of Air, Means to Protect Patient from: Ultrasonic Air-in-Line Detection
Maximum single bolus size = selectable 50, 75, 125, 175, or 250 microliters nominal (500 microliters in Anesthesia Mode)

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

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

Operating Principle: Positive displacement

Shock Protection: Type CF, defibrillation-proof patient applied part.

Volume to be Infused Programming Increments:

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

Weight: 2.6 lbs

NOTE:
The minimum VTBI for both Pump and Syringe Modules (applicable to all syringe sizes) is 0.1mL. This applies to continuous infusions, bolus dose, intermittent infusions, and IV fluids.

Alaris™ Syringe Module Specifications

Syringe Module specifications are provided in the following sections.

Standard Operating Conditions

Standard operating conditions is a term used to describe the conditions under which testing was performed for the BD Alaris™ System in the specifications section of this manual. They are listed below.

Performance test results vary when testing is performed in conditions other than standard operating conditions. For results from testing performed in non-standard operating conditions, refer to Appendix C – Non-Standard Performance.

- Temperature: 20 °C ± 2 °C
- Atmospheric Pressure: 645 mmHg to 795 mmHg
- Relative Humidity: 20% - 90% noncondensing
- Back Pressure: 0 mmHg ± 2 mmHg
- Solution Type: Distilled water
- Needle: 18 gauge, 40 mm, 1.5 inch length
- Infusion Set: Not expired, ≤ 3 years shelf life, ≤ 96 hours of usage

Syringe Module Performance Topic	Infusion Set Under Standard Operating Conditions
Rate Accuracy Bolus Accuracy Downstream Occlusion Post-Occlusion Bolus	**Infusion set with no pressure sensing disc** 60 inch - 75 inch set with < 0.100 inch tubing inner diameter, a slide clamp, no pressure sensing disc, and no flow restricting components (for example, check valve, anti-siphon valve, filters, stopcocks, or manifolds) Examples: • 30914 no pressure disc, micro bore (flow rate < 100 mL/h) • ME2010 no pressure disc, small bore (flow rate ≥ 100 mL/h)
Rate Accuracy Bolus Accuracy Downstream Occlusion Post-Occlusion Bolus	**Infusion set with pressure sensing disc** 60 inch - 75 inch set with < 0.100 inch tubing inner diameter, a slide clamp, pressure sensing disc, and no flow restricting components (for example, check valve, anti-siphon valve, filters, stopcocks, or manifolds) Examples: • 10014914 pressure disc, micro bore (flow rate < 100 mL/h) • 10014917 pressure disc, small bore (flow rate ≥ 100 mL/h)

Syringe Module Flow Rate Accuracy

The Syringe Module full scale plunger travel accuracy is ± 2%.
The Syringe Module system flow rate accuracy (module and syringe tested together as a system) is ± 5% at flow rates ≥ 10% of the syringe volume per hour[1], under standard operating conditions, with 95% confidence and 95% reliability.

Verification studies demonstrate that Syringe Module system flow rate accuracy performance under standard operating conditions are as shown in the tables.

Accuracy at 10% of the Syringe Volume per Hour[1]

Syringe	Flow Rate (mL/h)	Average Flow Rate Accuracy[2]
BD 1 mL	0.1	1.04%
BD 3 mL	0.3	0.13%
BD 5 mL	0.5	-1.24%
BD 10 mL	1.0	1.18%
BD 20 mL	2.0	0.01%
BD 30 mL	3.0	-0.23%
BD 50 mL	5.0	-0.48%
Monoject™ 3 mL	0.3	-1.89%
Monoject™ 6 mL	0.5	0.71%
Monoject™ 12 mL	1.0	-1.41%
Monoject™ 20 mL	2.0	-1.63%
Monoject™ 35 mL	3.0	-1.12%
Monoject™ 60 mL	5.0	-0.19%
Terumo™ 3 mL	0.3	-0.08%
Terumo™ 5 mL	0.5	-0.34%
Terumo™ 10 mL	1.0	-0.08%
Terumo™ 20 mL	2.0	-0.37%
Terumo™ 30 mL	3.0	-0.26%
Terumo™ 60 mL	5.0	-1.25%

1. Flow rate of 10% of the syringe volume per hour is based on BD syringe sizes. For Monoject™ and Terumo™ syringes, comparable syringe sizes were tested at the same flow rates.
2. Flow rate accuracy at steady-state.

Accuracy at 10 mL/h Flow Rate

Syringe	Flow Rate (mL/h)	Average Flow Rate Accuracy[1]
BD 1 mL	10	0.25%
BD 3 mL		0.36%
BD 5 mL		-0.56%
BD 10 mL		1.11%
BD 20 mL		0.55%
BD 30 mL		0.17%
BD 50 mL		-0.10%
Monoject™ 3 mL	10	0.59%
Monoject™ 6 mL		0.13%
Monoject™ 12 mL		0.41%
Monoject™ 20 mL		-0.27%
Monoject™ 35 mL		-0.02%
Monoject™ 60 mL		0.03%
Terumo™ 3 mL	10	0.33%
Terumo™ 5 mL		-0.28%
Terumo™ 10 mL		-0.14%
Terumo™ 20 mL		-0.27%
Terumo™ 30 mL		0.05%
Terumo™ 60 mL		-0.46%

1.Flow rate accuracy at steady-state.

Accuracy at Maximum Flow Rates

Syringe	Flow Rate (mL/h)	Average Flow Rate Accuracy[1]
BD 1 mL	30	-0.61%
BD 3 mL	100	0.29%
BD 5 mL	150	-0.32%
BD 10 mL	250	1.49%
BD 20 mL	500	0.82%
BD 30 mL	650	0.43%
BD 50 mL	999	0.32%
Monoject™ 3 mL	100	0.80%
Monoject™ 6 mL	150	0.85%
Monoject™ 12 mL	250	0.21%
Monoject™ 20 mL	500	0.13%
Monoject™ 35 mL	650	0.22%
Monoject™ 60 mL	999	-0.01%
Terumo™ 3 mL	100	1.50%
Terumo™ 5 mL	150	0.66%
Terumo™ 10 mL	250	0.79%
Terumo™ 20 mL	500	0.67%
Terumo™ 30 mL	650	0.45%
Terumo™ 60 mL	999	0.36%

1.Flow rate accuracy at steady-state.

Characterization studies demonstrate that Syringe Module flow rate accuracy at lower rates under standard operating conditions as shown in the tables.

Syringe	Flow Rate (mL/h)	Average Flow Rate Accuracy[1]
BD 3 mL	0.01	-5.05%
BD 3 mL	1	-0.10%
BD 20 mL	0.1	-3.15%
BD 20 mL	1	-0.39%
BD 50 mL	0.1	-4.04%
BD 50 mL	1	-1.47%

1.Flow rate accuracy at steady-state.

Syringe Module Occlusion Alarm Settings

Infusion set with no pressure sensing disc
- Settings include low, medium, high

Infusion set with pressure sensing disc
- Settings ranging from 25 mmHg to 1000 mmHg in 1 mmHg increments

Syringe Module Occlusion Time-to-Alarm

Syringe Module occlusion time-to-alarm is ≤ 5 minutes at the flow rates listed per syringe size in the tables below, under standard operating conditions, and with 95% confidence and 99% reliability.

Infusion Set with No Pressure Sensing Disc

Verification studies demonstrate occlusion time-to-alarm performance.

Low Occlusion Pressure Setting (Infusion Set with No Pressure Sensing Disc)

Syringe	Flow Rate (mL/h)	Time-to-Alarm Average	Time-to-Alarm Upper Bound[1]
BD 1 mL	2	38 sec	≤ 1 min 41 sec
BD 3 mL		1 min 3 sec	≤ 2 min 38 sec
BD 5 mL		1 min 46 sec	≤ 2 min 41 sec
BD 10 mL	3	1 min 7 sec	≤ 2 min 34 sec
BD 20 mL	5	1 min 33 sec	≤ 2 min 53 sec
BD 30 mL	10	1 min 5 sec	≤ 1 min 56 sec
BD 50 mL	11	2 min 20 sec	≤ 3 min 13 sec
Monoject™ 3 mL	2	53 sec	≤ 1 min 43 sec
Monoject™ 6 mL		1 min 20 sec	≤ 2 min 38 sec
Monoject™ 12 mL	3	1 min 45 sec	≤ 3 min 13 sec
Monoject™ 20 mL	5	1 min 21 sec	≤ 3 min 31 sec
Monoject™ 35 mL	10	1 min 39 sec	≤ 3 min 21 sec
Monoject™ 60 mL	11	1 min 46 sec	≤ 3 min 11 sec
Terumo™ 3 mL	2	48 sec	≤ 1 min 42 sec
Terumo™ 5 mL		1 min 57 sec	≤ 2 min 58 sec
Terumo™ 10 mL	3	1 min 49 sec	≤ 3 min 8 sec
Terumo™ 20 mL	5	2 min 21 sec	≤ 3 min 44 sec
Terumo™ 30 mL	10	1 min 3 sec	≤ 1 min 44 sec
Terumo™ 60 mL	11	1 min 29 sec	≤ 3 min 8 sec

1.Upper bound with 95% confidence and 99% reliability

High Occlusion Pressure Setting (Infusion Set with No Pressure Sensing Disc)

Syringe	Flow Rate (mL/h)	Time-to-Alarm Average	Time-to-Alarm Upper Bound[1]
BD 1 mL	3	38 sec	≤ 2 min 1 sec
BD 3 mL		59 sec	≤ 1 min 39 sec
BD 5 mL	5	1 min 42 sec	≤ 3 min 14 sec
BD 10 mL	6	1 min 47 sec	≤ 2 min 49 sec
BD 20 mL	13	1 min 46 sec	≤ 2 min 19 sec
BD 30 mL	20	1 min 16 sec	≤ 3 min 8 sec
BD 50 mL	30	2 min 7sec	≤ 2 min 42 sec
Monoject™ 3 mL	3	1 min 6 sec	≤ 1 min 53 sec
Monoject™ 6 mL	5	1 min 37 sec	≤ 3 min 11 sec
Monoject™ 12 mL	6	2 min 5 sec	≤ 3 min 34 sec
Monoject™ 20 mL	13	2 min 4 sec	≤ 2 min 52 sec
Monoject™ 35 mL	20	2 min 25 sec	≤ 3 min 2 sec
Monoject™ 60 mL	30	2 min 5 sec	≤ 3 min 6 sec
Terumo™ 3 mL	3	1 min 1 sec	≤ 1 min 28 sec
Terumo™ 5 mL	5	2 min 19 sec	≤ 3 min 1 sec
Terumo™ 10 mL	6	2 min 54 sec	≤ 4 min 16 sec
Terumo™ 20 mL	13	2 min 55 sec	≤ 4 min 10 sec
Terumo™ 30 mL	20	1 min 33 sec	≤ 2 min 11 sec
Terumo™ 60 mL	30	2 min 55 sec	≤ 3 min 39 sec

1.Upper bound with 95% confidence and 99% reliability

NOTE:
The time to generate an occlusion alarm increases as occlusion pressure settings increase.

As shown in the table above, verification studies demonstrate as syringe size increases, the Syringe Module occlusion time-to-alarm increases. A higher flow rate results in time-to-alarm of ≤ 5 minutes.
Characterization studies demonstrate Syringe Module occlusion time-to-alarm increases at flow rates < 2 mL/h under standard operating conditions, and may result in time-to-alarm as follows:

BD 3 mL syringe[2] at 0.01 mL/hr (infusion set with no pressure sensing disc)

- Low occlusion pressure setting
  3 hours 34 min (average)
  ≤ 5 hours 34 min (upper bound[1])

- Medium occlusion pressure setting
  5 hours 40 min (average)
  ≤ 10 hours 57 min (upper bound[1])

- High occlusion pressure setting
  15 hours 30 min (average)
  ≤ 28 hours 57 min (upper bound[1])

BD 50 mL syringe[2] at 0.1 mL/hr (infusion set with no pressure sensing disc)

- Low occlusion pressure setting
  4 hours 28 min (average)
  ≤ 7 hours 5 min (upper bound[1])

- Medium occlusion pressure setting
  8 hours 39 min (average)
  ≤ 11 hours 43 min (upper bound[1])

- High occlusion pressure setting
  16 hours 37 min (average)
  ≤ 21 hours 8 min (upper bound[1])

1. Upper bound with 95% confidence and 95% reliability
2. Testing was completed with BD syringes. Other syringe manufacturers may have different time-to-alarms.

Syringe Module Occlusion Time-to-Alarm

Syringe Module occlusion time-to-alarm is ≤ 5 minutes at the flow rates listed per syringe size, under standard operating conditions, and with 95% confidence and 99% reliability.

Verification studies demonstrate occlusion time-to-alarm performance as shown in the tables.

Infusion Set with Pressure Sensing Disc

Low 25 mmHg Occlusion Setting (Infusion Set with Pressure Sensing Disc)

Syringe	Flow Rate (mL/h)	Time-to-Alarm Average	Time-to-Alarm Upper Bound[1]
BD 1 mL	1	26 sec	≤ 1 min 13 sec
BD 3 mL		16 sec	≤ 1 min 14 sec
BD 5 mL		22 sec	≤ 1 min 24 sec
BD 10 mL		15 sec	≤ 42 sec
BD 20 mL		27 sec	≤ 1 min 14 sec
BD 30 mL	2	18 sec	≤ 54 sec
BD 50 mL	3	24 sec	≤ 1 min 31 sec
Monoject™ 3 mL	1	14 sec	≤ 48 sec
Monoject™ 6 mL		14 sec	≤ 37 sec
Monoject™ 12 mL		24 sec	≤ 1 min 25 sec
Monoject™ 20 mL		1 min 4 sec	≤ 3 min 45 sec
Monoject™ 35 mL	2	28 sec	≤ 1 min 25 sec
Monoject™ 60 mL	3	20 sec	≤ 1 min 6 sec
Terumo™ 3 mL	1	20 sec	≤ 1 min 33 sec
Terumo™ 5 mL		17 sec	≤ 52 sec
Terumo™ 10 mL		22 sec	≤ 1 min 13 sec
Terumo™ 20 mL		35 sec	≤ 1 min 53 sec
Terumo™ 30 mL	2	20 sec	≤ 55 sec
Terumo™ 60 mL	3	28 sec	≤ 1 min 42 sec

1.Upper bound with 95% confidence and 99% reliability

High 1000 mmHg Occlusion Setting (Infusion Set with Pressure Sensing Disc)

Syringe	Flow Rate (mL/h)	Time-to-Alarm Average	Time-to-Alarm Upper Bound[1]
BD 1 mL	4	1 min 25 sec	≤ 3 min 34 sec
BD 3 mL		1 min 14 sec	≤ 2 min 3 sec
BD 5 mL	5	1 min 42 sec	≤ 2 min 33 sec
BD 10 mL	6	2 min 5 sec	≤ 2 min 55 sec
BD 20 mL	13	1 min 47 sec	≤ 2 min 10 sec
BD 30 mL	20	1 min 34 sec	≤ 2 min
BD 50 mL	30	2 min 17 sec	≤ 2 min 58 sec
Monoject™ 3 mL	4	1 min 34 sec	≤ 2 min 38 sec
Monoject™ 6 mL	5	2 min 1 sec	≤ 2 min 53 sec
Monoject™ 12 mL	6	2 min 31 sec	≤ 3 min 32 sec
Monoject™ 20 mL	13	2 min 42 sec	≤ 4 min 24 sec
Monoject™ 35 mL	20	2 min 41 sec	≤ 3 min 9 sec
Monoject™ 60 mL	30	2 min 25 sec	≤ 2 min 44 sec
Terumo™ 3 mL	4	1 min 28 sec	≤ 2 min 30 sec
Terumo™ 5 mL	5	2 min 50 sec	≤ 3 min 46 sec
Terumo™ 10 mL	6	3 min	≤ 3 min 32 sec
Terumo™ 20 mL	13	3 min 5 sec	≤ 3 min 49 sec
Terumo™ 30 mL	20	2 min 11 sec	≤ 2 min 33 sec
Terumo™ 60 mL	30	3 min 13 sec	≤ 3 min 45 sec

1.Upper bound with 95% confidence and 99% reliability

NOTE:
The time to generate an occlusion alarm increases as occlusion pressure settings increase.

Syringe Module Maximum Occlusion Pressure

1060 mmHg (maximum occlusion pressure setting of 1000 mmHg plus 60 mmHg upper tolerance, when using the infusion set with pressure sensing disc)

Syringe Module Post-Occlusion Bolus Volume

Syringe Module post-occlusion bolus volume is ≤ 1 mL for syringe sizes ≤ 35 mL, under standard operating conditions, with 95% confidence and 99% reliability.

Infusion set with No Pressure Sensing Disc

Verification studies demonstrate post-occlusion bolus volume performance, under standard operating conditions. For a given occlusion pressure setting, as the syringe size increases the syringe compliance increases, resulting in a larger post-occlusion bolus volume. Syringes of the largest compatible size that produced a post-occlusion bolus volume ≤ 1 mL were tested at high and low occlusion pressure settings.

Low Occlusion Pressure Setting (Infusion Set with No Pressure Sensing Disc)

Syringe Size	Post-Occlusion Bolus Volume Average (mL)	Post-Occlusion Bolus Volume Upper Bound[1,2] (mL)
BD ≤ 50 mL	0.32	≤ 0.888
Monoject™ ≤ 60 mL	0.28	≤ 0.443
Terumo™ ≤ 60 mL	0.232	≤ 0.656

1.Uppper bound with 95% confidence and 99% reliability
2.Bolus volume throughout the Syringe Module flow rate range

High Occlusion Pressure Setting (Infusion Set with No Pressure Sensing Disc)

Syringe Size	Post-Occlusion Bolus Volume Average (mL)	Post-Occlusion Bolus Volume Upper Bound[1,2] (mL)
BD ≤ 30 mL	0.436	≤ 0.551
Monoject™ ≤ 35 mL	0.710	≤ 0.813
Terumo™ ≤ 30 mL	0.577	≤ 0.704

1.Uppper bound with 95% confidence and 99% reliability
2.Bolus volume throughout the Syringe Module flow rate range

NOTE:
Due to a large syringe compliance, the 50 and 60 mL syringe sizes at the high occlusion pressure settings may produce a post-occlusion bolus > 1 mL.

Syringe Module Post-Occlusion Bolus Volume

Syringe Module post-occlusion bolus volume is ≤ 1 mL for syringe sizes ≤ 35 mL, without the back off feature enabled, under standard operating conditions, with 95% confidence and 99% reliability.

Infusion Set with Pressure Sensing Disc

Verification studies demonstrate post-occlusion bolus volume performance, without the back off feature enabled, under standard operating conditions. For a given occlusion pressure setting, as the syringe size increases the syringe compliance increases, resulting in a larger post-occlusion bolus volume. Syringes of the largest compatible size that produced a post-occlusion bolus volume ≤ 1 mL were tested at high and low occlusion pressure settings.

Low 25 mmHg Occlusion Setting (Infusion Set with Pressure Sensing Disc) Back Off Feature Not Enabled

Syringe Size	Post-Occlusion Bolus Volume Average (mL)	Post-Occlusion Bolus Volume Upper Bound[1,2] (mL)
BD ≤ 50 mL	0.017	≤ 0.041
Monoject™ ≤ 60 mL	0.012	≤ 0.048
Terumo™ ≤ 60 mL	0.029	≤ 0.061

1.Uppper bound with 95% confidence and 99% reliability
2.Bolus volume throughout the Syringe Module flow rate range

High 1000 mmHg Occlusion Setting (Infusion Set with Pressure Sensing Disc) Back Off Feature Not Enabled

Syringe Size	Post-Occlusion Bolus Volume Average (mL)	Post-Occlusion Bolus Volume Upper Bound[1,2] (mL)
BD ≤ 30 mL	0.485	≤ 0.637
Monoject™ ≤ 35 mL	0.770	≤ 0.986
Terumo™ ≤ 30 mL	0.686	≤ 0.869

1.Uppper bound with 95% confidence and 99% reliability
2.Bolus volume throughout the Syringe Module flow rate range

NOTE:
Due to a large syringe compliance, the 50 and 60 mL syringe sizes at the high occlusion pressure settings may produce a post-occlusion bolus > 1 mL

Syringe Module Post-Occlusion Bolus Volume

Syringe Module post-occlusion bolus volume is ≤ 1 mL for all compatible syringes, with the back off feature enabled, under standard operating conditions, with 95% confidence and 99% reliability.

Infusion Set with Pressure Sensing Disc

Verification studies demonstrate post-occlusion bolus volume performance, with the back off feature enabled, under standard operating conditions. For a given occlusion pressure setting, as the syringe size increases the syringe compliance increases, resulting in a larger post-occlusion bolus volume. Syringes of the largest compatible size that produced a post-occlusion bolus volume ≤ 1 mL were tested at high and low occlusion pressure settings.

High 1000 mmHg Occlusion Setting (Infusion Set with Pressure Sensing Disc) Back Off Feature Enabled

Syringe Size	Post-Occlusion Bolus Volume Average (mL)	Post-Occlusion Bolus Volume Upper Bound[1,2] (mL)
BD ≤ 50 mL	0.194	≤ 0.355
Monoject™ ≤ 60 mL	0.151	≤ 0.254
Terumo™ ≤ 60 mL	0.377	≤ 0.692

1.Uppper bound with 95% confidence and 99% reliability
2.Bolus volume throughout the Syringe Module flow rate range

Syringe Module Bolus Volume Accuracy

Syringe Module system bolus volume accuracy (module and syringe tested together as a system) is ± 5% at greater than or equal to the bolus volumes and bolus flow rates listed below per syringe size under standard operating conditions, with 95% confidence and 97% reliability.

- Bolus Volumes: At least 10% of syringe volume or 1 mL (whichever is less)
- Bolus Flow Rates: At least 10% of syringe volume or 1 mL (whichever is less) divided by the maximum programmable bolus duration (99 minutes) or 0.1 mL/h (whichever is more)

Verification studies demonstrate that Syringe Module system bolus volume accuracy performance under standard operating conditions as shown in tables.

Syringe Size	Bolus Volume (mL)	Flow Rates (mL/h)	Average Bolus Volume Accuracy[1]
BD 1 mL	≥ 0.10	≥ 0.10	0.78%
BD 3 mL	≥ 0.30	≥ 0.18	0.24%
BD 5 mL	≥ 0.50	≥ 0.30	-0.08%
BD 10 mL	≥ 1	≥ 0.61	0.74%
BD 20 mL			0.45%
BD 30 mL			0.58%
BD 50 mL			0.18%
Monoject™ 3 mL	≥ 0.30	≥ 0.18	0.84%
Monoject™ 6 mL	≥ 0.60	≥ 0.36	-0.70%
Monoject™ 12 mL	≥ 1	≥ 0.61	0.68%
Monoject™ 20 mL			0.21%
Monoject™ 35 mL			0.23%
Monoject™ 60 mL			-0.05%
Terumo™ 3 mL	≥ 0.30	≥ 0.18	1.46%
Terumo™ 5 mL	≥ 0.50	≥ 0.30	0.81%
Terumo™ 10 mL	≥ 1	≥ 0.61	0.76%
Terumo™ 20 mL			0.41%
Terumo™ 30 mL			0.45%
Terumo™ 60 mL			-0.21%

1.Bolus volume accuracy at steady-state

Characterization studies demonstrate that Syringe Module system bolus accuracy at flow rates below the bolus volumes listed above per syringe size, and at maximum bolus flow rates, under standard operating conditions as shown in the table.

Syringe	Bolus Volume (mL)	Flow Rate (mL/h)	Average Bolus Volume Accuracy[1]
BD 3 mL	0.1	100	-1.48%
BD 20 mL		500	8.75%
BD 50 mL		999	-1.58%

1.Bolus volume accuracy at steady-state.

NOTE:
The characterization testing above is based on a sample size of 5 Pump Modules and 5 Syringe Modules with 24 boluses administered after the loading dose bolus per pump or until syringe is empty.

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: 4.75" W x 15.0" H x 7.5" D

Environmental Conditions:

Symbols	Meaning	Operating	Storage/Transport
	Atmospheric Pressure	525 - 795 mmHg (70 - 106 kPa)	375 - 760 mmHg (50 - 101 kPa)
	Relative Humidity (Avoid prolonged exposure to relative humidity >90%)	20 - 90% Noncondensing	5 - 90% Noncondensing
	Temperature Range	41 - 104°F (5 - 40°C)	-4 - 140°F (-20 - 60°C)

Equipment Orientation: To ensure proper operation, the 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:

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

Rate restriction by syringe size:

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

Fluid Ingress Protection: IPX2, Drip Proof

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

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

Operating Principle: Positive displacement

Shock Protection: Type CF, Defibrillator-Proof

Volume to be Infused Programming Increments:

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

NOTE:
The minimum VTBI for both Pump and Syringe Modules (applicable to all syringe sizes) is 0.1 mL. This applies to continuous infusions, bolus dose, intermittent infusions, and IV fluids.

Weight: 4.5 lbs

Chapter 3
Alaris™ PCA Module Model 8120

This chapter contains the following topics:

Summary of Warnings and Cautions

General

WARNING

- **Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System (see *About this Chapter* on page *238*).**
- **The BD Alaris™ System is not intended to replace supervision by medical personnel.**
- **Discard infusion set if packaging is not intact or protector caps are unattached.**
- **Before loading the syringe, check for damage or defects (see *Loading Syringe and Infusion Set* on page *246*).**
- **When loading a small size syringe, use extra care to avoid loss of medication and ensure correct loading:**
  - **Clamp tubing before loading.**
  - **Stabilize the syringe plunger while gently lowering the drive head.**
  - **Ensure that the plunger head makes contact with the small black sensor, located on the bottom of the drive head (between the plunger grippers).**
- **Only the patient should press the dose request button (see *Instructions for Patient Use of PCA Dose Request Button* on page *273*).**
- **Carefully locate the dose request cord to reduce the possibility of patient entanglement or strangulation (see *Attaching and Detaching Dose Request Cord* on page *244*).**

CAUTION

- Rx Only: Prescription use only.

Alaris™ PCA Module Programming

WARNING

- **If an error is made when entering DRUG AMOUNT or DILUENT VOLUME, it may result in an over- or under-infusion. If a lower concentration is entered in error, this may result in a higher than intended delivery (over-infusion).**

Alaris™ PCA Module Free-Flow Prevention

WARNING

- **Ensure that the syringe barrel, flange, and plunger are installed and secured correctly. Failure to install the syringe correctly can result in uncontrolled fluid flow to the patient.**
- **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 infusion set is not clamped or turned off (see *Loading Syringe and Infusion Set* on page *246*).**

Alaris™ PCA Module Rate Accuracy

WARNING

- **Rate accuracy can be affected by:**
  - **Temperature and viscosity of the IV solution**
  - **Height of the pump in relation to the patient**
  - **Back pressure related to the IV set and the IV catheter**
- **Avoid raising or lowering the pump during an infusion. Raising or lowering the pump during an infusion can result in a bolus of medication or fluid or a delay in the infusion or under infusion due to changes in hydrostatic pressure.**
- **Use only standard luer-lock syringes and infusion sets with integrated anti-siphon valves, designed for use on syringe-type PCA pumps. Ensure syringe sizes and models are compatible with the PCA Module. Use of incompatible syringes can impact pump operation resulting in inaccurate fluid delivery, delayed generation of occlusion alarms, and other potential problems (see *Preparing for an Infusion (Alaris™ PCA Module)* on page *245* and *Alaris™ PCA Module Compatible Syringes* on page *286*).**
- **Ensure that the displayed syringe manufacturer and syringe size match the installed syringe. Mismatches can impact flow rate accuracy (see *Selecting Syringe Type and Size* on page *250*).**
- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe can impact pump performance including delivery accuracy and startup time, and generation of occlusion alarms and bolus volume after occlusion. This is due to the increased friction and compliance of the syringe stopper with larger syringes. It is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h).**
- **Use the Prime Set with Syringe feature in the Channel Options menu, when starting an infusion or changing the syringe and tubing. Failure to do so can delay the infusion delivery startup time and lead to delivery inaccuracies.**

CAUTION

- Ensure that the device is as close to level with patient's heart as possible. Patient's heart level should be in line with the CHANNEL SELECT key.
- Minimize the height difference between the device and the patient and avoid changes in the height of the BD Alaris™ System to prevent unintended fluctuations in the flow rate.
- Use compatible sets with a small priming volume to minimize the time it takes for medication to reach the patient. This is particularly important when infusing at low rates (for example, < 5 mL/h) or very low flow rates (< 0.5 mL/h). It also helps to maintain delivery accuracy and reduces the time to alarm for an occlusion.

Alaris™ PCA Module Occlusion Detection

WARNING

- **When programming an infusion with the BD Alaris™ System using 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.**
- **Before each use, verify that all alarm limits, such as occlusion pressure limits, are appropriate for the patient to ensure that alarms occur as intended.**
- **Consider factors that can influence back pressure when setting occlusion pressure limits: infusion set configuration, IV solution viscosity, and IV solution temperature. Back pressure can also be affected by type of catheter.**
- **The BD Alaris™ System is capable of infusing during various conditions encountered in clinical practice, for instance through small gauge catheters, filters and other components. The system is designed to alarm and stop based on pressure limit settings, but you must monitor the infusion to ensure that it is proceeding as expected.**
- **Time-to-alarm for occlusion can be affected by:**
  - **Occlusion pressure setting**
  - **Flow rate**
  - **Location of the occlusion**
  - **Infusion set and components**
  - **Fluid viscosity**
- **Use lowest occlusion pressure settings when infusing at low or very low flow rates. High occlusion pressure settings result in longer time to alarm when an occlusion occurs.**
- **Follow proper infusion set loading instructions and ensure the set is free of kinks before starting an infusion. Improperly loaded sets can impact pump operation resulting in inaccurate fluid delivery.**

WARNING

- **Use only standard luer-lock syringes and infusion sets with integrated anti-siphon valves, designed for use on syringe-type PCA pumps. Ensure syringe sizes and models are compatible with the PCA Module. Use of incompatible syringes can impact pump operation resulting in inaccurate fluid delivery, delayed generation of occlusion alarms, and other potential problems (see *Preparing for an Infusion (Alaris™ PCA Module)* on page *245*).**
- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe can impact pump performance including delivery accuracy and startup time, and generation of occlusion alarms and bolus volume after occlusion. This is due to the increased friction and compliance of the syringe stopper with larger syringes. It is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h).**
- **To minimize the amount of time for the pump to generate an occlusion alarm while infusing at low rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h), do the following:**
  - **Consider the occlusion pressure limit setting and adjust it, as necessary. The lower the setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (for example, lipids), the occlusion pressure limit setting may need to be increased to reduce false alarms.**
  - **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, and so on).**
- **When loading a small size syringe, use extra care to avoid loss of medication and ensure correct loading:**
  - **Clamp tubing before loading.**
  - **Stabilize the syringe plunger while gently lowering the drive head.**
  - **Ensure that the plunger head makes contact with the small black sensor, located on the bottom of the drive head (between the plunger grippers).**
- **The BD Alaris™ System is neither designed nor intended to detect infiltrations and does not alarm under infiltration conditions.**

Alaris™ PCA Module Post-Occlusion Bolus

WARNING

- **An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus when the occlusion is cleared. The volume of this post-occlusion bolus can be affected by:**
  - **Height of the pump in relation to the patient**
  - **Increase in infusion set distal length**
  - **Increase in infusate temperature**
- **To prevent a bolus after release of an occlusion, 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.**
- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe can impact pump performance including delivery accuracy and startup time, and generation of occlusion alarms and bolus volume after occlusion. This is due to the increased friction and compliance of the syringe stopper with larger syringes. It is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h) and very low flow rates (< 0.5 mL/h).**

Alaris™ PCA Module Priming

WARNING

- **Ensure that patient is not connected when priming.**
- **Ensure that air is expelled from line prior to beginning infusion when priming (unexpelled air-in-line could have serious consequences) (see *Using Priming Option* on page *251*).**

Epidural Administration

WARNING

Follow Epidural Precautions:

- **Administer only anesthetics/analgesics that are approved and labeled for epidural administration (as indicated by the drug's package insert).**
- **Epidural administration of drugs other that those indicated can result in serious patient injury.**
- **Use only catheters, inserted by a qualified clinician, that are specifically labeled for epidural drug delivery,**
- **Use infusion sets without injection sites (also known as Y-sites or ports).**
- **Label the container and the infusion set to indicate that they are For Epidural Use Only.**
- **Clearly identify infusion pumps used for epidural infusions.**
- **Patients receiving epidural infusions should be closely monitored by clinicians who are trained and qualified to manage such infusions.**

About this Chapter

WARNING

Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System.

CAUTION

Rx Only: Prescription use only.

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

- Drug product labeling
- *Alaris™ Syringe Module, Model 8110 Series, Alaris™ PCA Module, Model 8120 Series Technical Service Manual*
- *PCU chapter of this manual (see About this Chapter* on page *8)*
- System maintenance software (and its instructions) for system check-in, maintenance, and configurations for connecting the PCUs to the wireless network

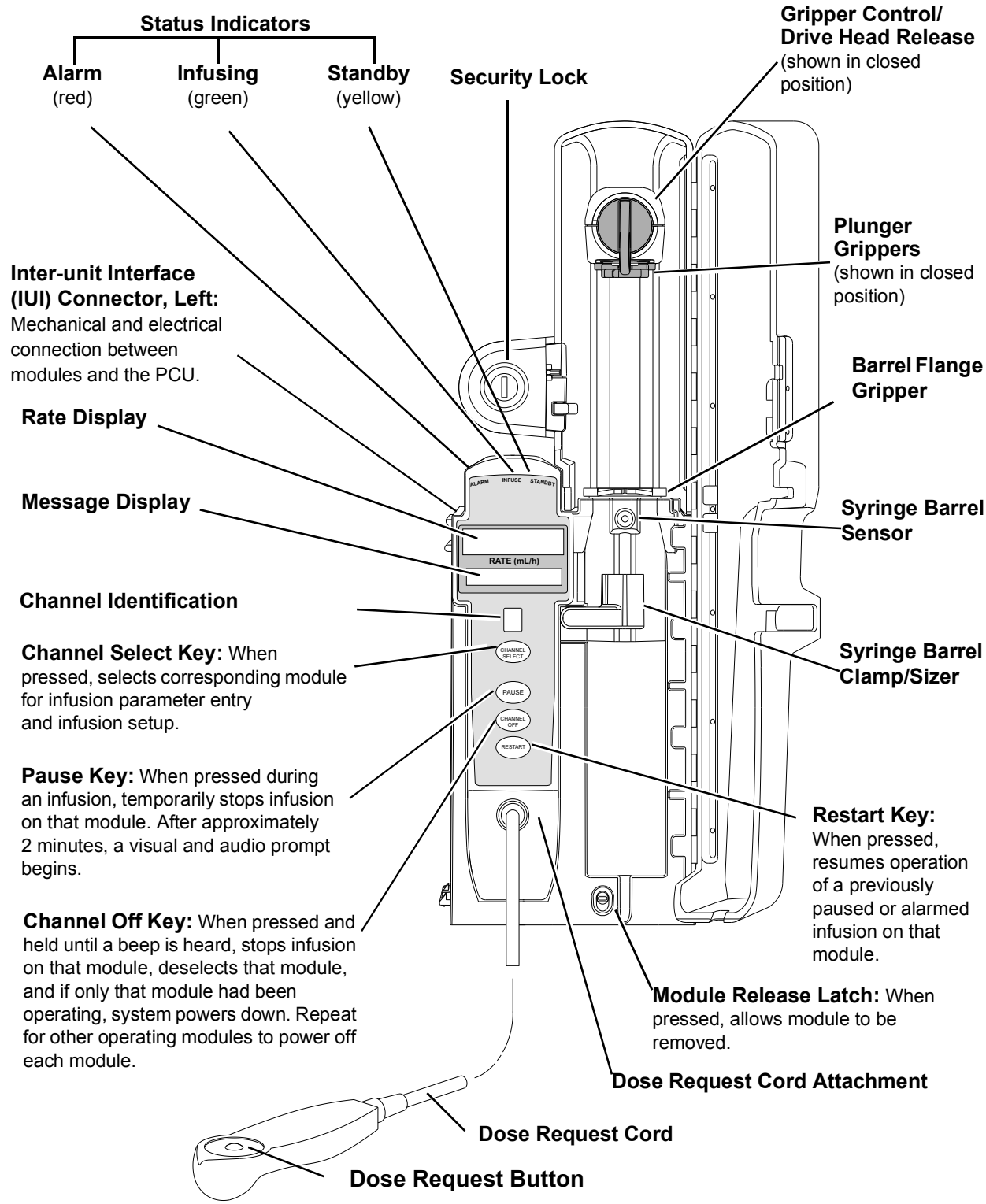
The PCA Module (patient controlled analgesia) is intended for facilities that use syringe pumps for the delivery of medications or fluids. The PCA Module is indicated for use on adults, pediatrics, and neonates for continuous or intermittent delivery through clinically acceptable routes of administration; such as, intravenous (IV), subcutaneous, or epidural. Although multiple PCA Modules may electrically connect, only one PCA Module will have PCA Module functionality.

Alaris™ PCA Module

The PCA Module is used to deliver primary continuous infusions, PCA dose-only infusions, primary continuous + PCA dose infusions, loading doses, or bolus doses. A dose request cord is provided that allows the patient to request PCA doses as needed, and provides clinicians with the ability to set a lockout interval during which no dose will be delivered. It also provides a tamper evident enclosure to secure the syringe.

Alaris™ PCA Module

Operating Features, Control, and Indicators



Features and Definitions

Feature	Definition
Auto Pressure Limit Adjustment	When a bolus is delivered, pressure alarm limits are temporarily raised to maximum limit.
Auto Syringe Identification	System automatically detects syringe size and narrows down syringe selection list.
Bolus Delivery Rate	Rate at which PCA, bolus, and loading doses (boluses) are infused.
Bolus Dose	Allows an additional amount of medication to be programmed once PCA infusion has begun. Current PCA infusion resumes following delivery of a bolus dose.
Concentration	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: Drug Amount1 mg Diluent Volume1 mL OR Drug Amount30 mg Diluent Volume30 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 audio tone and 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 30 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. • A soft limit is a programmed limit that can be overridden.
Loading Dose	Allows a bolus infusion to be programmed prior to initiation of PCA infusion. Can be programmed from Infusion Modes menu or applicable PCA, PCA + continuous, or continuous only programming screen prior to start of a new PCA infusion program.
Lockout Interval	A configurable interval of time that must pass between PCA patient doses. The lockout interval begins when the patient dose infusion starts. The lockout interval range is 1-99 minutes.

Feature	Definition
Max Dose Limit (Max Accumulated Dose Range)	Optional configuration that limits total amount of drug allowed to be delivered to patient in a defined period (1, 2, or 4 hours). • Should be configured in data set **before** drug library is developed. Once drugs are in profile PCA drug library, max accumulated dose limit cannot be changed. • Applies to **all** drug setups within profile PCA drug library. • Includes PCA dose, continuous dose, and optional bolus dose if selected to be included. Loading dose is not included.
Module Location Enforcement	Tamper resistant security feature that ensures PCA Module is in a tamper evident position. When enabled, PCA Module must be located to direct right of PCU to allow programming an infusion.
Near End of Infusion (NEOI)	The NEOI option allows an audio alarm to be configured based on a percentage of the syringe size. The alert time can be set to occur when 5-25% of the syringe size is remaining.
NEOI Snooze	Optional capability to remind users NEOI has been silenced. This is a shared Syringe and PCA Module setting.
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
	• Default view is 8-hr
	• Total amount of drug delivered using:
	  • PCA dose
	  • Continuous infusion
	  • Loading dose
	  • Bolus dose

PCA Dose	Enables a patient to self-administer a bolus infusion to be delivered at programmed lockout intervals through dose request cord. When programmed in PCA only mode and PCA + continuous mode, continuous infusion resumes following PCA dose.
PCA Pause Protocol	An optional and hospital-configurable feature intended to align with hospital/health system's current protocol for patient monitoring during PCA therapy. When enabled, PCA infusion pauses and alarms when defined monitoring value (respiratory rate low) for $EtCO_2$ Module are exceeded and sustained.
Pressure Limit	Downstream occlusion alarm threshold can be set to low, medium, or high. syringe variability might impact occlusion pressure sensing. Variability can reduce device's time to alarm and/or can require that a higher alarm pressure limit be programmed.
Priming	Allows a limited volume of fluid to be delivered in order to prime infusion 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.

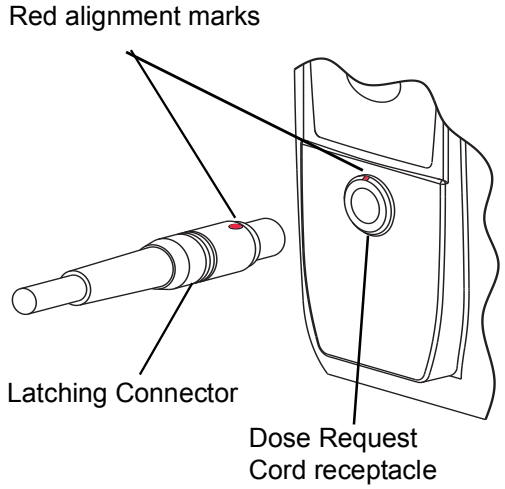
Feature	Definition
Restore	To simplify programming, can be used to recall previous PCA programmed parameters for same patient. The restore option is available for infusions on the same module and PCU if the system is powered up within 8 hours of last use and the user answers No to the New Patient prompt.
Security Access Level	Profile-specific security access level can be configured to provide varying levels of access to device. Security access is accomplished either through use of key or a 4-digit authorization code. For security level information, see *Security Access Levels* on page *274*.
Security Code	Four-character code assigned to allow access to PCU for setting bolus doses and subsequent programming changes. Ability to use profile- specific code is dependent upon configured security access level.
Syringe Empty	Instrument gives an alert and stops when an empty syringe is detected.
Syringe Volume Detection	System automatically detects fluid volume in a syringe when it is inserted.
Therapies	An optional hospital-defined therapy or clinical indication for delivery of that infusion. Different limits can be defined for same medication with different therapeutic indications.
Time Window (h)	1, 2, or 4 hours.

Attaching and Detaching Dose Request Cord

The dose request cord must be attached to the PCA Module when delivering a PCA dose or PCA + continuous dose infusion.

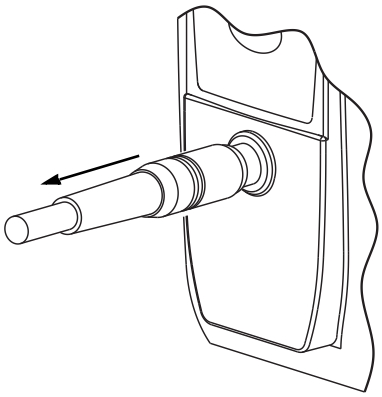
Attaching Dose Request Cord

Insert latching connector into dose request cord attachment. Red marking on latching connector should be aligned with red marking on dose request cord receptacle.



Detaching Dose Request Cord

Hold body of latching connector and pull straight out, without twisting or turning, from dose request cord receptacle.



Preparing for an Infusion (Alaris™ PCA Module)

WARNING

Use only standard luer-lock syringes and infusion sets with integrated anti-siphon valves, designed for use on syringe-type PCA Module pumps. Use of incompatible syringes can impact pump operation resulting in inaccurate fluid delivery, delayed generation of occlusion alarms, and other potential problems.

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 infusion set is not clamped or turned off.

1. Prepare syringe (for a list of compatible syringes, refer to *Alaris™ PCA Module Compatible Syringes* on page *286*)in accordance with manufacturer's user manual.
2. Prepare infusion set in accordance with manufacturer's user manual.
3. Attach upper fitting of infusion set to syringe tip.

Alaris™ PCA Module Infusion Set Compatibility

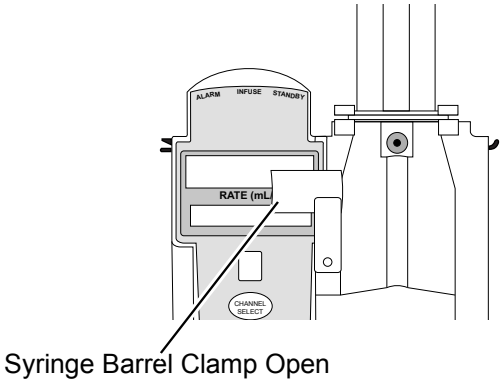
Compatible infusion sets for the Alaris™ PCA Module are shown in the table below. Other non-dedicated extension sets with anti-siphon valves appropriate for syringe-based PCA pumps can also be utilized. For the updated list, refer to the BD website: bd.com/Infusionlibrary. To locate the compatibility list on the BD website, enter **compatible disposables** in the search field.

Model Number	Description
30873	Microbore tubing, anti-siphon valve, back check valve, pinch clamp (2), Y-connector, female luers (2), 90", 3 mL, DEHP is not part of the material formulation
10800175	Microbore tubing, anti-siphon valve, back check valve, pinch clamp (2), Y-connector, female luers (2), with reusable Monoject™ plunger rod, 90", 3 mL, DEHP is not part of the material formulation
10800176	Microbore tubing, anti-siphon valve, pinch clamp, fixed male luer lock, with reusable Monoject™ plunger rod, 92", 2.1 mL, DEHP is not part of the material formulation
30883	Microbore tubing, anti-siphon valve, back check valve, pinch clamp, fixed male luers lock, 92", 2.1 mL, DEHP is not part of the material formulation
10800173	Microbore tubing, anti-siphon valve, back check valve, pinch clamp (2), fixed male luer lock, with reusable Monoject™ plunger rod, 70", 2.6 mL, DEHP is not part of the material formulation

Model Number	Description
30853	Microbore tubing, anti-siphon valve, back check valve, pinch clamp (2), Y-connector, female luers (2), 70", 2.6 mL, DEHP is not part of the material formulation
30863	Microbore tubing, anti-siphon valve, pinch clamp, fixed male luer lock, 63", 1.7 mL, DEHP is not part of the material formulation
10800174	Microbore tubing, anti-siphon valve, pinch clamp, fixed male luer lock, with reusable Monoject™ plunger rod, 63", 1.4 mL, DEHP is not part of the material formulation

Loading Syringe and Infusion Set

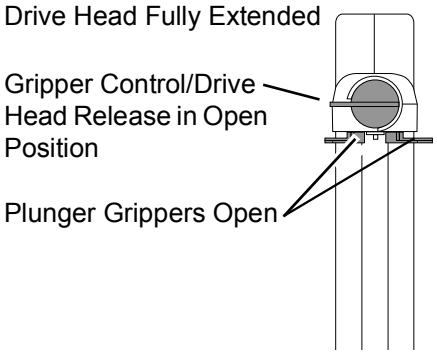
1. Open syringe barrel clamp.
   a. Pull syringe barrel clamp out and hold.
   b. Rotate clamp to left (clockwise or counter clockwise) until it clears syringe chamber.
   c. Gently release clamp.



2. Raise drive head to its fully extended position.
   a. Twist gripper control clockwise and hold in position.

   NOTE:
   The gripper control is spring loaded. When twisted to the open position and then released, gripper control (and the plunger grippers) returns to the closed position.

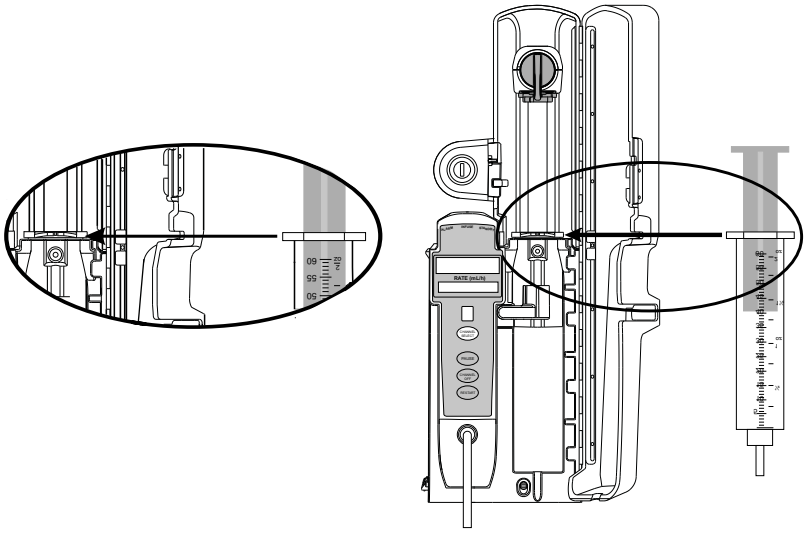
   b. While holding gripper control in open position, raise drive head to full extension.
   c. Gently release gripper control.



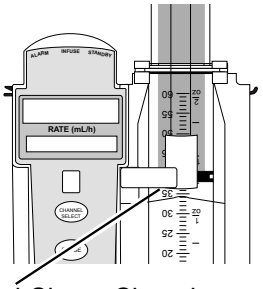
WARNING

Before loading the syringe, check for damage or defects.

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



4. Lock syringe in place.

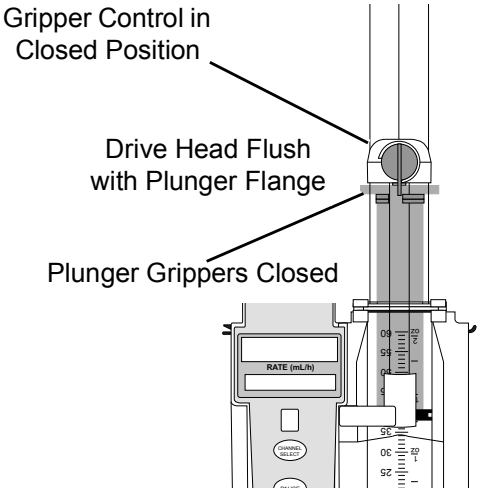


   a. Pull syringe barrel clamp out and hold.
   b. Rotate clamp to right (clockwise or counter clockwise) until it lines up with syringe.
   c. Gently release clamp against syringe.

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

NOTE:
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.

   b. While holding gripper control in open position, gently lower the 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.



Security Lock Key Positions

There are three key positions associated with the security lock:

- UNLOCK unlocks security door. Key must be in this position when loading or changing a syringe.
- PROGRAM allows for initial programming or changes in programming without unlocking security door or interrupting current infusion.
- LOCK locks security door. Key must be in this position to start an infusion.

Programming Infusions

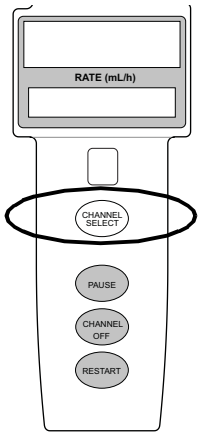
References throughout this procedure to specific drugs and drug doses are for illustration purposes only. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

Selecting Syringe Type and Size

WARNING

Ensure that the displayed syringe manufacturer and syringe size match the installed syringe. Mismatches can impact flow rate accuracy.

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



2. Select syringe type and size as follows.

   NOTE:
   At the start of a PCA 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.

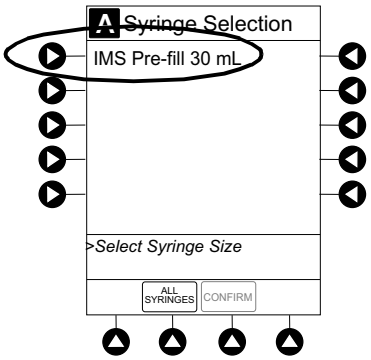
   If the installed syringe is loaded correctly, but not recognized, check for the following:

   a. If a label is between the syringe barrel and the barrel clamp, make sure that the label does not erroneously enlarge the barrel size of the syringe.

   b. If a needle-free valve or other component is added to the syringe, ensure that it is no larger than the diameter of the syringe barrel.

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

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



4. To accept, press **CONFIRM** soft key.

   Drug Library screen is displayed.

Using Priming Option

The priming option can be enabled when the system is configured for use. The priming selection (**PRIME** soft key) is available only after the syringe type and medication selection and prior to selection of infusion mode.

WARNING

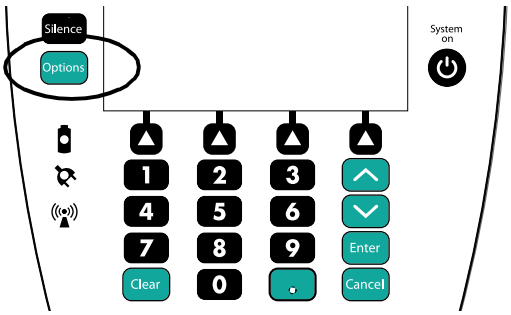
Ensure that patient is not connected when priming.

WARNING

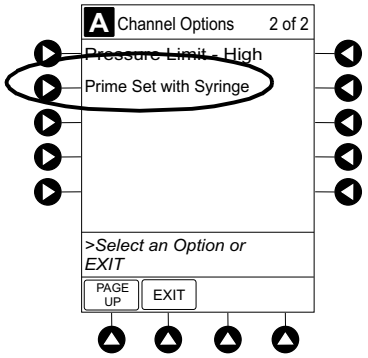
Ensure that air is expelled from line prior to beginning infusion when priming (unexpelled air-in-line could have serious consequences).

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

1. Press **OPTIONS** key.

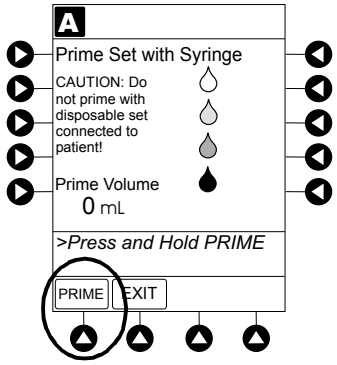


2. Press **Prime Set with Syringe** soft key.



3. Press and hold **PRIME** soft key until fluid flows and priming of PCA infusion set is complete.

   Fluid is delivered during priming only while the **PRIME** soft key is pressed. Each press of **PRIME** soft key delivers up to 2 mL at the maximum rate of the selected syringe per continuous press. To deliver additional amounts, press **PRIME** soft key again. (See *Alaris™ PCA Module Specifications* on page *288*).



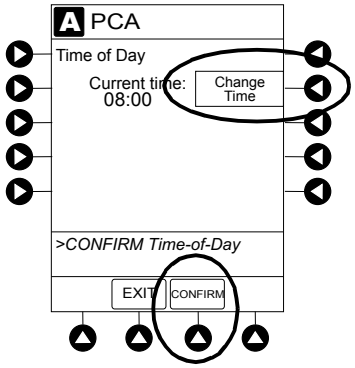
4. When priming is complete, release the **PRIME** soft key.

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

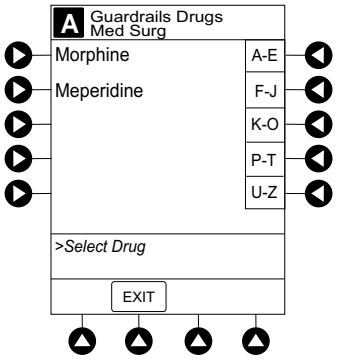
5. To return to main screen, press the **EXIT** soft key.
6. Press soft key next to desired drug.
7. **Drug/Concentration** screen appears.
8. Select and start applicable infusion mode, as directed in the following procedure.
   - *Programming a PCA Dose Only* on page *257*

Programming an Infusion

1. Perform the following steps:
   a. Power on system.
   b. Choose **Yes** or **No** to **New Patient?**
   c. Select profile, if required.
   d. Enter patient identifier, if required.
2. Press the **CHANNEL SELECT** key.
3. Unlock security door or set key to the **PROGRAM** position.
4. Confirm time of day or change time if necessary.

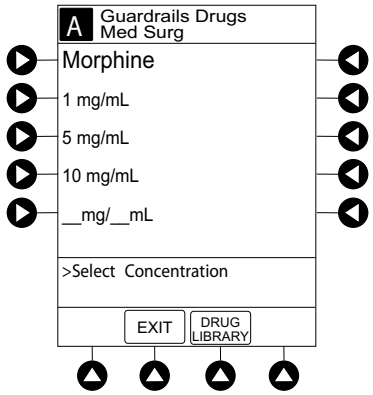


5. Perform the following steps:
   a. Load syringe and infusion set (see *Loading Syringe and Infusion Set* on page *246*).
   b. Select and confirm syringe type and size (see *Selecting Syringe Type and Size* on page *250*).
6. Press soft key next to desired drug.
   Drug/Concentration screen appears.



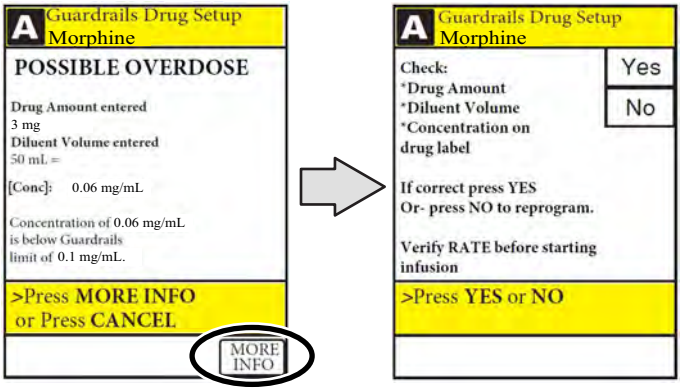
7. Press soft key next to desired concentration.
   - Drug/Concentration confirmation screen appears.
   - To view additional drugs/concentrations, press **PAGE UP** and **PAGE DOWN** soft keys.
   - If applicable, multiple concentration listings for delivery of this infusion could appear (as in illustrated example, which reflects use of Morphine).

   NOTE:
   The facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (_ _ / _ _ mL) and allow the clinician to enter the desired concentration.

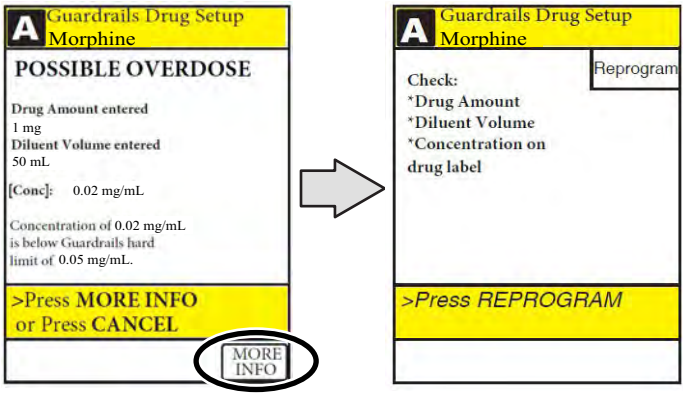


8. Confirm drug and concentration selection and press **Yes** soft key. To change selection, press the **No** soft key.
   - If **Yes** was selected and the facility has defined a Clinical Advisory for that drug, a message appears. To continue programming, press **CONFIRM** soft key.

9. If the programmed _ _ / _ _ mL concentration is outside the hospital-established Guardrails™ limit, an audio alert sounds and a visual Guardrails™ concentration alert appears, notifying the user that a potential over or under dose condition may be present.
   - The Guardrails™ alert screen displays the entered **DRUG AMOUNT, DILUENT VOLUME**, calculated concentration, and Guardrails™ concentration limit allowing the user to verify the parameters against the infusion order.
   - Press **CANCEL** to return to the programming screen to reenter the **DRUG AMOUNT** and **DILUENT VOLUME.**
   - Press **MORE INFO** to further verify the entered infusion parameters.
   - If the Guardrails™ alert is outside the soft limit and the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, the infusion must be reprogrammed.



   - If the programmed _ _ mg/ _ _ mL concentration is outside the hard limit for that care area. **MORE INFO** or **CANCEL** can be pressed but the **DRUG AMOUNT** and **DILUENT VOLUME** must be reprogrammed.



10. If there is a potential for a programmed "_ _ / _ _ mL" parameter to result in an excessive volume or dose being delivered (see *Checking PCA Volume* on page *268*), 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

11. Verify correct parameters and press **NEXT** soft key to confirm.
    - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
12. Prime syringe using Prime feature, if desired.

PCA Infusion Modes

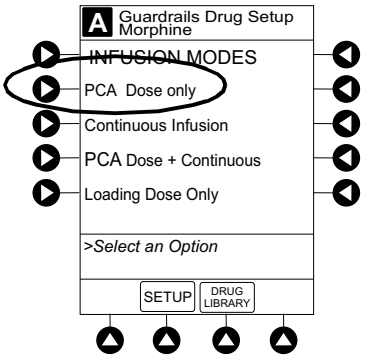
The PCA Module uses the following programming parameters, depending on infusion mode selected. See *Features and Definitions* on page *241* for infusion mode definitions and features.

- **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.

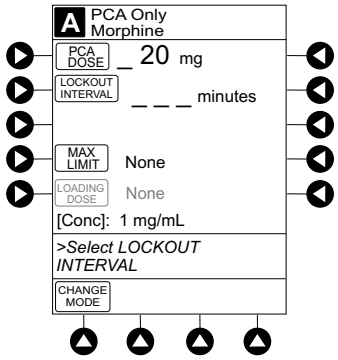
When the PCU is in the Infusion Mode Selection, Infusion Setup, or Bolus Setup screens, a patient dose request from the dose request cord is handled as an unmet demand.

Programming a PCA Dose Only

1. Perform steps in *Preparing for an Infusion (Alaris™ PCA Module)* on page *245*.
2. Press **PCA Dose Only** soft key from Infusion Mode screen.

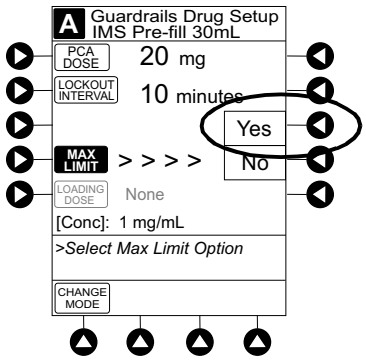


3. To enter PCA dose, use numeric data entry keys.



4. To enter lockout interval, press **LOCKOUT INTERVAL** soft key and use numeric data entry keys.
5. To enter maximum limit, press **MAX LIMIT** soft key and then **Yes** soft key.

   If **No** is selected - then no **MAX LIMITS** will be available for this infusion.



6. Enter maximum limit using numeric data entry keys.

   Time (in hours) associated with **Max Limit** is automatically entered based on setup in system configuration.
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 the programmed parameters are outside the soft limit of 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 the **No** soft key is pressed, infusion must be reprogrammed.
   - If the programmed parameters are outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
   - If there is a potential for a programmed "_ _ / _ _ mL" parameter to result in an excessive volume or dose being delivered (see *Checking PCA Volume* on page *268*), 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:

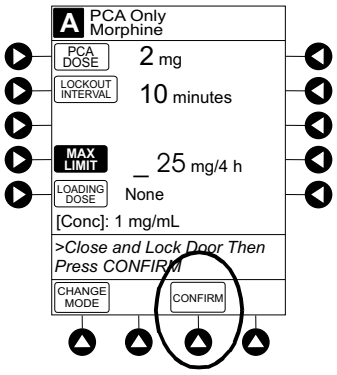
     Drug Amount 1 mg

     Diluent Volume 1 mL

     or

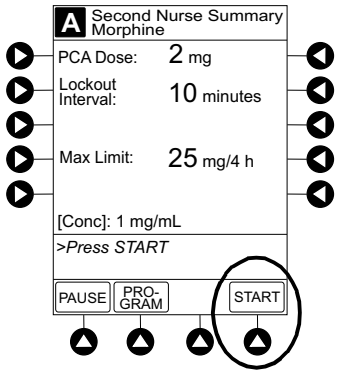
     Drug Amount 30 mg

     Diluent Volume 30 mL



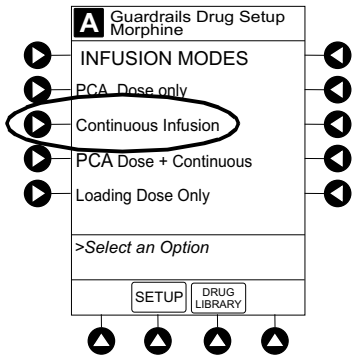
9. Close and lock security door.

10. Verify correct parameters on second nurse summary screen and press **START** soft key.
    - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
    - 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.

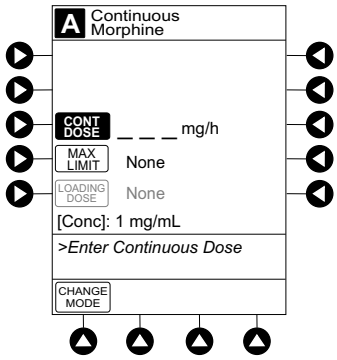


Programming Continuous Infusion

1. Perform steps in *Preparing for an Infusion (Alaris™ PCA Module)* on page *245*.
2. Press **CONTINUOUS INFUSION** soft key from Infusion Mode screen.



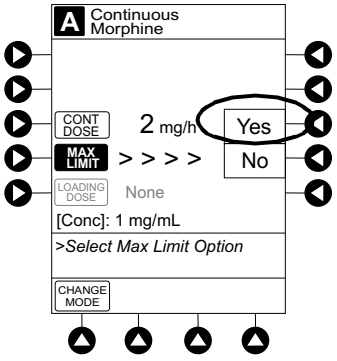
3. To enter Continuous Infusion dose, press **CONT DOSE** soft key and use numeric data entry keys.



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.

   If **No** is selected, no MAX LIMITS are available for this infusion.



5. To enter loading dose, press **LOAD DOSE** soft key, press **Yes** soft key, and use numeric data entry keys.

   Loading dose is included in volume infused but is not included in **Max Limit.**

6. Verify correct parameters and press **CONFIRM** soft key.
   - If the programmed parameters are outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
   - If the programmed parameters are outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
   - If there is a potential for a programmed "_ _ / _ _ mL" parameter to result in an excessive volume or dose being delivered (see *Checking PCA Volume* on page *268*), 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:

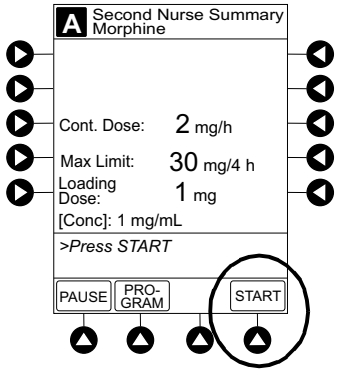
     Drug Amount 1 mg

     Diluent Volume 1 mL

     or

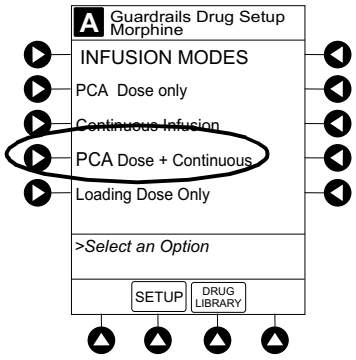
     Drug Amount 30 mg

     Diluent Volume 30 mL
7. Close and lock security door.
8. Verify correct programming parameters and press **START** soft key.
   - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
   - 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.

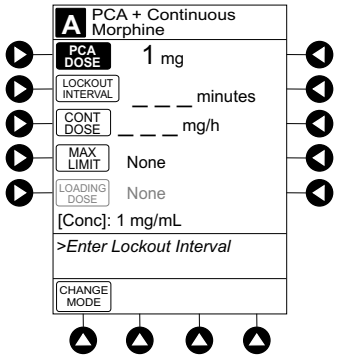


Programming PCA Dose and Continuous

1. Perform steps in *Preparing for an Infusion (Alaris™ PCA Module)* on page *245*.
2. Press **PCA DOSE + CONTINUOUS** soft key from Infusion Mode screen.



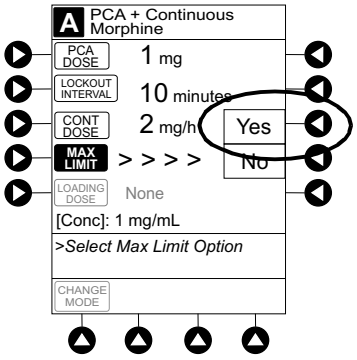
3. To enter PCA dose, press **PCA DOSE** soft key and use numeric data entry keys.



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.

   If **No** is selected - then no MAX LIMITS will be available for this infusion.



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 the programmed parameters are outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
   - If the programmed parameters are outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
   - If there is a potential for a programmed "_ _ / _ _ mL" parameter to result in an excessive volume or dose being delivered (see *Checking PCA Volume* on page *268*), 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:

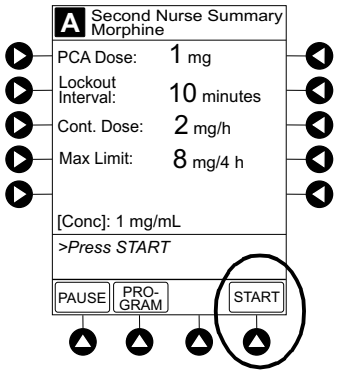
     Drug Amount 1 mg

     Diluent Volume 1 mL

     or

     Drug Amount 30 mg

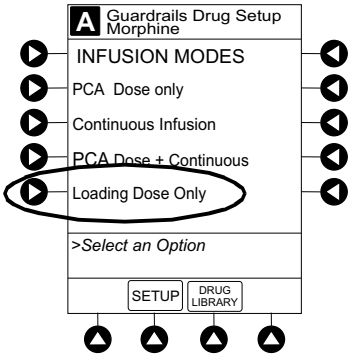
     Diluent Volume 30 mL
9. Close and lock security door.
10. Verify correct parameters on second nurse summary screen and press the **START** soft key.
    - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
    - Green Infusing Status Indicator illuminates.
    - **DELIVERING PCA** scrolls in Channel Message Display when started. 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.



Programming Loading Dose Only

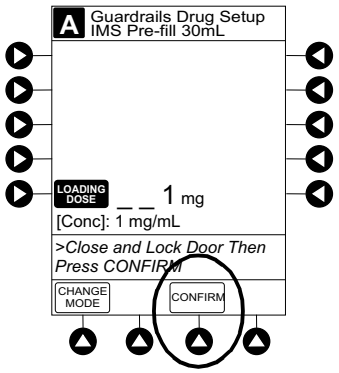
The following procedures should be used when setting a **LOADING DOSE ONLY** using the drug library.

1. Perform steps in *Preparing for an Infusion (Alaris™ PCA Module)* on page *245*.
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 the programmed parameters are outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
- If the programmed parameters are outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
- If there is a potential for a programmed "_ _ / _ _ mL" parameter to result in an excessive volume or dose being delivered (see *Checking PCA Volume* on page *268*), 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

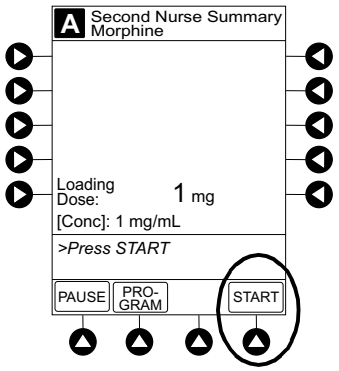
  or

  Drug Amount 30 mg

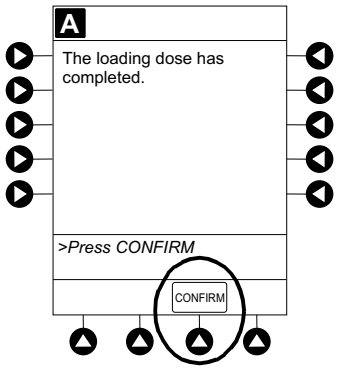
  Diluent Volume 30 mL

5. Close and lock security door.

6. Verify correct parameters on second nurse summary screen and press **START** soft key.
   - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
   - **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.



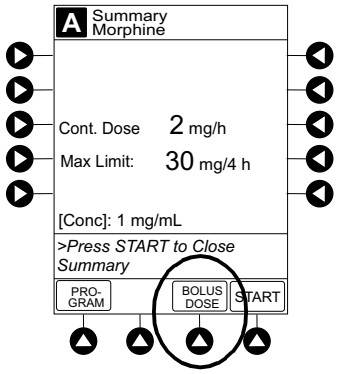
7. Press **CONFIRM** soft key.
   - When **CHANNEL SELECT** key is pressed, Infusion Mode screen becomes available for selection of infusion mode.



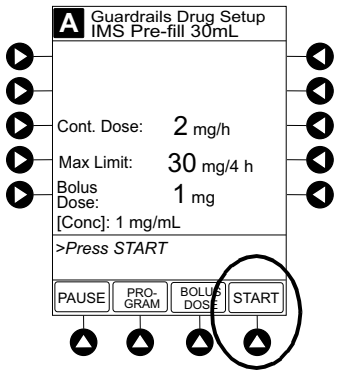
Setting Bolus Dose

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 and Continuous Infusion modes.

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



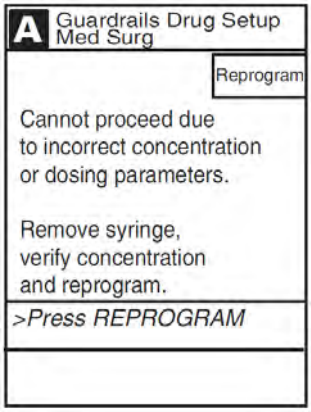
3. Set key to **PROGRAM** position or enter 4-digit authorization code and press **CONFIRM** soft key.
4. To enter dose value, use numeric data entry keys.
5. Press **CONFIRM** soft key.
   - If the programmed bolus dose is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
   - If the programmed bolus dose is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion must be reprogrammed.
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:
   - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.
   - **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.



Checking PCA Volume

To reduce the instances of programming errors, the PCA Module checks the total volume of all programmed PCA parameters against a percentage (35%) of the capacity of the installed syringe. A PCA infusion can only be started when the total programmed volume is less than 35% of the syringe capacity.

The PCA Module volume check includes one hour of Continuous Dose, PCA Dose, bolus dose, or Loading Dose. If the programmed volume is 35% or more of the capacity of the installed syringe during initial or subsequent programming, the clinician is presented with an alert which requires a reprogram.



PCA Syringe Sizes and the Correlating 35% of the Syringe Capacity

Syringe Size	35% of Syringe Capacity
60mL*	21mL
35mL	12.25mL
30mL	10.5mL
25mL	8.75mL
20mL	7mL

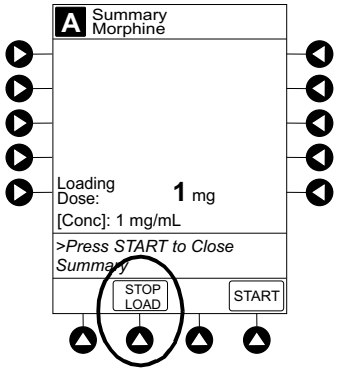
NOTE:

*BD® 50 mL Syringe model 309653 (formerly BD® 60 mL Syringe model 309653) markings no longer extend beyond 50 mL, but the syringe dimensions remain the same and continue to be compatible with both the Alaris™ Syringe and Alaris™ PCA Modules. Clinicians will continue to choose BD Plastipak 50/60 mL on the BD Alaris™ PCU display. The PCA volume check for the BD® 50 mL Syringe is based on a 60 mL capacity, therefore a 21 mL threshold applies.

Stopping a Loading, PCA, or Bolus Dose

1. Press **CHANNEL SELECT** key.
2. Press **STOP LOAD, STOP PCA,** or **STOP BOLUS** soft key as applicable.

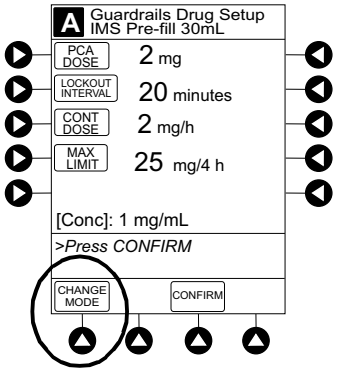
   Available soft key and stop confirmation screen are dependent on type of dose currently infusing and current infusion mode.



3. To stop dose and resume current program, press **Yes** soft key.

Changing 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 the applicable procedure:

   Programming a PCA Dose Only on page *257*

   Programming Continuous Infusion on page *260*

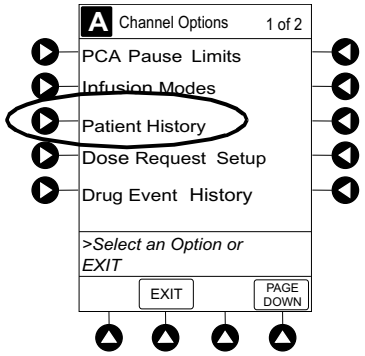
   Programming PCA Dose and Continuous on page *262*

   NOTE:
   Previously programmed values are carried over to new program.

7. Verify or change program settings and press **CONFIRM** soft key.
8. Close and lock door.
9. Verify correct programming parameters on summary screen and press **START** soft key.

Viewing Patient History

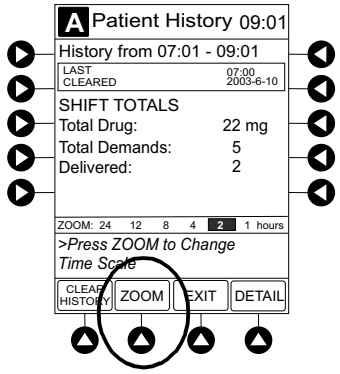
1. Press **CHANNEL SELECT** key.
2. From Main Display, press **OPTIONS** key.
3. Press **PATIENT HISTORY** soft key.



4. To select desired time period, press **ZOOM** soft key.

NOTE:

- Total drug delivered includes applicable loading dose, PCA dose, continuous dose, and bolus dose. Total drug delivered does not include priming volume.
- The patient history defaults to the 8 hour view.



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

NOTE:
Patient History stores a rolling 24-hour log and is automatically cleared when selecting:

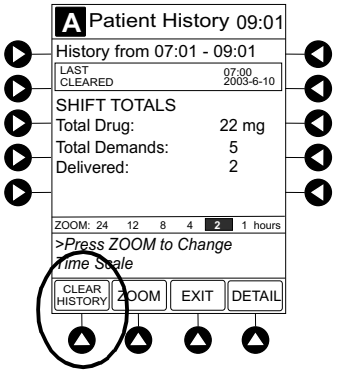
- **Yes** to **New Patient?** during startup.
- A different drug from the drug library.
- The same drug with different dosing units from the drug library.
- Same patient with a new profile.

6. To return to main patient history, press **MAIN HISTORY** soft key.
7. To return to Main Display, press **EXIT** soft key.

Clearing Patient History

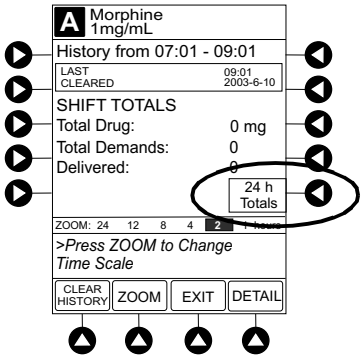
1. Press **CHANNEL SELECT** key.
2. From Main Display, press **OPTIONS** key.
3. Press **Patient History** soft key.
4. Press **CLEAR HISTORY** soft key.

   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, the last 24 hours of patient history data can be retrieved and viewed. To retrieve last 24 hours, press **24 h Totals** soft key from **Patient History** screen.

   24 h Totals soft key appears only if shift total is cleared and additional patient history information exists (up to previous 24 hours).

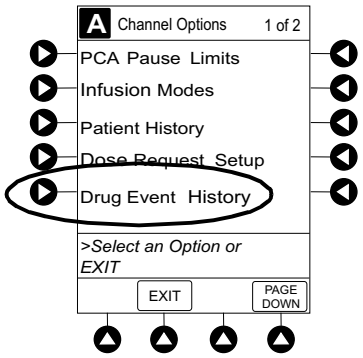


NOTE:
24 h Totals displays a rolling 24 hour history regardless of how many times the patient history has been cleared.

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

Viewing Drug Event History

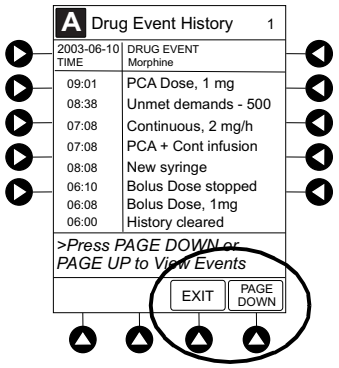
1. Press **CHANNEL SELECT** key.
2. From Main Display, press **OPTIONS** key.
3. Press **Drug Event History** soft key.



4. To scroll through history, press **PAGE DOWN** soft key.

   NOTE:
   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.

5. To return to Main Display, press **EXIT** soft key.



Instructions for Patient Use of PCA Dose Request Button

WARNING

Carefully locate the dose request cord to reduce the possibility of patient entanglement or strangulation.

WARNING

Only the patient should press the dose request button.

NOTE:
Make sure a responsible adult is present when communicating to a pediatric patient how to use the PCA dose request button.

The clinician should consider communicating the following information to the patient when using the PCA dose request button:

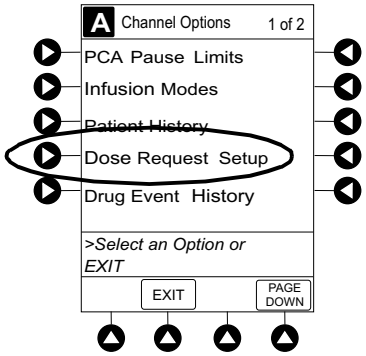
1. Press the PCA dose request button when they start to feel pain.
2. Wait a period of time to see if the pain is better.
3. Press the PCA dose request button again if the pain is not better.
4. Tell the nurse if the pain continues.
5. If the hospital configured the dose request cord to use profile 1, instruct the patient on the audio and LED light behavior. (See *Configuring Dose Request Cord* on page *273*.).

The patient information tip sheet can be found at bd.com/infusionlibrary. Enter **PCA patient guide** in the search field.

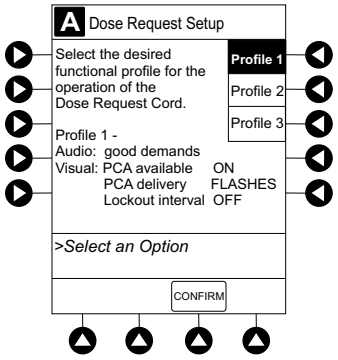
Configuring Dose Request Cord

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 button. Default configuration for the dose request cord is established in the system 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.



	Profile 1	Profile 2	Profile 3
PCA dose request button audio - single beep	Good demands: beeps when button is pressed and dose is available	All demands: beeps every time button is pressed	All demands: beeps every time button is pressed
PCA dose available	Light is on when dose is available	Light is on at all times	Light is off at all times
PCA dose delivery	Light flashes when dose is being delivered	Light is on at all times	Light is off at all times
PCA lockout interval	Light is off when dose is not available	Light is on at all times	Light is off at all times

5. Press **CONFIRM** soft key.

Security Access Levels

The security access level can be configured to provide varying levels of access to the device. Security access is accomplished either through the use of the key or a 4-digit authorization code.

Default configuration for the security access level is established for each profile or care area and can be changed in the system configuration. The 4-digit authorization code is established and can be changed in the system configuration.

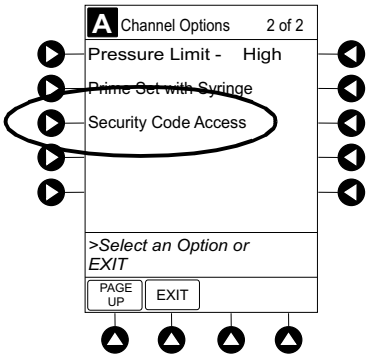
The 4-digit authorization code is configured for each profile with Level 2 or Level 3 security access.

Security Access Level	Initial Programming	Setting Bolus Dose	Subsequent Programming
Level 1	Key	Key	Key
Level 2	Key	Code or Key	Key
Level 3	Key	Code or Key	Code or Key

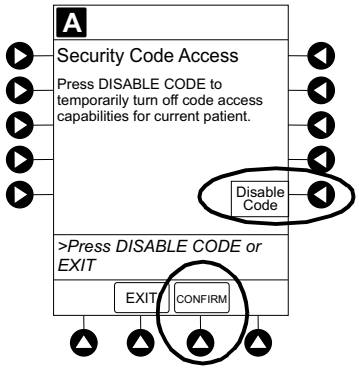
Disabling Security Access Code

The security code can be disabled for a specific infusion by using the following procedure.

1. Press **CHANNEL SELECT** key.
2. From Main Display, press **OPTIONS** key.
3. Press **Security Code Access** soft key.



4. Press **DISABLE CODE** soft key.

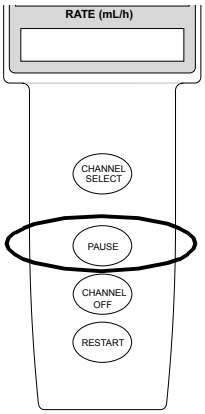


5. Press **CONFIRM** soft key.

   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.

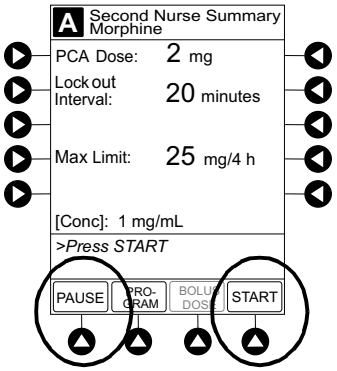
Pausing Infusion

1. Press **Pause** key.



or

From **Second Nurse Summary** screen, press **PAUSE** soft key.



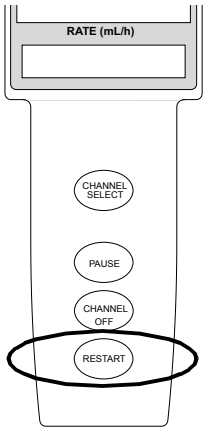
- **PAUSE** scrolls in Channel Message Display.
- **PAUSED** appears on Main Display.
- Yellow Standby Status Indicator illuminates.
- After 2 minutes, **PAUSE-RESTART CHANNEL** visual and audio prompts begin, and yellow Standby Status Indicator flashes.

2. To restart infusion:

   Press **RESTART** key.

   or

   Press **CHANNEL SELECT** key and then press **START** soft key on Main Display.



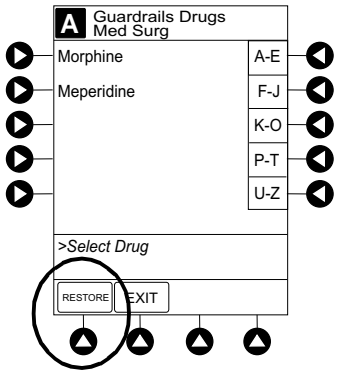
Changing Syringe and Restore Infusion

1. If syringe requires replacement:
   a. Unlock security door.
   b. Remove existing syringe and prepare new syringe (see *Loading Syringe and Infusion Set* on page *246*).

      If drug and/or drug concentration is different from previous syringe, attach and prime new infusion set.
   c. Load syringe and infusion set (see *Loading Syringe and Infusion Set* on page *246*).
   d. Select syringe type and size (see *Selecting Syringe Type and Size* on page *250*).
2. To restart infusion using restored parameters, press the **RESTORE** soft key and continue with next step.

   or

   To start a new infusion, select drug from drug library and follow steps for *PCA Infusion Modes* on page *256*.



3. Verify restored drug/concentration. Press the **NEXT** soft key.
4. Prime infusion set (see *Using Priming Option* on page *251*).

5. For restored parameters, verify valid parameters and press **CONFIRM** soft key.

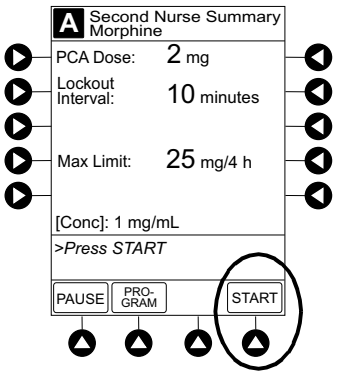
   Changing a restored parameter:

   a. Press applicable soft key.

   b. Enter desired parameter using numeric data entry keys.

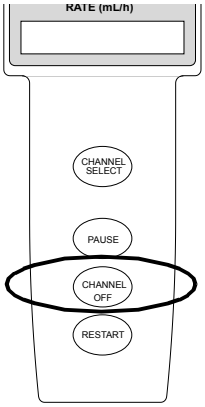
   c. Press **CONFIRM** soft key.

6. Close and lock security door.
7. Verify correct programming parameters on second nurse summary screen and press **START** soft key.



Stopping an 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.



Selecting Pressure Limit

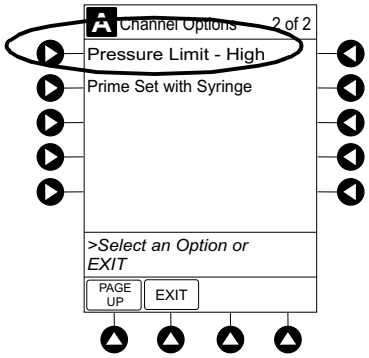
WARNING

Consider factors that can influence back pressure when setting occlusion threshold pressure limits are: infusion set configuration, IV solution viscosity, and IV solution temperature. Back pressure can also be affected by type of catheter.

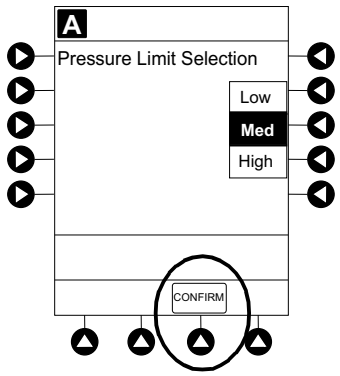
1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **PRESSURE LIMIT** soft key.

   NOTE:
   Option to change pressure limit can be selected:

   - After drug is selected, and before infusion mode is selected and infusion starts
   - After infusion starts



4. To select a pressure limit, press appropriate soft key.



5. Press **CONFIRM** soft key.

Viewing and Clearing Volume Infused

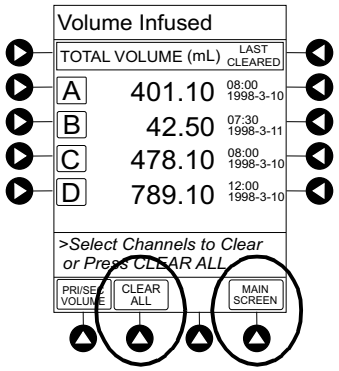
1. To view volume infused, press the **VOLUME INFUSED** soft key from Main Display.

   Total volume infused, and time and date volume infused was last cleared, are displayed for each channel.

   NOTE:
   Date format is year-month-day.

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.

   NOTE:
   - If no key is pressed, main screen appears after 30 seconds.
   - Clearing volume infused on a PCA Module does not clear patient history.



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

PCA Pause Protocol

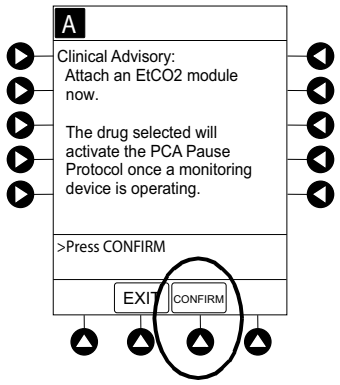
The PCA pause protocol is an optional, hospital-configurable feature that is intended to align with the healthcare facility's current protocol for patient monitoring during PCA therapy. All programming, data entry, and validation of PCA pause protocol parameters are performed by a healthcare professional according to hospital-defined protocol/procedure or a physician's order.

If an $EtCO_2$ Module is not attached or started, the PCA pause protocol does not activate.

Programming an Infusion with PCA Pause Protocol

If the PCA pause protocol feature is enabled, perform the following procedure.

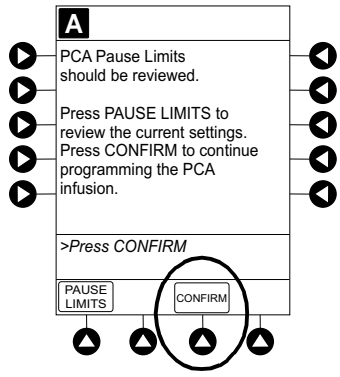
1. Perform steps in *Programming an Infusion* on page *253* and *Preparing for an Infusion (Alaris™ PCA Module)* on page *245*.
2. Confirm drug and concentration selections and press **Yes** soft key.
3. Review Clinical Advisory.



   - To continue, press **CONFIRM** soft key.
   - To activate PCA pause protocol, attach and start an $EtCO_2$ 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.

   NOTE:
   To review PCA pause limits, see *Reviewing or Changing the PCA Pause Alarm Limits* on page *282*.



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

NOTE:
Once the **START** soft key is pressed, the Main Display screen alternates between volume remaining (VTBI - volume to be infused) and PCA Module drug name with the infusion mode.

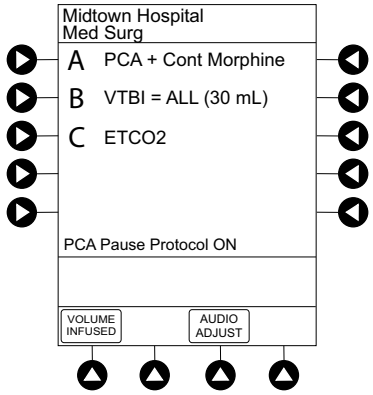
- The Main Display displays **PCA Pause Protocol ON**.
- If Patient ID is entered, **Patient ID** alternates with **PCA Pause Protocol ON**.

Programming a PCA Dose Only on page *257*

Programming Continuous Infusion on page *260*

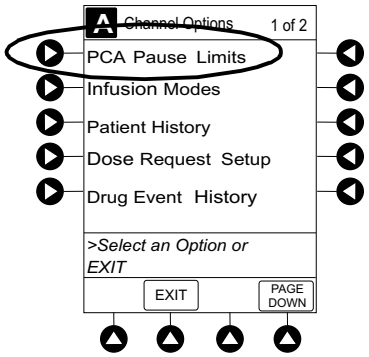
Programming PCA Dose and Continuous on page *262*

Programming Loading Dose Only on page *264*



Reviewing or Changing the PCA Pause Alarm Limits

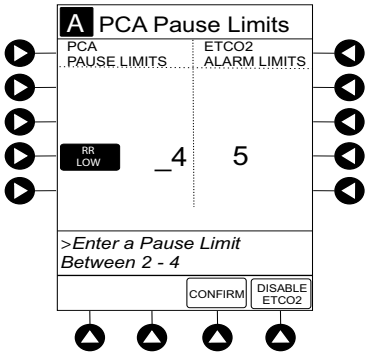
1. From Main Display press **CHANNEL SELECT.**
2. Press **OPTIONS** key.
3. Press **PCA PAUSE LIMITS** soft key.



4. Verify the PCA pause limits as per facility protocol or physician order.

5. To change the PCA pause limits, press **RR LOW** soft key and enter a value within acceptable range.

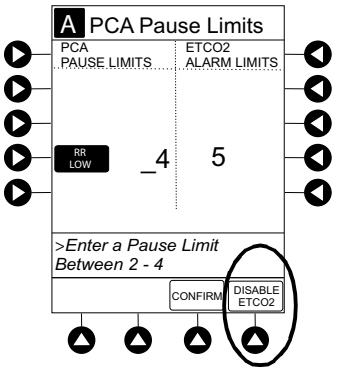
   NOTE:
   The acceptable range for PCA pause protocol is configurable and defined by the hospital within the data set using the Guardrails™ Suite MX. The **PCA PAUSE LIMITS** must be lower than the **ETCO2 ALARM LIMITS**. A prompt is provided if the **PCA PAUSE LIMITS** must be modified.



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

Disabling PCA Pause Alarm

1. From Main Display, press **CHANNEL SELECT**.
2. Press the **OPTIONS** key.
3. Press the **PCA Pause Limits** soft key.
4. Press the **DISABLE ETCO2** soft key.
   - Disabling $EtCO_2$ from this screen discontinues PCA pause feature only, without interrupting $EtCO_2$ monitoring functionality.
   - Once disabled, PCA pause 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 ETCO2** soft key, as appropriate.

Infusion Set/Syringe Information

The PCA Module uses standard, single-use, disposable syringes (with luer-lock connectors) and infusion sets with anti-siphon valves, designed for use on syringe-type PCA Module pumps.

- For specific infusion set instructions and set replacement interval, refer to user manual provided with set.
- For a list of compatible syringes, refer to *Alaris™ PCA Module Compatible Syringes* on page *286*.
- Use aseptic techniques when handling sets and syringes.
- Infusion sets are supplied with a sterile and nonpyrogenic fluid path for one-time use. Do not resterilize.
- Discard infusion set per facility protocol.
- For IV push medication (put instrument on hold), clamp tubing above port.
- Flush port(s) per facility protocol.

Alaris™ PCA Module Compatible Syringes

WARNING

Use only standard luer-lock syringes and infusion sets with integrated anti-siphon valves, designed for use on syringe-type PCA pumps. Ensure syringe sizes and models are compatible with the PCA Module. Use of incompatible syringes can impact pump operation resulting in inaccurate fluid delivery, delayed generation of occlusion alarms, and other potential problems.

The table shows the brands for each syringe size and order number. For the updated list, refer to the BD website: bd.com/Infusionlibrary. To locate the compatibility list on the BD website, enter **compatible syringe list** in the search field.

Compatible Syringes for PCA Module

Size	BD	Monoject™	Terumo™	IMS Pump Jet
20 mL	302830	Soft pack 1182000777 Rigid pack 8881520657	SS-20L2‡ (25 mL total)	N/A
30 mL	302832	N/A	SS-30L‡ (35 mL total)	NDC #76329-1911-1*
35 mL	N/A	Soft pack 1183500777 Rigid pack 8881535762 Detachable plunger version, empty barrel 8881135609**	N/A	N/A
50 mL	309653	N/A	N/A	N/A
60 mL	N/A	Soft pack 1186000777 Soft pack 1186000777T Rigid pack 8881560125	SS-60L	N/A

*Prefilled morphine sulfate 1 mg/mL
**Empty barrel only sold by BD. Detachable plunger is provided with the administration set.
‡Only available in Canada.

Displays

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

Configurable Settings

The configuration settings are selected during data set development and then uploaded to the system.

With the profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best practice data set must be uploaded to enable the profiles feature. Date and time is a system setting and is the same in all profiles.

Feature	Default Setting	Options
Authorization Code	None	4 digits (0 - 9) One code applies to all profiles
Bolus Delivery Rate	150 mL/h	75 - 500 mL/h (limited by syringe size)
Bolus Dose	Disabled	Enabled - Disabled
Bolus Dose include in Max. Limit	Disabled	Enabled - Disabled
Dose Request Cord Configuration	Profile 2	Profile 1, 2, 3
Forced Module Location	Enabled	Enabled - Disabled
Loading Dose	Disabled	Enabled- Disabled
Lockout Interval	1 - 99 minutes in 1-minute increments	Min/Max 1 - 99 minutes
Max Accumulated Dose Range	4-hour limit	Disabled; 1, 2, or 4-hour limit
Max Rate (for Continuous Dose)①	999 mL/h	0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments
NEOI • Alert Time	Disabled	Enabled - Disabled 5 - 25% of syringe size
NEOI Snooze①	Disabled	5, 10 or 15 minutes
Occlusion Pressure Set Point	High (800 mmHg)	Low (200 mmHg) Medium (500 mmHg) High (800 mmHg)
PCA Pause Protocol: • PCA Pause Protocol • Monitoring Module Attach Enforcement • PCA Pause Protocol Text • $EtCO_2$ Settings:② • Respiratory Rate Lower Limit (bpm) • Initial Value	 Disabled None PCA infusion has paused due to a decline in respiratory status. Check patient. None None	 Enabled - Disabled Enabled - Disabled Editable per hospital protocol 0 - 149 0 - 149
Priming	Enabled	Enabled - Disabled
Security Access Level	Level 1	Level 1, 2, 3

NOTE:

①This configuration setting is a shared setting between the PCA Module and the Syringe Module.

②These values are configured in the $EtCO_2$ Module settings within the Guardrails™ Editor software and can be changed by the clinician by accessing Channel Options on the PCA Module.

Alaris™ PCA Module Specifications

PCA Module specifications are provided in the following sections.

Standard Operating Conditions

Standard operating conditions is a term used to describe the conditions under which testing was performed for the BD Alaris™ System in the specifications section of this manual. They are listed below.

Performance test results vary when testing is performed in conditions other than standard operating conditions. For results from testing performed in non-standard operating conditions, refer to Appendix C – Non-Standard Performance.

- Temperature: 20 °C ± 2 °C
- Atmospheric Pressure: 645 mmHg to 795 mmHg
- Relative Humidity: 20% - 90% noncondensing
- Back Pressure: 0 mmHg ± 2 mmHg
- Solution Type: Distilled water
- Needle: 18 gauge, 40 mm, 1.5 inch length
- Infusion Set: Not expired, ≤ 3 years shelf life, ≤ 96 hours of usage

PCA Module Performance Topics	Infusion Set Under Standard Operating Conditions
Rate Accuracy Bolus Accuracy Downstream Occlusion Post-Occlusion Bolus	60 inch - 90 inch set with < 0.100 inch tubing inner diameter, an anti-siphon valve, back check valve, 1 Y-Site, and no other flow restricting components (for example, filters, stopcocks, or manifolds) Example: 30873 check valve, micro bore

PCA Module Flow Rate Accuracy

The PCA Module full-scale plunger travel accuracy is ± 2%.
PCA Module system flow rate accuracy (module and syringe tested together as a system) is ± 5% at flow rates ≥ 10% of the syringe volume per hour under standard operating conditions, with 95% confidence and 95% reliability.

The PCA and Syringe Module drive mechanism designs are the same. Verification studies demonstrate the Syringe Module flow rate accuracy performance under standard operating conditions are shown below.

Accuracy at 10% of the Syringe Volume per Hour[1]

Syringe	Flow Rate (mL/h)	Average Flow Rate Accuracy[2]
BD 20 mL	2.0	0.01%
BD 30 mL	3.0	-0.23%
BD 50 mL	5.0	-0.48%
Monoject™ 20 mL	2.0	-1.63%
Monoject™ 35 mL	3.0	-1.12%
Monoject™ 60 mL	5.0	-0.19%
Terumo™ 20 mL	2.0	-0.37%
Terumo™ 30 mL	3.0	-0.26%
Terumo™ 60 mL	5.0	-1.25%

1. Flow rate of 10% of the syringe volume per hour is based on BD syringe sizes. For Monoject™ and Terumo™ syringes, comparable syringe sizes were tested at the same flow rates.
2. Flow rate accuracy at steady-state.

Accuracy at 10 mL/h Flow Rate

Syringe	Flow Rate (mL/h)	Average Flow Rate Accuracy[1]
BD 20 mL	10	0.55%
BD 30 mL		0.17%
BD 50 mL		-0.10%
Monoject™ 20 mL	10	-0.27%
Monoject™ 35 mL		-0.02%
Monoject™ 60 mL		0.03%
Terumo™ 20 mL	10	-0.27%
Terumo™ 30 mL		0.05%
Terumo™ 60 mL		-0.46%

1.Flow rate accuracy at steady-state.

Characterization studies demonstrate that Syringe Module flow rate accuracy at lower rates under standard operating conditions as shown in the tables.

Syringe	Flow Rate (mL/h)	Average Flow Rate Accuracy[1]
BD 20 mL	0.1	-3.15%
BD 20 mL	1	-0.39%
BD 50 mL	0.1	-4.04%
BD 50 mL	1	-1.47%

1.Flow rate accuracy at steady-state.

PCA Module Occlusion Alarm Settings

Settings include low, medium, and high

PCA Module Occlusion Time-to-Alarm

PCA Module occlusion time-to-alarm is ≤ 5 minutes at the flow rates listed per syringe size in the tables below and the low occlusion pressure setting, under standard operating conditions, with 95% confidence and 99% reliability.

Verification studies demonstrate the PCA Module occlusion time-to-alarm performance as shown in the table.

Low Occlusion Pressure Setting

Syringe	Flow Rate (mL/h)	Time-to-Alarm Average	Time-to-Alarm Upper Bound[1]
BD 20 mL	5	1 min 19 sec	≤ 2 min 59 sec
BD 30 mL	10	37 sec	≤ 1 min 10 sec
BD 50 mL	11	1 min 23 sec	≤ 2 min 46 sec
Monoject™ 20 mL	5	33 sec	≤ 1 min 27 sec
Monoject™ 35 mL	10	32 sec	≤ 1 min 18 sec
Monoject™ 60 mL	11	47 sec	≤ 2 min 14 sec
Terumo™ 20 mL	5	1 min 5 sec	≤ 2 min 35 sec
Terumo™ 30 mL	10	39 sec	≤ 1 min 49 sec
Terumo™ 60 mL	11	28 sec	≤ 4 min 13 sec

1.Upper bound with 95% confidence and 99% reliability

PCA Module occlusion time-to-alarm is ≤ 10 minutes at the flow rates listed per syringe size in the tables below and the high occlusion pressure setting, under standard operating conditions, with 95% confidence and 97% reliability.

High Occlusion Pressure Setting

Syringe	Flow Rate (mL/h)	Time-to-Alarm Average	Time-to-Alarm Upper Bound[1]
BD 20 mL	6	4 min 7 sec	≤ 5 min 45sec
BD 30 mL	10	2 min 59 sec	≤ 4 min 3 sec
BD 50 mL	12	2 min 59 sec	≤ 4 min 33 sec
Monoject™ 20 mL	6	4 min 26 sec	≤ 8 min 5 sec
Monoject™ 35 mL	10	4 min 25 sec	≤ 5 min 44 sec
Monoject™ 60 mL	12	2 min 25 sec	≤ 3 min 40 sec
Terumo™ 20 mL	6	5 min 21 sec	≤ 9 min 50 sec
Terumo™ 30 mL	10	3 min 43 sec	≤ 5 min 52 sec
Terumo™ 60 mL	12	3 min 50 sec	≤ 5 min 18 sec

1.Upper bound with 95% confidence and 97% reliability

NOTE:
The time to generate an occlusion alarm increases as occlusion pressure settings increase.

As shown in the table above, verification studies demonstrate that as syringe size increases, the PCA Module occlusion time-to-alarm increases, and a higher flow rate results in time-to-alarm ≤ 5 minutes (low occlusion pressure setting) or ≤10 minutes (high occlusion pressure setting). The PCA and Syringe Module occlusion detection (without pressure sensing disc) mechanism designs are the same. Characterization studies performed on the Syringe Module occlusion time-to-alarm increases at flow rates < 11 mL/h under standard operating conditions, and may result in time-to-alarm as follows:

BD 50 mL syringe[2] at 0.1 mL/h
- Low occlusion pressure setting
  4 hours 28 min (average)
  ≤ 7 hours 5 min (upper bound[1])

- Medium occlusion pressure setting
  8 hours 39 min (average)
  ≤ 11 hours 43 min (upper bound[1])

- High occlusion pressure setting
  16 hours 37 min (average)
  ≤ 21 hours 8 min (upper bound[1])

1. Upper bound with 95% confidence and 95% reliability
2. Testing was completed with BD syringes. Other syringe manufacturers may have different time-to-alarm.

PCA Module Post-Occlusion Bolus Volume

PCA Module post-occlusion bolus volume is ≤ 1 mL for syringe sizes ≤ 35 mL, under standard operating conditions, with 95% confidence and 99% reliability.

Verification studies demonstrate the PCA Module post-occlusion bolus volume performance, under standard operating conditions. For a given occlusion pressure setting, as the syringe size increases the syringe compliance increases, resulting in a larger post-occlusion bolus volume. Syringes of the largest compatible size that produced a post-occlusion bolus volume ≤ 1 mL were tested at high and low occlusion pressure settings.

Low Occlusion Pressure Setting

Syringe Size	Post-Occlusion Bolus Volume Average (mL)	Post-Occlusion Bolus Volume Upper Bound[1,2] (mL)
BD ≤ 50 mL	0.252	≤ 0.709
Monoject™ ≤ 60 mL	0.140	≤ 0.439
Terumo™ ≤ 60 mL	0.078	≤ 0.252

1.Upper bound with 95% confidence and 99% reliability
2.Bolus volume throughout the PCA Module flow rate range

High Occlusion Pressure Setting

Syringe Size	Post-Occlusion Bolus Volume Average (mL)	Post-Occlusion Bolus Volume Upper Bound[1,2] (mL)
BD ≤ 30 mL	0.447	≤ 0.578
Monoject™ ≤ 35 mL	0.611	≤ 0.939
Terumo™ ≤ 30 mL	0.523	≤ 0.885

1.Upper bound with 95% confidence and 99% reliability
2.Bolus volume throughout the PCA Module flow rate range

NOTE:
Due to a large syringe compliance, the 50 and 60 mL syringe sizes at the high occlusion pressure settings may produce a post-occlusion bolus larger than 1 mL.

PCA Module Bolus Volume Accuracy

PCA Module bolus volume accuracy (module and syringe tested together as a system) is ± 5% at greater than or equal to the bolus volumes and bolus flow rates listed below per syringe size under standard operating conditions, with 95% confidence and 97% reliability.

- Bolus Volumes: ≥ 1 mL
- Bolus Flow Rates: 75 mL/h to 500 mL/h

The PCA and Syringe Modules drive mechanism designs are the same. Verification studies demonstrate the Syringe Module bolus volume accuracy performance under standard operating conditions are shown below.

Syringe Size	Bolus Volume (mL)	Flow Rates (mL/h)	Average Bolus Volume Accuracy[1]
BD 20 mL	≥ 1	≥ 0.61	0.45%
BD 30 mL			0.58%
BD 50 mL			0.18%
Monoject™ 20 mL	≥ 1	≥ 0.61	0.21%
Monoject™ 35 mL			0.23%
Monoject™ 60 mL			-0.05%
Terumo™ 20 mL	≥ 1	≥ 0.61	0.41%
Terumo™ 30 mL			0.45%
Terumo™ 60 mL			-0.21%

1.Bolus volume accuracy at steady-state.

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

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: 4.75" W x 15.0" H x 7.5" D (exclusive of security door)

Environmental Conditions:

Symbol	Meaning	Operating	Storage/ Transport
	Atmospheric Pressure	525 - 795 mmHg (70 - 106 kPa)	375 - 760 mmHg (50 - 101 kPa)
	Relative Humidity (Avoid prolonged exposure to relative humidity >90%)	20 - 90% Noncondensing	5 - 90% Noncondensing
	Temperature Range	41 - 104°F (5 - 40°C)	-4 - 140°F (-20 - 60°C)

Equipment Orientation: To ensure proper operation, the system must remain in an upright position.

Flow Rate Programming: Flow rate range is from 0.1 to 999 mL/h and can be selected as follows:

Flow Rates (mL/h)	Selectable Increments (mL/h)
0.1 - 9.99	0.01
10 - 99.9	0.1
100 - 999	1.0

Rate restriction by syringe size and PCA volume check:

Syringe Size (mL)	Flow Rate Range (mL/h)
20	0.1 - 6.99
30	0.1 - 10.49
35	0.1 - 12.24
50/60	0.1 - 20.99

Fluid Ingress Protection: IPX2, Drip Proof

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

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

Operating Principle:	Positive displacement
PCA Dose Range:	Configured according to hospital best-practice guidelines.
Shock Protection:	Type CF, defibrillation-proof patient applied part. (PCA disposable) Type BF, defibrillation-proof patient applied part. (Dose request cord)
Weight:	5.5 lbs (PCA max handle load weight is 5.5 lbs)

Chapter 4
Alaris™ $EtCO_2$ Module Model 8300

This chapter contains the following topics:

Summary of Warnings and Cautions

General

WARNING

- **Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System (see *About this Chapter* on page *300*).**
- **The BD Alaris™ System is not intended to replace supervision by medical personnel.**
- **Follow $EtCO_2$ monitoring precautions:**
  - **The $EtCO_2$ Module is not intended for use with high frequency surgical equipment such as, electrical cautery devices. Use of the $EtCO_2$ Module in this manner can cause improper performance.**
  - **Do not use the $EtCO_2$ Module or Microstream™ disposable inside a hyperbaric chamber.**
  - **Respond immediately to system alarms; patient monitoring can cease under certain alarm conditions.**
  - **The $EtCO_2$ 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 the $EtCO_2$ Module is functioning correctly.**
  - **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.**
  - **Leaks or internal venting of sampled gas can affect accuracy. If accuracy is in doubt, send the device to biomedical engineering for investigation and/or repair (see *Measurement Accuracy* on page *320*).**

Microstream™ Disposable

WARNING

- **Follow Microstream™ disposable precautions:**
  - **Before use, read the Microstream™ disposable user manual, including all warnings, cautions, and instructions.**
  - **Use only Microstream™ disposables. Use of a disposable other than those specified can cause improper $EtCO_2$ Module performance, resulting in inaccurate readings.**
  - **The Microstream™ disposables are designed for single patient use and are not to be reprocessed.**
  - **Do not use a connector or Microstream™ disposable that appears damaged.**
  - **Do not immerse or dampen the Microstream™ disposable.**
  - **Carefully locate the patient Microstream™ disposable to reduce the possibility of patient entanglement or strangulation.**

About this Chapter

WARNING

Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System.

CAUTION

Rx Only: Prescription use only.

This section of the user manual provides $EtCO_2$ Module (model 8300) instructions and information. It is used in conjunction with:

- $EtCO_2$ Module technical service manual
- Alaris™ $EtCO_2$ Module 8300 compatibility card
- Medtronic's Microstream™ disposable instructions
- PCU chapter of this manual (see *About this Chapter* on page *8*)
- System Maintenance software (and its instructions) for system check-in, maintenance, and configurations for connecting the PCUs to the wireless network

The $EtCO_2$ Module is a capnograph that provides continuous, noninvasive monitoring of end-tidal carbon dioxide ($EtCO_2$), fractional inspired carbon dioxide ($FiCO_2$) and respiratory rate (RR). The end-tidal gas reading is calculated as a maximum value. The recommended setting and factory default is a 20 second window. The window defines the maximum measured $EtCO_2$ and the minimum measured $FiCO_2$.

The $EtCO_2$ Module and disposables can be used with intubated and nonintubated patients; it is not for direct connection to ventilator or breathing systems. Clinical functions will only be provided to one $EtCO_2$ Module at a time.

The $EtCO_2$ Module is used with Medtronic's patented Microstream™ disposables/circuits for sidestream capnography. The Microstream™ $EtCO_2$ sampling lines deliver a sample of the inhaled and exhaled gases from direct contact to the patient via an oral/nasal cannula into the monitor for CO_2 measurement.

If calibration is required, all gases should be used in a well ventilated area. Follow your hospital's protocol for disposal of sampled, calibrated, or unused gases. If no hospital protocol exists, follow local regulations for the disposal of gases.

The $EtCO_2$ Module is not rated for defibrillation use. Disconnect the device from the patient prior to defibrillation.

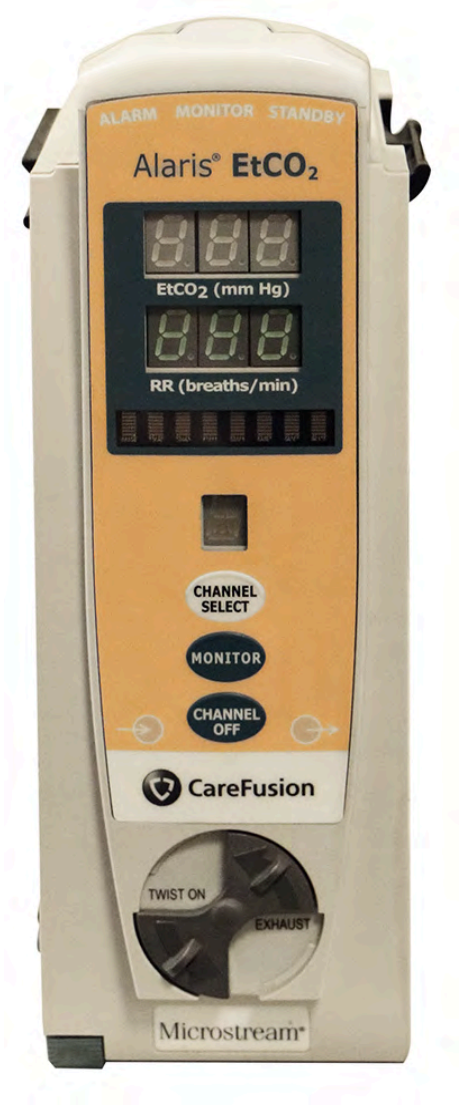
The $EtCO_2$ Module is not to be used as an apnea monitor.

NOTE:
Do not connect a gas scavenging system to the exhaust port on the $EtCO_2$ Module. The $EtCO_2$ Module should not be used in the presence of anesthetic gases.

Alaris™ $EtCO_2$ Module

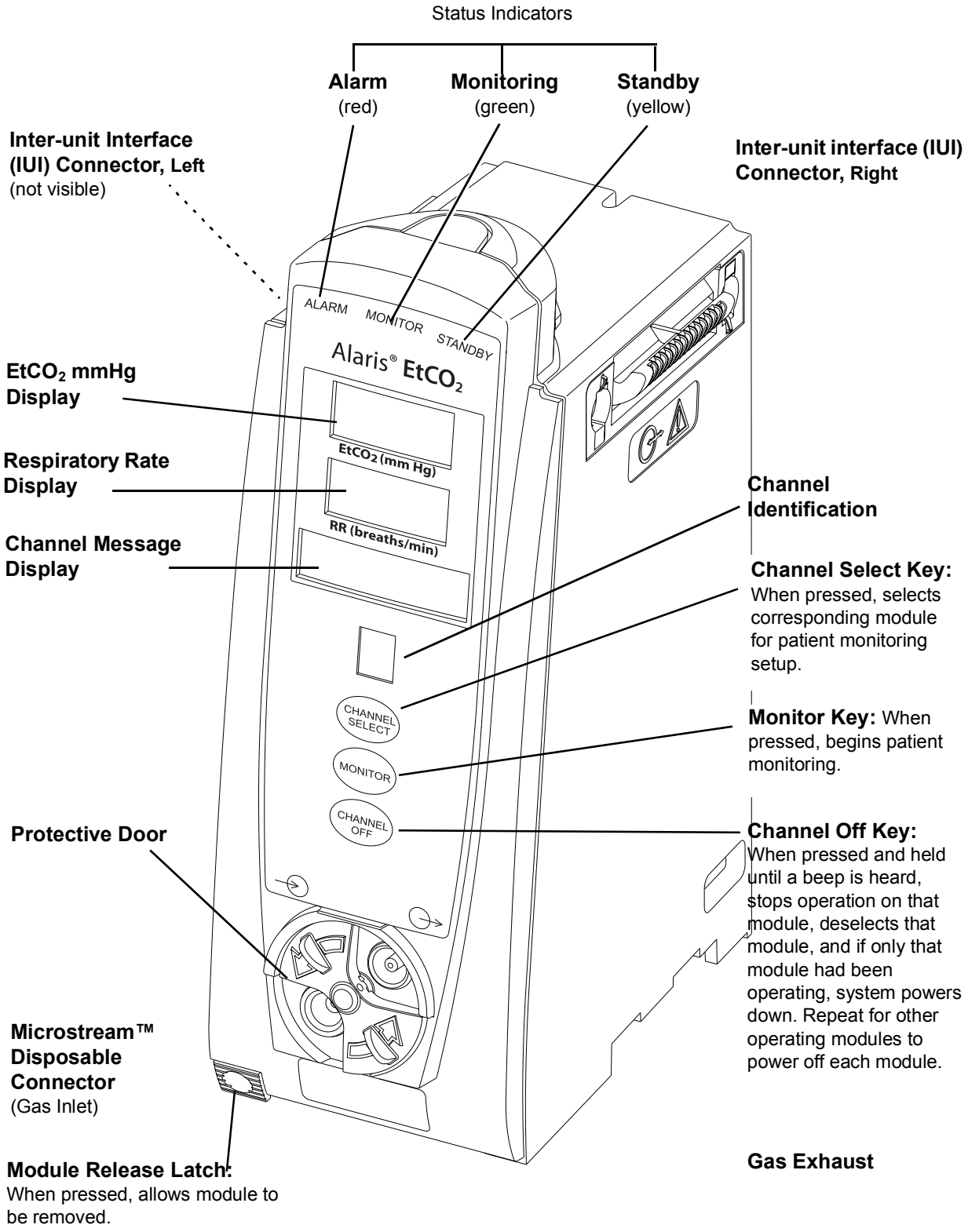
The $EtCO_2$ Module is a capnograph that provides continuous, noninvasive monitoring of end-tidal carbon dioxide ($EtCO_2$), fractional inspired carbon dioxide ($FiCO_2$) and respiratory rate (RR).

The Alaris™ $EtCO_2$ Module is shown below.



Alaris™ $EtCO_2$ Module

Operating Features, Controls, and Indicators



Features and Definitions

See *Features and Definitions* on page *12* for system features and definitions.

Feature	Definition
BPM	Breaths per minute.
Capnography Waveform	Real-time graphical display of CO_2 concentration throughout respiration.
Data Display	Waveforms, trended data, and numerical values are displayed.
$EtCO_2$	CO_2 concentration in mmHg at end of exhalation.
$FiCO_2$	Fractional-inspired CO_2; CO_2 concentration present during inhalation.
Limit Mode	Configurable mode that can be set to display either adult or neonatal monitoring mode. (See *Configurable Settings* on page *317* for additional configurable features.)
Microstream™ Disposable	Medtronic's line of Microstream™ disposables are available for neonatal, pediatric, and adult patients. Patients can be intubated or nonintubated.
Programmable Alarm Limits	Alarm limits for $EtCO_2$, $FiCO_2$, respiration rates, and no breath time periods are programmable.
Respiratory Rate	Patient's respiratory rate in breaths per minute (breaths/minute).
Trend Data	Tabular display of $EtCO_2$ and respiratory rate. Display shows average, high, and low values, and alarm conditions for time period displayed. Up to 24 hours of data is stored.

Microstream™ Disposables

WARNING

- **Follow Microstream™ disposable precautions:**
  - **Before use, read the Microstream™ disposable user manual, including all warnings, cautions, and instructions.**
- **Use only Microstream™ disposables. Use of a disposable other than those specified can cause improper $EtCO_2$ Module performance, resulting in inaccurate readings.**
- **The Microstream™ disposables are designed for single patient use and are not to be reprocessed.**
- **Do not use a connector or Microstream™ disposable that appears damaged.**
- **Do not immerse or dampen the Microstream™ disposable.**
- **Carefully locate the patient Microstream™ disposable to reduce the possibility of patient entanglement or strangulation.**

Compatible Microstream™ Disposables

WARNING

Use only Microstream™ disposables. Use of a disposable other than those specified can cause improper $EtCO_2$ Module performance, resulting in inaccurate readings.

When selecting a Microstream™ disposable, consider the patient's weight, condition, and intubation status. For more information on Microstream™ disposables, contact Medtronic at http://www.medtronic.com.

The compatible Microstream™ disposables used with the Alaris™ $EtCO_2$ Module are shown in the table below. Refer to bd.com/Infusionlibrary for the current list of compatible Microstream™ disposables. To locate the compatibility list on the BD website, enter **compatible disposables** in the search field.

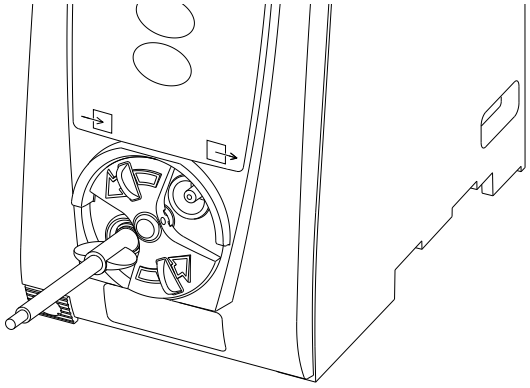
NOTE:
H denotes enhanced humidity control for longer term use.

$EtCO_2$ Microstream™ Filter Line Description
Microstream™ Non-Intubated Patients, Long-Term Use
Adult Smart CapnoLine® H Plus: Pain Management, Surgical GCF, Critical Care
Pediatric Smart CapnoLine® H: Pain Management, Surgical GCF, Critical Care
CapnoLine® H: When nasal sampling is preferred
Microstream™ Non-Intubated Patients, Short-Term Use
Adult Smart CapnoLine® Plus: Procedural Sedation, Pain Management, OR, EMS, ED, Rapid Response
Pediatric Smart CapnoLine®: Procedural Sedation, EMS, ED, Rapid Response
Smart CapnoLine® Guardian System: Procedural Sedation, including Upper Endoscopy, Bronchoscopy
O2/CO2 Nasal FilterLine®: When nasal sampling is preferred
Nasal/NIV Line™: EMS, ED
Microstream™ Intubated Patients, Long-Term Use
Adult/Pediatric FilterLine® H Set: Critical Care, humidified environments
Adult/Pediatric VitaLine™ H Set: Critical Care, high ambient humidity
FilterLine® H Set for Infant/Neonates: Critical Care, humidified environments
VitaLine™ H Set for Infant/Neonates: Critical Care, humidity controlled incubators
Microstream™ Intubated Patients, Short-Term Use
FilterLine Set for Infant/Neonates: OR, EMS, ED, Rapid Response, Transport Team

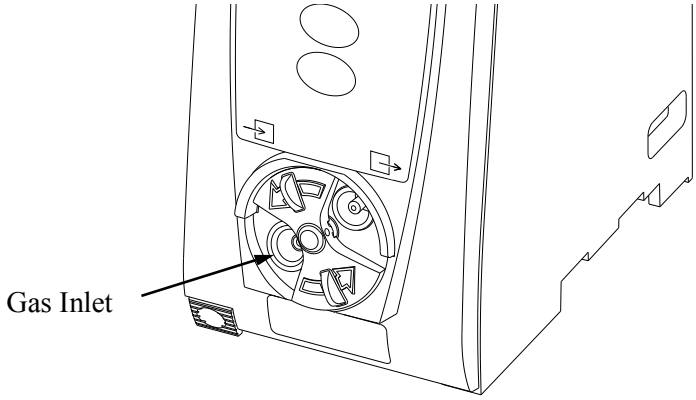
Connecting Microstream™ Disposable

1. Open gas inlet/outlet door by turning door counterclockwise until gas inlet is clearly visible. Hold in open position.

   Gas inlet is located on lower left corner of instrument and is marked with a gas inlet symbol ( ).

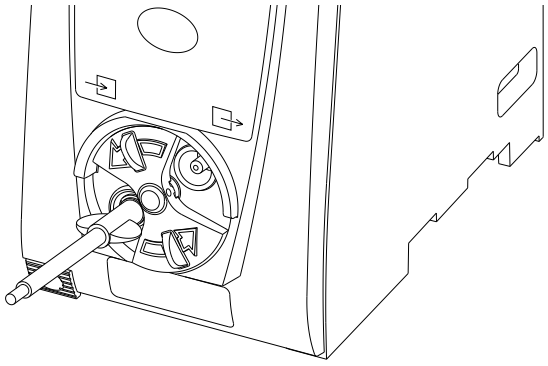


Closed Position



Open Position

2. Connect Microstream™ disposable:
   a. Press brightly colored end of disposable into gas inlet.
   b. Turn it clockwise until tightly secured to $EtCO_2$ 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 disposables user manual).

NOTE:
The Medtronic™ disposable may be used with 5 liters of oxygen with a nasal cannula. This disposable is not intended to be used with high flow oxygen through a nasal cannula. The use of a mask with high flow oxygen is recommended. Two nasal cannulas should not be used at one time.

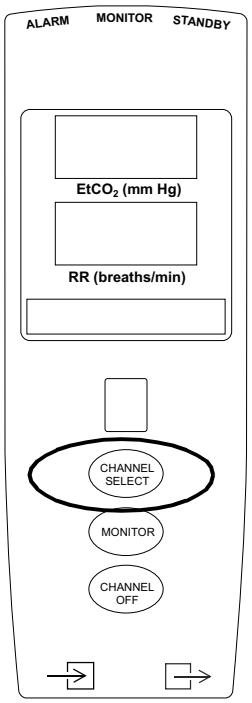
Programming

Display references throughout this procedure are for illustration purposes only.

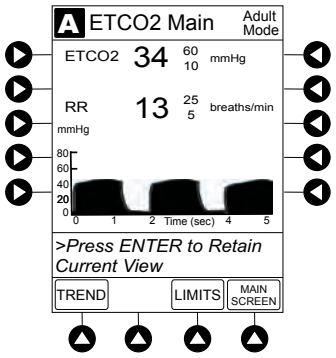
Monitoring Mode

1. Perform the following steps (see *About this Chapter* on page *8*, *Initial Setup* on page *14*, and *Powering On the System* on page *17* for more information):
   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 *About this Chapter* on page *300*).
3. Press **CHANNEL SELECT** key.

   SENSOR WARMING and then **SEARCHING** appear in Channel Message display until $EtCO_2$ and respiratory rate readings stabilize (up to **60** seconds).



4. Alarm limits:
   - To change settings, see *Setting Alarm Limits* on page *308*.
   - To accept settings and begin monitoring, press **ENTER** key.

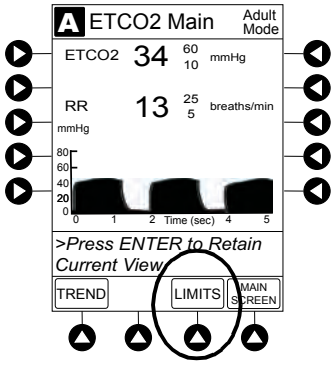


ETCO2 Main screen displays following information:
- Capnography waveform (scale adjustable).
- $EtCO_2$ value, as well as minimum and maximum $EtCO_2$ alarm limits.
- Limit Mode (Adult or Neonatal).
- Respiratory rate (RR, breaths/min), as well as minimum and maximum RR alarm limits.

NOTE:
PC unit display response time is approximately ½ second longer than the $EtCO_2$ Module response time.

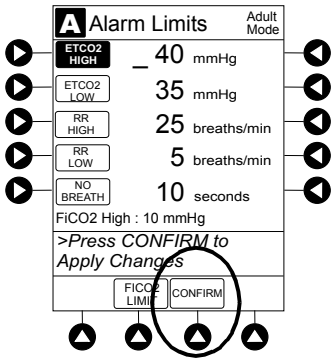
Setting Alarm Limits

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.

Instructions for Patient Use of $EtCO_2$ Oral/Nasal Cannula (Microstream™ Disposable)

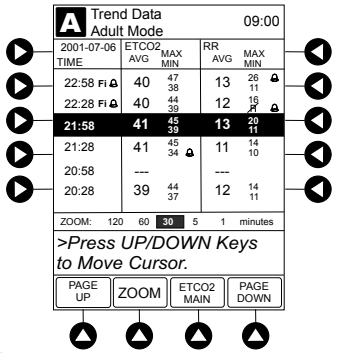
Ensure a responsible adult is present when communicating to a pediatric patient how to use the $EtCO_2$ oral/nasal cannula.

The clinician should consider communicating the following information to the patient when using the $EtCO_2$ cannula.

- The cannula monitors breathing (respiration).
- Remove cannula only when instructed.
- Closely monitoring respiration is important due to possible over-sedation.

Navigating Trend Data

1. To view Trend Data, press **TREND** soft key.



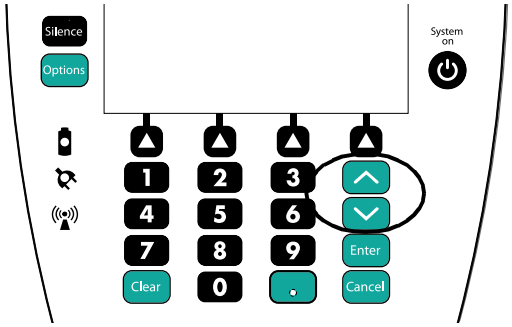
The following information is displayed:

- **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 $FiCO_2$ 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 $EtCO_2$ or respiratory rate values are available for time period displayed.

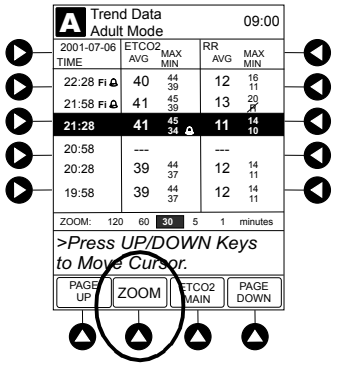
Tabular information is not updated while **Trend Data** view is displayed. Tabular data is updated, using new trend data stored in the $EtCO_2$ Module, after leaving **Trend Data** view. To view latest data, return to **Trend Data** view.

2. To navigate from page to page, press **PAGE UP** and **PAGE DOWN** soft keys.

3. To scroll data one row at a time, press ⌃ ⇧ or ⌄ ⇩ key.



4. To change the **TIME** increments for data review, move the cursor to the desired time period and press the **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.

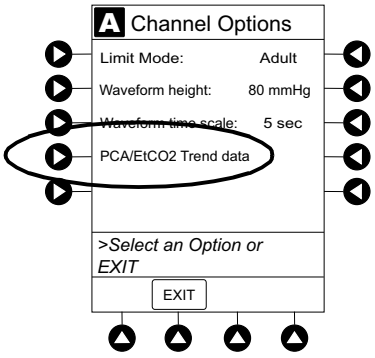
Navigating PCA Module/$EtCO_2$ Module Trend Data

To access and view shared trend data when a PCA Module is present, perform the following steps.

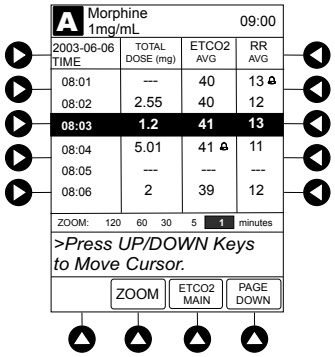
1. To view **ETCO2 Main** display, press **CHANNEL SELECT** key.
2. To access option to view trend data, press **OPTIONS** key.
3. To view **Trend Data**, press **PCA/ETCO2 Trend data** soft key.

   The following information is displayed:

   - **TIME** period for data review.
   - Average $EtCO_2$.
   - Average respiratory rate (**RR**).
   - Alarm icon (🔔).
   - **TOTAL DOSE** of medication infused through PCA Module (includes continuous Infusion, loading dose, bolus, and PCA dose).



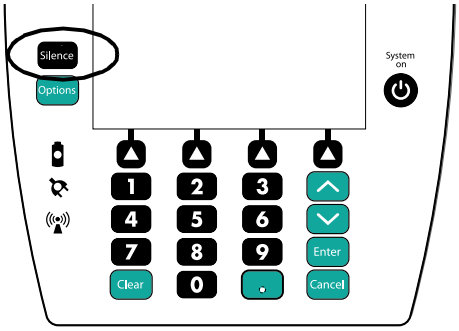
4. See *Navigating Trend Data* on page *310* for instructions on how to:
   - Navigate from page to page.
   - Change **TIME** increments.
   - Return to **ETCO2 Main** display.
   - Return to Main Display.



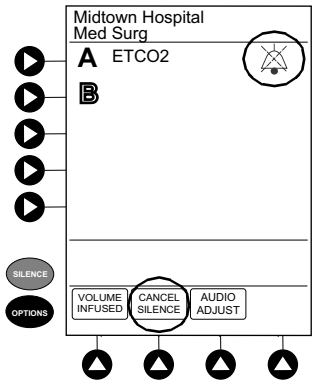
Presilencing Alarm

1. To presilence alarm, press **SILENCE** key.

   All monitoring alarms are silenced for 2 minutes and a Monitoring Alarm Silence symbol is displayed on the PCU main screen. Subsequent infusion alarms are not silenced.



2. To cancel pre-silence alarm and return to alarmable mode:
   - Press **CANCEL SILENCE** soft key.

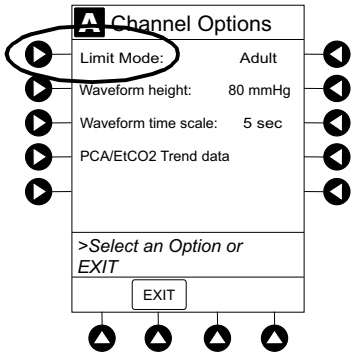


Channel Options

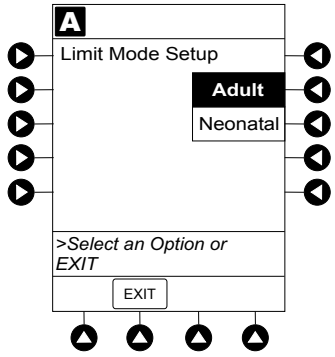
Changing Limit Mode

The following procedure can be performed only when the Guardrails™ Suite MX is not enabled (profile option not being used for programming).

1. Press the **Limit Mode** soft key.

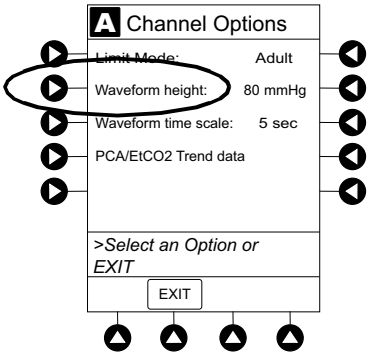


To change **Limit Mode Setup**, press applicable soft key.
or
To leave **Limit Mode Setup** unchanged and return to **ETCO2 Main** display, press **EXIT** soft key.

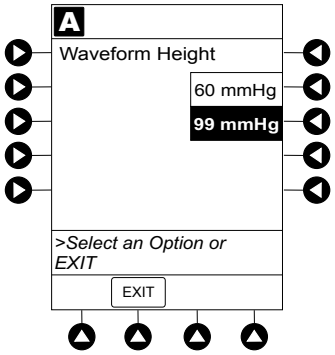


Changing Waveform Height

1. Press **Waveform height** soft key.



2. To change Waveform Height, select applicable range limit.

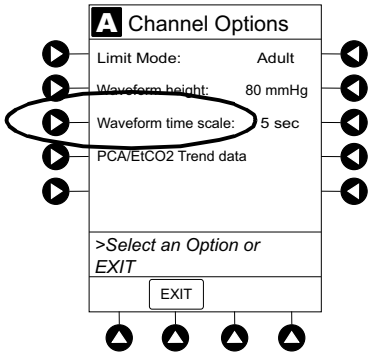


   - **60 mmHg:** Displays a waveform for $EtCO_2$ values within 0 – 60 mmHg range. If $EtCO_2$ value exceeds that range, **Waveform Out of Range; Adjust Scaling** message is displayed until waveform falls back into range or 0 – 99 mmHg option is selected.
   - **99 mmHg:** Displays a waveform for full $EtCO_2$ value range, 0 – 99 mmHg.

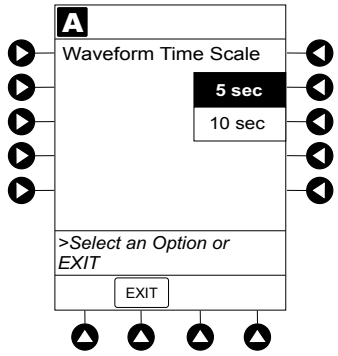
3. To return to **ETCO2 Main** display, press **EXIT** soft key.

Changing Waveform Time Scale

1. Press **Waveform time scale** soft key.



2. To change **Waveform Time Scale**, select applicable time scale.
   OR
   To leave **Waveform Time Scale** unchanged and return to **ETCO2 Main** display, press **EXIT** soft key.



System Start-Up/Setup

Displays

The displays illustrated throughout this document are for illustration purposes only. The display content varies, depending on configuration settings, type of disposable in use, hospital-defined data set uploaded using the Guardrails™ Suite MX, programmed parameters, and many other variables.

Configurable Settings

See *Features and Definitions* on page *12* 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 BD technical support, for technical, troubleshooting, and preventive maintenance information. Please use the facility's best practices guidelines on the preferred alarm settings for the monitoring of patients that are not continuously attended by a clinician.

NOTE:
When a Guardrails™ data set is enabled in the PCU the Guardrails™ data set overrides all configuration settings.

With the profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best-practice data set must be uploaded to enable the profiles feature. Date and time is a system setting and is the same in all profiles.

Feature	Default Setting	Options
$EtCO_2$ Alarm Limit, High	Adult: 60 mmHg Neonatal: 60 mmHg	5 - 99 mmHg
$EtCO_2$ Alarm Limit, Low	Adult: 10 mmHg Neonatal: 10 mmHg	0 - 98 mmHg
$FiCO_2$ Alarm Limit, High	Adult: 8 mmHg Neonatal: 8 mmHg	2 - 99 mmHg
Limit Mode	Adult	Adult or Neonatal
No Breath Alarm	Adult: 30 seconds Neonatal: 20 seconds	10 - 60 seconds
Respiratory Rate Alarm Limit, High	Adult Mode: 35 bpm Neonatal Mode: 80 bpm	1 - 150 bpm
Respiratory Rate Alarm Limit, Low	Adult Mode: 6 bpm Neonatal Mode: 12 bpm	0 - 149 bpm

Specifications and Symbols

Accuracy: $EtCO_2$ readings

CO_2 Partial Pressure (at sea level)	Accuracy
0 - 38 mmHg	±2 mmHg
39 - 99 mmHg	± (5% of reading + 8% for every 1 mmHg above 38 mmHg)

NOTE:
Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12% of reading whichever is greater, for $EtCO_2$ values exceeding 18 mmHg. This is tested by Medtronic according to and is compliant with ISO 80601-2-55. To achieve the specified accuracies for breath rates above 60 breaths/minute, the Microstream™ FilterLine™ H Set for Infant/Neonatal must be used. Above 55ºC module temperature, ± 1mmHg or ± 2.5%, whichever is greater, has to be added to the tolerance of the accuracy specifications.

The accuracy specification is maintained to within 4% of the values in the presence of interfering gases.
Above 55°C 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:

	Low	High
$EtCO_2$	0 - 98 mmHg	5 - 99 mmHg
$FiCO_2$	Not Applicable	2 - 99 mmHg
No Breath	10 - 60 sec	Not Applicable
Respiration Rate	0 - 149 breaths/min	1 - 150 breaths/min

Alarms: Audible and visual alarms for high and low $EtCO_2$ and respiratory rate, high $FiCO_2$, Microstream™ disposable condition, system failure, no breath, and low battery conditions.

Barometric Pressure: $EtCO_2$ Module is equipped with automatic barometric pressure compensation. There are no quantitative effects of barometric pressure for this device.

CO_2 Range: Measures and reports partial pressures of CO_2 in the range of 0 - 99 mmHg at sea level. $EtCO_2$ and $FiCO_2$ values are calculated for all valid breaths.

Dimensions: 3.3" W x 8.9" H x 5.5" D
(8.4 cm W x 22.6 cm H x 14 cm D)

Environmental Conditions:

Symbol	Meaning	Operating	Storage/ Transport
	Atmospheric Pressure	525 - 795 mmHg (70 - 106 kPa)	375 - 760 mmHg (50 - 101 kPa)
	Relative Humidity (Avoid prolonged exposure to relative humidity >90%)	20 - 90% Noncondensing	5 - 90% Noncondensing
	Temperature Range	41 - 104°F (5 - 40°C)	-4 - 140°F (-20 - 60°C)

Fluid Ingress Protection: IPX2, Drip Proof

Gas Interference: The following liquid anesthetics have been tested and were found to have no effect:

- Desflurane
- Enflurane
- Halothane
- Isoflurane

Sevoflurane

Internal Power Source: Operating time (fully charged): 5.5 hours

Measurement Range:

$EtCO_2$:	0 - 99 mmHg
$FiCO_2$:	0 - 99 mmHg
Respiratory Rate:	0 - 150 bpm

Mode of Operation Continuous

Sampling Gas Flowrate: Nominally 50 mL/min + 15 mL/min, -7.5 mL/min

Shock Protection: Type BF

Total System Response Time: $EtCO_2$ Module response: 4.9 seconds typical (includes rise time of 260 msec maximum)

Warm-Up Time: 30 seconds typical

Waveform Sampling: 20 samples/s

Weight: 2.5 lbs (1.13 kg)

NOTE:
The periodic auto zero function compensates for drifts between components, changes in ambient temperature and barometric conditions. This automatic process eliminates variances that might otherwise cause measurement drift. Therefore the module does not exhibit drift.

Measurement Accuracy

The $EtCO_2$ 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.

WARNING

- **Follow $EtCO_2$ monitoring precautions:**
  - **The $EtCO_2$ Module is not intended for use with high frequency surgical equipment such as, electrical cautery devices. Use of the $EtCO_2$ Module in this manner can cause improper performance.**
- **Do not use the $EtCO_2$ Module or Microstream™ disposable inside a hyperbaric chamber.**
- **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**
- **Leaks or internal venting of sampled gas can affect accuracy. If accuracy is in doubt, send the device to biomedical engineering for investigation and/or repair.**

An inaccurate $EtCO_2$ measurement can be caused by:

- Incorrect disposable application or use.
- Microstream™ disposable disconnected or not securely connected to the $EtCO_2$ Module.
- Airway connection clogged, twisted, or leaking.
- Placement too close to high frequency surgical equipment such as electrocautery devices.
- 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 the $EtCO_2$ Module.
- Airway connection clogged, twisted, or leaking.
- Patient not breathing.
- Placement too close to high frequency surgical equipment such as electrocautery devices.

Respiration Rate Test

The following test method is used to determine the module's rated respiration rate range and the corresponding effects of end-tidal gas readings accuracy as a function of respiratory rate:

- The system is set for operation.
- The power connection is verified.
- The module is connected to the PCU and power supply.
- A scope is connected to the digital/analog multifunction I/O.
- A digital output scheduler software is opened on the PC.
- Gas connections are checked.
- The power connection is verified.
- The gas mixes cylinders are open, set on the required pressure, and their condition is verified.
- A BPM setting is selected.
- The module is connected to the gas tube.
- The module is disconnected.

NOTE:
When CO_2 waveforms are generated the CO_2 reading line increases in height and then returns to the selected baseline rate (BPM).

Test Action	Expected Results	
Measure Accuracy/RR Tolerance mmHg / bpm for Adult/Pediatric FilterLine™ Sets at respiration rates of 10, 40, and 60 bpm.	10 bpm	±2mmHg/±1bpm
	40 bpm	±2mmHg/±1bpm
	60 bpm	±2mmHg/±1bpm
Measure CO_2 (mmHg) / RR (bpm) for Adult/Pediatric FilterLine™ Sets at respiration rates of 10, 40, and 60 bpm.	**CO_2 Partial Pressure**①	**Accuracy**②
	0-38 mmHg	± 2 mmHg
	39-99 mmHg	± (5% of reading + 8% for every 1 mmHg above 38 mmHg)
Measure Accuracy/RR Tolerance mmHg / bpm for Infant/Neonatal FilterLine™ H sets at respiration rates of 60, 80, 120 and 150 bpm.	60 bpm	±2mmHg/±1bpm
	80 bpm	±2mmHg/±2bpm
	120 bpm	±4.1mmHg/±2bpm
	150 bpm	±4.1mmHg/±3bpm
Measure CO_2 (mmHg) / RR (bpm) for Infant/Neonatal FilterLine™ H Sets at respiration rates of 60, 80, 120 and 150 bpm.	**CO_2 Partial Pressure**①	**Accuracy**②
	0-38 mmHg	± 2 mmHg
	39-99 mmHg	± (5% of reading + 0.08 for every 1 mmHg above 38 mmHg)

NOTE:

- ①At sea level.
- ②Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12% of reading whichever is greater, for $EtCO_2$ values exceeding 18 mmHg. This is tested according to and is compliant with ISO 80601-2-55. To achieve the specified accuracies for breath rates above 60 breaths/minute, the Microstream™ FilterLine™ H Set for Infant/Neonatal must be used.

Waveform Analysis

The $EtCO_2$ Module provides the option to display $EtCO_2$ Module readings as a waveform. The following graph is an example of a normal waveform (normal ventilation, 35 - 45 mmHg). In the event the $EtCO_2$ value is above the waveform display range, the top of the waveform will be clipped. Numerical $EtCO_2$ values continue to be displayed on both the $EtCO_2$ Module and PCU.

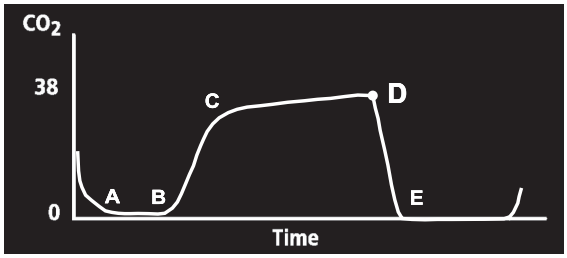
A–B baseline period of no CO_2; end of inhalation

B–C rapid rise in CO_2

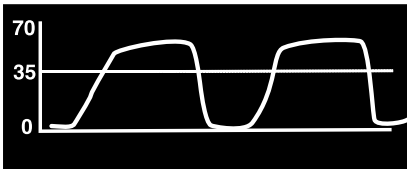
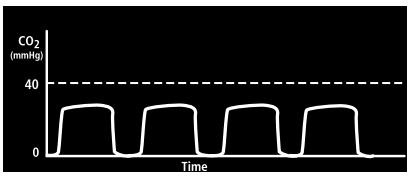
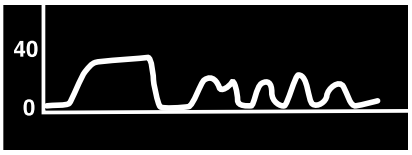
C–D alveolar plateau

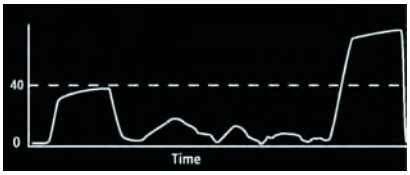
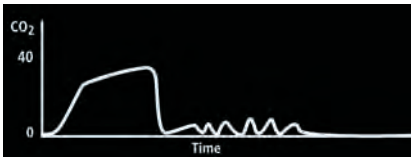
D end of expiration; end-tidal CO_2 ($EtCO_2$)

D–E inhalation



Waveforms can be used to troubleshoot problems with equipment or monitor configuration, as well as to monitor a patient's clinical status. The following graphs are examples of common problems identifiable through waveform analysis. These are examples only and do not represent all potential abnormal waveforms. Abnormal waveforms are not always associated with alarms.

Waveform	Possible Causes
Hypoventilation 	• Overmedication
Hyperventilation 	• Respiratory distress
Partial Airway Obstruction 	• Relaxation of upper airway • Head position

Waveform	Possible Causes
Hypoventilation with Shallow Breathing 	• Medication effect • Low tidal volume
No Breath Detected 	• Apnea • Very shallow breathing • Overmedication • Displaced cannula

Principle of Operation

The $EtCO_2$ Module uses Medtronic's patented Microstream™ nondispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO_2 during every breath, the amount of CO_2 present at the end of exhalation ($EtCO_2$) and during inhalation ($FiCO_2$), and the respiratory rate. The $EtCO_2$ 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 (using an oral/nasal cannula) into the monitor for CO_2 measurement. Moisture and patient secretions are extracted from the sample by the Microstream™ inline filter while maintaining the shape of the CO_2 waveform.

The 50 mL/min sampling gas flowrate reduces liquid and secretion accumulation, decreasing the risk of obstruction in the sample pathway in humid ICU environments. The small sample size eliminates the need for water traps and prevents excess fluid accumulation.

The $EtCO_2$ 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 260 ms and accurate CO_2 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 CO_2 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 $EtCO_2$ Module calculates the CO_2 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 $EtCO_2$ Module and Microstream™ disposables, humidity has no quantitative effect on the CO_2 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 $EtCO_2$ Module's operating specifications, the $EtCO_2$ Module presents a Remove Blocked Disposable message.

Due to the relatively small sampling size needed for $EtCO_2$ readings, partial pressure does not affect the ability of the $EtCO_2$ Module to measure $EtCO_2$, 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 disposables 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 $EtCO_2$ 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:

BTPS (body temperature, pressure, saturation assumed 37°C, 47 mmHg) calculations are made according to:
$PCO_2 = FCO_2 \times (Pb - 47)$

Where:
FCO_2 is fractional concentration of CO_2 in dry gas and
$FCO_2 = \% CO_2/100$.
Pb is ambient pressure.
PCO_2 is partial pressure of CO_2 at BTPS.

Chapter 5
Alaris™ Auto-ID Module Model 8600

This chapter contains the following topics:

Summary of Warnings and Cautions

General

WARNING

- **Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System (see *About this Chapter* on page *329*).**
- **The BD Alaris™ System is not intended to replace supervision by medical personnel.**
- **Use only the Auto-ID Handheld Scanner supplied by BD. Using other accessories can cause improper device operation (see *Associating PCU with New Patient ID* on page *334* and *Alaris™ Auto-ID Handheld Scanners* on page *333*).**
- **Carefully locate the Auto-ID Handheld Scanner to reduce the possibility of patient entanglement or strangulation.**
- **Always verify that information displayed on the PCU matches scanned data (see *Associating PCU with New Patient ID* on page *334*, *Associating PCU with Patient ID While Infusion is in Progress* on page *336*, *Programming a Primary Infusion Using Auto-ID* on page *338*, and *Programming a Secondary Infusion Using Auto-ID* on page *339*).**

CAUTION

- Class 1 LED devices are safe under reasonably foreseeable conditions of operation. To avoid potential harm do not stare into the beam or allow to strike a person's face (see *Alaris™ Auto-ID Handheld Scanners* on page *333*).

Electrical

WARNING

- **Do not open the Auto-ID Handheld Scanner case. If the case is opened, there is an electrical shock hazard and possible exposure to potentially hazardous LED light exists, which can result in serious personal injury and device damage (see *Alaris™ Auto-ID Handheld Scanners* on page *333*).**

About this Chapter

WARNING

Proper operation of the BD Alaris™ System requires that you are familiar with related features, setup, programming, IV sets, and accessories. Read all instructions, including those for all attached module(s) before using the BD Alaris™ System.

CAUTION

Rx Only: Prescription use only.

This section of the user manual provides Auto-ID Module (model 8600) instructions and information. It is used in conjunction with:

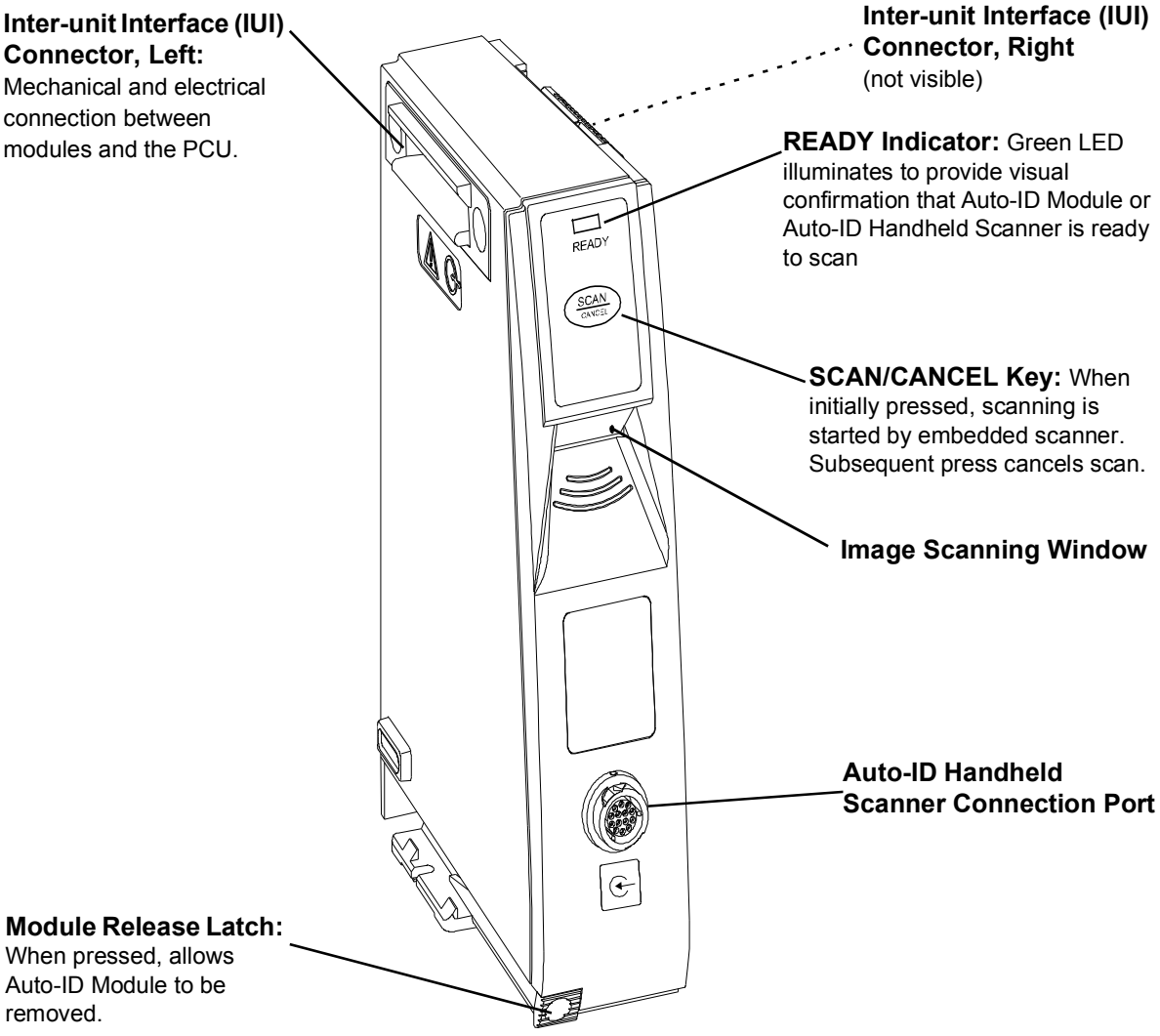
- *Auto-ID Label Guidelines*
- *Technical Service Manual Alaris™ Auto-ID Module, Model 8600*
- Module-specific chapters of this user manual
- PCU chapter of this manual (see *About this Chapter* on page *8*)
- System maintenance software (and its instructions) for system check-in, maintenance, and configurations for connecting the PCUs to the wireless network

Alaris™ Auto-ID Module

The Auto-ID Module contains an internal barcode image scanner and supports an optional Alaris™ Auto-ID Handheld Scanner supplied by BD. Scanning a barcoded clinician ID unlocks the PCU panel when authorized user mode is enabled and associates CQI event logs with the clinician. Scanning a barcoded patient identification band associates the CQI event logs with the patient. Scanning a barcoded IV fluid or medication allows for the specific fluid or medication and concentration to be automatically selected from the drug library for any of the infusion modules (Pump, Syringe, and PCA Modules). Although multiple Auto-ID Modules may electrically connect, only one module will have Auto-ID functionality. Auto-ID may be added to the PCU with any combination of one to four other modules.

The Alaris™ Auto-ID Module is shown below.

Operating Features, Controls, and Indicators



Features and Definitions

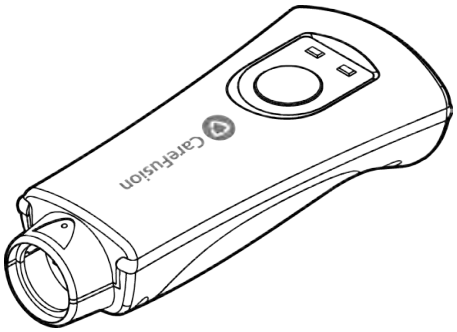
See *Features and Definitions* on page *12* for system features and definitions.

Feature	Definition
Audible Scan Indicator	Provides audible confirmation of a successful scan.
Barcode	A machine-readable label used for automatic identification. Automatic identification (Auto-ID) is the broad term given to a host of technologies used to help machines identify objects and is often coupled with automatic data capture. These technologies include barcodes, smart cards, voice recognition, some biometric technologies (for example, retinal scans), optical character recognition, and others.
Built-In Optical Scan Engine	Employs technology similar to a digital camera to read barcodes. Allows use of two-dimensional barcodes.
Auto-ID Handheld Scanner with Optical Scan Engine	Allows scanning of patient ID, and of IV containers that have already been hung on IV pole.
Light Emitting Diode (LED)	Barcode scanner uses an array of high intensity LEDs to illuminate barcode image (see *Specifications and Symbols* on page *340*).
Two-Dimensional Barcode	Can contain more information and is more easily read by Auto-ID Module; for example, patient ID and drug ID can be in same barcode.

Alaris™ Auto-ID Handheld Scanners

The Auto-ID Handheld Scanners supplied by BD are the only handheld scanners approved for use with the Auto-ID Module.

1st Generation Scanner



2nd Generation Scanner

WARNING

- **Do not open the Auto-ID Handheld Scanner case. If the case is opened, there is an electrical shock hazard and possible exposure to potentially hazardous LED light exists, which can result in serious personal injury and device damage.**
- **Use only the Auto-ID Handheld Scanner supplied by BD. Using other accessories can cause improper device operation.**

CAUTION

Class 1 LED devices are safe under reasonably foreseeable conditions of operation. To avoid potential harm do not stare into the beam or allow to strike a person's face.

Patient Identification (ID)

Associating the PCU with a patient links the specific patient to the infusions being delivered from the modules attached to that PCU.

Associating PCU with New Patient ID

WARNING

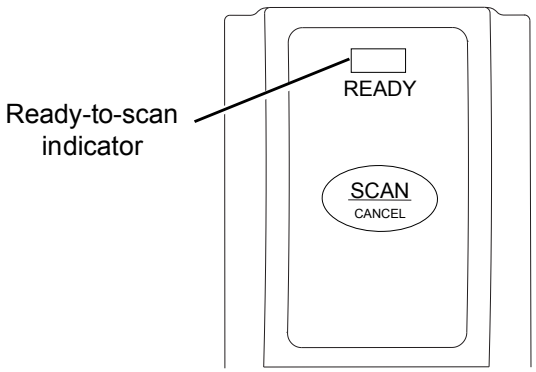
Use only the Auto-ID Handheld Scanner supplied by BD. Using other accessories can cause improper device operation.

1. Attach Auto-ID Handheld Scanner to connection port on Auto-ID Module. Ensure a secure connection.
2. Power on PCU.
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.

NOTE:
Automatic display of **Patient ID Entry** screen should be enabled in the System Configuration settings.



6. To scan barcode on patient identification band, press scan trigger on Auto-ID 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 barcode is scanned at main screen and panel is unlocked, a prompt to confirm type of barcode scanned appears. This occurs whether Authorized User Mode is enabled or disabled.

   NOTE:

   - If the patient ID is not entered at this time, it can still be entered later.
   - Patient ID can be entered manually using the PCU keypad (see *Entering Patient ID* on page *26*).

WARNING

Always verify that information displayed on the PCU matches scanned data.

7. To unlock panel, clinician's ID must be scanned.

1st Generation Scanner

2nd Generation Scanner

NOTE:
There is a prompt to accept or decline the change of patient ID if it is different from the patient ID already associated to the PCU.

Associating PCU with Patient ID While Infusion is in Progress

You can associate the PCU with a patient ID when the patient ID screen is not shown.

1. Attach Auto-ID Handheld Scanner to connection port on Auto-ID Module. Ensure a secure connection.

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

WARNING

Always verify that information displayed on the PCU matches scanned data.

CAUTION

Class 1 LED devices are safe under reasonably foreseeable conditions of operation. To avoid potential harm do not stare into the beam or allow to strike a person's face.

2. To scan barcode on patient identification band, press scan trigger on Auto-ID Handheld Scanner.

   If scan is successful, an audible tone sounds and patient ID appears on Main Display.

   NOTE:
   Patient ID can be entered manually using the PCU keypad (see *Entering Patient ID* on page *26*).

NOTE:
There is a prompt to accept or decline the change of patient ID if it is different from the patient ID already associated to the PCU.

Authorized User Mode

Authorized user mode is a feature that:

- Combines PCU tamper resist feature with Auto-ID application.
- Is designed to ensure that only clinicians with a barcode on their ID badge can program the system.
- Is available only if it is enabled in selected profile and there is an Auto-ID Module attached.

When the authorized user mode feature is enabled, the PCU automatically enables the tamper resist mode on 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 PCU) for 3 - 4 seconds.

To unlock the keypad, the user must scan their ID badge or use the **OPTIONS** menu to manually input their ID number. When a questionable barcode is scanned at the main screen and the keypad is unlocked, a prompt to confirm the type of barcode scanned appears. This occurs whether the authorized user mode is enabled or disabled.

To use the system with authorized user mode enabled:

1. Power on system and associate patient ID (see *Patient Identification (ID)* on page *334* for the specific procedure).

   Upon successful entry of patient ID, PCU automatically enables tamper resist feature.
2. To disable tamper resist, press **SCAN/CANCEL** key on the Auto-ID Module or the **SCAN** trigger on Auto-ID Handheld Scanner and scan clinician ID badge.

   In a very low battery condition, with less than 5 minutes of battery time remaining, Auto-ID Handheld Scanner is disabled. In this situation, disable tamper resist by pressing tamper resist switch on back of PCU for approximately 2 seconds.
3. Program infusion.

   When no keys have been pressed on PCU for a 5-minute period, tamper resist mode is automatically enabled.

NOTE:
There are three events that make the Authorized User Mode unavailable: a channel error, system error, or a discharged battery alarm.

Programming a Primary Infusion Using Auto-ID

Using the Auto-ID Module to scan IV medication containers provides the ability to select the correct medication and drug amount/diluent volume from the drug library, and enhances safety through the use of the Guardrails™ Suite MX. It compares the medication identifier from the IV container barcode with the medication identifier from the drug library. If the patient ID is in the IV container barcode, the system also compares the patient identifier in the barcode with the patient identifier in the PCU, only if a patient ID is programmed into the PCU.

NOTE:
There is a prompt to accept or decline the change of patient ID if it is different from the patient ID already associated to the PCU.

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

NOTE:
Auto-ID Module green **READY** scan light on the Auto-ID Module illuminates, indicating the screens that allow scanning. The green ready scan light **does not illuminate** when the programming steps have passed the point of being able to scan the medication.

WARNING

Always verify that information displayed on the PCU matches scanned data.

1. To scan barcode on IV container, press the **SCAN/CANCEL** key on Auto-ID Module or scan trigger on Auto-ID Handheld Scanner.

   The PCU displays the scanned medication/fluid information.
2. Press **CHANNEL SELECT** key on appropriate module.

   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 canceled.
3. The PCU displays the selected fluid, press **Yes** to confirm.
4. Program infusion (see applicable module-specific section).

Programming a Subsequent Primary Infusion Using Auto-ID

A subsequent primary infusion may be scanned with the Pump Module running if the following criteria match between the scanned label and the running infusion:

- Drug or Fluid Name (Alias or NDC)
- Drug Amount
- Drug Amount Units
- Diluent Volume

Programming a Secondary Infusion Using Auto-ID

Starting a secondary infusion while a primary infusion is in progress.

WARNING

Always verify that information displayed on the PCU matches scanned data.

1. To scan barcode on IV container, press **SCAN/CANCEL** key on Auto-ID Module or scan trigger on Auto-ID Handheld Scanner.

   The PCU displays the scanned medication/fluid information.
2. Press **CHANNEL SELECT** key on appropriate module.

   Primary infusion parameters display.
3. The PCU displays the selected medication/fluid, press **Yes** to confirm.
4. Press **Secondary** soft key.
5. Program secondary infusion (see *BD Alaris™ Pump Module Model 8100 and Alaris™ Syringe Module Model 8110* on page *49*).

Configurable Settings

If the configuration settings need to be changed from the **Factory default** settings, refer to the applicable technical service manual or contact BD technical support, for technical, troubleshooting, and preventive maintenance information.

NOTE:
When a Guardrails™ data set is enabled in the PCU the Guardrails™ data set overrides all configuration settings.

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

<table>
<tr><th colspan="2">Auto-ID Module and Auto-ID Handheld Scanner</th></tr>
<tr><td>Environmental Conditions:</td><td>
<table>
<tr><th>Symbols</th><th>Meaning</th><th>Operating</th><th>Storage/Transport</th></tr>
<tr><td>  </td><td>Atmospheric Pressure</td><td>525 - 795 mmHg
(70 - 106 kPa)</td><td>375 - 760 mmHg
(50 - 101 kPa)</td></tr>
<tr><td>  </td><td>Relative Humidity
(Avoid prolonged exposure to relative humidity >90%)</td><td>20 - 90%
Noncondensing</td><td>5 - 90%
Noncondensing</td></tr>
<tr><td>  </td><td>Temperature Range</td><td>41 - 104°F
(5 - 40°C)</td><td>-4 - 140°F
(-20 - 60°C)</td></tr>
</table>
</td></tr>
<tr><td>LED Light:</td><td>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</td></tr>
</table>

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)
Fluid Ingress Protection:	IPX2, Drip Proof
Mode of Operation:	Continuous
Shock Protection:	Type BF patient applied part.
Weight:	1.2 lbs (0.54 g)

Auto-ID Handheld Scanner	
Dimensions:	3.25" W x 7.25" H x 4.25" L (8.3 cm W x 18.4 cm H x 10.8 cm L)
Housing:	UL 94V0 flammability rating
Weight:	6.5 oz (178 g)

Symbology

The Auto-ID Module supports an optional Auto-ID Handheld Scanner that can be used to scan a patient's ID, medication labels, and clinician badges. The Auto-ID Module and Auto-ID Handheld Scanner read printed barcodes which are within the barcode print quality guidelines specified by ANSI X 3.182, CEN EN 1635, and ISO/IEC 15416 international standards. Some manufacturer-applied barcodes on IV bags are not compliant with these quality standards and might not be readable with the Auto-ID Module and Auto-ID Handheld Scanner. Refer to the *Auto-ID Label Guidelines* for more detailed barcode label information.

Errors and Messages

Alarms and Alerts: See *Appendix A, Troubleshooting and Maintenance* on page *346* for the following system references:

- Alarms and Alerts
- Audio Characteristics
- Definitions
- Display Color
- Radio Frequency Note

Errors

Error	Meaning	Response
Clinician ID is invalid	Clinician ID is not recognized.	Ensure that ID label is legible. Enter ID manually.
Patient ID is invalid	Patient ID is not recognized.	Ensure that ID label is legible. Enter ID manually.
Scanned label is invalid	Profile feature might be disabled. Barcode might not be readable or a supported symbology.	Ensure that profile is enabled. Ensure that ID label is legible. Inform pharmacy of problem.
Scanned medication label is invalid	Barcode might not be readable or a supported symbology.	Ensure that ID label is legible. Inform pharmacy of problem.

Messages

Message	Meaning	Response
Drug or Fluid not in current Profile	The current profile library does not contain a matching fluid or drug.	Verify that the correct profile is in use. If so, contact pharmacy for assistance.
Drug or Fluid Mismatch	The selected channel is currently infusing a fluid with a different name, or a drug with a different name, or concentration.	Select a channel that is idle in order to infuse a new primary infusion. Select a channel that is infusing a primary fluid that supports a secondary to delivery another secondary medication.
Patient ID will be changed	The Patient ID on the scanned barcode is not the same Patient ID that is currently associated with the device.	If the Patient ID associated to the PCU should be changed, press **Yes**. If the Patient ID associated to the PCU should not be changed, press **No** and verify that the scanned medication is for this patient.
Channel Unavailable	Channel is already infusing a secondary medication.	Select another channel that is infusing a primary fluid that supports a secondary to deliver another secondary medication. Select a channel that is not currently infusing to deliver a primary medication.

Appendix A
Troubleshooting and Maintenance

This appendix contains the following topics:

Summary of Warnings and Cautions

General

WARNING

- **Inserting a finger or other object into the inter-unit interface (IUI) connector when the module is attached to the PCU could result in electrical shock (see *Inspecting the IUI Connectors* on page *368*).**
- **The BD Alaris™ System may be interferred with by other equipment, even if that other equipment complies with CISPR emission requirements (see *Regulations and Standards* on page *372*).**

CAUTION

- Keep the pump module door closed when the device is not in use, to avoid damage to door components (see *Storage* on page *363*).
- Profile 4 audio setting supports standards compliance. Setting the alarm audio profile to Profile 4 could potentially result in the system alarms sounding similar to other medical devices, such as respirators and monitoring services that are compliant with the same safety standards.

Inspection

WARNING

- **Do not use a device that appears to be damaged. Send the device to biomedical engineering for repair (see *Inspection Requirements* on page *367*).**
- **Perform device inspections to prevent a damaged device from being returned to patient use. Use of a damaged device can result in patient harm (see *Inspection Requirements* on page *367*).**
- **Failure to perform device inspections can result in improper device operation (see *Inspecting the IUI Connectors* on page *368*).**
- **Inspection of inter-unit interface (IUI) connectors is required. Damaged IUI connectors can result in incorrect device operation. Use of a damaged device can result in patient harm (see *Inspecting the IUI Connectors* on page *368*).**
- **Do not return the device to patient use if there are cracks, surface contaminants, discoloration or other damage to inter-unit interface (IUI) connectors. Use of devices with damaged IUI connectors can result in patient harm. Send all damaged devices to biomedical engineering for repair (see *Inspecting the IUI Connectors* on page *368*).**
- **Preventive maintenance should be performed only by biomedical engineering (see *Inspection Requirements* on page *367*).**

Service

WARNING

- **The device cases should only be opened by qualified personnel using proper grounding techniques. When performing corrective maintenance:**
  - **Unplug the PCU and disconnect the battery.**
  - **Disconnect all modules and PCU from each other (see *General Service* on page *370*).**
- **During BD depot servicing, a device's configuration settings might be reset to the factory defaults. Qualified hospital/facility personnel are responsible for checking in the device and ensuring the current hospital approved data set is loaded (see *General Service* on page *370*).**
- **Do not modify device as it could affect the safety and efficacy of the BD Alaris™ System (see *Regulations and Standards* on page *372*).**
- **Worn-out batteries must be disposed of properly, according to local regulations. To prevent electrical shock, exposure to battery chemicals or fire, do not open, incinerate, or short circuit (see *Battery Disposal* on page *364*).**

Troubleshooting and Maintenance

Troubleshooting and maintenance should be performed only by qualified personnel, using the applicable technical service manual and system maintenance software. Do not perform troubleshooting, service, or maintenance while the system is in use with a patient.

BD Alaris™ PCU model 8015 Alaris™ PCU model 8015 BD Alaris™ Pump Module model 8100 Alaris™ Pump Module model 8100	*BD Alaris™ PCU Model 8015, Alaris™ PCU Model 8015, BD Alaris™ Pump Module Model 8100, and Alaris™ Pump Module Model 8100 Technical Service Manual*
Alaris™ Syringe Module model 8110 Alaris™ PCA Module model 8120	*Alaris™ Syringe Module, Model 8110 Series, Alaris™ PCA Module, Model 8120 Series Technical Service Manual*
Alaris™ $EtCO_2$ Module model 8300	*Alaris™ $EtCO_2$ Module Model 8300 Technical Service Manual*
Alaris™ Auto-ID Module model 8600	*Alaris™ Auto-ID Module, Model 8600 Technical Service Manual*

The service manuals and system maintenance user manual are available from BD. The service manuals include routine service schedules, interconnect diagrams, component parts lists and descriptions, test procedures, and other technical information to assist biomedical engineering in repair and maintenance of the device's repairable components. System maintenance is used to perform a new device check-in, preventive maintenance tests, calibration checks, calibration, and other maintenance functions.

Expected Service Life

The BD Alaris™ System has been tested for a seven year serviceable life. There are some components which experience wear, and are expected to need periodic attention and replacement within that serviceable life.

Examples of these components include:

- PCU Battery
- Pump Module Membrane Frame Seal
- IUI Connectors

NOTE:
The seven year serviceable life applies to the following hardware configurations that BD currently distributes as of June 2021:

- BD Alaris™ PCU
- BD Alaris™ Pump Module
- Alaris™ Syringe Module
- Alaris™ PCA Module
- Alaris™ $EtCO_2$ Module

Artifacts: It is normal for an infusion device to produce nonhazardous currents when infusing electrolytes. These currents vary proportionally to the infusion device flowrate. When an electrocardiogram (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.

BD Alaris™ Systems Manager Connections

When a Systems Manager connection is made, the wireless network indicator light on the PCU illuminates. If connection to the Systems Manager is interrupted, the indicator light is extinguished. Some of the causes for a communications failure include:

- Systems Manager is not accessible in network, server services are not running, or server has been shut down.
- Wireless connection to access point is down due to wireless network changes.
- Local interference.
- PCU has been moved outside the wireless coverage area.
- Wireless network card has been damaged.

If an interruption to the systems manager connection continues, contact the facility's information technology department.

Alarms and Alerts

BD recommends that the clinician monitor infusions from a distance that allows them to hear auditory alarms. The distance will vary depending on the facility's acoustics and ambient sound, but should be 4 meters or less. When an audible alarm occurs, the clinician should move to a distance no more than 1 meter from the device in order to identify the alarm condition and priority.

Display Color

Color is used in the title and prompt bars to help communicate the following types of information.

Communication	Color	Description
Normal Operation	Blue	All messages other than noted below (normal operating displays).
Guardrails™ limit	Yellow	Visual message indicating a Limit was exceeded.
Pertinent message	Yellow	Visual message that calls attention to a programming parameter or to the infusion status.
Informational	Green	Visual message.
Alarms and malfunctions	Red	Visual message indicating an error or system inconsistency occurred.

Alarm Definitions

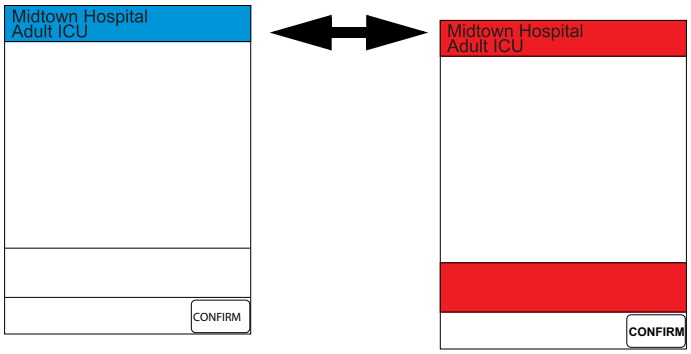
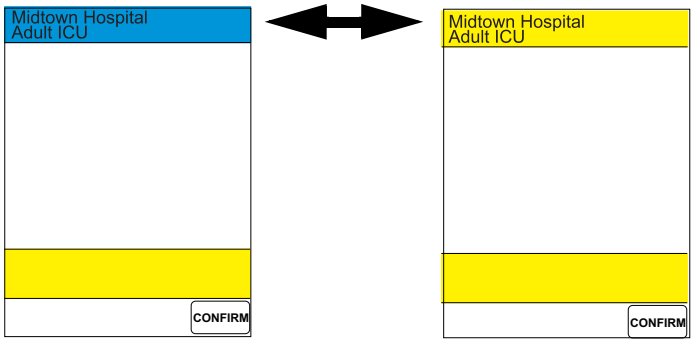
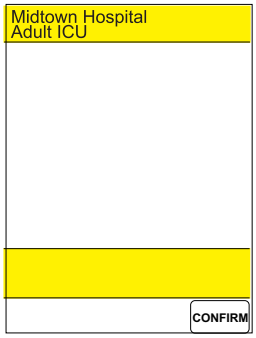
Alerts and alarms are indicated by a combination of audible tones, visual flashing behavior, and a descriptive message on either the PCU or scrolling module marquee.

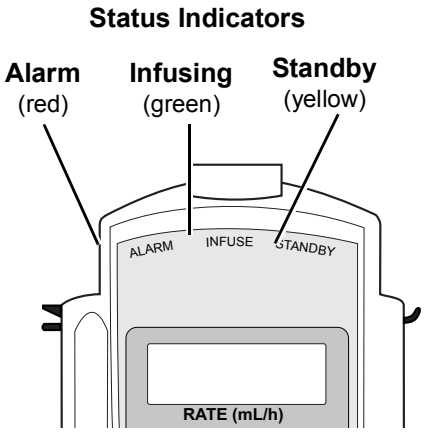
Alarms notify the clinician of a potential or an actual hazardous condition.

Terms	Definitions
High Priority	A high-priority alarm is started by any alarm condition requiring immediate user response.
Medium Priority	A medium-priority alarm is started by any alarm condition requiring prompt user response.
Low Priority	A low-priority alarm is started by any condition requiring user awareness.
Informational Signal	A signal that provides information which may, or may not, require action to be taken by the clinician.
Reminder Signal (NEOI Snooze)	A periodic audible signal that reminds the user that a near end of infusion alert has been previously silenced. When enabled in the data set, this reminder signal can be configured in 5, 10, and 15 minute intervals.

Definitions of Alarm Types

The system alarms are further categorized by type, as indicated in the table below.

Terms	Definitions
Technical Alarms	An alarm arising from a hardware or software problem condition. The signal priority is indicated by an audio tone and visually, by the color of the title bar on the PCU screen, which may include flashing behavior.
	Technical High Priority—Title Bar flashes red 
	Technical Medium Priority—Title bar flashes yellow. 
	Technical Low Priority—Title bar appears in steady yellow 
Infusion Alarms	An alarm arising from an infusion module (PCA, Syringe, or Pump Modules).

Terms	Definitions
Monitoring Alarms	An alarm arising from a monitoring module.
	Monitoring and Infusion high priority alarms—module status indicator flashes red Monitoring and Infusion medium priority alarms—module status indicator flashes yellow Infusion low priority alarms—module status indicator appears in steady yellow

NOTE:
Monitoring alarms are either high or medium priority, there are no low priority Monitoring alarms.

NOTE:
The signal priority for both Monitoring and Infusion alarms is indicated by both an audio signal and by the color of the module status indicator, which may include a flashing behavior.

Definitions of Alerts

Terms	Definitions
Advisory/Message	A sequence of audio and/or visual signals indicating the system operation status.
Alarm Signal	An audible and visual indicator of a potential or actual hazardous condition.
Alarm Silence	Alarms can be silenced for up to 120 seconds by pressing the **SILENCE** key. The alarm indicator remains on and the alarm silence symbol is displayed. The silence period can be ended by pressing the **CANCEL SILENCE** soft key. An alarm can be silenced in the **PANEL LOCKED** condition.
Alert	A visual, audible, or visual and audible signal provided by the system. This includes alarms, informational, and reminder signals.
Calibration Check	A technical procedure, defined in the technical service manual, to verify device calibration.
Cancel Silence	Alarm audio may be canceled by pressing the cancel silence soft key. If the alarm condition has not been resolved, the alarm audio resumes. **NOTE:** A previously silenced alarm audio can be reactivated by pressing the **Cancel Silence.** If the alarm condition has not been resolved, the alarm audio will resume.
Clinical Advisory	A visual message when a designated drug is selected to remind the clinician of specific hospital/facility standards of practice when programming an IV medication. A specific Clinical Advisory and/or message can be associated with a selected drug within any of the patient care profiles. Clinical Advisories are not displayed in Anesthesia mode.

Terms	Definitions
Control Unit	PCU and Auto-ID (barcode) Module
High Priority Alarm	A high-priority alarm is started by any alarm condition requiring immediate user response.
Information Signal	Any signal that is not an alarm signal or a reminder signal.
Infusion Alarm	An alarm arising from an infusion module (PCA, Syringe, Pump Modules)
Low Priority Alarm	A low-priority alarm is started by any condition requiring user awareness.
Maintenance Reminder	A visual message that when enabled appears at startup when a scheduled preventive maintenance is due/overdue for component of the system (PCU or attached module).
Medium Priority Alarm	A medium-priority alarm is started by any alarm condition requiring a prompt user response.
NEOI Snooze (Reminder signal)	Configurable alert, if enabled, provides an audio only tone when a Near End of Infusion alarm had been previously silenced.
Monitoring Alarm	An alarm arising from an $EtCO_2$ monitoring module.
Presilence	Allows the user to silence a monitoring module for 2 minutes. Also known as Audio Pause, the duration of Presilence (Audio Pause) is not configurable.
Prompt	An audio signal and/or a visual message appearing on bottom line of Main Display or in Message Display. Audio signal can be silenced for 12 seconds pressing the **SILENCE** key.
Technical Alarm	An alarm arising from a hardware or software failure condition.

Alert Prioritization Types and Sources

All the system alerts are prioritized by type and source and the condition of the alert.

ALERT Priority	ALERT Type/Source	Color Theme	Silenceable
HIGH Priority	Technical Software Fatal	N/A	NO
	Uncontrolled Infusion	Flashing Red	NO
	Technical Malfunction	Flashing Red	YES
	Monitoring	Flashing Red	YES
	Infusion/PCU	Flashing Red	YES
MEDIUM Priority	Monitoring	Flashing Yellow	YES
	Infusion/PCU	Flashing Yellow	YES
LOW Priority	Infusion/PCU	Steady Yellow	YES
INFORMATIONAL	Informational	N/A	N/A
Reminder Signal	Reminder Signal	N/A	NO

Audio Characteristics of Profiles

Audio Profile	Priority	Audio Characteristics	Visual Indicator
Profile 1	High	Repeating sequence of 10 beeps followed by an approximate 7 second pause for a monitoring alarm Repeating sequence of 2 beeps followed by an approximate 1.5 second pause for an infusion alarm	Flashing Red
	Medium	Repeating sequence of 6 beeps followed by an approximate 4 second pause for a monitoring alarm Repeating sequence of 1 beep followed by an approximate 2 second pause for an infusion alarm	Flashing Yellow
	Low	Repeating sequence of 1 beep followed by an approximate 3.5 second pause.	Steady Yellow
Profile 2	High	Repeating sequence of 10 beeps followed by an approximate 7 second pause for a monitoring alarm Repeating sequence of 2 beeps followed by an approximate 1 second pause for an infusion alarm	Flashing Red
	Medium	Repeating sequence of 6 beeps followed by an approximate 4 second pause for a monitoring alarm Repeating sequence of 1 beep followed by an approximate 2 second pause for an infusion alarm	Flashing Yellow
	Low	Repeating sequence of 1 beep followed by an approximate 3.5 second pause.	Steady Yellow
Profile 3	High	Repeating sequence of 10 beeps followed by an approximate 7 second pause for a monitoring alarm Repeating sequence of 2 beeps followed by an approximate 0.5 second pause for an infusion alarm	Flashing Red
	Medium	Repeating sequence of 6 beeps followed by an approximate 4 second pause for a monitoring alarm Repeating sequence of 1 beep followed by an approximate 2 second pause for an infusion alarm	Flashing Yellow
	Low	Repeating sequence of 1 beep followed by an approximate 3.5 second pause.	Steady Yellow
Profile 4	High	Repeating sequence of 10 beeps followed by an approximate 4 second pause	Flashing Red
	Medium	Repeating sequence of 3 beeps followed by an approximate 6 second pause	Flashing Yellow
	Low	Repeating sequence of 3 beeps followed by an approximate 15 second pause	Steady Yellow

Sound Pressure Level Ranges for Alarm Signals

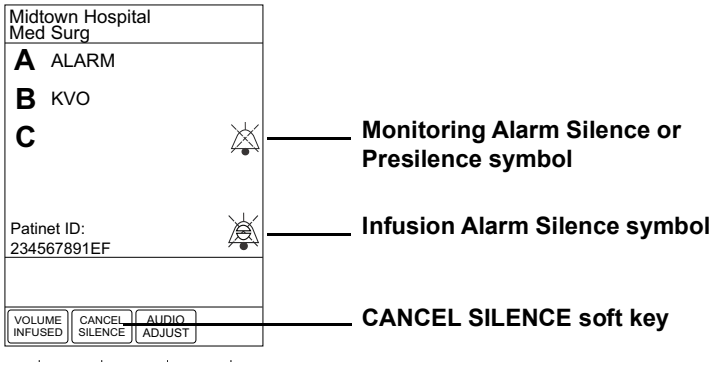
Alarm	Volume 5 (Max) Average SPL (dBA)	Volume 1 (Min) Average SPL (dBA)
HIGH - Malfunction		
HIGH - Monitoring		
HIGH - Infusion	68	60
MED - Monitoring		
MED - Infusion		
LOW - Infusion/PCU	68	55

CAUTION

Profile 4 audio setting supports standards compliance. Setting the alarm audio profile to Profile 4 could potentially result in the system alarms sounding similar to other medical devices, such as respirators and monitoring services that are compliant with the same safety standards.

Infusion Alarms

Infusion alarms can be silenced for 120 seconds by pressing the **SILENCE** key. Subsequent infusion alarms are not silenced during this period. Visual alarm indicators remain on and an infusion alarm silence icon is displayed on the PCU screen in the lower right corner. Silence period can be ended by pressing **CANCEL SILENCE** soft key. If the alarm condition still exists, the audible alarm tone will return.



Monitoring Alarms

Monitoring alarms may be presilenced, or silenced in response to a monitoring alarm condition. All monitoring alarms are silenced for 120 seconds (subsequent infusion alarms are not silenced during this period). Alarm indicators remain on and a monitoring alarm silence icon is displayed. Silence period can be ended by pressing **CANCEL SILENCE** soft key.

Alarms

Alarm Message	Device	Priority	Meaning	Response
ATTACH HANDSET	PCA	Low	The dose request cord detached from the device during an active infusion. The dose request cord is required only for PCA and PCA + continuous infusion modes.	Reattach the dose request cord and press the **RESTART** key.
ACCUMULATED AIR-IN-LINE ALARM	Pump	High	A large number of air bubbles smaller than the current air-in-line limit has recently passed the air-in-line detector.	Clear air from the infusion set. Press the **RESTART** key, or press the **CHANNEL SELECT** key and then the **START** soft key.
AIR-IN-LINE	Pump	High	Air has been detected in the infusion set during an infusion. The infusion stops on affected channel.	Ensure that the tubing is properly installed in the Air-in-Line detector. If air is present, clear the air from infusion set. Press the **RESTART** key, or press the **CHANNEL SELECT** key and then the **START** soft key.
ANESTHESIA MODE AC POWER CONNECTED	PCU	Informational	The AC power cord is connected	Select **Yes** to continue anesthesia mode or **No** to exit anesthesia mode.
ANESTHESIA MODE AC POWER DISCONNECTED	PCU	Informational	The AC power cord is disconnected	The anesthesia mode was discontinued when the AC power cord was disconnected.
ATTACH MONITORING MODULE	PCU	Informational	A Clinical Advisory is displayed for a PCA Infusion that contains PCA PAUSE PROTOCOL.	Attach the $EtCO_2$ Module.
AUDIO SYSTEM ERROR	PCU	Medium	The audio system has failed and the backup system is in use. The PCU currently in use may be continued temporarily with backup audio system. The audio notifications may sound altered.	Replace the PCU as soon as possible.
AUTOZERO IN PROGRESS	$EtCO_2$	Informational	The $EtCO_2$ Module performs a baseline by sampling CO_2 present in ambient air.	Wait for the device to complete its auto zeroing function. After the auto zero cycle is complete, the device begins measurement again. No user intervention is required.
BAR CODE MALFUNCTION	Auto-ID displayed on the PCU	Informational	A malfunction has occurred on the Auto-ID module disabling the barcode scanning functionality. The PCU continues to operate.	The Auto-ID module should be serviced by qualified personnel or replaced as soon as possible.
BAR CODE SCANNING ERROR	PCU	Informational	The Auto-ID scanner or handheld is not responding.	The Auto-ID module should be serviced by qualified personnel or replaced as soon as possible.

Alarm Message	Device	Priority	Meaning	Response
BAR CODE TRANSMISSION ERROR	PCU	Informational	A communication error has occurred.	Reconnect the Auto-ID module.
BATTERY DISCHARGED	PCU	High	All channels stopped. The device is in a low battery state where all channels are on standby to conserve battery life	To silence the alarm and restart the channels, plug in the power cord, or press **SYSTEM OFF**. Plug in or replace the device and restart the paused modules.
BATTERY DISCHARGED POWERING DOWN	PCU	High	The battery is completely discharged and the device is powering down.	Plug in or replace the device and restart the modules.
CHANNEL DISCONNECTED	Syringe PCA Pump $EtCO_2$	High	Module(s) have either been disconnected while in operation, or have a non-recoverable error.	To silence the alarm and clear the message from screen, press the **CONFIRM** soft key. Reattach the module, if desired, ensuring it is securely "clicked" into place at Channel Release Latch. If the alarm is still present, replace the module.
CHANNEL ERROR	Syringe PCA Pump $EtCO_2$	High	A malfunction is detected on the module.	Clear the channel error pop-up by pressing the **CONFIRM** soft key. Power down the system, or continue use of functional units, or replace the affected channel with an operable module.
CHECK IV SET	Pump	High	The infusion set is not properly installed. Infusion stops on affected module.	Close the roller clamp, remove and reinstall the infusion set, close the door, open the roller clamp, and then press the **RESTART** soft key.
CHECK SYRINGE	Syringe PCA	High	The lever, plunger, and/or barrel clamp is not engaged properly.	Inspect the syringe or PCA Module and adjust the appropriate sensor as needed. Reselect the syringe, restore or reprogram and start or restart the infusion.
CHECKING LINE	Pump	Informational	A patient-side occlusion has occurred; the Auto-Restart feature monitors downstream pressure to determine if infusion can continue.	Assess for closed clamp then, press **RESTART** key.
CLEARING DISPOSABLE	$EtCO_2$	Informational	The monitoring device is attempting to clear disposable of occlusion.	Wait for purging to complete.
CLOSE AND LOCK DOOR	PCA	High	The PCA door is unlocked/open during an active infusion. The infusion is stopped.	Lock the door and press the **RESTART** key.

Alarm Message	Device	Priority	Meaning	Response
CLOSE DOOR, then RESTART CHANNEL	Pump	High	The door was opened and closed during an infusion. The infusion stops on affected channel.	Close the door. Press **RESTART**, or press the **CHANNEL SELECT** key and then press the **START** soft key.
COMMUNICATION ERROR	All modules	High	The module has lost communication with the PCU.	Replace module
DEFECTIVE BATTERY	PCU	High	A battery failure is detected during normal operations. The active modules will continue as programmed.	Replace the device immediately. The settings are unrestorable; record the settings before powering down device.
DELAY COMPLETE	Syringe Pump	Medium	Delay time complete.	To resume the infusion, press **RESTART** on the module or press **CHANNEL SELECT** and then the **START** soft key.
DELAYED STATUS	Syringe Pump	Informational	The infusion has been delayed for a defined period of time.	No user response is expected.
DISCONNECT OCCLUDED DISPOSABLE	$EtCO_2$	Medium	The disposable is occluded.	Check the disposable. Obtain a new disposable and attach it to patient.
DISPLAY FAILURE - REPLACE MODULE	$EtCO_2$	High	There is a malfunction with the display on the $EtCO_2$ modules. The device continues to monitor.	Replace the module.
DISPOSABLE DISCONNECTED	$EtCO_2$	Informational	No disposable is connected to the module while attempting to search for a patient.	Ensure disposable is attached to module.
DISPOSABLE DISCONNECTED	$EtCO_2$	Medium	No disposable is connected to the module during monitoring or after approximately 30 seconds of searching for a patient.	Ensure disposable is attached to module.
HIGH ETCO2	$EtCO_2$	High	The $EtCO_2$ value is above the specified limit.	Assess the patient's condition. Confirm that the correct alarm limit values are selected.
HIGH FICO2	$EtCO_2$	High	$FiCO_2$ value is above the specified limit.	Assess the patient's condition. Confirm that the correct alarm limit values are selected.
HIGH RR	$EtCO_2$	High	The respiratory rate is above the specified limit.	Assess patient's the condition. Confirm that the correct alarm limit values are selected.
INFUSION COMPLETE	Syringe Pump	High	The current infusion is completed with no KVO.	Set up a new infusion or press the **CHANNEL OFF** key.
INFUSION COMPLETE - KVO	Pump Syringe	High	VTBI has been infused; the module is infusing at the KVO rate	Set up a new infusion, if required, and reinititate the infusion

Alarm Message	Device	Priority	Meaning	Response
INSTALL PRESSURE DISC	Syringe	High	The Pressure Sensing Disc is removed. If an infusion is running, the infusion stops on affected module.	Reinstall the Pressure Sensing Disc and press the **RESTART** key
LOW BATTERY < 30 MIN PLUG IN NOW	PCU	Low	Low battery threshold sensed; the remaining battery run time is limited.	Connect to a power source (alarm silenced). Low battery will continue to display after the AC is plugged in until the battery has built up sufficient charge to run the system for 30 minutes. To verify AC is charging, look at the AC LED on the front panel and verify that it is on.
LOW ETCO2	$EtCO_2$	High	The $EtCO_2$ value is below the specified limit.	Assess the patient's condition. Confirm that the correct alarm limit values are selected.
LOW RR	$EtCO_2$	High	The respiratory rate is below the specified limit.	Assess the patient's condition. Confirm that the correct alarm limit values are selected.
MAINTENANCE REMINDER	PCU	Informational	The device is due for Preventative Maintenance	Notify the biomed that Preventative Maintenance of the device is due
MAX LIMIT REACHED	PCA	Low	This alarm occurs when an attempt is made that exceeds the maximum allowed drug amount for the patient. The PCA dose cannot be delivered until the configured time passes.	To silence the alarm, press the **SILENCE** key. To change the Max Limit, press **CHANNEL SELECT**, press the **PROGRAM** soft key, and unlock the door or enter the Authorization Code applicable for current Security Access Level.
MAX MODULES EXCEEDED	PCU	Informational	The number of attached modules exceeds the maximum allowed.	Removed the unsupported module(s).
MISSING BATTERY	PCU	High	Missing battery while operating.	Replace the device immediately. The settings are unrestorable; record settings before powering down the device.
NEAR END OF INFUSION	Syringe PCA	Low	The syringe is almost empty. This is a timed event that can be configured in the data set. To set or change this option, see *Features and Definitions* on page *12* and *Configurable Settings* on page *203*.	To silence the alarm, press the **SILENCE** key. The module remains functional and continues the infusion.
NEOI Snooze	Syringe PCA	Reminder	A periodic audible signal that reminds the user that a Near End of Infusion alarm has been previously silenced.	None

Alarm Message	Device	Priority	Meaning	Response
NETWORK COMMUNICATION ERROR	PCU	Informational	Wireless connections lost.	The PCU continues to operate without wireless functionality.
NO BREATH DETECTED	$EtCO_2$	High	No breath has been detected for a specified period of time.	Assess the patient's condition. Confirm that the correct alarm limit values are selected. Check the Microstream™ disposable to confirm that the correct disposable is chosen. Confirm the correct disposable placement.
OCCLUDED - FLUID SIDE/EMPTY CONTAINER	Pump	High	Indicates either an upstream occlusion or an empty container. The infusion stops on affected module.	Clear the occlusion on fluid side of the device. If necessary, refill the drip chamber. Press the **RESTART** key, or press the **CHANNEL SELECT** key and then the **START** soft key.
OCCLUDED - PATIENT SIDE	Pump Syringe PCA	High	Increased back pressure sensed while infusing. The infusion stops on affected module.	Clear the occlusion. Press the **RESTART** key, or press the **CHANNEL SELECT** key and then the **START** soft key.
OCCLUSION	Syringe PCA	High	Excessive force is detected on the syringe driver head release.	Silence alarm and continue normal operation, press **CONFIRM** soft key.
PARTIAL OCCLUSION - PATIENT SIDE	Pump	High	A partial occlusion of the patient side of the IV line detected by the Auto-Restart feature.	Clear the occlusion. Press the **RESTART** key, or press the **CHANNEL SELECT** key and then the **START** soft key.
PATIENT NOT DETECTED	$EtCO_2$	Medium	The patient is not detected.	Assess the patient condition. Check the disposable
PAUSED	Syringe PCA Pump	Informational	The pause control was pressed and the infusion stopped.	To resume the infusion press **RESTART** on module or press **CHANNEL SELECT** and then the **START** soft key.
PAUSE-RESTART CHANNEL	Syringe PCA Pump	Low	The module has been paused for 2 minutes.	To resume the infusion press **RESTART** on module or press **CHANNEL SELECT** and then the **START** soft key.
PCA HANDSET STUCK	PCA	Low	The PCA handset has been pressed too long. The infusion continues as programmed.	Replace the handset when the device is not in use.

Alarm Message	Device	Priority	Meaning	Response
PCA PAUSED - LOCKOUT	PCA	High	The PCA infusion has paused due to a decline in respiratory status	Assess the patient status per hospital policy. Press **CONFIRM** once the patient's status and monitoring values have been addressed. Press the **RESTART** key per hospital policy. To view the trigger of the PCA Pause Alarm, press **CHANNEL SELECT > OPTIONS > DRUG EVENT HISTORY**, Press the Up/ Down key to view the text for the monitoring value causing the PCA Module to pause. Press **EXIT** and then **START**.
PRESSURE DISC INSERTED	Syringe	High	The Pressure Sensing Disc was installed during a running infusion. The infusion stops on affected module. The Pressure Sensing Disc should not be installed during an infusion. Installing the disc delivers a bolus.	Press the **CONFIRM** soft key and then the **RESTART** key.
PROGRAM STEP COMPLETE STATUS	Syringe PCA Pump	Informational	The Bolus/Loading dose has been delivered and the device is waiting for next programming instructions.	Program the next infusion step or turn the channel off.
PUMP CHAMBER BLOCKED	Pump	High	The tubing is blocked inside Pump Module (pump chamber).	1. Close the roller clamp and open the door. 2. Remove the tubing. 3. Massage the tubing from the top to the bottom to restore the flow. 4. Reload the set and close the door. 5. Press the **NEXT** soft key. 6. Press the **CONFIRM** soft key. 7. Open the roller clamp and press the **RESTART** key. 8. Verify the flow in the drip chamber after restarting the infusion. 9. Change the set if you are unable to establish flow.

Alarm Message	Device	Priority	Meaning	Response
REPLACE BATTERY	PCU	Low	The battery has reduced runtime capacity.	Press **CONFIRM** to continue operation with reduced battery capacity or power down and replace the device.
SAFETY CLAMP OPEN / CLOSE DOOR	Pump	High	The safety clamp device is in open position while the door is open.	Close the roller clamp on infusion set or close the door.
SEARCHING	$EtCO_2$	Informational	The monitoring device is attempting to start monitoring and is searching for patient vitals. Searching automatically follows initialization	N/A
SENSOR WARMING	$EtCO_2$	Informational	The monitoring device is preparing sensor mechanisms to search for and monitor the patient vitals.	N/A
SWITCHOVER STATUS	Syringe PCA Pump	Informational	The device is delivering medication/fluid.	No user response expected.
SYRINGE CALIBRATION REQUIRED	Syringe PCA	Medium	The module needs calibration before use. **CALIBRATE** scrolls in the Message Display. Other modules currently infusing will continue to operate.	Replace the module with an operational device as soon as possible. Service by qualified personnel is required. Press the **CONFIRM** soft key to continue.
SYRINGE DRIVER HEAD ERROR	Syringe PCA	High	A noninfusing module, with the plunger grippers open, senses that excessive pressure is being applied downward on the Drive Head. The word "OCCLUSION" scrolls in Message Display.	To silence the alarm and continue with normal operation, press the **CONFIRM** soft key.
SYRINGE EMPTY	Syringe PCA	High	The syringe VTBI has completed and the syringe contains less than 2% total disposable volume.	Set up a new syringe infusion or press the **CHANNEL OFF** key.
SYSTEM ERROR	PCU	High	A FATAL MALFUNCTION is detected on the PCU	Operating channels will continue as programmed; however, settings cannot be changed. Replace the device as soon as possible. Record the settings prior to powering down the device. Settings are unrestorable.

Alarm Message	Device	Priority	Meaning	Response
VERY LOW BATTERY <5 MIN TO SHUTDOWN PLUG IN NOW	PCU	High	The battery has an estimated run time of five minutes prior to infusion stopping.	Connect the AC power cord to the power source (alarm silenced). Very low battery will continue to display after the AC is plugged in until the battery has built up sufficient charge to run system for 5 minutes. To verify that AC is charging, look at the AC LED on the front panel.
WAIT STATUS	PCA	Informational	Device is waiting to deliver the next PCA dose.	No user response is expected
WALKAWAY AUDIO PROMPT/ INACTIVITY	Syringe Pump PCA $EtCO_2$	Low	Programming is incomplete. No key press has occurred in past 12 seconds	Complete programming

NOTE:
Delays in determining an alarm condition are inherent to the system. The infusion modules (Pump Module, Syringe Module, and PCA Module) contain sensors that directly measure conditions such as line pressure, force, or position, and express those measurements as voltages. Software periodically reads these voltages and processes them through filters that smooth out any occasional deviant readings in order to prevent false alarms. Because these filters need to examine multiple readings before producing a filtered reading, the filters add delays of approximately 0.4 seconds to the detection of an alarm condition, on average. For a Syringe Module, which has a Plunger Position sensor, the alarm condition delay can be up to 3.2 seconds at low infusion rates.

Storage

Plug the PCU into an AC outlet during storage to ensure a fully charged battery. The AC indicator light ( ) is on when the PCU is plugged in.

CAUTION

Keep the pump module door closed when the device is not in use.

Battery Type and Charging

The PCU is equipped with a 12 volt, 4000 mAh nickel metal hydride battery. The battery is charging whenever the device 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 device 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 *364*.

Use only BD batteries. The use of third party batteries could affect the safety and efficacy of BD Alaris™ products.

Battery Charging

The PCU is shipped with the battery in a discharged condition. Before the PCU is released for use, it should be plugged into a hospital grade AC outlet and the battery charged for at least 16 hours or have your biomed department perform battery conditioning (fast or optimal). This ensures proper battery operation when the BD Alaris™ System is first set up for patient use.

The battery is intended as a backup system. Leave the power cord connected to an external hospital grade AC power source whenever available.

If the device has been used on battery power, ensure that the battery is fully charged prior to using the device on battery power again. To fully charge a depleted battery connect the device to a hospital grade AC power source for 16 hours.

Battery Storage and Use Conditions

If you plan to store the PCU at temperatures in excess of 86°F (30°C) for one or more months, remove the battery from the PCU and store the battery in an environment of 50 - 86°F (10 - 30°C).

If the batteries are to be stored for more than 1 year, they should be fully charged (16 hours) at least once per year to prevent leakage and deterioration in performance due to self-discharge.

When the battery has been out of use for one or more months, it will not have full capacity.

Some temporary reduction in capacity may occur if the battery is repeatedly partially discharged.

Battery Disposal

Battery replacement should be performed by biomedical engineering while the device is not in use.

WARNING

Worn-out batteries must be disposed of properly, according to local regulations. To prevent electrical shock, exposure to battery chemicals or fire, do not open, incinerate, or short circuit.

Proper Battery Maintenance

The battery should be conditioned every 12 months by biomedical engineering.

The battery should be replaced every 2 years by biomedical engineering. See the *BD Alaris™ PCU Model 8015, Alaris™ PCU Model 8015, BD Alaris™ Pump Module Model 8100, and Alaris™ Pump Module Model 8100 Technical Service Manual* for more information about battery testing and replacement.

Wireless Connection Soft Key

Send the PCU to the biomedical engineering department to resolve wireless connectivity issues.

The Wireless Connection soft key is inactive (grayed out) for one of the following reasons:

- System maintenance was used to disable the wireless connection.
- The CF card flashing process was done without the programming of the proper AppConfig file (v9.12 or later).
- A valid network configuration has not been transferred.

To enable the wireless connection, consult the system maintenance software.

Wireless Connection Scenarios

At various locations, the PCU may or may not be able to complete a wireless connection. When connected, the connection icon lights. If the PCU cannot connect, the connection icon does not light, and device data is stored until a connection can be completed.

Wireless Icon

NOTE:
If there is no wireless connection, PCU data (such as log information) is stored until a connection is re-established. System history and CQI logs are stored in non-volatile compact flash memory and are retained until memory is full and older items are purged.

The following table explains how the pump functions under various wireless scenarios.

Full Connectivity	No Connectivity	Marginal Connectivity
• Connectivity icon lighted • Near real-time full data transfer	• Connectivity icon not lighted • Data stored unit connection is reestablished	• N/A • Data stored and transferred as PCU reestablishes connection

Clearing Historical Log Data

The PCU stores electronic protected health information (ePHI) data that requires HIPAA compliance. The ePHI data must be cleared from the historical log on the system when the PCU is transferred or moved as follows:

- When the PCU is moved from one hospital to another hospital that is outside the integrated delivery network (IDN)
- Between the rental company and hospital

HIPAA requires the implementation of policies and procedures:

- To address the final disposition of ePHI, and/or the hardware or electronic media on which it is stored;
- For removal of ePHI from electronic media before the media is made available for re-use (45 CFR 164.310(d)(2)(i)).

To clear historical log data, send the device(s) to biomedical engineering.

Inspection Requirements

To ensure that the BD Alaris™ System remains in good operating condition, visually inspect the system before each use. Check all visible surfaces and moving parts on the devices. If you observe damage of any kind or find the device does not function as expected, return it to biomedical engineering for repair.

WARNING

Perform device inspections to prevent a damaged device from being returned to patient use. Use of a damaged device can result in patient harm.

WARNING

Preventive maintenance should be performed only by biomedical engineering.

Inspecting the IUI Connectors

WARNING

Inspection of IUI connectors is required. Damaged IUI connectors can result in incorrect device operation. Use of a damaged device can result in patient harm.

WARNING

Inserting a finger or other object into the inter-unit interface (IUI) connector when the module is attached to the PCU could result in electrical shock.

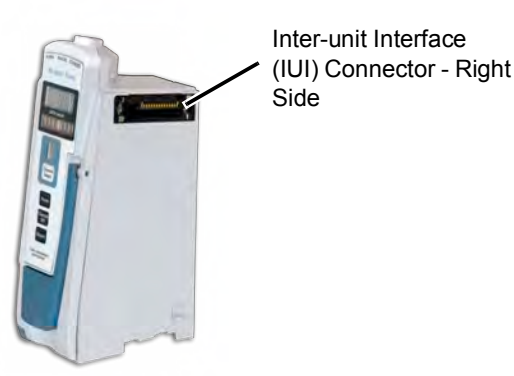
WARNING

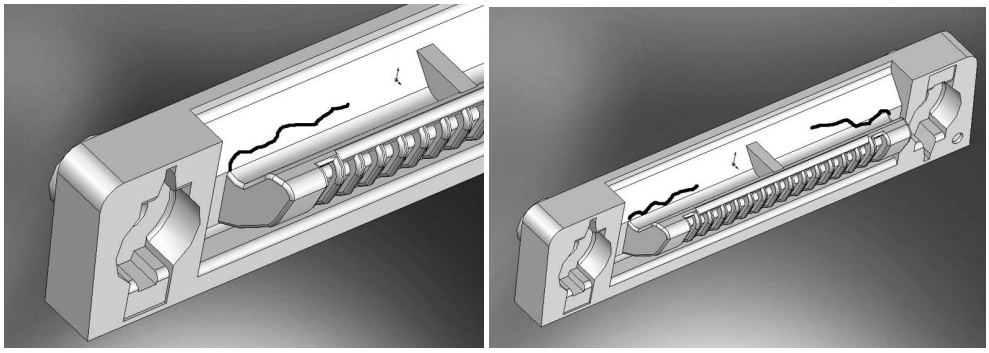
Failure to perform these inspections can result in improper device operation.

WARNING

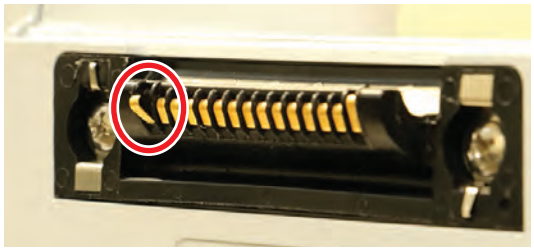
Do not return the device to patient use if there are cracks, surface contaminants, discoloration or other damage to IUI connectors. Use of devices with damaged IUI connectors can result in patient harm. Send all damaged devices to biomedical engineering for repair.

1. If any of the following are visible on an IUI connector, send the device to biomedical engineering:
   - Cracks on the surface of the plastic housing
   - Damaged plastic ribs between the metal contacts
   - Bent metal pins
   - Surface contaminants or green deposits





Cracks on Plastic Housing



Bent Pin

Surface Contaminants and Green Deposits

General Service

WARNING

- **The device cases should only be opened by qualified personnel using proper grounding techniques. When performing corrective maintenance:**
  - **Unplug the PCU and disconnect the battery.**
  - **Disconnect all modules and PCU from each other.**
- **During BD depot servicing, a device's configuration settings might be reset to the factory defaults. Qualified hospital/facility personnel are responsible for checking in the device and ensuring the current hospital approved data set is loaded.**

If the device 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 device fails to respond as described in this document and the cause cannot be determined, do not use the device. Contact qualified BD service personnel.

If it is necessary to return the device for service, obtain a return authorization number prior to shipment. Carefully package the device (preferably in the original packaging), refer to the return authorization information, and return it to the appropriate service or distribution center. BD does not assume any responsibility for loss of, or damage to, returned devices while in transit.

Technical Support

Technical support, service information, applications, and manuals can be obtained by contacting a BD representative at 888-812-3229 or DL-US-INF-Tech-Support@bd.com.

When submitting any request for service, include:

- Model number
- Description of difficulty experienced
- Device settings
- Infusion set/lot number
- Solution(s) used
- Message displayed at time of difficulty

WARRANTY

BD warrants that:

A. Each new BD Alaris™ or 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 BD 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 BD to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with BD to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at BD'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 BD be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any BD Alaris™ or 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 BD shall not be responsible for, any loss or damage arising in connection with the purchase or use of any BD Alaris™ or Alaris™ System product which has been:

1. repaired by anyone other than an authorized BD Service Representative;
2. altered in any way so as to affect, in BD's judgment, the product's stability, reliability, safety, effectiveness, or operation;
3. subjected to misuse or negligence or accident, or that 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 BD.
5. Customer's use of repair or service parts, accessories, or disposables that are not approved by BD is at Customer's own risk and could expose patients to risk of device failure, injury, or even death. In addition, use of such parts, accessories, or disposables may void the product warranty provided by BD.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of BD, and BD does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of BD any other liability in connection with the sale or use of Alaris™ System products.

BD DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

Regulations and Standards

WARNING

Do not modify this device. Modifying the device could affect the safety and efficacy of the BD Alaris™ System.

WARNING

The BD Alaris™ System may be interferred with by other equipment, even if that other equipment complies with CISPR emission requirements.

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 radiolelectriques 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 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the system is operated in a commercial environment.

This system generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the applicable user manual, it might cause harmful interference to radio communications.

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.

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 system includes an IEEE 802.11 RF transmitter, as designated by the icon on the rear of the system. It operates on the following frequencies with a maximum radiated power of 100 mW:

- **802.11a:** 5 GHz band, up to 54 Mbps physical RF specification.
- **802.11b:** 2.4 GHz band, up to 11 Mbps physical RF specification.
- **802.11g:** 2.4 GHz band, up to 54 Mbps physical RF specification.
- **802.11n:** 5 GHz or 2.4 GHz band, up to 72 Mbps physical RF specification.

The registration numbers are identified on the RF card installed in the rear of the PCU.

Tables: The system is intended for use in the electromagnetic environments specified in the following tables.

Table 1
Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
CISPR 11 RF Emissions	Group 1	The system uses RF energy only for its internal function in normal product offering. The following icon appears on product. Refer to network card's user manual for further information.  RF emissions are very low and are not likely to cause interference with nearby electronic equipment.
CISPR 11 RF Emissions	Class B	
IEC 61000-3-2 Harmonic Emissions	Class A	
IEC 61000-3-3 Voltage Fluctuations Flicker Emissions	Complies	

Table 2
Electromagnetic Immunity (3rd Edition)

Immunity Test	IEC 60601-1-2:2007 Test Level	Compliance Level	Electromagnetic Environment—Guidance
IEC 61000-4-2 Electrostatic Discharge (ESD)	For model 8015 and $EtCO_2$ Module: ±6 kV contact ±8 kV air	For model 8015 and $EtCO_2$ Module: ±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
IEC 61000-4-4 Electrical Fast Transient, Burst (EFT)	±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	±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 400 A/m 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-11 Voltage Dips, Short Interruptions, and Voltage Variations	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If continued operation of BD Alaris™ System is required during power mains interruptions, it is recommended that BD Alaris™ System be powered from an uninterruptible power supply or a battery. BD Alaris™ System does employ an internal short duration battery.
	40% U_T (60% dip in U_T) for five cycles	40% U_T (60% dip in U_T) for five cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 5 sec	

NOTE:
At 80 MHz and 800 MHz, the higher frequency applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the BD Alaris™ System is used exceeds the applicable RF compliance level above, the BD Alaris™ System be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BD Alaris™ System.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 3
Electromagnetic Immunity (4th Edition)

Immunity Test	IEC 60601-1-2:2014 Test Level[1]	Compliance Level[2]	Electromagnetic Environment - Guidance
IEC 61000-4-2 Electrostatic Discharge (ESD)	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
IEC 61000-4-4 Electrical Fast Transient, Burst (EFT)	±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	±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)	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz 30 A/m 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-11 Voltage Dips, Short Interruptions, and Voltage Variations**	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If continued operation of the system is required during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery. The system does employ an internal short duration battery.
	0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	
	0% U_T; 250/300 cycles	0% U_T; 250/300 cycles	

NOTE:
The BD Alaris™ System may be affected by an electrostatic discharge through air at levels above 15kV or by radio frequency radiation over 3 V/m. If the system is affected by this external interference, the system will remain in a safe mode. The system will stop the infusion and alert the user by generating a combination of visual and audible alarms. If any encountered alarm condition persists after user intervention, it is recommended to replace that particular system and quarantine it until appropriately trained technical personnel can address the problem.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, observe the system to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. U_T is the AC mains voltage prior to application of the test level.

Table 3 (Continued)
Electromagnetic Immunity (4th Edition)

Immunity Test	IEC 60601-1-2:2014 Test Level	Compliance Level[1]	Electromagnetic Environment - Guidance[2]
IEC 61000-4-6 Conducted RF	3Vrms 0.15 MHz - 80MHz 6Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 Vrms, 0.15 MHz - 80 MHz 6Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to BD Alaris™ System (including cables) than recommended separation distance calculated from equation applicable to frequency of transmitter. Recommended Separation Distance: $d = [\frac{12}{V_2}] \sqrt{P}$
IEC 61000-4-3 Radiated RF	3V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	3V/m 80MHz - 2.7 GHz 80% AM at 1 kHz	$d = [\frac{12}{E_1}] \sqrt{P}$ 80 MHz - 800 MHz
IEC 61000-4-3 Proximity fields from RF wireless communication equipment	See Table 9 in IEC 60601-1-2:2014	See Table 9 in IEC 60601-1-2:2014	$d = [\frac{12}{E_1}] \sqrt{P}$ 80 MHz - 2.5 GHz d = recommended separation distance in meters (m).[3] P = maximum output power rating of transmitter in watts (W) according to transmitter manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than compliance level in each frequency range.[4] Interference might occur in vicinity of equipment marked with the following symbol: 

1.Performed at the minimum and maximum rated input voltage.

2.These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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.

3.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 system is used exceeds the applicable RF compliance level, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating the system.

4.Over the frequency range 150 kHz - 80 MHz, field strengths should be less than $[V_1]$ V/m.

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.

Table 4
Electromagnetic Immunity - Life Support Equipment (3rd Edition)

Immunity Test	IEC 60601-1-2:2007 Test Level	Compliance Level	Electromagnetic Environment - Guidance
IEC 61000-4-6 Conducted RF	10 Vrms 150 kHz - 80 MHz	10 Vrms	Portable and mobile RF communications equipment should be used no closer to BD Alaris™ System (including cables) than recommended separation distance calculated from equation applicable to frequency of transmitter. Recommended Separation Distance: $d = \left[\frac{12}{V_2}\right]\sqrt{P}$ $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz - 800 MHz $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz - 2.5 GHz d = recommended separation distance in meters (m) P = maximum output power rating of transmitter in watts (W) according to transmitter manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than compliance level in each requency range. Interference might occur in vicinity of equipment marked with following symbol: 
IEC 61000-4-3 Radiated RF	10 V/m 80 MHz - 2.5 GHz	10 V/m	

Table 5[1]
Recommended Separation Distances

Reduce the potential for electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters), and the 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.

1.These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
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.
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 system is used exceeds the applicable RF compliance level, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating the system.

	Separation Distance Based on Transmitter Frequency (m)			
	150 kHz - 80 MHz Outside ISM Bands	**150 kHz - 80 MHz In ISM Bands**	**80 MHz - 800 MHz**	**800 MHz - 2.5 GHz**
Rated Maximum Output Power of Transmitter (W)	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	$d = \left[\frac{12}{V_2}\right]\sqrt{P}$	$d = \left[\frac{12}{E_1}\right]\sqrt{P}$	$d = \left[\frac{23}{E_1}\right]\sqrt{P}$
0.01	0.02	0.06	0.06	0.12
0.1	0.06	0.19	0.19	0.36
1	0.18	0.6	0.6	1.15
10	0.55	1.9	1.9	3.64
100	1.75	6	6	11.5

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 system to communicate with the systems manager connected to the hospital information system. The RF card is compliant with the rules and regulations in the locations where the CF wireless module is sold, and is labeled as required.

The United States Federal Communications Commission (FCC) and Industry Canada (IC) identification numbers are visible through the CIB's clear plastic cover. If an international country approval stamp is required, it is placed adjacent to the identification numbers in the area provided. If the FCC identification number or country approval stamp is not easily visible, the RF card cover may be removed so that the information provided can be read. If the RF card cover is removed, ensure that it is reattached—using the

screws that were removed, to ensure that the RF card is securely retained and protected against liquid ingress and damage.

The Class B digital device limits are designed to provide reasonable protection against harmful interference when the device is operated as intended. This device generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the applicable user manual, it might cause harmful interference to radio communications.

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 
Applicant:

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Appendix B
Fluid Delivery Performance Testing

This appendix contains the following topics:

BD Alaris™ Pump Module Rate Accuracy

Flow rate accuracy is shown in the characterization tables below under various operating conditions.These characterization studies involve the following analysis periods.

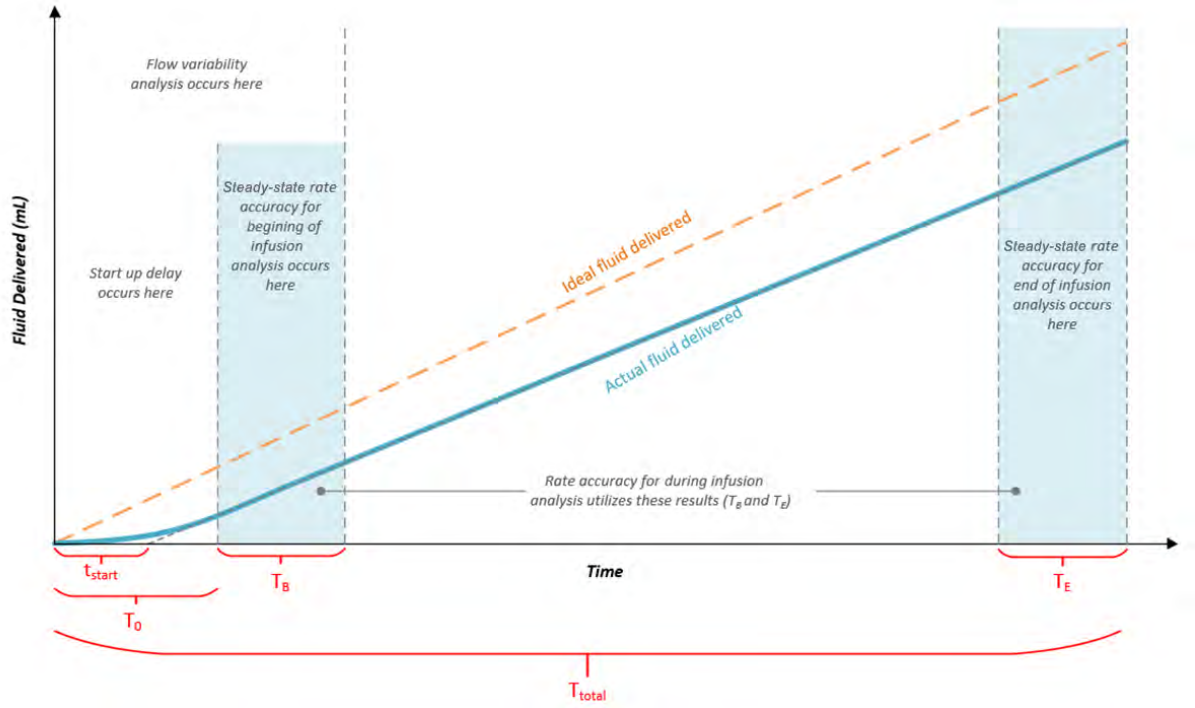
Term	Abbreviation	Definition
Test Period	T_{total}	Total duration of the test.
Start of Infusion Analysis Period	T_o	Evaluation period starting with the activation of the infusion test rate to the start of analysis period, T_B
Startup Delay Time	t_{start}	Measure of the lag time observed from the initiation of fluid delivery at a given rate to the effective start of delivery at that rate.
Begining of Infusion Analysis Period	T_B	Evaluation period following the start of infusion test period T_o
Start Test Point	t_{BS}	Start time of the analysis period T_B
End Test Point	T_{BF}	Finish time of the analysis period T_B
End of Infusion Analysis Period	T_E	Evaluation period at the end of the test period T_{total}
Start Test Point	t_{ES}	Start time of the end analysis period T_E
End Test Point	t_{EF}	Finish time of the end analysis period T_E

Time periods for the terms defined above are listed in the table below.

T_{total} [h]	T_0 [min]	T_B [min]	T_E[1] [min]	Note
$T_{total} \geq 3h$	60 min	60 min	60 min	
$3h > T_{total} \geq 2h$	60 min	60 min	60 min	T_B and T_E overlap
$2h > T_{total} \geq 1h$	60 min	60 min[Note 2]	N/A	T_0 and T_B overlap
$1h > T_{total}$	$T_0 = T_{total}$ [min]	$T_B = T_0 = T_{total}$ [min]	N/A	T_0 and T_B overlap

[1] T_E is not applicable for $T_{total} < 2$ hours
[2] last hour of T_{total}

An example of measured pump flow, when plotted as measured weight from a scale (converted to fluid volume), is displayed visually below. The terms in the table above are shown visually by highlighting the time durations they define.



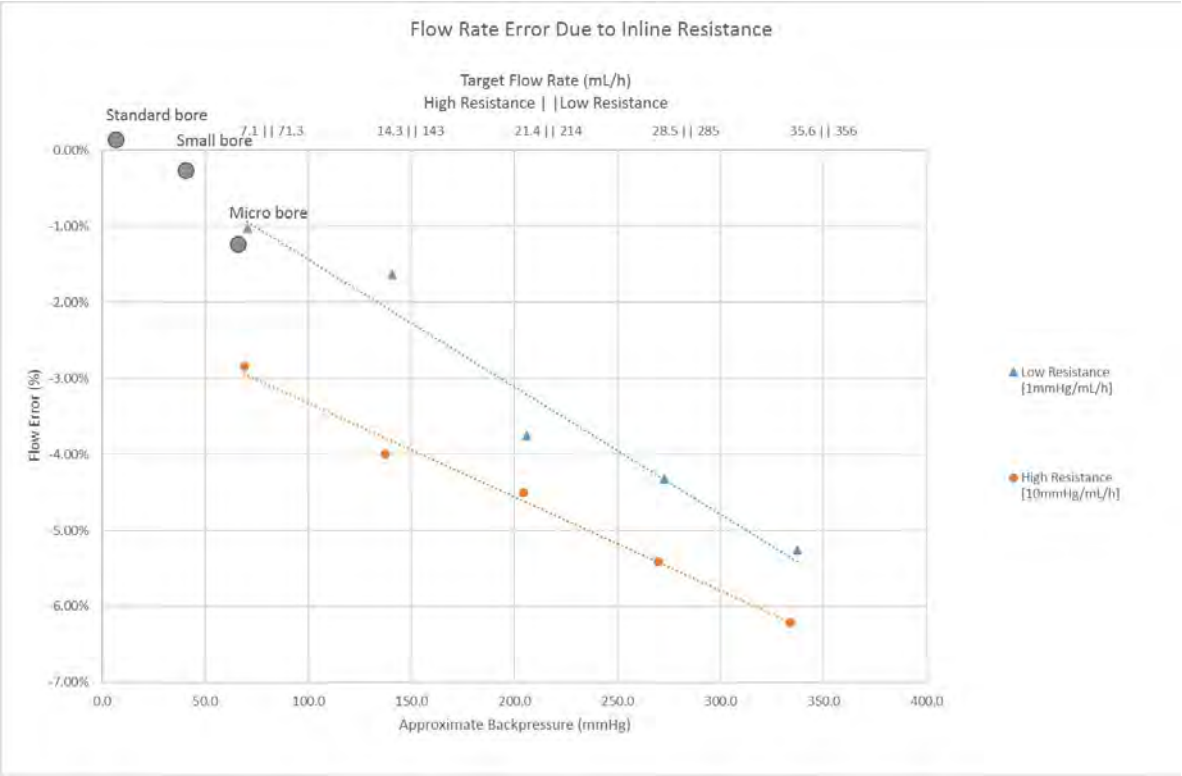
Pump Module flow rate accuracy is shown in the characterization table below under various operating conditions.

Test Condition[1]	Flow Rate (mL/h)	Start Up Delay	Steady-State Rate Accuracy (Average) Near Beginning of Administration Set Change Interval (After the Start Up Delay) (T_B)	Steady-State Rate Accuracy (Average) Near End of Administration Set Change Interval (T_E)	Steady-State Rate Accuracy (Average) Average Over Administration Set Change Interval (Average Over T_B and T_E)
Standard Operating Conditions	0.1	1 min 57 sec	-1.95%	-2.35%	-2.15%
	1	56 sec	-1.89%	-2.25%	-2.07%
	10	3 sec	-0.98%	-1.06%	-1.02%
	100	3 sec	-2.27%	-2.73%	-2.50%
	999	4 sec	0.30%	-0.25%	0.03%

Test Condition[1]		Flow Rate (mL/h)	Start Up Delay	Steady-State Rate Accuracy (Average) Near Beginning of Administration Set Change Interval (After the Start Up Delay) (T_B)	Steady-State Rate Accuracy (Average) Near End of Administration Set Change Interval (T_E)	Steady-State Rate Accuracy (Average) Average Over T_B and T_E)
Viscous Fluid: D50W		10	6 sec	-1.16%		
Environmental Testing	Operating Temperature 5°C	10	8 sec	-1.70%		
	Operating Temperature 40°C	10	10 sec	-0.89%		
	Operating Pressure 525 mmHg	10	1 min 23 sec	-1.85%		
	Operating Pressure 795 mmHg	10	1 min 6 sec	-1.21%		
Patient Height (for example, Outlet Pressure) Variation[2]	Patient Height[4] -53.6 inches (-100 mmHg)	10	7 sec	0.78%		
	Patient Height 0 inches (0 mmHg)	10	3 sec	-0.98%		
	Patient Height[4] +53.6 inches (+100 mmHg)	10	8 sec	-3.20%		
Head Height (for example Inlet Pressure) Variation[3]	Head Height[4] -19.7 inches (-36.8 mmHg)	10	8 sec	-5.32%		
	Head Height[4] 24 inches (+44.8 mmHg)	10	3 sec	-0.98%		
	Head Height[4] 51.2 inches (+95.6 mmHg)	10	9 sec	-0.18%		

1.All tests performed under standard operating conditions unless otherwise specified
2.Effect of outlet pressure (for example, patient height[4]) on rate accuracy: -0.04% per inch (-1.99% per 100 mmHg)
3.Effect of inlet pressure (for example, head height[4]) on rate accuracy: 0.07% per inch (4.01% per 100 mmHg)
4.Height values are based on density of distilled water and will vary based on density of the fluid

Tests were performed to measure the reduction in flow output based on backpressure generated as fluid is delivered through a restrictive cannula, which is the typical mechanism that causes high backpressures in a clinical setting. The flow rate error across a range of backpressures, generated by a flow resistor (for example, small diameter clinical use catheters or orifice flow restrictor), is in the graphs below.



Backpressure from inline resistance can be calculated by multiplying flow resistance and flow rate. Infusion sets in the Pump Module infusion set compatibility list range in downstream flow resistance from approximately 0.004 mmHg/mL/h (standard bore) to approximately 0.129 mmHg/mL/h (microbore). For these infusion sets, the flow rate accuracy is ± 5% at flow rates ≥ 1 mL/h and from -8% to +5 % at flow rates < 1 mL/h under standard operating conditions. Examples from microbore, smallbore, and standard bore sets are listed below:

- Using a microbore set with an 18 gauge 1.5 inch needle, with a downstream flow resistance of 0.129 mmHg/mL/h at 500 mL/h, results in the highest backpressure from a set (approximately 65 mmHg) within the Pump Module infusion set compatibility list. This results in an average flow rate accuracy of -1.20%.
- Using a smallbore set (for example, 2411-0500), with an 18 gauge 1.5 inch needle, with a downstream flow resistance of 0.043 mmHg/mL/h at 999 mL/h, results in a backpressure (approximately 43 mmHg) less than microbore sets. This results in an average flow rate accuracy of -0.19%.
- Using a standard bore set (for example, 24200-0007, 2420-0007, 2426-0007), with an 18 gauge 1.5 inch needle, with a downstream flow resistance of 0.004 mmHg/mL/h at 999 mL/h, results in a backpressure (approximately 4 mmHg) less than smallbore sets. This results in an average flow rate accuracy of +0.30%.

Restrictive cannuala and catheters add an order of magnitude of resistance beyond that of infusion sets, as illustrated on the graph above.

BD Alaris™ Pump Module Coefficient of Variation

The coefficient of variation CV% is a measure of the short-term flow variability. This measurement involves the following terms.

Term	Abbreviation	Definition
Coefficient of Variablity	CV% (%)	Measure of the short-term flow variability
Decay Time	$T_{D(S)}$	Time period required for half of the delivered volume to be removed or consumed from the site of delivery
Compartment Volume	V (mL)	Calculated volume contained by a single compartment pharmacokinetic model

The evaluation of the coefficient of variation first requires the transformation of the Pump Module flow waveform measured from weight measurements by a single-compartment pharmacokinetic model. This transformation includes the calculation of B, the unit-less recursion coefficient for a specific decay time (modeled after drug half-lives), from the equation below.

$$B = \exp^{[-\ln(2)*Tsample]/T_D}$$

- T_{sample} is the sample interval defined as 10 seconds
- T_D is the time period required for half of the delivered volume to be removed or consumed from the site of delivery, or the decay time in units of seconds (decay times evaluated include 2 min, 5 min, 10 min, 20 min)

The initial compartment volume, V_{init}, is computed from the following equation.

$$V_{init}\ (mL) = (T_{sample} * r_{average}) / K * (1-B)$$

- T_{sample} is the sample interval defined as 10 seconds
- $r_{average}$ is the average flow rate calculated over the analysis period
- B is the unit-less recursion coefficient for a specific decay time (modeled after drug half-lives)
- K is a units conversion constant (3600 seconds per hour)

The delivery compartment volume is then calculated from the following equations.

$$V(n)\ (\text{mL}) = V_{init}\ (\text{mL}),\ \text{for n=0}$$

$$V(n) = \text{B}^* V(n\text{-}1) + [W(n) - (W(n-1)]/\text{d},\ \text{for n=1 to } N_{BF}$$

- V_{init} is the initial compartment volume in mL
- V(n) is the compartment volume in mL at sample n
- V(n-1) is the compartment volume in mL at sample (n-1)
- B is the unit-less recursion coefficient for a specific decay time calculated above
- W(n) is the mass in grams measured at sample n
- W(n−1) is the mass in grams measured at sample (n-1)
- N_{BF} is the final data sample in the analysis period T_B
- d is the density of the fluid

The short-term flow variability coefficient of variation CV% is then calculated from the mean and standard deviation of the compartment volume, V(n), using the following equation.

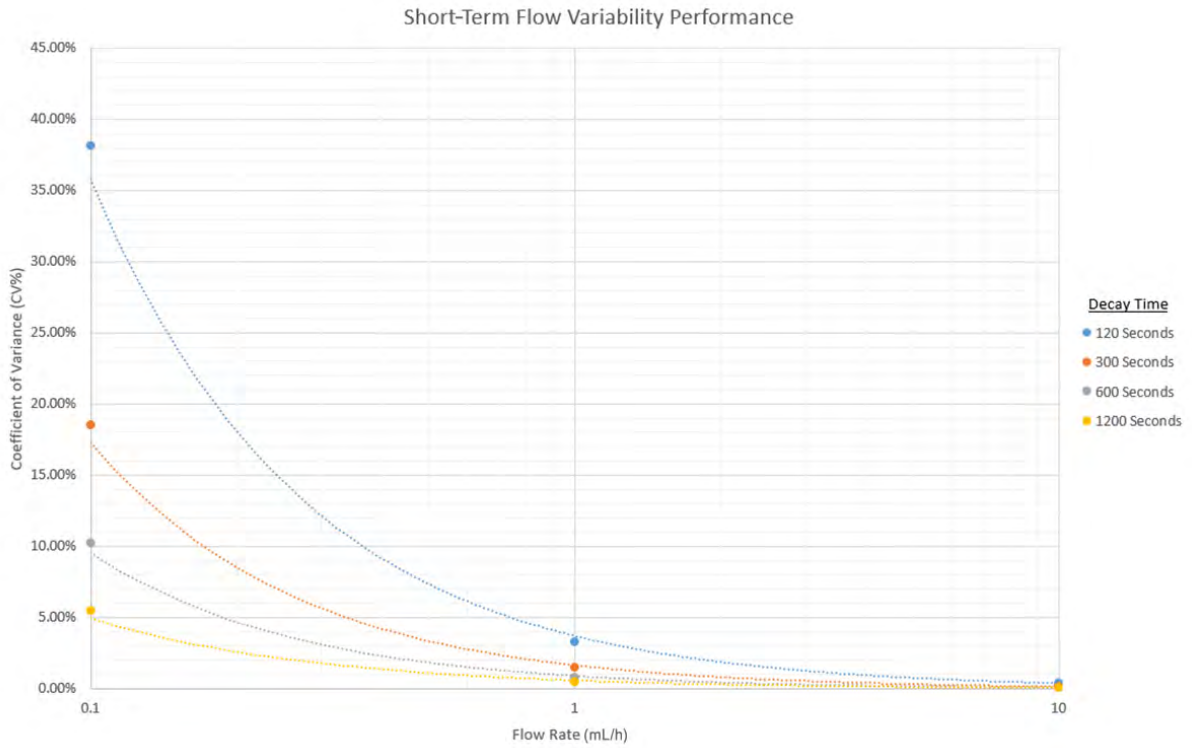
$$\text{CV\%} = \frac{\text{standard deviation of the compartment volume V(n)}}{\text{mean of the compartment volume V(n)}}$$

A low CV% indicates low flow variability. Higher CV% are expected to occur at lower flow rates and shorter decay times.

The Pump Module short-term flow variability coefficient of variation CV% is shown in the characterization table below under various flow rates and decay times (modeled after drug half-lives).

Test Condition	Flow Rate mL/h	Short-Term Variability (CV%)			
		Decay Time 2 min	Decay Time 5 min	Decay Time 10 min	Decay Time 20 min
Standard Operating Conditions	0.1	38.12%	18.51%	10.22%	5.45%
	1	3.27%	1.45%	0.79%	0.48%
	10	0.41%	0.17%	0.09%	0.08%

The Pump Module short-term flow variability coefficient of variation CV% from the table above is also shown in the graphs below.



BD Alaris™ Pump Module Bolus Volume Accuracy

A bolus delivered by the Pump Module at the beginning of an infusion is also known as a loading dose. The Pump Module does not have a loading dose feature. A loading dose can be accomplished by delivering a bolus dose at the beginning of an infusion.

Pump Module loading dose accuracy is shown in the characterization table below at the maximum bolus flow rate and loading dose of 5 mL (intermediate bolus volume).

NOTE:
The characterization testing is based on a sample size of 15 pumps and 15 infusion sets with 1 loading dose per pump.

Flow Rate[1,2] (mL/h)	Loading Dose Volume (mL)	Mean Error (%)	Standard Deviation (%)
300	5	-1.46	1.56
999	5	-0.24	1.08

1. The Pump Module minimum programmable bolus duration is 1 minute, resulting in a maximum flow rate of 6 mL/h for a 0.1 mL bolus, and 300 mL/h for a 5 mL bolus. The rapid bolus feature maximum rate is limited by the settings in the Guardrails™ data set. If the user selects the rapid bolus feature, the maximum flow rate could increase to 999 mL/h, depending on the settings in the Guardrails™ data set.
2. If configured with a Guardrails™ data set, the bolus dose and duration is limited by the Guardrails™ data set. Therefore, the Guardrails™ data set can limit the Pump Module maximum flow rate by bolus volume.

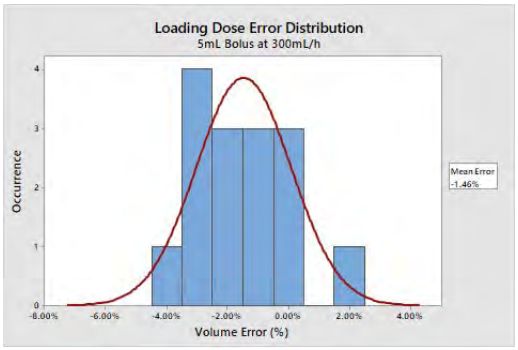
Pump Module loading dose accuracy is shown in the characterization table below at the maximum bolus flow rate and at loading dose volume of 0.1 mL (minimum bolus volume).

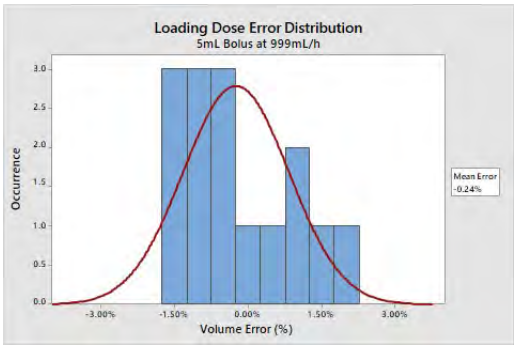
NOTE:
The characterization testing is based on a sample size of 15 pumps and 15 infusion sets with 1 loading dose per pump.

Flow Rate[1,2] (mL/h)	Loading Dose Volume (mL)	Mean Error (%)	Standard Deviation (%)
6	0.1	11.57	7.68
999	0.1	33.63	5.45

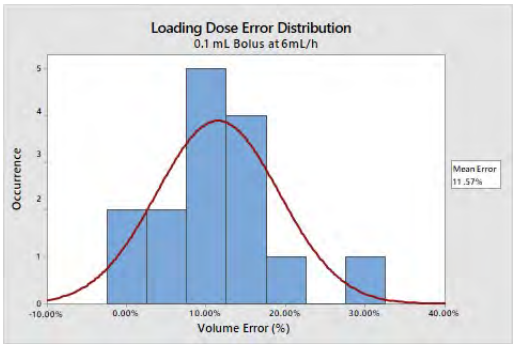
1. The Pump Module minimum programmable bolus duration is 1 minute, resulting in a maximum flow rate of 6 mL/h for a 0.1 mL bolus, and 300 mL/h for a 5 mL bolus. The rapid bolus feature maximum rate is limited by the settings in the Guardrails™ data set. If the user selects the rapid bolus feature, the maximum flow rate could increase to 999 mL/h, depending on the settings in the Guardrails™ data set.
2. If configured with a Guardrails™ data set, the bolus dose and duration is limited by the Guardrails™ data set. Therefore, the Guardrails™ data set can limit the Pump Module maximum flow rate by bolus volume.

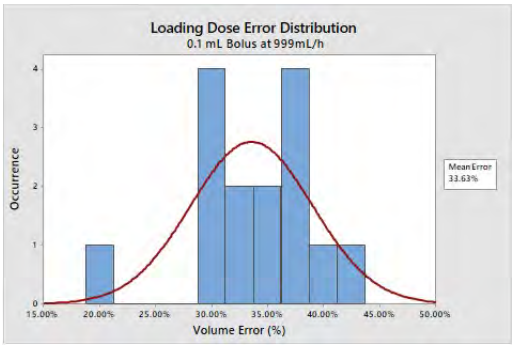
The performance data from the table above is also shown in a histogram format in the graphs below for the loading dose accuracy at the maximum bolus flow rate and a loading dose of 5 mL (intermediate bolus volume).





The performance data from the table above is also shown in a histogram format in the graphs below for the loading dose accuracy at the maximum bolus flow rate and a loading dose of 0.1 mL (minimum bolus volume).





Bolus volume accuracy is shown in the characterization table below at the maximum bolus flow rate for the Pump Module under three levels of backpressure and a bolus volume of 5 mL (intermediate bolus volume).

NOTE:
The characterization testing is based on a sample size of 15 pumps and 15 infusion sets with 25 boluses administered after the loading dose bolus per pump.

Flow Rate[1,2] (mL/h)	Bolus Volume (mL)	Nominal Backpressure			+ 100 mmHg			-100 mmHg		
		Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error
300	5	-1.14%	-1.24%	-1.04%	-2.66%	-2.72%	-2.55%	0.81%	0.56%	0.96%
999	5	0.46%	0.01%	0.62%	-1.14%	-1.52%	-0.81%	1.80%	1.57%	1.97%

1. The Pump Module minimum programmable bolus duration is 1 minute, resulting in a maximum flow rate of 6 mL/h for a 0.1 mL bolus, and 300 mL/h for a 5 mL bolus. The rapid bolus feature maximum rate is limited by the settings in the Guardrails™ data set. If the user selects the rapid bolus feature, the maximum flow rate could increase to 999 mL/h, depending on the settings in the Guardrails™ data set.
2. If configured with a Guardrails™ data set, the bolus dose and duration is limited by the Guardrails™ data set. Therefore, the Guardrails™ data set can limit the Pump Module maximum flow rate by bolus volume.

Bolus volume accuracy is shown in the characterization table below at the maximum bolus flow rate for the Pump Module under three levels of backpressure and a bolus volume of 0.1 mL (minimum bolus volume).

NOTE:
The characterization testing above is based on a sample size of 15 pumps and 15 infusion sets with 25 boluses administered after the loading dose bolus per pump.

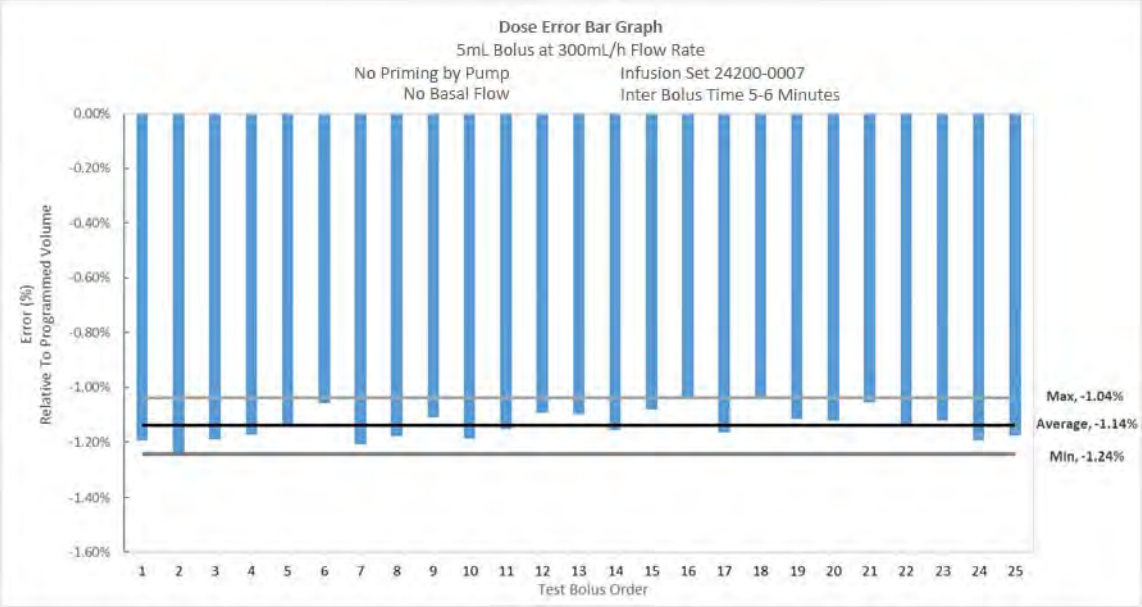
Flow Rate[1,2] (mL/h)	Bolus Volume (mL)	Nominal Backpressure			+ 100 mmHg			-100 mmHg		
		Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error
6	0.1	2.27%	-0.96%	5.46%	0.54%	-1.95%	3.30%	8.79%	-13.41%	13.87%
999	0.1	27.32%	16.82%	35.10%	26.44%	21.56%	31.32%	33.66%	24.15%	38.08%

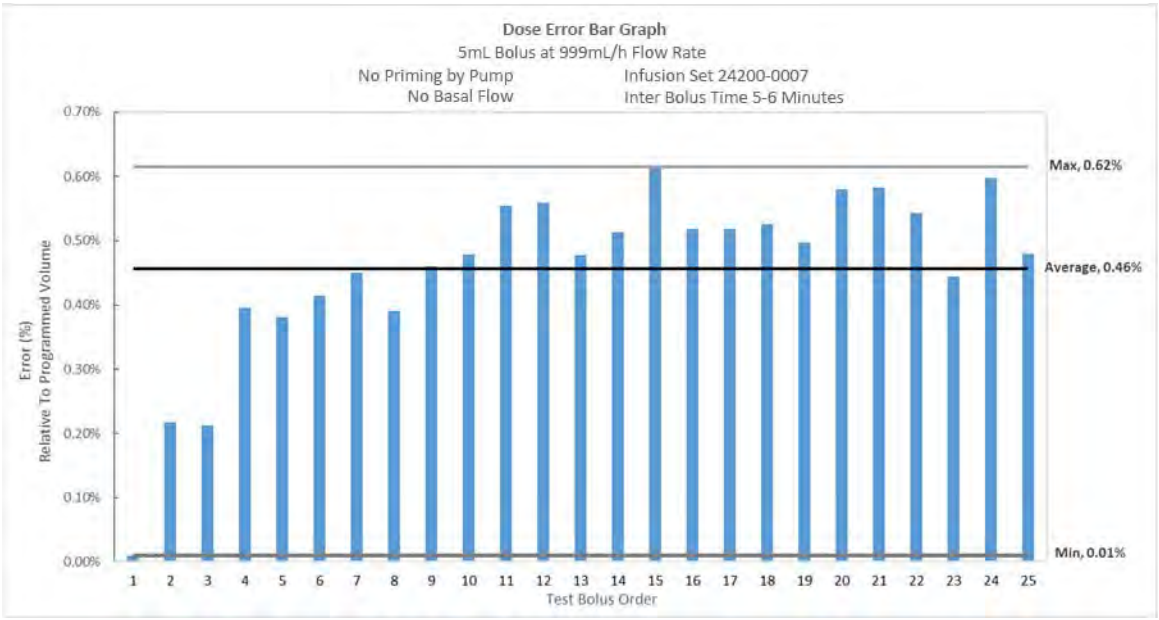
1. The Pump Module minimum programmable bolus duration is 1 minute, resulting in a maximum flow rate of 6 mL/h for a 0.1 mL bolus, and 300 mL/h for a 5 mL bolus. The rapid bolus feature maximum rate is limited by the settings in the Guardrails™ data set. If the user selects the rapid bolus feature, the maximum flow rate could increase to 999 mL/h, depending on the settings in the Guardrails™ data set.
2. If configured with a Guardrails™ data set, the bolus dose and duration is limited by the Guardrails™ data set. Therefore, the Guardrails™ data set can limit the Pump Module maximum flow rate by bolus volume.

A nominal backpressure means that the pump is at the same height compared to the patient's heart level. +100 mmHg backpressure means that the pump is 54 inches below the patient's heart level, while a -100 mmHg backpressure means that the pump is 54 inches above the patient's heart level.

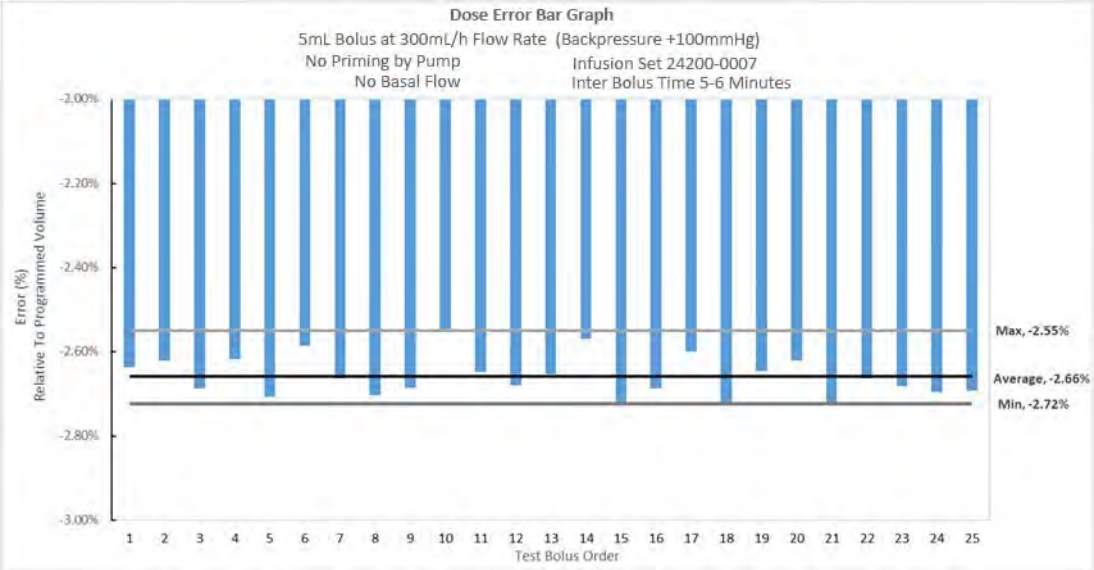
The bolus volume accuracy performance data from the characterization table above, at the maximum bolus flow rate and a bolus volume of 5 mL (intermediate bolus volume), is also shown per bolus tested in the graphs below at three levels of backpressure.

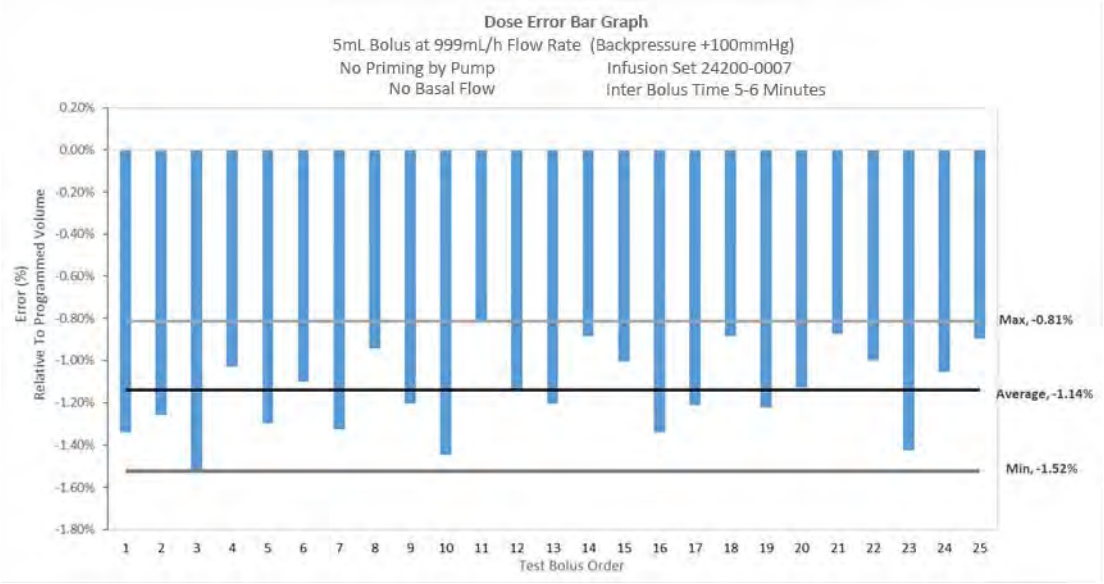
Nominal Backpressure



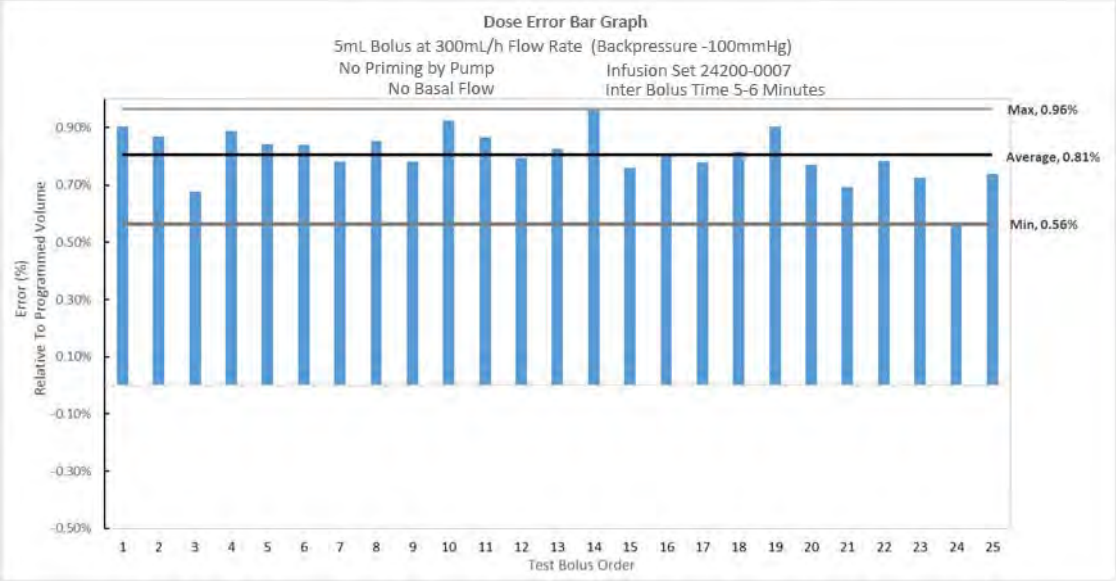


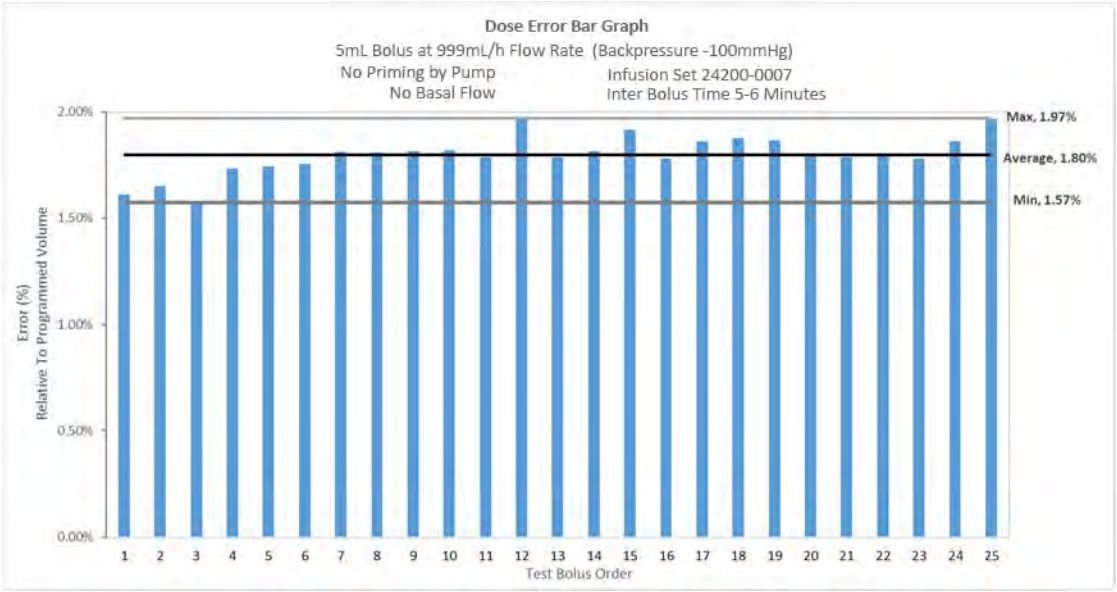
+100 mmHg Backpressure





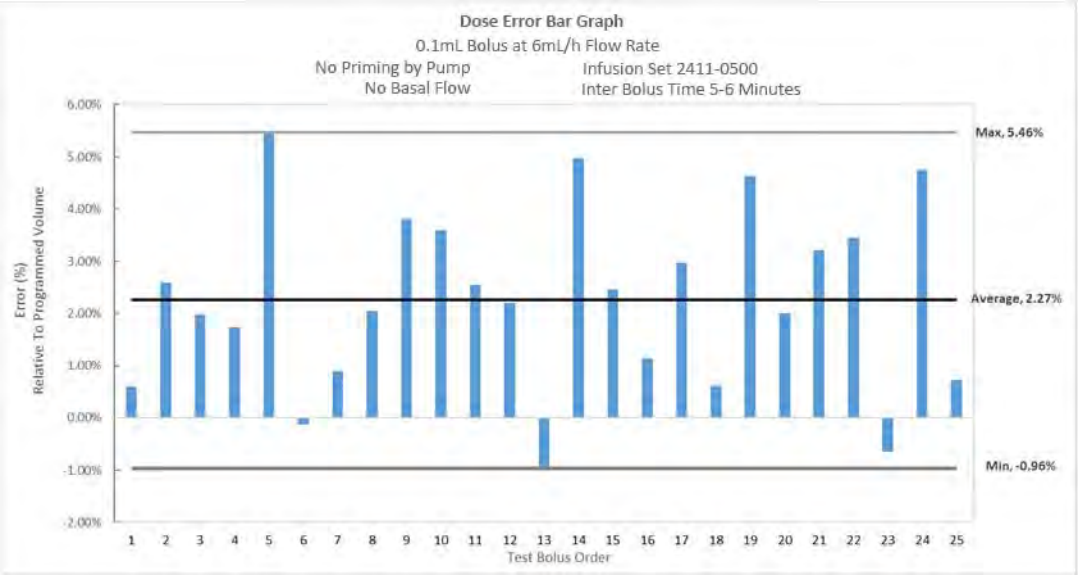
-100 mmHg Backpressure

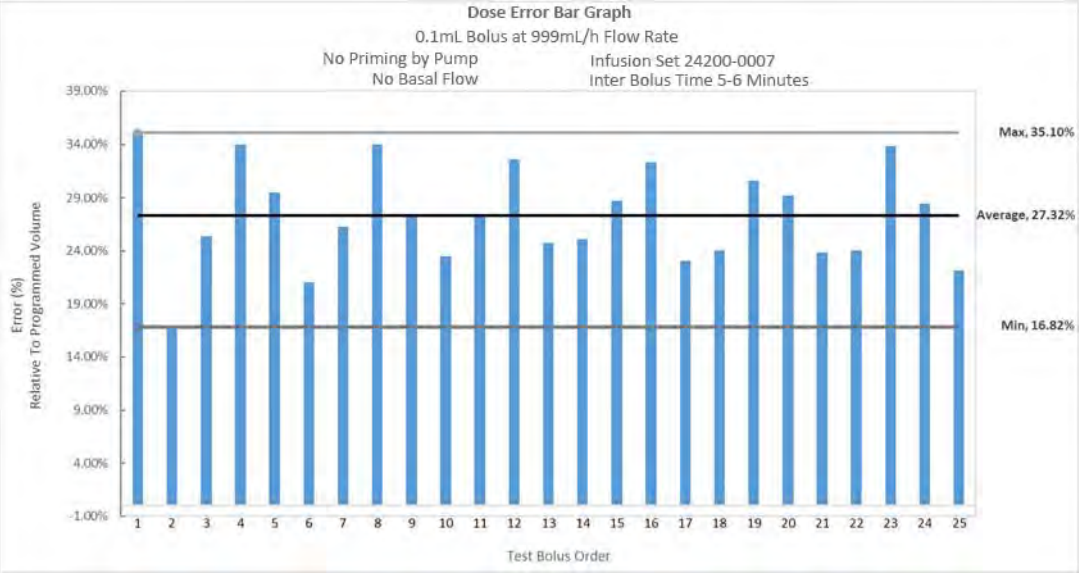




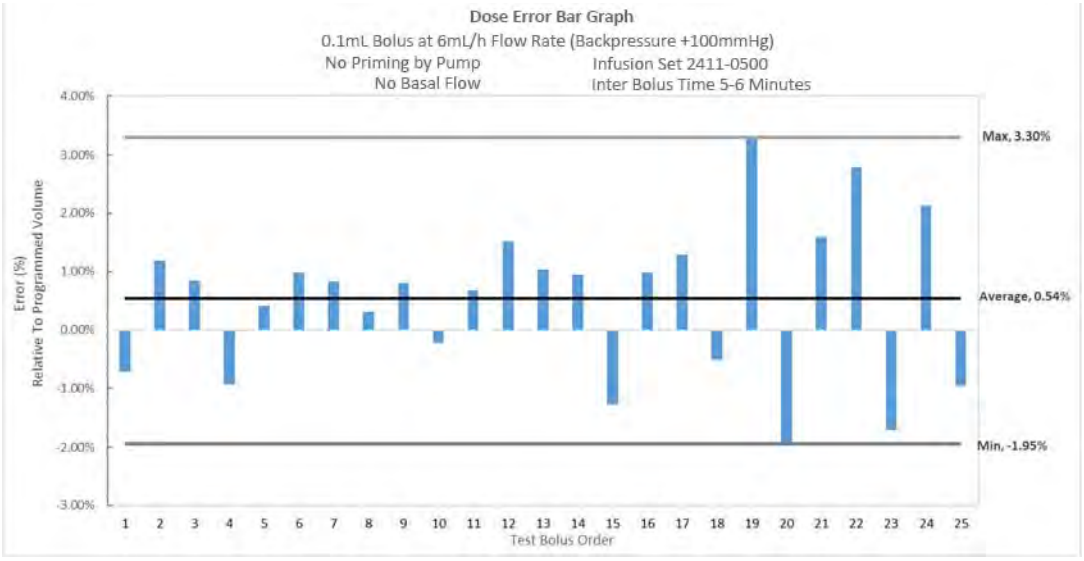
The bolus dose volume accuracy performance data from the characterization table above, at the maximum bolus flow rate and a bolus volume of 0.1 mL (minimum bolus volume), is also shown per bolus tested in the graphs below at three levels of backpressure.

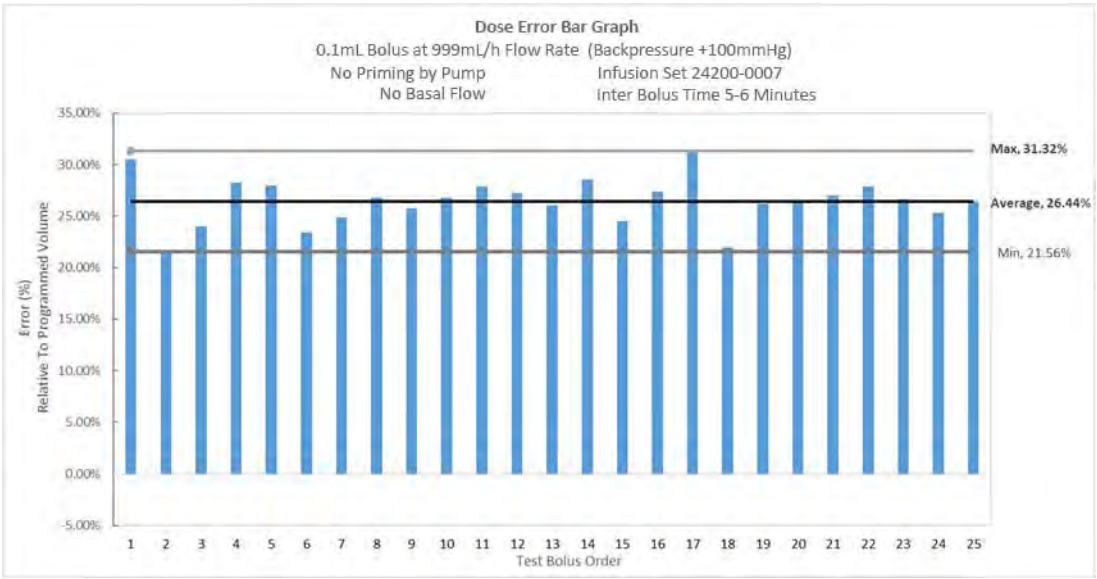
Nominal Backpressure



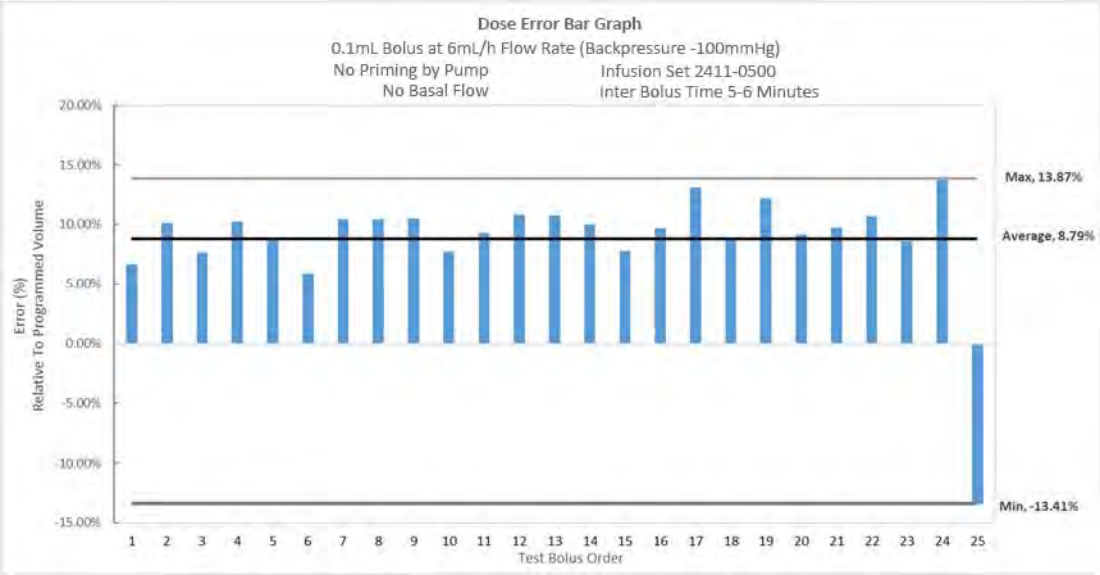


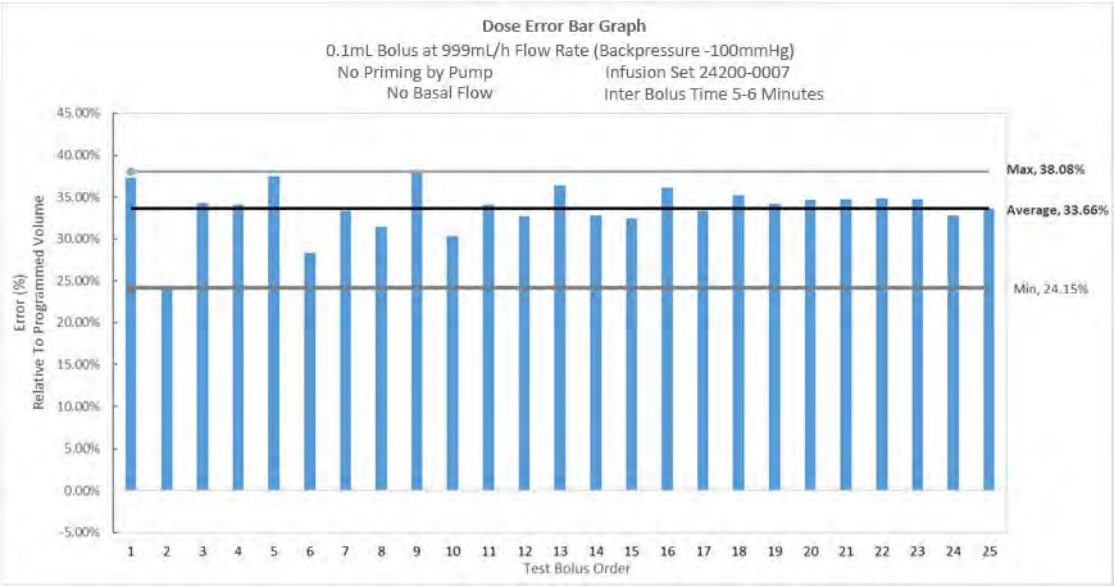
+100 mmHg Backpressure





-100 mmHg Backpressure





Alaris™ Syringe Module Rate Accuracy

Flow rate accuracy is shown in the characterization tables below under various operating conditions. These characterization studies involve the following analysis periods.

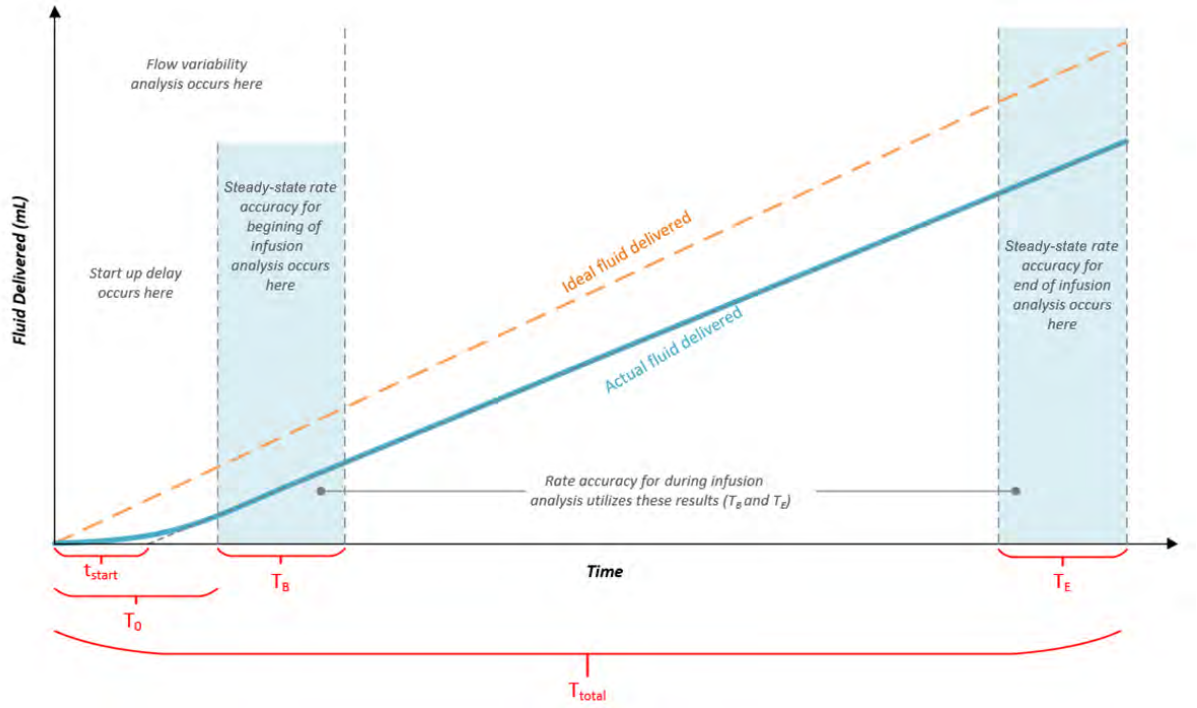
Term	Abbreviation	Definition
Test Period	T_{total}	Total duration of the test.
Start of Infusion Analysis Period	T_o	Evaluation period starting with the activation of the infusion test rate to the start of analysis period, T_B
Startup Delay Time	t_{start}	Measure of the lag time observed from the initiation of fluid delivery at a given rate to the effective start of delivery at that rate.
Begining of Infusion Analysis Period	T_B	Evaluation period following the start of infusion test period T_o
Start Test Point	t_{BS}	Start time of the analysis period T_B
End Test Point	T_{BF}	Finish time of the analysis period T_B
End of Infusion Analysis Period	T_E	Evaluation period at the end of the test period T_{total}
Start Test Point	t_{ES}	Start time of the end analysis period T_E
End Test Point	t_{EF}	Finish time of the end analysis period T_E

Time periods for the terms defined above are listed in the table below.

T_{total} [h]	T_0 [min]	T_B [min]	T_E[1] [min]	Note
$T_{total} \geq 3h$	60 min	60 min	60 min	
$3h > T_{total} \geq 2h$	60 min	60 min	60 min	T_B and T_E overlap
$2h > T_{total} \geq 1h$	60 min	60 min[Note 2]	N/A	T_0 and T_B overlap
$1h > T_{total}$	$T_0 = T_{total}$ [min]	$T_B = T_0 = T_{total}$ [min]	N/A	T_0 and T_B overlap

[1] T_E is not applicable for $T_{total} < 2$ hours
[2] last hour of T_{total}

An example of measured pump flow, when plotted as measured weight from a scale (converted to fluid volume), is displayed visually below. The terms in the table above are shown visually by highlighting the time durations they define.



Syringe Module flow rate accuracy is shown in the characterization table below under various operating conditions.

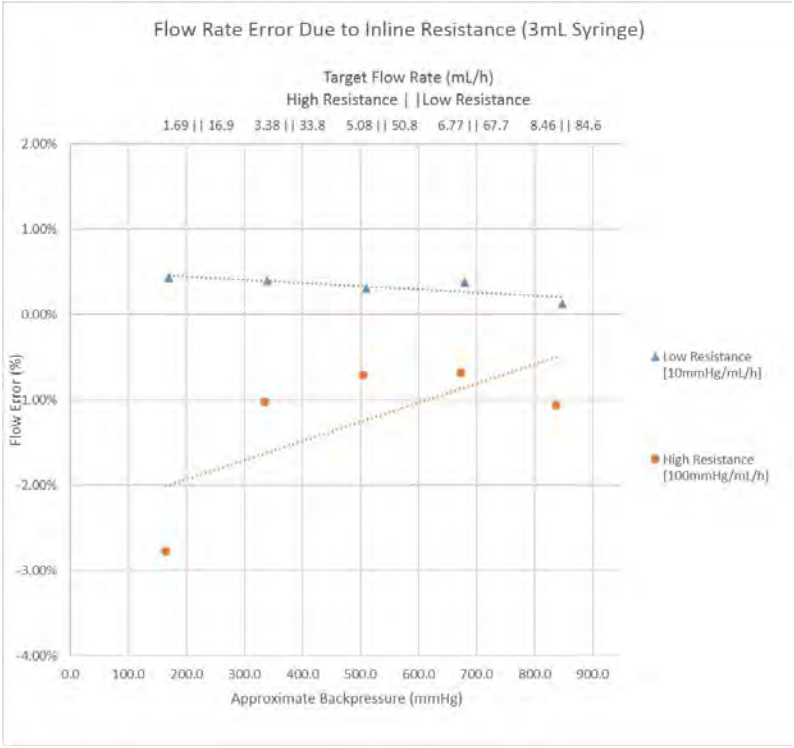
Test Condition[1]	Syringe	Flow Rate (mL/h)	Start Up Delay	Steady-State Rate Accuracy (Average) Near Beginning of Administration Set Change Interval (After the Start Up Delay) (T_B)	Steady-State Rate Accuracy (Average) Near End of Administration Set Change Interval (T_E)	Steady-State Rate Accuracy (Average) Average Over Administration Set Change Interval (Average Over T_B and T_E)
Standard Operating Conditions With Prime Set with Syringe Feature	BD 3 mL	0.01	3 h 33 min 15 sec	-5.07%	-4.91%	-5.05%
		0.1	23 min 31 sec	-0.98%	-0.50%	-0.74%
		1	2 min 59 sec	-0.10%	N/A[5]	-0.10%
		10	16 sec	0.05%	N/A[5]	0.05%
		100	5 sec	0.44%	N/A[5]	0.44%
	BD 20 mL	0.1	22 min 5 sec	-5.40%	-0.91%	-3.15%
		1	3 min 2 sec	-0.88%	0.10%	-0.39%
		10	40 sec	0.80%	N/A[5]	0.80%
		500	4 sec	0.59%	N/A[5]	0.59%
	BD 50 mL	0.1	23 min 53 sec	-5.04%	-3.05%	-4.04%
		1	2 min 42 sec	-2.25%	-0.71%	-1.47%
		10	51 sec	-0.28%	-0.14%	-0.21%
		999	2 sec	-0.26%	N/A[5]	-0.26%
Start Up Delay Without Prime Set with Syringe Feature	BD 3 mL	0.01	4 h 28 min 47 sec			
		0.1	31 min 25 sec			
		1	3 min 56 sec			
	BD 20 mL	0.1	1 h 3 min 3 sec			
		1	3 min 20 sec			
	BD 50 mL	0.1	1 h 15 min 44 sec			
		1	10 min 18 sec			
Viscous Fluid D50W[2]	BD 3 mL	1	1 min 15 sec	-0.17%		
	BD 20 mL	1	1 min 50 sec	1.02%		
	BD 50 mL	1	2 min 51 sec	-0.58%		

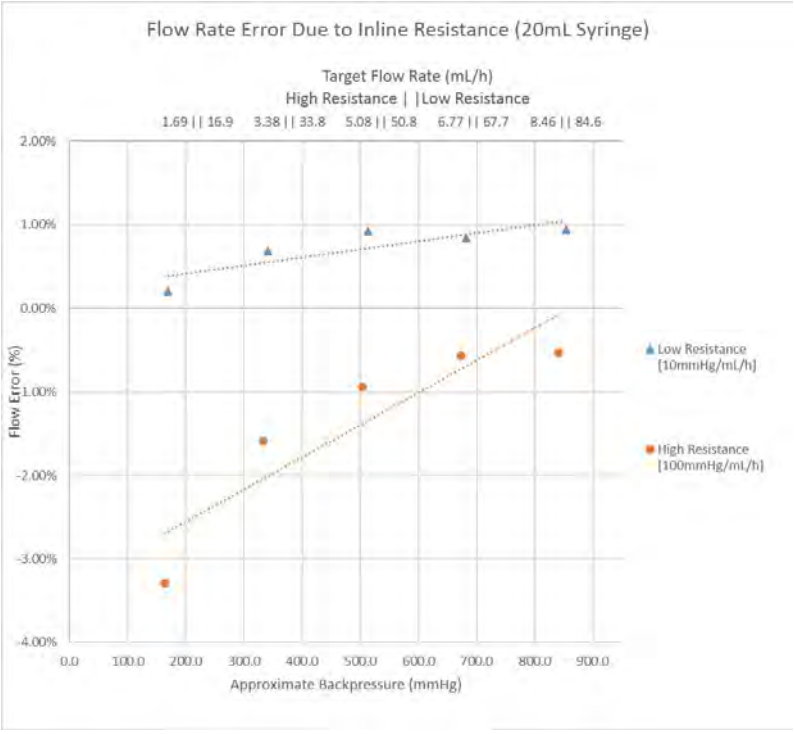
Test Condition[1]		Syringe	Flow Rate (mL/h)	Start Up Delay	Steady-State Rate Accuracy (Average) Near Beginning of Administration Set Change Interval (After the Start Up Delay) (T_B)	Steady-State Rate Accuracy (Average) Near End of Administration Set Change Interval (T_E)	Steady-State Rate Accuracy (Average) Average Over Administration Set Change Interval (Average Over T_B and T_E)
Environmental Testing[2]	Operating Temperature 5°C	BD 3 mL	1	4 min 8 sec	-0.77%		
		BD 20 mL	1	3 min 37 sec	-1.85%		
		BD 50 mL	1	4 min 15 sec	-2.14%		
	Operating Temperature 40°C	BD 3 mL	1	3 min 39 sec	0.55%		
		BD 20 mL	1	1 min 29 sec	0.90%		
		BD 50 mL	1	5 min 8 sec	1.54%		
	Operating Pressure 525 mmHg	BD 3 mL	1	16 min 19 sec	-0.05%		
		BD 20 mL	1	21 min 51 sec	0.02%		
		BD 50 mL	1	23 min 19 sec	-0.01%		
	Operating Pressure 760 mmHg	BD 3 mL	1	2 min 59 sec	-0.10%		
		BD 20 mL	1	3 min 2 sec	-0.88%		
		BD 50 mL	1	2 min 42 sec	-2.25%		

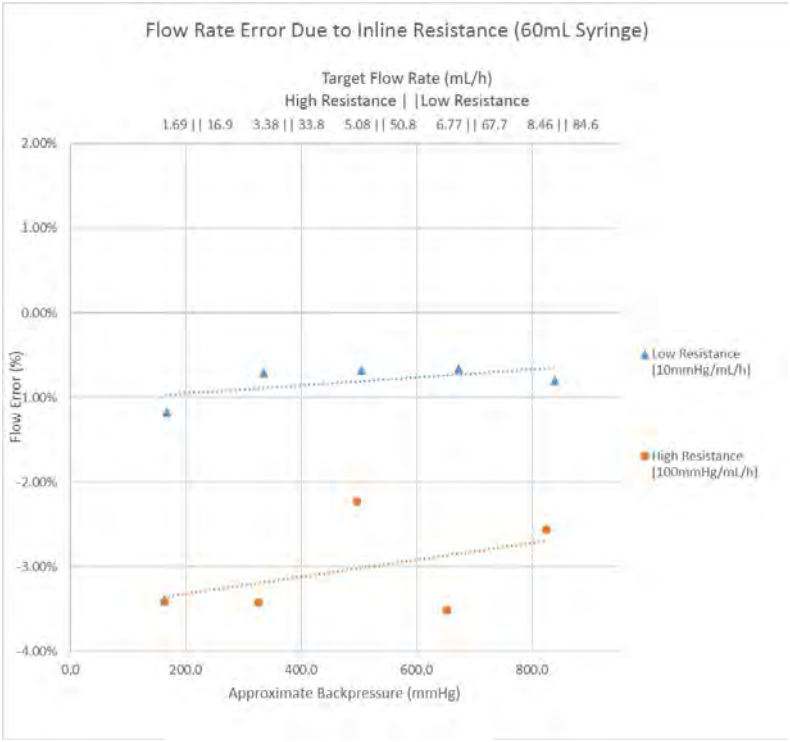
Test Condition[1]		Syringe	Flow Rate (mL/h)	Start Up Delay	Steady-State Rate Accuracy (Average) Near Beginning of Administration Set Change Interval (After the Start Up Delay) (T_B)	Steady-State Rate Accuracy (Average) Near End of Administration Set Change Interval (T_E)	Steady-State Rate Accuracy (Average) Average Over Administration Set Change Interval (Average Over T_B and T_E)
Patient Height (for example, Outlet Pressure) Variation [2,3]	Patient Height[4] -53.6 inches (-100 mmHg)	BD 3 mL	1	14 min 1 sec	1.65%		
		BD 20 mL	1	41 min 12 sec	-0.08%		
		BD 50 mL	1	18 min 16 sec	-0.02%		
	Patient Height 0 inches (0 mmHg)	BD 3 mL	1	2 min 59 sec	-0.10%		
		BD 20 mL	1	3 min 2 sec	-0.88%		
		BD 50 mL	1	2 min 42 sec	-2.25%		
	Patient Height[4] 53.6 inches (+100 mmHg)	BD 3 mL	1	42 sec	-0.37%		
		BD 20 mL	1	1 min 56 sec	0.04%		
		BD 50 mL	1	2 min 40 sec	-0.98%		

1. All tests performed under standard operating conditions unless otherwise specified using infusion sets with no pressure sensing disc
2. Test performed using prime set with syringe feature
3. Effect of outlet pressure (for example, patient height[4]) on rate accuracy: BD 3 mL syringe is -0.02 % per inch (-1.01% per 100 mmHg), BD 20 mL syringe is 0.001% per inch (0.06% per 100 mmHg), and BD 50 mL syringe is -0.009% per inch (-0.48% per 100 mmHg)
4. Height values are based on density of distilled water and will vary based on density of the fluid
5. Test run too short for the flow rate and syringe size combination to create T_E. In this case T_B=T_E.

Tests were performed to measure the reduction in flow output based on backpressure generated as fluid is delivered through a restrictive cannula, which is the typical mechanism that causes high backpressures in a clinical setting. The flow rate error across a range of backpressures, generated by a flow resistor (for example, small diameter clinical use catheters or orifice flow restrictor), is in the graphs below.






Flow Rate Error Due to Inline Resistance (60mL Syringe)
Target Flow Rate (mL/h)
High Resistance | |Low Resistance
1.69 || 16.9
3.38 || 33.8
5.08 || 50.8
6.77 || 67.7
8.46 || 84.6
2.00%
1.00%
0.00%
-1.00%
-2.00%
-3.00%
-4.00%
Flow Error (%)
0.0
200.0
400.0
600.0
800.0
Approximate Backpressure (mmHg)
Low Resistance (10mmHg/mL/h)
High Resistance (100mmHg/mL/h)

Alaris™ Syringe Module Coefficient of Variation

The coefficient is variation CV% is a measure of the short-term flow variability.This measurement involves the following terms.

Term	Abbreviation	Definition
Coefficient of Variablity	CV% (%)	Measure of the short-term flow variability
Decay Time	T_D (s)	Time period required for half of the delivered volume to be removed or consumed from the site of delivery
Compartment Volume	V (mL)	Calculated volume contained by a single compartment pharmacokinetic model

The evaluation of the coefficient of variation first requires the transformation of the pump's flow waveform measured from weight measurements by a single-compartment pharmacokinetic model. This transformation includes the calculation of B, the unit-less recursion coefficient for a specific decay time (modeled after drug half-lives), from the equation below.

$$B = \exp^{[-\ln(2)*Tsample]/T_D}$$

- T_{sample} is the sample interval defined as 10 seconds
- T_D is the time period required for half of the delivered volume to be removed or consumed from the site of delivery, or the decay time in units of seconds (decay times evaluated include 2 min, 5 min, 10 min, 20 min)

The initial compartment volume, V_{init}, is computed from the following equation.

$$V_{init}\ (mL) = (T_{sample} * r_{average}) / K * (1-B)$$

- T_{sample} is the sample interval defined as 10 seconds
- $r_{average}$ is the average flow rate calculated over the analysis period
- K is a units conversion constant (3600 seconds per hour)

The delivery compartment volume is then calculated from the following equations.

$$V(n)\ (\text{mL}) = V_{init}\ (\text{mL}),\ \text{for n=0}$$

$$V(n) = B^{*}\ V(n\text{-}1) + [W(n) - (W(n-1)]/d,\ \text{for n=1 to } N_{BF}$$

- V_{init} is the initial compartment volume in mL
- V(n) is the compartment volume in mL at sample n
- V(n-1) is the compartment volume in mL at sample (n-1)
- B is the unit-less recursion coefficient for a specific decay time calculated above
- W(n) is the mass in grams measured at sample n
- W(n−1) is the mass in grams measured at sample (n-1)
- N_{BF} is the final data sample in the analysis period T_B
- d is the density of the fluid

The short-term flow variability coefficient of variation CV% is then calculated from the mean and standard deviation of the compartment volume, V(n), using the following equation.

$$\text{CV\%} = \frac{\text{standard deviation of the compartment volume V(n)}}{\text{mean of the compartment volume V(n)}}$$

A low CV% indicates low flow variability. Higher CV% are expected to occur at lower flow rates and shorter decay times.

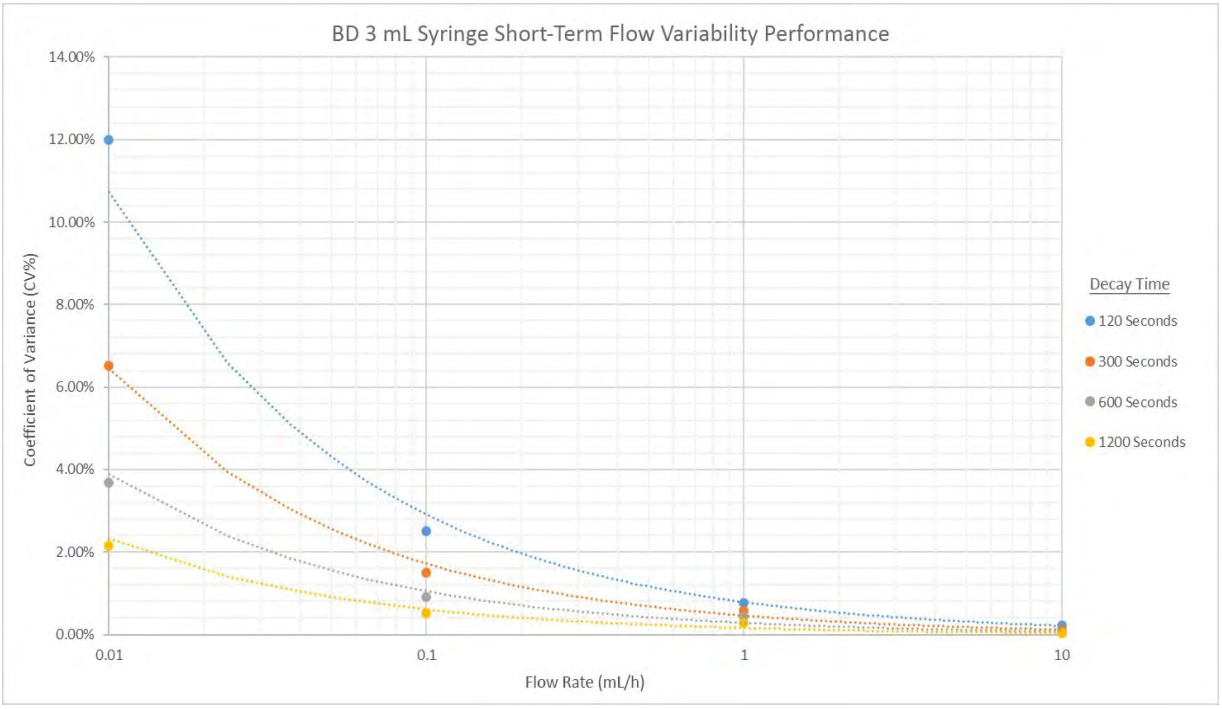
The Syringe Module short-term flow variability coefficient of variation CV% is shown in the characterization table below under various flow rates and decay times (modeled after drug half-lives).

Test Condition	Syringe	Flow Rate mL/h	Short-Term Variability (CV%)[1]			
			Decay Time 2 min	Decay Time 5 min	Decay Time 10 min	Decay Time 20 min
Standard Operating Conditions	BD 3 mL	0.01	12.00%	6.51%	3.69%	2.15%
		0.1	2.50%	1.51%	0.91%	0.51%
		1	0.76%	0.58%	0.44%	0.29%
		10	0.23%	0.11%	0.06%	0.03%
	BD 20 mL	0.1	6.08%	4.13%	3.21%	2.63%
		1	1.11%	0.72%	0.51%	0.34%
		10	0.48%	0.32%	0.20%	0.11%
	BD 50 mL	0.1	12.39%	7.51%	5.19%	4.03%
		1	2.52%	1.45%	0.85%	0.49%
		10	0.34%	0.22%	0.16%	0.10%

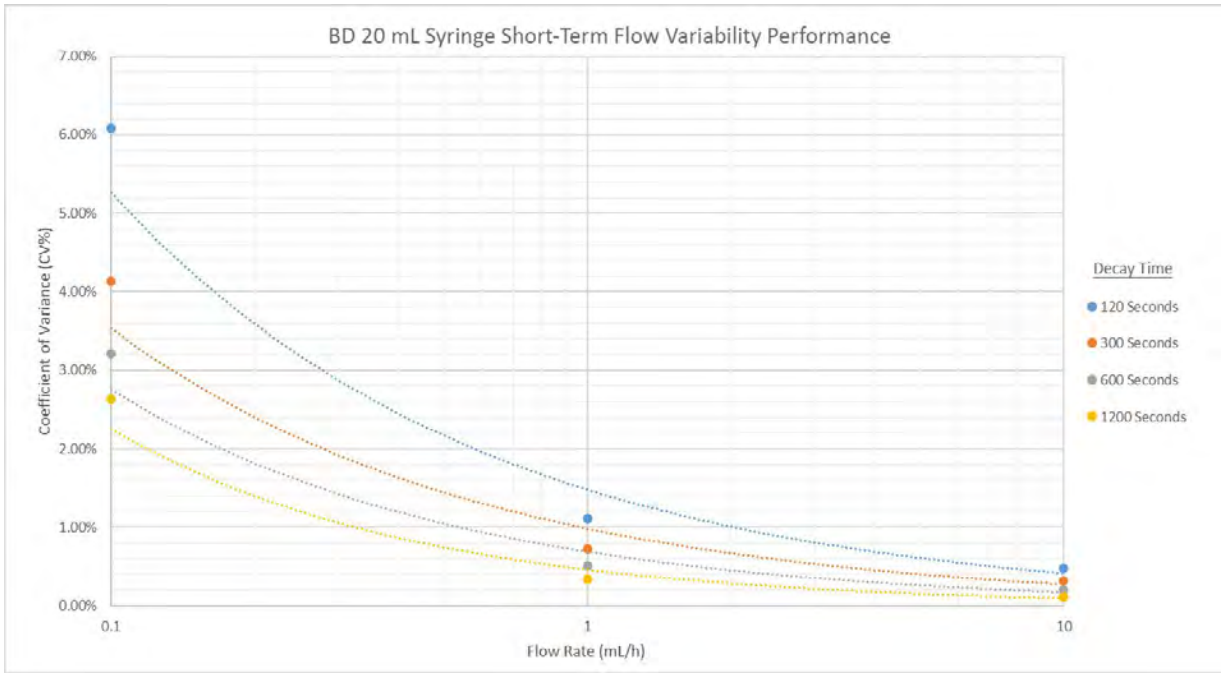
1.Calculated from steady-state period T_B

The Syringe Module short-term flow variability coefficient of variation CV% from the table above is also shown in the graphs below.

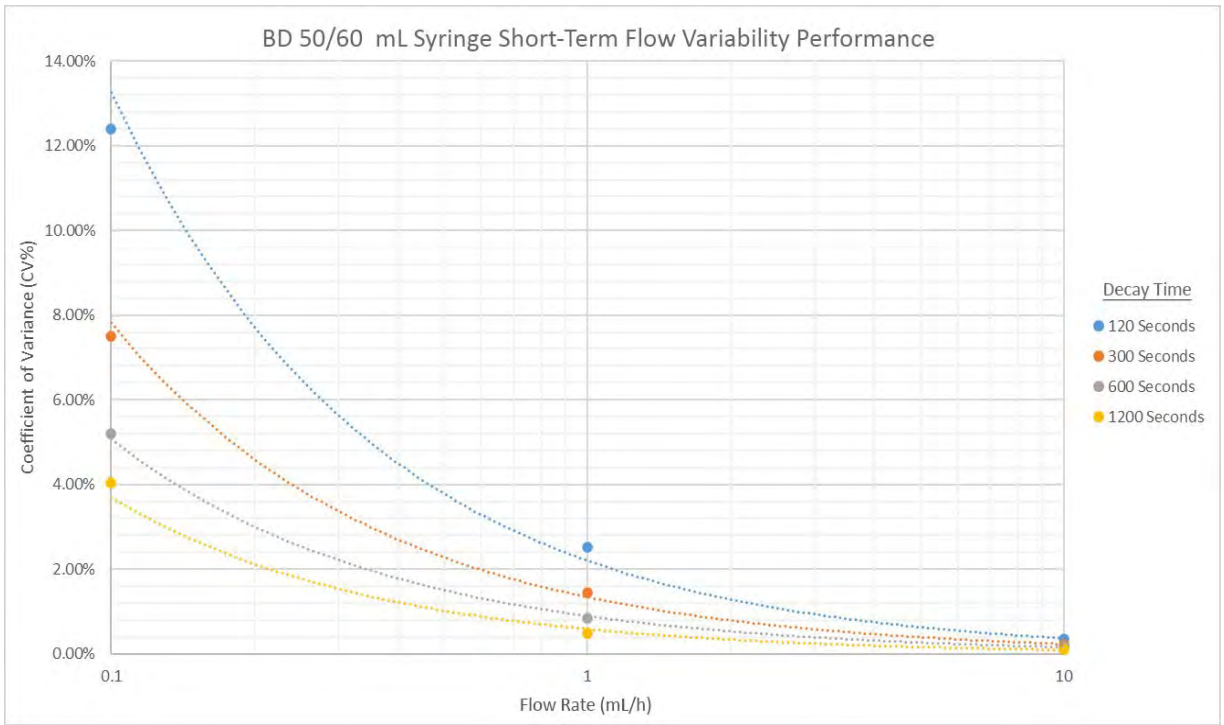
BD 3 mL



BD 20 mL



BD 50 mL



Alaris™ Syringe Module Bolus Volume Accuracy

A bolus delivered by the Syringe Module at the beginning of an infusion is also known as a loading dose. The Syringe Module does not have a loading dose feature. A loading dose can be accomplished by delivering a bolus dose at the beginning of an infusion.

Syringe Module loading dose accuracy is shown in the characterization table below at the maximum bolus flow rate and a loading dose of 10% syringe volume (intermediate bolus volume).

NOTE:
The characterization testing is based on a sample size of 15 pumps and 15 syringes with 1 loading dose per pump.

Syringe	Flow Rate[1,2] (mL/h)	Loading Dose Volume (mL)	Without Prime Set with Syringe Feature		With Prime Set with Syringe Feature	
			Mean Error	Standard Deviation	Mean Error	Standard Deviation
BD 3 mL	100	0.3	-0.88%	7.45%	-2.73%	3.85%
BD 20 mL	500	2.0	-0.99%	2.95%	-0.44%	0.65%
BD 50 mL	999	5.0	-1.46%	2.06%	0.47%	0.73%

1. The Syringe Module minimum programmable bolus duration is 1 minute, resulting in a maximum flow rate of 18 mL/h for a 0.3 mL bolus, 120 mL/h for a 2 mL bolus, and 300 mL/h for a 5 mL bolus. The rapid bolus feature maximum rate is limited by the settings in the Guardrails™ data set. If the user selects the rapid bolus feature, the maximum flow rate could increase to 100 mL/h for a 3 mL syringe, 500 mL/h for a 20 mL syringe, and 999 mL/h for a 50 mL syringe, depending on the settings in the Guardrails™ data set.
2. If configured with a Guardrails™ data set, the bolus dose and duration is limited by the Guardrails™ data set. Therefore, the Guardrails™ data set can limit the Syringe Module maximum flow rate by bolus volume.

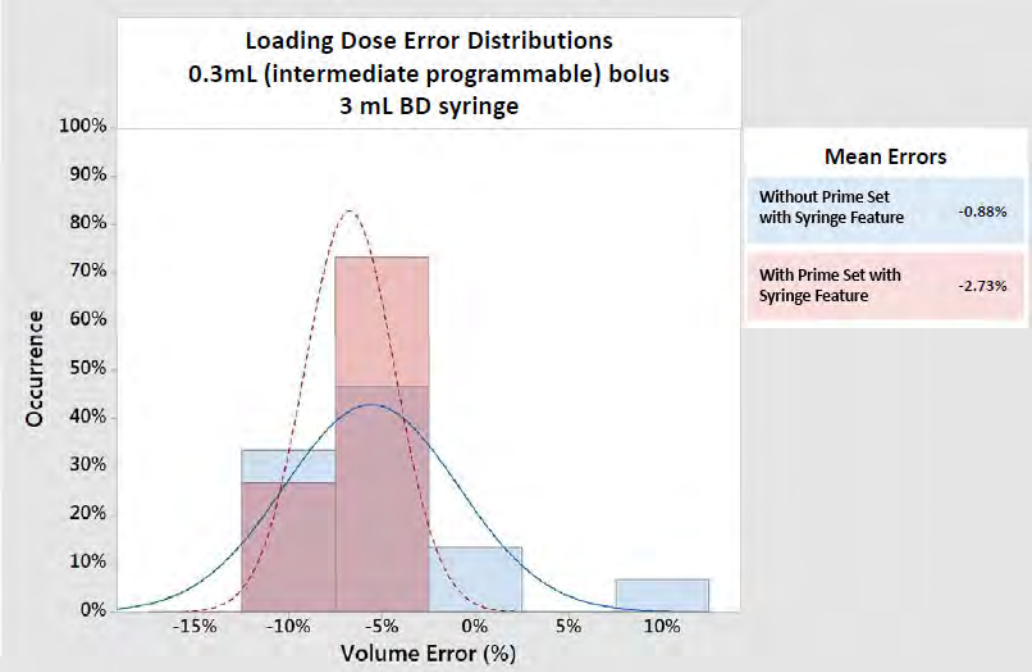
Syringe Module loading dose accuracy is shown in the characterization table at the maximum bolus flow rate and a loading dose volume of 0.1 mL (minimum bolus volume).

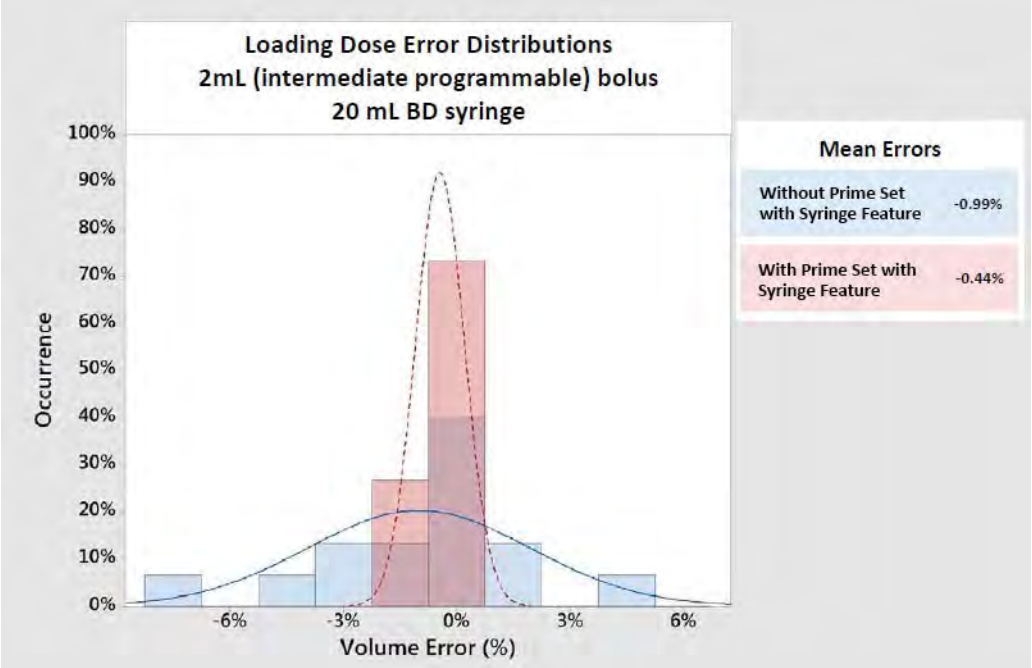
NOTE:
The characterization testing is based on a sample size of 15 pumps and 15 syringes with 1 loading dose per pump.

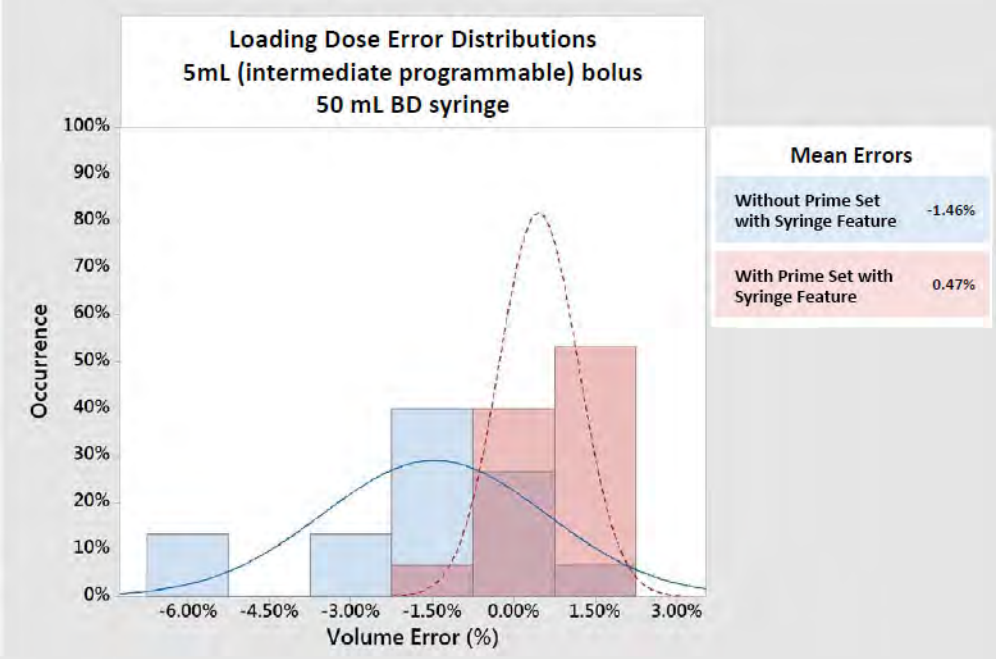
Syringe	Flow Rate[1,2] (mL/h)	Loading Dose Volume (mL)	Without Prime Set with Syringe Feature		With Prime Set with Syringe Feature	
			Mean Error	Standard Deviation	Mean Error	Standard Deviation
BD 3 mL	100	0.1	-9.24%	32.68%	-4.89%	4.45%
BD 20 mL	500	0.1	-44.17%	33.65%	-25.90%	30.42%
BD 50 mL	999	0.1	8.26%	121.69%	-67.89%	27.04%

1. The Syringe Module minimum programmable bolus duration is 1 minute, resulting in a maximum flow rate of 6 mL/h for a 0.1 mL bolus. The rapid bolus feature maximum rate is limited by the settings in the Guardrails™ data set. If the user selects the rapid bolus feature, the maximum flow rate could increase to 100 mL/h for a 3 mL syringe, 500 mL/h for a 20 mL syringe, and 999 mL/h for a 50 mL syringe, depending on the settings in the Guardrails™ data set.
2. If configured with a Guardrails™ data set, the bolus dose and duration is limited by the Guardrails™ data set. Therefore, the Guardrails™ data set can limit the Syringe Module maximum flow rate by bolus volume.

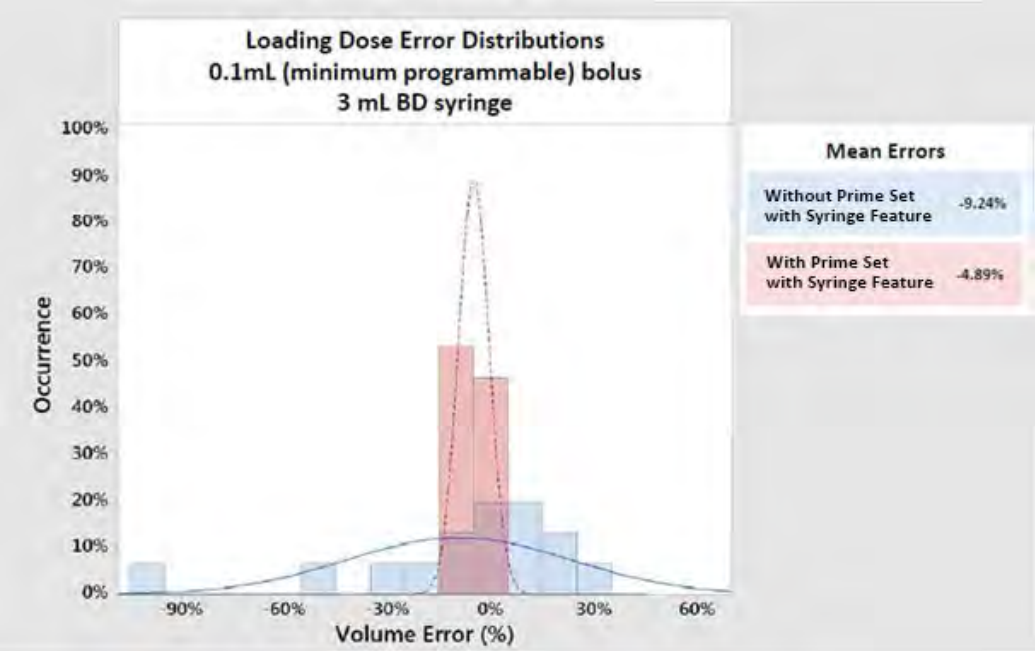
The performance data from the table above is also shown in a histogram format in the graphs below for the loading dose accuracy at the maximum bolus flow rate and a loading dose of 10% syringe volume (intermediate bolus volume).

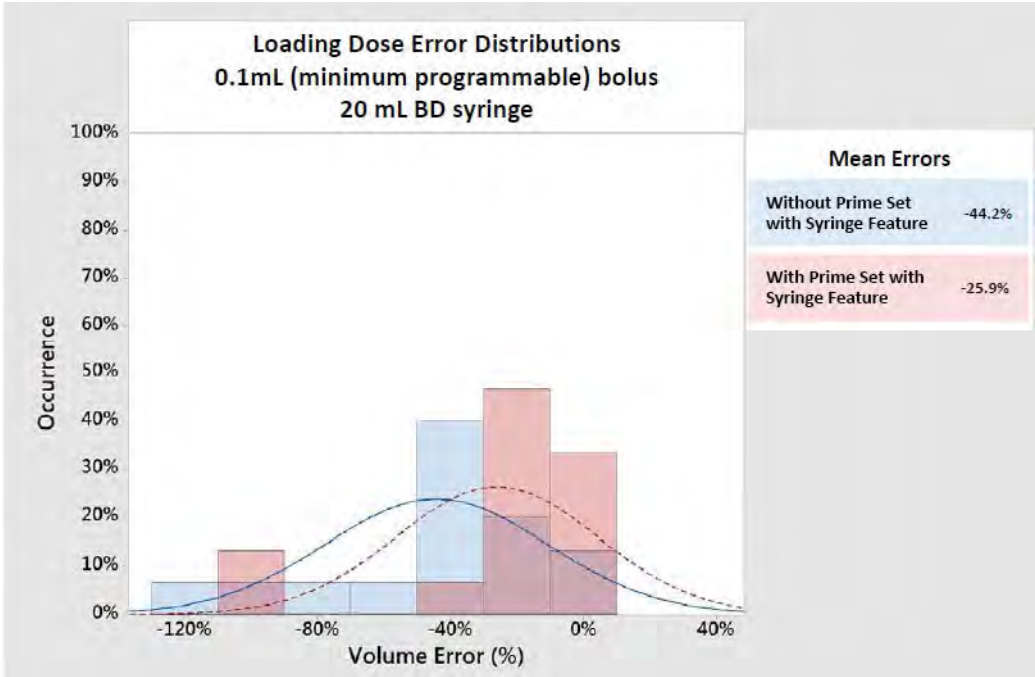


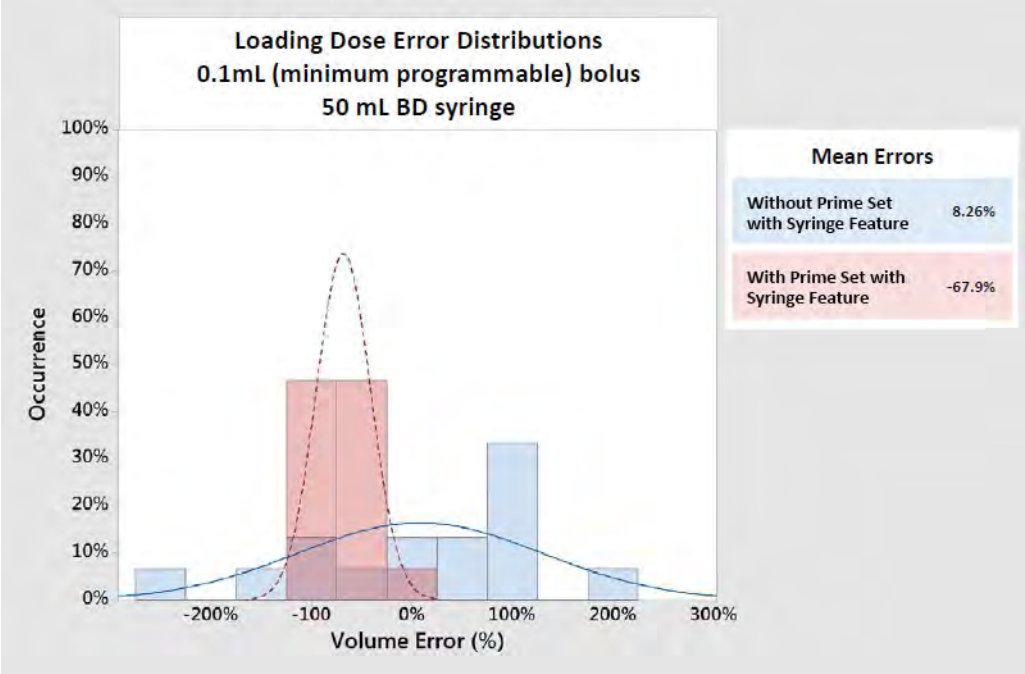



Loading Dose Error Distributions
5mL (intermediate programmable) bolus
50 mL BD syringe
Occurrence
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
-6.00%
-4.50%
-3.00%
-1.50%
0.00%
1.50%
3.00%
Volume Error (%)
Mean Errors
Without Prime Set with Syringe Feature
-1.46%
With Prime Set with Syringe Feature
0.47%

The performance data from the table above is also shown in a histogram format in the graphs below for the loading dose accuracy at the maximum bolus flow rate and a loading dose of 0.1 mL (minimum bolus volume).






Loading Dose Error Distributions
0.1mL (minimum programmable) bolus
50 mL BD syringe
Occurrence
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
-200%
-100
0%
100%
200%
300%
Volume Error (%)
Mean Errors
Without Prime Set with Syringe Feature
8.26%
With Prime Set with Syringe Feature
-67.9%

The Syringe Module bolus volume accuracy is shown in the characterization table below under three levels of backpressure, at the maximum bolus flow rate and a bolus volume of 10% syringe volume (intermediate bolus volume).

NOTE:
The characterization testing is based on a sample size of 5 pumps and 5 syringes with 9 boluses administered after the loading dose bolus per pump or until syringe is empty.

Syringe	Flow Rate[1,2] (mL/h)	Bolus Volume (mL)	Nominal Backpressure			+ 100 mmHg			-100 mmHg		
			Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error
BD 3 mL	100	0.3	-0.71%	-1.78%	0.46%	-0.46%	-1.02%	-0.13%	-0.97%	-4.14%	1.99%
BD 20 mL	500	2.0	0.13%	-0.26%	0.63%	0.25%	0.05%	0.52%	-0.15%	-0.76%	0.30%
BD 50 mL	999	5.0	0.02%	-0.50%	0.84%	0.28%	0.09%	0.53%	-0.14%	-0.50%	0.21%

1. The Syringe Module minimum programmable bolus duration is 1 minute, resulting in a maximum flow rate of 18 mL/h for a 0.3 mL bolus, 120 mL/h for a 2 mL bolus, and 300 mL/h for a 5 mL bolus. The rapid bolus feature maximum rate is limited by the settings in the Guardrails™ data set. If the user selects the rapid bolus feature, the maximum flow rate could increase to 100 mL/h for a 3 mL syringe, 500 mL/h for a 20 mL syringe, and 999 mL/h for a 50 mL syringe, depending on the settings in the Guardrails™ data set.
2. If configured with a Guardrails™ data set, the bolus dose and duration is limited by the Guardrails™ data set. Therefore, the Guardrails™ data set can limit the Syringe Module maximum flow rate by bolus volume.

The Syringe Module bolus volume accuracy is shown in the characterization table below under three levels of backpressure, at the maximum bolus flow rate and a bolus volume of 0.1 mL (minimum bolus volume).

NOTE:
The characterization testing is based on a sample size of 5 pumps and 5 syringes with 24 boluses administered after the loading dose bolus per pump or until syringe is empty.

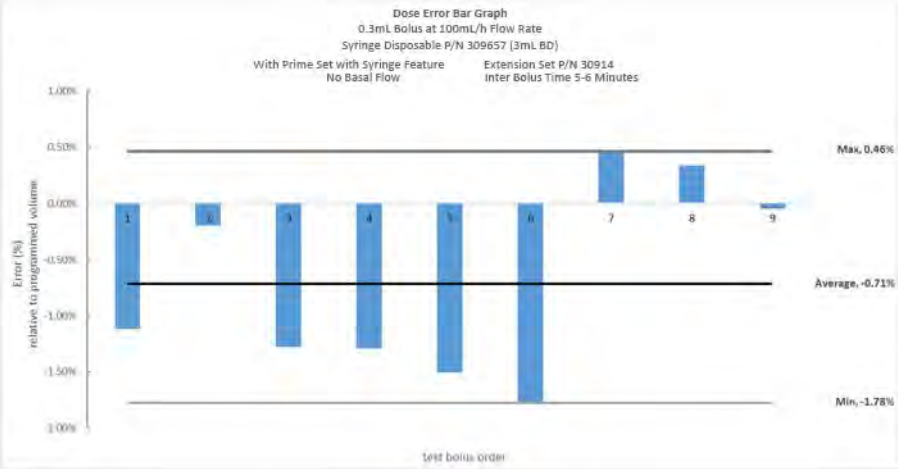
Syringe	Flow Rate[1,2] (mL/h)	Bolus Volume (mL)	Nominal Backpressure			+ 100 mmHg			-100 mmHg		
			Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error
BD 3 mL	100	0.1	-1.48%	-3.30%	0.32%	0.27%	-0.32%	0.95%	0.08%	-4.90%	4.58%
BD 20 mL	500	0.1	8.75%	-15.45%	11.54%	0.70%	-1.36%	2.72%	0.23%	-9.38%	6.23%
BD 50 mL	999	0.1	-1.58%	-7.87%	1.81%	-1.41%	-5.21%	2.30%	-4.51%	-21.86%	24.22%

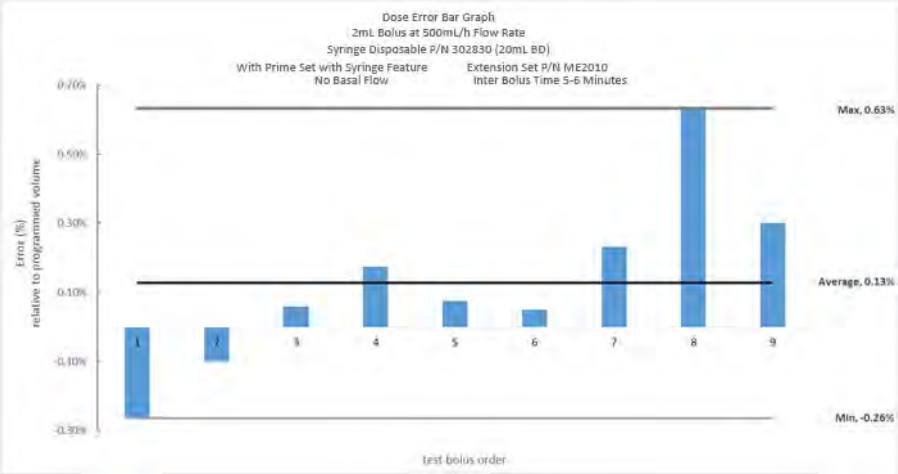
1. The Syringe Module minimum programmable bolus duration is 1 minute, resulting in a maximum flow rate of 6 mL/h for a 0.1 mL bolus. The rapid bolus feature maximum rate is limited by the settings in the Guardrails™ data set. If the user selects the rapid bolus feature, the maximum flow rate could increase to 100 mL/h for a 3 mL syringe, 500 mL/h for a 20 mL syringe, and 999 mL/h for a 50 mL syringe, depending on the settings in the Guardrails™ data set.
2. If configured with a Guardrails™ data set, the bolus dose and duration is limited by the Guardrails™ data set. Therefore, the Guardrails™ data set can limit the Syringe Module maximum flow rate by bolus volume.

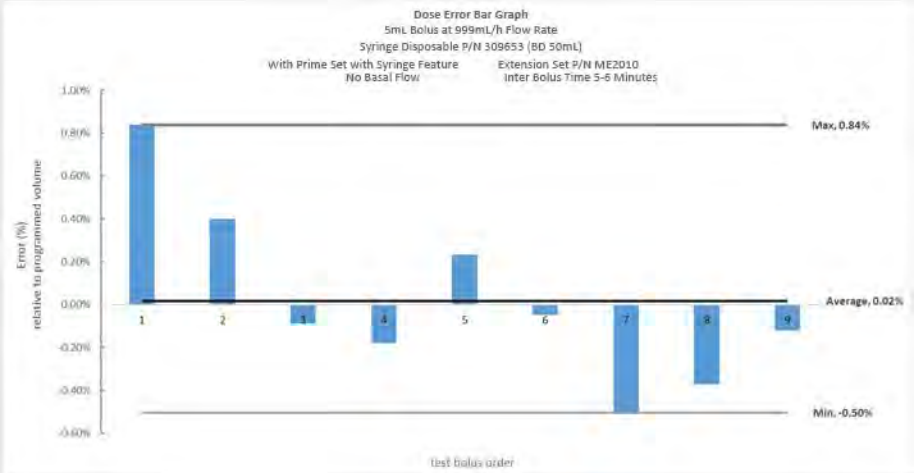
A nominal backpressure means that the pump is at the same height compared to the patient's heart level. +100 mmHg backpressure means that the pump is 54 inches below the patient's heart level, while a -100 mmHg backpressure means that the pump is 54 inches above the patient's heart level.

The bolus volume accuracy performance data from the characterization table above, at the maximum bolus flow rate and a bolus volume of 10% syringe volume (intermediate bolus volume), is also shown per bolus tested in the graphs below at three levels of backpressure.

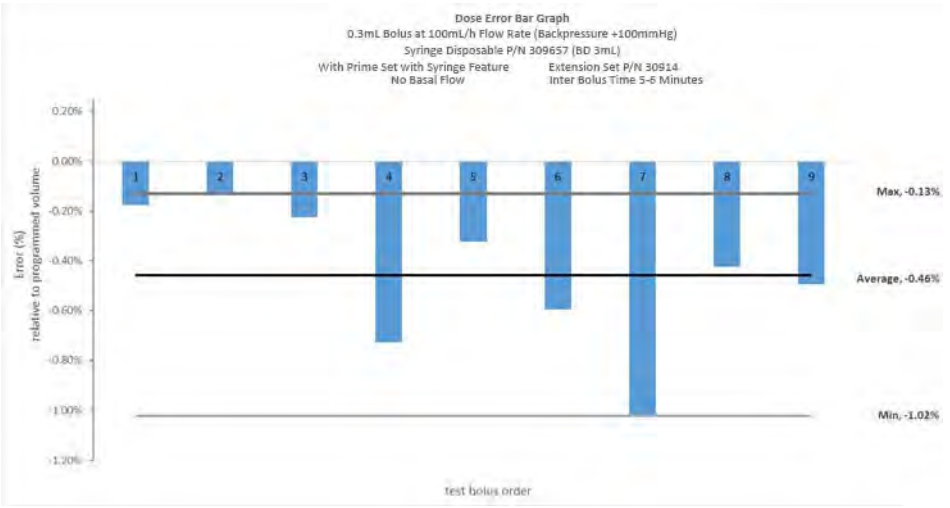
Nominal Backpressure

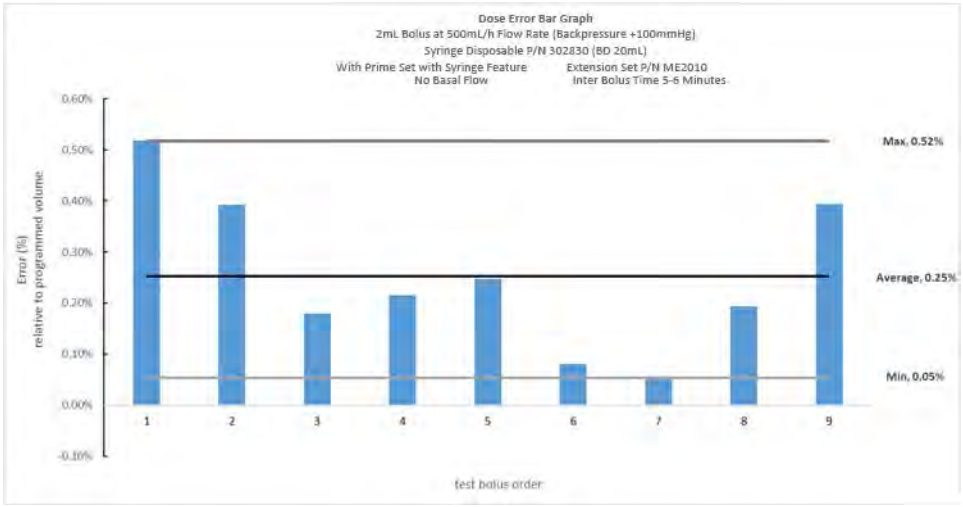


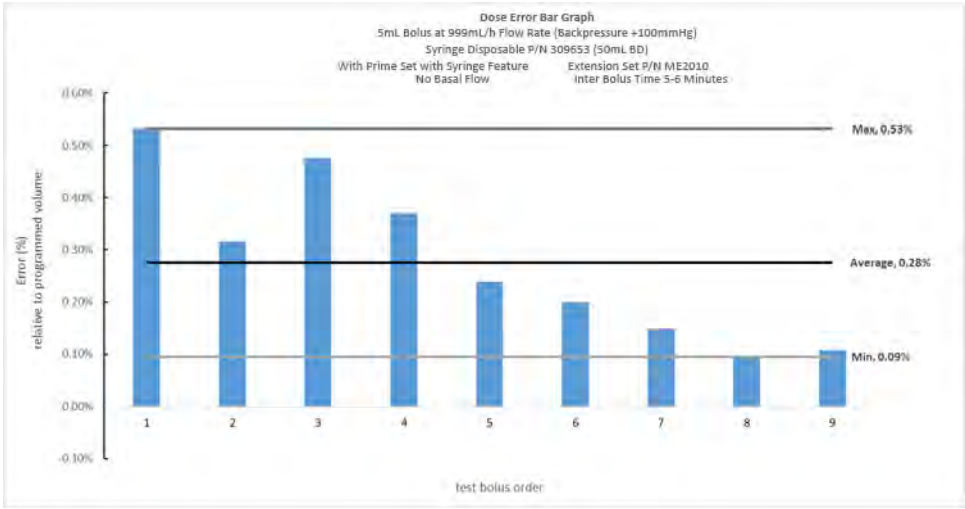




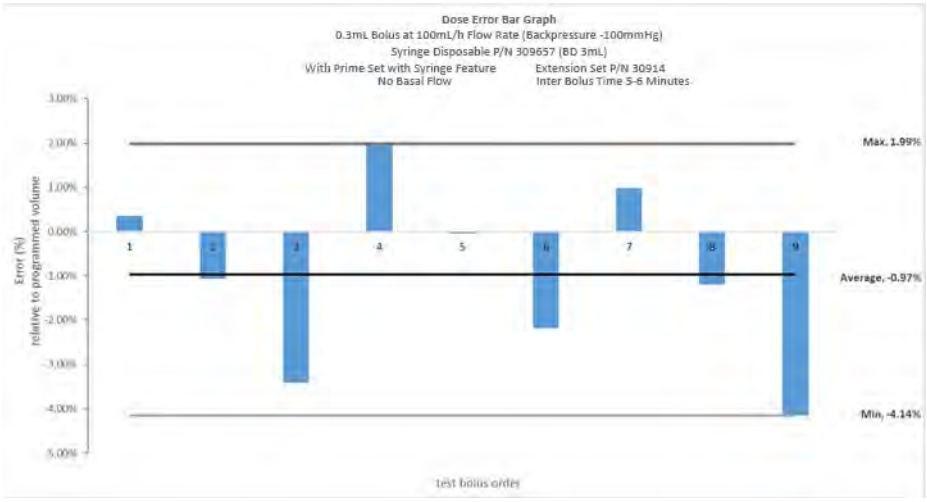
+100 mmHg Backpressure

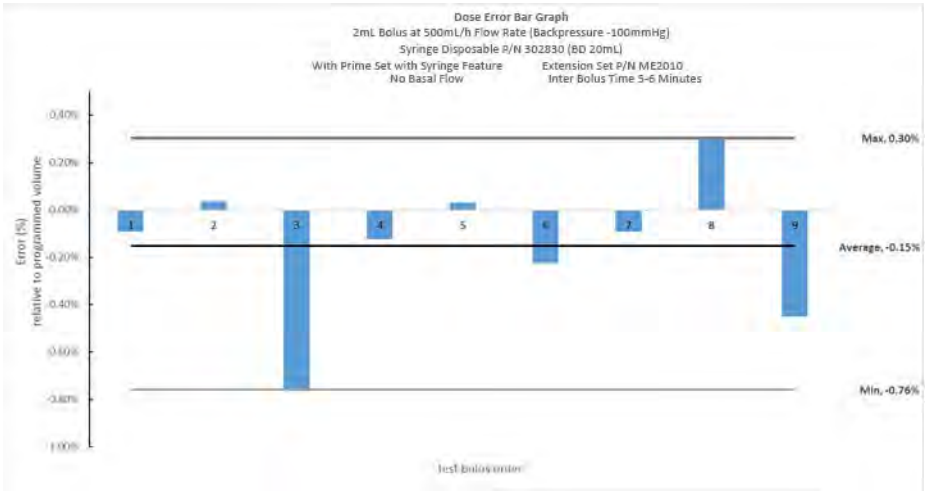


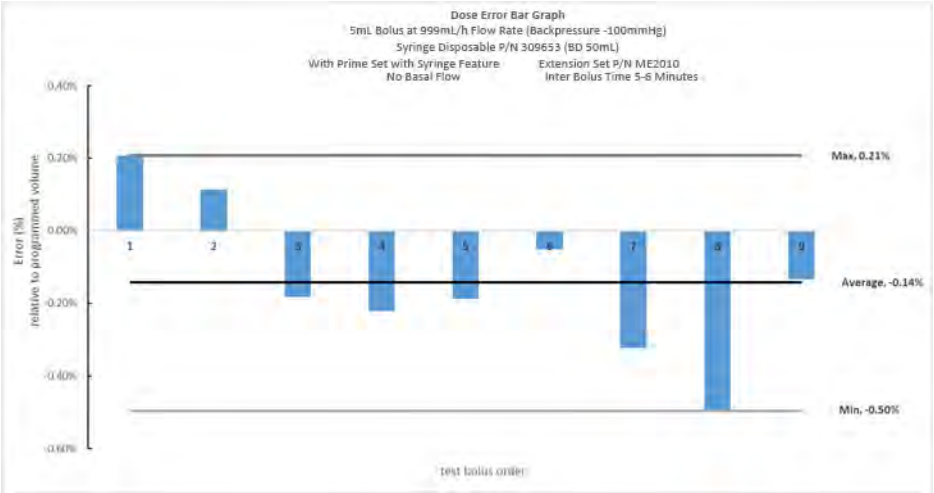




-100 mmHg Backpressure

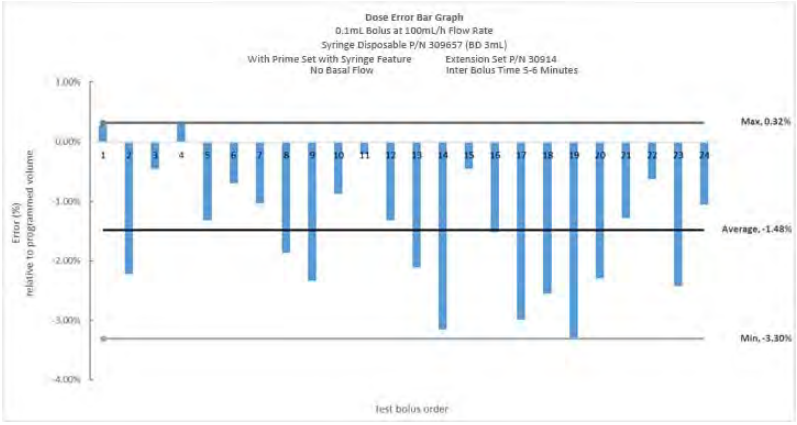


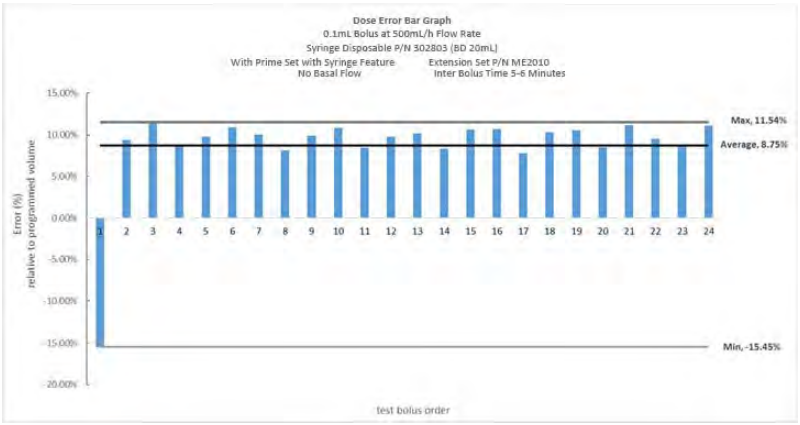


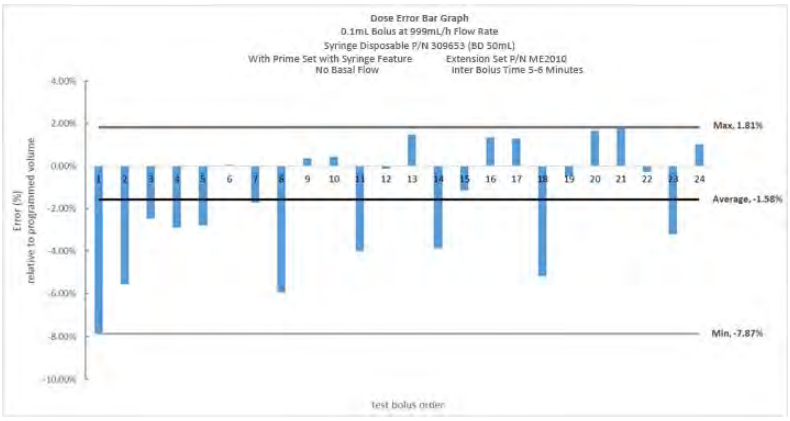


The bolus dose volume accuracy performance data from the characterization table above, at the maximum bolus flow rate and a bolus volume of 0.1 mL (minimum bolus volume), is also shown per bolus tested in the graphs below at three levels of backpressure.

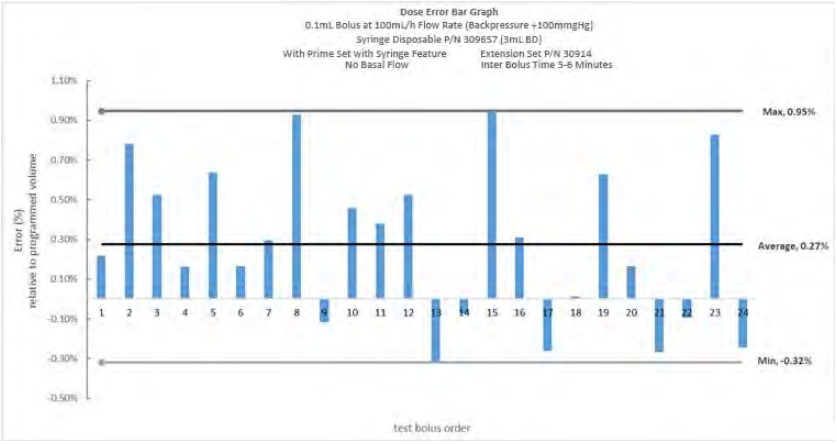
Nominal Backpressure

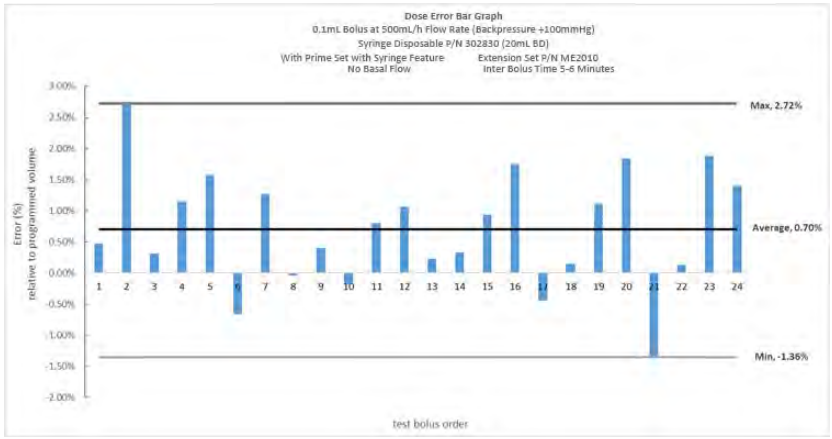


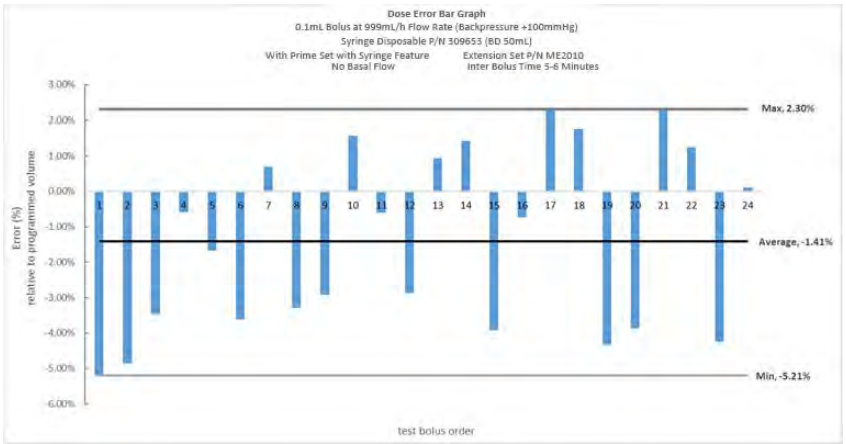




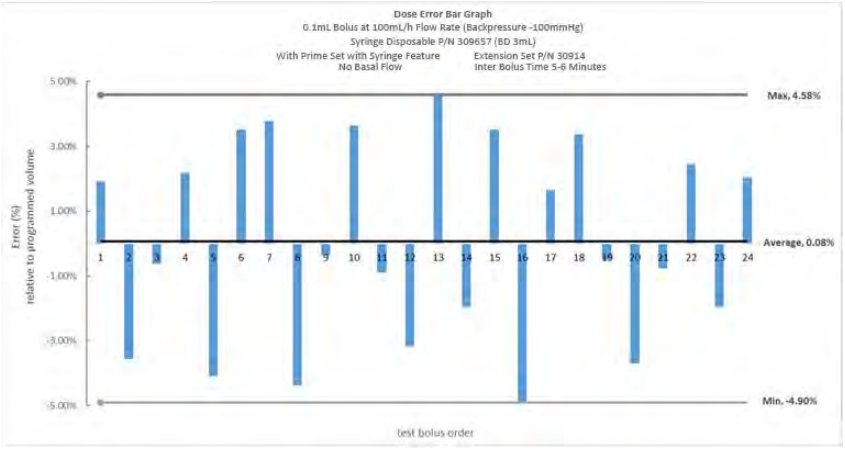
+100 mmHg Backpressure

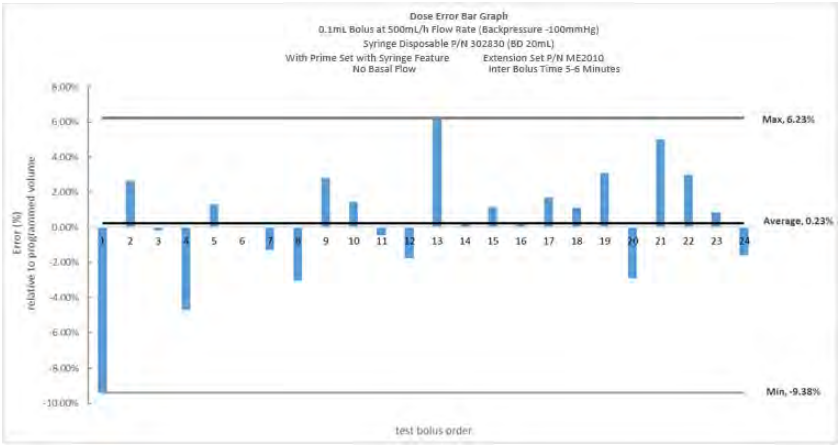


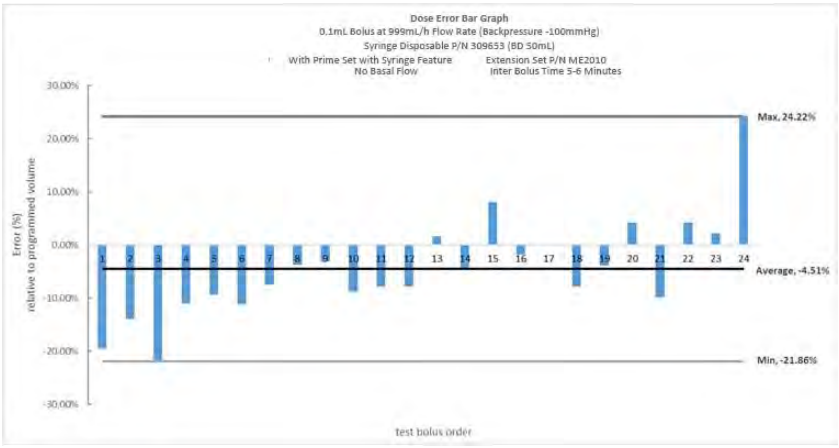




-100 mmHg Backpressure







Alaris™ PCA Module Rate Accuracy

PCA Module and Syringe Module drive mechanism designs are the same. For PCA Module rate accuracy characterization tables and graphs, see performance data from the Syringe Module for BD 20 mL and BD 50 mL syringes.

Alaris™ PCA Module Coefficient of Variation

PCA Module and Syringe Module drive mechanism designs are the same. For PCA Module coefficient of variation characterization tables and graphs, see performance data from the Syringe Module for BD 20 mL and BD 50 mL syringes.

Alaris™ PCA Module Bolus Volume Accuracy

A bolus delivered by the PCA Module at the beginning of an infusion is also known as a loading dose.

PCA Module loading dose accuracy is shown in the characterization table below at the maximum bolus flow rate for a loading dose of 10% syringe volume (intermediate bolus volume).

NOTE:
The characterization testing is based on a sample size of 15 pumps and 15 syringes with 1 loading dose per pump.

Syringe	Flow Rate (mL/h)	Loading Dose Volume (mL)	Without Prime Set with Syringe Feature		With Prime Set with Syringe Feature	
			Mean Error	Standard Deviation	Mean Error	Standard Deviation
BD 20 mL	500	2.0	-2.52%	2.87%	0.77%	1.66%
BD 50 mL	500	5.0	-4.14%	7.00%	0.06%	1.08%

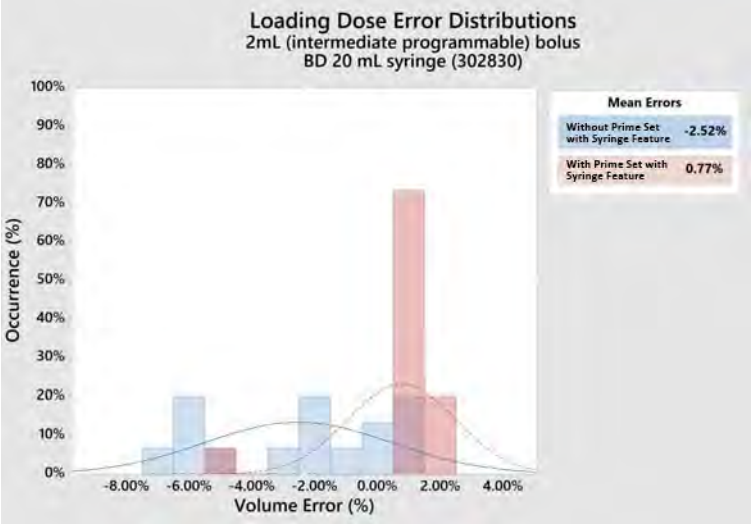
PCA Module loading dose accuracy is shown in the characterization table below at the maximum bolus flow rate and a loading dose volume of 0.1 mL (minimum bolus volume).

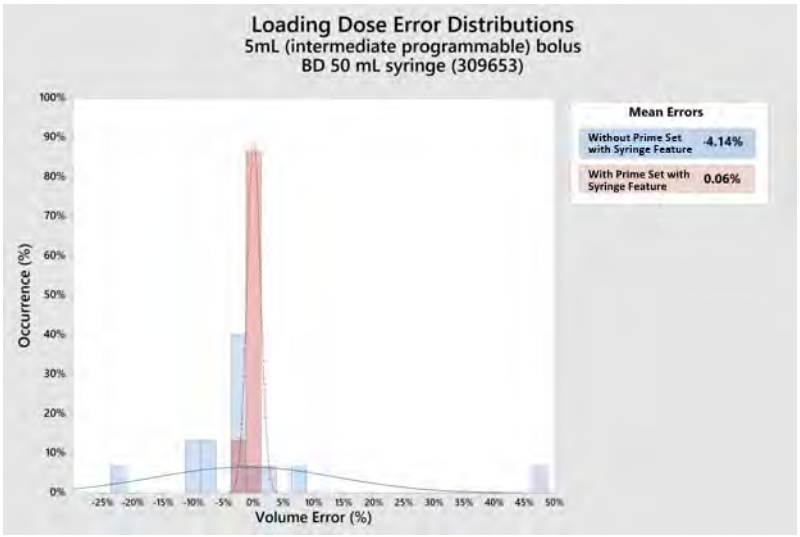
NOTE:
The characterization testing is based on a sample size of 15 pumps and 15 syringes with 1 loading dose per pump.

Syringe	Flow Rate (mL/h)	Loading Dose Volume (mL)	Without Prime Set with Syringe Feature		With Prime Set with Syringe Feature	
			Mean Error	Standard Deviation	Mean Error	Standard Deviation
BD 20 mL	500	0.1	-62.35%	36.18%	-21.54%	10.65%
BD 50 mL	500	0.1	-71.57%	52.78%	-37.14%	12.81%

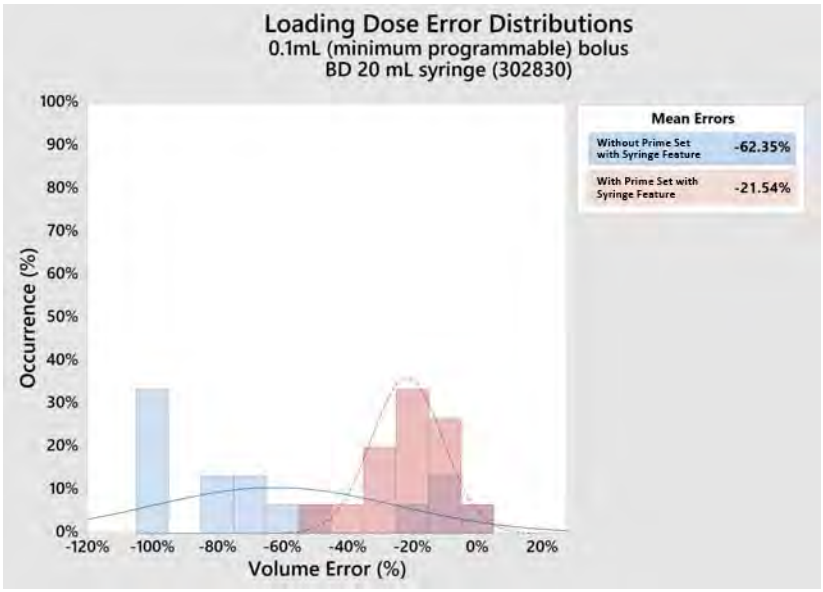
PCA Module bolus delivery rate is determined for each profile in your facility's data set. The default rate for bolus or loading dose delivery is 150 mL/h with an available range of 75 – 500 mL/h. PCA Module bolus or loading dose programming on the module occurs by entry of a dose within Guardrails™ limits. The dose volume is determined by the medication concentration and the bolus delivery rate is determined in the data set. Volume and rate of the bolus or loading dose cannot be edited at the device. Delivery accuracy may be reduced with PCA Module bolus volumes of 0.1 mL delivered at 500 mL/h.

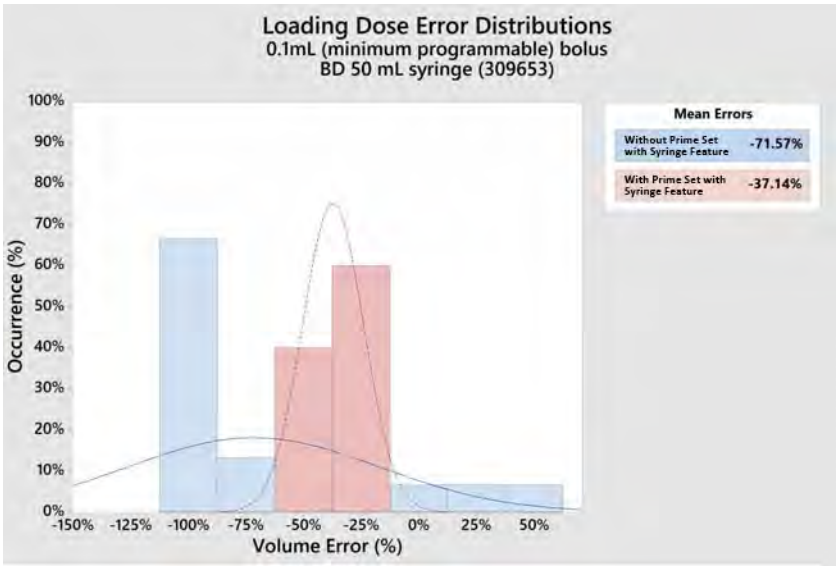
The performance data from the table above is also shown in a histogram format in the graphs below for the loading dose accuracy at the maximum bolus flow rate and a loading dose of 10% syringe volume (intermediate bolus volume).





The performance data from the table above is also shown in a histogram format in the graphs below for the loading dose accuracy at the maximum bolus flow rate and a loading dose of 0.1 mL (minimum bolus volume).





The PCA Module bolus volume accuracy is shown in the characterization table below under three levels of backpressure, at the maximum bolus flow rate and a bolus volume of 10% syringe volume (intermediate bolus volume).

NOTE:
The characterization testing is based on a sample size of 5 pumps and 5 syringes with 8 boluses administered after the loading dose bolus per pump or until syringe is empty.

	Flow Rate (mL/h)	Bolus Volume (mL)	Nominal Backpressure			+ 100 mmHg			-100 mmHg		
			Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error
BD 20 mL	500	2.0	1.55%	1.42%	1.66%	1.52%	1.43%	1.66%	1.47%	1.18%	1.78%
BD 50 mL	500	5.0	0.66%	0.36%	1.00%	0.63%	0.37%	1.17%	0.38%	0.12%	0.67%

The PCA Module bolus volume accuracy is shown in the characterization table below under three levels of backpressure, at the maximum bolus flow rate and a bolus volume of 0.1 mL (minimum bolus volume).

NOTE:
The characterization testing is based on a sample size of 5 pumps and 5 syringes with 24 boluses administered after the loading dose bolus per pump or until syringe is empty.

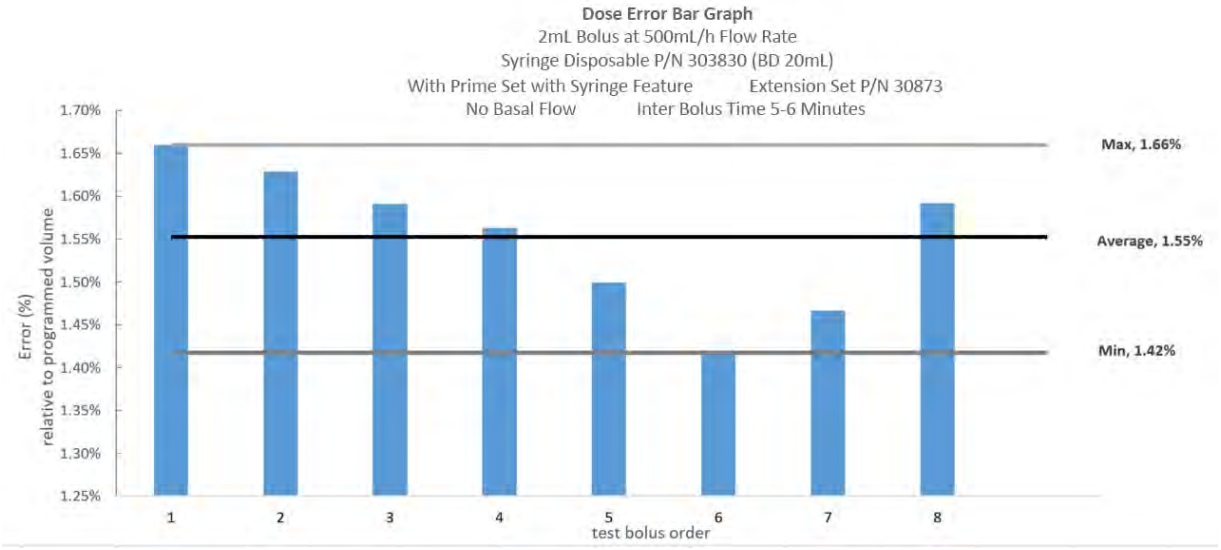
Syringe	Flow Rate (mL/h)	Bolus Volume (mL)	Nominal Backpressure			+ 100 mmHg			-100 mmHg		
			Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error	Mean Error	Minimum Error	Max Error
BD 20 mL	500	0.1	1.68%	0.72%	2.87%	0.07%	-2.78%	1.35%	1.95%	-3.30%	11.93%
BD 50 mL	500	0.1	-1.27%	-6.14%	3.31%	-0.57%	-2.48%	1.13%	-3.45%	-17.45%	5.92%

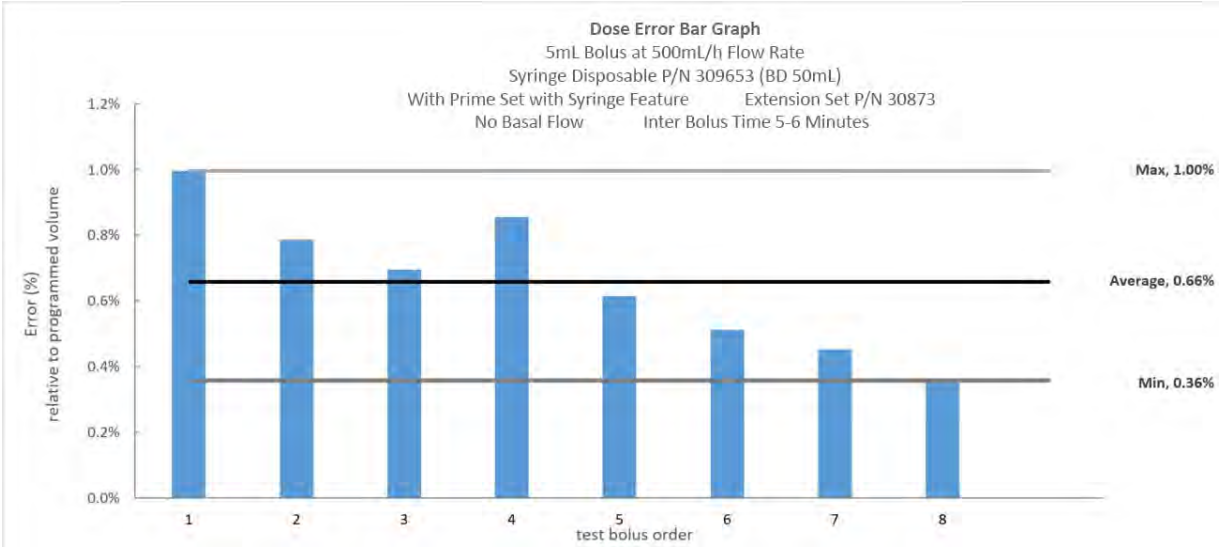
PCA Module bolus delivery rate is determined for each profile in your facility's data set. The default rate for bolus or loading dose delivery is 150 mL/h with an available range of 75 – 500 mL/h. PCA Module bolus or loading dose programming on the module occurs by entry of a dose within GuardrailsTM limits. The dose volume is determined by the medication concentration and the bolus delivery rate is determined in the data set. Volume and rate of the bolus or loading dose cannot be edited at the device. Delivery accuracy may be reduced with PCA Module bolus volumes of 0.1 mL delivered at 500 mL/h.

A nominal backpressure means that the pump is at the same height compared to the patient's heart level. A +100 mmHg backpressure means that the pump is 54 inches below the patient's heart level, while a -100 mmHg backpressure means that the pump is 54 inches above the patient's heart level.

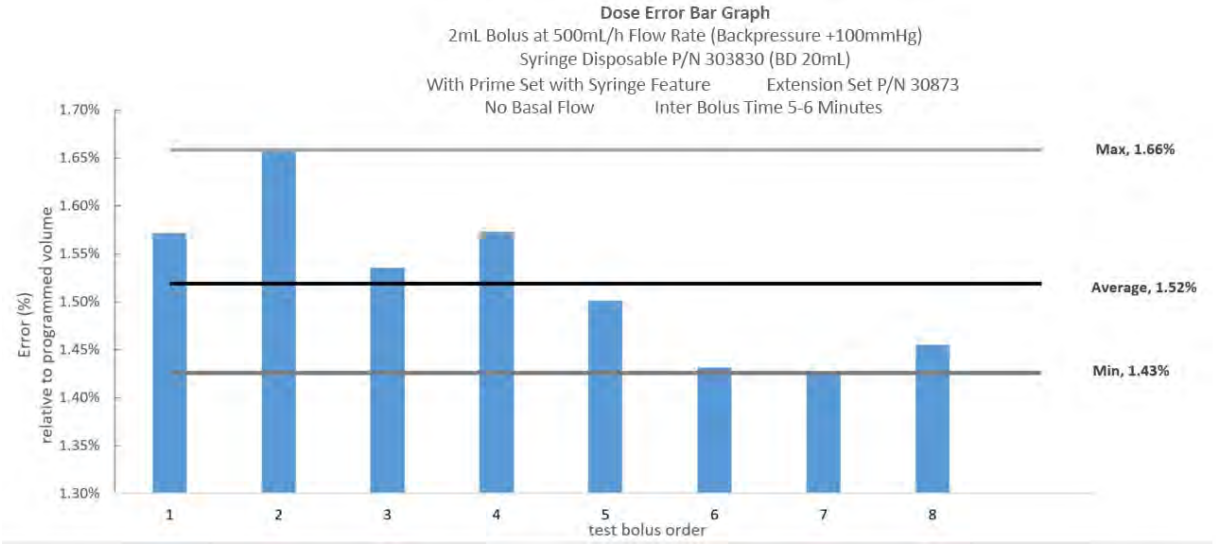
The bolus volume accuracy performance data from the characterization table above, at the maximum bolus flow rate and a bolus volume of 10% syringe volume (intermediate bolus volume), is also shown per bolus tested in the graphs below at three levels of backpressure.

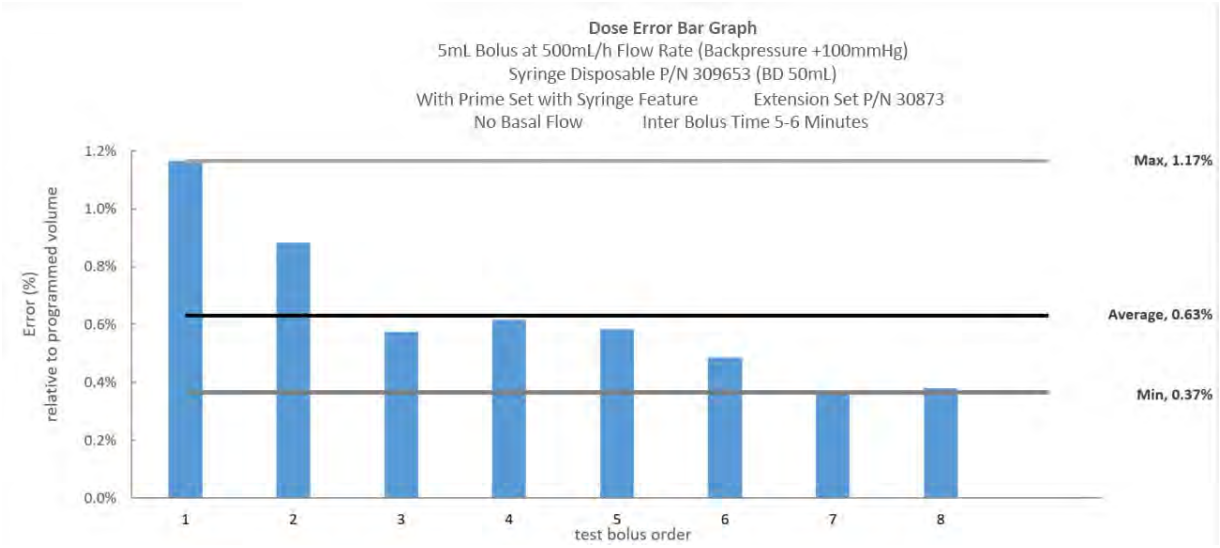
Nominal Backpressure



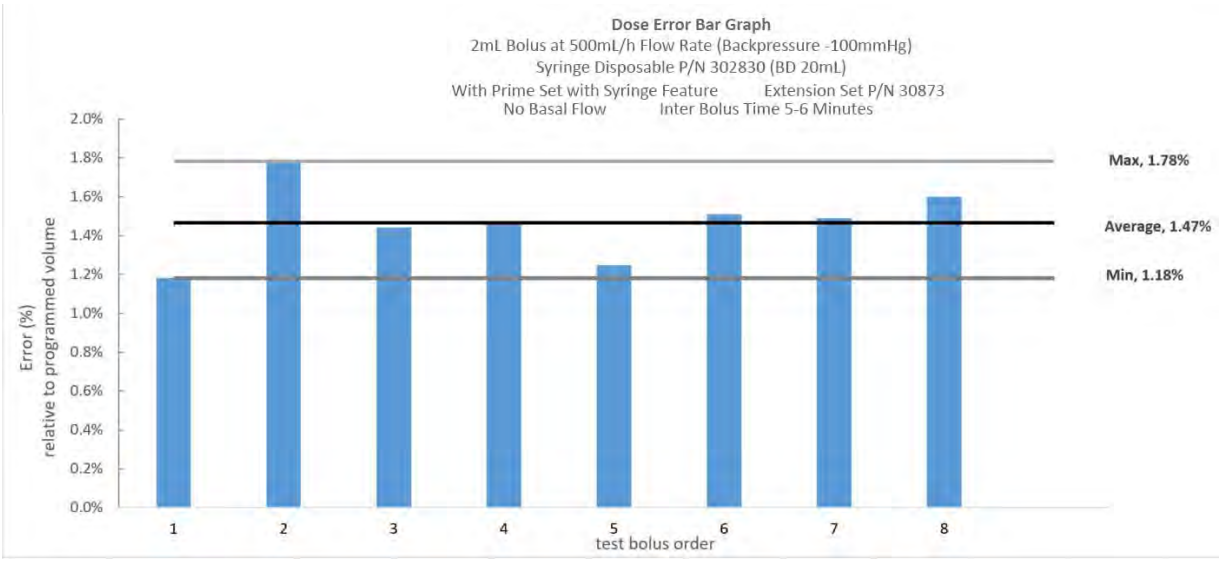


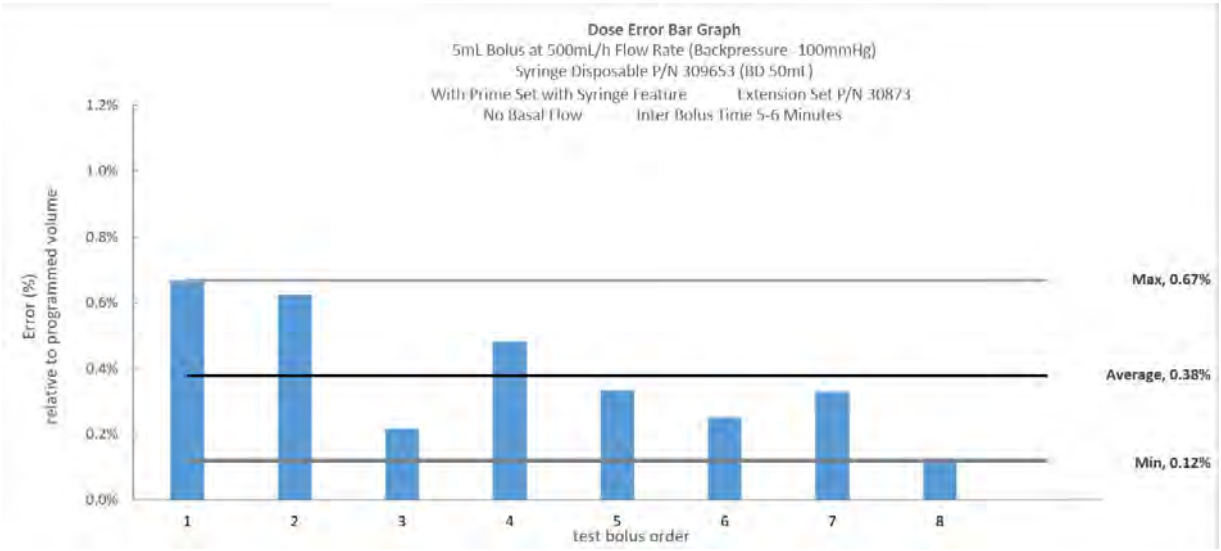
+100 mmHg Backpressure





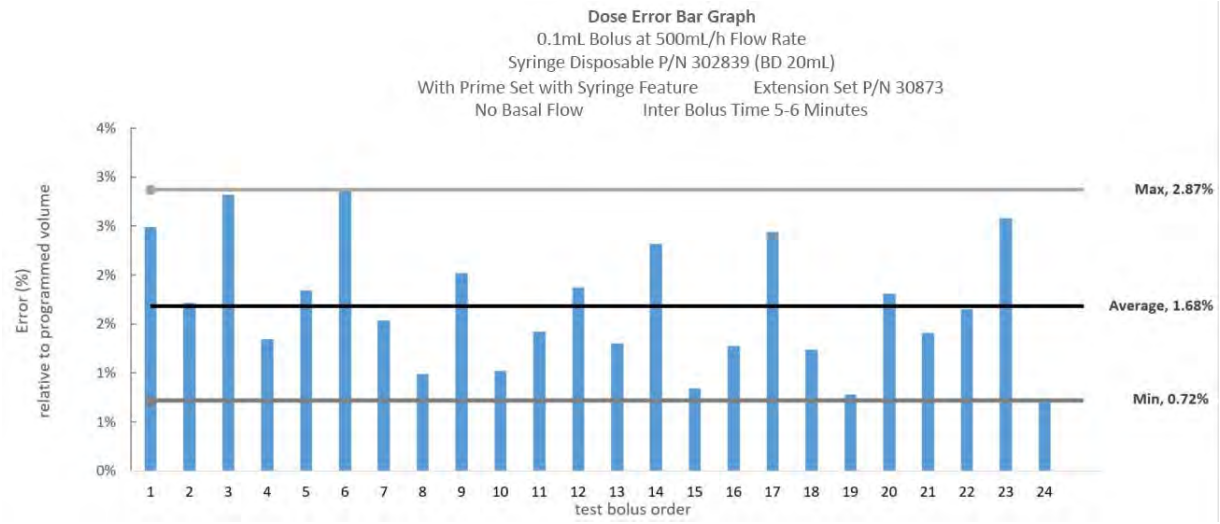
-100 mmHg Backpressure

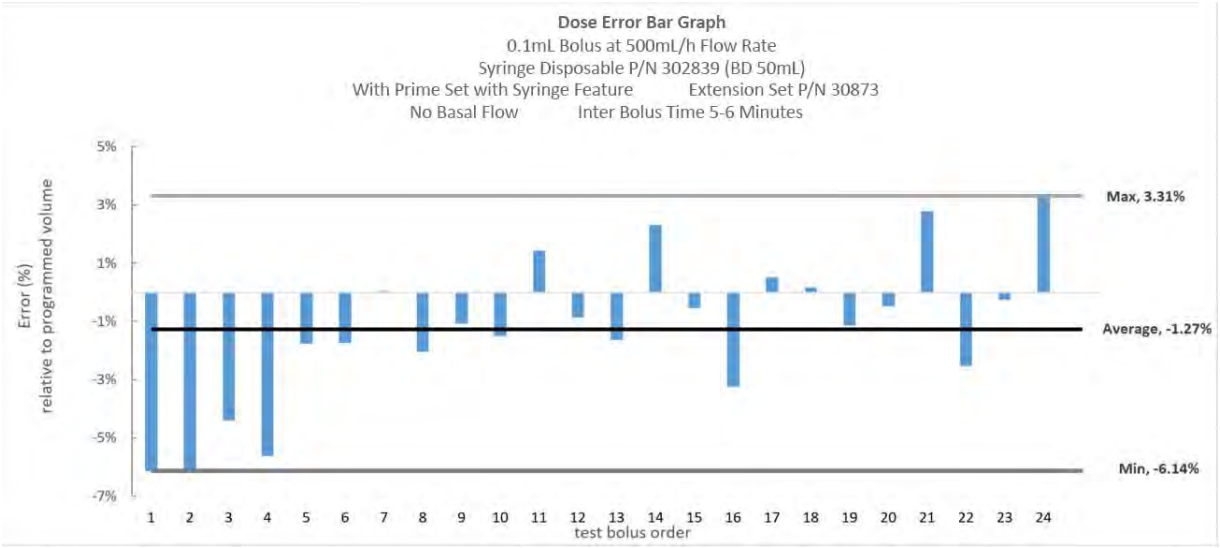




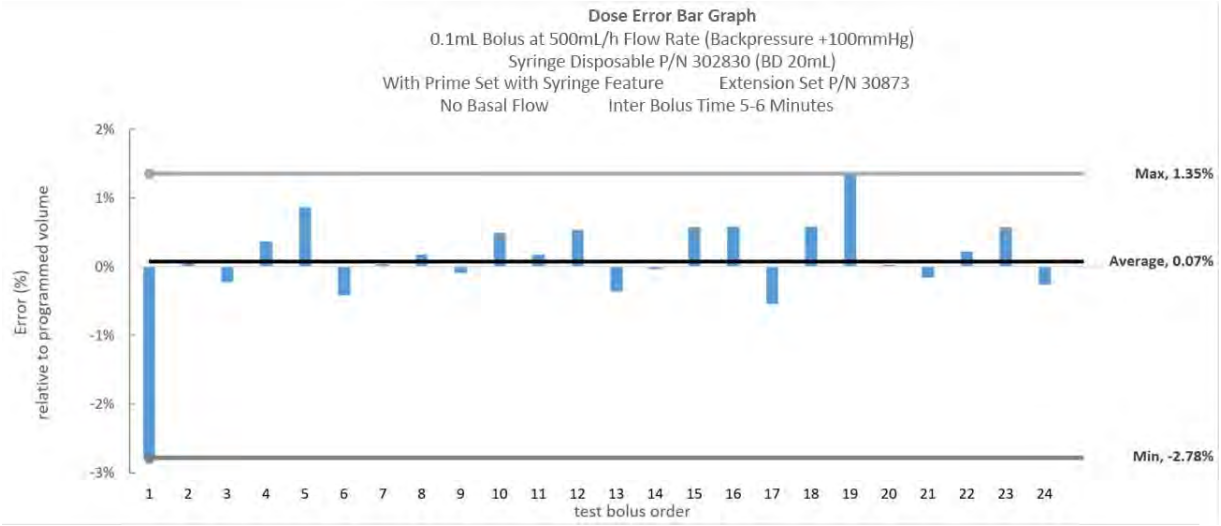
The bolus dose volume accuracy performance data from the characterization table above, at the maximum bolus flow rate and a bolus volume of 0.1 mL (minimum bolus volume), is also shown per bolus tested in the graphs below at three levels of backpressure.

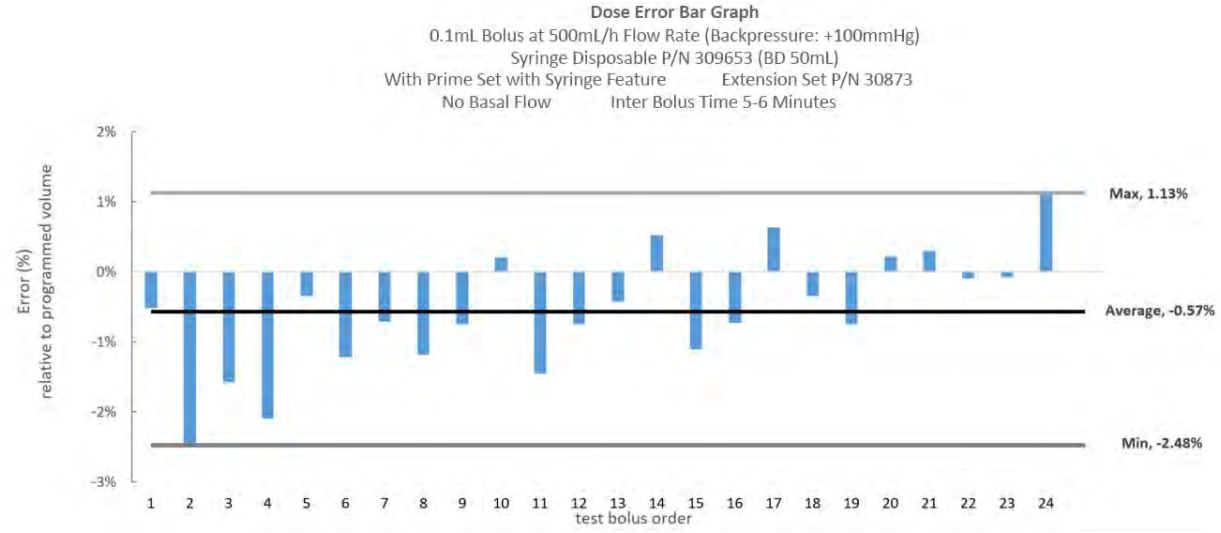
Nominal Backpressure



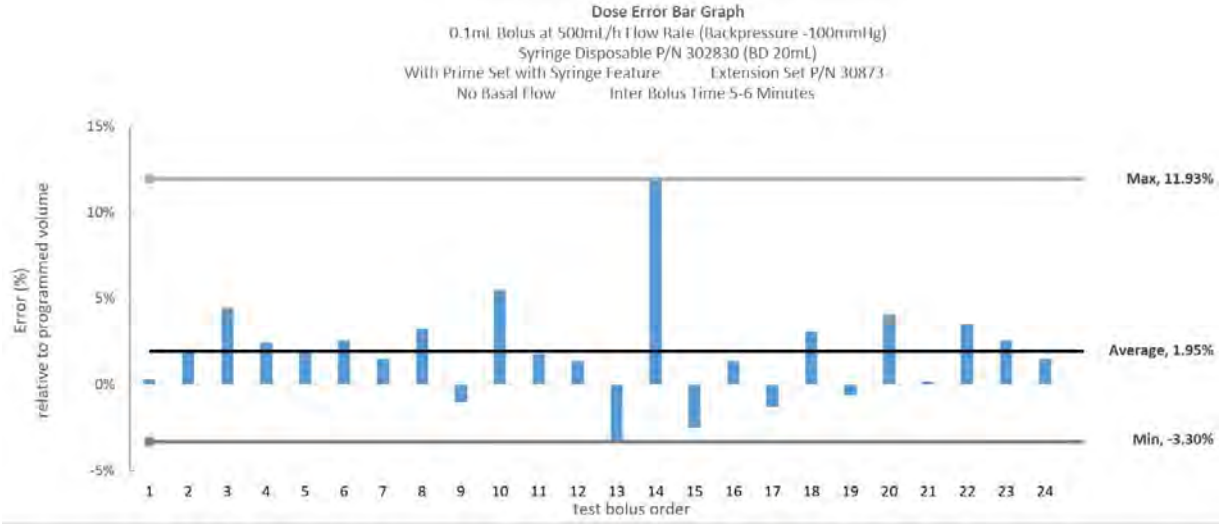


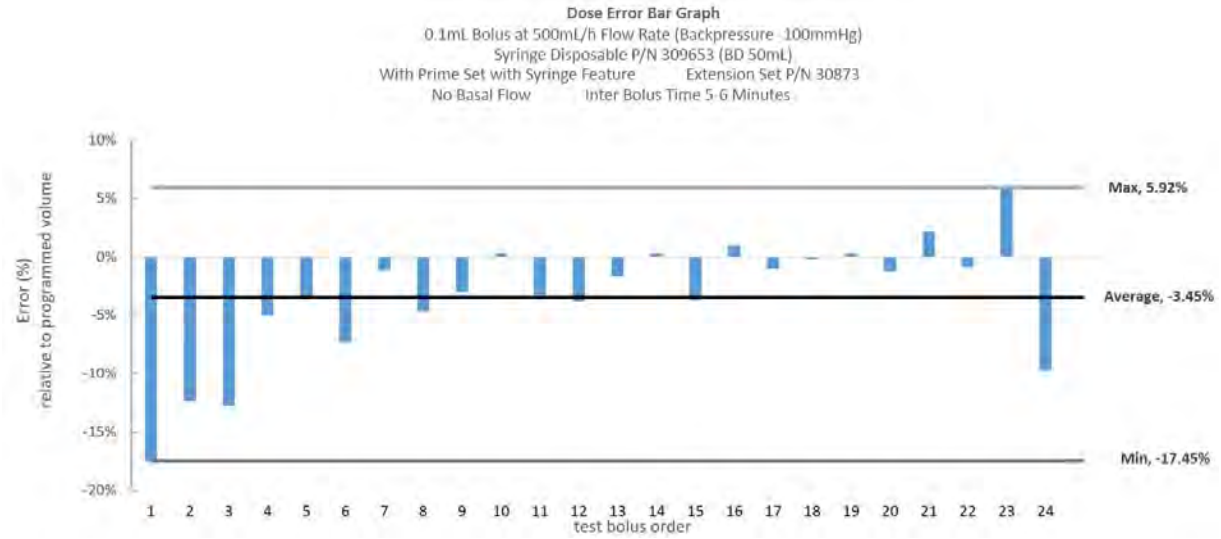
+100 mmHg Backpressure





-100 mmHg Backpressure





Appendix C
Non-Standard Performance

This appendix contains the following topics:

BD Alaris™ Pump Module Non-Standard Operating Conditions

This section contains information about pump performance when conditions change from standard operating conditions. Conditions evaluated include the following:

- Module location
- IV fluid bag location (head height)
- Back pressure (dynamic and hydrostatic)
- Flow rate
- Bolus volume
- Occlusion pressure setting
- Infusion set (set age, set usage time, set components, compliance, and infusate temperature)
- Environmental in-use conditions (ambient temperature, atmospheric pressure, relative humidity)

If a use condition is not described in this non-standard operating condition performance section, the use condition was not found to have a significant effect on the Pump Module performance.

BD Alaris™ Pump Module Performance

Pump Module Flow Rate Accuracy

Pump Module characterization studies demonstrate that flow rate accuracy degrades as conditions change from standard operating conditions as listed.

Conditions that shift flow rate accuracy up
- Pump Module above patient heart level
- IV fluid bag raised above standard operating conditions (> 24 inches from the center of the primary pumping segment)

Conditions that shift flow rate accuracy down
- Pump Module below patient heart level
- IV fluid bag lowered below Pump Module (negative head height)
- Back pressure caused by high viscosity infusates, small inner diameter catheters, and small bore tubing

A combination of foreseeable worst case intended use conditions, based on the above list, may result in rate accuracy exceeding ± 5% at flow rates ≥ 1 mL/h and from -8% to +5% at flow rates < 1 mL/h as shown in the table.

Clinical Use Case Test Scenarios[1]	Infusate	Pump Module Location	IV Fluid Bag Height	Infusion Set and Filter	Catheter or Needle	Flow Rate (mL/h)	Flow Rate Accuracy (Average)
Adult ICU Treatment for Hypoglycemia	D50W (viscous solution)	10 inches above patient heart level	24 inches above center of primary pumping segment	Set wth standard bore tubing (24200-0007) with no filter	3fr PICC 18 inches	375	-6.14% [-10.27% to -2.01%][2]
Adult ICU Treatment for Hypovolemic Shock	Dextran 40 (viscous solution)	10 inches below patient heart level	34 inches above center of primary pumping segment	Set wth standard bore tubing (24200-0007) with 0.2 µm filter (10012217)	7fr 18 inches	999	-5.23% [-11.35% to 0.89%][2]
NICU Treatment for Hypoglycemia	D10W	29 inches below patient heart level	6 inches below center of primary pumping segment	Set wth small bore tubing (2411-0500) with no filter	2fr PICC 12 inches	20	-5.97% [-9.48% to -2.46%][2]
Adult Medical Surgical Parental Nutrition Support	Intralipid	At patient heart level	Level of center of primary pumping segment	Set wth small bore tubing (2411-0500) with 1.2 µm filter (10012218)	22G 1.5 inch	50	-6.64% [-12.01% to -1.27%][2]
NICU/PICU Hydration protocol with normal saline	Normal saline	29 inches below patient heart level	19 inches above center of primary pumping segment	Set with small bore tubing (2411-0500) with no filter	3fr 12 inches	6	-3.67% [-7.09% to -0.25%][2]

1. Clinical use cases with test conditions were designed to stress test the pump to demonstrate flow rate accuracy performance
2. Upper bounds of 95% confidence, 99% reliability tolerance interval

Epidural Flow Rate Accuracy

When using microbore infusion sets for epidural delivery:

- Follow epidural precautions (*BD Alaris™ Pump Module and Alaris™ Syringe Module Epidural* on page *65*)
- Epidural continuous infusions are commonly delivered at flow rates between 1 mL/h and 100 mL/h. For microbore infusion sets without injection ports, the flow rate accuracy is consistent with standard operating conditions at flow rates ≤ 500 mL/h and ± 7% at flow rates > 500 mL/h.

Pump Module Bolus Volume Accuracy

Pump Module characterization studies demonstrate that bolus volume accuracy degrades as conditions change from standard operating conditions as listed.

Conditions that shift bolus volume accuracy up
- Pump Module above patient heart level
- IV fluid bag raised above standard operating conditions (> 24 inches from the center of the primary pumping segment)
- Low bolus volumes at high flow rates
- Infusion set length longer than standard operating condition set

Conditions that shift bolus volume accuracy down
- Pump Module below patient heart level.
- IV fluid bag lowered below Pump Module (negative head height).
- Back pressure caused by the following: high viscosity infusates, small inner diameter catheters, and small bore tubing.
- A bolus delivered at the beginning of an infusion (loading dose).

A combination of the above conditions may result in a bolus volume accuracy that exceeds ± 5% as listed.
- With the pump 30 inches above the patient, a 1 mL bolus after the start of an infusion, and a set length of 61 inches, the bolus volume accuracy is approximately +2.70%.
- With the pump 30 inches below the patient, a 5 mL loading bolus at the start of an infusion, and a set length of 61 inches, the bolus volume accuracy is approximately -3.74%.
- For additional non-standard operating conditions bolus volume accuracy examples, see the Fluid Delivery Performance Testing.

Pump Module Upstream Occlusion Time-to-Alarm

Pump Module characterization studies demonstrate that upstream occlusion time-to-alarm increases as conditions change from standard operating conditions as listed.
- Flow rates < 5 mL/h
- Use of an infusion set with a check valve.
- Increase in distance between top of pump and occlusion location.

A combination of the above conditions may result in a time-to-alarm that exceeds 5 minutes as listed.
- With the distance between the top of the pump and occlusion location of 23 inches, using a set with a check valve, and flow rate of 0.1 mL/h, the upstream occlusion time-to-alarm is approximately 3 hours and 31 minutes.
- For additional occlusion time-to-alarm at low flow rates, see the Standard Operating Conditions section.

Pump Module Downstream Occlusion Time-to-Alarm

Pump Module characterization studies demonstrate that downstream occlusion time-to-alarm increases as conditions change from standard operating conditions as listed.
- Flow rates < 1 mL/h
- Use of selectable pressure mode at pressure settings higher than those listed for the default pump mode.
- Infusion set downstream length longer than standard operating condition set.
- Increase in infusate temperature up to 40°C.

A combination of the above conditions may result in a time-to-alarm that exceeds 5 minutes as listed.
- With a selectable pressure setting of 525 mmHg, an infusion set downstream length of 65 inches, an infusate temperature of 40°C, and a programmed flow rate of 1 mL/h, the downstream occlusion time-to-alarm is approximately 55 minutes.
- For additional occlusion time-to-alarm at low flow rates, see the Standard Operating Conditions section.

Pump Module Post-Occlusion Bolus Volume

Pump Module characterization studies demonstrate that post-occlusion bolus volume increases as conditions change from standard operating conditions as listed.
- Infusion set downstream length longer than standard operating condition set.
- Increase in infusate temperature up to 40°C.
- Pump module above patient heart level.

A combination of the above conditions may result in a post-occlusion bolus volume that exceeds 0.3 mL as listed.
- With an infusion set downstream length of 65 inches, an infusate temperature 40°C, and a Pump Module 12 inches above the patient heart level, the post-occlusion bolus volume is approximately 0.6 mL.

Alaris™ Syringe Module Non-Standard Operating Conditions

This section contains information about pump performance when conditions change from standard operating conditions. Conditions evaluated include the following:

- Module location
- Back pressure (dynamic and hydrostatic)
- Flow rate
- Bolus volume
- Occlusion pressure setting
- Infusion set (set age, set usage time, set components, compliance, and fluid temperature)
- Syringe size
- Environmental in-use conditions (ambient temperature, atmospheric pressure, relative humidity)

If a use condition is not described in this non-standard operating condition performance section, the use condition was not found to have a significant effect on the Syringe Module performance.

Syringe Module Flow Rate Accuracy

Syringe Module characterization studies demonstrate that flow rate accuracy degrades as conditions change from standard operating conditions as listed.

Conditions that shift flow rate accuracy up
- Increase in infusate temperature up to 40°C
- Back pressure caused by high infusate viscosity or small inner diameter catheters

Conditions that shift flow rate accuracy down
- Decrease in infusate temperature down to 5°C
- Use of flow rates below 10% of the syringe volume per hour

A combination of foreseeable worst case intended use conditions based on the above list may result in rate accuracy exceeding ± 5% as listed.
- With a 60 mL Terumo™ syringe at a flow rate of 0.1 mL/h and an infusate temperature of 24°C, the average flow rate accuracy is -5.45% [-10.23% to -0.67%][1,2]

1. Upper and lower bounds of 95% confidence and 99% reliability tolerance interval
2. Clinical use cases with test conditions were designed to stress test the pump to demonstrate flow rate accuracy performance

Syringe Module Bolus Volume Accuracy

Syringe Module characterization studies demonstrate that bolus volume accuracy degrades as conditions change from standard operating conditions as listed.

Conditions that shift bolus volume accuracy up
- Increase in infusate temperature up to 40°C
- Back pressure caused by a high infusate viscosity or small inner diameter catheters

Conditions that shift bolus volume accuracy down
- Decrease in infusate temperature down to 5°C
- Use of flow rates below 10% of syringe volume or 1 mL (whichever is less) divided by the maximum programmable bolus duration (99 minutes) or 0.1 mL/h (whichever is more)
- Infusing with a programmed bolus < 10% of syringe volume or 1 mL (whichever is less)
- A bolus delivered at the beginning of an infusion (loading dose)

A combination of the above conditions may result in a bolus volume accuracy that exceeds ± 5% as listed.
- With a 0.1 mL loading bolus delivered with a BD 3 mL syringe at 100 mL/h, the average bolus volume error is -9.24%.
- For additional non-standard operating conditions bolus volume accuracy examples, see the Fluid Delivery Performance Testing.

Syringe Module Occlusion Time-to-Alarm

Syringe Module characterization studies demonstrate that occlusion time-to-alarm increases as conditions change from standard operating conditions as listed.
- Flow rate less than those listed by syringe in standard operating conditions tables
- Increase in infusate temperature up to 40°C
- Syringe Module above patient heart level
- Occlusion pressure settings higher than those listed in the standard operating conditions table (by syringe size and flow rate)
- Increase in infusion set length and distance between syringe and occlusion location

A combination of the above conditions may result in a time-to-alarm that exceeds 5 minutes as listed.
- With a pressure setting of 500 mmHg, using a 60 mL Terumo™ syringe at a flow rate of 1 mL/h, and an infusate temperature of 40°C, and with the Syringe Module 30 inches above the patient heart level, and an infusion set length of 60 inches, the occlusion time-to-alarm is approximately 1 hour and 46 minutes.
- For additional occlusion time-to-alarm at low flow rates, see the Standard Operating Conditions section.

Syringe Module Post-Occlusion Bolus Volume

Syringe Module characterization studies demonstrate that post-occlusion bolus volume increases as conditions change from standard operating conditions as listed.
- Occlusion pressure settings higher than those listed in the standard operating conditions table (by syringe size and flow rate)
- Increase in infusate temperature up to 40°C
- Syringe Module above patient heart level
- Increase in infusion set length and distance between syringe and occlusion location

A combination of the above conditions may result in a post-occlusion bolus volume that exceeds 1 mL as listed.
- With a pressure setting of 500 mmHg, using a 60 mL Terumo™ syringe (flow rate of 1 mL/h), and an infusate temperature of 40°C, and with the Syringe Module 30 inches above the patient heart level, and an infusion set length of 60 inches, the post-occlusion bolus volume is approximately 0.721 mL.

Alaris™ PCA Module Non-Standard Operating Conditions

This section contains information about pump performance when conditions change from standard operating conditions. Conditions evaluated include the following:

- Module location
- Back pressure (dynamic and hydrostatic)
- Flow rate
- Bolus volume
- Pressure setting
- Infusion set (set age, set usage time, set components, compliance, and fluid temperature)
- Syringe size
- Environmental in-use conditions (ambient temperature, atmospheric pressure, relative humidity)

If a use condition is not described in this non-standard operating condition performance section, the use condition was not found to have a significant effect on the PCA Module performance.

PCA Module Flow Rate Accuracy

PCA Module and Syringe Module drive mechanism designs are the same. The following information is based on Syringe Module characterization studies under non-standard operating conditions.

Syringe Module characterization studies demonstrate that flow rate accuracy degrades as conditions change from standard operating conditions as listed.

Conditions that shift flow rate accuracy up

- Increase in infusate temperature up to 40°C
- Back pressure caused by high infusate viscosity or small inner diameter catheters

Conditions that shift flow rate accuracy down

- Decrease in infusate temperature down to 5°C
- Use of flow rates below 10% of the syringe volume per hour

A combination of foreseeable worst case intended use conditions based on the above list may result in rate accuracy exceeding ± 5% as listed.

- With a 60 mL Terumo™ syringe at a flow rate of 0.1 mL/h and an infusate temperature of 24°C, the average flow rate accuracy is -5.45% [-10.23% to -0.67%][1,2]

1. Upper and lower bounds of 95% confidence and 99% reliability tolerance interval
2. Clinical use cases with test conditions were designed to stress test the pump to demonstrate flow rate accuracy performance

PCA Module Bolus Volume Accuracy

PCA Module and Syringe Module's drive mechanism designs are the same.
The following information is based on Syringe Module characterization studies under non-standard operating conditions.
Syringe Module characterization studies demonstrate that bolus volume accuracy degrades as conditions change from standard operating conditions as listed.

Conditions that shift bolus volume accuracy up
- Increase in infusate temperature up to 40°C
- Back pressure caused by a high infusate viscosity or small inner diameter catheters

Conditions that shift bolus volume accuracy down
- Decrease in infusate temperature down to 5°C
- Infusing with a programmed bolus < 1 mL
- A bolus delivered at the beginning of an infusion (loading dose)

A combination of the above conditions may result in a bolus volume accuracy that exceeds ± 5% as listed.
- For non-standard operating conditions bolus volume accuracy examples, see the Fluid Delivery Performance Testing.

PCA Module Occlusion Time-to-Alarm

PCA Module and Syringe Module occlusion detection (without pressure sensing disc) designs are the same. The following information is based on Syringe Module characterization studies under non-standard operating conditions.
Syringe Module characterization studies demonstrate that occlusion time-to-alarm increases as conditions change from standard operating conditions as listed.
- Flow rate less than those listed by syringe in standard operating conditions tables
- Increase in infusate temperature up to 40°C
- Syringe Module above patient heart level
- Occlusion pressure settings higher than those listed in the standard operating conditions table (by syringe size and flow rate)
- Increase in infusion set length and distance between syringe and occlusion location

A combination of the above conditions may result in a time-to-alarm that exceeds 5 minutes as listed.
- With a pressure setting of 500 mmHg, using a 60 mL Terumo™ syringe at a flow rate of 1 mL/h, and an infusate temperature of 40°C, and with the Syringe Module 30 inches above the patient heart level, and an infusion set length of 60 inches, the occlusion time-to-alarm is approximately 1 hour and 46 minutes.
- For additional occlusion time-to-alarm at low flow rates, see Standard Operating Conditions section.

PCA Module Post-Occlusion Bolus Volume

PCA Module and Syringe Module's drive mechanism designs are the same. The following information is based on Syringe Module characterization studies under non-standard operating conditions.
Syringe Module characterization studies demonstrate that post-occlusion bolus volume increases as conditions change from standard operating conditions as listed.
- Occlusion pressure settings higher than those listed in the standard operating conditions table (by syringe size and flow rate)
- Increase in infusate temperature up to 40°C
- Syringe Module above patient heart level
- Increase in infusion set length and distance between syringe and occlusion location

A combination of the above conditions may result in a post-occlusion bolus volume that exceeds 1 mL as listed.
- With a pressure setting of 500 mmHg, using a 60 mL Terumo™ syringe (flow rate of 1 mL/h), and an infusate temperature of 40°C, and with the Syringe Module 30 inches above the patient heart level, and an infusion set length of 60 inches, the post-occlusion bolus volume is approximately 0.721 mL.

Appendix D
Cleaning

This appendix contains the following topic:

Summary of Warnings and Cautions

WARNING

- **Perform device inspections to prevent a damaged device from being returned to patient use. Use of a damaged device can result in patient harm.**
- **Inspection of IUI connectors is required. Damaged IUI connectors can result in incorrect device operation. Use of a damaged device can result in patient harm.**
- **Inserting a finger or other object into the IUI connector, when the module is attached to the PCU, could result in electrical shock.**
- **Failure to perform these inspections can result in improper instrument operation.**
- **Do not clean while devices are connected to a patient because this can lead to patient harm.**
- **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.**
- **Use IUI connector covers during cleaning to prevent damage to the IUI connectors. Use of a damaged device can result in patient harm.**
- **Do not wipe the air-in-line sensor with any cleaning product. Cleaning products can damage the sensor and lead to patient harm.**
- **Brush IUI connectors up and down. Do not brush them side-to-side.**
  Brushing the IUI connectors side-to-side can damage the pins and result in patient harm.
- **Do not return the device to patient use if there are cracks, surface contaminants, discoloration, or other damage to IUI connectors. Use of devices with damaged IUI connectors can result in patient harm. Send all damaged devices to Biomedical Engineering for repair.**
- **Missing screws and washers on the PCU can result in a loss of power and patient harm.**
- **Do not return a damaged device to patient use. Damaged devices can result in patient harm. Send the damaged device to Biomedical Engineering for repair.**
- **Do not store the device in a plastic bag. Storing a device in a plastic bag can lead to moisture buildup that can damage electronic parts and result in patient harm.**

CAUTION

- Preventive maintenance inspections should only be performed by qualified service personnel.
- The use of chemicals that can damage the surface of the instrument and failure to follow the BD Alaris™ and 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.
- Do not allow cleaning solutions to collect on the instrument. Residue buildup might cause the moving parts to become sticky and hinder their operation over time.
- Certain chemicals can damage the surfaces of the instrument. Refer to the following website for a list of chemicals that should NOT be used: www.bd.com/alarissystemcleaning.
- Do not use chemicals that can damage the surface of the instrument. When possible use cleaning products that are recommended for use by BD.
- 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.

Inspecting IUI Connectors

WARNING

Inspection of IUI connectors is required. Damaged IUI connectors can result in incorrect device operation. Use of a damaged device can result in patient harm.

WARNING

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

WARNING

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

CAUTION

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

1. Visually inspect the right side (male) IUI connector for cracks on the entire surface of the black colored plastic housing. See Figures 1 and 2 for the male IUI inspection area and typical cracks.

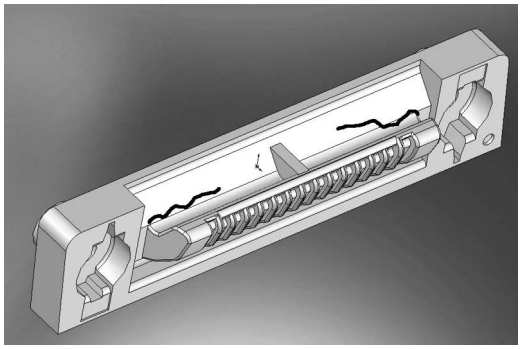


Figure 1 Male IUI Connector (right side)

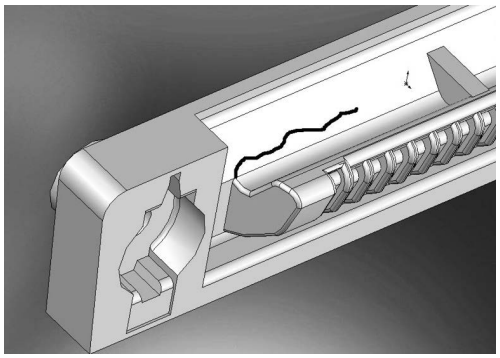


Figure 2 Male IUI Connector

2. Visually inspect the left side (female) IUI connector for cracks on the edges of the black colored plastic housing.
3. If cracks are found, replace the IUI connector before use.

NOTE:
While visually inspecting the IUI connectors, look for fractures on the connectors black-colored plastic. If you see any damage, do not use an instrument with fractured IUI connectors. The IUI connector must be replaced before the instrument can be used again.

NOTE:
Use the recommended healthcare-grade solutions and DO NOT use chemicals that can damage the surfaces of the instrument.

Cleaning

Devices should be cleaned before each patient use. Inspect and clean the product per the following procedures. Read all warnings and cautions before continuing with this procedure.

Follow hospital infection control protocols when transporting contaminated devices for cleaning.

Cleaning Products

Refer to the following website for cleaning product information:

www.bd.com/alarissystemcleaning

WARNING

Do not clean while devices are connected to a patient because this can lead to patient harm.

WARNING

To prevent an electrical hazard:

- **Turn the instrument off and unplug the power cord from AC power before cleaning.**
- **Do not spray fluids directly onto the instrument or into the IUI connectors.**
- **Do not steam autoclave, EtO sterilize, immerse the instrument in fluids, or allow fluids to enter the instrument case.**
- **Do not connect a module until the IUI connectors are thoroughly dry.**

WARNING

Do not use compressed air to dry the instrument; this could force fluid into the instrument.

CAUTION

- The use of chemicals that can damage the surface of the instrument and failure to follow the BD Alaris™ and 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.
- Do not allow cleaning solutions to collect on the instrument. Residue buildup might cause the moving parts to become sticky and hinder their operation over time.
- Certain chemicals can damage the surfaces of the instrument. Refer to the following website for a list of chemicals that should NOT be used: www.bd.com/alarissystemcleaning.
- Do not use chemicals that can damage the surface of the instrument. When possible use cleaning products that are recommended for use by BD.

Using IUI Connector Covers

WARNING

Use IUI connector covers during cleaning to prevent damage to the IUI connectors. Use of a damaged device can result in patient harm.

Order information:

Color	Part Number/Quantity	Location
Green	49000418/10	All IUI connectors except the PCA right-side IUI connector
Pink	49000419/5	Only the PCA right-side IUI connector

1. Inspect IUI connector covers for any damage. Do not use the cover if there is visible cracking, indentations, severe bending, or it is not fitting over the IUI connector.
2. Align the sockets of the covers with the mounting screws of the IUI connectors.

3. Ensure the tab points upward and press the cover firmly onto the IUI connector.

NOTE:

- IUI connector covers should be cleaned when soiled using 70% isopropyl alcohol (IPA).
- It is recommended that the IUI connector covers are replaced after six months of use.
- Discard IUI connector covers when there is visible cracking, indentations, severe bending, or if they fail to remain engaged with the IUI connector.

Cleaning the Case

NOTE:
Use the recommended healthcare-grade solutions and DO NOT use chemicals that can damage the surfaces of the instrument.

1. Make sure the instrument is upright, turned off, and the power cord is unplugged.
2. Attach an IUI connector cover to each IUI connector.

   There are two IUI connectors per device.
3. Wipe all the exposed device surfaces.

   DO NOT use a cloth that drips. Be sure to wring out the cloth to squeeze out excess liquid.

4. Use a dedicated soft-bristled brush to clean the case to remove any visible residue. The brush may also be used to clean narrow or hard-to-reach areas.

   DO NOT use any hard, abrasive or pointed objects to clean any part of the instrument.

WARNING

Do not wipe the air-in-line sensor with any cleaning product. Cleaning products can damage the sensor and lead to patient harm.

5. Follow the cleaner manufacturer's instructions on the time to leave it on the device surface. Then, wipe off the cleaner using a soft cloth dampened with water.

   DO NOT allow the cleaner to collect on the instrument.

Cleaning the Auto-ID and 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 the 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.

Cleaning the IUI Connector

1. Remove the IUI connector covers.
2. Apply 70% IPA directly to the dedicated IUI connector cleaning brush. To prevent cross-contamination, do not dip the brush into the IPA.

   DO NOT use the same brush used on the case to clean the IUI connectors. Doing so could inadvertently transfer the cleaner or contaminants to the electrical contacts.

   Take care not to allow fluids to come in contact with electrical components and openings, with the exception of the IUI connector, as outlined below. Ensure that the rubber boot is secured before and during cleaning to help prevent fluid from entering the electrical RJ45 plug.

WARNING

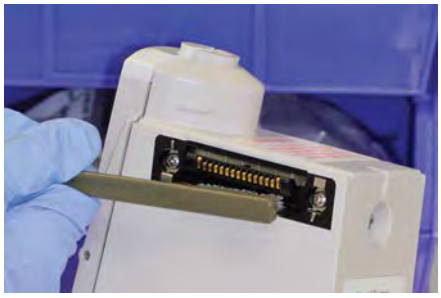
Brush IUI connectors up and down. Do not brush them side-to-side.

Brushing the IUI connectors side-to-side can damage the pins and result in patient harm.

3. Clean both IUI connectors with the dedicated IUI connector cleaning brush. Brush the IUI connectors up and down. Do not brush them side-to-side.

   To avoid accidentally depositing fluid on the connectors, DO NOT use any spray cleaners anywhere near the IUI connectors.

   NEVER ALLOW ANY CLEANER OTHER THAN 70% IPA TO CONTACT THE IUI CONNECTORS.



Inspecting and Drying

WARNING

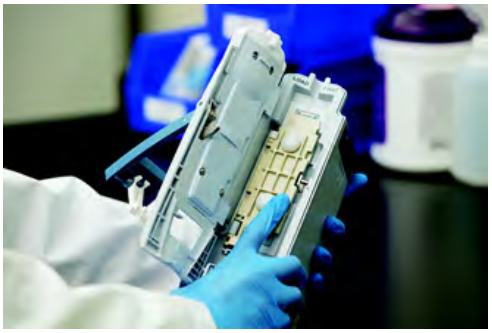
Inserting a finger or other object into the IUI connector, when the module is attached to the PCU, could result in electrical shock.

WARNING

Do not return the device to patient use if there are cracks, surface contaminants, discoloration, or other damage to IUI connectors. Use of devices with damaged IUI connectors can result in patient harm. Send all damaged devices to Biomedical Engineering for repair.

1. Inspect surfaces and moving parts for signs of damage, such as cracks and broken parts. Open the Pump Module and PCA Module doors and inspect the parts inside.

   DO NOT use a device with any damage. Send it to Biomedical Engineering for repair.

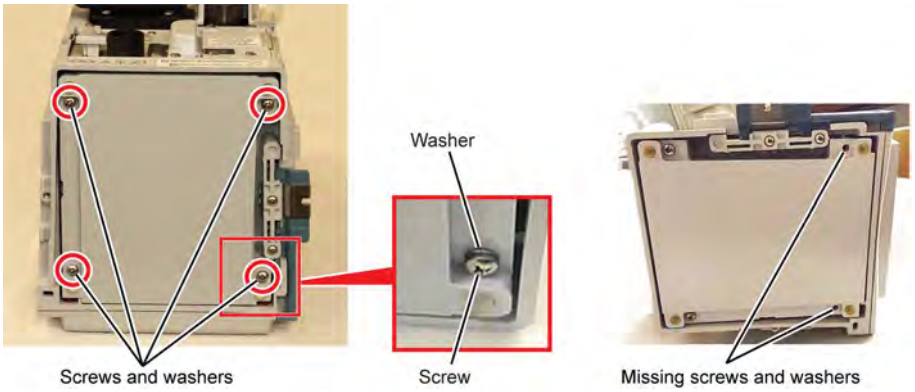


WARNING

Missing screws and washers on the PCU can result in a loss of power and patient harm.

2. Inspect the bottom of the PCU to check if any of the four battery screws or washers are missing.

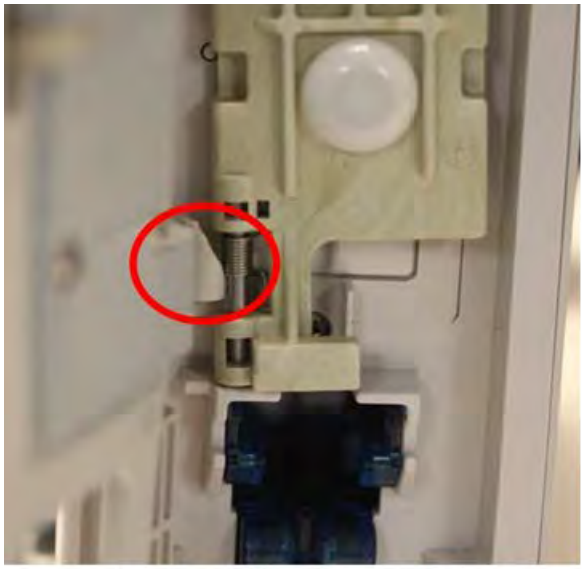
   If any of the screws or washers are missing, send the device to Biomedical Engineering for repair.



Examples of damage inside the Pump Module door:

Cracked hinge on membrane frame

Broken platen post



Broken platen lower hinge bracket

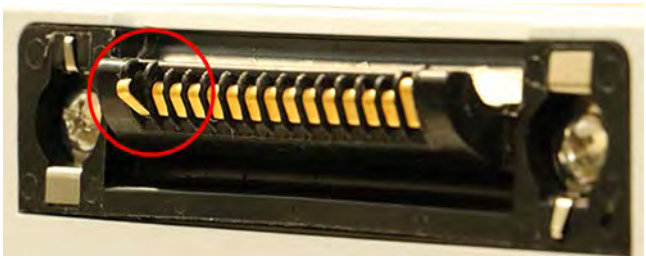
Membrane frame breakage

WARNING

Do not return a damaged device to patient use. Damaged devices can result in patient harm. Send the damaged device to Biomedical Engineering for repair.

3. Inspect the IUI connectors on each PCU and module prior to use.

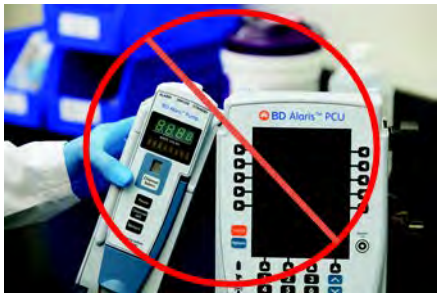
Deposits on IUI connector



Bent pin on a male IUI connector

4. Confirm that the instruments and IUI connectors are completely dry for approximately 15 minutes before connecting them to another device.

   DO NOT attach devices that have not fully dried to one another. “Wet mating” can hinder proper instrument operation.



WARNING

Do not store the device in a plastic bag. Storing a device in a plastic bag can lead to moisture buildup that can damage electronic parts and result in patient harm.

Appendix E
Summary of Software and User Manual Changes

This appendix contains the following topic:

Summary of Software and User Manual Changes

Version	Changes	Hardware	Software	User Manual
12.1.2	• New message for user to verify secondary clamp is open before the start of a secondary infusion.		X	X
	• Change in delay options to remove Delay Until selection.		X	X
	• Clear all data history log function in maintenance mode.		X	
	• Removal of SpO_2 Module compatibility		X	X
	• Removal of BD 60 mL syringe			X
	• Removal of IVAC 50 mL and Astra Zeneca 50 mL syringes		X	X
	• New or updated warnings and cautions			X
	• Updated module specifications			X
	• Incorporation of infusion set compatibility for Pump Module, Syringe Module, and PCA Module			X
	• Appendix B provides fluid delivery performance testing			X
	• Appendix C non-standard performance for Pump Module, Syringe Module, and PCA Module			X
	• Improved PCU battery capacity estimation.		X	
	• Eliminated suppression of KVO when programming an infusion with a delay.		X	X
	• Change all Pump Module and Syringe Module INFUSION COMPLETE and INFUSION COMPLETE – KVO alarms from medium priority to high priority.		X	X
	• Incorporated two-screen Guardrails™ alert notification on the PCU when programming custom concentration on Pump Module, Syringe Module, or PCA Module.		X	X

Version	Changes	Hardware	Software	User Manual
12.1.0	• No Guardrails™ notification for basic infusion programming.		X	X
	• Optional Clinical Advisory associated with non-Guardrails™ selection.		X	X
	• Display of programmed value for Guardrails™ limit alerts.		X	X
	• Support for two additional air-in-line thresholds (125 and 175 microlitres).		X	X
	• Removal of multi-dose option.		X	X
	• Terumo™ 50 mL syringe removed from master syringes list.			X
	• Improved software behavior for system error 255 – xx-xxx when user selects two functions at the same time.		X	X
	• Reinforcement of HIPPA compliance to clear historical log data under specified transport scenarios.		X	X
	• Updated weight change dose recalculation text on pop up screen.		X	X