BD Alaris™ System with Guardrails™ Suite MX

For BD Alaris™ PC Unit Model 8015 and
Alaris™ PC Unit Model 8015
Software Version 12.1 and Supported Modules

User Manual

BD

CareFusion 303, Inc.
10020 Pacific Mesa Blvd.
San Diego, CA 92121
United States

888-876-4287

bd.com

CE
2797

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 CareFusion 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 CareFusion. 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 CareFusion, contact CareFusion 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.

For countries not listed below, contact your local Alaris System distributor for technical support.

North America

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

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

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

Southeast Asia

Technical Support - Singapore
(Maintenance and service information support; troubleshooting.)
Phone: 65 6432 2099
E-mail: Infusion.SEA@bd.com

United Arab Emirates

Technical Support - United Arab Emirates
(Maintenance and service information support; troubleshooting.)
Phone: 971.4.5592555
E-mail: Infusion.EMA@bd.com

United Kingdom

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

Customer Care - United Kingdom
(Product return, service assistance, and order placement.)
Phone: 0800 917 8776
E-mail: BDUK_CustomerService@bd.com
www.bd.com/en-uk/customer-support

Australia/New Zealand

Technical Service - Australia
(Maintenance and service information support; troubleshooting, service assistance.)
Phone: 1300 729 258
http://www.bd.com/anz/contactus.asp

Technical Service - New Zealand
(Maintenance and service information support; troubleshooting, service assistance.)
Phone: 0508 422 734
http://www.bd.com/anz/contactus.asp

Customer Service - Australia
(Product return and order placement.)
Phone: 1800 656 100
E-mail: aus-customerservice@bd.com

Customer Service - New Zealand
(Product return and order placement.)
Phone: 0800 572 468
E-mail: nz_customerservice@bd.com

Authorized Representatives

Authorized Australian Representative
Becton Dickinson Pty Ltd
66 Waterloo Road
Macquarie Park
NSW 2113
Australia

Authorized New Zealand Representative
Becton Dickinson Ltd
14b George Bourke Drive
Mt Wellington
Auckland 1060
New Zealand

Authorized European Representative EC REP
BD Switzerland Sàrl
Route de Crassier 17
Business Park Terre-Bonne
Batiment A4
1262 Eysins
Switzerland

Contents

Chapter 1—Introduction

Chapter 2—BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015

Contents

Chapter 3—BD Alaris™ Pump Module Model 8100, Alaris™ Pump Module Model 8100, and Alaris™ Syringe Module Model 8110

Contents

Chapter 4—Alaris™ PCA Module Model 8120

Chapter 5—Alaris™ SpO$_2$ Module Models 8210 and 8220

Chapter 6—Alaris™ EtCO$_2$ Module Model 8300

Chapter 7—Alaris™ Auto-ID Module Model 8600

Contents

Appendix A—Troubleshooting and Maintenance

Contents

Chapter 1
Introduction

This chapter contains the following topics:

Introduction

⚠️ **WARNING**

Read all instructions before using the BD Alaris™ system.

⚠️ **CAUTION**

℞ Only

The BD Alaris™ PC unit (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). The Alaris™ auto-ID module can be included as a fifth module. The use of the system is restricted to one patient at a time.

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 an Alert that occurs during use is stored within the PCU, and can be accessed using the Guardrails™ CQI reporter software.

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

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

Intended Use

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

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

Essential Performance

The BD Alaris^{TM} pump module, Alaris^{TM} pump module, Alaris^{TM} syringe module, and Alaris^{TM} 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 of proper infusion set loading (free flow detection), pressure (occlusion detection), and air-in-line detection.

The Alaris^{TM} EtCO$_2$ and Alaris^{TM} SpO$_2$ modules will monitor and alarm when a patient's physiological condition is out of range.

The Alaris system will alarm when the monitoring modules (SpO$_2$ and/or EtCO$_2$ modules) are unable to detect patient vitals.

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 to the possibility of a problem with the device associated with the use or misuse of the device.

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

Defined Terms

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

Product/Feature	Defined Term
Alaris auto-ID module	auto-ID module
Alaris EtCO$_2$ module	EtCO$_2$ module
Alaris PCA module	PCA module
Alaris PC unit	PCU
Alaris pump module	pump module
Alaris SpO$_2$ module	SpO$_2$ module
Alaris syringe module	syringe module
BD Alaris PC unit	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, SpO$_2$ 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
Guardrails hard limit	hard limit
Guardrails IV fluid	IV fluid
Guardrails limit	limit
Guardrails PCA pause protocol	PCA pause protocol
Guardrails soft limit	soft limit
SmartSite™ needle-free valve	needle-free valve

Approved Parts Recommendation

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

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 electromagnetic compliance of the Alaris System.

* PCU Power Cord
* PCU Serial Cable
* PCA Dose Request Cord
* Handheld Barcode Scanner

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*^{TM} *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*^{TM} *System Maintenance User Manual* or *BD Alaris*^{TM} *Guardrails*^{TM} *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 *23*). ①

NOTE:
① 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. Follow the procedure in *Cleaning* on page *346*.

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, (except SpO$_2$ module), and device labels	NA
	Do not dispose of electronic products in the general waste stream.	Waste stream disposal status	PCU and all modules, device labels (except SpO$_2$ module)	Directive 2002/96EC (WEEE)
	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, EtCO$_2$ module 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
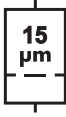
Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
⚠	Caution: Refer to accompanying documentation.	Caution	PCU and all modules, PCA handset, device labels, and external packaging	Ref 0434A IEC-TR-60878 Graphic symbols for electrical equipment used in a medical practice
IPX1	Degree of particle and water ingress protection.	Degrees of ingress protection provided by enclosure	SpO$_2$ module device label	Ref. 2: IEC 60601-1, Table D.3, General requirements for basic safety and essential performance
IPX2	Degree of particle and water ingress protection.	Degrees of ingress protection provided by enclosure	PCU, pump module, syringe module, PCA module, PCA handset, EtCO$_2$ module, and Auto-ID module 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, all modules side panel	Ref. 5448 IEC-TR-6078 Graphic symbols for electrical equipment in a medical practice
⋀⋀ XXXX-XX-XX	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
℞ Only	Federal Law restricts device to sale by or on the order of a licensed health provider.	Prescription use only	User manual and external packaging	21 CFR 801.109
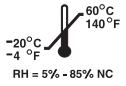
Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
$C\epsilon$ **2797**	Signifies European Technical Conformity	CE marking, Conformité Européenne, Notified Body 2797: BSI Group, The Netherlands B.V.	PCU and all modules device labels, (except EtCO$_2$, SpO$_2$, and Auto ID modules), PCA handset device label, user manual, and shipping label (International only)	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II
	Complies with Australian Communications Requirements.	Australian Communications Authority	PCU device label and user manual	NA
FC	Meets FCC requirements per 21 CFR Part 15.	Federal Communication Authority	PCU and all modules and device labels	Meets FCC requirements per 21 CFR Part 15
	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
	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	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	Pump module, syringe module, PCA module, SpO$_2$ module, and 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

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	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 (except SpO_2 module), device labels, user manual	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
	Type BF applied part complying with IEC 60601-1.	Type BF applied part	SpO_2 module, $EtCO_2$ 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

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.	Catalogue number	Disposable packaging	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
(②) crossed out	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
STERILE	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.
STERILE R	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
STERILIZE crossed out	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
NON STERILE	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
(non-pyrogenic symbol)	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

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
20 / **ml**	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
15 μm	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
LATEX	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
PHT / DEHP	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
(symbol)	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
(recycle symbol)	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
(stacking symbol, 6)	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

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
60°C 140°F −20°C −4°F RH = 5% - 85% NC	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
(umbrella symbol)	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
(up arrows symbol)	This side up.	This way up	External packaging	Ref No. 13 ISO 780 Packaging Distribution Packaging-Graphical Symbols for handling and storage of packages
(sun/light symbol)	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
(fragile glass symbol)	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
EC | REP	Authorized EC Representative.	Authorized representative in the European Community	PCU and all modules, (except SpO_2 module), 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
STERILE|EO	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

Symbol (Graphical Image)	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	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 2
BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015

This chapter contains the following topics:

Getting Started

⚠ **WARNING**

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

⚠ **CAUTION**

℞ Only

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

- *BD Alaris™ PC Unit Model 8015, Alaris™ PC Unit 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.

Alarms and Alerts: See *Alarms and Alerts* on page *325* for specific PCU alarms and alerts.

Contraindications: None known.

Electromagnetic Environment: See *Electromagnetic Environment* on page *354*.

The BD Alaris PCU has the visual characteristics shown in the following figure:

BD Alaris PCU

The Alaris PCU has the visual characteristics shown in the following figure:

Alaris PCU

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

General Setup and Operation

Attaching the System to an IV Pole

⚠ **CAUTION**

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

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/detaching to/from a PCU or another module.

An individual hospital/facility can choose to permanently attach modules. To remove permanently attached modules, contact qualified service personnel.

⚠ **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.

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. The auto-ID module can be included as a fifth module. A module can be attached in any position; however, when mounted on an IV pole, it is recommended that a balanced configuration be maintained.

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

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

IUI Connector

Aligned IUI Connectors

Front View

Top View

IUI Connectors Not Aligned

Top View
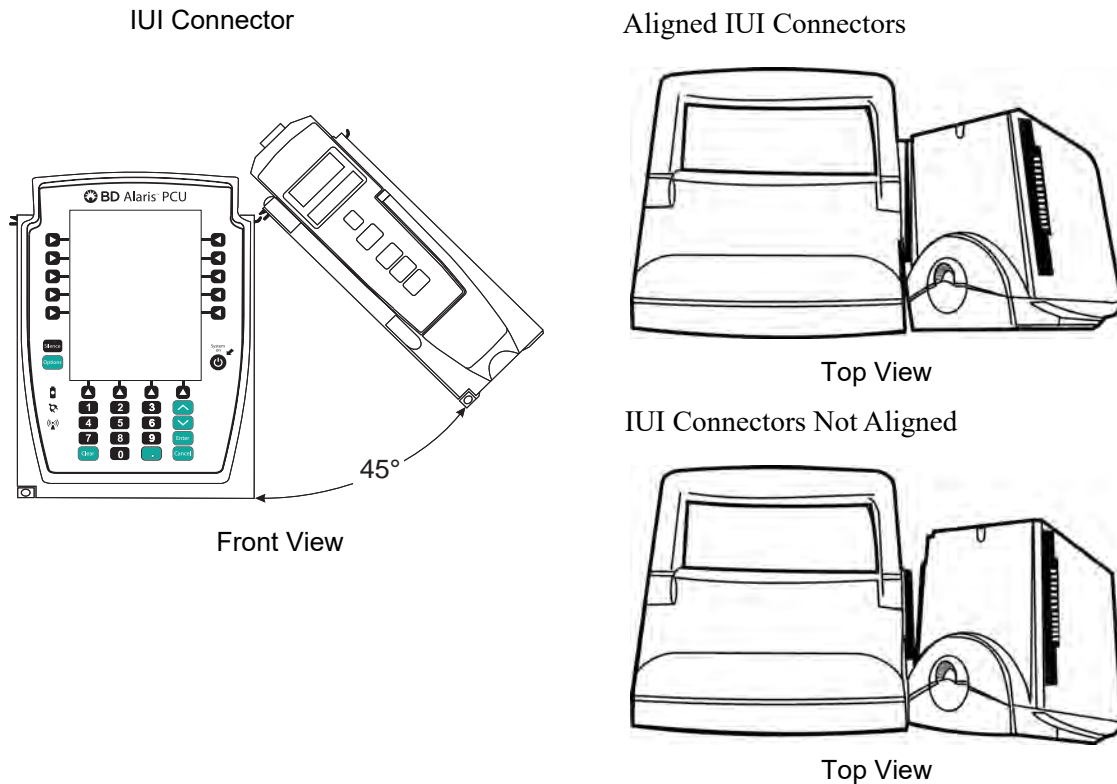
2. Rotate free module down against PCU or attached module until release latch snaps in place.

⚠ **WARNING**

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

⚠ **WARNING**

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

⚠ **WARNING**

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

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 *18* 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.

Release Latch
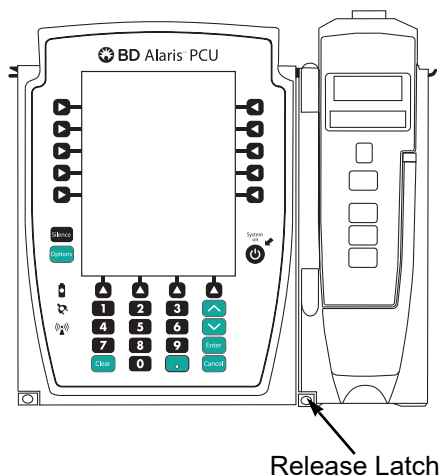
Adding a Module While the System is Powered On

Adding a module is described in *Attaching a Module* on page *18*.

• 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.

• 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.

Start-Up

Powering On the System

1. Connect the PCU to an external AC power source.

2. Press the **SYSTEM ON** key.①②

   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.

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

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 *18*).
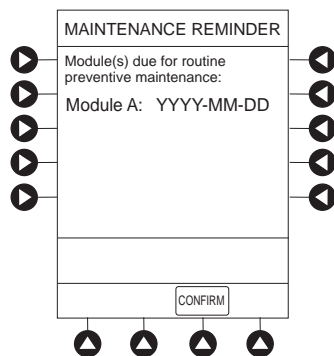
2. If the system was powered off to replace the PCU, reinitiate the start-up process.

   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.
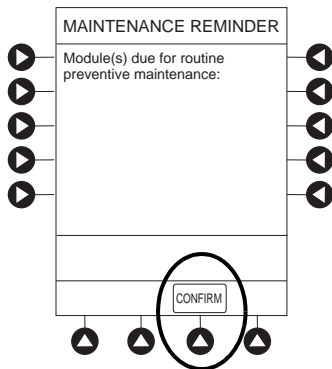
Adjusting Display Contrast

1. Press **DISPLAY CONTRAST** soft key.
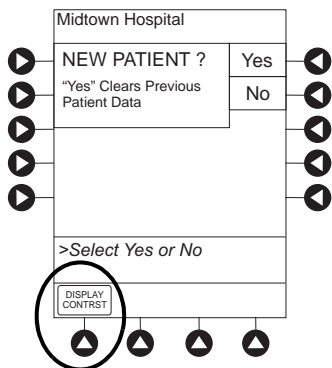
2. To adjust display for optimum viewing, use **Lighter/Darker** soft keys.
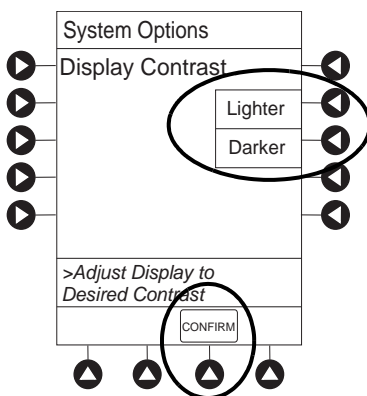
3. To return to main screen, press the **CONFIRM** soft key.

Selecting New Patient and Profile Options

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.
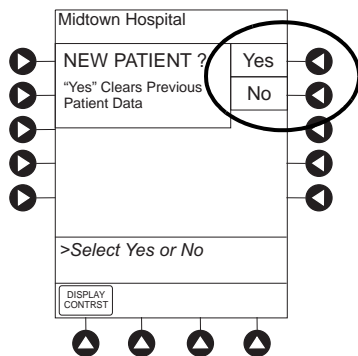
2. Accept or change current profile:

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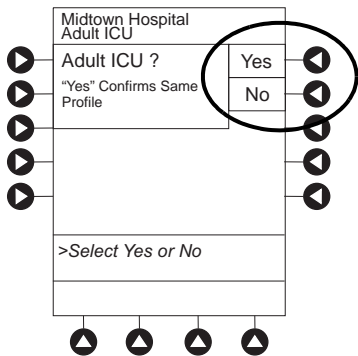
3. To select a profile, press the corresponding left soft key. To view additional choices, press the **PAGE DOWN** soft key.

4. To confirm profile selection, press the **CONFIRM** soft key.
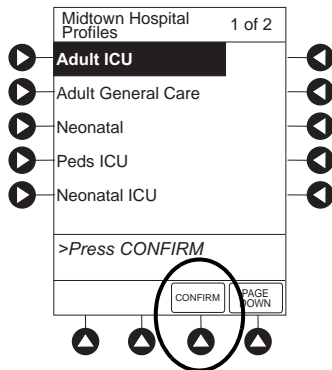
Main screen appears.

Updating the Data Set

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 *47*. 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.

Patient ID Entry Feature

The option to enter and display a 16-character alphanumeric patient identifier is always available. The instrument can be configured to automatically display the **Patient ID Entry** screen during start-up or to provide access only through the **Systems Options** menu (see *System Options* on page *28*).

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

- If patient identifier is not required, press the **CONFIRM** or **EXIT** soft key.
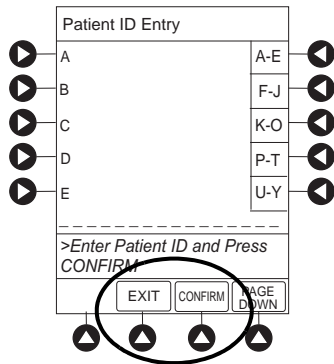
- To manually enter patient identifier, use numeric data entry keys and/or alpha speed keys.
  - An alphanumeric identifier, of up to 16 characters, can be entered.
  - Press soft key next to a letter group to list letters in that group. Press soft key next to an individual letter to enter that letter.
  - To access letter "Z" and special characters (hyphen, underscore, space), press 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 barcode on patient identification band, see *Alaris™ Auto-ID Module Model 8600* on page *309*.

Adjusting Audio Volume

⚠ **WARNING**

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

⚠ **WARNING**

A hazard can exist if different alarm presets are used for the same or similar equipment in a single area, such as an intensive care unit or a cardiac operating theatre.

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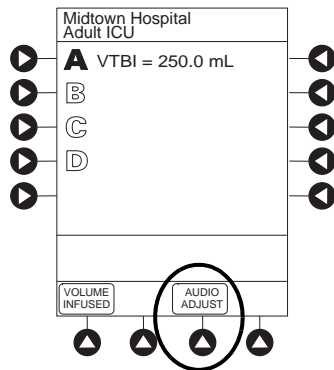
⚠ **CAUTION**

Setting the audio volume to the lowest level will lower all system alarms, including secondary alarms such as end of infusion.

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).
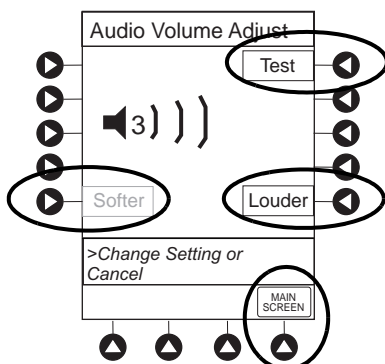
Locking and Unlocking Tamper Resist

1. Initiate 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, Indicators* on page *53* for more information).[1]
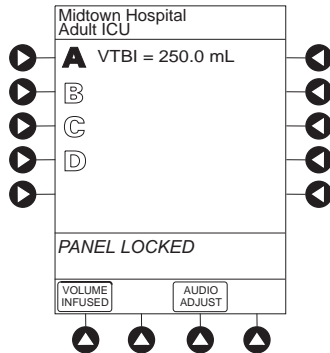
- An advisory tone (if **Key Click Audio** is enabled) and a 3-second **Panel Locked** prompt on the main display confirms activation.

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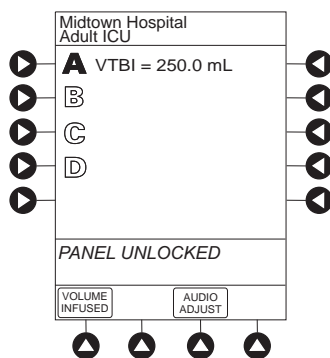
NOTE:
[1] The PCU exits the tamper resist mode when a channel error, system error, or the discharge battery screen is displayed.

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 initiate power down.

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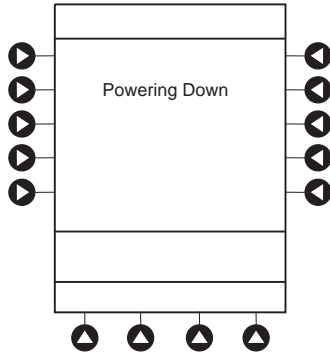
- To interrupt the power down sequence, quickly press any key (except **SYSTEM ON**) on the PCU. If a device needs to be used on a new patient, the system should be completely powered down and then restarted with the **SYSTEM ON** key. When all attached modules are powered off, the PCU automatically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

System Options

Adjusting Display Contrast

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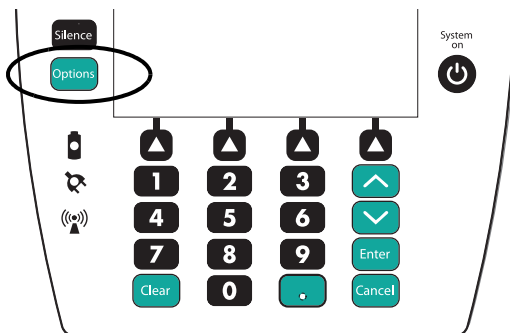
2. Press the **Display Contrast** soft key.

```
┌─────────────────────────────┐
│ System Options      1 of 3   │
│ ○ ─ Display Contrast      ◐  │
│ ○ ─ Patient ID            ◐  │
│ ○ ─ Clinician ID          ◐  │
│ ○ ─ Power Down All Channels ◐│
│ ○ ─ Anesthesia Mode       ◐  │
│                              │
│ >Select an Option or         │
│ EXIT                         │
│      ┌──────┐    ┌──────┐    │
│      │ EXIT │    │ PAGE │    │
│      └──────┘    │ DOWN │    │
│                  └──────┘    │
└─────────────────────────────┘
      △     △     △     △
```
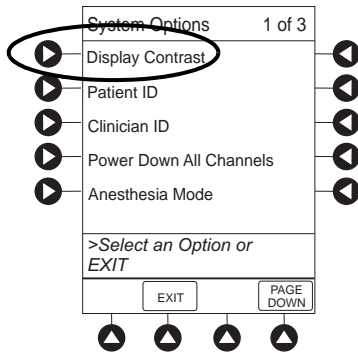
3. Adjust the display and return to the main screen (see *Adjusting Display Contrast* on page *22* for the procedure).

Patient ID

Entering Patient ID

1. Press the **OPTIONS** key.

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

```
┌─────────────────────────────┐
│ System Options      1 of 3   │
│ ○ ─ Display Contrast      ◐  │
│ ○ ─ Patient ID            ◐  │
│ ○ ─ Clinician ID          ◐  │
│ ○ ─ Power Down All Channels ◐│
│ ○ ─ Anesthesia Mode       ◐  │
│                              │
│ >Select an Option or         │
│ EXIT                         │
│      ┌──────┐    ┌──────┐    │
│      │ EXIT │    │ PAGE │    │
│      └──────┘    │ DOWN │    │
│                  └──────┘    │
└─────────────────────────────┘
      △     △     △     △
```
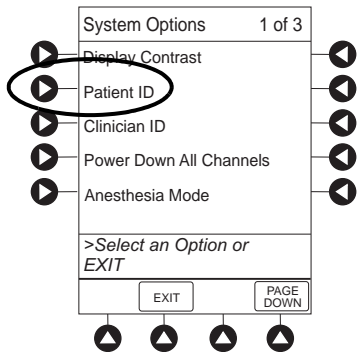
3. Scan or manually enter patient identifier:

    •   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 *309* for more information.

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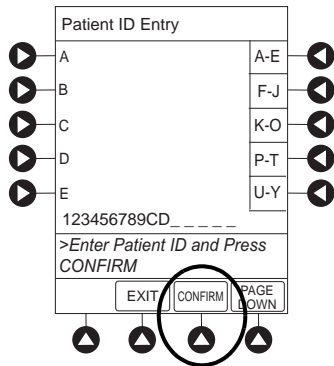
Modifying Patient ID

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.
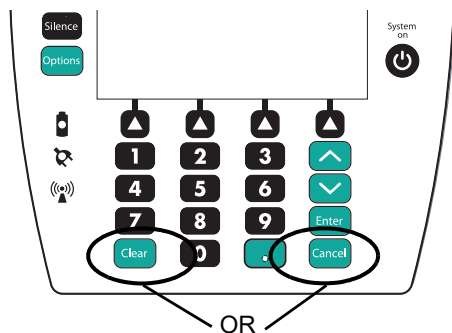
4. To enter modified patient identifier, use numeric data entry keys and/or alpha speed keys.

   • 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.

    ```
    Patient ID Entry

    ▶ A                    A-E ◀
    ▶ B                    F-J ◀
    ▶ C                    K-O ◀
    ▶ D                    P-T ◀
    ▶ E                    U-Y ◀
      234567891EF _ _ _ _ _
      >Enter Patient ID and Press
      CONFIRM

         EXIT   CONFIRM   PAGE
                          DOWN
          △      △    △    △
    ```
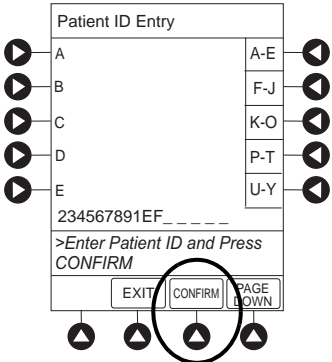
6. To accept modified patient ID, press the **Yes** soft key.

    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.

    ```
    Patient ID Entry

    ▶ Patient ID        Yes ◀
      123456789CD
    ▶ will be changed to No  ◀
    ▶ 234567891EF           ◀
    ▶ Is this correct?      ◀
    ▶                       ◀

      >Press Yes or No


          △      △    △    △
    ```
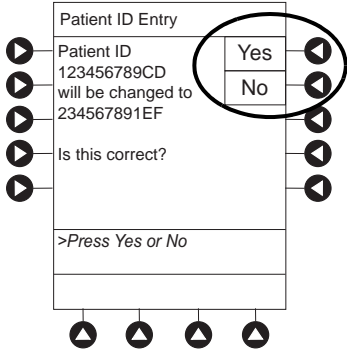
Entering Clinician ID

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

    ```
    System Options      1 of 3

    ▶ Display Contrast       ◀
    ▶ Patient ID             ◀
    ▶ Clinician ID           ◀
    ▶ Power Down All Channels ◀
    ▶ Anesthesia Mode        ◀

      >Select an Option or
      EXIT

         EXIT          PAGE
                       DOWN
          △      △    △    △
    ```
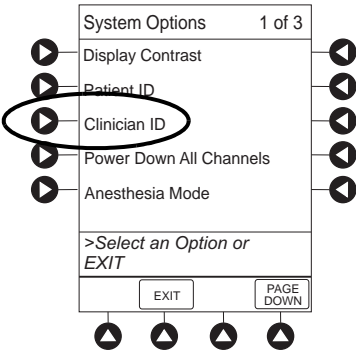
3. Scan or manually enter clinician identifier:

   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.
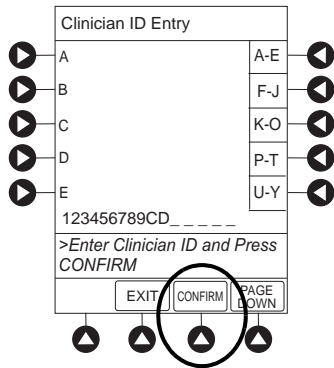
Powering Down All Channels

1. Press the **OPTIONS** key.

2. Press the **Power Down All Channels** soft key.
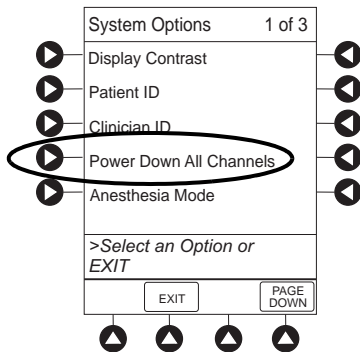
3. Press the **Yes** soft key.

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

    System Options

    Power Down
    All Channels?   Yes
                     No

    >*Press Yes or No*
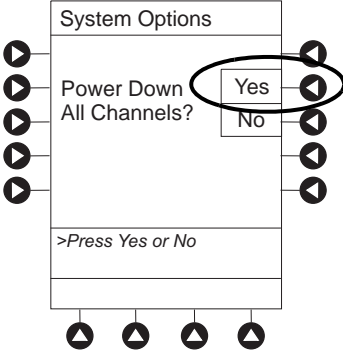
Anesthesia Mode

⚠ **WARNING**

When the system is set up for use in anesthesia mode, it is important to select the profile that corresponds with the care area the patient will be taken to when the anesthesia mode is discontinued. Doing this ensures that the system will be in the correct profile following the use of the anesthesia mode.

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

When anesthesia mode is enabled:

- A channel can be paused indefinitely without an alarm.
- The air-in-line associated with the profile can be set up to 500 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 suite MX drug list defaults to drugs designated by editor software as anesthesia only. All Guardrails suite MX drugs in a profile can be viewed by pressing the **ALL DRUGS** soft key.
- Bolus dose is automatically available for:
  - Guardrails suite MX drugs that have bolus dose limits defined
  - Generic drug calculation setup
- Anesthesia mode, alternating with other required prompts, is displayed in prompt bar of main display.
- Callback audio for paused module is permanently silenced.
- Review of drug calculation setup page is omitted when restoring a stopped drug calculation.
- Clinical advisories are not displayed.

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

Enabling Anesthesia Mode

1. Press the **OPTIONS** key.

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

```
System Options          1 of 3
  ▶— Display Contrast                 ◀
  ▶— Patient ID                       ◀
  ▶— Clinician ID                     ◀
  ▶— Power Down All Channels          ◀
  ▶— Anesthesia Mode                  ◀

>Select an Option or
EXIT
        ┌──────┐      ┌──────┐
        │ EXIT │      │ PAGE │
        └──────┘      │ DOWN │
                      └──────┘
     ▲      ▲      ▲      ▲
```

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

```
System Options
  ▶— Anesthesia Mode      Enable     ◀
  ▶—                      Disable    ◀
  ▶—                                 ◀
                    500
  ▶—                250    Up        ◀
                    175
  ▶— Pump Module    125    Down      ◀
     Air Detection = 75
     250 microliters  50
>Select  an Option or Press
CONFIRM
            ┌─────────┐
            │ CONFIRM │
            └─────────┘
     ▲      ▲      ▲      ▲
```
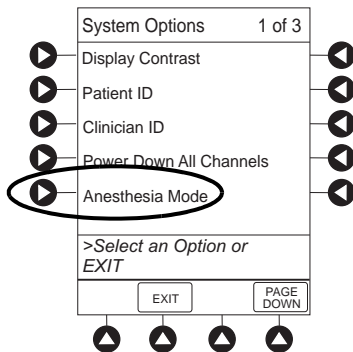
4. Press the **Up** or **Down** soft key to set the pump module air detection to 50, 75, 125, 175, 250, or 500 microliters.

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 the System Options menu.

• Disconnecting from AC power.

• Connecting to AC power.

From System Options Menu

1. Press **OPTIONS** key.

2. Press **Anesthesia Mode** soft key.

3. Press **Disable** soft key.

4. Press **CONFIRM** soft key.

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

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.
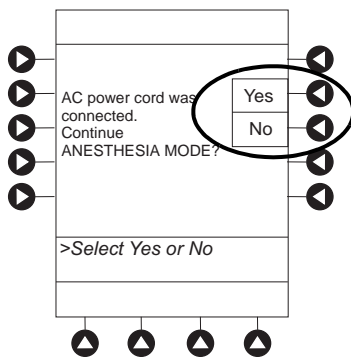
Disconnecting from AC Power

1. Disconnect system from AC.

   • Anesthesia mode is automatically disabled.

   • Hard Guardrails limits are re-established for program changes.

   • All currently running infusions continue.

   • A prompt appears as an alert that anesthesia mode has been discontinued.

2. Press the **CONFIRM** soft key.
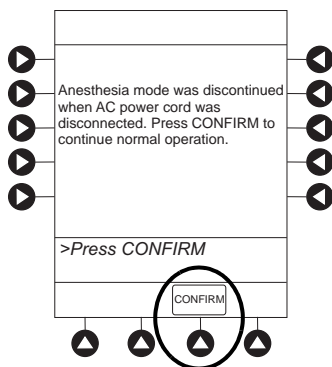
Displaying Battery Runtime

1. Press the **OPTIONS** key.

2. Press the **PAGE DOWN** soft key.

3. Press the **Battery Runtime** soft key.

```
System Options          2 of 3
  Battery Runtime
  System Configurations
  Serial Numbers
  Software Versions
  Time of Day

>Select an Option or
EXIT
PAGE UP   EXIT        PAGE
                      DOWN
```
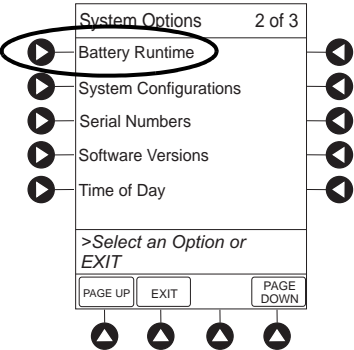
4. To return to main screen, press the **CANCEL** key or the **EXIT** soft key.

```
System Options

  Estimated battery
  runtime at current
  operating parameters


      9.5 hours


>Press CANCEL or EXIT

          EXIT
```
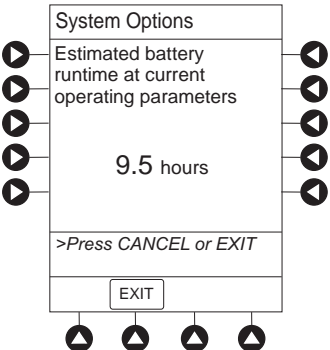
System Configuration

1. Press the **OPTIONS** key.

2. Press the **PAGE DOWN** soft key.

3. Press the **System Configurations** soft key.

```
System Options          2 of 3
  Battery Runtime
  System Configurations
  Serial Numbers
  Software Versions
  Time of Day

>Select an Option or
EXIT
PAGE UP   EXIT        PAGE
                      DOWN
```
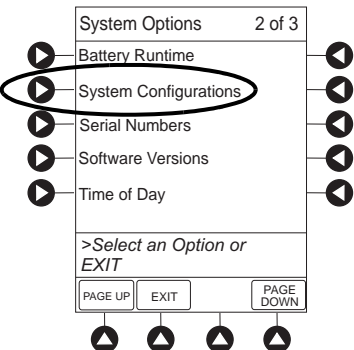
4. Press the **PC Unit** soft key.
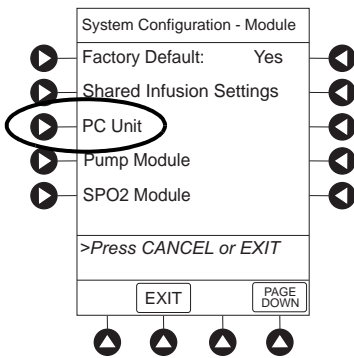
5. To review various system configuration settings, press the **PAGE DOWN** and **PAGE UP** soft keys.[1][2]
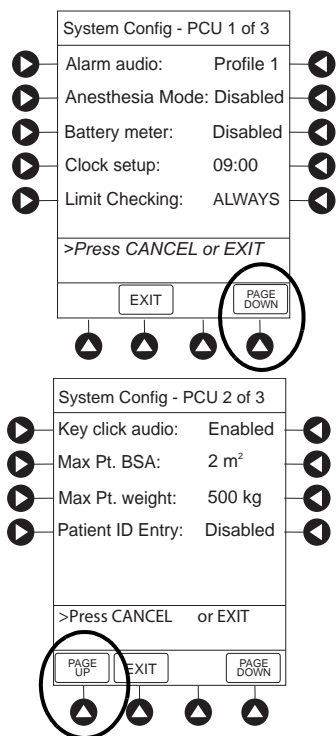
6. To return to main screen, press the **CANCEL** key or **EXIT** soft key.

```
System Config - PCU 3 of 3
PM Reminder:      Disabled
Tamper resist:    Disabled




>Press CANCEL or EXIT
┌──────┐ ┌──────┐
│ PAGE │ │ EXIT │
│  UP  │ │      │
└──────┘ └──────┘
```
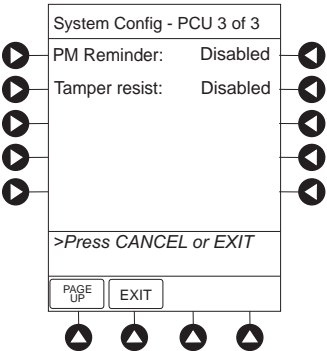
NOTE:
① The **Profiles** option is listed only if it is disabled.
② The **Limit Checking** and **Max Pt. BSA** options are listed only if the **Profiles** option is enabled and a valid data set is loaded.

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.[1]

```
System Options      2 of 3
Battery Runtime
System Configurations
Serial Numbers
Software Versions
Time of Day

>Select an Option or
EXIT
┌────────┐ ┌──────┐   ┌────────┐
│ PAGE UP│ │ EXIT │   │  PAGE  │
│        │ │      │   │  DOWN  │
└────────┘ └──────┘   └────────┘
```

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

```
Serial Number Review
PC Unit:   nnnn-nnnnnnnn
Module A: nnnn-nnnnnnnn
Module B: nnnn-nnnnnnnn
Module C: nnnn-nnnnnnnn
Module D: nnnn-nnnnnnnn

>Press CANCEL or EXIT
          ┌──────┐
          │ EXIT │
          └──────┘
```
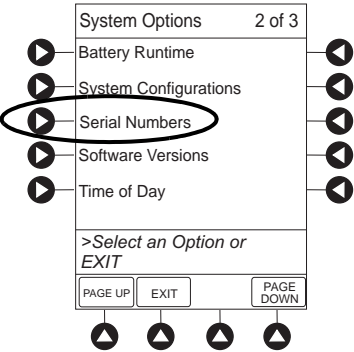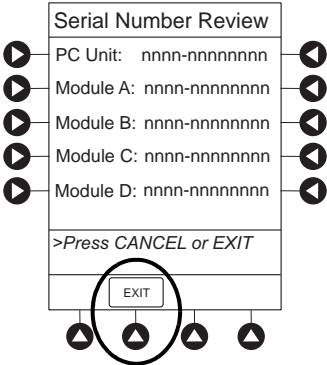
NOTE:
① "nnnn-nnnnnnnn" in the illustrated display represents a model and serial number.

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.
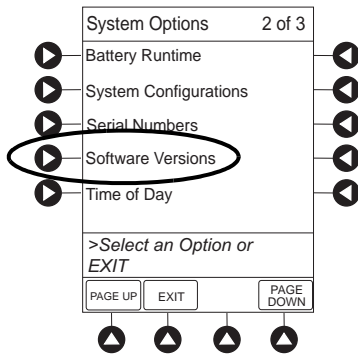
4. Do one of the following:

   • To view software components and configurations on the PCU, press the **View** soft key for the PCU.
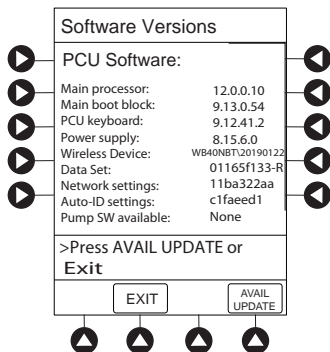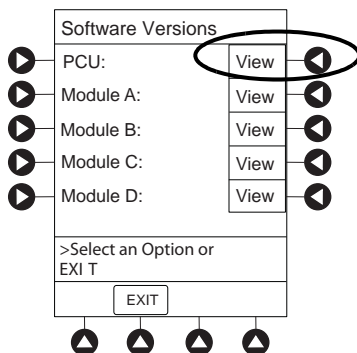
   The PCU Software screen appears.[1]

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

```
┌─────────────────────────────┐
│ Software Versions           │
│                             │
│ PCU:              │ View │  │
│ Module A:         │ View │  │
│ Module B:         │ View │  │
│ Module C:         │ View │  │
│ Module D:         │ View │  │
│                             │
│ >Select an Option or        │
│ EXI T                       │
│        │ EXIT │             │
└─────────────────────────────┘
```

```
┌─────────────────────────────┐
│ Software Versions           │
│                             │
│ Module Software: A          │
│ Main processor:    12.1.0.32 │
│ Main boot block:   12.0.0.18 │
│ Keyboard:            1.1.1.0 │
│ Safety:              1.1.1.0 │
│                             │
│ >Press CANCEL or EXIT       │
│        │ EXIT │             │
└─────────────────────────────┘
```
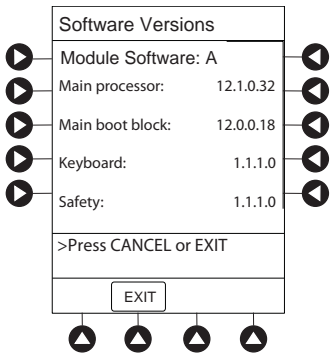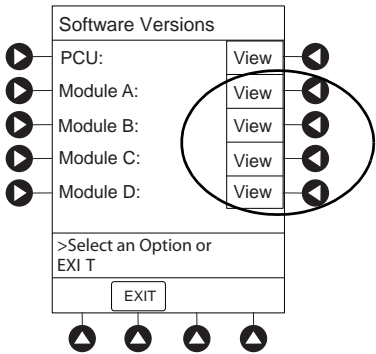
The Module Software screen appears.[1]

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

NOTE:

[1] The illustrations shown are examples and may not reflect the software versions or configuration IDs on your device.

Setting Time of Day

1. Press the **OPTIONS** key.

2. Press the **PAGE DOWN** soft key.

3. Press the **Time Of Day** soft key.

```
┌─────────────────────────────┐
│ System Options       2 of 3 │
│ Battery Runtime             │
│ System Configurations       │
│ Serial Numbers              │
│ Software Versions           │
│ Time of Day                 │
│                             │
│ >Select an Option or        │
│ EXIT                        │
│ │PAGE UP│ │EXIT│ │PAGE DOWN│ │
└─────────────────────────────┘
```
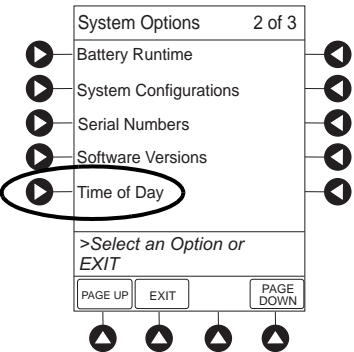
4.   If time is correct, press the **CONFIRM** soft key.[1]

or

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

```
┌─────────────────────────┐
│ System Options          │
│                         │
│ Time of Day             │
│   Current time: ┌──────┐│
│       09:00     │Change││
│                 │ Time ││
│                 └──────┘│
│                         │
│                         │
│                         │
│ >CONFIRM Time-of-Day    │
│                         │
│  ┌─────┐ ┌───────┐      │
│  │EXIT │ │CONFIRM│      │
│  └─────┘ └───────┘      │
└─────────────────────────┘
```
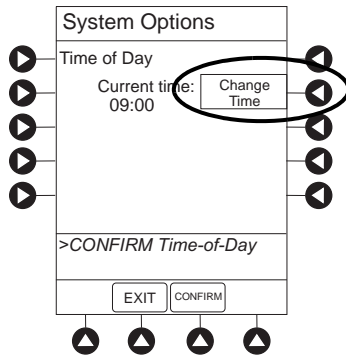
5.   Enter the current time of day.

```
┌─────────────────────────┐
│ System Options          │
│                         │
│ Time of Day             │
│   Current time: ┌──────┐│
│        __:__    │Change││
│                 │ Time ││
│                 └──────┘│
│                         │
│                         │
│                         │
│ >Enter Current Time     │
│                         │
│  ┌─────┐ ┌───────┐      │
│  │EXIT │ │CONFIRM│      │
│  └─────┘ └───────┘      │
└─────────────────────────┘
```

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

```
┌─────────────────────────┐
│ System Options          │
│                         │
│ Time of Day             │
│   Current time: ┌──────┐│
│       14:30     │Change││
│                 │ Time ││
│                 └──────┘│
│                         │
│                         │
│                         │
│ >Press CONFIRM          │
│                         │
│  ┌─────┐ ┌───────┐      │
│  │EXIT │ │CONFIRM│      │
│  └─────┘ └───────┘      │
└─────────────────────────┘
```
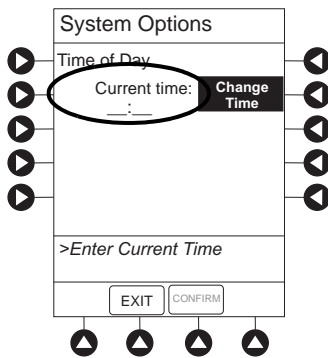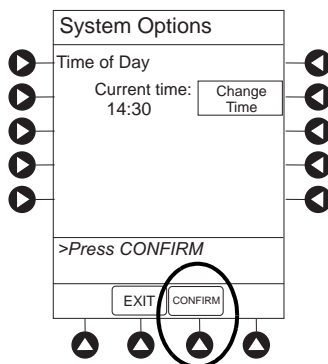
NOTE:
[1]   The format is a 24-hour clock (military time).

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.

```
┌─────────────────────────────┐
│  System Options      3 of 3  │
│ ▶ Network Status          ◀  │
│ ▶ Wireless Connection     ◀  │
│ ▶ Data Set Status         ◀  │
│ ▶ Maintenance Due   Yes   ◀  │
│ ▶                         ◀  │
│                              │
│ >Select an Option or         │
│ EXIT                         │
│ ┌────────┐ ┌──────┐          │
│ │PAGE UP │ │ EXIT │          │
│ └────────┘ └──────┘          │
└─────────────────────────────┘
     ▲     ▲     ▲     ▲
```
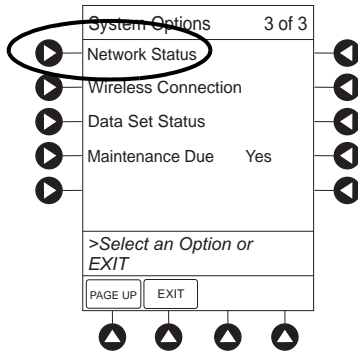
4. Enter the password (refer to *BD Alaris System Maintenance Software User Manual*) and press the **CONFIRM** soft key.

```
┌─────────────────────────────┐
│  System Options              │
│ ▶                         ◀  │
│ ▶ Viewing Network Status  ◀  │
│ ▶ is only to be used by   ◀  │
│ ▶ qualified personnel.    ◀  │
│ ▶      * _ _ _ _          ◀  │
│                              │
│ >Enter Password or           │
│ EXIT                         │
│    ┌──────┐ ┌────────┐       │
│    │ EXIT │ │CONFIRM │       │
│    └──────┘ └────────┘       │
└─────────────────────────────┘
     ▲     ▲     ▲     ▲
```
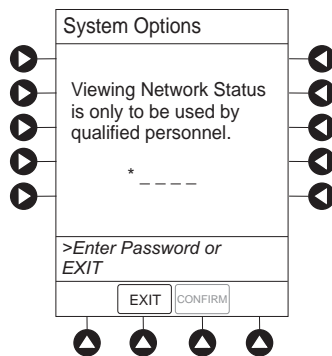
- Information based on a wireless status of **DISABLED**, **DISASSOCIATED**, **CONFIGURING**, **ASSOCIATING**, **ASSOCIATED**, or **AUTHENTICATING** is displayed.

- 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.
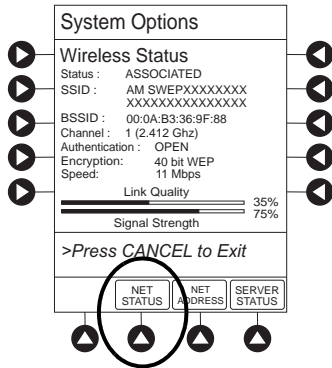
6. To view network address information, press the **NET ADDRESS** soft key.
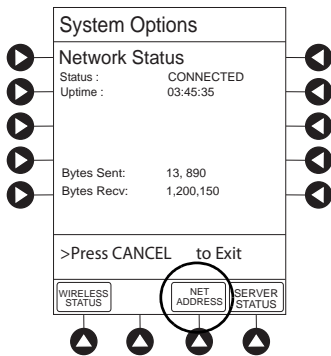
- The **MAC Address** of the wireless RF card attached to the PCU is displayed.

- 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.
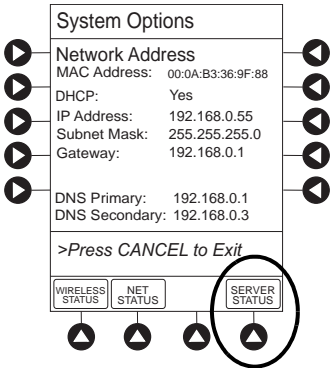
- Information based on a status of **DISABLED**, **DISCONNECTED**, **CONNECTING**, or **CONNECTED** is displayed.
- If the status is **CONNECTED**, the PCU is connected to the systems manager and the following information is displayed:
  - **Uptime**—length of time PCU has been connected.
  - **Server 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.
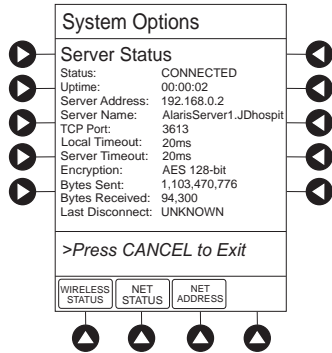
Wireless Connection

1. Press the **OPTIONS key.**

2. Press the **PAGE DOWN** soft key two times.

3. Press the **Wireless Connection** soft key.

```
System Options        3 of 3
  Network Status
  Wireless Connection
  Data Set Status
  Maintenance Due    Yes

 >Select an Option or
 EXIT
 PAGE UP   EXIT
```
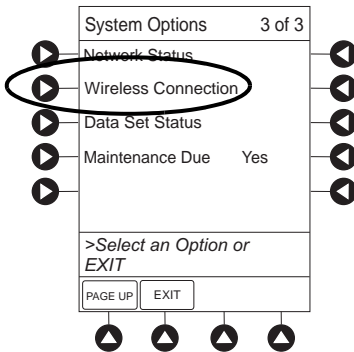
If the **Wireless Connection** soft key is inactive (grayed out), the PCU has the following configuration:

- 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™ PC Unit Model 8015 and Alaris™ PC Unit 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.

```
System Options

 Wireless          Enable
 Connection        Disable


 >Press ENABLE or
 DISABLE
```
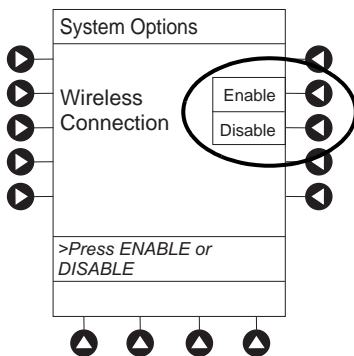
Activating a New Data Set:

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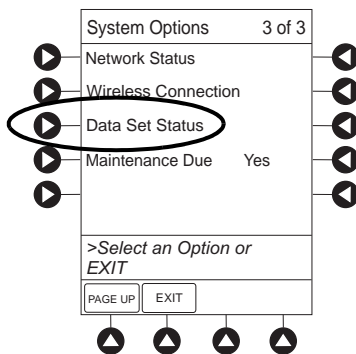
A status of **Current** or **Pending** is displayed. A **Pending** status also notes that the data set is **Transferring** or **Not Activated**.
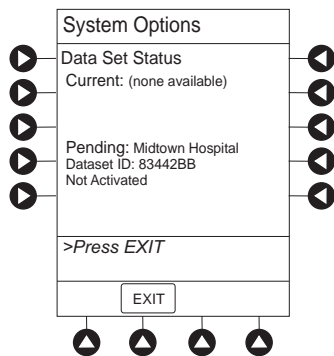
Viewing Maintenance Due

1. Press the **OPTIONS** key.

2. Press the **PAGE DOWN** soft key two times.

3. Press the **Maintenance Due** soft key.

```
System Options        3 of 3
Network Status
Wireless Connection
Data Set Status
Maintenance Due    Yes

>Select an Option or
EXIT
PAGE UP   EXIT
```

4. To return to the main screen, press the **EXIT** soft key.[1]

```
System Options
Maintenance Due Dates
PC Unit:      YYYY-MM-DD
Module A:    YYYY-MM-DD
Module B:    YYYY-MM-DD
Module C:    YYYY-MM-DD
Module D:    YYYY-MM-DD

>Press CANCEL or EXIT
        EXIT          PAGE
                      DOWN
```

```
System Options
Maintenance Due Dates
Bar Code:    YYYY-MM-DD
Bar Code:    YYYY-MM-DD
(Hand held)

>Press CANCEL or EXIT
PAGE UP    EXIT
```
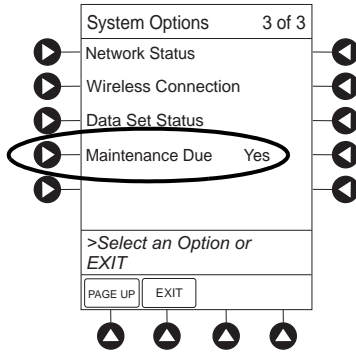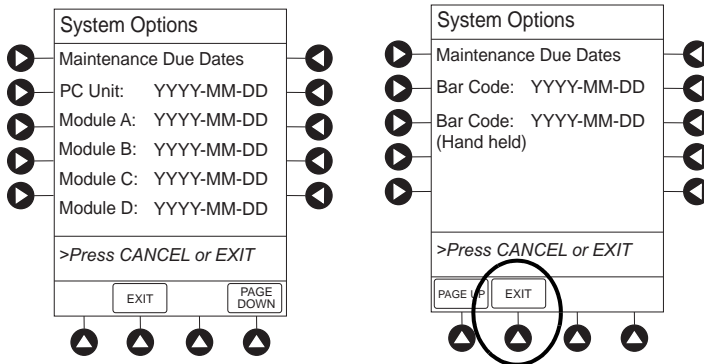
NOTE:

[1] The **PAGE DOWN** soft key appears only if an auto-ID module is attached.

General Information

Warnings and Cautions

General

⚠️ **WARNINGS**

- **Explosion risk if used in the presence of flammable anesthetic agents or gases.**
- **Assess patient's condition before silencing an alarm. Do not silence alarm if patient safety might be compromised.**
- **Before each use, verify that the alarm limits are appropriate for the patient.**
- **The 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.**
- **When properly secured/snapped, the release latch provides a very secure connection between modules. If not properly latched, a module can be dislodged during operation.**
- **Disconnect from main (AC) and battery power when performing maintenance.**
- **Use only CareFusion batteries. The use of third party batteries could affect the safety and efficacy of BD Alaris and Alaris products.**
- **The battery cannot be repaired and should not be opened.**
- **The battery is intended as a backup system. Leave the power cord connected to a hospital grade AC power source whenever available.**
- **Battery replacement should be performed by qualified service personnel while the instrument is not in use.**
- **Electrical shock hazard. Do not open case. Refer to qualified service personnel.**
- **Due to the intermittent nature of a wireless environment, some data can be lost if a connection cannot be established or is lost. The systems manager and wireless network card are designed to minimize these incidents but cannot eliminate them.**
- **The system is not intended to replace supervision by medical personnel. The user must become thoroughly familiar with the system features, operation and accessories prior to use.**
- **Do not modify this equipment without authorization of the manufacturer. Authorization should be obtained through written communication from the manufacturer.**

⚠   **CAUTIONS**

- Always use a grounded three-wire receptacle. Where the integrity of the protective earth grounding system is in doubt, operate on internal battery.
- **Hyperbaric Chamber Operation:**
    - The system is not certified for use in oxygen-enriched environments.
    - The system, with the exclusion of the $EtCO_2$ module, has been verified to operate with no malfunction alarms due to the hyperbaric chamber environment or unintentional key presses when used in a hyperbaric chamber.
    - The healthcare facility's hyperbaric safety director is responsible for all equipment used in the hyperbaric chamber environment.
- Should an instrument or accessory be **dropped or severely jarred**, it should be immediately taken out of use and inspected by qualified service personnel to ensure its proper function prior to reuse.
- If an instrument appears **damaged**, contact CareFusion for authorization to return it for repair.

Electromagnetic Compatibility

⚠️ **WARNINGS**

Do not use the system near magnetic resonance imaging (MRI), including Stereotaxis technology.

Do not use the system near therapeutic radiation equipment, such as linear accelerators.

Use of any accessory, transducer or cable other than those specified can result in increased emissions or decreased system immunity and result in improper operation.

Do not use an RF device within 7.8 inches/20 cm of the radio card on the PCU. FCC approval of the radio card excludes co-location with any other transmitter.

Per FCC regulations, maintain a distance of at least 7.8 inches/20 cm between the radio card on the 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 Alaris System, including cables. Otherwise, degradation of the performance of this equipment could result.

The Alaris System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, monitor the Alaris System to verify that it is operating normally in that setup.

⚠️ **CAUTIONS**

- **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 Alaris System, including cables. Otherwise, degradation of the performance of this equipment could result.

- **Interconnected data communications systems** must be certified to IEC 60950 (data processing equipment) or IEC 60601–1 (electromedical equipment).

- The system is intended for use by healthcare professionals only. This is a CISPR 11 Class B Group 1 medical system. This 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.

- 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 *Compliance* on page *354*).

Features and Displays

Features and Definitions

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

Feature	Definition
Clinician ID	An optional alphanumeric 16-character clinician identifier that can be entered and displayed.
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, instrument configurations, therapies, and channel labels.
Guardrails Suite MX	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: • Instrument configuration settings. • A drug library, which includes drug names, standard concentrations, dosing units, duration limits, and optional associated clinical advisories for both continuous and bolus dose infusion. • An IV fluid library, an optional library consisting of IV fluids (for example, TPN) and limits around rate of delivery. • A channel label library with text (alphanumeric) labels, which allows identification (on modules) that can be used to indicate route of delivery (for example, epidural). Profile settings are established by the facility's own multi-disciplinary team prior to system implementation. Profile parameters are used to create a data set, which is then transferred to the 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 a SpO_2 or $EtCO_2$ 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.

Operating Features, Controls, Indicators

IUI Connector, Left (not visible)

IUI Connector, Right

Main Display: When a key is not pressed during a 2 minute (± 10 sec) interval, the display dims. Returns to normal brightness when any key is pressed or at initiation of alarm or advisory.

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

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

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

Soft Keys (see above)

Battery Indicator: When illuminated, indicates system is operating on battery power.

Power Indicator: When illuminated, indicates system is connected to an AC power source.

Wireless Network Indicator: When illuminated, indicates the system is connected to systems manager. When blinking, indicates data transfer.

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

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

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

Enter Key: When pressed, confirms current parameter entry.

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

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

Numeric Keypad

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

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

IUI Connector, Right

IUI Connector, Left

Power Cord Strap

Rear Cover

Primary Audio Speaker

Connector Plug over RJ45
Communication Data Port

Wireless Antenna/
Network Card

Tamper Resist Switch

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

IUI Connector, Right

IUI Connector, Left

Power Cord Strap

Compact Flash Wireless Network Card

Primary Audio Speaker

Connector Plug over RJ45 Communication Data Port

Tamper Resist Switch
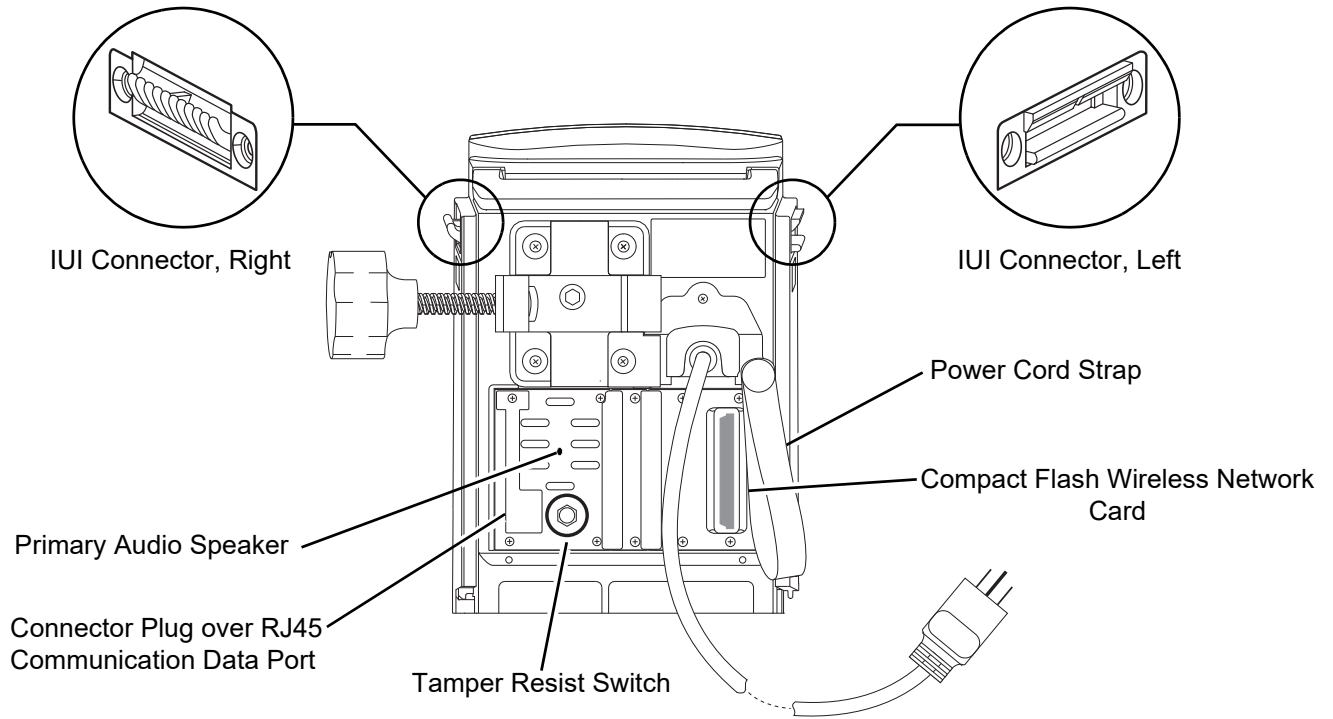
Alaris^TM PCU Rear Panel - Compact Flash b/g or a/b/g Wireless Card

Quick attach
pole clamp
knob

Enhanced
thread design
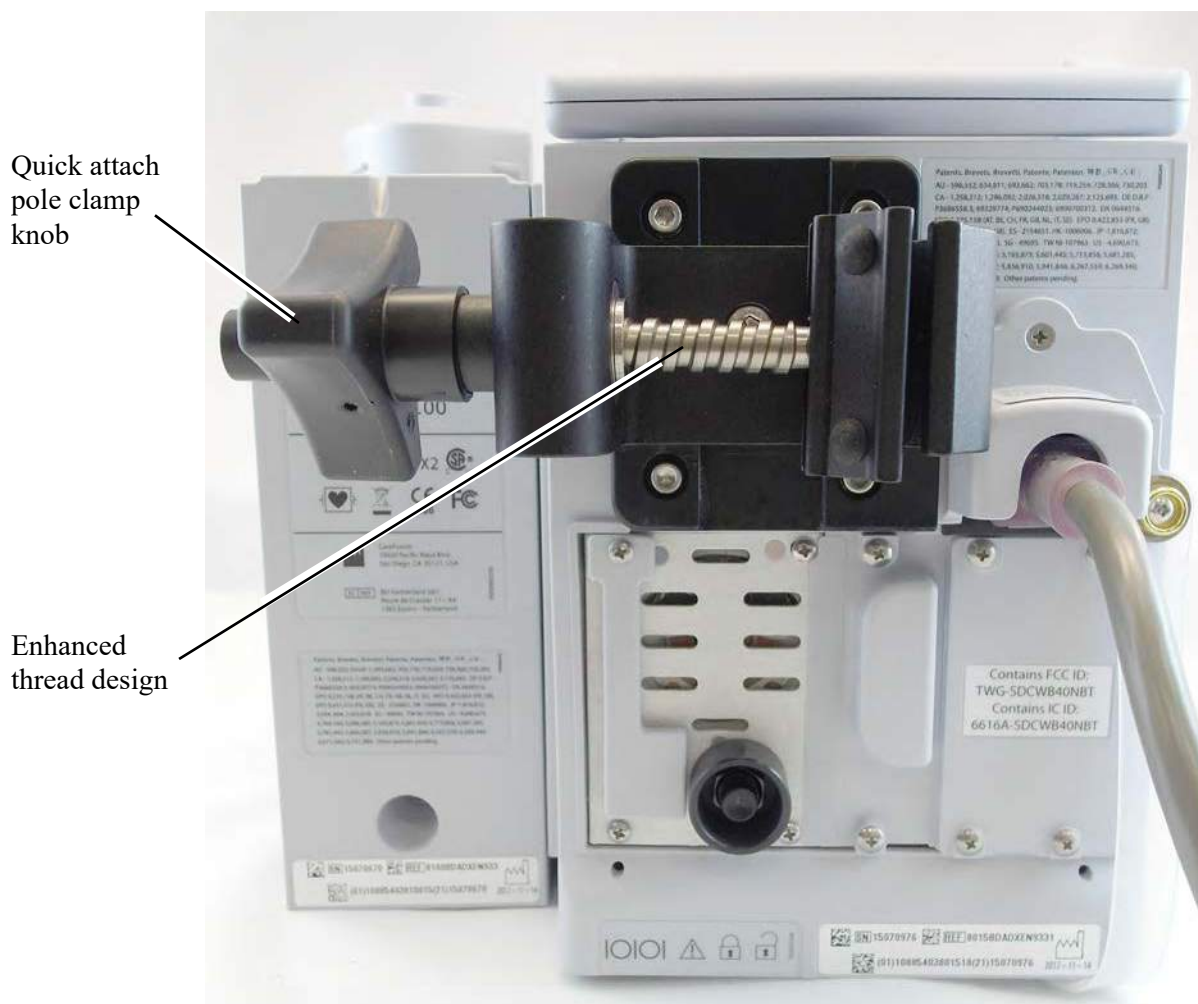
BD Alaris™ PCU Rear Panel - Pole Clamp

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 *325* for additional color categories.

Main Display

Title Bar

Midtown Hospital
Adult ICU

Module Status

- A solid letter display indicates module is operating.

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

A VTBI = 250.0 mL
B
C
D

Soft Keys

VOLUME INFUSED   AUDIO ADJUST
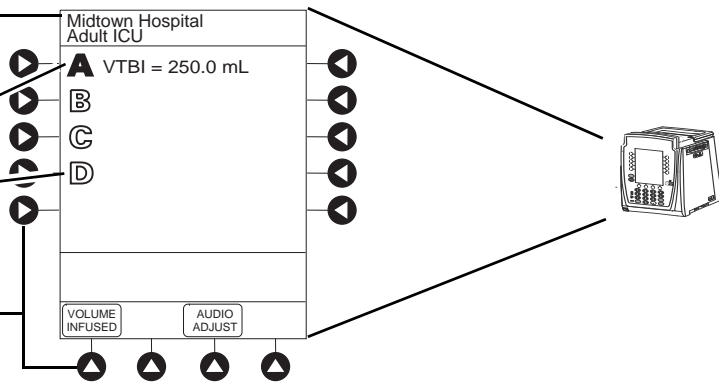
Module Selected Indicator

A Infusion Setup

"Inactive" Soft Key

RATE   40 mL/h

Non-highlighted indicates a non-selected soft key.

VTBI   _250 mL

"Active" Soft Key

Highlighted indicates a selected soft key.

>*Press START*

Prompt Bar

PAUSE   SECOND-ARY   START

Look here for user prompts.
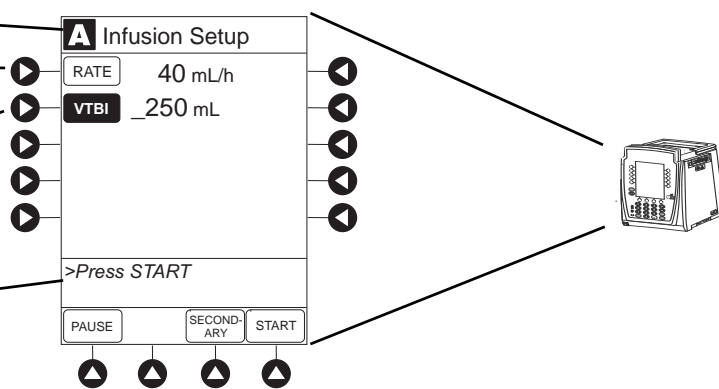
System Configuration Settings

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

With the profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best practice data set must be uploaded to 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

Specifications

Battery Operation:	Battery run time is a function of the number of modules attached and module activity. With a new, fully charged battery, the system operates as follows before a "BATTERY DISCHARGED" message occurs: • 1 hour with four pump modules 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 • 4.5 hours with one active SpO_2 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, SpO_2 or $EtCO_2$ module is detached and replaced with another PCA, SpO_2, 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 - 4560 mmHg (70 - 608 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 3
BD Alaris™ Pump Module Model 8100, Alaris™ Pump Module Model 8100, and Alaris™ Syringe Module Model 8110

This chapter contains the following topics:

Getting started

Introduction

⚠️ **WARNING**

Read all instructions, for both the infusion modules and PCU, before using the system.

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™ administration set instructions
- Drug product labeling
- PCU chapter of this manual (see *Getting started* on page *62*)
- *Alaris™ Pump Module Set Compatibility Card*
- *Alaris™ Syringe Module Set Compatibility Card*
- *BD Alaris™ PC Unit Model 8015, Alaris™ PC Unit Model 8015, BD Alaris™ Pump Module Model 8100, and Alaris™ Pump Module Model 8100 Technical Service Manual*
- *Syringe Module Model 8110 and 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

Essential Performance

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

The $EtCO_2$ and SpO_2 modules monitor and alarm when a patient physiological condition is out of range.

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

Administration Sets/Syringes: See *Administration Set/Syringe Information* on page *173* for specific administration set and syringe information.

Alarms and Alerts: See *Alarms and Alerts* on page *325* (Appendix A) for module-specific alarms and alerts.

Contraindications: None known.

Electromagnetic Environment: See *Regulations and Standards* on page *354* and *Compliance* on page *354* for electromagnetic environmental information.

The BD Alaris pump module has the visual characteristics shown in the following figure.

BD Alaris Pump Module

The Alaris pump module has the visual characteristics shown in the following figure.

Alaris Pump Module

NOTE:
In this document, pump module refers to both BD Alaris pump module and Alaris pump module.

Preparing an Administration Set (Pump Module)

For instructions on how to go from checking in a pump module to preparing it for an infusion setup, see *General Setup and Operation* on page *165*.

<table>
<tr><td>⚠</td><td>**WARNING**</td></tr>
</table>

Administration Sets:

*   **Use only BD Alaris™ Pump Infusion administration sets. The use of any other set can cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard. For a list of compatible administration sets, please refer to the *Alaris^TM Pump Module Set Compatibility Card*.**

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

Priming

1. Prepare primary solution container in accordance with manufacturer's user manual.

2. Open administration set package, remove set, and close roller clamp. (Refer to set's user manual.)

3. Insert administration set spike into prepared fluid container, following accepted hospital/facility procedure, and hang container 20 inches above pump module.

4. Allow solutions to warm to room temperature, if possible. (When infusing a chilled solution, air bubbles may form as cold solutions begin to warm).

5. Fill drip chamber to ⅔ full. Hang drip chamber vertically.

6. If container requires venting, open vent cap on administration set spike.

7. Priming tubing should be done slowly to help prevent turbulence. Slowly open roller clamp to prime tubing and clear air from injection sites and tubing fitments.

8. When priming is complete, close roller clamp.

9. Verify no fluid flow.

Loading

1. Pause the channel before replacing a new fluid container to avoid air from entering the IV tubing.

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

Align with Patient's level
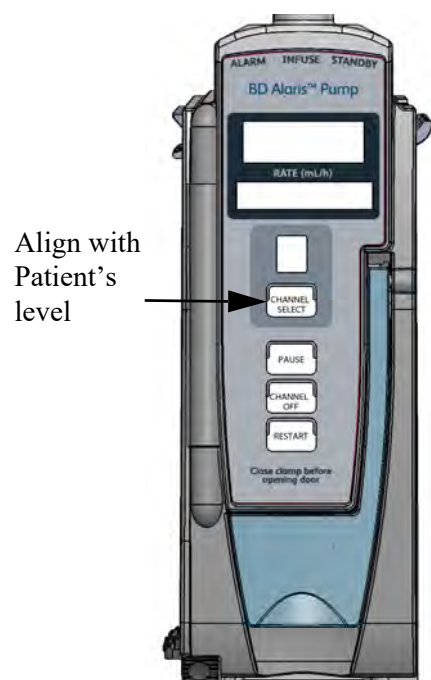
⚠️ **CAUTION**

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

- Use compatible components which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times.

3. If a new set is being loaded, prime the set. See *Adjust the flow rate using set's roller clamp.Prime* on page *79* for more information.

⚠ **CAUTION**

- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (for example, 50 - 200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h).
- Failure to follow proper administration set loading instructions might lead to an instrument malfunction.
- Before operating the instrument, verify that the administration set is free from kinks and correctly installed.
- Insert upper fitment before installing safety clamp[①] fitment.
- When reloading an administration set, leave the safety clamp[①] fitment in the closed position (see *Safety Clamp Fitment (Pump Module)* on page *174*).

4. Open the pump module door.

5. Load the administration set, as follows:

    a. Hold upper fitment above fitment recess and lower into recess. The upper fitment fits loosely in the recess.

    b. Ensure that tubing is not twisted or stretched.
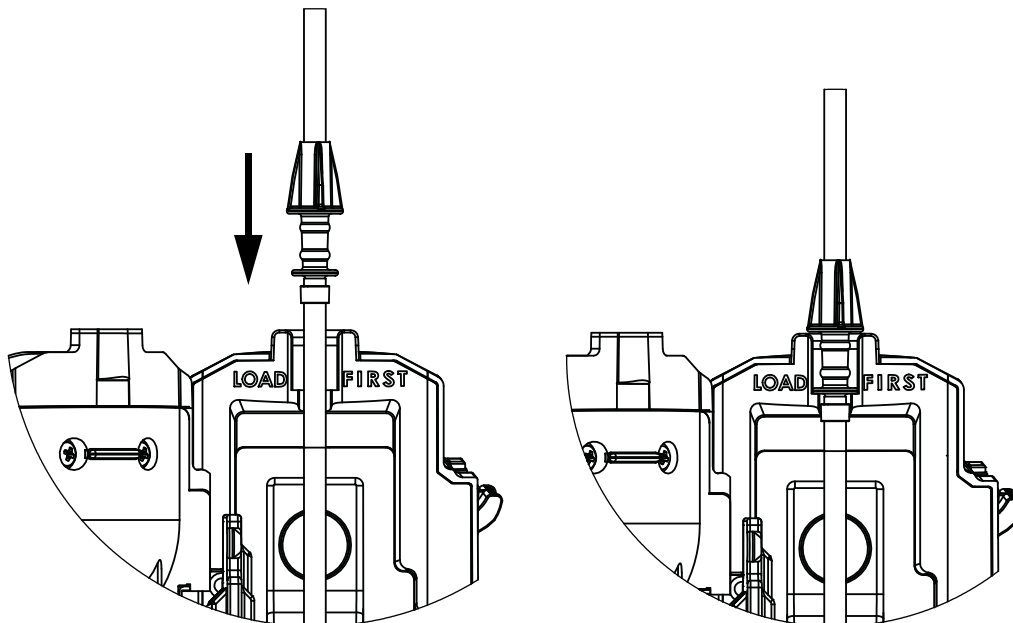
    c. Press the safety clamp fitment into recess below mechanism.

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

Administration Set

LOAD FIRST

Upper Pressure Sensor

Lower Pressure Sensor

Tubing Guide Arm (BD Alaris Pump module only)

Air-in-line Detector
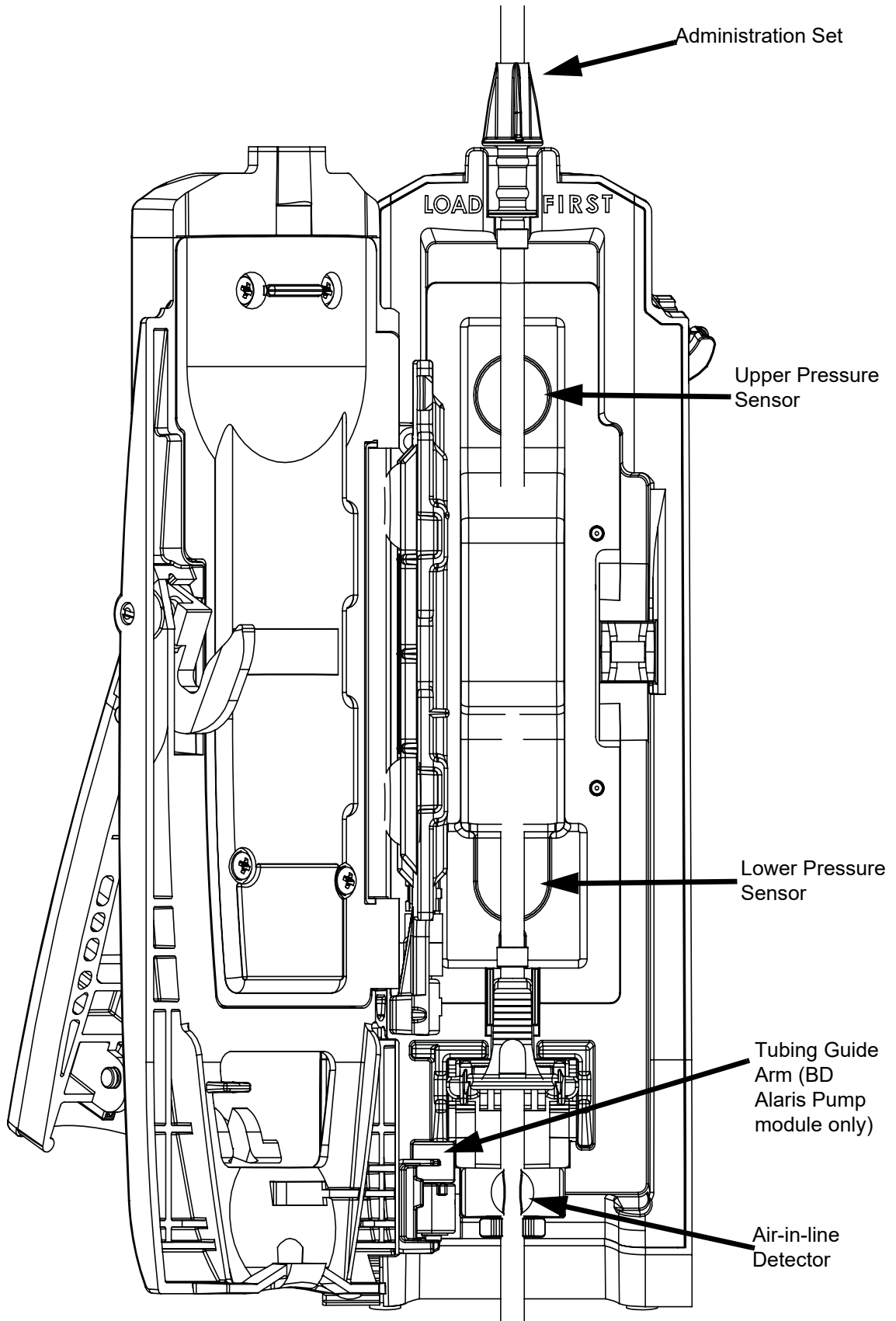
⚠️ **CAUTION**

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

Safety Clamp Fitment[1]

AIL Detector

Push tubing toward back of AIL Detector.
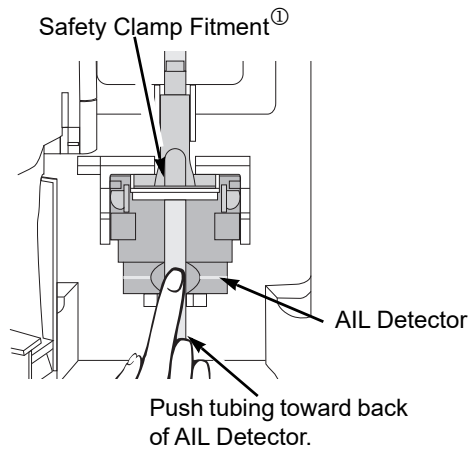
6. Close the door and latch, as follows:

   a. Close the door and hold it in a closed position by grasping both the door and the instrument case with one hand.

   b. Gently lower the latch.

     The safety clamp device is automatically disengaged.[1]
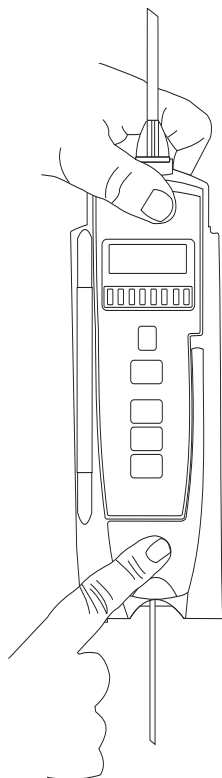
⚠ **WARNING**

- **Do not touch the administration set while closing the door. Failure to follow this instruction can result in infusion rate inaccuracy.**
- **Ensure tubing placement is over pressure sensors.**
- **Ensure the upper fitment is not elevated above the receptacle on the pump. This could be caused by maintaining traction on the set (or stretching the set) while closing and latching the door. If the set is loaded in this manner, infusion inaccuracies may occur. See example and pictures.**
- **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.**

⚠️ **WARNING**

> **For BD Alaris pump module ensure that the tubing guide arm is not missing and that it opens when the pump module door opens. A tubing guide arm failure can result in a nuisance air-in-line alarm. If there is a failure, send the pump module to CareFusion for repair.**

7. Open the roller clamp.

8. Verify that no fluid is flowing through the drip chamber.

Removing

1. Close the roller clamp.

2. Open the pump module door.

   The set's safety clamp fitment automatically closes to prevent accidental free-flow.
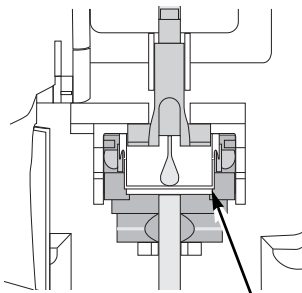
White Slide Clamp
(shown in closed position)

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 Syringe and Administration Set (Syringe Module)

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

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

⚠️ **WARNING**

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

⚠ **CAUTION**

- Use compatible components which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (for example,< 5 mL/h, and especially flow rates < 0.5 mL/h). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times.

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

- Use the **PRIME SET WITH SYRINGE** channel option on the syringe module to speed up the engagement of the module's mechanical components and decrease the syringe's internal friction (see *Prime—Using Options Menu* on page *79*).

- If using a pre-run infusion practice (to allow for medication equilibration prior to connection to the patient), ensure that the distal end of the administration set is level with or higher than the device.

- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (for example, 50 - 200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (for example, < 5 mL/h and especially flow rates < 0.5 mL/h).

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

For instructions on how to go from checking in a syringe module to preparing it for an infusion setup, including how to change a syringe during infusion, see *General Setup and Operation* on page *165*.

1. Prepare syringe (for a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page *175*) in accordance with manufacturer's user manual.

2. Prepare administration set (for a list of compatible Alaris syringe module sets, refer to *Alaris™ Syringe Module Set Compatibility Card*) in accordance with manufacturer's user manual.

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

NOTE:
① For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page *175.* For a list of compatible sets, refer to the *Alaris™ Syringe Module Set Compatibility Card.*

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

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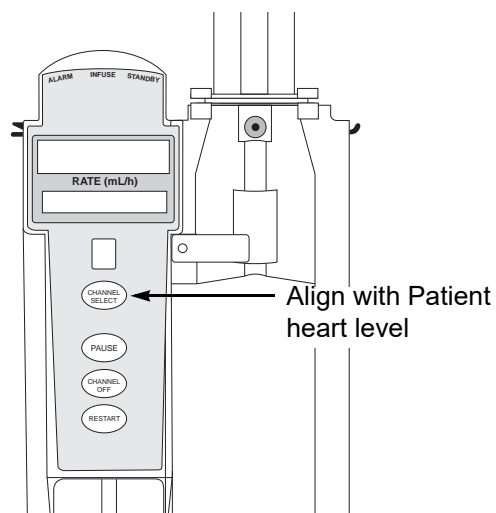
1. Ensure that the instrument is as close to level of patient's heart as possible—patient's heart level should be in line with **CHANNEL SELECT** key.

   • Keep the system level with the patient's heart to maintain positive pressure.

   • If using a pre-run infusion practice (to allow for medication equilibration prior to connection to the patient), ensure that the distal end of the administration set is level with or higher than the device.

⚠️ **WARNING**

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

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.

Syringe Barrel Clamp Open
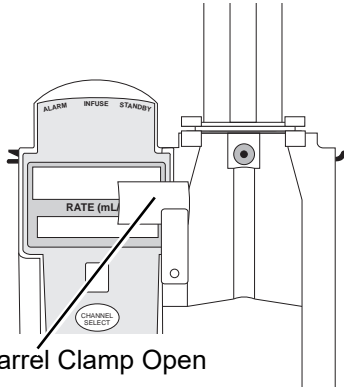
3. Raise the drive head to its fully extended position.

    a. Twist gripper control clockwise and hold in position.[1]

    b. While holding gripper control in open position, raise the drive head to full extension.

    c. Gently release gripper control.

Drive Head Fully Extended

Gripper Control/Drive Head Release in Open Position

Plunger Grippers Open
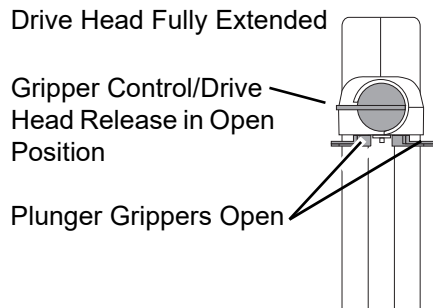
4. Insert syringe (from front of instrument) by sliding flat edge of syringe barrel flange between barrel flange grippers.

⚠ **WARNING**

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

⚠ **CAUTION**

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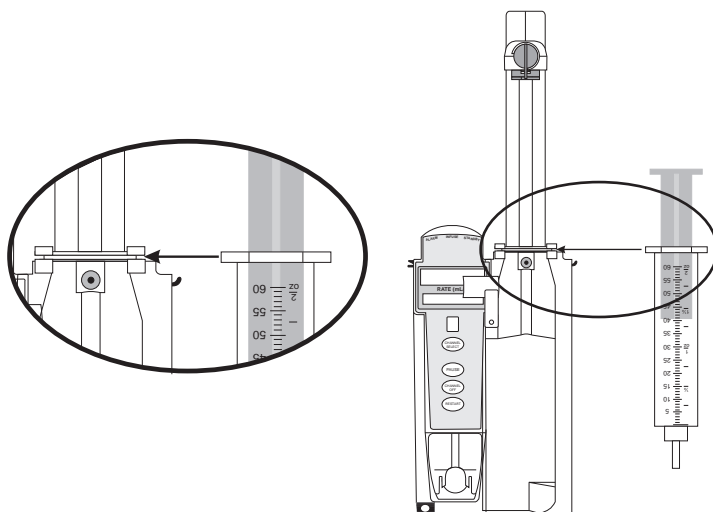
5. Lock syringe in place.

   a. Pull syringe barrel clamp out and hold.

   b. Rotate clamp to right (clockwise or counter-clockwise) until it lines up with syringe.

   c. Gently release clamp against syringe.

⚠ **WARNING**

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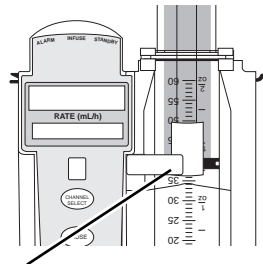
Syringe Barrel Clamp Closed

6. Lower the drive head and lock plunger in place with plunger grippers.

   a. Twist gripper control clockwise and hold in position.[①]

   b. While holding gripper control in open position, gently lower 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.

⚠ **CAUTION**

• To **avoid an occlusion** when loading a smaller size syringe, use extra care to close off administration set tubing and gently lower drive head against syringe plunger.

• For **smaller syringes** (such as 1, 3, or 5 mL), stabilize the syringe plunger with thumb and index finger while carefully lowering the drive head. Ensure that the syringe plunger head makes contact with the small black sensor, located on the bottom of the drive head (between the plunger grippers).

Gripper Control in Closed Position

Drive Head Flush with Plunger Flange

Plunger Grippers Closed
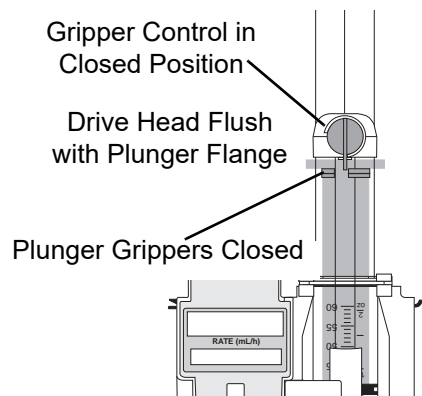
7. Insert pressure sensing disc (if used), as follows:[2]

⚠️ **WARNING**

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

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

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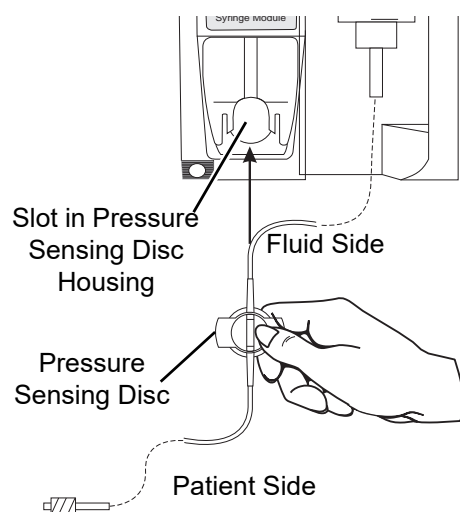
c. Apply firm upward pressure on pressure sensing disc (not tubing) until disc snaps into place.

Pressure Sensing Disc
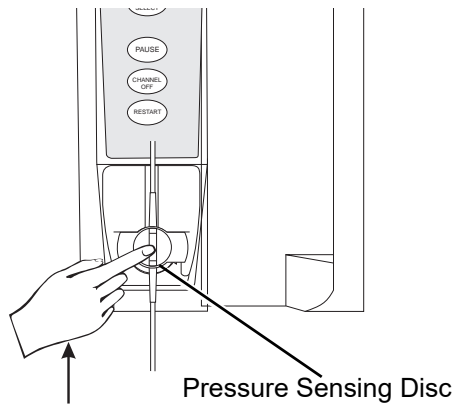
⚠ **WARNING**

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

NOTE:
① The gripper control is spring loaded. When twisted to the open position and then released, it (and the plunger grippers) returns to the closed position.
② The following syringe module features are available only with extension sets fitted with a pressure sensing disc:

- Auto Pressure

- Back Off (upon occlusion)

- Customized Pressure Alarm Settings (see *Occlusion Pressure* on page *178* for the feature definition)

- Dynamic Pressure Display

- Numeric Pressure Display

- Fast Start
(See *General Information* on page *168* and *Features and Displays* on page *176* for definitions.)

Prime—Using Options Menu

The priming option can be enabled at the time 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.

⚠️ **WARNING**

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

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

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

⚠️ **CAUTION**

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

Priming Administration Set With Pressure Sensing Disc

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

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

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

⚠️ **CAUTION**

The pressure sensing disc, if left installed during priming, can trap air that might not be completely expelled. **To ensure that entrapped air is eliminated**, it is recommended that the pressure sensing disc be removed prior to priming and the membrane gently massaged with a finger while priming. After priming is completed, reinstall the pressure sensing disc.
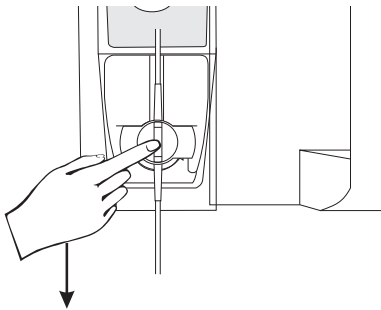
3. Press the **OPTIONS** key.
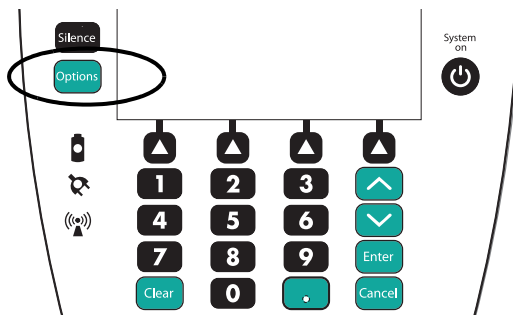
4. Press the **Prime Set with Syringe** soft key.
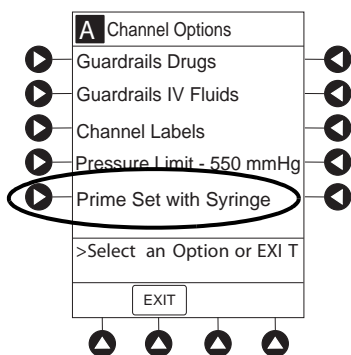
If pressure sensing disc was not removed prior to pressing **Prime Set with Syringe** soft key, a pressure sensing disc removal prompt is displayed.
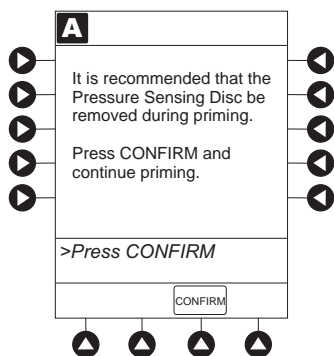
5. Invert pressure sensing disc so that patient side is up.
6. Hold pressure sensing disc between two fingers.

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

```
┌─────────────────────────┐
│ ■A                      │
│ ● Prime Set with Syringe ◄
│ ● CAUTION: Do      ○     ◄
│ ● not prime with         ◄
│ ● disposable set   △     
│ ● connected to           ◄
│   patient!         ◐     ◄
│ ● Prime Volume     ●     ◄
│      0 mL               │
│ >Press and Hold PRIME   │
│                         │
│ [PRIME] [EXIT]          │
│   ▲    ▲    ▲    ▲       │
└─────────────────────────┘
```
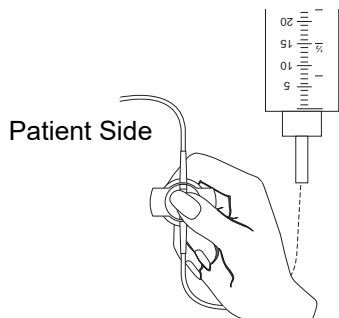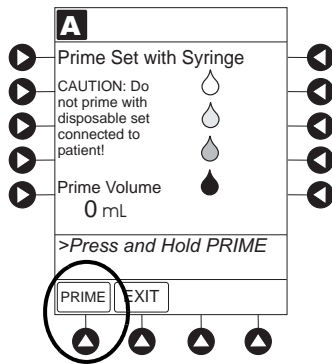
8. Gently massage pressure sensing disc to ensure that all air is expelled. The disc must remain inverted only until the air is expelled. Continue to gently massage disc throughout priming to ensure that it does not become under- or over-filled.

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 *252*)

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.

```
┌─────────────────────────┐
│ ■A                      │
│ ● Prime Set with Syringe ◄
│ ● CAUTION: Do      ○     ◄
│ ● not prime with         ◄
│ ● disposable set   △     ◄
│ ● connected to           
│   patient!         ◐     ◄
│ ● Prime Volume     ●     ◄
│      2 mL               │
│ >Press and Hold PRIME   │
│                         │
│ [PRIME] [EXIT]          │
│   ▲    ▲    ▲    ▲       │
└─────────────────────────┘
```
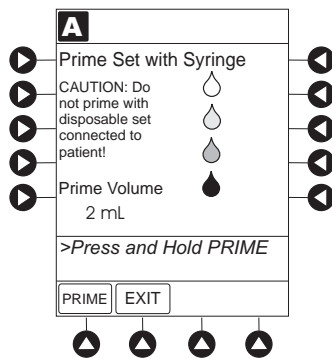
11. Reinstall pressure sensing disc, as follows:

    a. Orient pressure sensing disc, as follows:

        ◦   fluid side up (patient side down)

        ◦   cavity forward (membrane toward instrument)

b. Gently slide pressure sensing disc up into slot in pressure sensing disc housing.
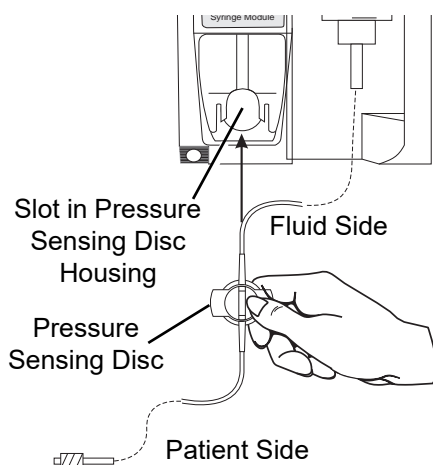
c. Apply firm upward pressure on pressure sensing disc (not tubing) until disc snaps into place.
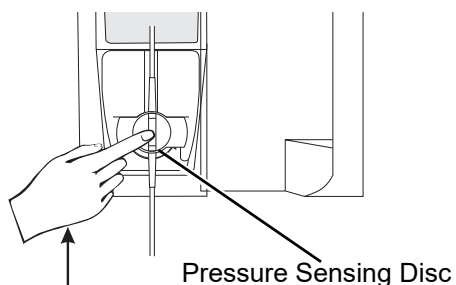
12. To return to main screen, press the **EXIT** soft key.

If the **EXIT** soft key is pressed before pressure sensing disc is reinstalled, a prompt to reinstall pressure sensing disc is displayed.
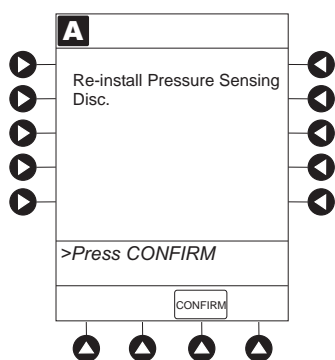
Priming Administration Set With No Pressure Sensing Disc

1. Press the **OPTIONS** key.

2. Press the **Prime Set with Syringe** soft key.
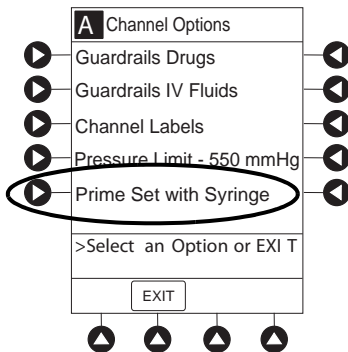
3. Press and hold the **PRIME** soft key until fluid flows and priming is complete.

    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.

Prime—Manual

Use the following procedures to manually prime the administration set.

⚠️ **WARNING**

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

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

Priming Administration Set <u>With</u> Pressure Sensing Disc

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

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

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

⚠ **CAUTION**

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

3. Invert pressure sensing disc so that patient side is up.

4. Hold pressure sensing disc between 2 fingers.[1]

Patient Side
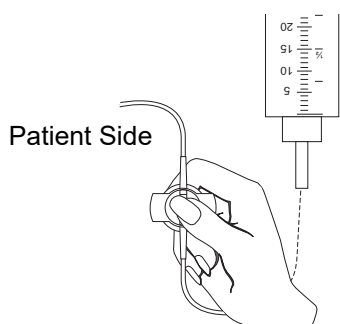
5. Slowly prime set while gently massaging pressure sensing disc to ensure that all air is expelled. The disc must remain inverted only until the air is expelled. Continue to gently massage disc throughout priming to ensure that it does not become under- or over-filled.

6. When priming is complete (no air exists), close set clamp.

NOTE:

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

Priming Administration Set With No Pressure Sensing Disc

1. Prime per hospital protocol.

2. When priming is complete (no air exists), close set clamp.

Eliminating Mechanical Slack

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

1. Load syringe (see *Loading* on page *73*). If a pressure sensing disc is being used, do not install disc until priming is complete.

2. Select syringe and infusion type (see *Programming* on page *87* for more information).

3. Open administration set clamp.

4. Prime, as follows, using the Priming option (see *Prime—Using Options Menu* on page *79* 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).

Programming

Introduction

The system can be programmed with Guardrails suite MX protection or with no Guardrails suite MX protection:

- Guardrails suite MX protection
    - Manual Programming *(see Manually Programming — Primary Infusion on page 88)*
    - Programming with Interoperability (see *Programming with Interoperability and Guardrails™ Suite MX* on page *121*)
    - Auto-ID (Refer to *Alaris™ Auto-ID Module Model 8600* on page *309*)
- No Guardrails suite MX protection
    - *Manual Programming — No Guardrails™ Selections* on page *142*
    - *No Guardrails - Basic Infusion with Drug Calculation* on page *144*

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

See *Features and Definitions* on page *176* and *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* for information about:

- Displays
- Operating Features, Controls, Indicators

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

Manual Programming with Guardrails™ Suite MX

Manually Programming — Primary Infusion

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

1. Perform the following steps (see *General Setup and Operation* on page *165*, and *System Start Up/ Setup* on page *165* 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. Prepare and load syringe/administration set (see *Getting started* on page *62*).

3. Prime (see *Getting started* on page *62*).

pump module   syringe module
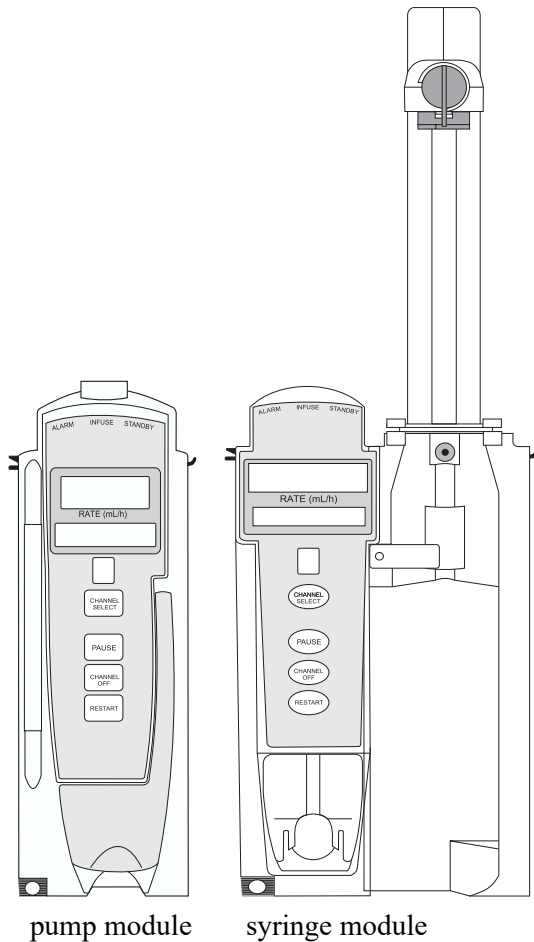
⚠ **WARNING**

Ensure that the displayed syringe manufacturer and syringe size correctly identify the installed syringe. Mismatches might cause an under-infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page *175*.

4. Press the **CHANNEL SELECT** key.

5. Syringe module: Select syringe type and size as follows, otherwise proceed to step 6.[1]

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

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.

WARNING

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

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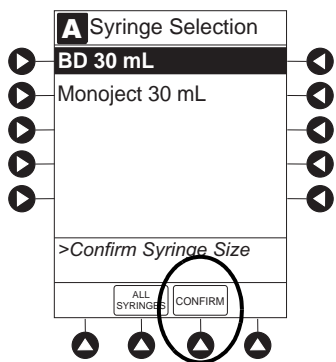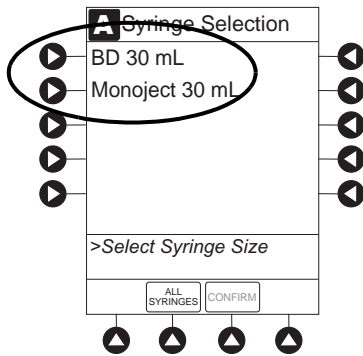
d. To accept, press the **CONFIRM** soft key.

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

Programming a Continuous Infusion on page *91*

Bolus Dose on page *146*

Intermittent Infusion on page *129*

Fluid Infusion on page *128*

NOTE:

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

NOTE:

It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the 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

•   weight entry (if required)

•   rate or dose entry

•   VTBI entry (syringe module—if other than All)

1.   Press the **GUARDRAILS DRUGS** soft key.
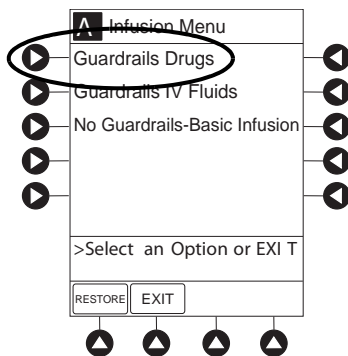
2. Press the soft key next to desired drug.

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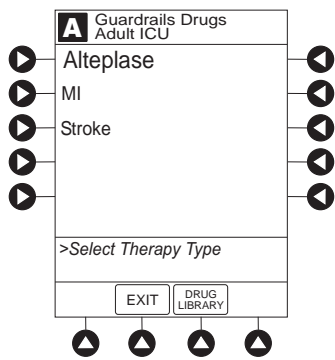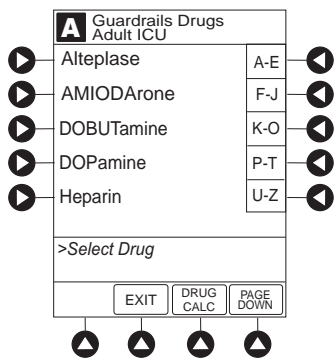
   • If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion could appear—as in illustrated example, which reflects use of Alteplase. Different limits can be defined for same drug with different therapeutic indications.

   • Therapy indication appears on drug or IV fluid confirmation screen. Once drug or IV fluid has been confirmed, therapy indication appears in title bar.
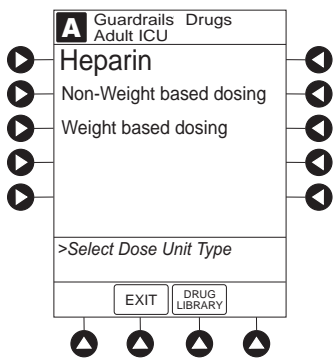
- • If applicable, a weight-based or non weight-based option for delivery of this infusion could appear (as in illustrated example, which reflects use of Heparin).
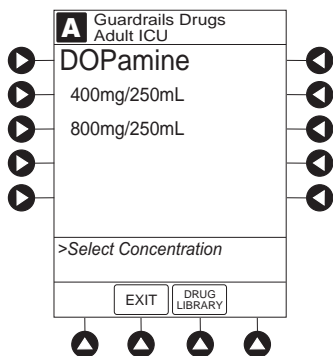
- • If applicable, multiple concentration listings for delivery of this infusion could appear (as in illustrated example, which reflects use of Dopamine).

3. To continue programming, press the **Yes** soft key.[①]

    Bolus dose units appear if bolus dose is enabled.

    or

    To change selection, press the **No** soft key.
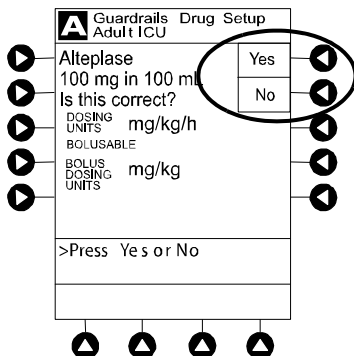
- • If **Yes** was selected and facility has defined a clinical advisory for that drug, a message appears. To indicate information has been noted and continue programming, press the **CONFIRM** soft key.
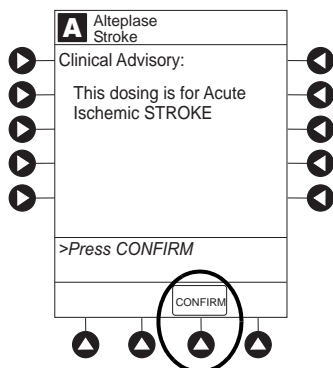
- If **Yes** was selected to continue programming, drug amount and diluent volume (if defined in drug library) are automatically entered for selected drug.
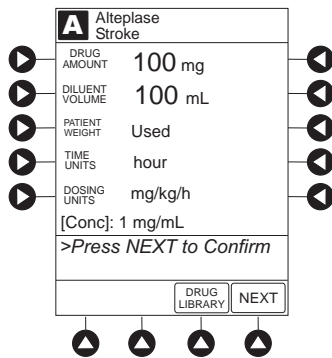
- If the selected drug had "_ _ / _ _ mL" concentration, the drug amount and diluent volume need to be entered.

- 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).[2][3]
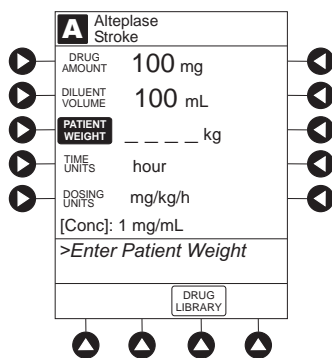
4. Verify correct parameters and press the **Next** soft key to confirm.

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).
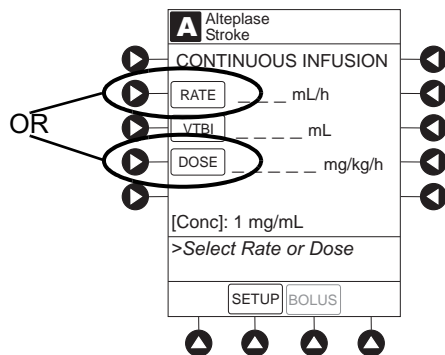
6. To enter the volume to be infused, press the **VTBI** soft key and enter value.

    • 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.
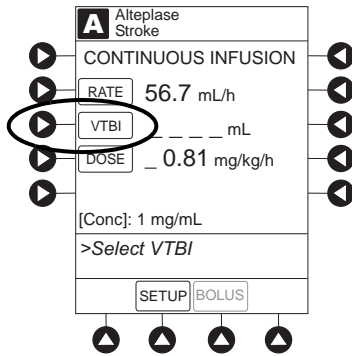
    • Syringe module:

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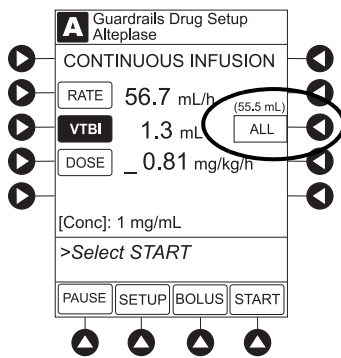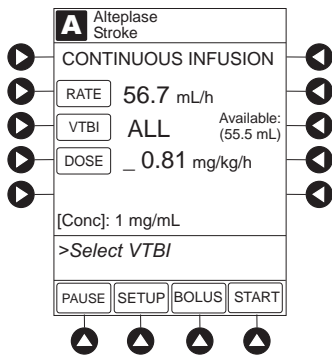
7. Verify the correct parameters and press the **START** soft key.

   - For a continuous infusion, the drug name and dose will scroll on the module message display.
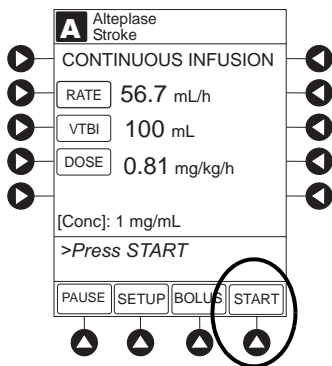
- If the programmed continuous dose infusion is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion needs to be reprogrammed.
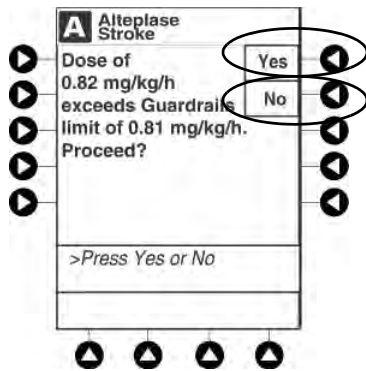
- If the programmed continuous dose infusion is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.

- If a dose outside of the soft limits has been entered and verified as correct, message display also shows either "LLL" for a low dose or "↑↑↑" for a high dose.

- If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

8. Syringe module:

    •   Unclamp tubing and attach administration set to patient.

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

NOTE:
① The facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (_ _ / _ _ mL) and allow the clinician to enter the desired concentration.
② Patient weight can be edited during a continuous infusion.

③ Once a patient weight is entered and an infusion is started for any module, the patient weight is automatically entered for any additional weight-based calculation. The patient weight remains an editable field, therefore patient weight can be adjusted for any module. Changing the patient weight on one module does not affect the patient weight on any other module.

NOTE:
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.

Bolus Dose

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

1. Set up infusion as described in *Programming a Continuous Infusion* on page *91*, 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.
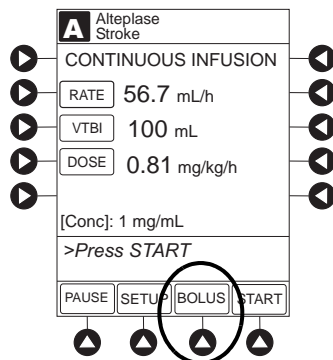
3. An optional hospital-defined and editable starting value for bolus dose and/or bolus rate duration might already be entered.

or

To enter bolus dose, use numeric data entry keys.

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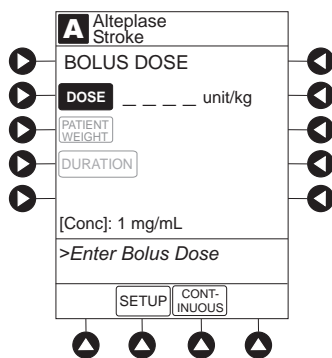
4. Enter or change patient weight (if used), use applicable following procedure, depending on whether or not continuous dose is weight-based.

   a. To enter a weight when continuous dose is non weight-based:
      - Press the **PATIENT WEIGHT** soft key.
      - To enter patient weight, use numeric data entry keys.

   or

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

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

  ◦ Press the **BOLUS** soft key.

  ◦ To enter bolus dose, use numeric data entry keys.
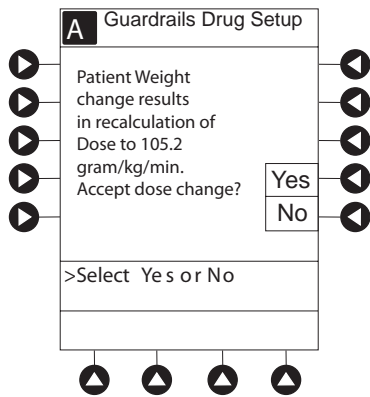
5. Press the **DURATION** soft key.

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

   or

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

   • **TOTAL DOSE** alternates with **INFUSE AT** rate.
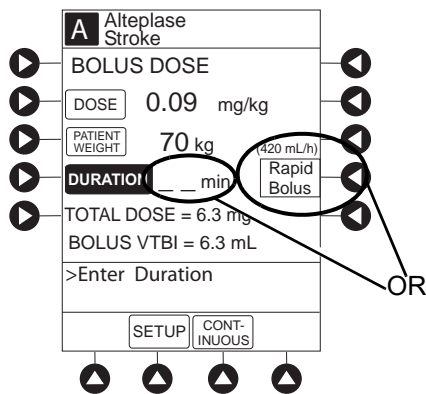
7. Verify correct parameters and press the **START** soft key.[5]

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

- If the programmed bolus dose and/or bolus dose duration is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Infusion needs to be reprogrammed.
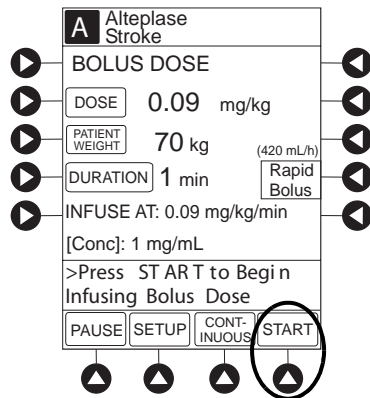
- If a bolus dose outside of soft limits has been entered and verified as correct, Message Display also shows either "LLL" for a low dose or "↑↑↑" for a high dose.
- If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

8. Syringe module:

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

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.
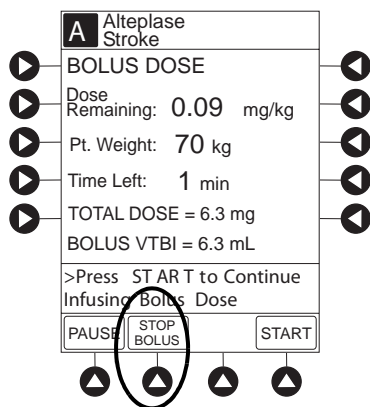
3. To stop bolus and start a Continuous Infusion, press the **Yes** soft key.
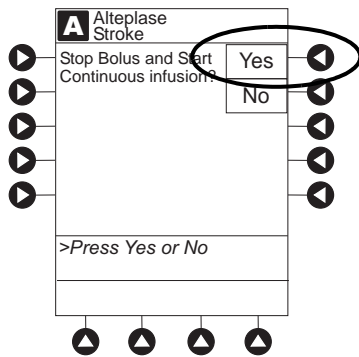
4. To stop Continuous Infusion, press and hold the **CHANNEL OFF** key until a beep is heard (approximately 1.5 seconds).[6]
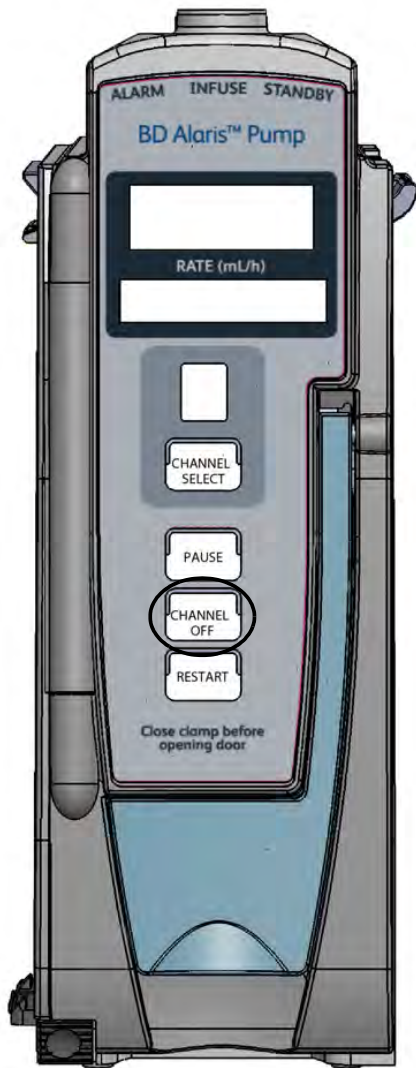
Restoring a Bolus Dose

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 <u>not</u> 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.

NOTE:

① If the bolus dose feature is enabled, the **BOLUS** soft key appears in the Continuous Infusion screen and becomes active when a VTBI is entered.

② The bolus VTBI cannot exceed the programmed Continuous Infusion VTBI.

③ Programming and starting a bolus dose deletes any programmed delay.

④ If no continuous rate is entered or if the bolus dose VTBI equals the Continuous Infusion VTBI, the infusion ends when the bolus has been delivered. No KVO infusion follows.

⑤ To see details during the bolus infusion, press the **CHANNEL SELECT** key.

⑥ The pump module keypad is used in the illustration but the key is the same for the syringe module.

Intermittent Infusion

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

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

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

1. Press 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.

3. To continue programming, press the **Yes** soft key.[1]

    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.

- If selected drug is not weight-based, **NOT USED** is displayed in **PATIENT WEIGHT** field.

- If hospital/facility practice guidelines identify selected drug as weight-based or by BSA, a prompt for a patient weight in kilograms or BSA appears (as in illustrated example, which reflects the use of Methotrexate).[2]

```
┌─────────────────────────────┐
│ ┌─┐ Guardrails Drug Setup    │
│ │A│ Methotrexate            │
│ └─┘                          │
│ ▶ ┌──────┐                 ◀ │
│   │DRUG  │  6840 mg          │
│   │AMOUNT│                   │
│ ▶ ┌──────┐                 ◀ │
│   │DILUENT│  50 mL           │
│   │VOLUME │                  │
│ ▶ ┌──────┐                 ◀ │
│   │ BSA  │  _ _ _ m²         │
│ ▶ DOSE =  _ _ _ mg/m²      ◀ │
│ ▶                          ◀ │
│                              │
│ [Conc]: 136.8 mg/mL          │
│ >Enter BSA                   │
│ ──────────────────────────── │
│            ┌──────┐          │
│            │DRUG  │          │
│            │LIBRARY│         │
│            └──────┘          │
└─────────────────────────────┘
   ▲     ▲     ▲     ▲
```

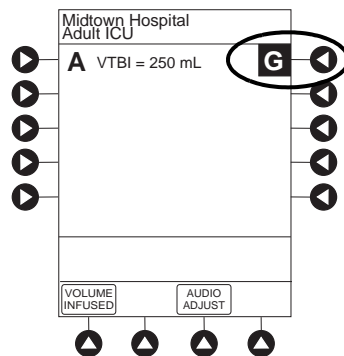4. Verify correct parameters and press the **NEXT** soft key to confirm.

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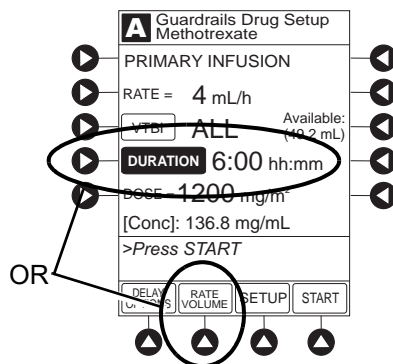
7. Verify correct parameters and press the **START** soft key.

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

- If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

- For an Intermittent Infusion, the drug name and dose will scroll on the module Message Display.

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

8. Syringe module:

    • Unclamp tubing and attach administration set to patient.

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

NOTE:
① The facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (_ _ / _ _ mL) and allow the clinician to enter the desired concentration.
② Patient weight or BSA is not editable on that module during an Intermittent Infusion.

③ Once a patient weight or BSA is entered and the infusion started, the patient weight or BSA is automatically entered for any additional weight-based or BSA calculation. Prior to the start of an intermittent infusion, the patient weight or BSA remains an editable field so that patient weight or BSA can be adjusted for any module. Changing the patient weight or BSA on one module will not affect the patient weight or BSA on any other module.

NOTE:
It is possible to program an infusion with a rate that is displayed with two decimal places (one-hundredth of a mL per hour) on the 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.

Fluid Infusion

1. Press the **Guardrails IV Fluids** soft key.

2. Press the soft key next to IV fluid to be delivered.
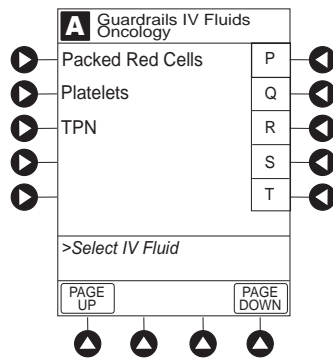
3. To confirm selection, press the **Yes** soft key.

    or

    To return to list, press the **No** soft key.
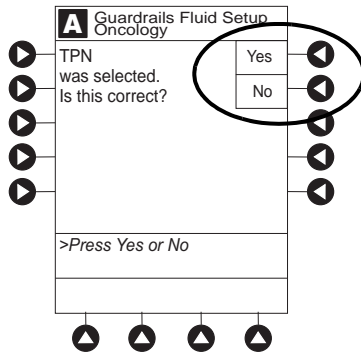
    If **Yes** was selected and facility has defined a Clinical Advisory for that drug, a message appears. To indicate information has been noted and continue programming, press the **CONFIRM** soft key.

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

    Rate/Volume Infusion on page *109*

    Volume/Duration Infusion on page *111*

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.[①]

    •   If the programmed IV fluid is outside the soft limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. If 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. Syringe module:

    •   Unclamp tubing and attach administration set to patient.

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

Volume/Duration Infusion

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

2. To enter **VTBI**, press the **VTBI** soft key and use numeric data entry keys.
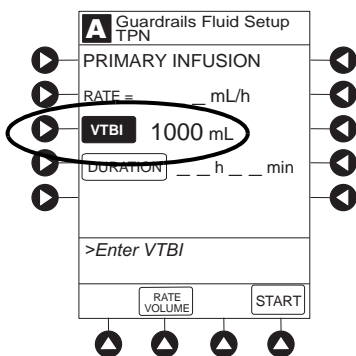
- • Syringe module:

  - ◦ 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.
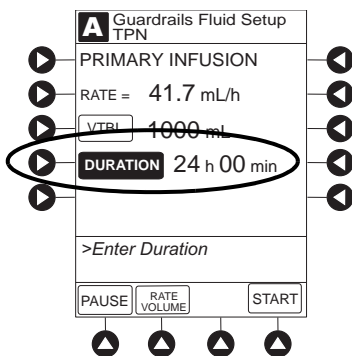
4. Verify correct infusion parameter entry and press the **START** soft key.[2]

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

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

- If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

5. Syringe module:

- Unclamp tubing and attach administration set to patient.

- Unclamping tubing and starting infusion before attaching administration set to patient minimizes any potential bolus that can be released from pressure built up in set due to normal syringe loading and priming.
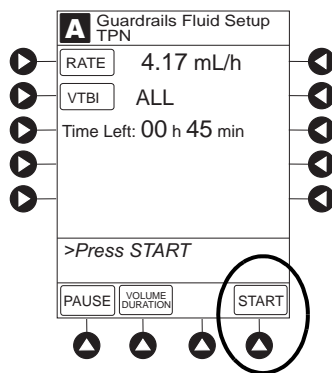
NOTE:
① The infusion can be paused by pressing the **PAUSE** soft key. See *Pausing and Restarting Infusion* on page *149* for more information.
② To view infusion **Time Left** during a volume/duration infusion, press the **CHANNEL SELECT** key. To return to previous screen, press the **START** soft key.

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.

Manual Programming — Secondary Infusion (Pump Module)

⚠️ **WARNING**

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

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

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

Setup

1. Open secondary administration set package, remove set and close clamp.

2. Insert administration set spike into prepared fluid container and hang secondary container, following accepted hospital/facility procedure.

3. Fill drip chamber to ⅔ full.

4. Open secondary administration set clamp and prime set. Close clamp.

⚠️ **WARNING**

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

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

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

⚠️ **WARNING**

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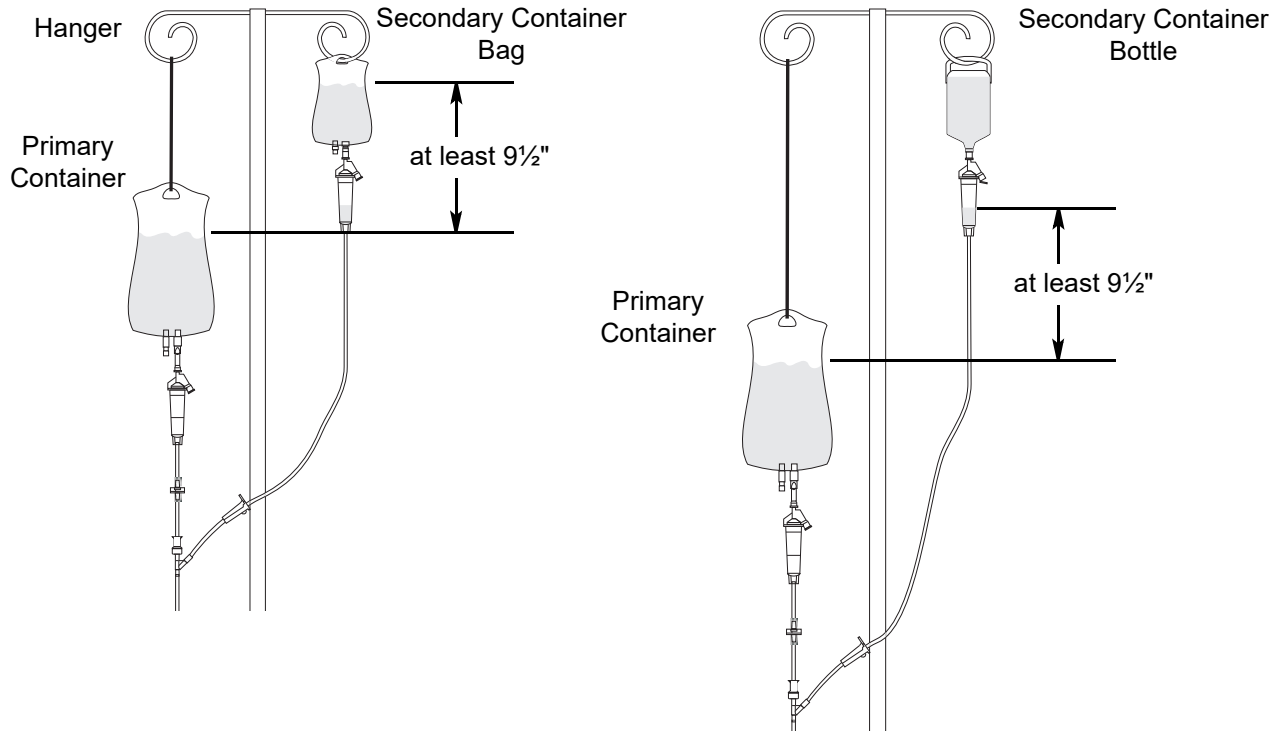
NOTE:
The top of the fluid container should never be lower than the Y-site port to reduce the risk of air entering the primary set.

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.

Infusion

The following procedure should be used only when:

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

To program a primary infusion, see *Fluid Infusion* on page *108*. To program a No Guardrails - Basic Infusion, see *Manual Programming — No Guardrails™ Selections* on page *142*.

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

2. Press the **SECONDARY** soft key.
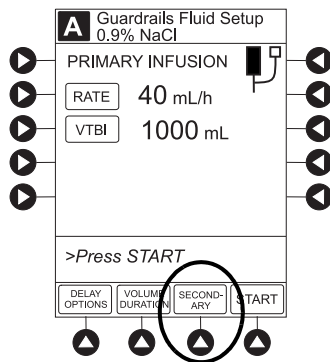
3. Press soft key next to desired drug.

   - 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.[1]

    or

    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 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.

*   If selected drug is not weight-based, **Not Used** is displayed in **PATIENT WEIGHT** field.

*   If hospital/facility practice guidelines identify selected drug as weight-based, prompt for a patient weight in kilograms or BSA appear (as in illustrated example, which reflects use of Methotrexate).[2][3]

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.

6. VTBI entry:

    •   When VTBI is less than 10 mL/h, entry can be to two decimal places (one-hundredth of a mL).

⚠   **WARNING**

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

    •   VTBI is pre-populated with diluent volume of infusion. To change VTBI, press the **VTBI** soft key and use numeric data entry keys.
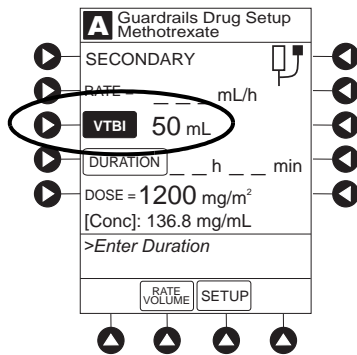
7. If an optional hospital-defined and editable starting value for intermittent duration is not already entered, enter duration or rate, as follows:

    •   To enter duration, press 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.
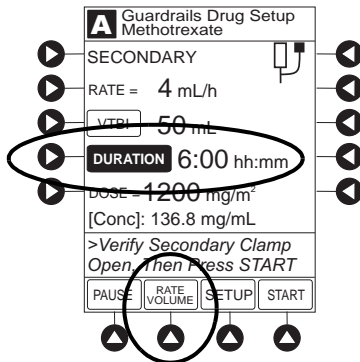
8. Open clamp on secondary administration set.

⚠ **WARNING**

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

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 drops are flowing from the secondary container drip chamber.

NOTE:
① The facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (_ _ / _ _ mL) and allow the clinician to enter the desired concentration
② Patient weight or BSA is not editable during a Secondary Infusion.

③ Once a patient weight or BSA is entered and the infusion started, the patient weight or BSA is automatically entered for any additional weight-based or BSA calculation. Prior to the start of infusion, the patient weight or BSA key remains an editable field so that patient weight or BSA can be adjusted for any module. Changing the patient weight or BSA on one module will not affect the patient weight or BSA on any other module.

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 administration set.

   or

   Disconnect secondary administration 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.①

   • Secondary infusion stops and primary infusion begins.

   • Main screen appears.

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

Programming with Interoperability and Guardrails™ Suite MX

Interoperability is designed to help automate existing manual workflows with regard to programming infusions on the 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:

- *HL7 Infusion Status Message Specification for CareFusion Coordination Engine—Regulated Infusion Adapter User Guide*

- *HL7 Order Message Specification for CareFusion Coordination Engine—Regulated Infusion Adapter User Guide*

- *BD Alaris™ System Interoperability Services User Reference Guide*

- *BD Alaris™ System Interoperability Services Guide for Clinical Workflow Testing 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.

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** infusions 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 Calc 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.

Programming with Interoperability — Initial Primary Infusion

1. Perform the following steps on the PCU (see *General Setup and Operation* on page *18 and Start-Up* on page *21*):

   a. Power on system. (Scanning the module will not power on the device.)

   b. Select **Yes** or **No** to **New Patient?**

   c. Confirm current profile or select a new profile. This places the module in an *idle state* (not infusing or in the process of being programmed as illustrated Channels A and B).

2. Prepare the Administration Set for the pump module, see *Preparing an Administration Set (Pump Module)* on page *64*.

3. Prime the Administration Set, see *Preparing Syringe and Administration Set (Syringe Module)* on page *71*.
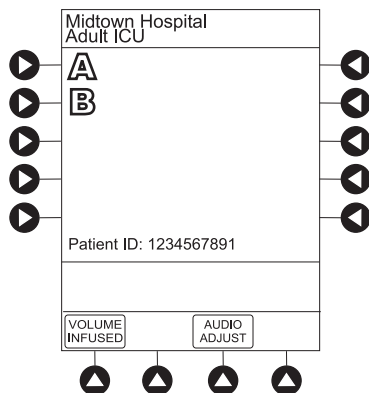
```
Midtown Hospital
Adult ICU

  ▶   Ⓐ                    ◀
  ▶   Ⓑ                    ◀
  ▶                        ◀
  ▶                        ◀
  ▶                        ◀

      Patient ID: 1234567891


   ┌────────┐      ┌────────┐
   │VOLUME  │      │AUDIO   │
   │INFUSED │      │ADJUST  │
   └────────┘      └────────┘

     ▲      ▲      ▲      ▲
```

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 <u>may</u> 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.

⚠ **WARNING**

Ensure that the displayed syringe manufacturer and syringe size correctly identify the installed syringe. Mismatches might cause an under-infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page *175*. If the installed syringe is displayed and selected but is not recognized, servicing is required. (See *Troubleshooting and Maintenance* on page *324*.)

⚠ **WARNING**

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

For the pump module, proceed to step 6.

4. For the syringe module, select the syringe type and size; otherwise proceed to step 6. If the installed syringe is loaded correctly, but not recognized, check the following:

  a. If a label is between the syringe barrel and the barrel clamp, make sure that the label does not erroneously enlarge the barrel size of the syringe.

  b. If a needle-free valve or other component is added to the syringe, ensure that it is no larger than the diameter of the syringe barrel.

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

  • The capability of the syringe module to recognize a new syringe and read the volume is unchanged from manual programming.

c. Press the soft key next to the installed syringe type and size. If a default syringe list has been enabled and the correct syringe cannot be found, press the **ALL SYRINGES** soft key to select from a list of all compatible syringes.
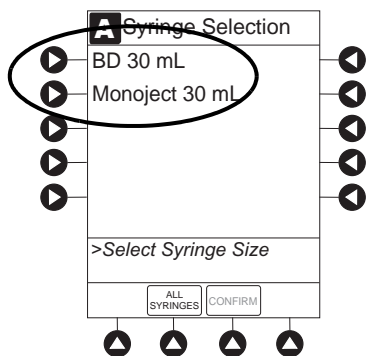
d. To accept the syringe type and size, press the **CONFIRM** soft key.
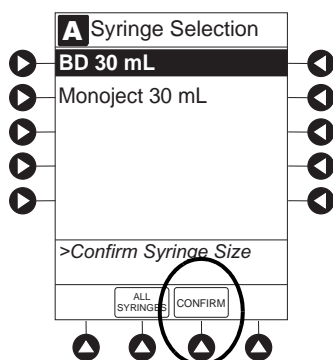
5. If applicable, select the Therapy on the PCU.

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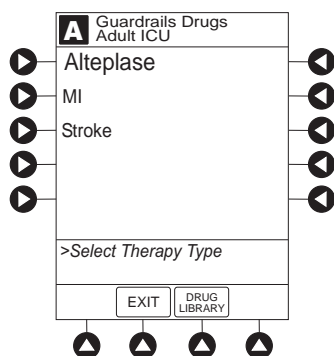
NOTE:
Once the Therapy has been confirmed, the name is displayed in the title below the drug or fluid name on the infusion setup and programming screen of the PCU.

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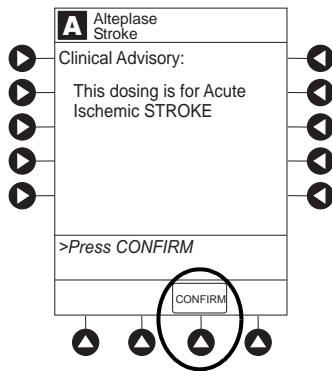
The Patient ID and, depending on the infusion type, the following infusion parameters are pre-populated on the system from the automated programming request:

- 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 are unable to 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 *91*

Fluid Infusion on page *128*

Intermittent Infusion on page *129*

Continuous Infusion

The following workflow assumes that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Programming with Interoperability — Initial Primary Infusion* on page *123*.

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.
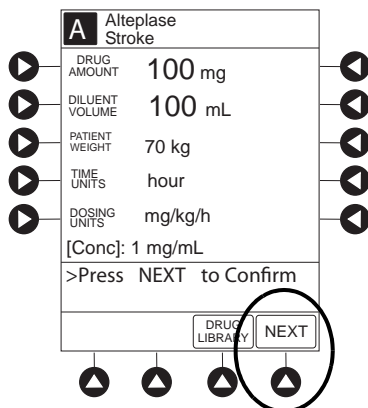
NOTE:

  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 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.

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

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

Fluid Infusion

The following workflow assumes that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned. See *Programming with Interoperability — Initial Primary Infusion* on page *123*.

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.

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 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 administration set to patient.

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

Intermittent Infusion

The following workflow assumes that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Programming with Interoperability — Initial Primary Infusion* on page *123*.

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.

   ```
   ┌─────────────────────────────┐
   │ A  Potassium Chloride       │
   ├─────────────────────────────┤
   │ DRUG                        │
   │ AMOUNT    10   mEq          │
   │                             │
   │ DILUENT                     │
   │ VOLUME    50   mL           │
   │                             │
   │ PATIENT                     │
   │ WEIGHT    70 kg             │
   │                             │
   │ DOSE    0.143 mEq/kg        │
   │                             │
   │                             │
   │ [Conc]:  0.2 mEq/kg         │
   │ >Press NEXT to Confirm      │
   │                             │
   │                    ( NEXT ) │
   └─────────────────────────────┘
   ```

   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 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.

```
┌─────────────────────────────┐
│ ┌─┐ Guardrails Drug Setup    │
│ │A│ Potassium Chloride       │
│ └─┘                          │
│  PRIMARY INFUSION            │
│                              │
│  RATE=  50  mL/h             │
│  ┌────┐                      │
│  │VTBI│  50  mL              │
│  └────┘                      │
│  ┌─────────┐                 │
│  │DURATION │  1:00  hh:mm    │
│  └─────────┘                 │
│  DOSE =  0.143   mEq/kg      │
│  [Conc]: 0.2 mEq/kg          │
│  >Press  START               │
│ ┌──────┬──────┬─────┬─────┐  │
│ │DELAY │ RATE │SETUP│START│  │
│ │OPTIONS│VOLUME│     │     │  │
│ └──────┴──────┴─────┴─────┘  │
└─────────────────────────────┘
```

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

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

Programming with Interoperability — Subsequent Primary Infusion (Pump Module)

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

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

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

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

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

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

The pre-population of infusion parameters workflow for subsequent bags is unchanged from the initial bag; scan patient, scan medication label, scan pump module, see *Programming with Interoperability — Initial Primary Infusion* on page *123*. 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 *155*.
- 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.
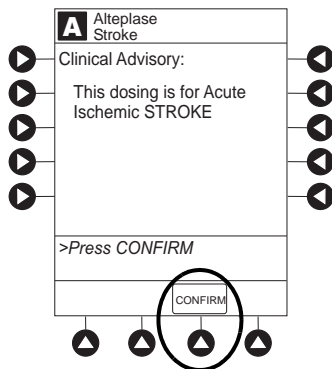
NOTE:
If the infusion parameters are unable to be pre-populated on the system, error messages will be displayed in the EMR/HIS. Error messages will not be displayed on the PCU. Consult the EMR/HIS.

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

   Programming a Continuous Infusion on page *91*

   Infusion on page *116*

   Intermittent Infusion on page *129*

Continuous Infusion

The following workflow assumes that the pump module has already been programmed with an Initial Primary Continuous Infusion and that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, *see Programming with Interoperability — Initial Primary Infusion* on page *123*.

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.
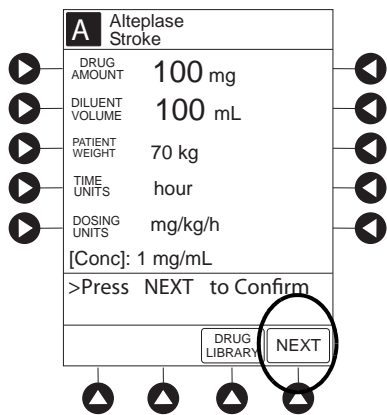
3. After the parameters are confirmed, press the **START** soft key.
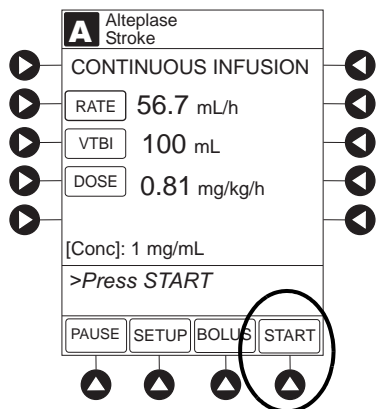
The rate, VTBI, and dose are pre-populated from the automated programming request.

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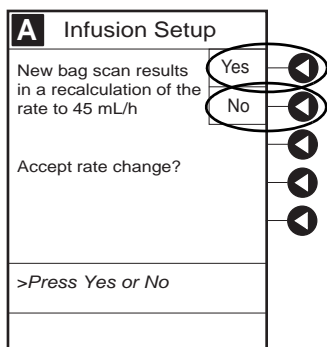
5. Review and verify that all parameters pre-populated on the system are correct prior to starting the infusion.

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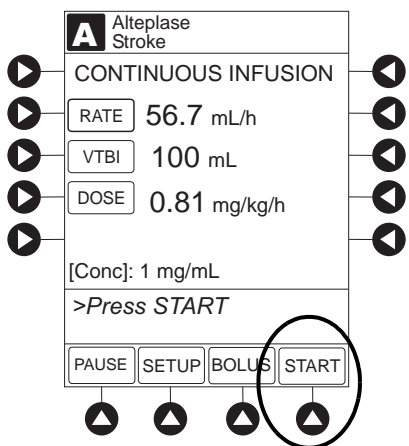
Fluid Infusion

The following workflow assumes that the pump module has already been programmed with an Initial Primary Fluid Infusion and that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned, see *Programming with Interoperability — Initial Primary Infusion* on page *123*.

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.

```
┌─────────────────────────────┐
│ ┌─┐                          │
│ │A│ 0.45% Sodium Chloride    │
│ └─┘                          │
│ ▶  PRIMARY INFUSION       ◀  │
│ ▶  ┌──────┐                ◀  │
│    │ RATE │  100 mL/h         │
│ ▶  └──────┘                ◀  │
│    ┌──────┐                   │
│ ▶  │ VTBI │ _1000 mL       ◀  │
│    └──────┘                   │
│ ▶                          ◀  │
│                               │
│ >Press START                  │
│ ┌──────┐┌──────┐┌──────┐┌─────┐│
│ │DELAY ││VOLUME││SECOND││START││
│ │OPTIONS││DURATION││ARY││     ││
│ └──────┘└──────┘└──────┘└─────┘│
│    ▲      ▲      ▲      ▲      │
└─────────────────────────────┘
```

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.

```
┌─────────────────────────────┐
│ ┌─┐                          │
│ │A│  Infusion Setup          │
│ └─┘                          │
│ New bag scan results  ┌────┐ │
│ in a recalculation of │Yes │◀│
│ the rate to 45 mL/h   └────┘ │
│                       ┌────┐ │
│                       │ No │◀│
│                       └────┘ │
│ Accept rate change?        ◀ │
│                            ◀ │
│                            ◀ │
│                              │
│ >Press Yes or No             │
│                              │
└─────────────────────────────┘
```
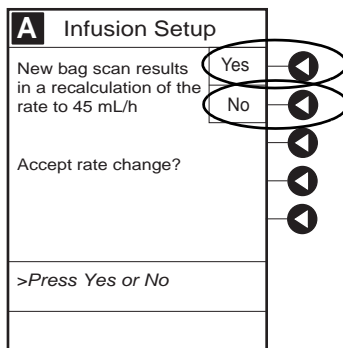
4. Review and verify that all parameters pre-populated on the system are correct.

5. Press the **START** soft key.
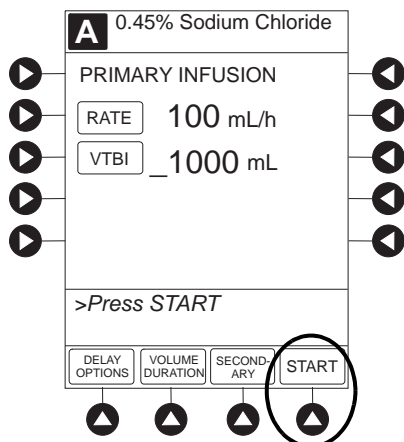
```
┌─────────────────────────────┐
│ ┌─┐                          │
│ │A│ 0.45% Sodium Chloride    │
│ └─┘                          │
│ ▶  PRIMARY INFUSION       ◀  │
│ ▶  ┌──────┐                ◀  │
│    │ RATE │  100 mL/h         │
│ ▶  └──────┘                ◀  │
│    ┌──────┐                   │
│ ▶  │ VTBI │ _1000 mL       ◀  │
│    └──────┘                   │
│ ▶                          ◀  │
│                               │
│ >Press START                  │
│ ┌──────┐┌──────┐┌──────┐┌─────┐│
│ │DELAY ││VOLUME││SECOND││START││
│ │OPTIONS││DURATION││ARY││     ││
│ └──────┘└──────┘└──────┘└─────┘│
│    ▲      ▲      ▲      ▲      │
└─────────────────────────────┘
```

Intermittent Infusion

The following workflow assumes that the pump module has already been programmed with an Initial Primary Intermittent Infusion and that the Patient's ID band, medication/fluid barcode label, and the module barcode labels have been scanned. *See Programming with Interoperability — Initial Primary Infusion* on page *123* 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.
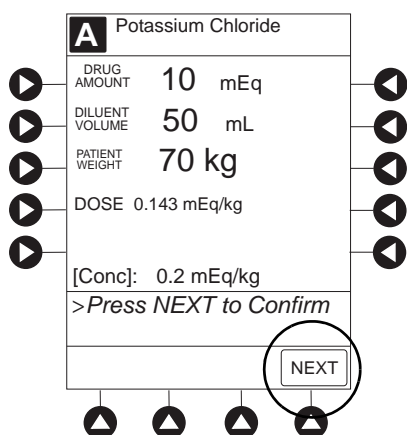
3. Review and verify that all parameters pre-populated on the system are correct.

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

4. Press the **START** soft key.
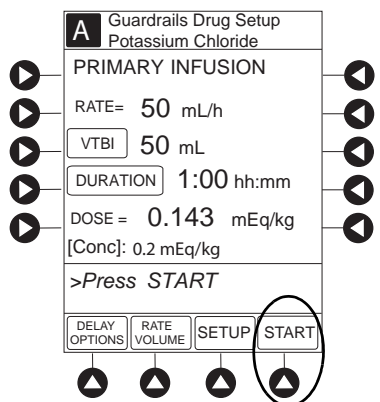
5. If the subsequent automated programming request contains an infusion parameter (rate or duration) that affects or changes the current infusion rate, a message appears with a recalculation of the rate notification.

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.

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

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

Programming with Interoperability — Subsequent Primary Infusion (Syringe Module)

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

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

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

NOTE:
If an infusion is in Delay when a subsequent automated programming request is sent, the Delay will be canceled and the subsequent automated programming request infusion parameters will be pre-populated on the PCU. To add a delay manually, see *Delay Options* on page *155*.

Pre-population of infusion parameters for a subsequent syringe is the same workflow as an Initial Primary Infusion. See *Programming with Interoperability — Initial Primary Infusion* on page *123* for more information.

Programming with Interoperability — Secondary Infusion (Pump Module)

⚠ **WARNING**

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

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

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

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

Infusion

In order to pre-populate infusion parameters for a secondary infusion, a primary fluid that supports a secondary must already be programmed or infusing. For more information, see *Programming with Interoperability — Initial Primary Infusion, Fluid Infusion* on page *128* and *Manual Programming — Secondary Infusion (Pump Module), Fluid Infusion* on page *128*.

Setup

1. Open a secondary administration set package, remove set, and close clamp.

2. Insert the administration set spike into the prepared fluid container and hang the secondary container, following accepted hospital/facility procedure.

3. Fill drip chamber to 2/3 full.

4. Open the secondary administration set clamp and prime the set. Close clamp.

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

⚠ **WARNING**

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

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

⚠ **WARNING**

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

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

• Scan Patient's ID Band.

• Scan fluid/medication barcode label.
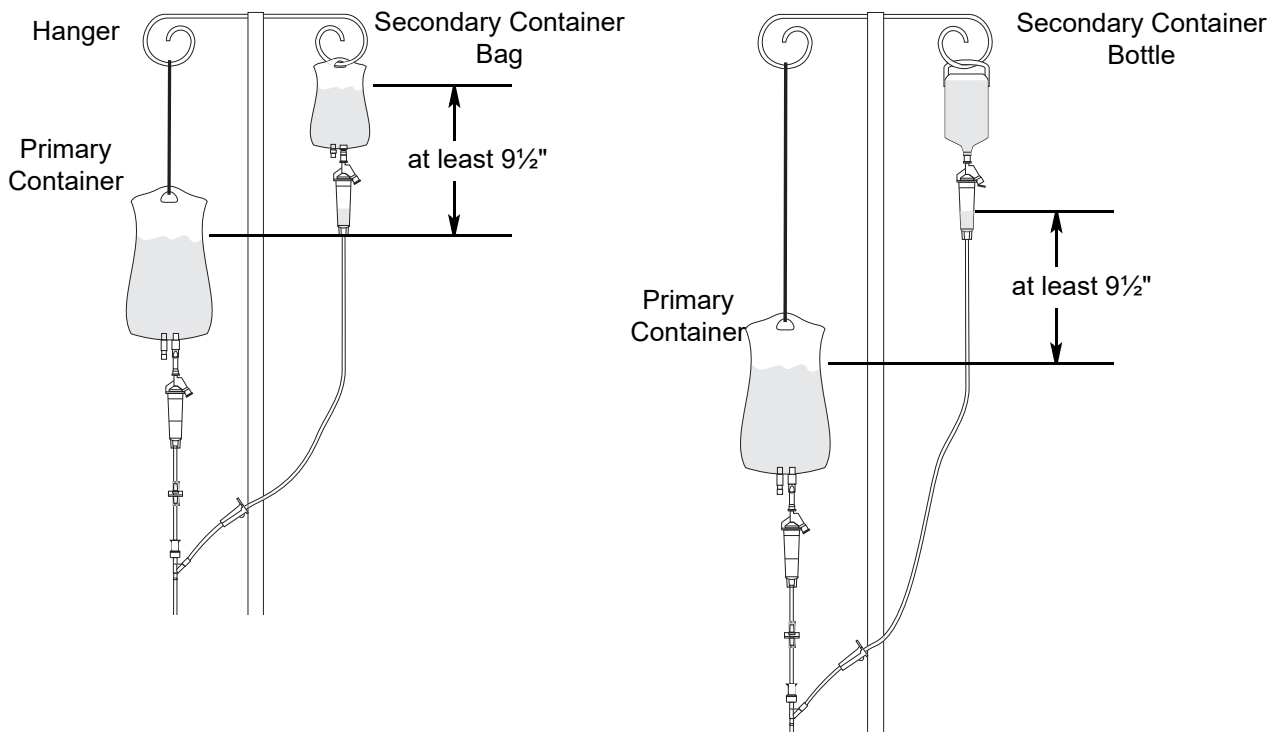
• Scan barcode label on the pump module.

NOTE:
If the infusion parameters are unable to be pre-populated on the 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.

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.

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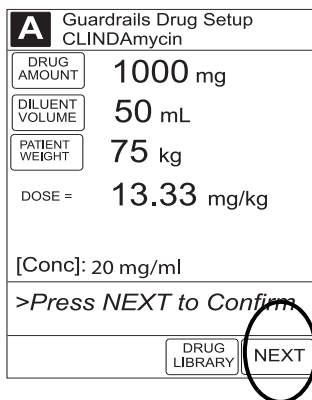
10. Review and verify that all parameters pre-populated on the system are correct prior to starting the infusion.

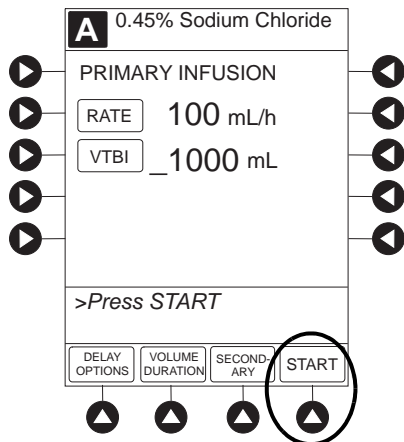   The rate, VTBI, and duration are pre-populated from the automated programming request.

⚠ **WARNING**

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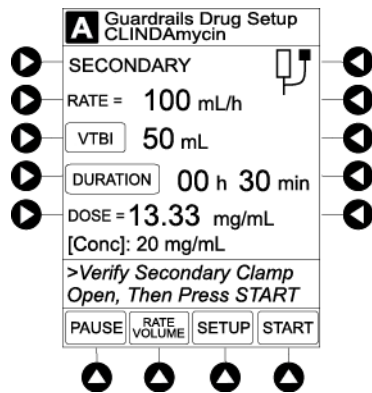
11. Open the clamp on secondary administration set.

⚠ **WARNING**

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

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 that drops are flowing from the secondary container 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 administration set.

   or

   Disconnect the secondary administration set from the upper injection port.

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

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

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

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

Programming — No Guardrails™ Selections

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

Manual Programming — No Guardrails™ Selections

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

1. Perform the following steps (see *Start-Up* on page *21* 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/administration set (see *Getting started* on page *62*).

3. Prime (see *Getting started* on page *62*).

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

    No Guardrails - Basic Infusion without Drug Calculation on page *143*

    Bolus Dose on page *98*

No Guardrails - Basic Infusion without Drug Calculation

The following procedure should only be used to set up a No Guardrails - Basic Infusion. To program an infusion using **Guardrails Drugs**, see *Programming with Interoperability — Initial Primary Infusion* on page *123*.

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

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

A Infusion Menu
▶ Guardrails Drugs   ◀
▶ Guardrails IV Fluids   ◀
▶ No Guardrails-Basic Infusion   ◀
▶   ◀
▶   ◀
>Select an Option or EXI T
EXIT
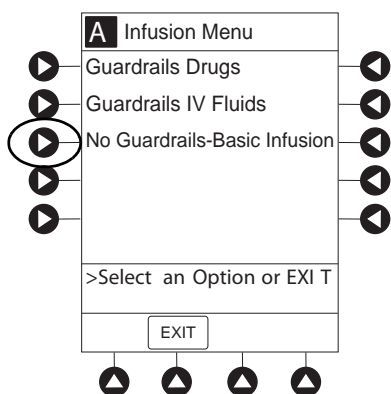
- An optional hospital-defined Clinical Advisory message may appear reminding the clinician that No Guardrails-Basic Infusion feature does not have limits. Press **CONFIRM** soft key to continue programming.

A
▶ Clinical Advisory: ◀
▶   ◀
▶ This infusion selection   ◀
▶ DOES NOT have   ◀
▶ Guardrails Protection   ◀
CONFIRM
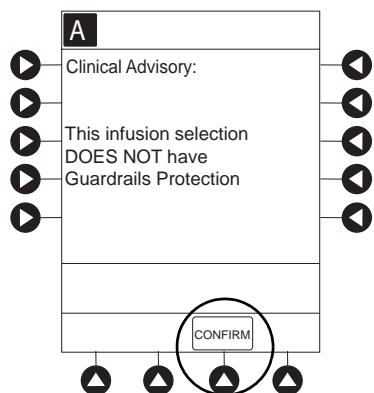
Infusion Setup screen appears.

3. Start applicable infusion as described in the following procedures (see *Programming with Interoperability — Initial Primary Infusion*):

   Fluid Infusion on page *108*

   Rate/Volume Infusion on page *109*

   Volume/Duration Infusion on page *111*

Promoting No Guardrails - Basic Infusion to Guardrails Software Protection Infusion

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

2. Press the **OPTIONS** key.
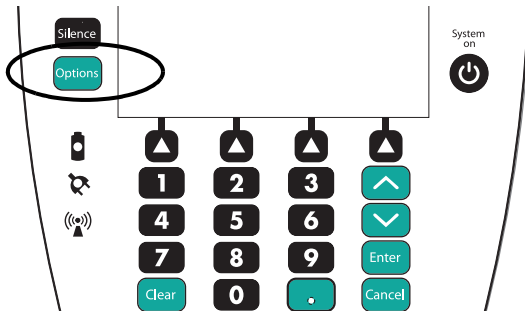
3. Press the **Guardrails Drugs** soft key.

4. Continue programming (see *Programming with Interoperability — Initial Primary Infusion* on page *123*).

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.

No Guardrails - Basic Infusion with Drug Calculation

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

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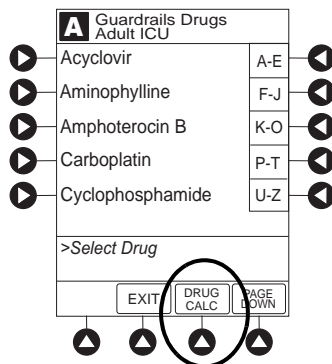
3. To enter **DRUG AMOUNT**, use numeric data entry keys.
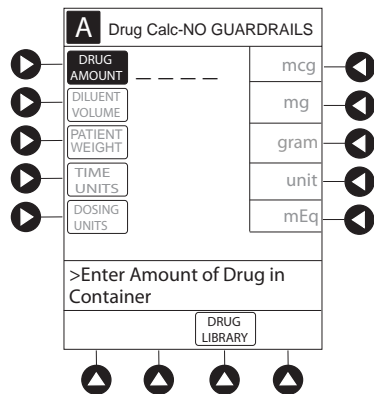
4. Press soft key for appropriate unit of measure for drug amount.

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.
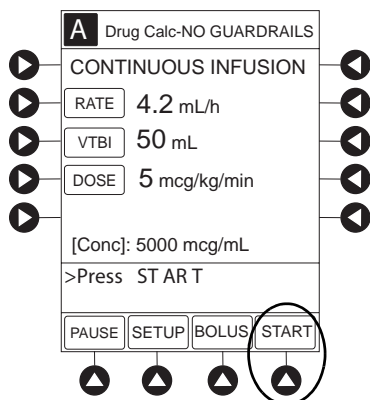
16. Syringe module:

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

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

Bolus Dose

1. Set up infusion as described in *Programming a Continuous Infusion* on page *91*, 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.
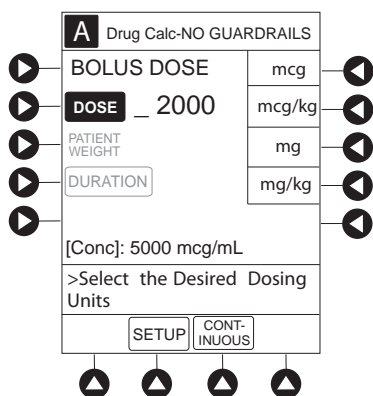
4. Press the soft key next to appropriate unit of measure for dose.

    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. Syringe module:

    • If bolus dose was programmed at beginning of infusion, unclamp tubing and attach administration set to patient.

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

Stopping and Restoring Bolus Dose

See *Programming with Interoperability — Initial Primary Infusion*, *Bolus Dose* on page *98* for the procedure.

Secondary Infusion

See *Manual Programming — Secondary Infusion (Pump Module)* on page *114* for a description of the secondary infusion mode and for setup instructions.

Infusion

The following procedure should be used only when:

- drug to be infused is not listed in drug library,

- primary infusion is running, and

- a check valve administration set is being used.

To program a primary infusion, see *Manually Programming — Primary Infusion* on page *88*. To program a No Guardrails - Basic Infusion, see *No Guardrails - Basic Infusion without Drug Calculation* on page *143*.

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 administration set.

5. Verify correct infusion parameters and press the **START** soft key.

6. Verify that drops are flowing from the secondary container 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 *Manual Programming — Secondary Infusion (Pump Module)* on page *114*.

General Programming

Pause, Change, Restart Infusion

Pausing and Restarting Infusion

1. Press the **PAUSE** key.[1][2][3]

    - **PAUSE** scrolls in Message Display.

    - **PAUSED** appears on Main Display.

    - Yellow Standby Status Indicator illuminates.

    - After 2 minutes, **PAUSE-RESTART CHANNEL** visual and audio prompts begin, and yellow Standby Status Indicator flashes.

2. To reinitiate infusion:

    Press the **RESTART** key.

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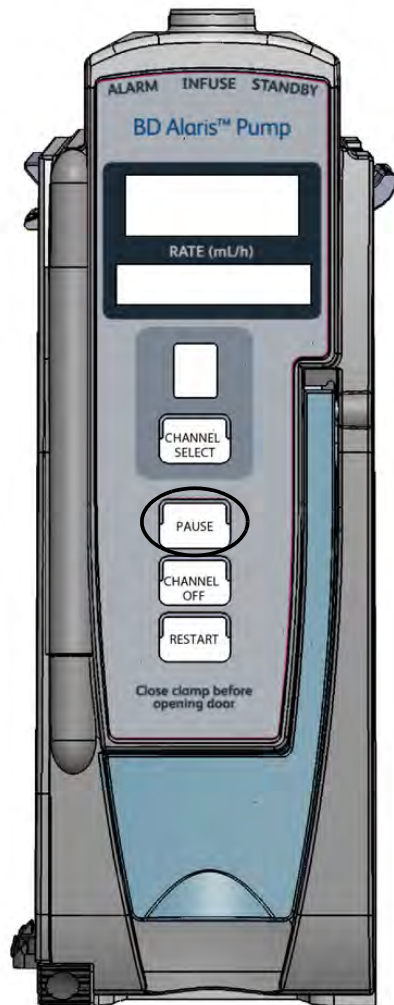
    Press the **CHANNEL SELECT** key and then press the **START** soft key.
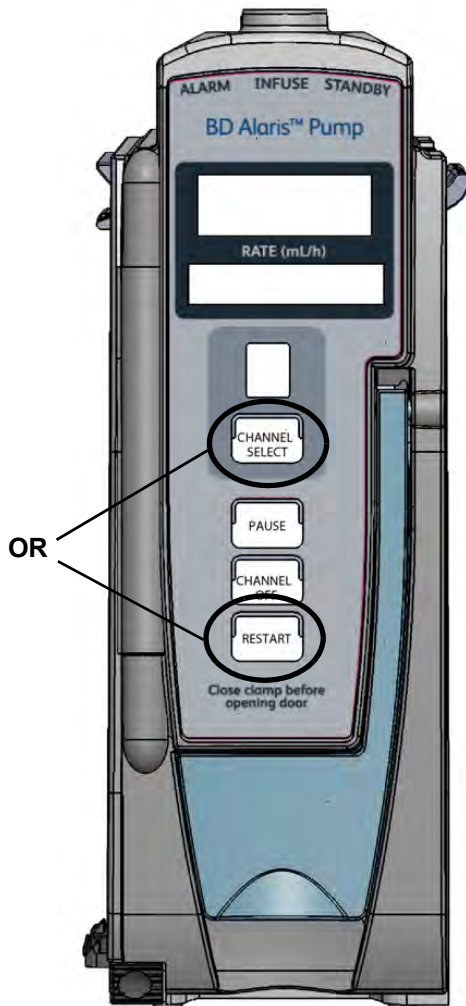
NOTE:

① To stop a bolus dose, see *Bolus Dose* on page *98* for the procedure.

② The pump module keypad is used in the illustrations but the keys are the same for the syringe module.

③ An infusion can also be paused by pressing the **PAUSE** soft key (on PCU), if the Delay Options are disabled. To pause an infusion programmed with Delay Options enabled, see *Delay Options* on page *155* and *Pausing Infusion* on page *158*.

Changing Rate or VTBI During 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.

Restoring Infusion

1. To restart infusion using stored parameters, press the **RESTORE** soft key.[1][2]

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

NOTE:

[1] To restore a bolus dose, see *Bolus Dose* on page *98*.

[2] The restore option is only available if the system is powered up within 8 hours of the last use and when the prompt for **New Patient?** is selected as **No**.

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.[1][2]
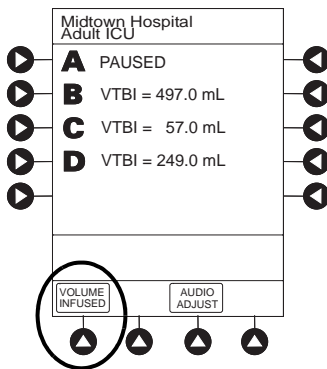
2. Pump module: To view primary and secondary volume(s) infused, press the **PRI/SEC VOLUME** soft key.
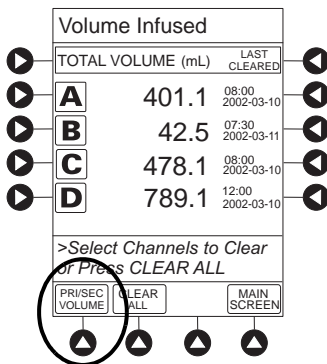
3. To clear volume infused:

    •   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.③④
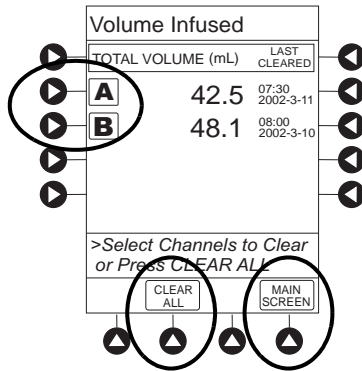
    •   To return to main screen, press the **MAIN SCREEN** soft key.③
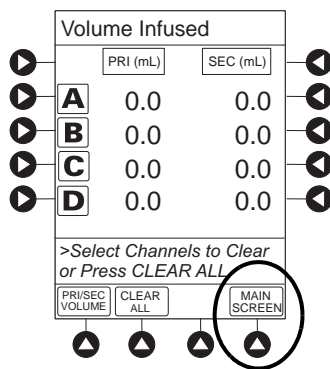
NOTE:

①   Date format is year-month-day.

②   Pump module: A **PRI/SEC VOLUME** soft key is available to allow secondary volume infused to be displayed.

③   If no key is pressed, main screen appears after 30 seconds.

④   The illustrated example is a syringe module display. A pump module display has a PRI/SEC VOLUME soft key.

Channel Labels

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

Selecting

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

2. Press the **OPTIONS** key.

3. Syringe module: Press the **PAGE DOWN** soft key.
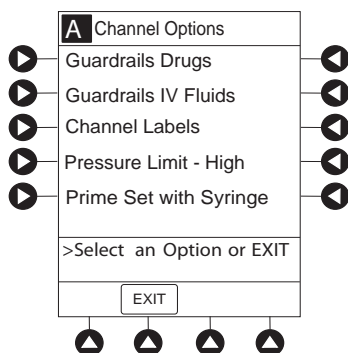
4. Press the **Channel Labels** soft key.
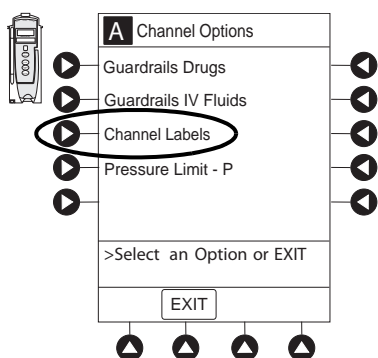
5. Press the soft key for desired label.[1]

    •   Selected label is highlighted and scrolls in Message Display.
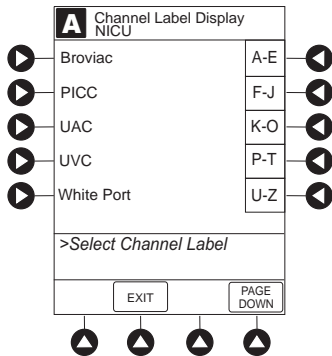
6. To continue infusion, press the **START** soft key.

    or

    Program infusion as previously described.

NOTE:

[1] 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.

Removing

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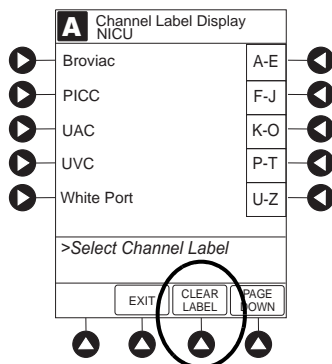
6. To begin infusion, press the **START** soft key.

    or

    Program infusion as previously described.

Anesthesia Mode

See *Anesthesia Mode* on page *34* for more information.

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.

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

Delaying Infusion

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

Specifying by Minutes

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

1. Press the **DELAY OPTIONS** soft key.
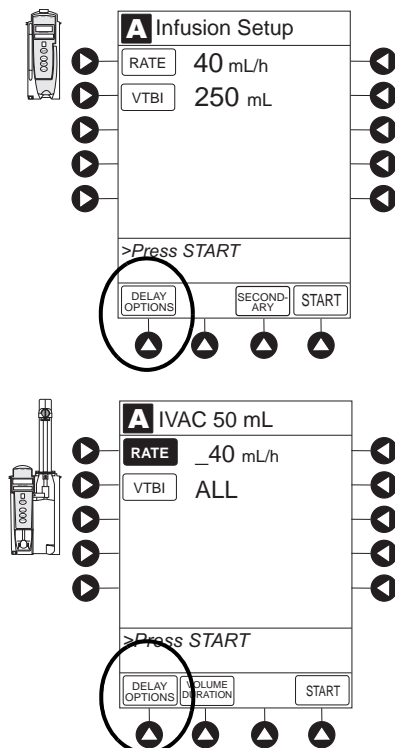
2. Press the **Delay for** soft key.
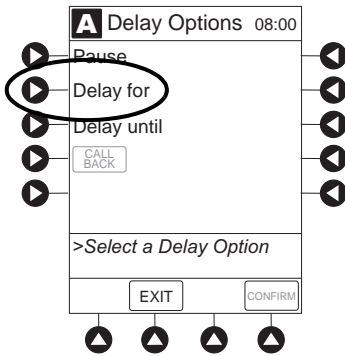
3. To enter number of minutes (up to 120) infusion is to be delayed for, use numeric data entry keys.

4. Press 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 *157*), infusion automatically initiates at end of delay period.

Specifying by Time of Day

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

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

2. Press the **Delay until** soft key.
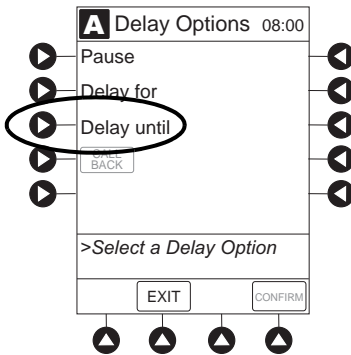
3. If **Current time** displayed is correct, press the **CONFIRM** soft key; otherwise, press the **Change Time** and enter correct time. (See *System Options* on page *28* and *Setting Time of Day* on page *41*.)[1]
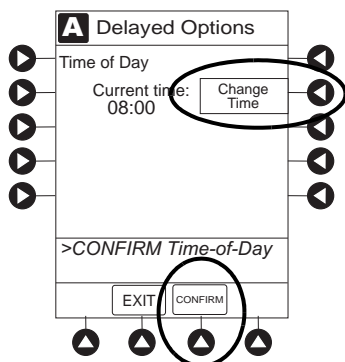
4. To enter time of day infusion is to be initiated (up to 23 hours 59 minutes), use numeric data entry key.

5. Press the **CONFIRM** soft key.

   • Time infusion is scheduled to start appears on Main Display.

   • If a **Before** callback has not been scheduled (see *Scheduling a Callback* on page *157*), infusion automatically initiates at the end of the delay period.

NOTE:

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

Scheduling a Callback

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

• **Before**—gives an alert when delay period is completed and infusion needs to be initiated.

• **After**—gives an alert when delayed infusion has completed.

• **Before** and **After**—gives an alert when delay period is completed and infusion needs to be initiated and when delayed infusion has completed.
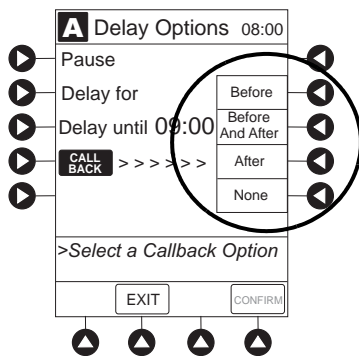
The default callback (After), or the callback for the current profile, appears on the Main Display. To schedule a different callback:

1. Prior to pressing **CONFIRM** soft key to initiate delay during **Delay for** or **Delay until** programming process, press the **CALL BACK** soft key.

2. Press the soft key corresponding to desired callback option.

   Scheduled callback appears on Main Display.

3. To initiate delay, press the **CONFIRM** soft key.

    •   If **Delay until** programming, time infusion is scheduled to start appears on Main Display.

    or

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

    •   If **Before** option was selected:

        ◦   An audio prompt sounds when delay period has ended.

        ◦   Yellow Standby Status Indicator flashes.

        ◦   **DELAY COMPLETE** scrolls in Message Display and appears on Main Display.

    •   If **After** option was selected:

        ◦   An audio prompt sounds when delayed infusion completes, and continues to sound until responded to.

        ◦   Yellow Standby Status Indicator flashes until audio is silenced.

        ◦   Infusion completed message appears on Main Display.

        ◦   **Infusion Complete** scrolls in Message Display.

    •   If **Before and After** option was selected, same prompts and indicators mentioned above for both **Before** and **After** options are exhibited.

4. To respond to a callback:

    •   **Before** callback:

        Press 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 Infusion

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

2. Press the **Pause** soft key.[①]

    If an alert has occurred, pause is not initiated by system until alert is addressed.
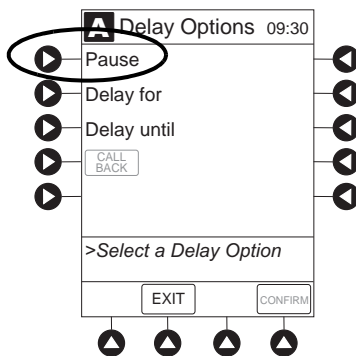
3. Press the **CONFIRM** soft key.

- • **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 reinitiate infusion:

- • Press the **RESTART** key.

   or

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

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

Select Pressure Limit

Pump Module

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

2. Press the **OPTIONS** key.
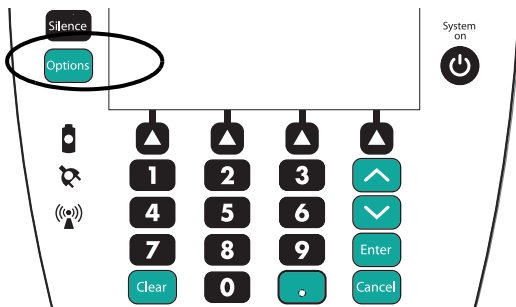
3. Press the **PRESSURE LIMIT** soft key.
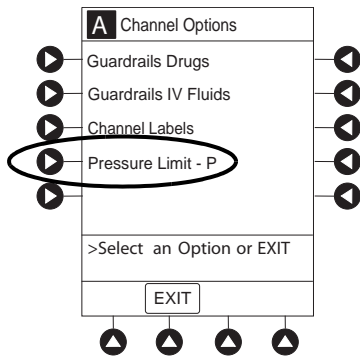
4. Press either the **Pump** or **Selectable** pressure soft key. If **Selectable** is pressed, continue with next step; otherwise, proceed to last step.
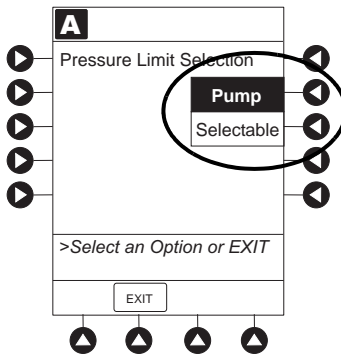
5. To select occlusion pressure limit, press either the **Up** or **Down** soft key.
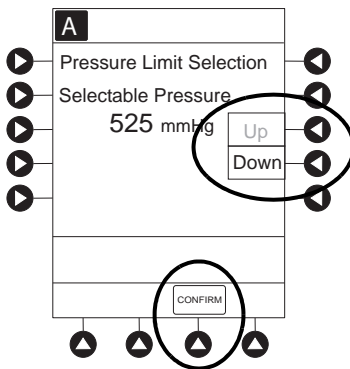
6. Verify correct occlusion pressure limit input and press the **CONFIRM** soft key.

7. Press the **START** soft key.

Syringe Module

Pressure Sensing Disc Installed

⚠ **WARNING**

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

1. Ensure that pressure sensing disc is installed correctly.

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

3. Press the **OPTIONS** key.
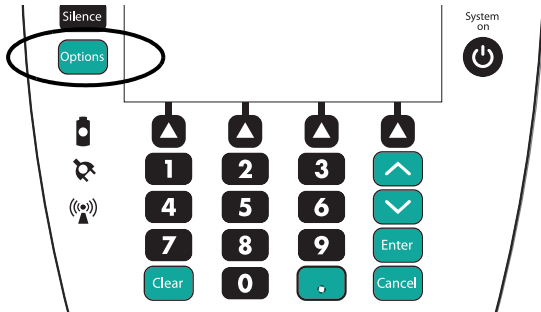
4. Press the **Pressure Limit** soft key.
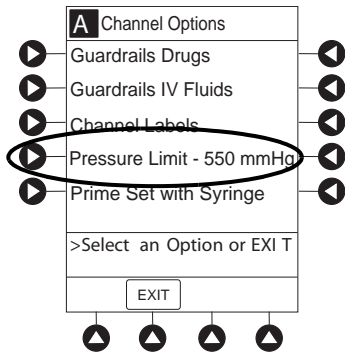
5. To enter a new pressure limit value, press the **Change Value** soft key.[1]

    or

    If Auto Pressure feature is enabled, press the **Auto Pressure** soft key.[2]

```
┌─────────────────────────────┐
│  ▐A▌                        │
│ ▶│Pressure Limit Selection ◀│
│ ▶│Current pressure         ◀│
│ ▶│  30 mmHg                ◀│
│ ▶│Current limit  ┌───────┐ ◀│
│ ▶│               │ Auto  │   │
│   │ _ 550 mmHg   │Pressure│◀ │
│   │              │Change │   │
│   │              │ value │ ◀ │
│   │                        │
│   │      ┌─────────┐        │
│   │      │ CONFIRM │        │
│   │      └─────────┘        │
│    ▲     ▲    ▲    ▲         │
└─────────────────────────────┘
```

⚠

WARNING

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

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

*   **Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance of the syringe stopper. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.**

*   **Use the Prime Set with Syringe feature on the pump when changing a syringe and/or tubing.**

*   **Use accessory devices, which have the smallest internal volume or deadspace (for example, use microbore tubing when infusing at low rates, shorter length of tubing, and so on).**

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

NOTE:

① The optimal occlusion alarm limit setting achieves a balance between the risk of false alarms and timely response to occlusions. To avoid interruptions in therapy, the limit should be set at a value higher than the expected actual "working" pressure, which will allow normal events such as patient movement and titrations to occur without alarms.

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

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

② If Auto Pressure is selected and current pressure is:

- 100 mmHg or less – system adds 30 mmHg to current pressure to create a new alarm limit
- greater than 100 mmHg – system adds 30% to current pressure to create a new alarm limit

Pressure Sensing Disc NOT Installed

⚠️ **WARNING**

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

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

2. Press the **OPTIONS** key.

3. Press the **Pressure Limit** soft key.
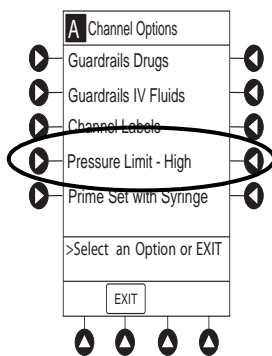
4. To select a pressure limit, press the appropriate soft key.

5. Press the **CONFIRM** soft key.

⚠ **WARNING**

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

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

- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance of the syringe stopper. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.**

- **Use the Prime Set with Syringe feature on the pump when changing a syringe and/or tubing.**

- **Use accessory devices, which have the smallest internal volume or deadspace (for example, use microbore tubing when infusing at low rates, shorter length of tubing, and so on).**

General Setup and Operation

System Start Up/Setup

See *BD Alaris™ Pump Module Model 8100, Alaris™ Pump Module Model 8100, and Alaris™ Syringe Module Model 8110* on page *61* and *General Setup and Operation* on page *18* for various system start-up and setup procedures.

Setting Up for Gravity Infusion (Pump Module)

1. Prime administration set (see *Getting started*, *Adjust the flow rate using set's roller clamp.Prime* on page *79* for the procedure).

2. Adjust container to hang 20 inches above patient's vascular access device.

3. Attach administration set to patient's vascular access device.

4. Adjust flow rate with administration set roller clamp.

Changing Solution Container (Pump Module)

1. To stop infusion, press the **PAUSE** key.

2. Close roller clamp.

3. Remove empty solution container.

4. Insert administration set spike into prepared fluid container, following accepted hospital/facility procedure, and hang container 20 inches above pump module.

5. Press 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 Syringe During Infusion (Syringe Module)

If a critical medication is being infused at a flow rate less than1.0 mL/h and the patient is not stable enough to experience even a short period of time without the drug, it is recommended that the new syringe and administration set be installed as part of a second 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.
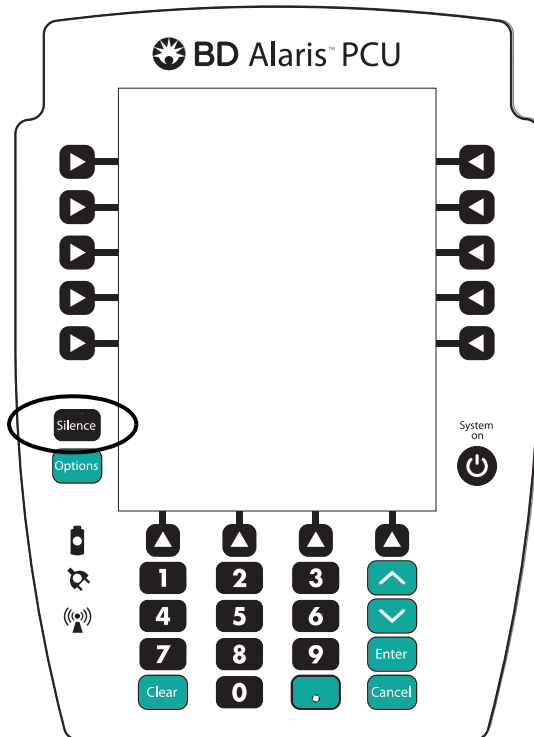
   • Red Alarm Status Indicator flashes.

   • **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.
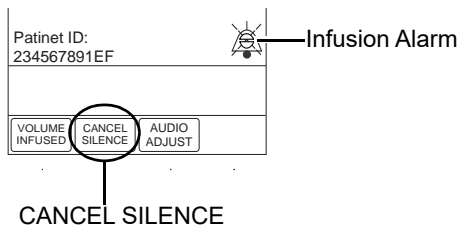
3. Remove syringe and separate administration set from syringe.

4. Reattach administration set to new syringe and load new syringe (see *Preparing Syringe and Administration Set (Syringe Module)* on page *71*).

5. Select syringe type and size (see *Manual Programming with Guardrails™ Suite MX* on page *88*).

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

7. Prime administration set using options menu or manually (see *Prime—Using Options Menu* on page *79*, *Priming Administration Set With No Pressure Sensing Disc* on page *84*, and *Prime—Manual* on page *84*).

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.

General Information

Warnings and Cautions

General

⚠️ **WARNING**

- Ensure syringe sizes and models are compatible with the syringe module. The use of any other syringe or administration set can cause improper pump operation, resulting in inaccurate fluid delivery, insufficient occlusion (blockage) sensing, or other potential hazards.

- Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h). Using a larger syringe when infusing at low rates can lead to inadequate syringe pump performance including delivery inaccuracies, delay of therapy, and delayed generation of occlusion alarms. This is due to the increased friction and compliance of the syringe stopper with larger syringes.

- Ideally, the syringe module should be level with the patient's heart. If the syringe module height is raised relative to the patient's heart level (for example, during patient transport), the increase in height of the syringe module can result in a temporary increase in fluid delivery or bolus until the flow rate stabilizes. Alternatively, if the syringe module is lowered relative to the patient's heart level, the decrease in the height of the syringe module may result in a decrease in delivery or under-infusion until the flow rate stabilizes.

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

- During programming and prior to starting an infusion, verify that the syringe size and model on the PCU display screen matches the syringe size and model loaded into the syringe module.

- The pump and syringe modules are designed to stop fluid flow under alarm conditions. Periodic patient monitoring must be performed to ensure that the infusion is proceeding as expected. It is a positive displacement delivery system, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters, and intra-arterial infusion. It is neither designed nor intended to detect infiltrations and does not alarm under infiltration conditions.

- The use of positive displacement infusion devices ported together with gravity flow infusion systems into a common IV site can impede the flow of common "gravity only" systems, affecting their performance. Hospital/ facility personnel must ensure that the performance of the common IV site is satisfactory under these circumstances.

- To prevent a potential free-flow condition, ensure that no extraneous object (for example, bedding, tubing, glove) is enclosed or caught in the pump module door.

⚠️ ▬ **CAUTION** ▬

- Use compatible components which have the smallest internal volume or "deadspace" to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times.

- Minimize the height difference between the pump and the patient and avoid changes in the height of the syringe module (for example, during transport of critically ill patients) to prevent unintended fluctuations in the flow rate.

- If using multiple syringe pumps and it is not clinically feasible to have all pumps level with the patient's heart, place the high risk or life-sustaining medications as close to the heart level as possible. When infusing multiple high risk or life-sustaining medications, consider placing the ones infusing at the lowest rates as close to the level of the patient's heart as possible.

- Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (for example, 50 - 200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (for example, < 5 mL/h, and especially flow rates < 0.5 mL/h).

Administration Sets

⚠️ **WARNING**

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

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

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

- **Use only BD Alaris Pump Infusion administration sets with the pump module. The use of any other set can cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard. For a list of compatible sets, refer to the *Alaris^{TM} Pump Module Set Compatibility Card* and the *Alaris^{TM} Syringe Module Set Compatibility Card*.**

- **Use only standard, approved, single-use, disposable syringes with luer-lock connectors, and administration sets designed for use on syringe pumps. The use of any other syringe or administration set can cause improper instrument operation, resulting in an inaccurate fluid delivery or pressure sensing, or other potential hazards.**

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

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

- **Ensure that the displayed syringe manufacturer and syringe size correctly identifies the installed syringe. Mismatches can cause an under-infusion or over- infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page *175*.**

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

NOTE:
① For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page *175*. For a list of compatible administration sets, refer to the *Alaris™ Syringe Module Set Compatibility Card* and the *Alaris™ Pump Module Set Compatibility Card*.

⚠️ **CAUTION**

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

Occlusions

⚠️ **WARNING**

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

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

- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance of the syringe stopper. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.**

- **Use the Prime Set with syringe feature on the pump when changing a syringe and/or tubing.**

- **Use accessory devices, which have the smallest internal volume or deadspace (for example, use microbore tubing when infusing at low rates, shorter length of tubing, and so on).**

⚠️ **WARNING**

When addressing or clearing an occlusion:

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

- **Using a set with a pressure sensing disc and Back Off (after occlusion) enabled will cause the motor to reverse plunger movement during an occlusion until pressure returns to preocclusion levels, automatically reducing bolus flow.**

- **Being aware that using larger size syringes on a high plunger force setting may produce a larger post occlusion bolus due to excessive syringe stopper compliance.**

Epidural Administration

⚠️ **WARNING**

- Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.

- It is strongly recommended that the source container, administration set, and pump module used for epidural drug delivery be clearly differentiated from those used for other types of administration.

- It is strongly recommended that the syringe, administration set, and syringe module used for epidural drug delivery be clearly differentiated from those used for other types of administration.

- The system can be used for epidural administration of anesthetic and analgesic drugs. This application is only appropriate when using anesthetics and analgesics labeled for continuous epidural administration and catheters intended specifically for epidural use. Use only a BD Alaris Pump Infusion administration set or syringe set, without a 'Y' connector or injection port, for epidural infusions.

  - Epidural administration of anesthetic drugs: Use indwelling catheters specifically indicated for short-term (96 hours or less) anesthetic epidural drug delivery.

  - Epidural administration of analgesic drugs: Use indwelling catheters specifically indicated for either short- term or long-term analgesic epidural drug delivery.

Guardrails^{TM} Suite MX

⚠️ **WARNING**

- The Guardrails Suite MX incorporates dosing limits and instrument configuration parameters based on hospital/facility protocol. The software adds a test of reasonableness to drug programming based on the limits defined by the hospital/facility. Qualified personnel must ensure that the appropriateness of drug dosing limits, drug compatibility, and instrument performance, as part of the overall infusion. Potential hazards include drug interactions, inaccurate delivery rates and pressure alarms, and nuisance alarms.

- When loading a data set with the Guardrails Suite MX, ensure that the correct profile (for patient care area) is selected prior to starting an infusion. Failure to use the appropriate profile could cause serious consequences.

Administration Set/Syringe Information

Infusion modules:

- For specific administration set instructions and replacement interval, refer to user manual provided with set.

- For a listing of compatible pump module and syringe module administration sets, refer to the *Alaris™ Pump Module Set Compatibility Card* and the *Alaris™ Syringe Module Set Compatibility Card*.

- Use aseptic techniques when handling sets and syringes.

- Administration sets are supplied with a sterile and nonpyrogenic fluid path for one-time use. Do not resterilize.

- Discard administration set per facility protocol.

- For IV push medication (put instrument on hold), clamp tubing above port.

- Do not administer IV pushes through ports that are above the system.

- Flush port(s) per facility protocol.

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

- Primary set must be primed before use. It can be loaded into pump module to deliver a large volume infusion or it can be set up to deliver a gravity infusion.

- Safety clamp fitment is a unique clamping device on the pumping segment that is part of all BD Alaris Pump Infusion sets (see *Safety Clamp Fitment (Pump Module)* on page *174*).

The syringe module uses standard, single-use, disposable syringes (with luer-lock connectors) and administration sets designed for use on syringe pumps. For a list of compatible syringes, refer to *Compatible Syringes (Syringe Module)* on page *175*.

SmartSite Infusion Set (Pump Module)

1. Prior to every access, swab top of Needle-Free Valve port with 70% isopropyl alcohol (1 - 2 seconds) and allow to dry (approximately 30 seconds).[1]

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

3. Replace every 96 hours or after 100 activations, whichever occurs first. For infusions of blood, blood products or lipid emulsions, replace every 24 hours.

NOTE:

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

⚠ **CAUTION**

- If the Needle-Free Valve is **accessed by a needle** in an emergency, the valve will be damaged, causing leakage. Replace the Needle-Free Valve immediately.

- The Needle-Free Valve is **contraindicated** for blunt cannula systems.

- Do not leave **slip luer syringes** unattended.

Safety Clamp Fitment (Pump Module)

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

Safety Clamp Fitment in Open Position

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

Blue Fitment

White Slide Clamp
(shown in open position)
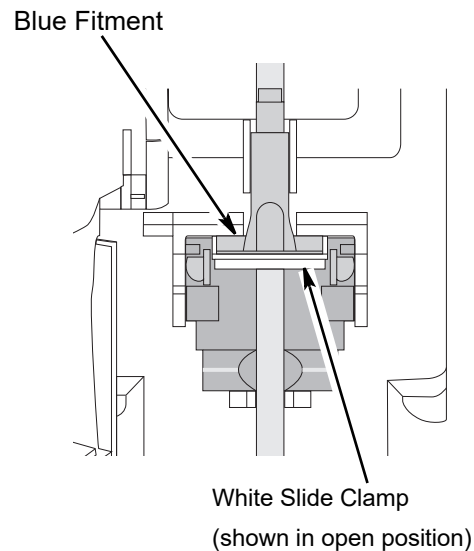
Safety Clamp Fitment in Closed Position

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

Blue Fitment

White Slide Clamp
(shown in open position)
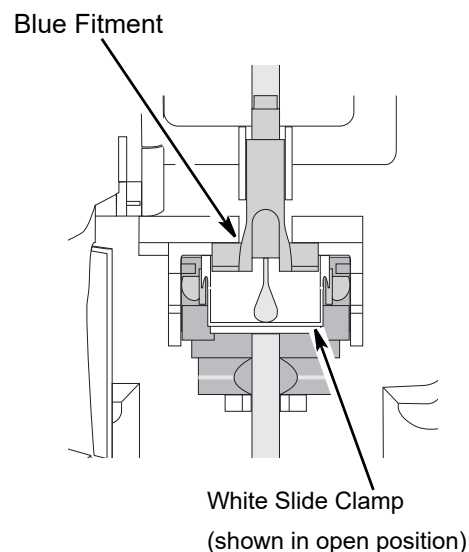
Compatible Syringes (Syringe Module)

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

⚠️ **CAUTION**

When 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.

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

Manufacturer	1 mL	3 mL	5 mL	6 mL	10 mL	12 mL	20 mL	30 mL	35 mL	50 mL	60 mL
BD Plastipak	✗	✗	✗		✗		✗	✗		✗	✗
Monoject		✗[1]		✗		✗	✗		✗		✗
Terumo		✗	✗[2]		✗[2]		✗	✗[2]			✗

NOTE:

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

[2] The Terumo 5 mL can also be used as a 6 mL, the 10 mL as a 12 mL, and the 30 mL as a 35 mL.

Features and Displays

Features and Definitions

See *Features and Definitions* on page *52* 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 *155* for a definition) can be scheduled to give an alert **Before** an infusion is to be initiated, **After** an infusion is completed, **Before and After** an infusion, or no alert (**None**).
Channel Labels	Available when profiles feature is enabled. It provides a hospital-defined list of labels, displayed in Channel (module) Message Display, and identifies module with catheter location or other helpful information.
Concentration Limits	Limits specified for range of concentrations allowed for a particular drug in a profile.
Delay Options	Allows system to be programmed to delay start of an infusion **a)** for up to 120 minutes or **b)** for a specific time up to 23 hours 59 minutes.
Dose Checking	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 *Displays* on page *184* and *Dynamic Pressure Display* on page *184* for more information.)
Event Logging	Event Logging records instrument operations.
Initial Value	An optional and editable starting value for Continuous Infusion dose, duration, bolus dose, bolus rate of administration or bolus dose duration.

Feature	Definition—Pump and Syringe Modules
IV Fluid Library	An optional library consisting of IV Fluids (for example, TPN) and limits around rate of delivery (mL/h).
Limit	A programming limit or best-practice guideline determined by hospital/health system and entered into system's data set. Supports concentration limits for all infusions that utilize concentration. Profile-specific limits can be defined for flow rate, patient weight, body surface area (BSA), maximum and minimum continuous dose, or total dose and duration for each drug in a drug library. Dose and duration limits can be defined by hospital/health system as a hard and/or soft limits. A hard limit is a programmed limit that cannot be overridden, except in anesthesia mode. A soft limit is a programmed limit that can be overridden.
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. This option is only available if patient is not new and system is powered up within 8 hours of last usage.
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 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 which can be configured by profile in 25 mmHg increments.
Free Flow Protection	All BD Alaris Pump Infusion administration sets use a unique clamping device (safety clamp on the lower fitment) to prevent inadvertent free-flow when administration set is removed from instrument.
KVO Rate Adjust	Used to select KVO (Keep Vein Open) rate (0.1 to 20 mL/h allowed), which is rate of fluid flow after an "Infusion Complete" occurs. KVO rate never exceeds infusion rate.
Occlusion Pressure	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 *178*.) 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 administration 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 only available when administration set in use has a pressure sensing disc. When enabled, motor reverses plunger movement during an occlusion until pressure returns to preocclusion levels, automatically reducing bolus flow.
Fast Start	When Fast Start is enabled and an administration set having a pressure sensing disc is used, instrument runs at an increased rate when an infusion is first started, taking up any slack in drive mechanism.
Infusion Complete	An alert is given when current infusion is complete and VTBI has reached zero.
KVO	If enabled, allows continuous infusions to automatically switch into KVO mode upon completion. KVO option setting cannot be changed after instrument is powered on and a profile selected.
Near End of Infusion (NEOI)[1]	Allows an alarm to be configured to sound anywhere from 1 to 60 minutes prior to the end of the infusion. The NEOI alarm can be configured separately between continuous type infusions and intermittent infusions. A separate alert time can be set for continuous and intermittent infusions.

NOTE:

[1] If the duration of the programmed infusion is less than or equal to the configured limit set in the 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 shared syringe and PCA setting.
Numeric Pressure Display	Dynamic pressure display is numerical and only available 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 instrument's pressure sensing capabilities for a faster occlusion detection time, and makes following features available: • Auto Pressure • Back-Off • Customizable Pressure Alarm Settings (see *Occlusion Pressure* on page *180*) • Fast Start • Pressure Tracking
Priming	Allows a limited volume of fluid to be delivered in order to prime administration set prior to being connected to a patient or after changing a syringe. When priming, a single continuous press of **PRIME** soft key delivers up to 2 mL of priming fluid.
Syringe Empty	Instrument gives an alert and stops when an empty syringe is detected.
Syringe Volume Detection	System automatically detects fluid volume in a syringe when it is inserted.

Operating Features, Controls, Indicators

Status Indicators

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

IUI Connector, Left

ALARM INFUSE STANDBY

BD Alaris™ Pump

RATE (mL/h)

CHANNEL SELECT

PAUSE

CHANNEL OFF

RESTART

Close clamp before opening door

IUI Connector, Right

Rate Display

Channel (module) Message Display

Channel (module) Identification

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

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

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

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

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

Door Handle

IUI Connector, Left
(not visible)

Upper Tubing Fitment
Retainer

IUI Connector,
Right

Platen

Upper Pressure
Sensor

Upper Occluder

Upper Pumping
Finger

Door Latch
Cam/Slide

Lower Occluder

Lower Pumping
Finger

Lower Pressure
Sensor

Safety Clamp
Sensor and
Door Sensor

Air-in-line
Sensor

Tubing Guide Arm
(BD Alaris pump module only)

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

Plunger Grippers (shown in closed position)

Status Indicators

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

Barrel Flange Grippers

IUI Connector, Left

Rate Display

Syringe Barrel Sensor

Message Display

ALARM   INFUSE   STANDBY

IUI Connector, Right

RATE (mL/h)

Channel (module) Identification

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

CHANNEL SELECT

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

PAUSE

CHANNEL OFF

Syringe Barrel Clamp/Sizer

RESTART

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

Pressure Transducer/Pressure Sensing Disc Housing

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

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

Displays

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

Main Display

See *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* for more information.

Dynamic Pressure Display

Dynamic Pressure Display

Current operating pressure is indicated by solid bar.

Patient-side occlusion pressure set point is indicated by tick mark.

The tick mark moves when the Pressure Limit changes.
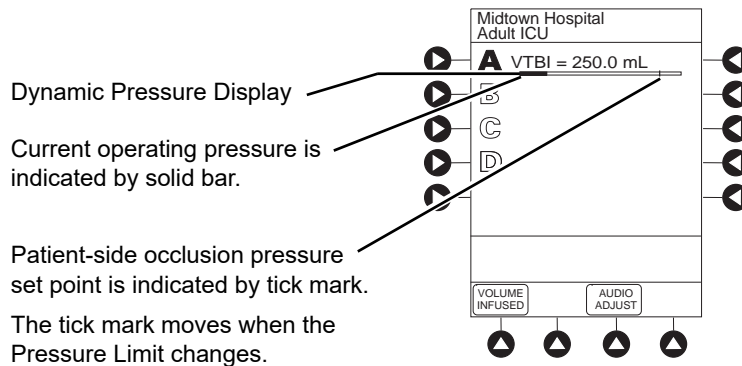
⚠ **CAUTION**

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

Drug Calculation Definitions and Formulas

⚠️ **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

See *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* for system configurable settings.

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

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

Shared Infusion

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

Pump Module

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

Feature	Default Setting	Options
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

Syringe Module

Feature	Default Setting	Options
ALL Mode	Disabled	Enabled - Disabled
Auto Pressure	Disabled	Enabled - Disabled
Back Off (after occlusion)	Enabled	Enabled - Disabled
Fast Start	Enabled	Enabled - Disabled
KVO (Keep Vein Open) • 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 Point cannot be set higher than the default setting.

Specifications

Pump Module

Accumulated Air Window:

Single Bolus Setting (mcL)[1]	Volume Window (mL)	% Air that Causes Alarm	Volume (mL) that Causes Alarm
50	2.8	10%	0.28
75	8.0	20%	1.6
125	8.0	20%	1.6
175	8.0	20%	1.6
250	8.0	30%	2.4
500[2]	12.0	30%	3.6

NOTE:

[1] In a standard bore tubing set:
- 50 mcL is approximately 0.34 inches of air
- 75 mcL is approximately 0.51 inches of air
- 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

[2] In Anesthesia Mode only.

Bolus Volume, Maximum after Occlusion:

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

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

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

Environmental Conditions:

Symbols	Meaning	Operating	Storage/Transport
	Atmospheric Pressure	525 - 4560 mmHg (70 - 608 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)

Air-In-Line Settings, with Tolerance Non-Lipids: 50 ± 20, 75 ± 30, 125 ± 50, 175 ± 70, or 250 ± 100 mcL (500 ± 100 mcL in Anesthesia Mode)
Lipids: 50 ± 35, 75 ± 45, 125 ± 50, 175 ± 70, or 250 ± 100 mcL, where testing is limited to 125 mL/h or less. (500 ± 100 mcL in Anesthesia Mode)

Infusion Pressure, Maximum: 654 mmHg (Maximum Occlusion Alarm Threshold 525 mmHg, plus tolerance 129 mmHg)

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

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

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

Operating Principle: Positive displacement

Rate Accuracy: Rate accuracy of the system is ±5% at rates between 1 and 999 mL/h and ±5.5% at rates <1 mL/h, 95% of the time with 95% confidence, under conditions listed below.

Infusion Rate Range:	0.1 - 999 mL/h
Ambient Temperature:	68 ±4°F (20 ±2°C)
Source Container Height:	20 (+/- 2%) inches above top of pump module
Test Solution:	Distilled Water
Distal Back pressure:	0 mmHg (0 kPa)
Needle:	18 gauge
Administration Set Model:	2210

⚠️

WARNING

Variations of head height, back pressure, or any combination of these can affect time to alarm for occlusions and rate accuracy. Factors that can influence head height and back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure can also be affected by type of catheter. See *Trumpet and Start-Up Curves* on page *195* for data on how these factors influence rate accuracy.

Shock Protection: Type CF, defibrillation-proof patient applied part.

Time to Alarm, Maximum:

Pressure Limit (mmHg)	Rate (mL/h)	Time to Alarm
50	0.1	≤50 minutes
50	1	≤5 minutes
50	25	≤15 seconds
525	0.1	≤7.5 hours
525	1	≤45 minutes
525	25	≤2 minutes

Volume to be Infused Programming Increments:

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

Weight: 2.6 lbs

NOTE:
The minimum Volume To Be Infused (VTBI) for both pump and syringe modules (applicable to all syringe sizes) is 0.1mLs. This applies to Continuous Infusions, bolus dose, Intermittent Infusions, and IV Fluids. The set length and temperature of the administration set can affect occlusion time to alarm. Increases in temperature and increases in length may increase time to alarm.

Syringe Module

Bolus Volume, Maximum after Occlusion:

Bolus Volume, Maximum after Occlusion is measured using two different setups.
The first setup simulates an actual clinical setup and includes a device at heart height, a full length administration set, and an 18 gauge needle at the end of the administration set. Test setup uses a BD 50/60 mL syringe at 5 mL/h.

> **WARNING**
>
> **Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates.**

The second setup is a laboratory test setup that includes a 1 meter administration set, a device above the height of the collection container, rigid tubing connecting the administration set to a pressure transducer, and no needle at the end of the administration set.

Clinical Simulation Test Setup

Without Pressure Sensing Disc:

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

With Pressure Sensing Disc:

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

Laboratory Test Setup

Without Pressure Sensing Disc:

Pressure Setting	Bolus Volume (mL)
Low	0.350
High	0.560

With Pressure Sensing Disc:

Pressure Setting	Bolus Volume (mL)	
	Back Off Disabled	Back Off Enabled
25 mmHg	0.170	0.160
1000 mmHg	0.610	0.450

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

⚠️

WARNING

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

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

Atmospheric Pressure: 645 - 795 mmHg
Disposable Type:
   No Pressure Disc: #30914
   With Pressure Disc: #10014917
Humidity: 20 - 90%
Rate: 5 mL/h
Syringe Type: BD 50/60 mL (Clinical), BD 20 mL (Laboratory)
Temperature: 68 ±4°F
Volume Collection Time: approximately 2 minutes

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

Dimensions: 4.75" W x 15.0" H x 7.5" D

Environmental Conditions:

Symbols	Meaning	Operating	Storage/Transport
	Atmospheric Pressure	525 - 4560 mmHg (70 - 608 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

Infusion Pressure, Maximum:

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

KVO (Keep Vein Open) Rate:

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

KVO Rate Range:	KVO rate can be set in System Configuration, in 0.01 mL/h increments, as follows: 0.01 - 2.5 mL/h (0.01 - 0.09 mL/h available for 1 mL and 3 mL syringes)
Occlusion Alarm Thresholds:	Without Pressure Sensing Disc: Three settings—Low, Medium, High With Pressure Sensing Disc: User selected, 25 - 1000 mmHg in 1 mmHg increments.
Operating Principle:	Positive displacement
Rate Accuracy:	±2% of full scale plunger travel (not including syringe variation)

⚠️ **WARNING**

Syringe size and running force, variations of back pressure, or any combination of these can affect time to alarm for occlusions and rate accuracy. Factors that can influence back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure can also be affected by type of catheter. See *Trumpet and Start-Up Curves* on page *195* for data on how these factors influence rate accuracy.

Shock Protection:	Type CF, Defibrillator-Proof

Time to Alarm, Maximum:

	High Pressure Limit	
Rate (mL/h)	**No Disc High Setting**	**With Disc Highest (1000 mmHg) Setting**
0.1	30 hours	24 hours
1	120 minutes	105 minutes
5	30 minutes	30 minutes

	Low Pressure Limit	
Rate (mL/h)	**No Disc Low Setting**	**With Disc Lowest (25 mmHg) Setting**
0.1	11 hours 30 minutes	4 hours 7 minutes
1	50 minutes	17 minutes
5	23 minutes	9 minutes

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

Atmospheric Pressure:	645 - 795 mmHg
Back Pressure:	0 mmHg before producing occlusion
Disposable Type:	
No Pressure Disc:	#30914
With Pressure Disc:	#10014917
Humidity:	20 - 90%
Syringe Type:	BD 50/60 mL
Temperature:	68 ±4°F

Volume to be Infused Programming Increments:	Range (mL)	Increments (mL)
	0.01 - 9.99	0.01
	10 - 60	0.1

Weight: 4.5 lbs

Bolus Accuracy:

Syringe	Disposable Set	Bolus (Set Value)	Calculated Percentage Deviation from Set Value	Maximum Positive Deviation from Set Value	Maximum Negative Deviation from Set Value
BD 60 ml 309653	30914	Maximum 60 mL	2.68 %	0.110 mL	- 1.022 mL
BD 5 ml 302135	30914	Minimum 0.1 mL	8.2 %	0.069 mL	- 0.050 mL
BD 60 ml 309653	10014914	Maximum 60 mL	2.5 %	0.020 mL	- 3.9278 mL
BD 5 ml 302135	10014914	Minimum 0.1 mL	9.4 %	0.063 mL	-0.088 mL

NOTE:
The minimum Volume To Be Infused (VTBI) for both pump and syringe modules (applicable to all syringe sizes) is 0.1mLs. This applies to Continuous Infusions, bolus dose, Intermittent Infusions, and IV Fluids. The set length and temperature of the administration set can affect occlusion time to alarm. Increases in temperature and increases in length may increase time to alarm.

Trumpet and Start-Up Curves

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

• Accuracy during various time periods over which fluid delivery is measured (trumpet curves).

• Delay in onset of fluid flow when infusion commences (start-up curves).

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

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

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

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

Pump Module

Effects of Pressure Variations

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

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

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

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

Effects of Negative Solution Container Heights

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

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

Ambient Temperature: 68 ±4°F (20 ±2°C)

Test Solution: ISO Class III Distilled Water

Sample Size: 1 pump module

Needle Type: 18 gauge

Administration Set Model: #2210

Syringe Module

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

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

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

Ambient Temperature: 68 ±4°F (20 ±2°C)

Test Solution: ISO Class III Distilled Water

Sample Size: 1 syringe module

Syringe Type: 5 mL syringe for 1 mL/h, and 20 mL syringe for 5 mL/h Administration Set Model: # 30914

Administration Set Model: #10014917, #10014914

Graphs

Pump Module

Start-up at 0.1 mL/h (initial)

Start-up at 1 mL/h (initial)

Trumpet Curve at 0.1 mL/h (initial)

Trumpet Curve at 1.0 mL/h (initial)

Trumpet Curve at 0.1 mL/h (96 hrs)

Trumpet Curve at 1.0 mL/h (96 hrs)
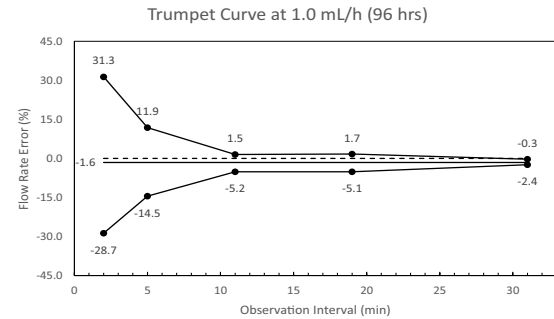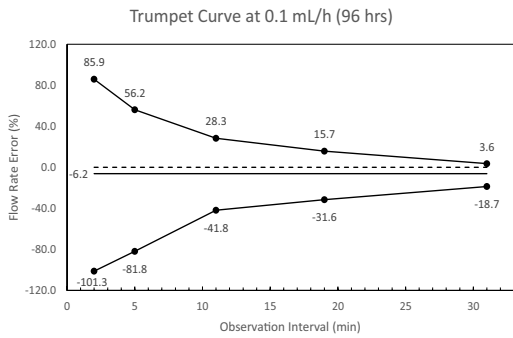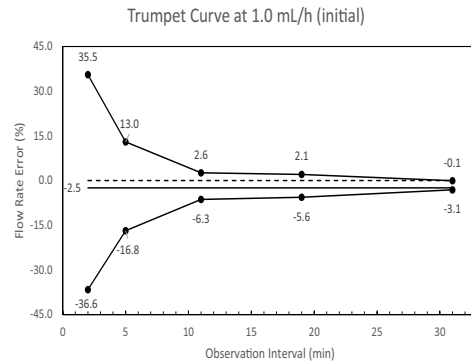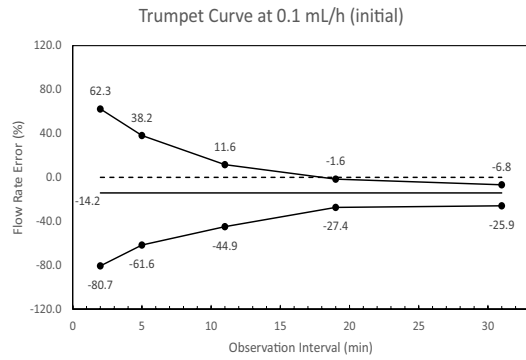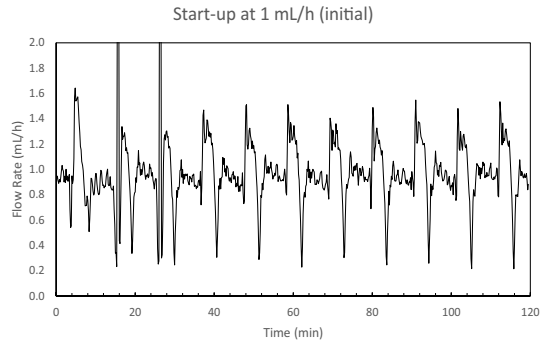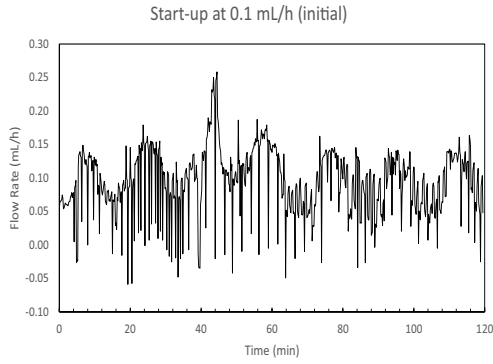
Legend:
- ■ Maximum rate error
- ▬ Overall rate error
- ◆ Minimum rate error

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

Start-up at 25 mL/h (initial)

Start-up at 999 mL/h (initial)

Trumpet Curve at 25 mL/h (initial)

Trumpet Curve at 999 mL/h (initial)

Trumpet Curve at 25 mL/h (96 hrs)

Trumpet Curve at 999 mL/h (24 hrs)

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

Syringe Module

Trumpet Curve at 1 mL/h (Initial)

Start-Up Curve at 5 mL/h (Initial)

Trumpet Curve at 1 mL/h (Initial)

Trumpet Curve at 5 mL/h (Initial)

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

Chapter 4
Alaris™ PCA Module Model 8120

This chapter contains the following topics:

Getting Started

Introduction

⚠ **WARNING**

Read all instructions, for both the PCA module and PCU, before using the system.

This section of the user manual provides PCA module (model 8120) instructions and information. It is used in conjunction with:

- Drug product labeling
- *Syringe Module Model 8110 and PCA Model 8120 Technical Service Manual*
- PCU chapter of this manual (see *Getting Started* on page *16*)
- 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.

Administration Sets/Syringes: See *General Information* on page *241* for specific administration set and syringe instructions.

- Administration Set Information
- Compatible Syringes

Alarms, Errors, Messages: See *Troubleshooting and Maintenance* on page *323* for module-specific alarms, errors, and messages.

Contraindications: None known.

Electromagnetic Environment: See Appendix A, *Regulations and Standards* on page *354* and *Compliance* on page *354*.

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.

⚠ **WARNING**

Carefully locate the dose request cord to reduce the possibility of patient entanglement or strangulation.

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.

Red alignment marks

Latching Connector

Dose Request
Cord receptacle
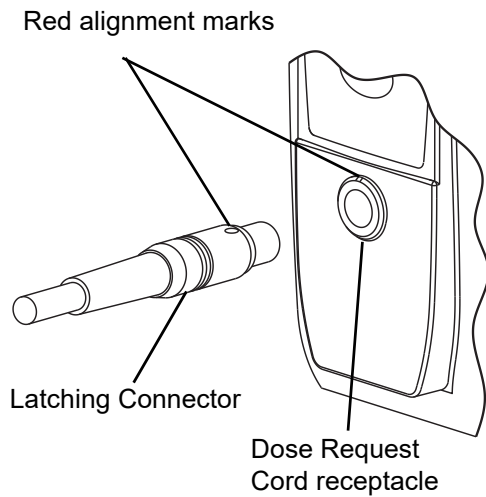
Detaching Dose Request Cord

Hold body of latching connector and pull straight out, without twisting or turning, from dose request cord receptacle.
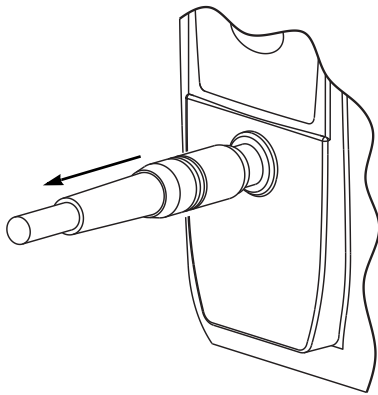
Prepare and Load Syringe and Administration Set

For instructions on how to go from checking in a PCA module to preparing it for an infusion setup, see *General Setup and Operation* on page *240*.

Preparing Syringe and Administration Set

⚠️ **WARNING**

Use only standard or pre-filled, single-use, disposable syringes (with luer-lock connectors) and nondedicated administration sets with integrated anti-siphon valves, designed for use on syringe-type PCA module pumps. The use of any other syringe or administration set can cause improper instrument operation, resulting in inaccurate fluid delivery, pressure sensing, or other potential hazards. For a list of compatible syringes, refer to page 244.

⚠️ **WARNING**

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

1. Prepare syringe (see *Compatible Syringes* on page *244*) in accordance with manufacturer's user manual.

2. Prepare administration set in accordance with manufacturer's user manual.

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

Loading Syringe and Administration Set

1. Open syringe barrel clamp.

   a. Pull syringe barrel clamp out and hold.

   b. Rotate clamp to left (clockwise or counter clockwise) until it clears syringe chamber.

   c. Gently release clamp.
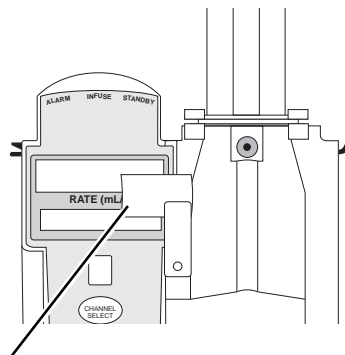
Syringe Barrel Clamp Open

2. Raise drive head to its fully extended position.

   a. Twist gripper control clockwise and hold in position.[1]

   b. While holding gripper control in open position, raise drive head to full extension.

   c. Gently release gripper control.

   Drive Head Fully Extended

   Gripper Control/Drive Head Release in Open Position

   Plunger Grippers Open
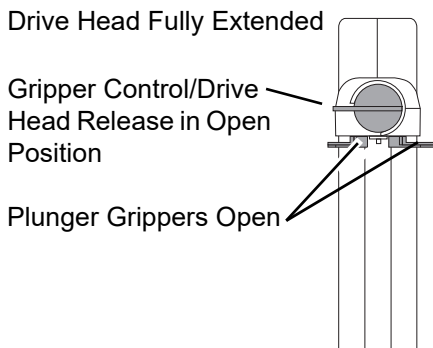
3. Insert syringe (from front of instrument) by sliding flat edge of syringe barrel flange between barrel flange grippers.

⚠ **WARNING**

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

⚠ **CAUTION**

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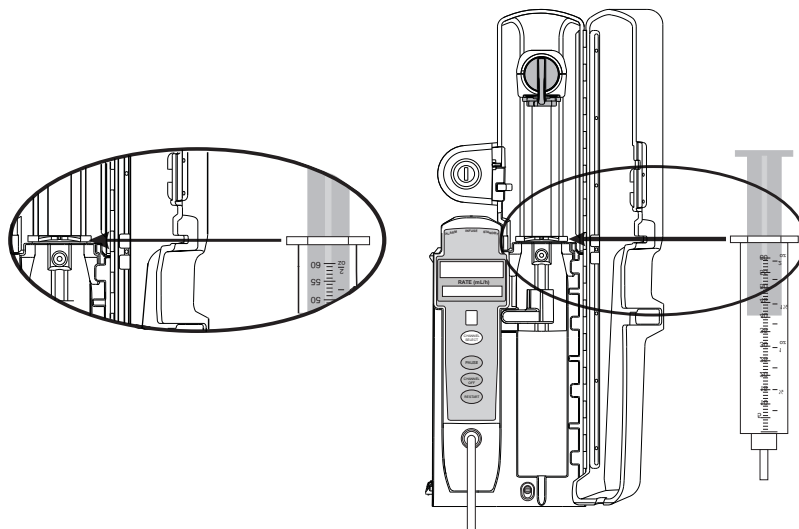
4. Lock syringe in place.

⚠️ **WARNING**

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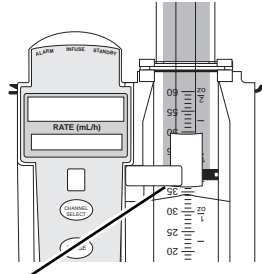
Syringe Barrel Clamp Closed

   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.
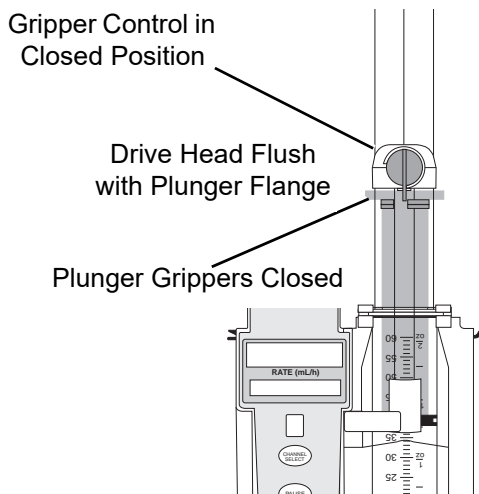
Gripper Control in
Closed Position

Drive Head Flush
with Plunger Flange

Plunger Grippers Closed

   a. Twist gripper control clockwise and hold in position.[1]

   b. While holding gripper control in open position, <u>gently</u> lower drive head until it makes contact with plunger flange.

   c. Gently release gripper control.

   d. Ensure that plunger grippers lock and hold plunger in place.

NOTE:

[1] 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.

Security Lock Key Positions

There are three key positions associated with the security lock:

- UNLOCK unlocks security door. Key must be in this position when loading or changing a syringe.

- PROGRAM allows for initial programming or changes in programming without unlocking security door or interrupting current infusion.[1]

- LOCK locks security door. Key must be in this position to start an infusion.

NOTE:

[1] See *Changing Programming Parameters During an Infusion* on page *224*.

Programming

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

See *Features and Displays* on page *245* and *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* for information about the following:

- Displays
- Operating Features, Controls, Indicators

Preparing Infusion

Selecting Syringe Type and Size

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

⚠️   **WARNING**

Ensure that the displayed syringe manufacturer and size correctly identifies the installed syringe. Mismatches can cause an under- infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, see *General Information* on page *241*, *Compatible Syringes* on page *244*. For a listing of administration sets, refer to the *Alaris™ Pump Module Set Compatibility Card* and the *Alaris™ Pump Module Set Compatibility Card*.

1. Press the **CHANNEL SELECT** key. Key must be in the **PROGRAM** position.
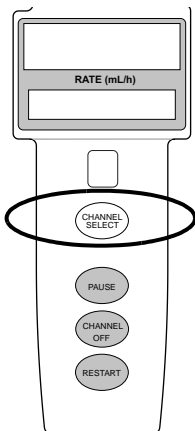
2. Press soft key next to installed syringe type and size. If installed syringe is not listed, press the **ALL SYRINGES** soft key and select syringe from list.

    - Selection is highlighted.

    - **CONFIRM** soft key is activated.
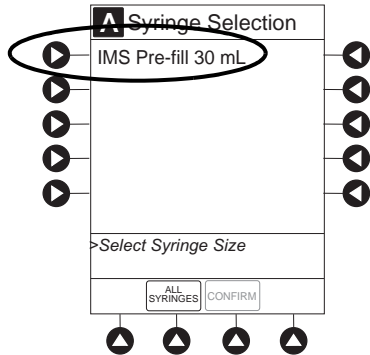
3. To accept, press **CONFIRM** soft key.

    Drug Library screen is displayed.

Priming

The priming option can be enabled at the time the system is configured for use. The priming selection (**PRIME** soft key) is available only after the syringe type and medication selection (prior to infusion mode selection).

 WARNING

When priming:

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

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

 CAUTION

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

1. Press **OPTIONS** key.
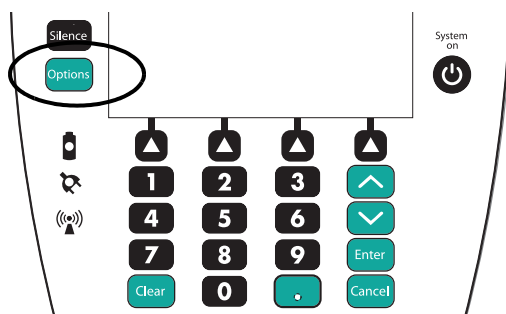
2. Press **Prime Set with Syringe** soft key.
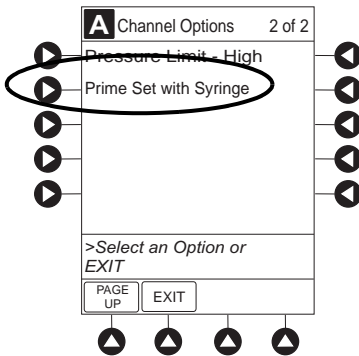
3. Press and hold **PRIME** soft key until fluid flows and priming of syringe administration set is complete.

    • Volume used during priming is displayed but is not added to **VTBI**.

    • Fluid is delivered during priming only while 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. (see *Rate restriction by syringe size:* on page *252*) of priming/fluid per continuous press. To deliver additional amounts, press **PRIME** soft key again.
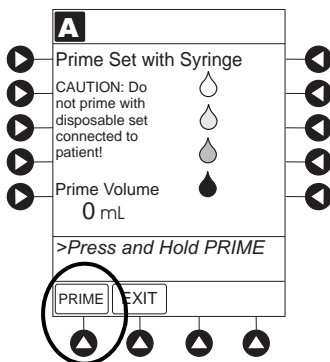
4. When priming is complete, release the **PRIME** soft key.

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

    Guardrails Drug Setup screen is displayed.

6. Select infusion mode**.**

Programming an Infusion

1. Perform steps in *Getting started* on page *62* and *Preparing Syringe and Administration Set (Syringe Module)* on page *71*.

2. Perform the following steps (see *General Setup and Operation* on page *18* and *Start-Up* on page *21* for more information):

    a. Power on system.

    b. Choose **Yes** or **No** to **New Patient?**

    c. Select profile, if required.

    d. Enter patient identifier, if required.

3. Press the **CHANNEL SELECT** key.

4.   Unlock security door or set key to the **PROGRAM** position.

5.   Confirm time of day or change time if necessary.
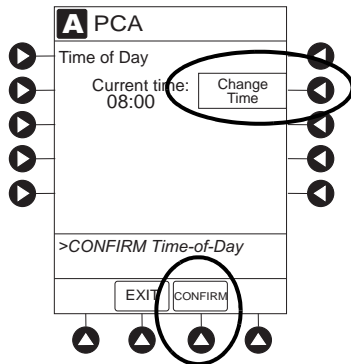
6.   Perform the following steps:

a.   Load syringe and administration set (see *Loading Syringe and Administration Set* on page *204*).

b.   Select and confirm syringe type and size (see *Selecting Syringe Type and Size* on page *208*).

7.   Press soft key next to desired drug.

Drug/Concentration screen appears.
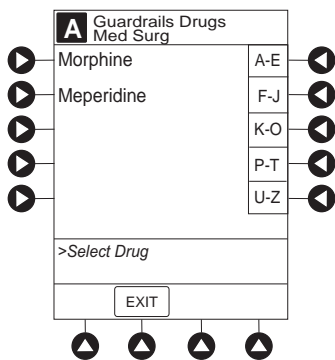
8.   Press soft key next to desired concentration.

•   Drug/Concentration confirmation screen appears.

•   To view additional drugs/concentrations, press **PAGE UP** and **PAGE DOWN** soft keys.

•   Facility can choose to pre-populate standard drug concentrations, or leave a custom concentration (_ _ / _ _ mL) and allow clinician to enter drug amount and diluent volume.
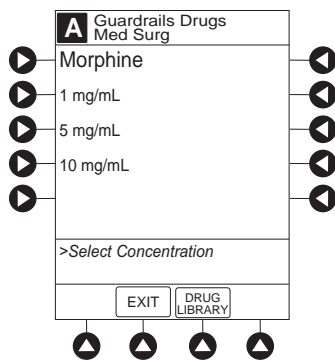
9. Confirm drug and concentration selection and press **Yes** soft key. To change selection, press the **No** soft key.

   • 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.

   • If the programmed "_ _ / _ _ mL" concentration is the outside the soft limit, an audio alert sounds and a visual prompt appears before programming can continue. If **Yes** soft key is pressed, programming continues; if **No** soft key is pressed, infusion must be reprogrammed.

   • If the programmed "_ _ / _ _ mL" concentration is outside the hard limit for that care area, an audio alert sounds and a visual prompt appears before programming can continue. Drug amount and diluent volume must be reprogrammed.

   • If there is a potential for a programmed "_ _ / _ _ mL" parameter to result in an excessive volume or dose being delivered, following prompt appears:

     Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram.

     The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:

Drug Amount	1 mg
Diluent Volume	1 mL

     or

Drug Amount	30 mg
Diluent Volume	30 mL

   • If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

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

11. Prime syringe using Prime feature, if desired.

Infusion Modes

Programming Parameters

The PCA module uses the following programming parameters, depending on infusion mode selected. See *General Information* on page *241* and *Features and Displays* on page *245* 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.

Setting Up PCA Dose Only

1. Perform steps in *Preparing Infusion* on page *208*.

2. Press **PCA Dose Only** soft key from Infusion Mode screen.
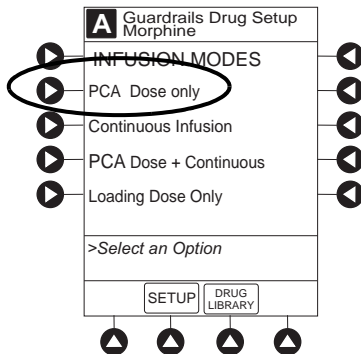
3. To enter PCA dose, use numeric data entry keys.
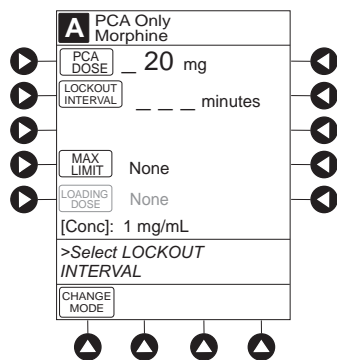
4. To enter lockout interval, press **LOCKOUT INTERVAL** soft key and use numeric data entry keys.

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.
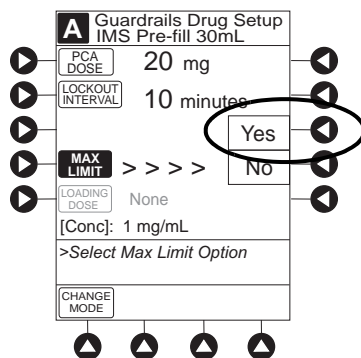
6. Enter maximum limit using numeric data entry keys.

    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, 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, following prompt appears:

        Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram.

        The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:

        Drug Amount   1 mg

        Diluent Volume   1 mL

        or

        Drug Amount   30 mg

        Diluent Volume   30 mL

    •   If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

9. Close and lock security door.

10. Verify correct parameters on second nurse summary screen and press **START** soft key.

   - Infusion mode and PCA drug name scroll in Channel Message Display. If a loading dose has been entered, scrolls **DELIVERING LOAD**.

   - Main Display alternates between volume remaining and PCA drug name with infusion mode.

   - When PCA dose is delivered:

      ◦ Green Infusing Status Indicator illuminates.

      ◦ Rate display flashes "_ _ _ _ _".

      ◦ **DELIVERING PCA** scrolls in Channel Message Display.

      ◦ When PCA dose is complete, **PCA COMPLETE** scrolls in Channel Message Display.
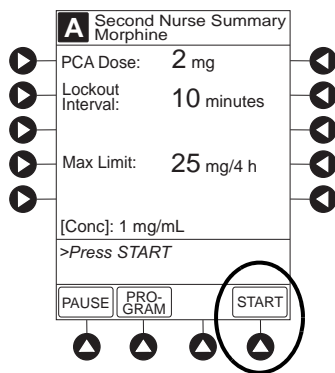
Setting Up Continuous Infusion Only

1. Perform steps in *Preparing Infusion* on page *208*.

2. Press **CONTINUOUS INFUSION** soft key from Infusion Mode screen.
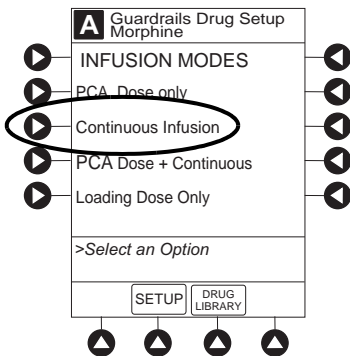
3. To enter Continuous Infusion dose, press **CONT DOSE** soft key and use numeric data entry keys.
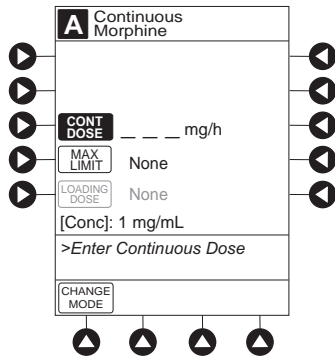
4. To enter maximum limit, press **MAX LIMIT** soft key, press **Yes** soft key, and use numeric data entry keys.

   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.
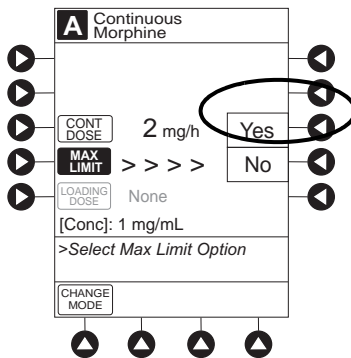
5. To enter loading dose, press **LOAD DOSE** soft key, press **Yes** soft key, and use numeric data entry keys.

   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, following prompt appears:

     Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram.

     The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:
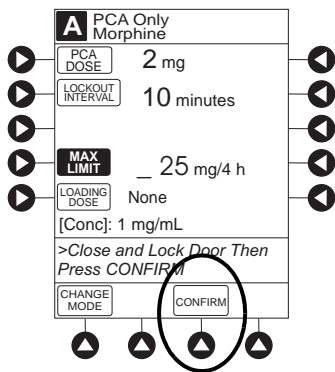
 | | |
     |---|---|
     | Drug Amount | 1 mg |
     | Diluent Volume | 1 mL |
     | or | |
     | Drug Amount | 30 mg |
     | Diluent Volume | 30 mL |

   - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

7. Close and lock security door.

8. Verify correct programming parameters and press **START** soft key.

   - Green Infusing Status Indicator illuminates.

   - Infusion mode and drug name scroll in Channel Message Display. If a loading dose has been entered, **DELIVERING LOAD** scrolls.

   - Volume infused in mL/h is displayed in Rate Display.

   - Main Display alternates between volume remaining and infusion mode with drug name.

Setting Up PCA Dose and Continuous Infusion

1. Perform steps in *Preparing Infusion* on page *208*.

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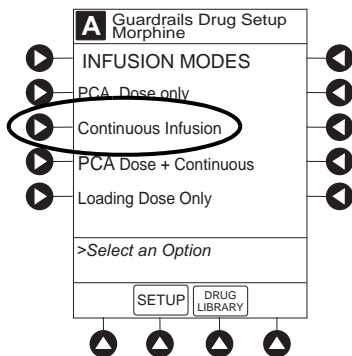
3. To enter PCA dose, press **PCA DOSE** soft key and use numeric data entry keys.
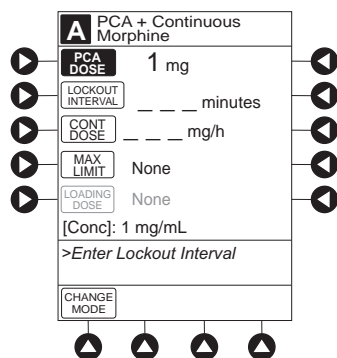
4. To enter lockout interval, press **LOCKOUT INTERVAL** soft key and use numeric data entry keys.

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, following prompt appears:

     Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram.

     The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:

Drug Amount	1 mg
Diluent Volume	1 mL

     or

Drug Amount	30 mg
Diluent Volume	30 mL

   - If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

9. Close and lock security door.

10. Verify correct parameters on second nurse summary screen and press the **START** soft key.

    During PCA dose + Continuous Infusion:

    - Green Infusing Status Indicator illuminates.

    - **DELIVERING PCA** scrolls in Channel Message Display when initiated. Continuous and PCA drug name scrolls in Channel Message Display between PCA doses.

    - Volume infused for continuous dose is displayed in Rate Display.

    - Main Display alternates between volume remaining and infusion mode with PCA drug name.

    - When PCA dose is complete, **PCA COMPLETE** scrolls in Channel Message Display and resumes continuous dose.
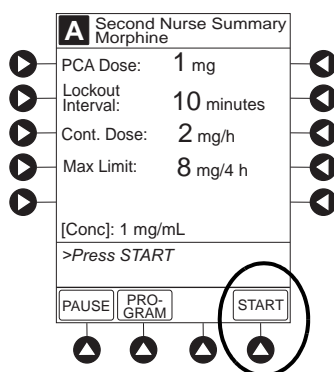
Setting Loading Dose Only

The following procedures should be used when setting a **LOADING DOSE ONLY** using the Drug Library.

1. Perform steps in *Preparing Infusion* on page *208*.

2. Press **LOADING DOSE ONLY** soft key from Infusion Mode screen.

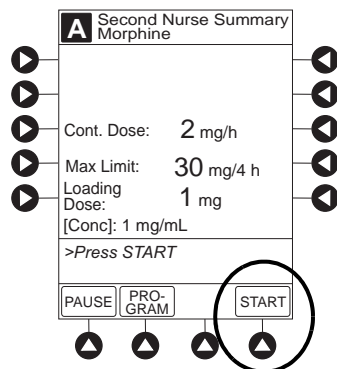3. To enter dose value, use numeric data entry keys.

4. Verify correct dose value and then press **CONFIRM** soft key.
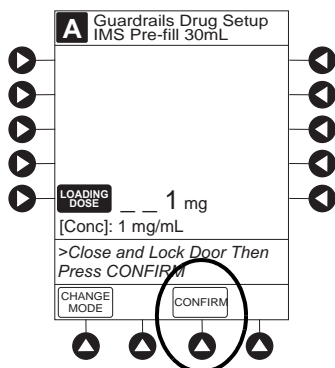
*   Loading dose is included in VTBI but is not included in **Max Limit.**

*   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, following prompt appears:

    Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram.

    The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:

 | Drug Amount | 1 mg |
    | Diluent Volume | 1 mL |
    | or | |
    | Drug Amount | 30 mg |
    | Diluent Volume | 30 mL |

*   If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

5. Close and lock security door.

6. Verify correct parameters on summary screen and press **START** soft key.
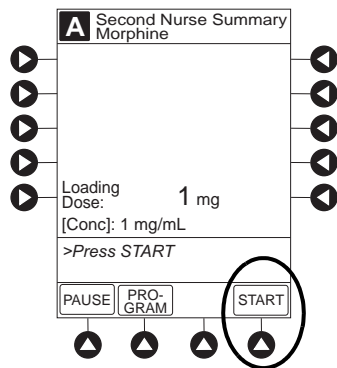
- **DELIVERING LOAD** scrolls in Channel Message Display.
- Infusion mode and drug name alternate with VTBI in Main Display.
- When loading dose is complete, **The Loading Dose has Completed** appears on Main Display.

7. Press **CONFIRM** soft key.

   When **CHANNEL SELECT** key is pressed, Infusion Mode screen becomes available for selection of infusion mode.
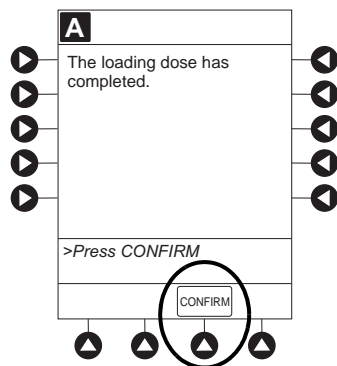
Setting Bolus Dose

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 + Continuous Infusion modes.

1. Press **CHANNEL SELECT** key.

2. Press **BOLUS DOSE** soft key.
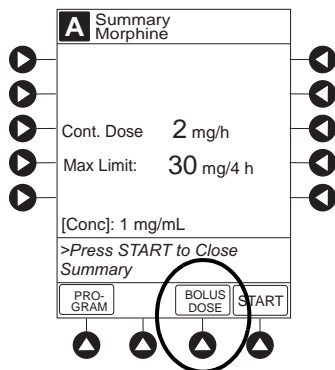
3. Set key to **PROGRAM** position or enter 4-digit authorization code and press **CONFIRM** soft key.

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.

    *   If there is a potential for a programmed "_ _ / _ _ mL" parameter to result in an excessive volume or dose being delivered, following prompt appears:

        Cannot proceed due to incorrect concentration or dosing parameters. Remove syringe, verify concentration, and reprogram.

        The prompt can be (a) the result of an incorrect drug amount and/or diluent volume entry, or (b) can occur if hospital-established Guardrails limits are very wide. Be sure to enter either a drug amount per 1 mL or total drug amount per total volume—for example, a 30 mL syringe with a concentration of 1 mg/1 mL can be entered in one of two ways:

Drug Amount	1 mg
Diluent Volume	1 mL

        or

 | Drug Amount | 30 mg |
        |---|---|
        | Diluent Volume | 30 mL |

    *   If a soft limit is overridden, **G** icon is displayed. When **G** soft key is pressed, all applicable out-of-range limits are listed.

6. If Authorization Code is disabled, door must be locked before starting bolus dose.

7. Verify correct dose value and then press **START** soft key:

   - **Delivering Bolus** scrolls in Channel Message Display.

   - Bolus and drug name alternate with VTBI in Main Display.

   - When bolus dose is complete, **BOLUS COMPLETE** scrolls in Channel Message Display.

   - Programmed infusion resumes.
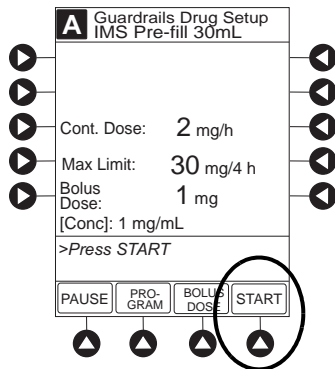
Checking PCA Volume

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.
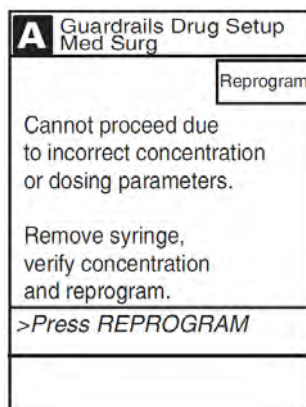
PCA Syringe Sizes and the Correlating 35% of the Syringe Capacity

Syringe Size	35% of Syringe Capacity
60mL [1]	21mL
35mL	12.25mL
30mL	10.5mL
25mL	8.75mL
20mL	7mL

NOTE:

[1] 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 Alaris™ PC unit 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.
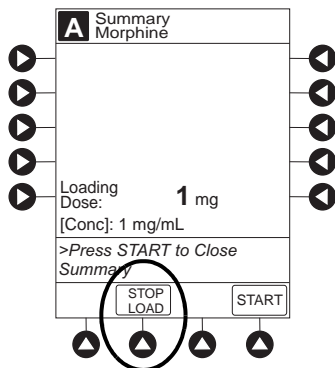
3. To stop dose and resume current program, press **Yes** soft key.

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.
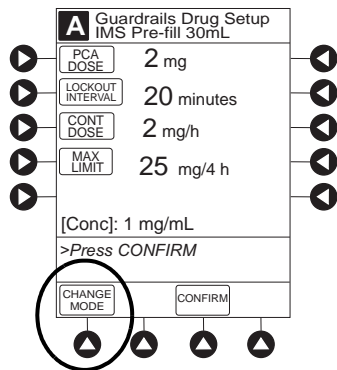
5. Select desired infusion mode.

6. Continue programming. See the applicable procedure:[1]

   Setting Up PCA Dose Only on page *213*

   Setting Up Continuous Infusion Only on page *215*

   Setting Up PCA Dose and Continuous Infusion on page *218*

7. Verify or change program settings and press **CONFIRM** soft key.

8. Close and lock door.

9. Verify correct programming parameters on summary screen and press **START** soft key.

NOTE:

[1] Previously programmed values are carried over to new program.

Viewing Patient History

1. Press **CHANNEL SELECT** key.

2. From Main Display, press **OPTIONS** key.

3. Press **PATIENT HISTORY** soft key.
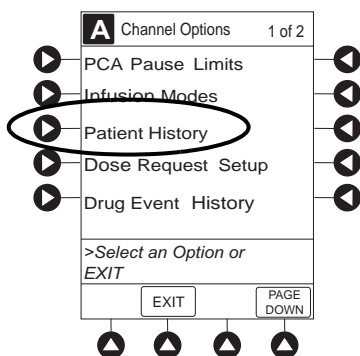
4. To select desired time period, press **ZOOM** soft key.[1][3]

A Patient History 09:01
History from 07:01 - 09:01
LAST CLEARED 07:00 2003-6-10
SHIFT TOTALS
Total Drug: 22 mg
Total Demands: 5
Delivered: 2
ZOOM: 24 12 8 4 **2** 1 hours
>Press ZOOM to Change Time Scale
CLEAR HISTORY | ZOOM | EXIT | DETAIL
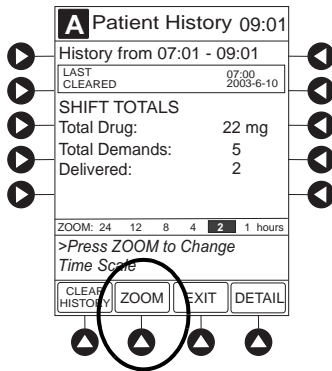
5. To view detailed patient history, press **DETAIL** soft key.[2]

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

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

NOTE:

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

[2] **Patient History** stores a rolling 24-hour log and is automatically cleared when selecting:
- **Yes** to **New Patient?** during startup.
- A different drug from the drug library.
- The same drug with different dosing units from the drug library.
- A new **Therapy** for an mL-based drug.
- Same patient with a new profile.

[3] The patient history defaults to the 8 hour view.

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.

A Patient History 09:01
History from 07:01 - 09:01
LAST CLEARED 07:00 2003-6-10
SHIFT TOTALS
Total Drug: 22 mg
Total Demands: 5
Delivered: 2
ZOOM: 24 12 8 4 **2** 1 hours
>Press ZOOM to Change Time Scale
CLEAR HISTORY | ZOOM | EXIT | DETAIL
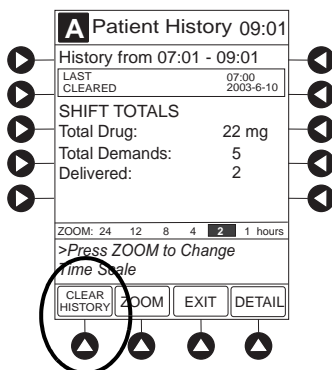
5. To continue and clear patient history, press **Yes** soft key. To cancel and return to patient history, press **No** soft key.

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).
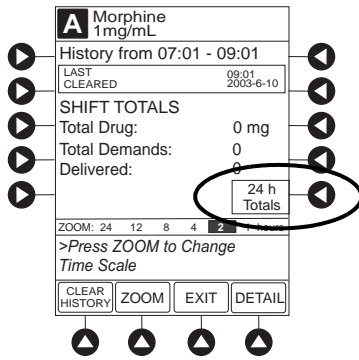
NOTE:
24 h Totals displays a rolling 24 hour history regardless of how many times the patient history has been cleared.

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.
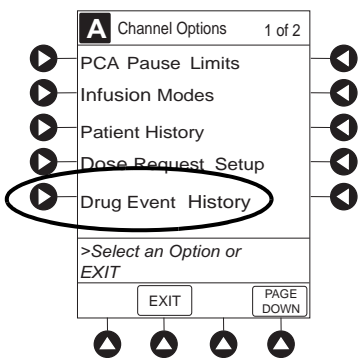
4. To scroll through history, press **PAGE DOWN** soft key.[1]

5. To return to Main Display, press **EXIT** soft key.
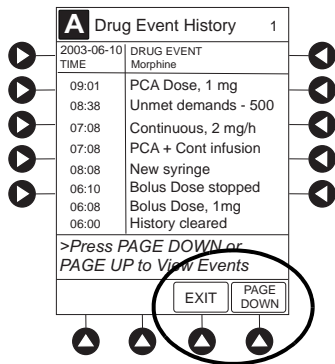
NOTE:

① The **Drug Event History** stores approximately 12 hours of events and is automatically cleared upon selection of **New Patient?**, **Yes** during start-up or upon changing drug in drug library.

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 cord. 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.
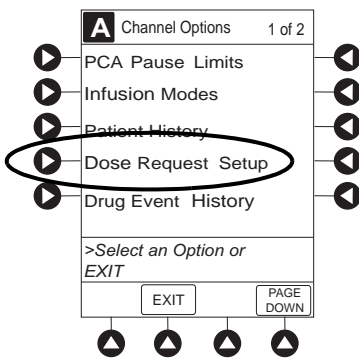
4. Review and select **Profile** soft key for desired operation of dose request cord.
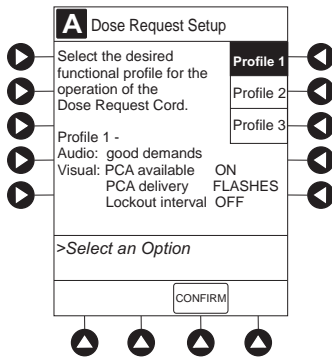
	Profile 1	**Profile 2**	**Profile 3**
Dose request cord audio - single beep	met demands only	all demands	all demands
Dose request cord led indicator:			
PCA available	On	On	Off
PCA delivery	Flashing	On	Off
Lockout interval	Off	On	Off

5. Press **CONFIRM** soft key.

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.
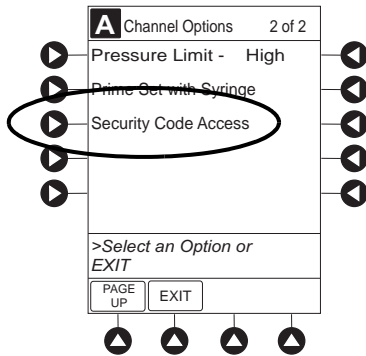
4. Press **DISABLE CODE** soft key.
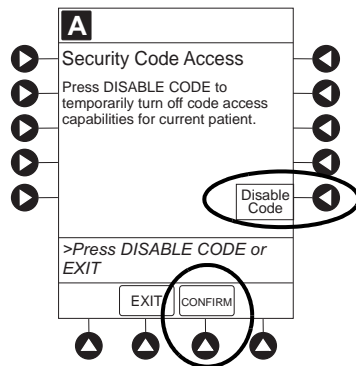
5. Press **CONFIRM** soft key.

    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.
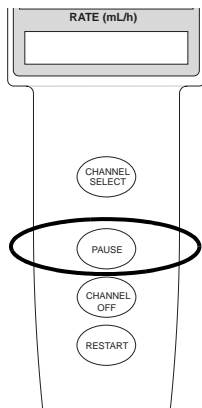
or

From **Second Nurse Summary** screen, press **PAUSE** soft key.
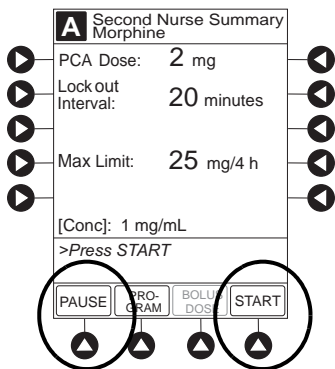
- **PAUSE** scrolls in Channel Message Display.

- **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 reinitiate infusion:

   Press **RESTART** key.

   or

   Press **CHANNEL SELECT** key and then press **START** soft key on Main Display.
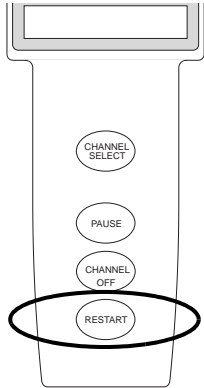
Changing Syringe and Restore Infusion

1. If syringe requires replacement:

   a. Unlock security door.

   b. Remove existing syringe and prepare new syringe (see *Preparing Syringe and Administration Set* on page *204* and *Loading Syringe and Administration Set* on page *204*).

      If drug and/or drug concentration is different from previous syringe, attach and prime new administration set.

   c. Load syringe and administration set (see *Loading Syringe and Administration Set* on page *204*).

   d. Select syringe type and size (see *Selecting Syringe Type and Size* on page *208*).

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 *Infusion Modes* on page *212*.
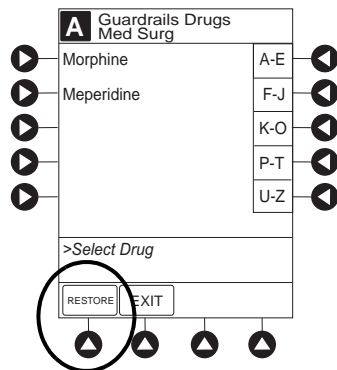
3. Verify restored drug/concentration. Press the **NEXT** soft key.

4. Prime administration set (see *Priming* on page *209*).

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 summary screen and press **START** soft key.
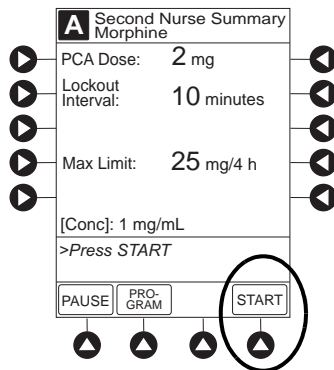
Stopping Infusion

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.
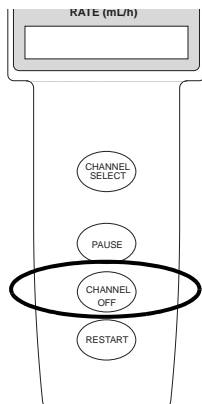
Selecting Pressure Limit

1. Press **CHANNEL SELECT** key.

2. Press **OPTIONS** key.

3. Press **PRESSURE LIMIT** soft key.[1]
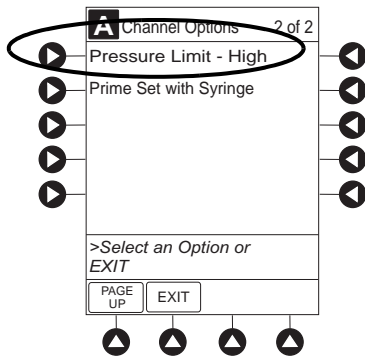
4. To select a pressure limit, press appropriate soft key.
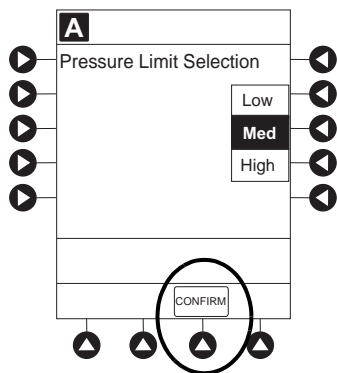
5. Press **CONFIRM** soft key.

NOTE:

[1] Option to change pressure limit can be selected:

   • After drug is selected, and before infusion mode is selected and infusion starts, or

   • After infusion starts.

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.[1]

2. To clear volume infused:[2][3]

   - If only selected channels are to be cleared, press soft key next to applicable channel(s) and press **CLEAR CHANNEL** soft key.

   - If all channels are to be cleared, press **CLEAR ALL** soft key.
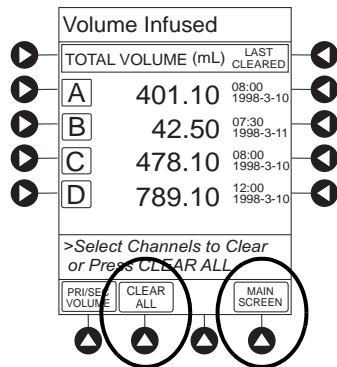
3. To return to main screen, press **MAIN SCREEN** soft key.

NOTE:
[1] Date format is year-month-day.
[2] If no key is pressed, main screen appears after 30 seconds.
[3] Clearing volume infused on a PCA module does not clear patient history.

PCA Pause Protocol Feature

The PCA pause protocol is an optional, hospital-configurable feature that is intended to align with the healthcare facility's current protocol for patient monitoring during PCA therapy. All programming, data entry, and validation of PCA pause protocol parameters are performed by a healthcare professional according to hospital-defined protocol/procedure or a physician's order.

If a monitoring module is not attached or started, the PCA pause protocol does not activate.

Programming an Infusion

If the PCA pause protocol feature is enabled, perform the following procedure.

1. Perform steps 1-8 in *Programming an Infusion* on page *210* and *Preparing Infusion* on page *208*.

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

3. Review Clinical Advisory.
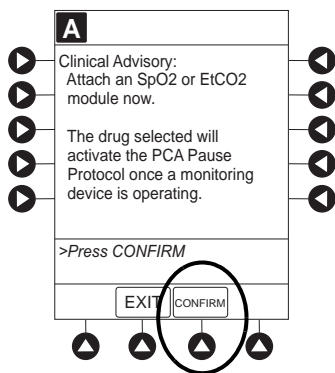
- To continue, press **CONFIRM** soft key.

- To activate PCA pause protocol, attach and start an $EtCO_2$ module and/or SpO^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.[1]
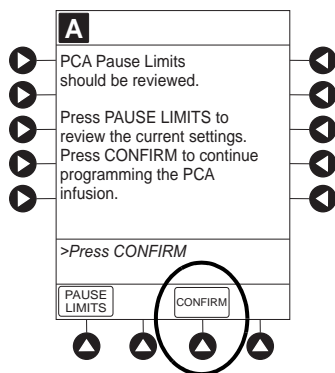
6. Start applicable infusion, as described in following procedures:[2]

   Setting Up PCA Dose Only on page *213*

   Setting Up Continuous Infusion Only on page *215*

   Setting Up PCA Dose and Continuous Infusion on page *218*

   Setting Loading Dose Only on page *220*

NOTE:

[1] To review PCA pause limits, see *Reviewing or Changing the PCA Pause Alarm Limits* on page *238*.

[2] 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 code.

   • The Main Display displays **PCA Pause Protocol ON**.

   • If Patient ID is entered, **Patient ID** alternates with **PCA Pause Protocol ON**.

```
┌─────────────────────────────┐
│ Midtown Hospital            │
│ Med Surg                    │
│  A  PCA + Cont Morphine     │
│  B  VTBI = ALL (30 mL)      │
│  C  ETCO2                   │
│  D  SPO2                    │
│                             │
│ PCA Pause Protocol ON       │
│                             │
│ ┌──────┐      ┌──────┐      │
│ │VOLUME│      │AUDIO │      │
│ │INFUSED│     │ADJUST│      │
│ └──────┘      └──────┘      │
└─────────────────────────────┘
```
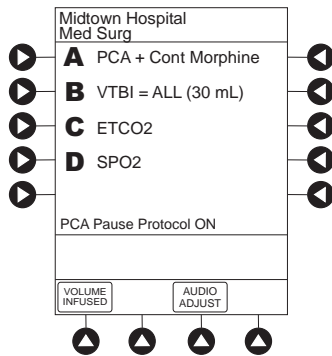
Reviewing or Changing the PCA Pause Alarm Limits

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

2. Press **OPTIONS** key.

3. Press **PCA PAUSE LIMITS** soft key.
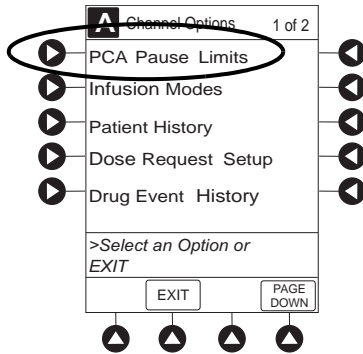
4. Verify the PCA pause limits as per facility protocol or physician order.

5. To change the PCA pause limits, press soft key that corresponds to alarm limit and enter a value within acceptable range.[1]
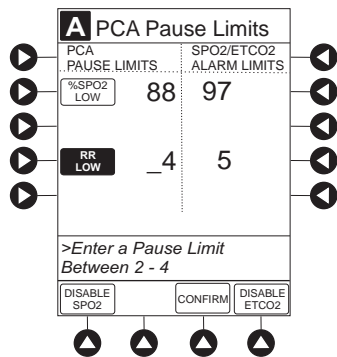
6. Press the **CONFIRM** soft key.

7. Press the **START** soft key.

NOTE:

[1] The acceptable range for PCA pause protocol is configurable and defined by the hospital within the data set using the Guardrails suite MX.
The **PCA PAUSE LIMITS** must be lower than the **SpO2/EtCO2 ALARM LIMITS**. A prompt is provided if the **PCA PAUSE LIMITS** must be modified.

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 SpO2** or **DISABLE EtCO2** soft key, as appropriate.

    •   Disabling SpO_2 or $EtCO_2$ from this screen discontinues PCA pause feature only, without interrupting monitoring functionality.

    •   Once disabled, alarm limits are grayed out and are not editable.
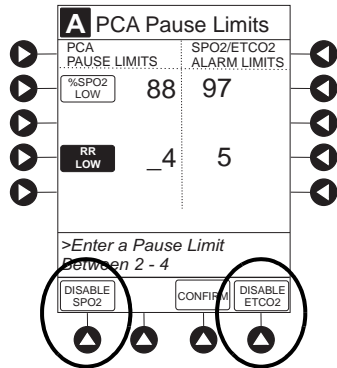
5. Press **CONFIRM** soft key.

6. Press **START** soft key.

7. To enable PCA pause feature, follow steps 1-3 above and press **ENABLE SPO2** or **ENABLE ETCO2** soft key, as appropriate.

General Setup and Operation

System Start-Up/Setup

See *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* and *General Setup and Operation* on page *18* for various system start-up and setup procedures.

General Information

Warnings and Cautions

General

WARNING

- **The PCA module is designed to stop fluid flow under alarm conditions. Periodic patient monitoring must be performed to ensure that the infusion is proceeding as expected. It is a positive displacement delivery system, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters and intra-arterial infusion. It is neither designed nor intended to detect infiltrations and does not alarm under infiltration conditions.**

- **The use of positive displacement infusion devices ported together with gravity flow infusion systems into a common IV site can impede the flow of common "gravity only" systems, affecting their performance. Hospital/facility personnel must ensure that the performance of the common IV site is satisfactory under these circumstances.**

- **Each time the system is turned on, verify and/or set the monitoring mode, resistance alert, and/or pressure alarm limit. If the monitoring mode, resistance alert, and/or pressure alarm limit are not verified, the instrument might not operate within the desired occlusion detection parameter(s).**

Administration Sets

WARNING

- **Use only standard, single-use, disposable syringes (with luer-lock connectors) and non-dedicated administration sets with integrated anti-siphon valves, designed for use on syringe-type PCA module pumps. The use of any other syringe or administration set can cause improper instrument operation, resulting in an inaccurate fluid delivery or pressure sensing, or other potential hazards. For a list of compatible syringes, refer to *Compatible Syringes* on page *244*.**

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

- **When an occlusion occurs, there is a risk of infusing pressurized buildup of infusates upon correction of the occlusion. To avoid an inadvertent bolus, relieve the pressure before restarting the infusion.**

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

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

- **Ensure that the syringe manufacturer and syringe size displayed matches syringe manufacturer and syringe size installed in the PCA module. Mismatches can cause an under-infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, refer to *Compatible Syringes* on page *244*.**

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

CAUTION

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

Epidural Administration

⚠️ **WARNING**

- **Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.**
- **It is strongly recommended that the syringe, administration set, and PCA module used for epidural drug delivery be clearly differentiated from those used for other types of administration.**
- **The system can be used for epidural administration of anesthetic and analgesic drugs. This application is only appropriate when using anesthetics and analgesics labeled for continuous epidural administration and catheters intended specifically for epidural use. Use only standard or pre-filled, single-use, disposable syringes (with luer-lock connectors) and non-dedicated administration sets with integrated anti-siphon valves, designed for use on syringe-type PCA devices without a 'Y' connector or injection port, for epidural infusions.**
  - **Epidural administration of anesthetic drugs: Use indwelling catheters specifically indicated for short-term (96 hours or less) anesthetic epidural drug delivery.**
  - **Epidural administration of analgesic drugs: Use indwelling catheters specifically indicated for either short- term or long-term analgesic epidural drug delivery.**

Dose Request Cord

⚠️ **WARNING**

- **Only the patient should press the dose request cord.**
- **Carefully locate the dose request cord to reduce the possibility of patient entanglement or strangulation.**

Guardrails Software

⚠️ **WARNING**

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

Administration Set/Syringe Information

The PCA module uses standard, single-use, disposable syringes (with luer-lock connectors) and administration sets with anti-siphon valves, designed for use on syringe-type PCA module pumps.

- For specific administration set instructions and set replacement interval, refer to user manual provided with set.

- For a list of compatible syringes, refer to *Compatible Syringes* on page *244*.

- Use aseptic techniques when handling sets and syringes.

- Administration sets are supplied with a sterile and nonpyrogenic fluid path for one-time use. Do not resterilize.

- Discard administration set per facility protocol.

- For IV push medication (put instrument on hold), clamp tubing above port.

- Flush port(s) per facility protocol.

Compatible Syringes

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

Syringe variability can impact occlusion pressure sensing. The variability can reduce the device's time to alarm and/or might require that a higher alarm pressure limit be programmed.

Manufacturer	20 mL	30 mL	35 mL	50 mL	60 mL
BD Plastipak	✗	✗		✗	✗
IMS Pump Jet		✗[1]			
Monoject	✗		✗		✗
Terumo	✗	✗			✗

NOTE:
[1] Prefilled morphine sulfate 1 mg/mL.

Features and Displays

Features and Definitions

See *Features and Displays* on page *52* for system features and definitions.

Feature	Definition
Auto Pressure Limit Adjustment	When a bolus is delivered, pressure alarm limits are temporarily raised to maximum limit.
Auto Syringe Identification	System automatically detects syringe size and narrows down syringe selection list.
Bolus Delivery Rate	Rate at which PCA, bolus, and loading doses (boluses) are infused.
Bolus Dose	Allows an additional amount of medication to be programmed once PCA infusion has begun. Current PCA infusion resumes following delivery of a bolus dose.
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 Amount .... 1 mg Diluent Volume .... 1 mL OR Drug Amount .... 30 mg Diluent Volume .... 30 mL
Continuous Dose	Basal rate dose
Dose Request Cord	Allows a patient to self-administer a PCA dose, to be delivered according to programmed PCA parameters ("PATIENT USE ONLY" label is available for optional attachment to cord). Dose request cord features an indicator light that can be configured to provide feedback to patient on requested PCA doses. Dose request cord is enabled in PCA only and PCA + continuous modes.
Drug Event History	Records and displays sequential device events for a typical 12 hours, subject to change upon usage and number of modules.
Drug Library	When profiles feature is enabled, it provides a hospital-defined list of drugs and concentrations appropriate for use in as many as 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 (1-99 minutes) that must pass between PCA patient doses. The lockout interval begins when the patient dose infusion starts. The lockout interval range is 1-99 minutes.

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+continuous mode, Continuous infusion resumes following PCA dose.
PCA Pause Protocol	An optional and hospital-configurable feature intended to align with hospital/health system's current protocol for patient monitoring during PCA therapy. When enabled, PCA infusion pauses and alarms when defined monitoring values (% SpO_2 and/or respiratory rate low) for SpO_2 and/or $EtCO_2$ module are exceeded and sustained.
Pressure Limit	Downstream occlusion alarm threshold can be set to low, medium, or high. syringe variability might impact occlusion pressure sensing. Variability can reduce device's time to alarm and/or can require that a higher alarm pressure limit be programmed.
Priming	Allows a limited volume of fluid to be delivered in order to prime administration set prior to being connected to a patient or after changing a syringe. When priming, a single continuous press of **PRIME** soft key delivers up to 2 mL of priming/fluid.

Feature	Definition
Restore	To simplify programming, can be used to recall previous PCA programming parameters for same patient. This option is only available if patient is not new and system is powered up within 8 hours of last usage.
Security Access Level	Profile-specific security access level can be configured to provide varying levels of access to device. Security access is accomplished either through use of key or a 4-digit authorization code. For security level information, see *Programming* on page *208*, *Infusion Modes* on page *212*, and *Security Access Levels* on page *229*.
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.

Operating Features, Control, Indicators

Security Lock

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

Status Indicators

Alarm
(red)

Infusing
(green)

Standby
(yellow)

Plunger Grippers
(shown in closed
position)

IUI Connector, Left

**Barrel Flange
Gripper**

Rate Display

ALARM   INFUSE   STANDBY

Message Display

RATE (mL/h)

**Syringe Barrel
Sensor**

Channel (module) Identification

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

CHANNEL
SELECT

PAUSE

**Syringe Barrel
Clamp/Sizer**

CHANNEL
OFF

RESTART

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

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

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

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

Dose Request Cord Attachment

Dose Request Cord

Displays

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

Configurable Settings

See the *This chapter contains the following topics:* on page *15* for system configurable settings.

The configuration settings are selected during data set development and then uploaded to the system as part of the data.

With the profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best practice data set must be uploaded to enable the profiles feature. Date and time is a system setting and is the same in all profiles.

Feature	Default Setting	Options
Authorization Code	None	4 digits (0 - 9) One code applies to all profiles
Bolus Delivery Rate	150 mL/h	75 - 500 mL/h (limited by syringe size)
Bolus Dose	Disabled	Enabled - Disabled
Bolus Dose include in Max. Limit	Disabled	Enabled - Disabled
Dose Request Cord Configuration	Profile 2	Profile 1, 2, 3
Forced Module Location	Enabled	Enabled - Disabled
Loading Dose	Disabled	Enabled- Disabled
Lockout Interval	1 - 99 minutes in 1-minute increments	Min/Max 1 - 99 minutes
Max Accumulated Dose Range	4-hour limit	Disabled; 1, 2, or 4-hour limit
Max Rate (for Continuous Dose)[1]	999 mL/h	0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments
NEOI • Alert Time	Disabled	Enabled - Disabled 5 - 25% of syringe size
NEOI Snooze[1]	Disabled	5, 10 or 15 minutes
Occlusion Pressure Set Point	High (800 mmHg)	Low (200 mmHg) Medium (500 mmHg) High (800 mmHg)

Feature	Default Setting	Options
PCA Pause Protocol: • PCA Pause Protocol • Monitoring Module Attach Enforcement • PCA Pause Protocol Text • SpO2 Settings:[2] • % SpO$_2$Low Limit • Initial Value • EtCO$_2$ Settings:[3] • Respiratory Rate Lower Limit (bpm) • Initial Value	Disabled None PCA infusion has paused due to a decline in respiratory status. Check patient. None None None None	Enabled - Disabled Enabled - Disabled Editable per hospital protocol 20 - 99 20 - 99 0 - 149 0 - 149
Priming	Enabled	Enabled- Disabled
Security Access Level	Level 1	Level 1, 2, 3

NOTE:

① This configuration setting is a shared setting between the PCA module and the syringe module.

② These values are configured in the SpO$_2$ module settings within the Guardrails editor software and can be changed by the clinician by accessing Channel Options on the PCA module.

③ These 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.

Specifications and Symbols

Specifications

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

Bolus Volume, Maximum   Bolus Volume, Maximum after Occlusion is measured using two different setups.
after Occlusion:

The first setup simulates an actual clinical setup and includes a device at heart height, a full length administration set, and an 18 gauge needle at the end of the administration set. Test setup uses a 50/60 mL syringe at 5 mL/h.

⚠

> **WARNING**
>
> **Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates.**

The second setup is a laboratory test setup that includes a 1 meter administration set, a device above the height of the collection container, rigid tubing connecting the administration set to a pressure transducer, and no needle at the end of the administration set.

Clinical Test Setup

Occlusion Pressure Limit	Bolus Volume (mL)
Low	0.396
High	0.997

Laboratory Test Setup

Occlusion Pressure Limit	Bolus Volume (mL)
Low	0.170
High	0.470

Maximum Bolus Volume specifications are based on following standard operating conditions:
Atmospheric Pressure: 645 - 795 mmHg
Disposable Type: #30883
Humidity: 20 - 90%
Rate: 5 mL/h
Syringe Type: 50/60 mL (clinical), 20 mL (laboratory)
Temperature: 68 ±4°F
Volume Collection Time: approximately 2 minutes

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

Delivery Units: mcg, mcg/h, mg, mg/h, mL, mL/h

Dimensions: 4.75" W x 15.0" H x 7.5" D (exclusive of security door)

Environmental Conditions:

Symbol	Meaning	Operating	Storage/ Transport
	Atmospheric Pressure	525 - 4560 mmHg (70 - 608 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)
0.10 - 9.99	0.01
10 - 99.9	0.1
100 - 999	1.0

Rate restriction by syringe size:

Syringe Size (mL)	Flow Rate Range (mL/h)
20	0.1 - 500
30/35	0.1 - 650
50/60	0.1 - 999

Fluid Ingress Protection: IPX2, Drip Proof

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

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

Occlusion Alarm Thresholds: Three settings:
- Low
- Medium
- High

Operating Principle: Positive displacement

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

Rate Accuracy: ±2% of full scale plunger travel (not including syringe variation) S

⚠️

WARNING

Syringe size and running force, variations of back pressure, or any combination of these can affect time to alarm for occlusions and rate accuracy. Factors that can influence back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure can also be affected by type of catheter. See *Trumpet and Start-Up Curves* on page *254* for data on how these factors influence rate accuracy.

Shock Protection: Type CF, defibrillation-proof patient applied part. (PCA disposable)
Type BF, defibrillation-proof patient applied part. (Dose request cord)

Time to Alarm, Maximum:

Rate (mL/h)	High	Low
0.1	30 hours	17 hours 40 minutes
1	120 minutes	37 minutes
5	30 minutes	7 minutes

Maximum Time to Alarm specifications are based on following standard operating conditions:
Atmospheric Pressure: 645 - 795 mmHg
Back Pressure: 0 mmHg before producing occlusion
Disposable Type: #30883
Humidity: 20 - 90%
Syringe Type: 50/60 mL
Temperature: 68 ±4°F

Weight: 5.5 lbs (PCA max handle load weight is 5.5 lbs)

Bolus Accuracy:

Syringe	Disposable Set	Bolus (Set Value)	Calculated Percentage Deviation from Set Value	Maximum Positive Deviation from Set Value	Maximum Negative Deviation from Set Value
60 ml 309653	30883	Maximum 20mL	6.57 %	0.060 mL	- 1.092 mL
60 ml 309653	30883	Minimum 0.1mL	5.22 %	0.008 mL	-0.095 mL

NOTE:
The minimum volume to be infused (VTBI) for both pump module and syringe module (applicable to all syringe sizes) is 0.1mLs. This applies to Continuous Infusions, Bolus Dose, Intermittent Infusions, and IV Fluids. The set length and temperature of the administration set can affect occlusion time to alarm. Increases in temperature and increases in the length may increase time to alarm.

Trumpet and Start-Up Curves

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

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

Trumpet and start-up curves have been provided for 0.1 mL/h, 1.0 mL/h, and 5.0 mL/h. Measurements for trumpet curve rates above 5.0 mL/h are not provided, as the syringe volume is displaced in a very short time with a rate up to 999 mL/h. Accuracy, however, is assured with the design implementation.Trumpet curves are named for their characteristic shape. They display discrete accuracy data averaged over particular time periods or "observation windows," not continuous data versus operating time.

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

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

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

Under conditions of -100 mmHg, +100 mmHg, and +300 mmHg pressures, the PCA module typically exhibits an accuracy of approximately 0.2% or less from the mean value.

Ambient Temperature: 68 ±4°F (20 ±2°C)

Test Solution: ISO Class III Distilled Water

Sample Size: 1 PCA module

Syringe Type: 20 mL syringe

Administration Set Model: #30883
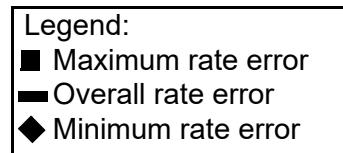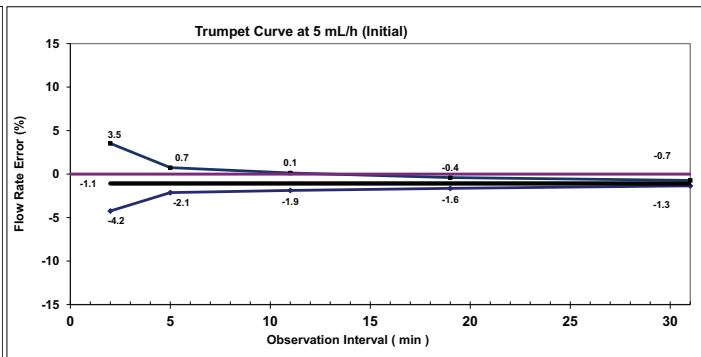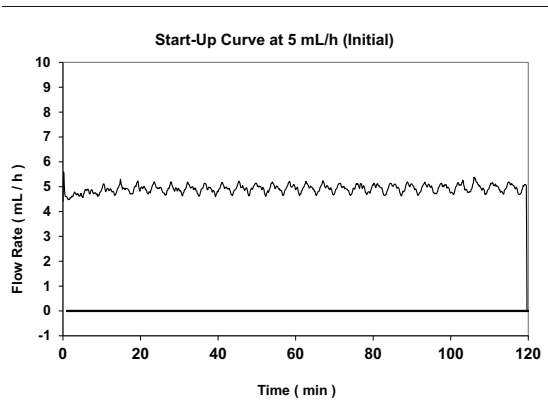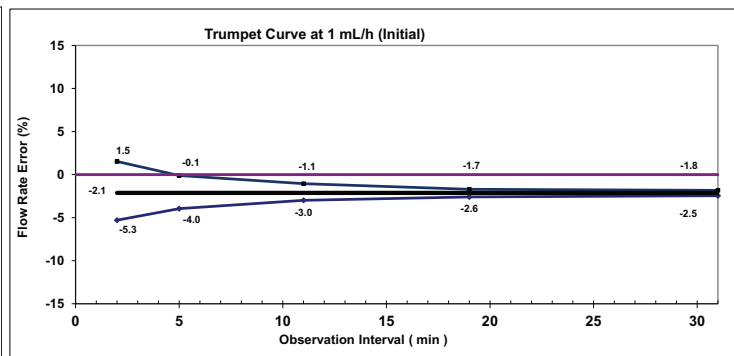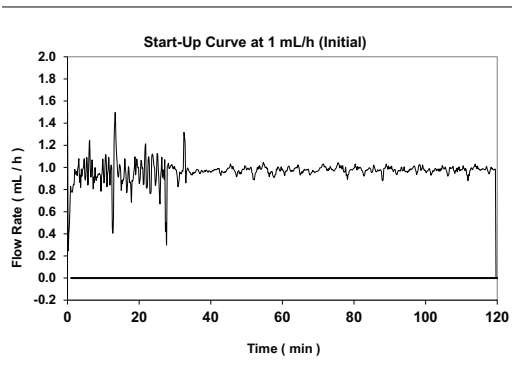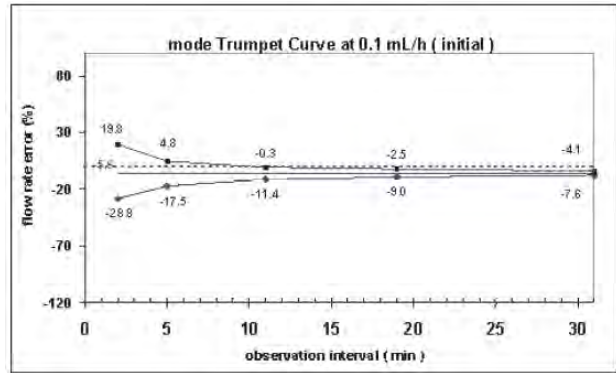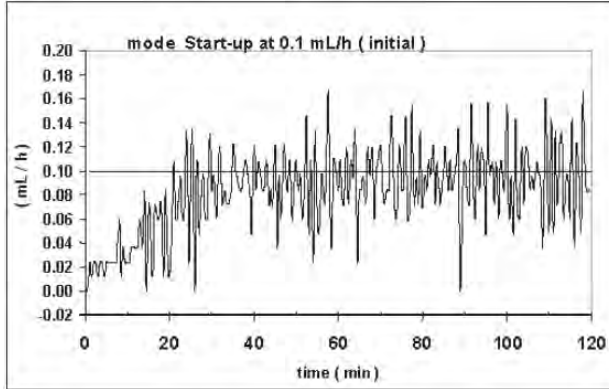
mode Start-up at 0.1 mL/h (initial)

mode Trumpet Curve at 0.1 mL/h (initial)

Start-Up Curve at 1 mL/h (Initial)

Trumpet Curve at 1 mL/h (Initial)

Start-Up Curve at 5 mL/h (Initial)

Trumpet Curve at 5 mL/h (Initial)

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

This chapter contains the following topics:

Getting Started

Introduction

⚠️ **WARNING**

Read all instructions for the SpO$_2$ module and PCU, before using the system.

This section applies to SpO$_2$ modules upgraded with v9.33 software.

This section of the user manual provides SpO$_2$ module (models 8210 and 8220) instructions and information. It is used in conjunction with:

- Nellcor™ and Masimo SET™ cable and sensor instructions
- PCU chapter of this manual (see *Getting Started* on page *16*)
- Nellcor™ Monitor Sensor Compatibility Card - Alaris™ SpO$_2$ module model 8210
- Masimo™ Monitor Sensor Compatibility Card - Alaris™ SpO$_2$ module model 8220
- *SpO$_2$ module 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 SpO$_2$ modules are indicated for continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO$_2$) and pulse rate measured by a SpO$_2$ sensor. The SpO$_2$ modules and accessories are indicated for use with adult, pediatric, and neonatal patients, and for patients who are well or poorly perfused in hospitals and hospital type facilities. The model 8220 SpO$_2$ module is also indicated for use during motion and no motion conditions. Clinical functions will only be provided to one SpO$_2$ module at a time.

Please consult the facility's best practices guidelines on the preferred alarm settings for the monitoring of patients that are not continuously attended by a clinician.

The majority of user interface programming is identical for both SpO$_2$ modules. If a procedure/information applies to a specific module, the following identifiers indicate the applicable model.

Model 8210:   ◈**NELLCOR**
           (8210)

Model 8220:   **ᴍᴀsɪᴍᴏ SET**
           (8220)

Cables and Sensors: See *Sensors and Cables* on page 273 for information.

Alarms, and Messages: See Appendix A *Troubleshooting and Maintenance* on page 324 for module-specific alarms and messages.

Contraindications: The SpO$_2$ modules are contraindicated for use as apnea monitors.

Electromagnetic Environment: See Appendix A *Regulations and Standards* on page *354* and *Compliance* on page *354* for this information.

Attaching Cable and Sensor

The operator is responsible for checking the compatibility of the monitor, probe, and cable before use.

1. Attach applicable patient cable to SpO$_2$ module. Ensure a secure connection and that patient cable is not twisted, sliced, or frayed.

⚠️ **WARNING**

The misapplication of a sensors and patient cables with excessive pressure for prolonged periods can induce pressure injury.

⚠️ **WARNING**

Model 8210:
Use only approved Nellcor sensors and pulse oximetry cables.

Model 8220:
Use only approved Masimo sensors and patient cables.

Use of sensors, transducers, cables, and accessories other than those specified can cause improper SpO$_2$ module performance resulting in inaccurate readings, increased emission, and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO$_2$ module. For a list of compatible sensors and cables, refer to the Monitor Sensor Compatibility Alaris^{TM} SpO$_2$ module 8220 Series.

2. Attach applicable sensor to patient cable. Refer to sensor's user manual for detailed instructions.

Patient Cable

Attach patient cable here.
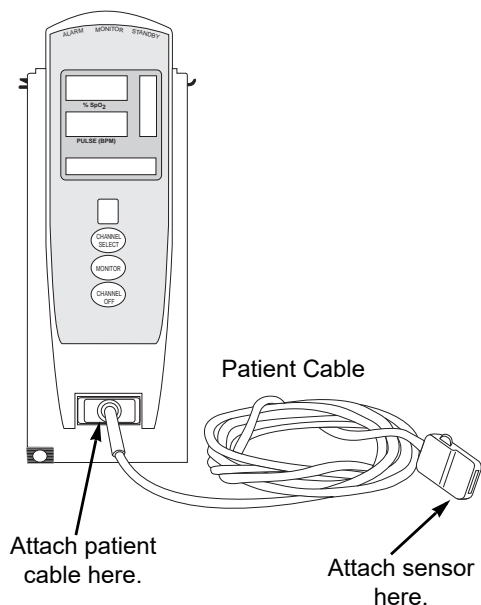
Attach sensor here.

3. Attach sensor to patient. Refer to sensor's user manual for detailed instructions.

Programming

Display references throughout this procedure are for illustration purposes only.

See *General Information* on page *49*, *Features and Displays* on page *52* and the *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* for information about:

- Displays
- Operating Features, Controls, Indicators

The majority of user interface programming is identical for both SpO₂ modules.

Monitoring Mode

1. Perform the following steps (see *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015*, *General Setup and Operation* on page *18* and *Start-Up* on page *21* for specific 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. Attach patient cable and sensor (see *Getting Started* on page *258*).

3. Press **CHANNEL SELECT** key.
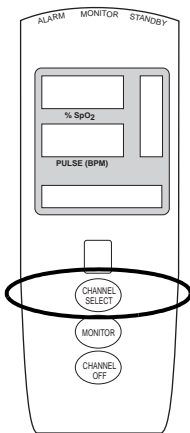
- **SEARCHING** might appear in Channel Message display until SpO₂ and pulse readings stabilize (approximately 15 seconds).
- If sensor is not attached to a site, **SENSOR OFF** is displayed.
- To prevent screen from reverting to Main Display, press **ENTER** key within 30 seconds after **SPO2 Main** screen is displayed.
- If sensor is not attached during message display, module goes into sleep mode. To begin monitoring once module is in this mode, press **MONITOR** key.

4. Ensure that sensor's red LED is on.

5. Alarm limits:
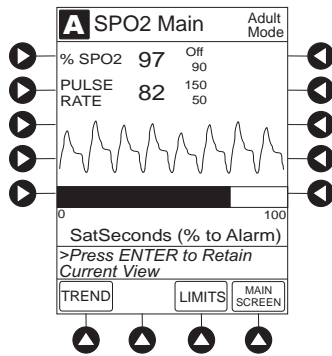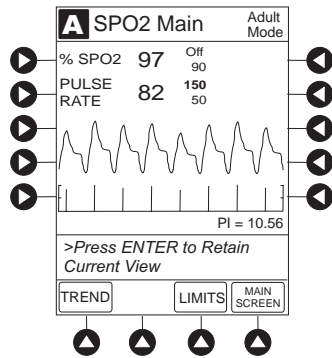
- To change settings, see *Setting Alarm Limits* on page *262* for the procedures.
- To accept settings and begin monitoring, press **ENTER** key.
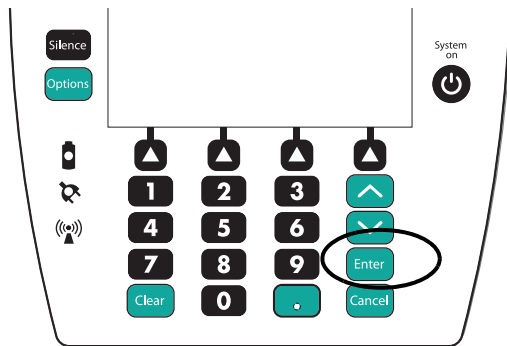
Setting Alarm Limits
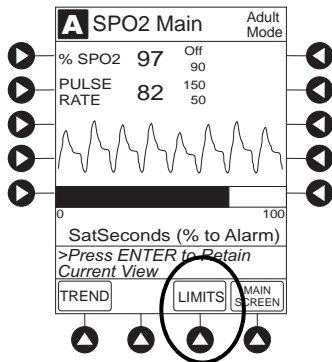
1. Press **LIMITS** soft key.

2. To change a limit setting, press soft key next to applicable parameter.
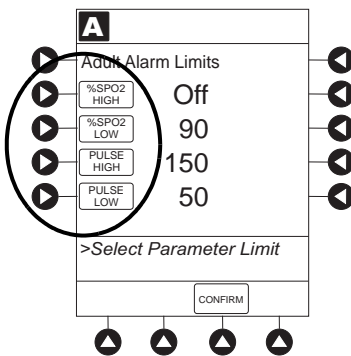
3. Enter a numeric value for selected alarm limit.

    %SPO2 HIGH limit can be **Off** or a numeric value.

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

5. To confirm alarm settings and return to **SPO2 Main** display, press **CONFIRM** soft key.
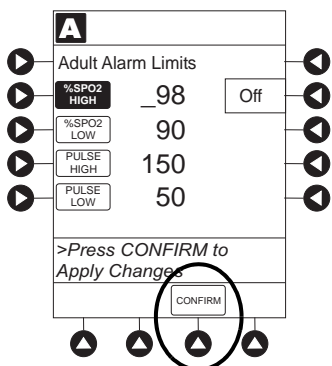
6. To return to Main Display, press **MAIN SCREEN** soft key.

Navigating Trend Data

1. To view **Trend Data**, press **TREND** soft key.
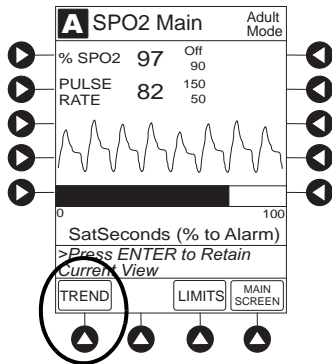
    - Tabular information is not updated while **Trend Data** view is displayed. Tabular data is updated, using new trend data stored in SpO$_2$ module, after leaving **Trend Data** view. To view latest data, return to **Trend Data** view.

    - ⌂ is displayed if an alarm limit is reached.

    - If no **SPO2** or **PULSE** rate values are available for time period displayed, dashes (---) are displayed.

2. To navigate from page to page, press **PAGE UP** and **PAGE DOWN** soft keys.

3. To scroll data one row at a time, press ⌃ ⌃ or ⌄ ⌄ key.
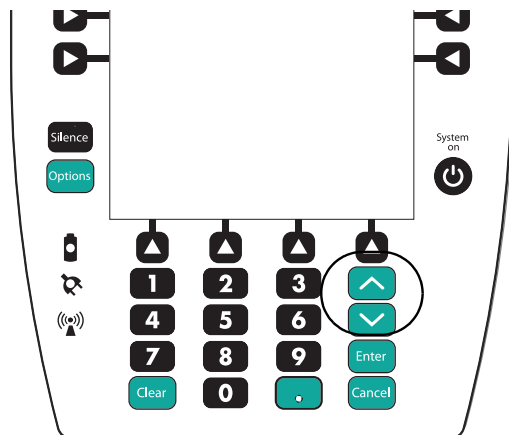
4. To change **TIME** increments for data review, move cursor to desired time period and press **ZOOM** soft key.
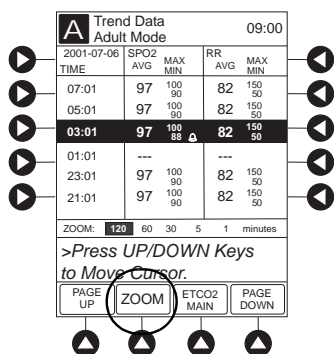
- New time increments display.
- Each press of **ZOOM** soft key changes time increments.

5. To return to **SPO2 Main** display, press **SPO2 Main** soft key.

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

Navigating Alaris™ PCA Module and Alaris™ SpO$_2$ Module Trend Data

To access and view shared trend data when a PCA module is present, perform the following steps:

1. To access option to view trend data, press **OPTIONS** key while in **SPO2 Main** display.

2. To view **Trend Data**, press **PCA/SPO2 Trend Data** soft key.
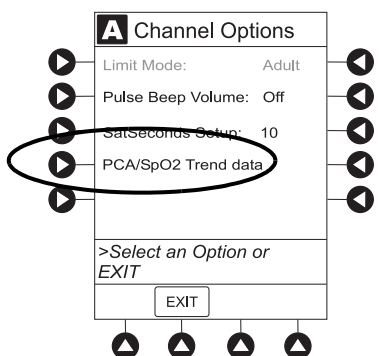
- Tabular information is not updated while **Trend Data** view is displayed. Tabular data is updated, using new trend data stored in SpO$_2$ module, after leaving **Trend Data** view. To view latest data, return to **Trend Data** view.

- ⌂ is displayed if an alarm limit is reached.

- If no **SpO$_2$** or **PULSE** rate values are available for time period displayed, dashes (---) display.

3. See *Navigating Trend Data* on page *263* for instructions on how to:

    *   Navigate from page to page.

    *   Change **TIME** increments.

    *   Return to **SPO2 Main** display.

    *   Return to Main Display.
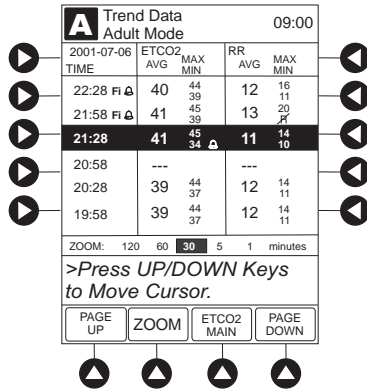
Presilencing Alarms

1. To presilence an alarm, press **SILENCE** key.

    All monitoring alarms are silenced for 120 seconds and a monitoring alarm silence symbol is displayed on the PCU main screen. Subsequent infusion alarms are not silenced.

2. To cancel presilence alarm and return to alarmable mode:

    *   Press **CANCEL SILENCE** soft key.
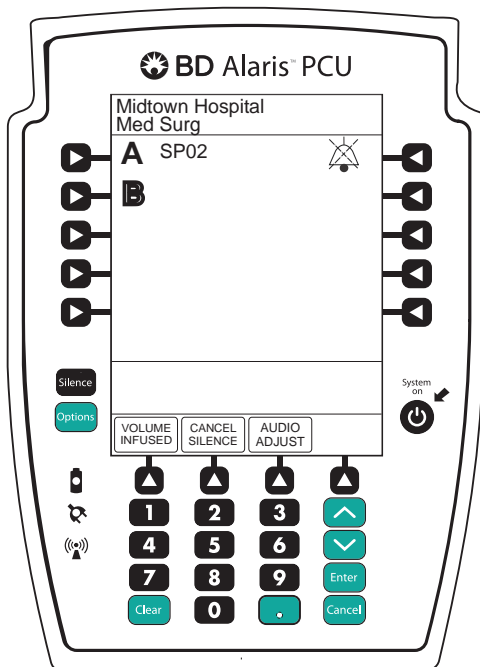
Channel Options

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 **Limit Mode** soft key.
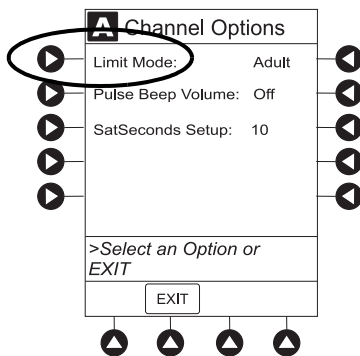
2. To change **Limit Mode Setup**, press applicable soft key.

    OR

    To leave **Limit Mode Setup** unchanged and return to **SPO2 Main** display, press **EXIT** soft key.
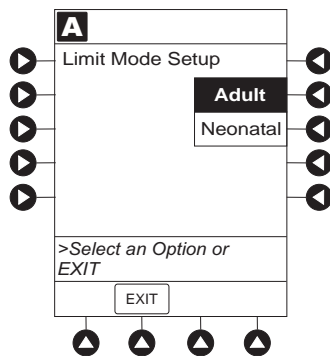
Changing Pulse Beep Volume

1. Press **Pulse Beep Volume** soft key.
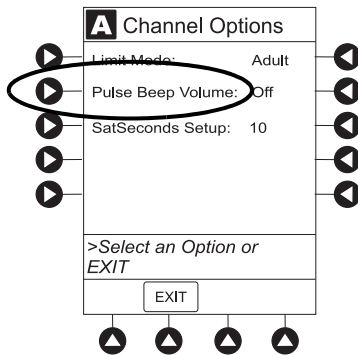
2. To test or change:

   a. To test volume level (when not attached to patient), press **Test** soft key.

      Pulse beep must be on to test volume level. To turn pulse beep on, press **Louder** soft key and adjust as needed.

   b. To increase volume, press **Louder** soft key until desired volume level is attained (**1**, **2**, or **3**).

   c. To decrease volume, press **Softer** soft key until desired volume level is attained.

   d. To turn off pulse beep, press **Off** soft key.
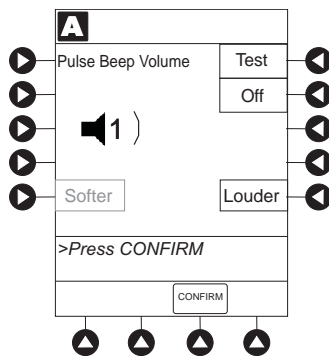
3. To return to **SPO2 Main** display, press **CONFIRM** soft key.

Changing SatSeconds Limit

◈**NELLCOR**
(8210)

1. Press **SatSeconds Setup** soft key.
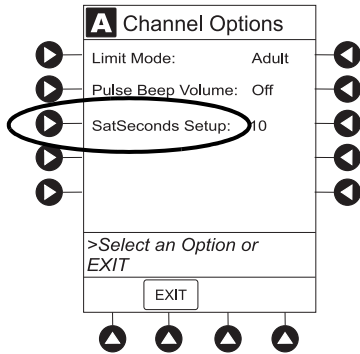
2. To change SatSeconds™, press applicable soft key. Selectable **Increase** and **Decrease** options are **10**, **25**, **50**, and **100** seconds.

3. To return **SPO2 Main** display, press **CONFIRM** soft key.
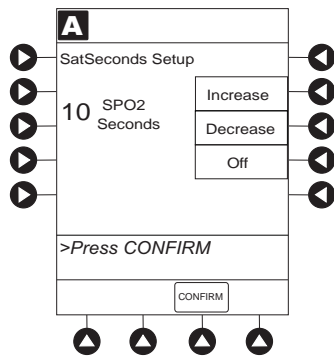
Changing Saturation Averaging Time

Ⴤ MASIMO SET.
(8220)

1. Press **Saturation Averaging Time** soft key.
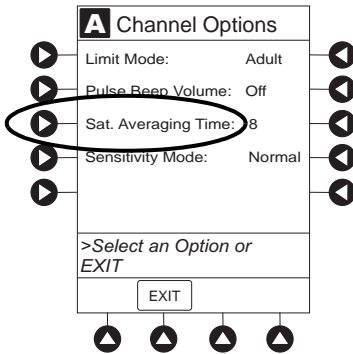
2. To change **Saturation Averaging Time**, press applicable soft key. Selectable options are **2**, **4**, **8**, **10**, **12**, **14**, and **16** seconds.

    FAST SAT is enabled when **2** or **4** seconds is selected.

3. To return **SPO2 Main** display, press **CONFIRM** soft key.
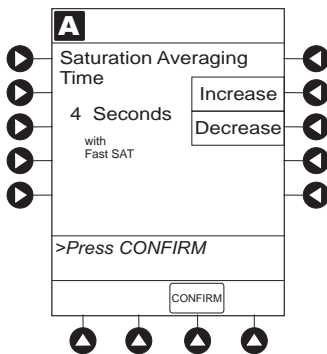
Changing Sensitivity Mode

(8220)

1. Press **Sensitivity Mode** soft key.
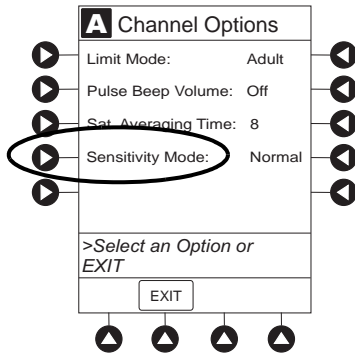
2. To change **Sensitivity Mode**, press applicable soft key.[1]

    •   **Normal:** Normal patient monitoring.

    •   **Maximum:** Improved low perfusion performance.
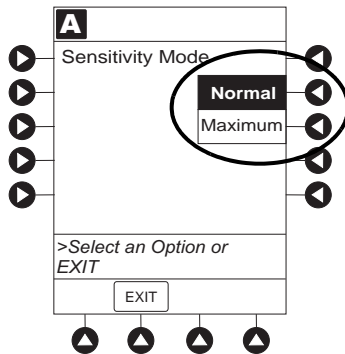
NOTE:

[1] The sensitivity mode is displayed on the SPO2 Main display only when maximum is selected.

General Setup and Operation

System Start-up/Setup

See *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* and *General Setup and Operation* on page *18* for various system start-up and setup procedures.

General Information

Warnings and Cautions

General

⚠️ **WARNING**

- **The SpO$_2$ module is not to be used as an apnea monitor.**

- **Pulse oximetry readings and pulse signal can be affected by certain ambient conditions, sensor application errors, and certain patient conditions.**

- **The SpO$_2$ module is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**

- **The SpO$_2$ module should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-Oximeter to completely understand the patient's condition.**

- **Interfering Substances: Carboxyhemoglobin and methemoglobin can erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation can cause erroneous readings.**

- **The SpO$_2$ module is not rated for defibrillation use. Disconnect the sensor from the patient or patient cable from the module prior to defibrillation.**

- **Do not lift the SpO$_2$ module by the cable because it could disconnect from the instrument, causing it to drop on the patient. Do not place the SpO$_2$ module in any position that could cause it to fall onto the patient.**

- **Respond immediately to system alarms; patient monitoring can cease under certain alarm conditions.**

Sensors and Cables

WARNING

- **Inspect the SpO$_2$ module sensor site regularly to ensure correct sensor positioning, application, and site integrity. Tissue damage could occur over prolonged time periods, depending on the patient profile (such as neonates) and method of application. Refer to the sensor instructions for additional information.**

- **Do not use a sensor, cable, or connector that appears damaged. Do not use a sensor with exposed optical components.**

- **The sensor disconnect error message and associated alarm indicate the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor.**

- **Model 8210:**

  - **Use only approved Nellcor sensors and pulse oximetry cables.**

- **Model 8220:**

  - **Use only approved Masimo sensors and patient cables.**

  - **Use of sensors, transducers, cables, and accessories other than those specified can cause improper SpO$_2$ module performance resulting in inaccurate readings, increased emission, and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO$_2$ module.**

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

- **Before use, read the sensor user manual, including all warnings, cautions, and instructions.**

CAUTION

- **Do not immerse or dampen** the sensor or cable. Clean per manufacturer's instructions.

- The system is not intended for use with high frequency surgical equipment.

Cables and Sensors

Nellcor Patient Cables and Sensors

◈NELLCOR
(8210)

The Nellcor patient cables interface the SpO$_2$ module with the patient sensors.

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. Use only Nellcor sensors. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the user manual accompanying the sensor.

For a list of compatible sensors and cables, refer to the Monitor Sensor Compatibility Card Alaris^{TM} SpO$_2$ Module 8210 Series.

Masimo Patient Cables and Sensors

(8220)

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. Use only Masimo SET sensors. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the user manual accompanying the sensor.

For a list of compatible sensors and cables, refer to the Masimo Monitor Sensor Compatibility Card, Alaris™ SpO₂ Module 8220 Series.

Features and Displays

Features and Definitions

See *Features and Displays* on page *52* for system features and definitions.

Models 8210 **and 8220**

Feature	Definition
% SpO₂ Alarm Limits	Upper and lower saturation limits for %SpO₂ alarm can be adjusted by clinician.
% SpO₂ Display	Functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO₂.
Limit Mode	Configurable mode that can be set to display either adult or neonatal monitoring mode. (See *Configurable Settings* on page *277* for additional configurable features.)
Pleth Waveform	Plethysmographic (pleth) waveform is a graphic representation of changes in extremity blood volume during cardiac cycle events. Displayed waveform is a simulated signal (non-normalized).
Pulse Beat Volume	Sound of each pulse beep can be configured to be off or to a volume level of 1, 2, or 3.
Pulse Rate	Displayed in beats per minute (bpm).
Pulse Rate Alarm Limits	Upper and lower pulse rate alarm limits can be adjusted by clinician.
Trend Data	Tabular display of %SpO₂ and pulse rate. Display shows average high and low values, and alarm conditions for time period displayed. Up to 24 hours of data is stored.

Model 8210 ◈ *NELLCOR*

Feature	Definition
SatSeconds™	SatSeconds™ limits controls time %SpO$_2$ level can fall outside the alarm limits before an audible alarm sounds. Method of calculation is as follows: Number of percentage points %SpO$_2$ falls outside of the alarm limit is multiplied by number of seconds %SpO$_2$ level remains outside that limit. Points x Seconds = SatSeconds™ Points = %SpO$_2$ percentage points outside of limit Seconds = number of seconds %SpO$_2$ remains at that point outside of the limit Saturation levels might fluctuate rather than remain steady for a period of several seconds. %SpO$_2$ levels might fluctuate above and below alarm limit, reentering nonalarm range several times. During such fluctuations, %SpO$_2$ module integrates number of %SpO$_2$ points, both positive and negative, until either SatSeconds™ limit (SatSeconds™ time setting) is reached or %SpO$_2$ level returns to within a normal range and remains there. SatSeconds™ "Safety Net" is for patients with saturation levels having frequent excursions below limit but not staying below limit long enough for SatSeconds™ time setting to be reached. When three or more limit violations occur within 60 seconds, an alarm sounds, even if SatSeconds™ time setting has not been reached.
SatSeconds™ alarm management	With SatSeconds™ alarm management technology, upper and lower alarm limits are set in the same way as with traditional alarm management. A SatSeconds™ limit can be set to allow monitoring of %SpO$_2$ below selected low alarm limit for a period of time before an audible alarm sounds.

Model 8220 *Masimo SET*

Features	Definition
Fast SAT	When Fast SAT is enabled and there is one data point that is significantly different from a previous data point, averaging is disregarded and most recent data point is displayed. For example, if readings were 97%, 96%, 95%, and 85%, displayed saturation level would be 85%.
PI	Perfusion index (PI) is a scaled numeric value derived from magnitude of pulsations displayed on plethysmographic (pleth) waveform. It is calculated as a percentage of pulsatile signal to nonpulsatile signal. PI is used to find best perfused site for sensor placement (larger the PI, stronger the perfusion). Operating range is 0.02 to 20. Desired number is greater than 1 or as large as possible.
Saturation Averaging Time	Averaging time can be set to 2, 4, 8, 10, 12, 14, or 16 seconds.
Sensitivity Mode	Sensitivity mode, normal or maximum, of current monitoring configuration is displayed in options mode. Normal setting is used for normal patient monitoring purposes. Maximum setting is used for improved low perfusion performance.
SET Technology	Signal extraction technology (SET) uses adaptive filters to separate arterial signal from nonarterial noise. SET provides for accurate readings under extreme conditions (such as low perfusion and motion).
Signal I.Q™ Feature	A visual indication of pulsation at sensor site. Vertical bar height indicates quality of measured signal. Signal I.Q™ feature is related to proper sensor application, adequate arterial signal, and intensity of motion. Use Signal I.Q™ feature to verify optimal sensor placement.

Operating Features, Controls, Indicators

Status Indicators

Alarm
(red)

Monitoring
(green)

Standby
(yellow)

IUI Connector, Left
(not visible)

IUI Connector, Right

%SpO₂ Display

ALARM   MONITOR   STANDBY

Pulse Rate Display

%SpO₂

Pulse Bar Display

PULSE (BPM)

**Channel (module)
Message Display**

Channel (module) Identification

CHANNEL
SELECT

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

MONITOR

Monitor Key: When pressed,
begins patient monitoring.

CHANNEL
OFF

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

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

Patient Cable Connector

Displays

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

Main Display

See the *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15*.

SpO₂ Main Display

Pleth Waveform

Pleth Waveform
Signal I.Q™
PI
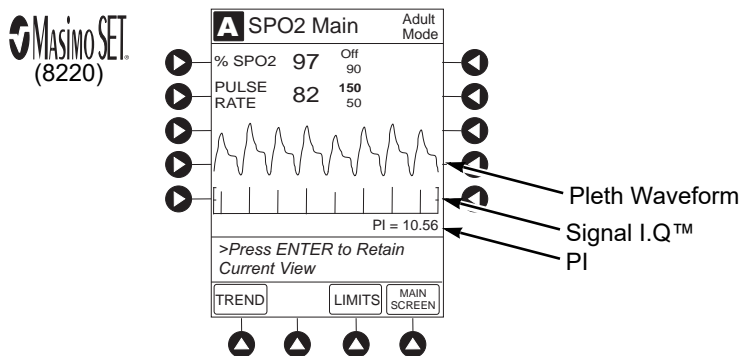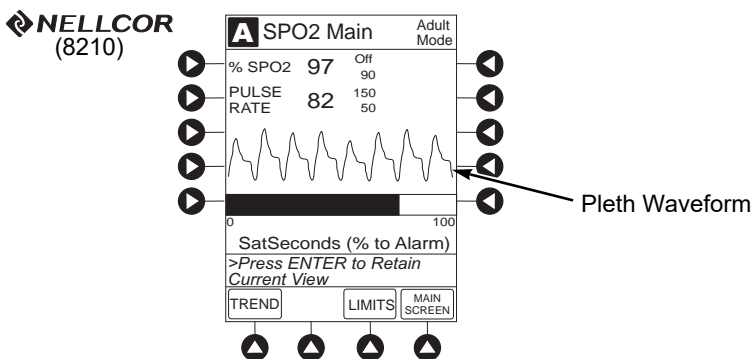
Configurable Settings

See the *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* for system configurable settings.

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

With the profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best practice data set must be uploaded to enable the profiles feature. Date and time is a system setting and is the same in all profiles.

Models 8210 ◈ *NELLCOR* and 8220 〇Masimo SET		
Feature	**Default Setting**	**Options**
Limit Mode	**Adult**	**Adult, Neonatal**
Pulse Beep Volume	1	1, 2, 3, Off
Pulse Rate Alarm Limit, High	Adult Mode: 120 bpm Neonatal Mode: 200 bpm	31 - 240 bpm
Pulse Rate Alarm Limit, Low	Adult Mode: 50 bpm Neonatal Mode: 100 bpm	30 - 239 bpm
SpO₂ Alarm Limit, High	Adult: Off Neonatal: 95%	21 - 100%, Off
SpO₂ Alarm Limit, Low	Adult: 90% Neonatal: 80%	20 - 99%

Model 8210 ◈ *NELLCOR*		
Feature	**Default Setting**	**Options**
SatSeconds	Off	10, 25, 50, 100 seconds; Off

Model 8220 〇Masimo SET		
Feature	**Default Setting**	**Options**
Saturation Averaging Time (display update period)	8 seconds	2, 4, 8, 10, 12, 14, 16 seconds
Sensitivity Mode	Normal	Normal, Maximum

Specifications and Symbols

Specifications

Models 8210 ◊NELLCOR and 8220 Masimo SET	
Alarms:	Audible and visual alarms for high and low saturation and pulse rate, sensor condition, system failure, and low battery conditions.
Alarm Limits:	<table><tr><td></td><td>**Low**</td><td>**High**</td></tr><tr><td>Pulse Rate:</td><td>30 - 239 bpm</td><td>31 - 240 bpm</td></tr><tr><td>SpO_2</td><td>20 - 99%</td><td>21 - 100%</td></tr></table>
Dimensions:	3.3" W x 8.9" H x 5.5" D (8.4 cm W x 22.6 cm H x 14 cm D)
Environmental Conditions:	<table><tr><td>**Symbols**</td><td>**Meaning**</td><td>**Operating**</td><td>**Storage/ Transport**</td></tr><tr><td></td><td>Atmospheric Pressure</td><td>525 - 4560 mmHg (70 - 608 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>
Fluid Ingress Protection:	IPX1, The SpO_2 module is protected against harmful effects of dripping water per IEC 60529
Mode of Operation:	Continuous
Shock Protection:	Type BF patient applied part
Weight:	2.5 lbs (1.13 kg)

Model 8210 ◆*NELLCOR*			
Accuracy Tolerance:		**Low Perfusion**[1]	**Adult**[2]	**Neonate**[2]

	Low Perfusion[1]	**Adult**[2]	**Neonate**[2]
Pulse Rate	20 - 250 bpm ±3 digits	20 - 250 bpm ±3 digits	20 - 250 bpm ±3 digits
Functional Saturation	70 - 100% ±2 digits	70 - 100% ±2 digits	70 - 100% ±3 digits

Display Update Period:	2.25 seconds
Measurement Range:	Perfusion: 0.03 - 20% Pulse Rate: 20 - 250 bpm SpO₂: 1 - 100%
Pulse Amplitude Display:	Visual indicators for pulse signals represent proportional pulse amplitude strength.
Sensor:	Emitted light wavelength range is within 500 - 1000 nm. Output power does not exceed 15 mw.

Model 8220 *MASIMO SET*				
Accuracy and Motion Tolerance:				

	Low Perfusion[3]	**Motion**[4][5]	**No Motion**[6]	**Resolution**
Pulse Rate	25 - 240 bpm Adults, Pediatrics, Neonates: ±3 digits	25 - 240 bpm Adults, Pediatrics, Neonates: ±5 digits	25 - 240 bpm Adults, Pediatrics, Neonates: ±3 digits	1 bpm
Saturation	70 - 100% Adults, Pediatrics: ±2 digits; Neonates: ±3 digits	70 - 100% Adults, Pediatrics, Neonates: ±3 digits	70 - 100% Adults, Pediatrics: ±2 digits; Neonates: ±3 digits	1% SpO₂

Display Update Period:	Approximately 1 second.
Measurement Range:	Perfusion: 0.02 - 20% Pulse Rate: 25 - 240 bpm SpO₂: 1 - 100%
Pulse Amplitude Display:	Proportional to height of I.Q. signal.
Sensor:	Emitted light wavelength range is within 500 - 1000 nm. Output power does not exceed 1 mw.

NOTE:
Wavelength range information can be especially useful to clinicians, for example, those performing photodynamic therapy.

NOTE:

① Specification applies to monitor performance.

② Adult specifications are shown for OXIMAX MAX-A and MAX-N sensors. Neonate specifications are shown for OXIMAX MAX-N sensors. Saturation accuracy varies by sensor type.

③ Masimo Board performance has been validated for low perfusion accuracy in bench–top testing against a BIO-TEK simulator and a Masimo simulator.

④ Masimo Board performance has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies, while performing rubbing and tapping motions at 2 - 4 Hz at an amplitude of 1 - 2 cm and a nonrepetitive range of 70 - 100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

⑤ Masimo Board performance with Masimo LNOP™ Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates, while moving the neonate's foot at 2 - 4 Hz at an amplitude of 1 - 2 cm against a laboratory co–oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

⑥ Masimo Board performance has been validated for no-motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies, in the range of 70 - 100% SpO_2 against a laboratory co–oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Measurement Accuracy

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the SpO_2 module to ensure that it is functioning properly.

NOTE:
Because the SpO_2 module's measurements are statistically distributed, only about two-thirds of the SpO_2 module measurements can be expected to fall within ±Arms of the value measured by a co-oximeter.

An inaccurate measurement can be caused by:

• Incorrect sensor application or use.

• Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin).

• Intravascular dyes (such as indocyanine green or methylene blue).

• Exposure to excessive illumination; such as, a surgical lamp (especially one with a xenon light source), bilirubin lamp, fluorescent light, infrared heating lamp, or direct sunlight.[①]

• Prolonged and/or excessive patient movement.

• Venous pulsations.

• Sensor placed on an extremity with a blood pressure cuff, arterial catheter, intravascular line or other causes of insufficient perfusion.

• Nail irregularity, such as nail polish or fungus. Remove nail polish and/or move sensor to an unaffected site.

• Placement is too close to electrosurgery equipment.

• Defibrillation.

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

• The sensor is too tight.

• Exposure to excessive illumination; such as, a surgical lamp (especially one with a xenon light source), bilirubin lamp, fluorescent light, infrared heating lamp, or direct sunlight.

• The sensor placed on an extremity with a blood pressure cuff, arterial catheter, intravascular line, or other causes of insufficient perfusion.

• The patient has hypotension, severe vasoconstriction, severe anemia or hypothermia, is in cardiac arrest or is in shock.

• There is an arterial occlusion proximal to sensor.

• Placement is too close to electrosurgery equipment.

NOTE:

① Exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.

Chapter 6
Alaris™ EtCO$_2$ Module Model 8300

This chapter contains the following topics:

Getting Started

Introduction

⚠️   **WARNING**

Read all instructions, for both the EtCO₂ module and PCU, before using the system.

This section of the user manual provides EtCO₂ module (model 8300) instructions and information. It is used in conjunction with:

- EtCO₂ module technical service manual
- Alaris™ EtCO₂ module 8300 compatibility card
- Medtronic's Microstream™ disposable instructions
- PCU chapter of this manual (see *Getting Started* on page *16*)
- System maintenance software (and its instructions) for system check-in, maintenance, and configurations for connecting the PCUs to the wireless network

The EtCO₂ module is a capnograph indicated for continuous, noninvasive monitoring of end tidal carbon dioxide (EtCO₂), fractional inspired carbon dioxide (FiCO₂) and respiratory rate (RR). The end-tidal gas reading is calculated as a maximum value. The recommended setting and factory default is a 20 second window. The window defines the maximum measured EtCO₂ and the minimum measure FiCO₂.

The EtCO₂ module and disposables are indicated for use with intubated and nonintubated adult, pediatric and neonatal patients. It is not intended for direct connection to ventilator or breathing systems. Clinical functions will only be provided to one EtCO₂ module at a time.

The EtCO₂ module is used with Medtronic's patented Microstream Disposables/circuits for sidestream capnography. The Microstream™ EtCO₂ sampling lines deliver a sample of the inhaled and exhaled gases from direct contact to the patient via an oral/nasal cannula into the monitor for CO₂ measurement.

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 EtCO₂ module is not rated for defibrillation use. Disconnect the device from the patient prior to defibrillation.

Microstream™ Disposable: See *Microstream Disposable* on page *297* for more information.

Alarms and Messages: See the Appendix A, *Troubleshooting and Maintenance* on page 324 for module-specific alarms and messages.

Contraindications: None known.

Electromagnetic Environment: See Appendix A, *Regulations and Standards* on page *354* and *Compliance* on page *354*).

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

Gas Inlet

Open Position
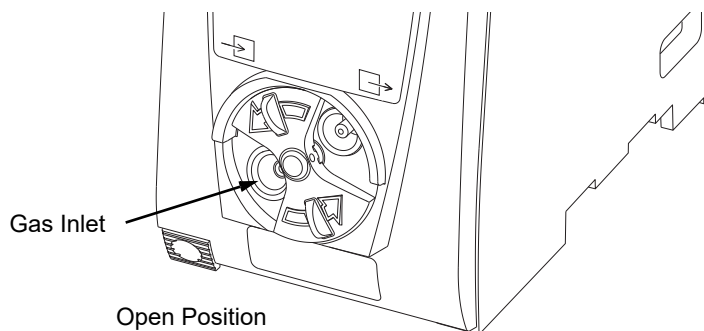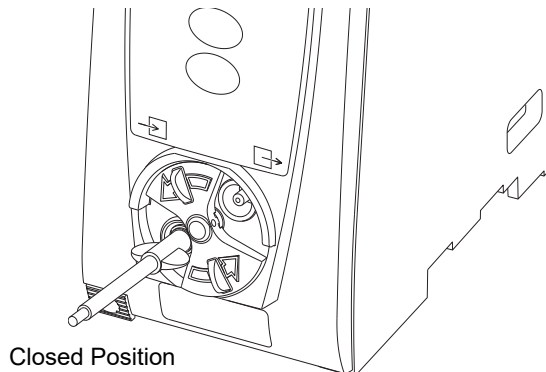
⚠️ **WARNING**

Use only Microstream disposables. Use of a disposable other than those specified can cause improper EtCO$_2$ module performance, resulting in inaccurate readings.

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.
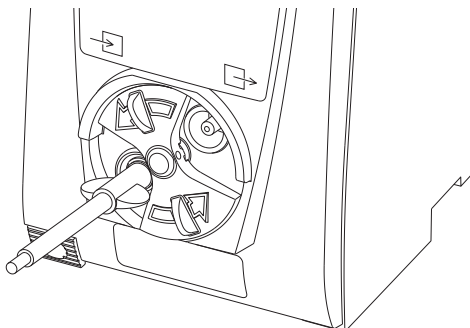
3. Release door.

   NOTE
   Tubing connected to the EtCO$_2$ exhaust port must be appropriately labeled and marked with symbol ISO 7000-0795.

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.

Attaching Gas Scavenging System

In the presence of high oxygen or anesthesia concentrations, it might be necessary to connect a gas scavenging system to the EtCO$_2$ module.

⚠ **WARNING**

There is a risk of patient cross-infection if the sampled gas is returned to the breathing system.

1. Open gas inlet/outlet door by turning door counterclockwise until gas outlet is clearly visible. Hold in open position.

   Gas outlet is located on lower right corner of instrument and is marked with a gas outlet symbol

   (▭→).

2. Secure gas scavenger system tubing to EtCO$_2$ module by firmly pushing tubing into fitting on gas outlet.

3. Release door.
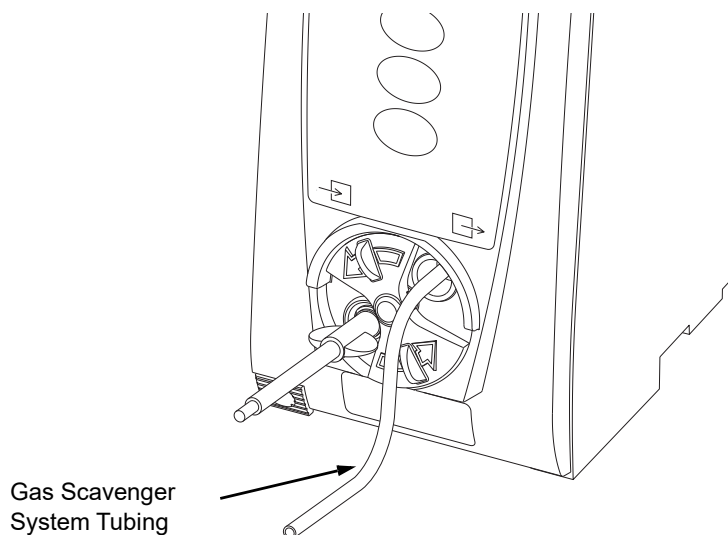
Gas Scavenger
System Tubing

   NOTE
   Tubing connected to the EtCO$_2$ exhaust port must be appropriately labeled and marked with symbol ISO 7000-0795.

Programming

Display references throughout this procedure are for illustration purposes only.

See *General Information* on page *49*, *Features and Displays* on page *52*, and *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* for information about:

- Displays
- Operating Features, Controls, Indicators

Monitoring Mode

1. Perform the following steps (see *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15*, *General Setup and Operation* on page *18*, and *Start-Up* on page *21* 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 *Getting Started* on page *284*).

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).
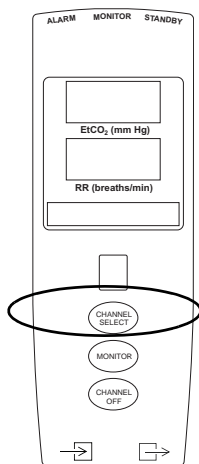
4. Alarm limits:

    • To change settings, see *Setting Alarm Limits* on page *288.*

    • To accept settings and begin monitoring, press **ENTER** key.
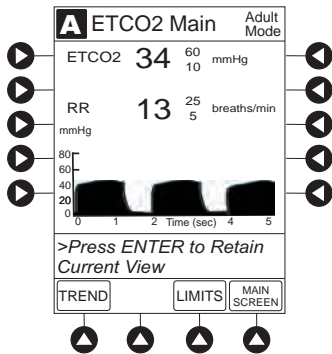
ETCO2 Main screen displays following information:[1]

    ◦ Capnography waveform (scale adjustable).

    ◦ EtCO₂ value, as well as minimum and maximum EtCO₂ alarm limits.

    ◦ Limit Mode (Adult or Neonatal).

    ◦ Respiratory rate (RR, breaths/min), as well as minimum and maximum RR alarm limits.

NOTE

[1] PC unit display response time is approximately ½ second longer than the EtCO₂ module response time.

Setting Alarm Limits
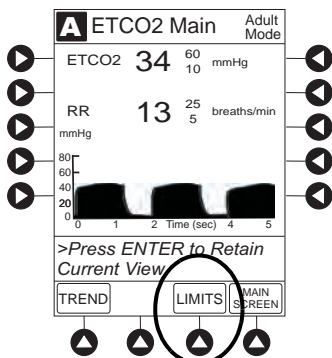
1. Press **LIMITS** soft key.

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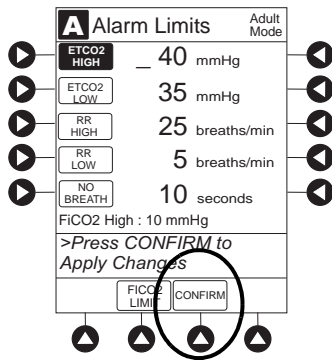
6. To return to Main Display, press **MAIN SCREEN** soft key.

Navigating Trend Data

1. To view Trend Data, press **TREND** soft key.
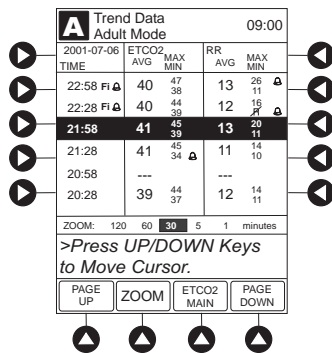
The following information is displayed:

-   **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.
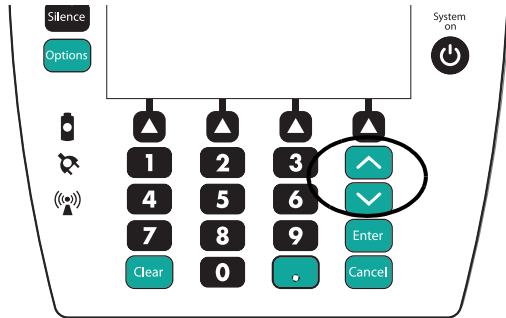
4. To change the **TIME** increments for data review, move the cursor to the desired time period and press the **ZOOM** soft key.
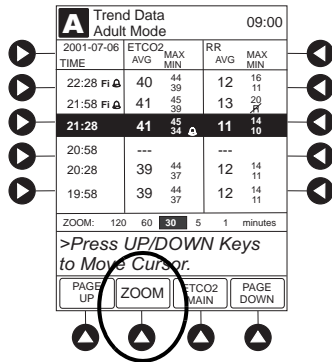
- New time increments display.

- 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/EtCO₂ Module Trend Data

To access and view shared trend data when a PCA module is present, perform the following steps.

1. To view **ETCO2 Main** display, press **CHANNEL SELECT** key.

2. To access option to view trend data, press **OPTIONS** key.

3. To view **Trend Data**, press **PCA/ETCO2 Trend data** soft key.

   The following information is displayed:

   - **TIME** period for data review.

   - Average EtCO₂.

   - Average respiratory rate (**RR**).

   - Alarm icon (🔔).

   - **TOTAL DOSE** of medication infused through PCA module (includes continuous Infusion, loading dose, bolus, and PCA dose).
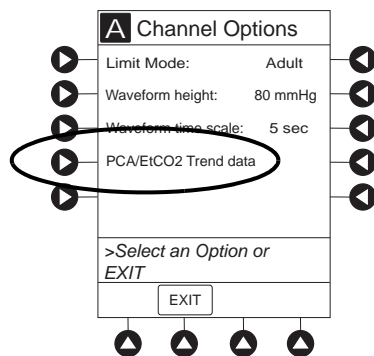
4. See *Navigating Trend Data* on page *289* for instructions on how to:

   - 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 120 seconds and a Monitoring Alarm Silence symbol is displayed on the PCU main screen. Subsequent infusion alarms are not silenced.
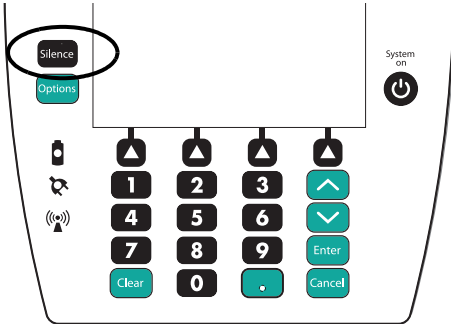
2. To cancel pre-silence alarm and return to alarmable mode:
    *   Press **CANCEL SILENCE** soft key.
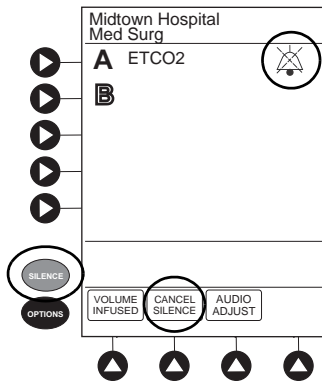
Channel Options

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.

```
        ┌─────────────────────────┐
  ▶     │ A  Channel Options      │   ◀
        │ Limit Mode:      Adult  │
  ▶     │ Waveform height: 80 mmHg│   ◀
  ▶     │ Waveform time scale: 5 sec  ◀
  ▶     │ PCA/EtCO2 Trend data    │   ◀
  ▶     │                         │   ◀
        │ >Select an Option or    │
        │ EXIT                    │
        │      ┌──────┐           │
        │      │ EXIT │           │
        │      └──────┘           │
        └─────────────────────────┘
          ▲     ▲     ▲     ▲
```

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.

```
        ┌─────────────────────────┐
  ▶     │ A                       │   ◀
  ▶     │ Limit Mode Setup        │   ◀
  ▶     │        ┌────────┐       │   ◀
  ▶     │        │ Adult  │       │   ◀
  ▶     │        │Neonatal│       │   ◀
        │        └────────┘       │
        │ >Select an Option or    │
        │ EXIT                    │
        │      ┌──────┐           │
        │      │ EXIT │           │
        │      └──────┘           │
        └─────────────────────────┘
          ▲     ▲     ▲     ▲
```
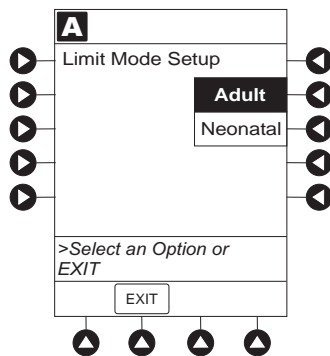
Changing Waveform Height

1. Press **Waveform height** soft key.
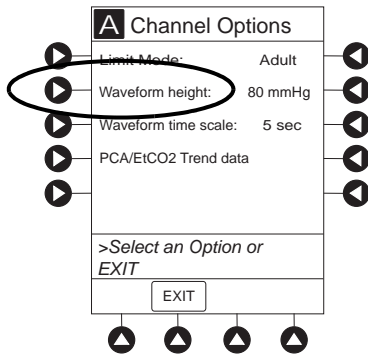
2. To change Waveform Height, select applicable range limit.
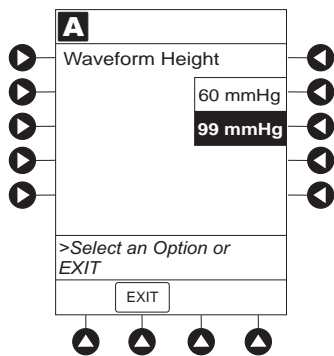
*   **60 mmHg:** Displays a waveform for EtCO₂ values within 0 – 60 mmHg range. If EtCO₂ value exceeds that range, **Waveform Out of Range; Adjust Scaling** message is displayed until waveform falls back into range or 0 – 99 mmHg option is selected.

*   **99 mmHg:** Displays a waveform for full EtCO₂ value range, 0 – 99 mmHg.

3. To return to **ETCO2 Main** display, press **EXIT** soft key.

Changing Waveform Time Scale

1. Press **Waveform time scale** soft key.
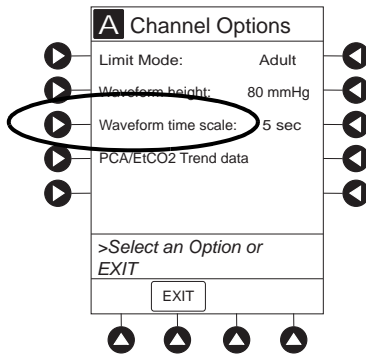
2. To change **Waveform Time Scale**, select applicable time scale.
   OR
   To leave **Waveform Time Scale** unchanged and return to **ETCO2 Main** display, press **EXIT** soft key.
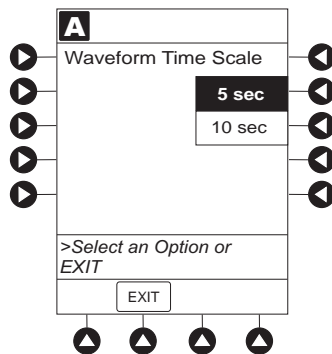
General Setup and Operation

System Start-Up/Setup

See the *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* and *General Information* on page *49* for various system start-up and setup procedures.

General Information

Warnings and Cautions

General

⚠ **WARNING**

- **EtCO₂ and respiratory rate readings can be affected by certain ambient environmental and patient conditions.**
- **The EtCO₂ module is not to be used as an apnea monitor.**
- **The EtCO₂ module is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**
- **If uncertain about measurement accuracy, assess patient's condition and vital signs by alternate means, then ensure that the EtCO₂ module is functioning correctly.**
- **Do not lift the EtCO₂ module by Microstream disposable because it could disconnect from the instrument, causing it to drop on the patient. Do not place the EtCO₂ module in any position that could cause it to fall onto the patient.**
- **Do not use the EtCO₂ module or Microstream disposable inside a hyperbaric chamber.**
- **Respond immediately to system alarms; patient monitoring can cease under certain alarm conditions.**
- **The system is not intended for use with High Frequency surgical equipment.**

Microstream™ Disposable

⚠ **WARNING**

- **Do not use a connector or Microstream disposable that appears damaged.**
- **The Microstream disposable disconnect error message and associated alarm indicate the Microstream disposable is disconnected. Check the Microstream disposable connection and, if necessary, replace the Microstream disposable.**
- **Use only Microstream disposables. Use of a disposable other than those specified can cause improper EtCO₂ module performance, resulting in inaccurate readings.**
- **Before use, read Microstream disposable user manual, including all warnings, cautions, and instructions.**
- **Carefully locate the patient Microstream disposable to reduce the possibility of patient entanglement or strangulation.**

⚠ **CAUTION**

- Do not immerse or dampen the Microstream disposable.
- The Microstream disposables are **designed for single patient use** and are not to be reprocessed. Do not attempt to disinfect or flush the disposable as the EtCO₂ module can be damaged.

Microstream Disposable

When selecting a Microstream disposable, consider the patient's weight, condition, and intubation status. For more information on Microstream disposables, contact Medtronic at http://www.medtronic.com.

For a list of compatible disposables, refer to the Alaris™ EtCO₂ module 8300 Series Compatibility Card (provided separately).

Features and Displays

Features and Definitions

See *Features and Displays* on page *52* for system features and definitions.

Feature	Definition
BPM	Breaths per minute.
Capnography Waveform	Real-time graphical display of CO_2 concentration throughout respiration.
Data Display	Waveforms, trended data, and numerical values are displayed.
EtCO₂	CO_2 concentration in mmHg at end of exhalation.
FiCO₂	Fractional-inspired CO_2; CO_2 concentration present during inhalation.
Limit Mode	Configurable mode that can be set to display either adult or neonatal monitoring mode. (See *Configurable Settings* on page *299* 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.

Operating Features, Controls, Indicators

Status Indicators

Alarm (red)　**Monitoring**
(green)　**Standby**
(yellow)

IUI Connector, Left
(not visible)

IUI Connector,
Right

ALARM　MONITOR　STANDBY

EtCO$_2$ mmHg Display

Respiratory Rate Display

Channel (module) Message
Display

Channel (module) Identification

CHANNEL
SELECT

MONITOR

CHANNEL
OFF

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

Monitor Key: When pressed,
begins patient monitoring.

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

Protective Door

**Microstream™ Disposable
Connector** (Gas Inlet)

Gas Exhaust: Gas scavenging
system connection

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

Displays

The displays illustrated throughout this document are for illustration purposes only. The display content
varies, depending on configuration settings, type of disposable in use, hospital-defined data set uploaded
using the Guardrails suite MX, programmed parameters, and many other variables.

Main Display

See *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* section of this User Manual for more details.

Configurable Settings

See *Features and Displays* on page *52* for system configurable settings.

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

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

Specifications

Accuracy: EtCO$_2$ readings

CO$_2$ Partial Pressure (at sea level)	Accuracy[1]
0 - 38 mmHg	±2 mmHg
39 - 99 mmHg	± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg)

NOTE:

[1] Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12% of reading whichever is greater, for 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 module temperature, ±1 mmHg or 2.5% (whichever is greater), has to be added to tolerance of accuracy specifications.

Respiration rate, measured in range of 0 - 150 bpm with following accuracy:

0 - 70 bpm:	±1 bpm
71 - 120 bpm:	±2 bpm
121 - 150 bpm:	±3 bpm

Alarm Limits:

	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 CO2 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

Frequency Response: $EtCO_2$ accuracy applies for breath rates of up to 80 bpm. For maintaining accuracy for respiration rates above 80 bpm, accuracy is 4 mmHg or ±12% of reading, whichever is greater, for $EtCO_2$ values exceeding 18 mmHg. To achieve specified accuracies for breath rates above 60 bpm, Microstream neonatal airway adapter M1996A must be used.

Gas Interference: 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 -7.5 +15 mL/min

Shock Protection: Type BF, defibrillation-proof patient applied part.

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 EtCO₂ module has been designed and manufactured to exacting standards and should perform well within given environmental and performance standards. There are certain conditions under which an inaccurate measurement or the loss of respiratory rate signal can occur.

⚠️ **WARNING**

- **If uncertain about measurement accuracy, assess patient's condition and vital signs by alternate means, then ensure that the EtCO₂ module is functioning correctly.**
- **Leaks or internal venting of sampled gas can affect accuracy.**

An inaccurate EtCO₂ measurement can be caused by:

- Incorrect disposable application or use.
- Microstream disposable disconnected or not securely connected to the EtCO₂ module.
- Airway connection clogged, twisted, or leaking.
- Placement too close to electro-surgery equipment.
- Mechanically ventilated patient breathes spontaneously.

Loss of a respiratory rate signal can occur in any of the following situations:

- Incorrect disposable application or use.
- Microstream disposable disconnected or not securely connected to the EtCO₂ module
- Airway connection clogged, twisted, or leaking.
- Patient not breathing.
- Placement too close to electro surgery equipment.

Respiration Rate Test

The following test method is used to determine the module's rated respiration rate range and the corresponding effects of end-tidal gas readings accuracy as a function of respiratory rate:

- The system is set for operation.

- The power connection is verified.

- The module is connected to the PC and power supply.

- A scope is connected to the digital/analog multifunction I/O.

- A digital output scheduler software is opened on the PC.

- Gas connections are checked.

- The power connection is verified.

- The gas mixes cylinders are open, set on the required pressure, and their condition is verified.

- A BPM setting is selected.

- The module is connected to the gas tube.

- The module is disconnected.

NOTE:
When 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 + 0.08 for every 1 mmHg above 38 mmHg)
	100-150 mmHg***	± (5% of reading + 0.08 for every 1 mmHg above 38 mmHg)
Measure Accuracy/RR Tolerance mmHg / bpm for Infant/Neonatal FilterLine H Sets at respiration rates of 60, 80, 120 and 150 bpm.	60 bpm	±2mmHg/±1bpm
	80 bpm	±2mmHg/±2bpm
	120 bpm	±4.1mmHg/±2bpm
	150 bpm	±4.1mmHg/±3bpm
Measure CO_2 (mmHg) / RR (bpm) for Infant/Neonatal FilterLine H Sets at respiration rates of 60, 80, 120 and 150 bpm.	**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)
	100-150 mmHg***	± (5% of reading + 0.08 for every 1 mmHg above 38 mmHg)

NOTE:

[1] At sea level.

[2] Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12% of reading whichever is greater, for EtCO₂ values exceeding 18 mmHg. This is tested according to and is compliant with ISO 80601-2-55. To achieve the specified accuracies for breath rates above 60 breaths/minute, the Microstream FilterLine H Set for Infant/Neonatal must be used.

Waveform Analysis
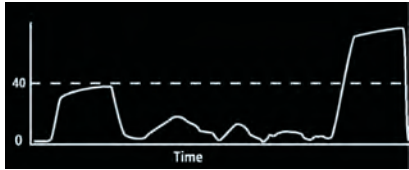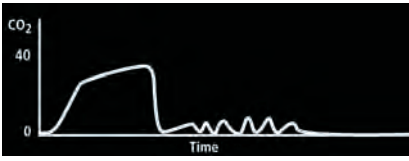
The $EtCO_2$ module provides the option to display $EtCO_2$ module readings as a waveform. The following graph is an example of a normal waveform (normal ventilation, 35 - 45 mmHg). In the event the $EtCO_2$ value is above the waveform display range, the top of the waveform will be clipped. Numerical $EtCO_2$ 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
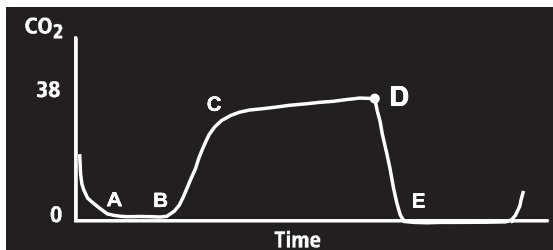
Waveforms can be used to troubleshoot problems with equipment or monitor configuration, as well as to monitor a patient's clinical status. The following graphs are examples of common problems identifiable through waveform analysis. These are examples only and do not represent all potential abnormal waveforms. 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 (via 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 190 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.[1] There is no effect on accuracy due to cyclic pressure up to 10 kPa.

NOTE:
[1] BTPS (body temperature, pressure, saturation assumed 37°C, 47 mmHg) calculations are made according to:
$PCO_2 = FCO_2 \times (Pb - 47)$
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 7
Alaris™ Auto-ID Module Model 8600

This chapter contains the following topics:

Getting Started

Introduction

This section of the user manual provides auto-ID module (model 8600) instructions and information. It is used in conjunction with:

* *Auto-ID Label Guidelines*
* *Technical Service Manual Alaris® Auto-ID Module, Model 8600*
* Module-specific chapters of this user manual
* PCU chapter of this manual (see *Getting Started* on page *16*)
* System maintenance software (and its instructions) for system check-in, maintenance, and configurations for connecting the PCUs to the wireless network

⚠️ **WARNING**

Read all instructions, for both the auto-ID module and PCU, before using the system.

The addition of the auto-ID module to the system with Guardrails suite MX combines dose limit technology and barcode technology to enhance medication safety. The auto-ID module contains an internal barcode image scanner and supports an optional Alaris™ auto-ID handheld scanner supplied by CareFusion. Scanning a barcoded clinician ID and/or a barcoded patient identification band supports verification of the correct patient and associates the CQI event logs with the clinician and/or patient. In addition, using the auto-ID handheld scanner allows an IV solution drug and concentration to be automatically selected from the drug library. Scanned solution containers can be used for pump module, syringe module, and PCA module infusions. Although multiple auto-ID modules may electrically connect, only one module will have auto-ID functionality. Auto-ID may be added as a fifth module.

The system with the auto-ID module is intended to provide trained healthcare caregivers a way to automate infusion parameter input, thereby decreasing the number of manual steps necessary to enter infusion data. All data entry and infusion parameter validation is performed by the trained healthcare professional according to a physician's order.

Electromagnetic Environment: See Appendix A, *Regulations and Standards* and *Compliance* on page *354*).

Programming

Patient Identification

Associating the PCU with a patient provides a means of identifying the module(s) that will deliver IV medications to that particular patient.

Associating PCU with New Patient ID

1. Attach auto-ID handheld scanner to connection port on auto-ID module. Ensure a secure circuit connection.

⚠️ **WARNING**

Use only the auto-ID handheld scanner supplied by CareFusion. Using other accessories can result in increased emissions or decreased immunity of the system.

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.[1]

   - Green **READY** indicator illuminates, indicating system is ready to scan.

Ready-to-scan indicator

READY
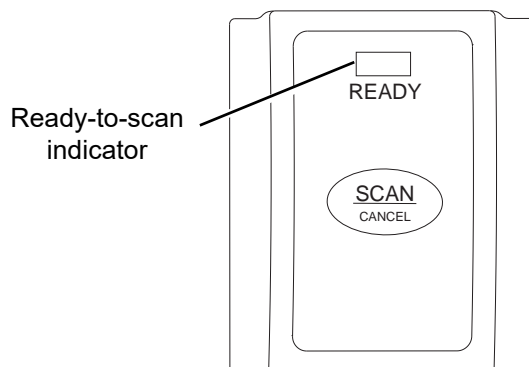
SCAN
CANCEL

6. To scan barcode on patient identification band, press scan trigger on auto-ID handheld scanner. [2][3]

   - 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.

7. To unlock panel, clinician's ID must be scanned.

⚠ **CAUTION**

- CLASS 1 LED PRODUCT: Do not stare into the beam or allow beam to strike patient's face.
- Always verify that information displayed on the PCU matches scanned data.

Scan Trigger

1st Generation Scanner

Scan Trigger
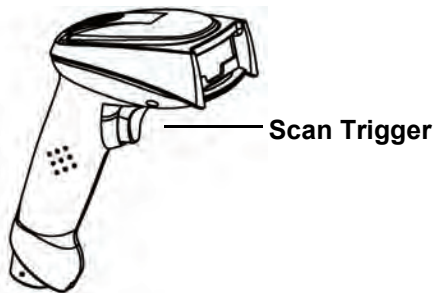
2nd Generation Scanner

NOTE:
① Automatic display of **Patient ID Entry** screen should be enabled in the System Configuration settings.
② If the patient ID is not entered at this time, it can still be entered later.
③ Patient ID can be entered manually using the PCU keypad (see *Patient ID Entry Feature* on page *25*).

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 circuit connection.

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

2. To scan barcode on patient identification band, press scan trigger on auto-ID handheld scanner.[①]

   If scan is successful, an audible tone sounds and patient ID appears on Main Display.

⚠ **CAUTION**

- CLASS 1 LED PRODUCT: Do not stare into the beam or allow beam to strike patient's face.
- **Always verify** that information displayed on the PCU matches scanned data.

NOTE:
① Patient ID can be entered manually using the PCU keypad (see *Patient ID Entry Feature* on page *25*).

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 this feature is enabled, the PCU automatically enables the tamper resist mode upon power on and 5 minutes after programming is completed. If the system is configured to do so, the authorized user mode can be disabled without scanning a clinician's ID; press and hold the tamper resist switch (on back of 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* on page *311* 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.

Primary Infusion

Using the auto-ID module to scan IV medication containers provides the ability to select the correct medication and drug amount/diluent volume from the drug library, and enhances safety through the use of the Guardrails suite MX. It compares the medication identifier from the IV container barcode with the medication identifier from the drug library. If the patient ID is in the IV container barcode, the system also compares the patient identifier in the barcode with the patient identifier in the PCU.[1]

When the green **READY** indicator illuminates, the system is ready to scan.[2]

⚠️   **CAUTION**

*   CLASS 1 LED PRODUCT: Do not stare into the beam or allow beam to strike patient's face.
*   **Always verify** that information displayed on the PCU matches scanned data.

NOTE:
[1] There is a prompt to accept or decline the change of patient ID if it is different from the patient ID already associated to the PCU.
[2] **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.

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. Program infusion (see applicable module-specific section).

Subsequent Primary Infusion

A subsequent primary infusion may be scanned with the pump module running if the following criteria match between the scanned label and the running infusion:

*   Drug or Fluid Name (Alias or NDC)
*   Drug Amount
*   Drug Amount Units
*   Diluent Volume

Starting Secondary Infusion

Starting a secondary infusion while a primary infusion is in progress.

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.

⚠ **CAUTION**

*   CLASS 1 LED PRODUCT: Do not stare into the beam or allow beam to strike patient's face.
*   **Always verify** that information displayed on the PCU matches scanned data.

2. Press **CHANNEL SELECT** key on appropriate module.

    Primary infusion parameters display.

3. Press **Secondary** soft key.

4. Program secondary infusion (see *BD Alaris™ Pump Module Model 8100, Alaris™ Pump Module Model 8100, and Alaris™ Syringe Module Model 8110* on page *61*).

General Setup and Operation

System Start-Up/Setup

See *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* and *General Setup and Operation* on page *18* for various system start-up and setup procedures.

Warnings and Cautions

⚠ WARNING

- **Do not open the auto-ID handheld scanner case. If the case is opened, an electrical shock hazard and possible exposure to potentially hazardous LED light exists which can result in serious personal injury and product damage.**
- **Carefully locate the auto-ID handheld scanner to reduce the possibility of patient entanglement or strangulation.**
- **Use only the auto-ID handheld external scanner supplied by CareFusion. Using other accessories can result in increased emissions or decreased immunity of the system.**

⚠ CAUTION

Class 1 LED devices are safe under reasonably foreseeable conditions of operation, including the use of optical instruments for intrabeam viewing. To **avoid potential harm**, avoid looking into the beam or allowing the beam to strike the patient's face.

Auto-ID Handheld Scanners

The auto-ID handheld scanners supplied by CareFusion are the only handheld scanners approved for use with the auto-ID module.
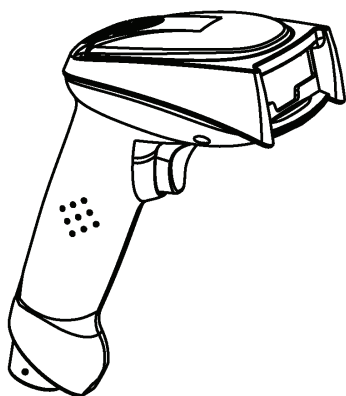
1st Generation Scanner

2nd Generation Scanner

⚠️ **WARNING**

- **Do not open the auto-ID handheld scanner case. If the case is opened, an electrical shock hazard and possible exposure to potentially hazardous LED light exists which can result in serious personal injury and product damage.**
- **Use only the auto-ID handheld scanner supplied by CareFusion. Using other accessories can result in increased emissions or decreased immunity of the system.**

⚠️ **CAUTION**

Class 1 Led Product. Do not stare into the beam or allow beam to strike patient's face.

Features

Features and Definitions

See *Features and Definitions* on page *52* 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 *319*).
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.

Operating Features, Controls and Indicators
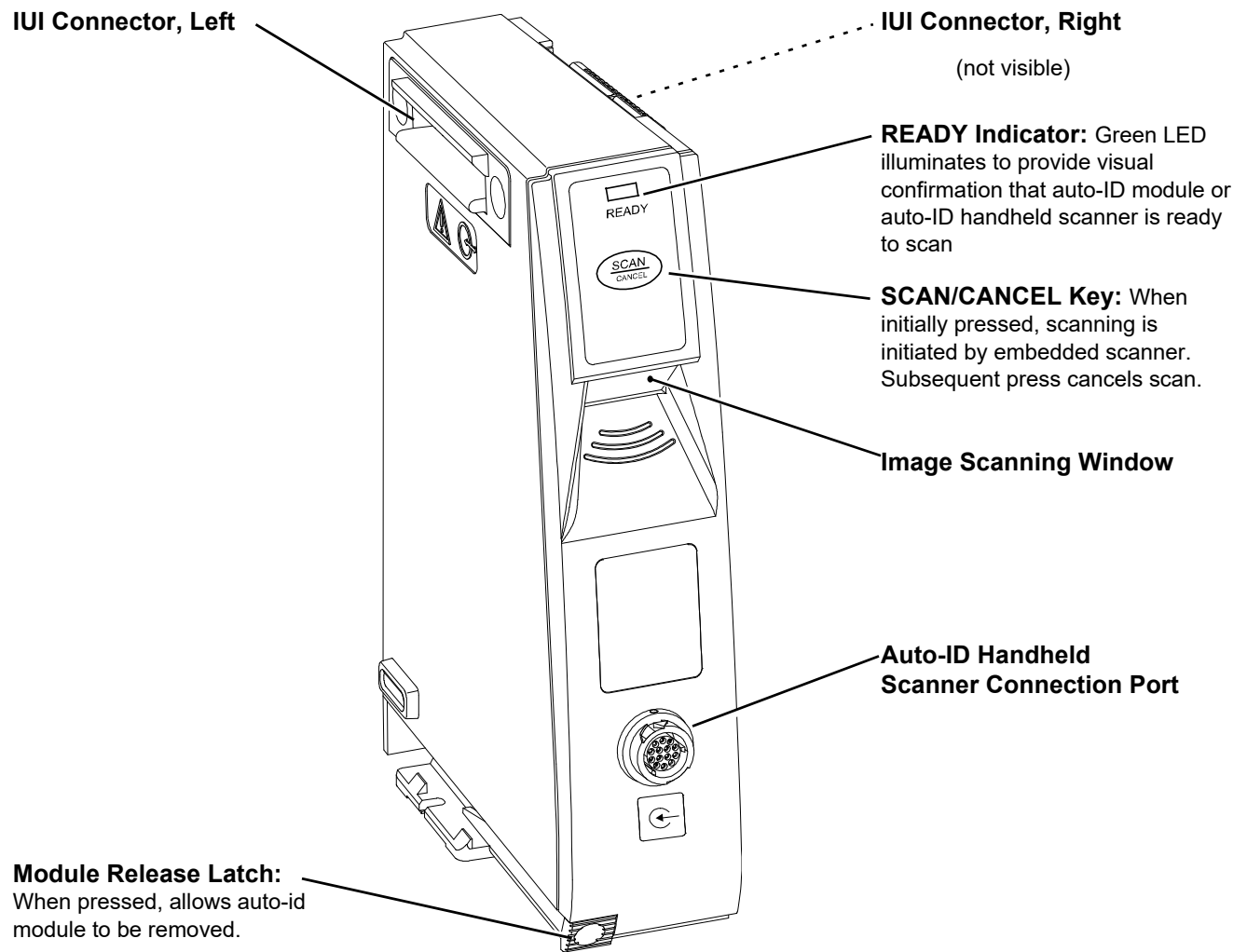
IUI Connector, Left

IUI Connector, Right

(not visible)

READY Indicator: Green LED illuminates to provide visual confirmation that auto-ID module or auto-ID handheld scanner is ready to scan

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

Image Scanning Window

Auto-ID Handheld Scanner Connection Port

Module Release Latch: When pressed, allows auto-id module to be removed.

Configurable Settings

See *BD Alaris™ PCU Model 8015 and Alaris™ PCU Model 8015* on page *15* for system configurable settings.

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

With the profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best-practice data set must be uploaded to enable the profiles feature. Date and time is a system setting and is the same in all profiles.

Specifications and Symbols

Specifications

Auto-ID Module and Auto-ID Handheld Scanner				
Environmental Conditions:	**Symbols**	**Meaning**	**Operating**	**Storage/Transport**
		Atmospheric Pressure	525 - 4560 mmHg (70 - 608 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)
LED Light:	Class 1 LED product. Aiming LED: 523 nm, cw, 0.412 mW average radiant power Illumination LED: 635 nm, cw, 2.226 mW average radiant power			

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.

Troubleshooting and Maintenance

Errors and Messages

Alarms and Alerts: See *Appendix A, Troubleshooting and Maintenance* on page *324* 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	Drug and its concentration might not be in currently selected profile.	Ensure that correct profile is selected and that it has correct drug and concentration.
Channel Unavailable	Channel is currently infusing and cannot support scanned infusion.	If secondary infusion was scanned, select a channel with a primary infusion that supports the secondary. If primary infusion was scanned, select an idle channel to program.
Patient ID will be changed	The Patient ID is not the same Patient ID that is currently associated with the device.	If the Patient ID associated to the PCU should be changed, press **Yes**. If the Patient ID associated to the PCU should not be changed, press **No**.

Appendix A
Troubleshooting and Maintenance

This appendix contains the following topics:

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™ PC Unit Model 8015, Alaris™ PC Unit 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	*Technical Service Manual Alaris Syringe Module, 8110 Series* *Alaris PCA Module, 8120 Series*
Alaris SpO$_2$ module models 8210 and 8220	*Technical Service Manual Alaris SpO$_2$ Modules*
Alaris EtCO$_2$ module model 8300	*Technical Service Manual Alaris EtCO$_2$ Module, 8300 Series*
Alaris auto-ID module model 8600	*Technical Service Manual Alaris Auto-ID Module, Model 8600*

The service manuals and system maintenance are available from CareFusion. The service manuals include routine service schedules, interconnect diagrams, component parts lists and descriptions, test procedures, and other technical information to assist qualified service personnel in repair and maintenance of the instrument's repairable components. System maintenance is used to perform a new instrument check-in, preventive maintenance tests, calibration checks, calibration, and other maintenance functions.

Artifacts: It is normal for an infusion device to produce nonhazardous currents when infusing electrolytes. These currents vary proportional to the infusion device flowrate. When an ECG monitoring system is not functioning under optimal conditions, these currents might appear as artifacts, simulating actual ECG readings. To determine if ECG abnormalities are caused by patient condition or the ECG equipment, place the infusion device on hold. If the ECG readings become normal, the ECG equipment requires attention. Proper setup of the ECG equipment should eliminate these artifacts. Refer to the appropriate ECG monitoring system documentation for instructions on setup and maintenance.

BD Alaris™ Systems Manager Connections

When a systems manager connection is made, the wireless network indicator 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

Clinician's Position for Alarm Monitoring

CareFusion recommends that the clinician's position should be at a distance no greater than 1 meter to monitor visual alarm signals, four meters to monitor alarm condition and priority, and in proximity of the device so that any auditory alarm can be heard. The distance to monitor auditory alarms will vary depending upon your facility's acoustics and ambient sound. Auditory alarms signal sound pressure levels that are less than ambient levels can impede the clinician's recognition of an alarm condition and the alarm system.

Display Color

Color is used in the title and prompt bars to help communicate the following types of information.

Display Color

Communication	Color	Description
Normal Operation	Blue	All messages other than noted below (normal operating displays).
Guardrails™ limit	Yellow	Visual message indicating a Limit was exceeded.
Pertinent message	Yellow	Visual message that calls attention to a programming parameter or to the infusion status.
Informational	Green	Visual message.
Alarms and malfunctions	Red	Visual message indicating an error or system inconsistency occurred.

Definitions

Alerts and alarms are indicated by a combination of audible tones, visual flashing behavior, and a descriptive message on either the PCU or scrolling module marquee.
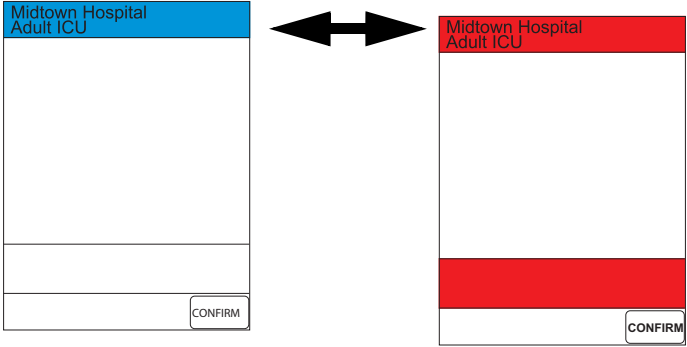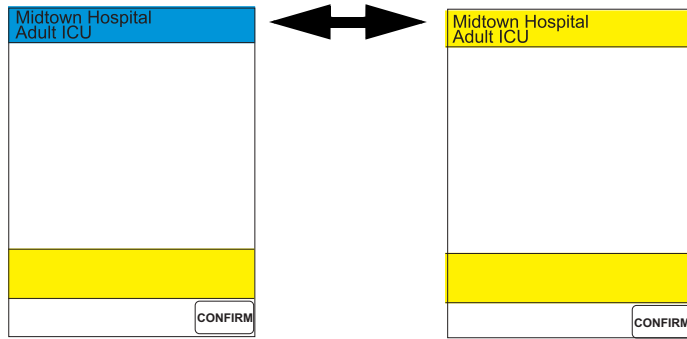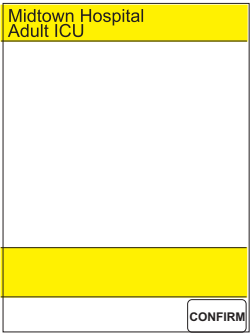
Alarms notify the clinician of a potential or an actual hazardous condition.
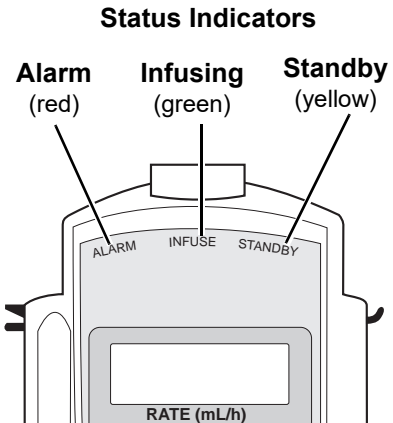
Definitions of Alarms

Terms	Definitions
High Priority	A high-priority alarm is initiated by any alarm condition requiring immediate user response.
Medium Priority	A medium-priority alarm is initiated by any alarm condition requiring prompt user response.
Low Priority	A low-priority alarm is initiated by any condition requiring user awareness.
Informational Signal	A signal that provides information which may, or may not, require action to be taken by the clinician.
Reminder Signal (NEOI Snooze)	A periodic audible signal that reminds the user that a near end of infusion alert has been previously silenced. When enabled in the data set, this reminder signal can be configured in 5, 10, and 15 minute intervals.

The system alarms are further categorized by type:

Definitions of Alarm Types

Terms	Definitions
Technical Alarms	An alarm arising from a hardware or software failure condition. The signal priority is indicated by an audio tone and visually, by the color of the title bar on the 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, pump).

Terms	Definitions
Monitoring Alarms	An alarm arising from a monitoring module.
Status Indicators **Alarm** (red) **Infusing** (green) **Standby** (yellow) ALARM INFUSE STANDBY **RATE (mL/h)**	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 silence for up to 120 seconds by pressing the **SILENCE** key. The alarm indicator remains on and the alarm silence symbol is displayed. The silence period can be ended by pressing the **CANCEL SILENCE** soft key. An alarm can be silenced in the **PANEL LOCKED** condition.
Alert	A visual, audible, or visual and audible signal provided by the system. This includes alarms, informational, and reminder signals.
Calibration Check	A technical procedure, defined in the Technical Services Manual, to verify instrument calibration.
Cancel Silence[1]	An alarm may be canceled by pressing the cancel silence soft key. If the alarm condition has not been resolved, the alarm audio resumes.
Clinical Advisory	A visual message when a designated drug is selected to remind the clinician of specific hospital/facility standards of practice when programming an IV medication. A specific Clinical Advisory and/or message can be associated with a selected drug within any of the patient care profiles. Clinical Advisories are not displayed in Anesthesia mode.
Control Unit	PCU and Auto-ID (barcode) module
High Priority Alarm	A high-priority alarm is initiated by any alarm condition requiring immediate user response.

Terms	Definitions
Information Signal	Any signal that is not an alarm signal or a reminder signal.
Infusion Alarm	An alarm arising from an infusion module (PCA, syringe, pump)
Low Priority Alarm	A low-priority alarm is initiated by any condition requiring user awareness.
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 initiated by any alarm condition requiring a prompt user response.
NEOI Snooze (Reminder signal)	Configurable alert, if enabled, provides an audio only tone when a Near End of Infusion alarm had been previously silenced.
Monitoring Alarm	An alarm arising from a monitoring module (SpO_2 or $EtCO_2$).
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.

NOTE:

① A previously silenced alarm audio can be reactivated by pressing the **Cancel Silence.** If the alarm condition has not been resolved, the alarm audio will resume.

Alert Prioritization

All the system Alerts are prioritized by type/source and the condition of the alert.

Alert Prioritization Types and Sources

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

Audio Characteristics of Profiles

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 Alarm Silence or Presilence symbol

Infusion Alarm Silence symbol

CANCEL SILENCE soft key
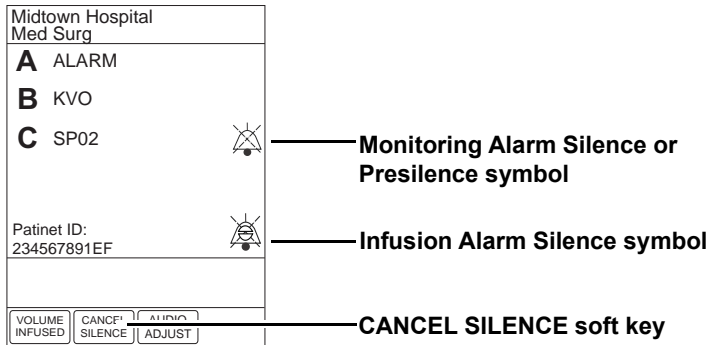
Monitoring Alarms:

Monitoring alarms may be presilenced, or silenced in response to a monitoring alarm condition. All monitoring alarms are silenced for 120 seconds (subsequent infusion alarms are not silenced during this period). Alarm indicators remain on and a monitoring alarm silence icon is displayed. Silence period can be ended by pressing **CANCEL SILENCE** soft key.

Alarms

Alarms

Alarm Message	Device	Priority	Meaning	Response
ATTACH HANDSET	PCA	Low	The Dose Request Cord detached from the device during an active infusion. The Dose Request Cord is required only for PCA and PCA + Continuous Infusion modes.	Reattach the Dose Request Cord and press the **RESTART** key.
ACCUMULATED AIR-IN-LINE ALARM	Pump	High	A large number of air bubbles smaller than the current air-in-line limit has recently passed the air-in-line detector.	Clear air from the administration set. Press the **RESTART** key, or press the **CHANNEL SELECT** key and then the **START** soft key.
AIR-IN-LINE	Pump	High	Air has been detected in the administration set during an infusion. The infusion stops on affected channel.	Ensure that the tubing is properly installed in the Air-in-Line detector. If air is present, clear the air from administration set. Press the **RESTART** key, or press the **CHANNEL SELECT** key and then the **START** soft key.
ANESTHESIA MODE AC POWER CONNECTED	PCU	Informational	The AC power cord is connected	Select **Yes** or **No** to continue in the 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 $EtCO_2$ or SpO_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 autozero cycle is complete, the device begins measurement again. No user intervention is required.
BAD SENSOR	SpO_2	Medium	A broken or unknown SpO_2 sensor or patient cable is attached. The device cannot monitor the patient's vital signs.	Check or replace the sensor and the patient cable.

Alarm Message	Device	Priority	Meaning	Response
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.
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 SpO_2 $EtCO_2$	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 SpO_2 $EtCO_2$	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 administration set is not properly installed. Infusion stops on affected module.	Close the roller clamp, remove and reinstall the administration set, close the door, open the roller clamp, and then press the **RESTART** soft key.
CHECK SENSOR - ELECTRIC/ OPTIC INTERFERENCE	SpO_2	Medium	External interference on SpO_2 sensor.	Check the sensor. Identify the source of external interference if it is other than sensor.

Alarm Message	Device	Priority	Meaning	Response
CHECK SENSOR - EXCESS AMBIENT LIGHT	SpO$_2$	Medium	SpO$_2$ sensor is detecting excessive light.	Check the sensor. Remove or reduce the lighting. Cover or reposition the sensor.
CHECK SENSOR - HIGH PULSE AMPLITUDE	SpO$_2$	Medium	An artifact is interfering with the pulse reading.	Check the sensor. Relocate the sensor to a site with less artifact interference.
CHECK SENSOR - MOTION INTERFERENCE	SpO$_2$	Medium	The patient's motion has inhibited monitoring.	Check the sensor. Move the sensor to a site with less motion.
CHECK SENSOR - WEAK PULSE	SpO$_2$	Medium	The SpO$_2$ sensor is receiving a weak pulse signal due to low perfusion.	Check the sensor. Confirm the correct sensor placement. Move the sensor to a better perfused site.
CHECK SENSOR - WEAK SIGNAL	SpO$_2$	Medium	The SpO$_2$ sensor is receiving a low quality signal.	Check the sensor. Confirm the correct sensor placement. Move the sensor to a better perfused site.
CHECK SYRINGE	Syringe PCA	High	The lever, plunger, and/or barrel clamp is not engaged properly.	Inspect the syringe/PCA module and adjust the appropriate sensor as needed. Reselect the syringe, restore or reprogram and start or restart the infusion.
CHECKING LINE	Pump	Informational	A patient-side occlusion has occurred; the Auto-Restart feature monitors downstream pressure to determine if infusion can continue.	No user response expected.
CLEARING DISPOSABLE	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.
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.

Alarm Message	Device	Priority	Meaning	Response
DELAY COMPLETE	Syringe Pump	Medium	Delay time complete.	To resume the infusion, press **RESTART** on the module or press **CHANNEL SELECT** and then the **START** soft key.
DELAYED STATUS	Syringe Pump	Informational	The infusion has been delayed for a defined period of time.	No user response is expected.
DISCONNECT OCCLUDED DISPOSABLE	$EtCO_2$	Medium	The disposable is occluded.	Check the disposable. Obtain a new disposable and attach it to patient.
DISPLAY FAILURE - REPLACE MODULE	SpO_2 $EtCO_2$	High	There is a malfunction with the display on the SpO_2 or $EtCO_2$ modules. The device continues to monitor.	Replace the module.
DISPOSABLE DISCONNECTED	$EtCO_2$	Informational	No disposable is connected to the module while attempting to search for a patient.	Ensure disposable is attached to module.
DISPOSABLE DISCONNECTED	$EtCO_2$	Medium	No disposable is connected to the module during monitoring or after approximately 30 seconds of searching for a patient.	Ensure disposable is attached to module.
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.
HIGH SATURATION	SpO_2	High	The high saturation alarm limits have been exceeded.	Assess the patient's condition. Confirm that the correct alarm limit values are selected.
HIGH_PULSE	SpO_2	High	The high pulse rate alarm limit has been exceeded.	Assess the patient's condition. Confirm that the correct alarm limit values are selected.
INCOMPATIBLE MODULE	PCU	Informational	The PCU is unable to recognize the attached MODULE because it is an unsupported module type	Remove the unsupported module.
INFUSION COMPLETE	Syringe Pump	Medium	The current infusion is completed with no KVO.	Set up a new infusion or press the **CHANNEL OFF** key.
INFUSION COMPLETE - KVO	Pump Syringe	Medium	VTBI has been infused; the module is infusing at the KVO rate	Set up a new infusion, if required, and 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.
LOW SATURATION	SpO$_2$	High	The low saturation alarm limits have been exceeded.	Assess the patient's condition. Confirm that the correct alarm limit values are selected.
LOW_PULSE	SpO$_2$	High	The low pulse rate alarm limit has been exceeded.	Assess the patient's condition. Confirm that the correct alarm limit values are selected.
MAINTENANCE REMINDER	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.

Alarm Message	Device	Priority	Meaning	Response
NEAR END OF INFUSION	Syringe PCA	Low	The syringe is almost empty. This is a timed event that can be configured in the data set. To set or change this option, see *General Information* on page *168* and *Configurable Settings* on page *186*.	To silence the alarm, press the **SILENCE** key. The module remains functional and continues the infusion.
NEOI Snooze	Syringe PCA	Reminder	A periodic audible signal that reminds the user that a Near End of Infusion alarm has been previously silenced.	None
NETWORK COMMUNICATION ERROR	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.
NO SENSOR	SpO$_2$	Informational	No sensor is connected to the module while attempting to search for a patient.	Attach the sensor to the module.
NO SENSOR	SpO$_2$	Medium	No sensor is connected to the module during monitoring or after approximately 30 seconds of searching.	Check the patient. Attach the sensor to patient.
NO SIGNAL	SpO$_2$	Medium	Failure to find a patient signal	Check the sensor. Confirm the correct sensor placement.
OCCLUDED - FLUID SIDE/EMPTY CONTAINER	Pump	High	Indicates either an upstream occlusion or an empty container. The infusion stops on affected module.	Clear the occlusion on fluid side of the device. If necessary, refill the drip chamber. Press the **RESTART** key, or press the **CHANNEL SELECT** key and then the **START** soft key.
OCCLUDED - PATIENT SIDE	Pump	High	Increased back pressure sensed while infusing. The infusion stops on affected module.	Clear the occlusion. Press the **RESTART** key, or press the **CHANNEL SELECT** key and then the **START** soft key.
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.

Alarm Message	Device	Priority	Meaning	Response
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.
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.

Alarm Message	Device	Priority	Meaning	Response
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.
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 administration set or close the door.
SEARCHING	SpO$_2$ EtCO$_2$	Informational	The monitoring device is attempting to start monitoring and is searching for patient vitals. Searching automatically follows initialization	N/A
SENSOR OFF	SpO$_2$	Medium	The sensor is not connected to the patient while monitoring or after approximately 30 seconds of searching for patient.	Check the patient. Attach the sensor to the patient.
SENSOR WARMING	EtCO$_2$	Informational	The monitoring device is preparing sensor mechanisms to search for and monitor the patient vitals.	N/A
SWITCHOVER STATUS	Syringe PCA Pump	Informational	The device is delivering medication/fluid.	No user response expected.

Alarm Message	Device	Priority	Meaning	Response
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.
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

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.

Battery Care and Maintenance

Battery Type and Charging

The PCU is equipped with a 12 volt, 4000 mAh nickel metal hydride battery. The battery is charging whenever the instrument is plugged into an AC receptacle. The life expectancy of the battery is dependent on the amount of use, the depth of discharge, and the state of the charge that is maintained. Generally, the battery has the longest life if the instrument is plugged in and battery use is infrequent. Frequent use of battery power and insufficient battery charge cycles significantly decrease the life of the battery.

Normally a battery will last 2 years if used under proper maintenance. See *Proper Battery Maintenance* on page *341*.

Use only CareFusion batteries. The use of third party batteries could affect the safety and efficacy of 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. This ensures proper battery operation when the Alaris System is first set up for patient use.

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

If the device has been used on battery power, ensure that the battery is fully charged prior to using the device on battery power again. To fully charge a depleted battery connect the device to a hospital grade AC power source for 16 hours.

Battery 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 qualified service personnel while the instrument is not in use.

⚠️ **CAUTION**

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

Proper Battery Maintenance

The battery should be conditioned every 12 months by qualified service personnel.

The battery should be replaced every 2 years by qualified service personnel. See the *BD Alaris™ PC Unit Model 8015, Alaris™ PC Unit 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

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 Alaris PCU stores electronic protected health information (ePHI) data that requires HIPAA compliance. The ePHI data must be cleared from the historical log on the Alaris 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)).

Instructions on how to clear the historical log data is outlined in *Service Bulletin 597A*, *Clearing BD Alaris*^{TM} *PCU and Alaris*^{TM} *PCU Historical Log Data*.

Inspection Requirements

To ensure that the Alaris System remains in good operating condition, both regular and preventive maintenance inspections are required. Refer to system maintenance for detailed instructions.

⚠️ **WARNING**

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

⚠️ **CAUTION**

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

Regular Inspections

Procedure	Frequency
INSPECT FOR DAMAGE	
• Exterior Surfaces • IUI Connector* • Keypad • Pole Clamp • Power Cord	• Each usage • Each usage • Each usage • Each usage • Each usage
CLEANING	As required
START-UP	Each usage

NOTE:
*While visually inspecting the IUI connectors, look for fractures on the connectors black-colored plastic. If you see any damage, do not use an instrument with fractured IUI connectors. The IUI connector must be replaced before the instrument can be used again.

Inspect IUI Connectors

If any surface contaminants or blue or green deposits are visible, the connector must be replaced.

⚠️ **WARNING**

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

⚠️ **WARNING**

Inserting a finger or other object into the IUI connector, when the module is attached to the PC unit, could result in electrical shock.
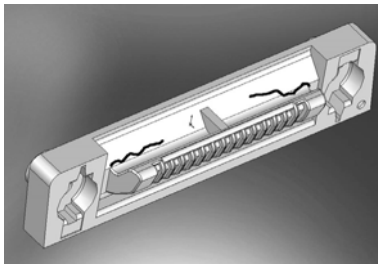
Figure 1: Male IUI Connector (right side)

Figure 2: Male IUI Connector

1. Visually inspect the right side (male) IUI connector for cracks on the entire surface of the black colored plastic housing. See Figures 1 and 2 for the male IUI inspection area and typical cracks.
2. Visually inspect the left side (female) IUI connector for cracks on the edges of the black colored plastic housing.
3. If cracks are found, replace the IUI connector before use.

Cleaning

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

⚠️ **WARNING**

- **To prevent an electrical hazard:**
    - **Turn the instrument off and unplug the power cord from AC power before cleaning.**
    - **Do not spray fluids directly onto the instrument or into the IUI connectors.**
    - **Do not steam autoclave, EtO sterilize, immerse the instrument in fluids, or allow fluids to enter the instrument case.**
    - **Do not connect a module until the IUI connectors are thoroughly dry.**
- **Do not use compressed air to dry the instrument; this could force fluid into the instrument.**

BD Alaris™ and Alaris™ System

Cleaning Products

Refer to the following website for cleaning product information: *www.carefusion.com/alarissystemcleaning*.

Procedure

Inspect IUI Connectors

⚠️ **WARNING**

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

⚠️ **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.
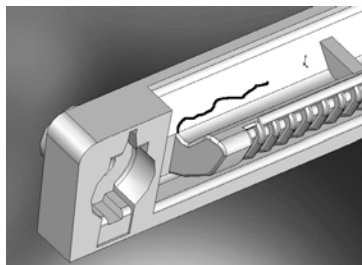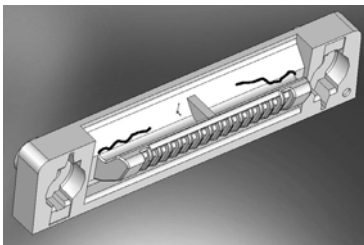

Figure 1: Male IUI Connector (right Side)
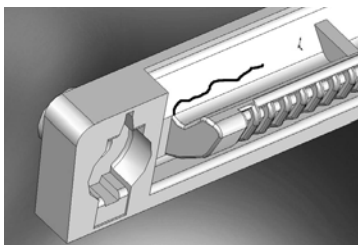
Figure 2: Male IUI Connector

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.

⚠ **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.

⚠ **CAUTION**

•   Do not allow cleaning solutions to collect on the instrument. Residue buildup might cause the moving parts to become sticky and hinder their operation over time.

•   Certain chemicals can damage the surfaces of the instrument. Refer to the following website for a list of chemicals that should NOT be used: *www.carefusion.com/alarissystemcleaning*

•   Do not use chemicals that can damage the surface of the instrument. When possible use cleaning products that are recommended for use by CareFusion.

Cleaning the Case

1. Make sure the instrument is turned off, unplug the power cord and wipe all of the exposed device surfaces EXCEPT the inter-unit interface (IUI) connectors.

    DO NOT use an oversaturated cloth. Be sure to squeeze out excess liquid.

2. Use a dedicated soft-bristled brush to clean the case to remove any visible residue. The brush may also be used to clean narrow or hard-to-reach areas.

    DO NOT use any hard, abrasive or pointed objects to clean any part of the instrument.

3. Follow the cleaner manufacturer's instructions on the time to leave it on the device surface. Then, remove the cleaner using a soft cloth dampened with water.

    DO NOT allow the cleaner to collect on the instrument.
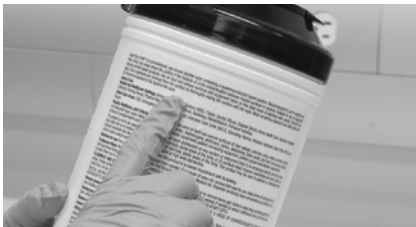
Cleaning the IUI

1. Apply 70% isopropyl alcohol directly to the dedicated IUI cleaning brush. To prevent cross-contamination, do not dip the brush into the IPA.

    DO NOT use the same brush used on the case to clean the IUI connectors. Doing so could inadvertently transfer the cleaner or contaminants to the electrical contacts.

    Take care not to allow fluids to come in contact with electrical components and openings, with the exception of the IUI, as outlined below. Ensure that the rubber boot is secured before and during cleaning to help prevent fluid from entering the electrical RJ45 plug.

2. Clean both IUIs with the dedicated IUI cleaning brush.

    To avoid accidentally depositing fluid on the connectors, DO NOT use any spray cleaners anywhere near the IUI connectors.

    NEVER ALLOW ANY CLEANER OTHER THAN 70% IPA TO CONTACT THE IUI CONNECTORS.

Drying and Inspection

⚠️ **WARNING**

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

1. Confirm that the instruments and IUI connectors are thoroughly dry before using them again.

    DO NOT attach devices that have not fully dried to one another. "Wet mating" can hinder proper instrument operation.

2. Fully inspect the instrument during each cleaning. Look for any visible external damage such as a cracked or broken door, handle, or latch. Open the door of each pump module and inspect the platen and hinge for cracks or other damage.

DO NOT use a device with any damage. Send it to Biomedical Engineering for repair.

3. Inspect the IUI connectors on each PCU and module prior to use. Replace any IUI connector with surface contaminants, blue or green deposits, or cracks.

DO NOT use a device with any cracks or surface contaminants on the IUI connectors. Rather, send it to Biomedical Engineering for repair.

Service Information

Auto-ID 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.

WARNING

- **The instrument case should only be opened by qualified personnel using proper grounding techniques. Prior to performing maintenance, disconnect attached module from the system and the PCU from AC power.**

- **During servicing, an instrument's configuration settings might be reset to the factory defaults. Qualified hospital/facility personnel are responsible for checking in the instrument and ensuring the current hospital approved data set is loaded.**

If the instrument shows evidence of damage in transit, notify the carrier's agent immediately. Do not return damaged equipment to the factory before the carrier's agent has authorized repairs.

If the instrument fails to respond as described in this document and the cause cannot be determined, do not use the instrument. Contact qualified CareFusion service personnel.

If it is necessary to return the instrument for service, obtain a return authorization number prior to shipment. Carefully package the instrument (preferably in the original packaging), refer to the return authorization information, and return it to the appropriate service or distribution center. CareFusion does not assume any responsibility for loss of, or damage to, returned instruments while in transit.

Technical Support

Technical support, service information, applications, and manuals can be obtained by contacting a CareFusion representative. 888-812-3229.

When submitting any request for service, include:

- model number
- a description of difficulty experienced
- instrument settings
- administration set/lot number
- solution(s) used
- message displayed at time of difficulty

<hr>

WARRANTY

CareFusion 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 CareFusion to the original purchaser.

B. The battery and each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by CareFusion to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with CareFusion to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at CareFusion's expense. The product requiring service should be returned promptly, properly packaged and postage prepaid by purchaser. Loss or damage in return shipment to the repair facility shall be at purchaser's risk.

In no event shall CareFusion be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any 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 CareFusion 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 CareFusion Service Representative;

2. altered in any way so as to affect, in CareFusion's judgment, the product's stability or reliability;

3. subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, effaced or removed; or

4. improperly maintained or used in any manner other than in accordance with the written instructions furnished by CareFusion.

5. Customer's use of repair or service parts or disposables that are not approved by CareFusion is at Customer's own risk and may void the product warranty provided by CareFusion.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of CareFusion, and CareFusion does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of CareFusion any other liability in connection with the sale or use of Alaris System products.

CAREFUSION DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

See packing inserts for international warranty, if applicable.

Regulations and Standards

Compliance

Electromagnetic Environment

BD Alaris^{TM} System

⚠️ **CAUTION**

Any changes or modifications not expressly approved by the personnel responsible for compliance could void the user's authority to operate the system.

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

Immunity Test	IEC 60601-1-2:2014 Test Level[3]	Compliance Level[3]	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[2]	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 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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, 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.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Table 2 (Continued)
Electromagnetic Immunity

Immunity Test	IEC 60601-1-2:2014 Test Level	Compliance Level[1]	Electromagnetic Environment - Guidance[4][5]
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 - 80MHz 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 Alaris System (including cables) than recommended separation distance calculated from equation applicable to frequency of transmitter. Recommended Separation Distance: $$d = \left[\frac{12}{V_2}\right]\sqrt{P}$$
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	$$d = \left[\frac{12}{E_1}\right]\sqrt{P} \quad 80\ MHz - 800\ MHz$$
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	$$d = \left[\frac{12}{E_1}\right]\sqrt{P} \quad 80\ MHz - 2.5\ GHz$$ d = recommended separation distance in meters (m).[6] 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.[7][8] Interference might occur in vicinity of equipment marked with the following symbol:

Table 3[4][5][6][9]
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.

Rated Maximum Output Power of Transmitter (W)	Separation Distance Based on Transmitter Frequency (m)			
	150 kHz - 80 MHz Outside ISM Bands	150 kHz - 80 MHz In ISM Bands	80 MHz - 800 MHz	800 MHz - 2.5 GHz
	$d = \left[\dfrac{3.5}{V_1}\right]\sqrt{P}$	$d = \left[\dfrac{12}{V_2}\right]\sqrt{P}$	$d = \left[\dfrac{12}{E_1}\right]\sqrt{P}$	$d = \left[\dfrac{23}{E_1}\right]\sqrt{P}$
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

NOTE:

① Performed at the minimum and maximum rated input voltage.

② U_T is the AC mains voltage prior to application of the test level.

③ At 80 MHz and 800 MHz, the higher frequency range applies.

④ These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⑤ 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.

⑥ 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.

⑦ Over the frequency range 150 kHz - 80 MHz, field strengths should be less than [V_1] V/m.

⑧ The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz, and 40.66 - 40.70 MHz.

Compact Flash Wireless Networking Module

The CF Wireless module contains a radio frequency, wireless, local-area network interface (RF card). The RF card allows the 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:

Becton Dickinson Pty Ltd
4 Research Park Drive
North Ryde, NSW
Australia 2113
Phone: 02 9838 0255
Fax: 02 9674 4444

Standards

The system has been assessed and complies with the following standards:

- **PCU and overall System:** CAN/CSA C22.2 No. 60601-1 (3.0 Edition 2014), IEC 60601–1 (3.1 Edition 2012), IEC 60601-1-8 (2012)

- **PCU, LVP, Syringe, PCA, and Auto-ID** are compliant with IEC 60601-1-2 (2014)

- **Auto-ID handheld scanner:** IEC 62471 Photo biological Safety of Lamps and Lamp Systems

- **Compact Flash Wireless Networking Module:** Class B digital device limits pursuant to Parts 15 (RF Devices and Computing Devices 2015) and 18 (Medical Devices) of the FCC Rules and Regulations 2015. To comply with FCC and Industry Canada exposure requirements, the CF Wireless Module is approved for operation when there is more than 20 cm between the antenna and the user's or patient's body.

- **EtCO$_2$ module:** ISO 80601-2-55 (2011), IEC 60601-2-49 (2011), IEC 60601-1-2 (2007)

- **PCA, pump, and syringe modules:** IEC 60601-2-24 (Edition 2.0 2012)

The system, when upgraded to v12.1 software only, has been assessed and complies with the following standards:

- **PCU and overall System:** UL 60601–1 (2003), CAN/CSA C22.2 No. 601.1-M90 (2.0 Edition 1990), IEC 60601–1 (2.0 Edition 1988)

- **Auto-ID handheld scanner:** IEC 62471 Photo biological Safety of Lamps and Lamp Systems.

- **Compact Flash Wireless Networking Module:** Class B digital device limits pursuant to Parts 15 (RF Devices and Computing Devices 2015) and 18 (Medical Devices) of the FCC Rules and Regulations 2015. To comply with FCC and Industry Canada exposure requirements, the CF Wireless module is approved for operation when there is more than 20 cm between the antenna and the user's or patient's body.

- **EtCO$_2$ module:** ISO 9918: 1993, ASTM F 1456 (2001), ASTM F 1463 (1993), EN 475 (1995), EN 864 (1997)

- **PCA, pump, and syringe modules:** IEC 60601-2-24 (1.0 Edition (1998), ANSI/ AAMI ID26 (1998)

- **SpO$_2$ module:** EN 865 (1997)

Hardware Dependencies

Additional test evidence is available for the $EtCO_2$ hardware included in devices manufactured with v9.33 software. This test evidence does not apply to devices upgraded to v9.33.

EtCO₂ Hardware Dependencies	v9.33 Software Upgrade Only	Device Manufactured with v9.33 Software
Note 1 for Accuracy of $EtCO_2$ Readings (on page 300)	Does not apply	Applies
Accuracy Specification for Interfering Gases (on page 300)	Does not apply	Applies
Waveform Sampling (on page 301)	Does not apply	Applies
Respiration Rate Test Table (on page 303)	Does not apply	Applies
Note 2 in the Accuracy in Respiration Rate Test Table (on page 304)	Does not apply	Applies