BD Alaris™ Guardrails™ Editor Model 8961 v12.1.3 for BD Alaris™ Guardrails™ Suite MX

Software User Manual

2023-09

Part Number: P00000456

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

858-617-2000

bd.com

BD Alaris™ Guardrails™ Editor Model 8961 v12.1.3 for BD Alaris™ Guardrails™ Suite MX Software User Manual

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

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

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

Within the United States: Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to the FDA's MedWatch Program:

www.fda.gov/medwatch

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

North America

BD Designated Complaint Handling Unit - North America
(Clinical and technical feedback.)
Phone: 844.823.5433
E-mail: ProductComplaints@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: 866.488.1408
Phone, Canada: 800.387.8309

For Internal Use Only
DME: 10000365787-01

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About this Guide

This software user manual provides information on BD Alaris™ Guardrails™ Editor Model 8961 v12.1.3 for BD Alaris™ Guardrails™ Suite MX.

- The Guardrails™ Editor software version produces a data set that is compatible with the PCU v12.3.1.
- The SpO_2 Module Models 8210 and 8220 are not supported or compatible with the BD Alaris™ PCU and Alaris™ PCU Model 8015 v12.3.1. SpO_2 Module support including configuration settings have been removed from v12.1.3 of the GRE software.
- The software version number and UDI number depicted in all screenshots are representative only.

Indications for Use

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

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

BD Alaris™ Pump Module and Syringe Module and Alaris™ PCA Module are indicated for varying patient populations, routes of administration, and infusates.

Pediatric* and Neonate** Patient Populations

Module	Route of Administration	Infusates
BD Alaris™ Pump Module	Intravenous	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets, and fresh frozen plasma.
	Subcutaneous	Fluids and pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
BD Alaris™ Syringe Module	Intravenous	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets, and fresh frozen plasma.
	Subcutaneous	Pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
Alaris™ PCA Module	Intravenous	Pain management drugs approved for intravenous use.
	Epidural	Pain management drugs approved for epidural use.

*Pediatric Patient Population: one month to 21 years

**Neonate Patient Population: Newborns up to one month, includes preterm or term

Adult Patient Population

Module	Route of Administration	Infusates
BD Alaris™ Pump Module	Intravenous	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets, and fresh frozen plasma.
	Subcutaneous	Fluids and pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
	Irrigation of fluid spaces	Fluids approved for irrigation.
BD Alaris™ Syringe Module	Intravenous	Pharmaceutical drugs used for intravenous use.
	Subcutaneous	Pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
Alaris™ PCA Module	Intravenous	Pain management drugs approved for intravenous use.
	Subcutaneous	Pain management drugs approved for subcutaneous use.
	Epidural	Pain management drugs approved for epidural use.

Intended Use Environment

The following BD Alaris™ System devices are intended to be used in a professional healthcare facility. These devices may be disconnected from the AC source and transported within the healthcare setting.

- BD Alaris™ PCU
- BD Alaris™ Pump Module
- BD Alaris™ Syringe Module
- Alaris™ PCA Module
- BD Alaris™ $EtCO_2$ Module
- Alaris™ Auto-ID Module

The following software are intended to support the BD Alaris™ PCU and its connected modules within the healthcare setting:

- BD Alaris™ Guardrails™ Editor
- BD Alaris™ Systems Manager
- BD Alaris™ Systems Maintenance
- BD Care Coordination Engine
- Infusion Adapter
- Calculation Services

The BD Alaris™ Guardrails™ Editor software is intended to be used by a healthcare professional in their desired workspace. The BD Alaris™ System Maintenance software is intended to be used by service personnel in their desired workspace.

Contraindications

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

BD Alaris™ System Contraindications

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

Warnings, Cautions, and Notes

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

WARNING

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

CAUTION

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

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

Summary of Warnings and Cautions

WARNINGS

- **Before you install and use this software product, read all of the instructions.**
- **Ensure a data set is developed and approved by qualified clinical decision-makers in the hospital who are familiar with the BD Alaris™ System. Qualified clinical decision-makers must verify the appropriateness of the drug setup parameters, dosing limits, and instrument configuration settings. Potential hazards include inaccurate delivery rates, inaccurate alerts, nuisance alerts, inaccurate pressure alarms, and nuisance alarms.**
- **The effectiveness of using this software as a means to protect patients and clinicians against programming errors is entirely dependent on the hospital's policy to establish, implement, and manage the data set transferred to the BD Alaris™ System. Data sets should accurately reflect the hospital's best-practice guidelines.**
- **References in this document to specific drugs and drug doses are for illustration purposes only. For information concerning appropriate administration techniques and dosages, refer to specific drug product labeling.**
- **Do not use accessories or cables other than the ones specified to avoid degraded electromagnetic compatibility performance.**
- **Ensure that drug or fluid setups are entered in the correct Library (Continuous/Bolus, Intermittent, PCA and Fluids) that supports appropriate order elements. Failure to do so could result in incorrect programming leading to an over or under infusion. For example, heparin ordered with a dose unit of units/kg/hour should be entered in the Continuous/Bolus Library (see *Adding a Drug on page 75*, *Overview on page 98*, *Overview on page 116*, and *Overview on page 126*).**
- **Concentration Limit Units are determined by the dosing unit selected. Verify that your concentration limit values correctly align with the associated dosing unit to avoid a potential over or under infusion (see *Adding a Drug on page 75* and *Editing Parameter Settings on page 95*).**
- **Transfer only released data sets to devices that are used on patients. Data sets in draft or approved status may have unreviewed or incorrect data leading to over or under infusion and should only be used for interface testing and/or training purposes (see *Overview on page 184*, *Transferring a Data Set by Using Send Mode on page 207*, and *Transferring a Data Set by Using Send Mode on page 207*).**
- **Ensure that air-in-line configuration settings are appropriate for the designated care area profile. Failure to do so may increase the risk of clinically significant volumes of air infusing into the patient (see *Pump Module on page 164* and *Pump Module Settings on page 172*).**

WARNINGS

- **When copying a setup group from one Profile to another or copying an existing Profile to create a new Profile, review all relevant drug or fluid setup group parameters, configurations, and/or the Profile name. Failure to do so may result in incorrect data set parameters on the PCU, contributing to over, under, or delayed infusions (see *Creating a Profile by Copying an Existing Profile on page 66*, *Copying a Drug Setup Group from Another Profile on page 91*, *Copying a Drug Setup Group from Another Profile on page 110*, *Copying a Fluid Setup Group from Another Profile on page 121*, and *Copying a Drug Setup Group from Another Profile on page 140*).**
- **Delivering low volumes of high-risk medications with the Pump Module (particularly for neonatal populations, including low, very low, and extremely low birthweight neonates) can lead to less optimal pump performance including, but not limited to, over or under infusion and increased time to alarm for an occlusion. Consider use of the Syringe Module instead of the Pump Module using the smallest syringe size necessary for these low volumes of high-risk medications (see *Compatible Syringes on page 56*, *Adding a Drug on page 75*, *Adding a Drug on page 99*, and *Adding a Fluid on page 116*).**
- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe can impact pump performance, including delivery accuracy and startup time, and generation of occlusion alarms and bolus volume after occlusion. This is due to the increased friction and compliance of the syringe stopper with larger syringes. It is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, less than 5 mL/h) and very low flow rates (less than 0.5 mL/h) (see *Compatible Syringes on page 56*).**

WARNINGS

- **Avoid delivering low flow rates with larger syringes using the Syringe Module. This is of particular importance for the low, very low, and extremely low birth weight neonate. See the *Minimum Recommended Flow Rate for the Syringe Module on page 59*. Consider Syringe Module performance, recommended doses, dose volumes, and syringe size when developing drug concentration standards and data set parameters (see *Compatible Syringes on page 56*, *Adding a Drug on page 75*, *Adding a Drug on page 99*, and *Adding a Fluid on page 116*).**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 1 mL/h with syringe sizes greater than or equal to 20 mL.**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 0.1 mL/h with syringe sizes 1mL and 3 mL.**
  - **The standard rate accuracy is the rate accuracy under standard operating conditions, which is ±5% at flow rates greater than or equal to 10% of the syringe capacity per hour; and ±10% for flow rates less than 10% of the syringe capacity per hour and greater than or equal to 0.1 mL/h (with syringe sizes less than 20 mL) or 1 mL/h (with syringe sizes greater than or equal to 20 mL).**
- **Avoid delivering low flow rates with larger syringes using the PCA Module. This is of particular importance for the low, very low, and extremely low birth weight neonate. Flow rates below 1 mL/h can cause approximately 10% over or under infusion beyond the standard rate accuracy. See the *Minimum Recommended Flow Rate for the PCA Module on page 61*. Consider PCA Module performance, recommended doses, dose volumes, and syringe size when developing drug concentration standards and data set parameters (see *Compatible Syringes on page 56* and *Adding a Drug on page 128*).**
  - **The standard rate accuracy is the rate accuracy under standard operating conditions, which is ± 5% at flow rates greater than or equal to 10% of the syringe capacity per hour; and ±10% for flow rates less than 10% of the syringe capacity per hour and greater than or equal to 1 mL/h.**
- **Avoid delivering extremely small volumes (less than 0.2 mL) via the Pump Module bolus feature. Over infusion and/or under infusion by 15% beyond the standard bolus volume accuracy can occur (see the *Pump Module Flow Rate Accuracy* section in the BD Alaris™ System user manual). Consider giving extremely small volume boluses IV push rather than with the Pump Module bolus feature. See the *BD Alaris™ Pump Module Bolus Duration by Bolus Volume on page 86*. Also consider Pump Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters (see *Adding a Drug on page 75*).**
  - **The standard bolus volume accuracy is the bolus volume accuracy under standard operating conditions, which is +10%.**

WARNINGS

- **When using the Pump Module bolus feature, avoid delivering bolus volumes that are less than 0.6 mL with durations of less than 1 minute. Over infusion from significant bolus volume inaccuracies can occur (potentially up to 45% over infusion beyond the standard bolus volume accuracy for bolus volumes less than 0.6 mL). To avoid over infusions when delivering extremely small volume boluses, consider giving boluses IV push rather than with the Pump Module bolus feature, or giving the bolus over the longest recommended duration if using the Pump Module bolus feature. See the *BD Alaris™ Pump Module Bolus Duration by Bolus Volume on page 86*. Also consider Pump Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters (see *Bolus Dose Administration on page 84*).**
  - **The standard bolus volume accuracy is the bolus volume accuracy under standard operating conditions, which is ±10%.**
- **Avoid delivering an extremely small volume bolus (less than 0.2 mL) with the Syringe/PCA Module. Over or under infusion by approximately ±10% beyond the standard bolus volume accuracy can occur. Consider giving extremely small volume boluses IV push rather than with the Syringe/PCA Module bolus feature. See the *Minimum Recommended Flow Rate for the Syringe Module on page 59* and *Minimum Recommended Flow Rate for the PCA Module on page 61*. Also consider Syringe/PCA Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters (see *Compatible Syringes on page 56*, *Bolus Dose Administration on page 84*, and *Adding a Drug on page 128*).**
  - **The standard bolus volume accuracy is the bolus volume accuracy under standard operating conditions, which is ±10%.**
- **Avoid delivering loading bolus volumes less than 5 mL with the Pump Module as significant bolus volume inaccuracies can occur, resulting in under or over infusions (potentially up to 50% over infusion at 0.1 mL). Consider giving small volume loading boluses IV push rather than through the Pump Module bolus feature. Also consider Pump Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters (see *Bolus Dose Administration on page 84*).**
- **Avoid delivering loading bolus volumes of less than 1 mL (when the Prime Set with Syringe feature is utilized) with the Syringe Module as significant bolus volume inaccuracies can occur, resulting in under or over infusions (potentially down to 68% under infusion at 0.1 mL). Consider giving extremely small volume boluses IV push rather than with the Syringe Module bolus feature. Also consider Syringe Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters (see *Compatible Syringes on page 56* and *Bolus Dose Administration on page 84*).**

WARNINGS

- **Avoid delivering loading bolus volumes of less than 1 mL (when the Prime Set with Syringe feature is utilized) with the PCA Module as significant bolus volume inaccuracies can occur, resulting in under or over infusions (potentially down to 75% under infusion at 0.1 mL). Consider giving extremely small volume boluses IV push rather than with the PCA Module bolus feature. Also consider PCA Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters (see *Compatible Syringes on page 56*, and *Adding a Drug on page 128*).**
- **Ensure that Priming is enabled for the Syringe/PCA Module. Failure to do so prevents the clinician's ability to use the Prime Set with Syringe feature on the PCU to decrease pump mechanical slack. This can delay the infusion delivery startup time and lead to delivery inaccuracies (see *Syringe Module on page 165*, *PCA Module on page 167*, *Syringe Module Settings on page 175*, and *PCA Module Settings on page 179*).**

CAUTION

Ensure that the correct PCA infusion mode option button is selected prior to clicking **OK** or **Apply**. Incorrect selection of the PCA infusion mode within Guardrails™ Editor will impact PCA infusion mode availability on the PCU for the clinician, leading to delayed infusions (see *Adding a Drug on page 128*).

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

The screen and dialog box images in this manual might be different than on your computer, depending on the operating system and software version the computer is running. Read the section titled *Terms on page xix* before installing or using this software. These definitions contain important information about the use of this software.

Terms

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

Product/Feature	Defined Term
Alaris™ Auto-ID Module	Auto-ID Module
Alaris™ PCA Module	PCA Module
BD Alaris™ EtCO2 Module	EtCO2 Module
BD Alaris™ Guardrails™ Editor Software	Guardrails™ Editor Software
BD Alaris™ Guardrails™ Editor-Transfer Tool	Editor-Transfer Tool
BD Alaris™ PCU	PCU
BD Alaris™ Pump Module	Pump Module
BD Alaris™ Syringe Module	Syringe Module
BD Alaris™ System (includes PCU and one or more modules, such as Pump Module, Syringe Module, PCA Module, $EtCO_2$ Module, or Auto-ID Module)	System

Conventions

This documentation uses the following conventions:

- The names of document titles, cross-references, and text that requires emphasis are formatted in *italics*.
- The names of buttons, menu commands, options, icons, file names, and folders are formatted in **bold**.
- User input is formatted in **`Courier bold`**.
- Programming code is formatted in `Courier fixed width`.

About the Software

Guardrails™ Editor software is provided under and subject to a license from BD.

BD Alaris™ Guardrails™ Editor is a desktop application used for developing a hospital-defined best practice data set of medication and fluid dosing and delivery guidelines. Guardrails™ Editor includes the Guardrails™ Editor Transfer Tool, which may be used to transfer data sets from a personal computer (PC) to the BD Alaris™ System. Data sets may also be transferred using the BD Alaris™ Systems Manager or BD Alaris™ System Maintenance software.

The BD Alaris™ System with Guardrails™ Suite MX includes the BD Alaris™ System, BD Alaris™ System Maintenance, BD Alaris™ Guardrails™ Editor, and BD Alaris™ Systems Manager. Functions of Guardrails™ Suite MX include development and transfer of a hospital-defined best practice data set to the BD Alaris™ System.

The dose error reduction system (DERS) includes the components and functions of the BD Alaris™ System, Guardrails™ Suite MX, and hospital-defined best practice data set that aid in the prevention of programming errors and alerts users of potential over- or under-delivery of medications or fluids. The use of the term Guardrails™ throughout this manual refers to the DERS for the BD Alaris™ System.

NOTE:

- The Guardrails™ Editor software version produces a data set that is compatible with the PCU v12.3.1.
- Model 8000 PCUs are not supported with this software version.

The Guardrails™ Editor software allows your hospital to develop a best-practice data set of IV fluid and IV medication dosing and delivery guidelines for up to 30 patient-specific care areas, referred to as profiles.

- Each profile contains a specific library of drug setups as well as instrument configurations appropriate for the care area.
- Each setup within a profile contains either hard limits that cannot be overridden during infusion programming or soft limits that can be overridden, based on clinical requirements.

Software Features

The Guardrails™ Editor software can be used to:

- Enter and maintain a hospital's best-practice drug list for BD Alaris™ Pump Module, BD Alaris™ Syringe Module, and patient controlled analgesia (Alaris™ PCA Module) infusion delivery.
- Create up to 30 different patient care area profiles.
- Create up to 10,000 unique drug/concentration or fluid setups distributed across all profiles created.

  NOTE:
  A maximum of 1500 drug or fluid setups can be created in a single profile.
- Create profile libraries for continuous/bolus, intermittent, fluids, and PCA infusion delivery.
- Assign up to 250 optional therapies to profile drug and fluid setups.
- Create up to 100 clinical advisories and assign them to specific drugs within each Profile.
- Create channel labels that can be displayed on the Pump Module or the Syringe Module display windows.
- Create up to 100 channel labels and include them with each profile.
- Set minimum and maximum dosing limits for drugs.
- Create optional and editable starting values for infusion modules.
- Set soft and hard limits for selected drugs.
- Create Microsoft™ Excel or Microsoft™ Word reports to support data set development and review program settings.
- Quickly and easily transfer a data set to a BD Alaris™ System based on hospital-defined care area profiles.
- Create instrument configurations for infusion and monitoring modules specific to individual care area profiles.
- Use optional master drug and fluid list aliases and national drug codes (NDCs) to support the Alaris™ Auto-ID Module and Programming with Interoperability and Guardrails™ Suite MX.
- Copy and paste drug setups between profiles to provide efficiency of data entry.
- Use default master lists for new data development to reduce manual master list entries.
- Set PCA pause protocol alarm limits for the BD Alaris™ $EtCO_2$ Module.
- Include a master syringe favorites list for the PCA Module and the Syringe Module.
- Set a no Guardrails™-basic infusion clinical advisory.

See *Appendix B: Revision Highlights and Previous Versions on page 215* for more information on software features and revisions.

Symbols Glossary

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

Symbol	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	Signifies a general warning.	General warning	PCU, all modules, and PCA handset device labels, disc and box labels, and external packaging	Ref W001 ISO 7010 Graphical symbols - Safety colors and safety signs - Registered safety signals
	Indicates that caution is necessary when operating the device or control close to where the *symbol* is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	Caution	PCU, all modules, and PCA handset device labels, and external packaging	Ref 5.4.4 ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Federal Law restricts device to sale by or on the order of a licensed health provider.	Prescription use only	User manuals, disc and box labels, external packaging, and disposable packaging	Ref §801.109 Prescription devices (b)(1) US Code of Federal Regulations Title 21– Food and Drugs
	Consult Instructions for Use	Consult instructions for use symbol	Pump Module, Syringe Module, and PCA Module device labels, disc and box labels, ,and external packaging	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
	Identifies the manufacturer of a product.	Manufacturer	PCU and all modules device labels, user manuals, disc and box labels, external packaging, and disposable packaging	Ref 5.1.1 ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

Symbol	Definition	Symbol Title	Symbol Location	Ref. No. Standard
	Indicates the manufacturer's catalogue number so that the medical device can be identified.	Catalogue number	PCU and all modules device labels, disc and box labels, external packaging, and disposable packaging	Ref 5.1.6 ISO 15223-1Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirement
	Indicates a carrier that contains unique device identifier information.	Unique device identifier	PCU and all modules device labels, disc and box labels, external packaging, and disposable packaging	Ref 5.7.10 ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General Requirements
	Indicates the manufacturer's batch code so that the batch or lot can be identified. Synonyms for batch code are lot number, lot code, and batch number.	Batch code	Disc and box labels, external packaging, and disposable packaging	Ref 5.1.5 ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

Chapter 1
Installation and Setup

This section contains the following topics:

System Requirements

You must have administrator privileges on your Windows™ computer in order to install the Guardrails™ Editor software.

For optimum performance the software should only be installed on a computer running Windows™ 10 meeting the current recommended system requirements as specified by Microsoft™. Guardrails Editor™ is designed to run best on computers with at least 1024 x 768 graphics resolution.

PCU connectivity requires the presence of at least one RS232 serial communications (COM) port on the computer (when using the BD Alaris™ Guardrails™ Editor Transfer Tool). The COM ports may be physical components of the computer, or provided externally using a universal serial bus (USB) adapter. The approved USB to serial port adapter is the Keyspan USA-19HS (PN 12273817 or equivalent) and is available from BD.

Guardrails™ Editor requires Microsoft™ Word and Excel versions 2013 or 2016 for generating reports.

NOTE:
Ensure adequate measures are in place to prevent malicious users from accessing sensitive files on the software workstation or server.

Software Installation

This section contains the following topics:

Installing BD Alaris™ Guardrails™ Editor Software

Read through all of these installation instructions before installing the Guardrails™ Editor software. Ensure that an application capable of opening a rich text file (RTF) file is installed on your computer before beginning this software installation.

NOTE:
Some RTF file editors are not able to support the formatting and graphics produced by the Guardrails™ Editor. For best results, use Microsoft™ Word.

Determine the type of user (pharmacist or biomed) for the computer on which you are installing the Guardrails™ Editor Software before beginning the installation. Each computer can only be set up for one type of user. Each type of user has a specific set of available rights:

- **Pharmacist users** have access to all functions: the Guardrails™ Editor software (including reports), the Guardrails™ Editor Transfer Tool, and the user manual.
- **Biomed users** only have access to the Guardrails™ Editor Transfer Tool.

Screen prompts guide you through the installation. Read all screen prompts carefully and follow the instructions.

NOTE:

- Hospitals should utilize desktop policies that restrict access to only users authorized to use software tools loaded on the individual computer. This would include password protecting the directories where executable files and data set files are located.
- Hospitals should consider making desktop access contingent on network user account access. This will create an audit trail by linking the network user ID to any actions on the application for troubleshooting purposes.

To Install the Software

1. Insert the software CD into the CD-ROM drive.

   The installation program starts automatically.

   If the program does not start, perform one of the following actions:

   - Choose **Start > Run**, then type: **`D:\GuardrailsEditorv12.exe`** (where *D*: is the CD-ROM drive), and press **Enter.**
   - Or, from the CD — browse to the **GuardrailsEditorv12.exe** file and double-click the file.

   This version of the Guardrails™ Editor software requires the Microsoft™ .NET Framework version 4.6.2. The installation program checks the target computer for the presence of this component, and displays a screen that identifies what is needed if this component is missing.

2. If applicable, click **Install** to install the missing component(s).

   The Microsoft .NET Framework component may take several minutes to install.

   NOTE:
   A message displays if the installation is attempted on an unsupported operating system, see *System Requirements on page 2*.

The Guardrails™ Editor setup wizard appears and guides you through the installation.

3. Click **Next**.

NOTE:

- Guardrails™ Editor v12.x software can co-exist with other major versions of the Guardrails™ Editor software (for example, v9.x).
- A PDF reader is required to read the user manual. The installer checks for the presence of a PDF reader on the system. If a PDF reader is not detected on the system, you can download Adobe™ Acrobat Reader from Adobe's website.

4. To download the PDF reader, navigate to https://get.adobe.com and follow the download instructions.

   NOTE:
   The most current web browsers are capable of viewing PDF files.

5. Verify that the desired installation folder is listed on the Destination Folder screen and click **Next.**

   NOTE:
   You can browse to an alternate location by clicking **Change**, or enter a different path in the Folder box.

6. On the Select the Setup Type screen select a setup type (**Pharmacist** or **Biomed**) and click **Next**.

7. To confirm the installation, click **Install**.

   The InstallShield Wizard Completed dialog box appears when the installation is complete.

8. Click **Finish**.

   The installer creates shortcuts for the user manual and application on the desktop and the application folder of the Start Menu.

   NOTE:
   For Pharmacist setup installations, a PDF version of the user manual is installed with this software and removed whenever this software is removed.

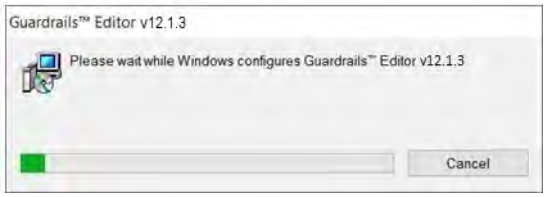
Uninstalling the BD Alaris™ Guardrails™ Editor Software

These uninstall directions apply only to v12.1.3. For information about exporting data sets and uninstalling a specific version of this software, refer to the applicable software user manual.

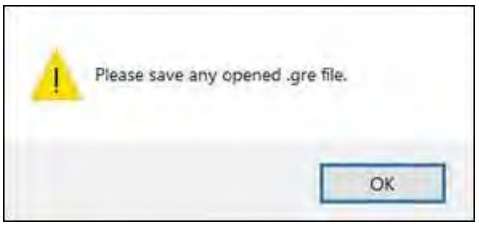
NOTE:
To prevent loss of data sets, ensure that you've saved any existing data sets prior to uninstalling the Guardrails™ Editor. Information about saving data sets can be found in *Opening, Closing, or Saving a Data Set on page 12*.

1. Click **Start** > **Settings**.
2. Click **Apps**.
3. Select **Guardrails™ Editor 12.1.3**.
4. Click **Uninstall**.
5. In the pop-up prompt, click **Uninstall** again.

   The software uninstaller will open and display its progress.



6. When the save any open .gre files pop-up appears, click **OK**.



NOTE:
Saved data sets are not erased from your computer even if you uninstall the software.

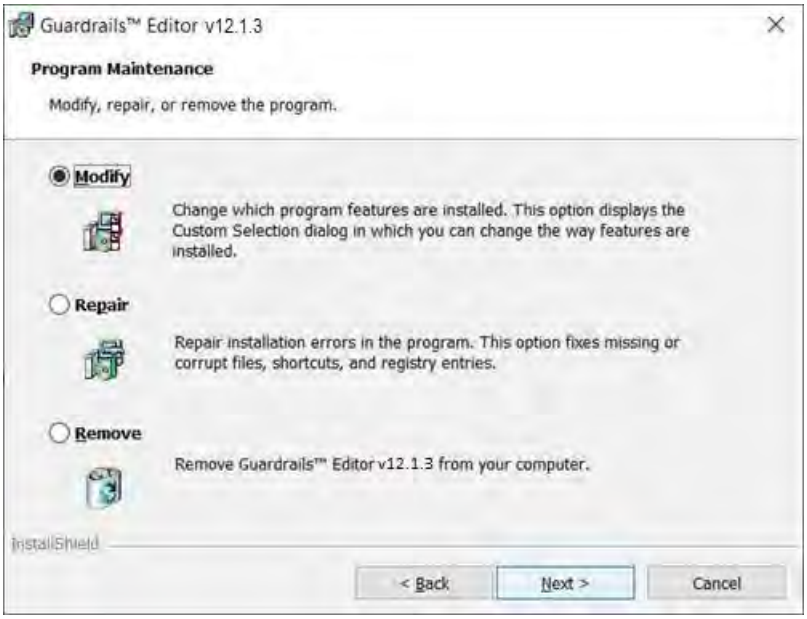
Modifying the BD Alaris™ Guardrails™ Editor Software

1. Click **Start** > **Settings**.
2. Click **Apps**.
3. Select **Guardrails™ Editor v12.1.3**.
4. Click **Modify**.

   The Maintenance Wizard appears.

5. Click **Next**.

The Program Maintenance screen appears.



6. Click **Modify**.
7. Click **Next**.
   The Select the Setup Type screen appears.
8. On the Select the Setup Type screen select a setup type (Pharmacist or Biomed) and click **Next**.
   The Ready to Modify the Program screen appears.
9. Click **Install**.
   The InstallShield Wizard Completed screen appears when the installation is complete.
10. Click **Finish**.

Repairing the BD Alaris™ Guardrails™ Editor Software

1. Click **Start** > **Settings**.
2. Click **Apps**.
3. Select **Guardrails™ Editor v12.1.3**.
4. Click **Modify**.

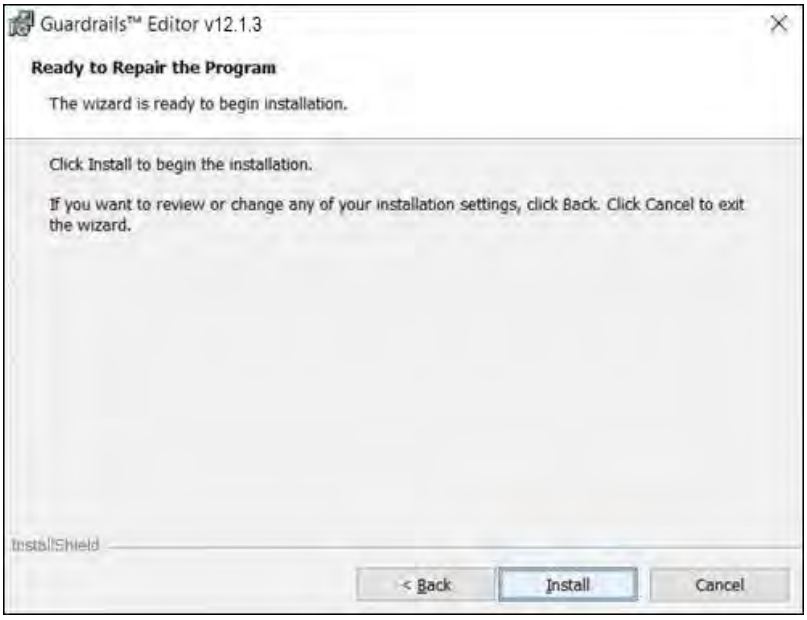
   The Maintenance Wizard screen appears.

5. Click **Next**.

   The Program Maintenance screen appears.

6. Select **Repair**.
7. Click **Next**.

   The Ready to Repair the Program screen appears.



8. Click **Install**.

   The InstallShield Wizard is completed.

9. Click **Finish**.

Chapter 2
Starting the BD Alaris™ Guardrails™ Editor Software

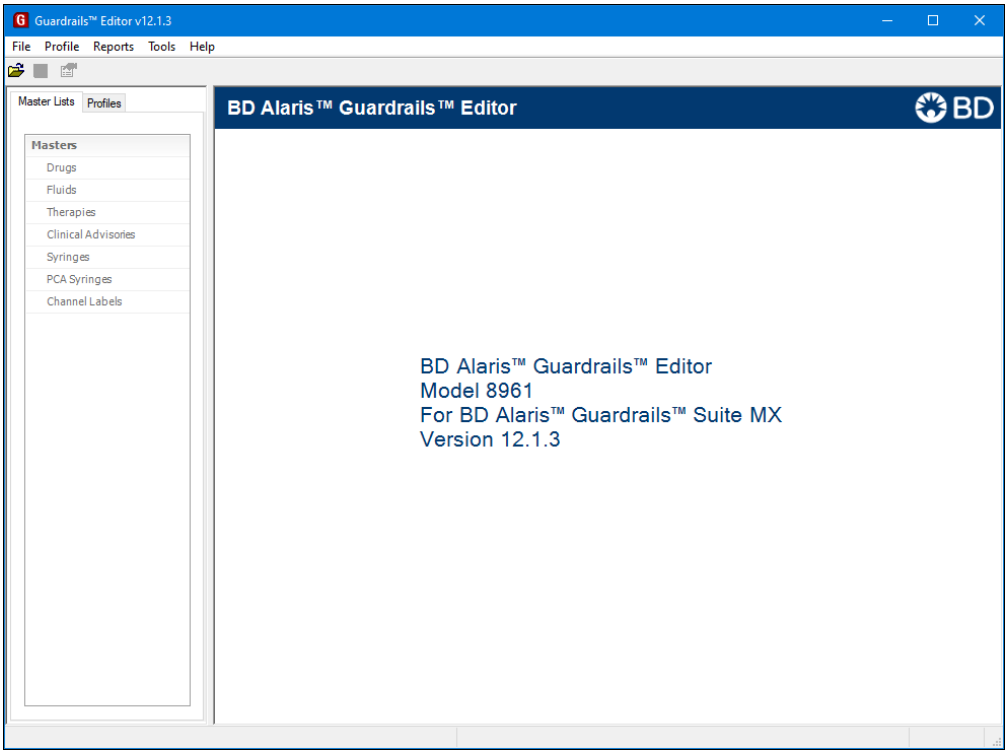
This section contains the following topics:

Launching the Software

This procedure describes how to launch the Guardrails™ Editor software.

1. Do one of the following:
   - On the desktop, double-click the **Guardrails™ Editor v12.1.3** shortcut.
   - Click **Start** > **Programs** > **Alaris™ System** > **Guardrails™ Editor v12.1.3**.

   The main screen appears. You begin most activities from this screen.

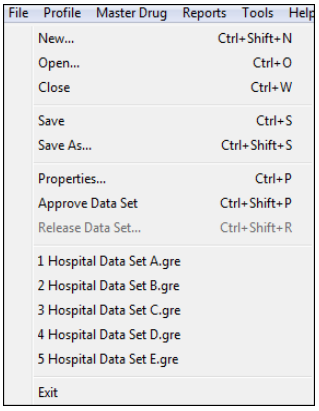


2. If your hospital has not previously used this software, begin by creating a new data set.

Creating, Opening, and Saving a Data Set File

The File menu contains options to create a new data set file, open an existing data set, close an open data set, save the open data set to disk, or save the data set with a different name. It also includes options for viewing data set properties and for approving or releasing a data set.

NOTE:
You can open data sets created in a previous version of the Guardrails™ Editor. If you save that data set, it is saved using a Guardrails™ Editor v12 format and can no longer be opened in versions below v12 of the Guardrails™ Editor.



You can open a data set by selecting a recently opened data

The data set file format is .gre. The filename for this data set example is Hospital Data Set A.gre

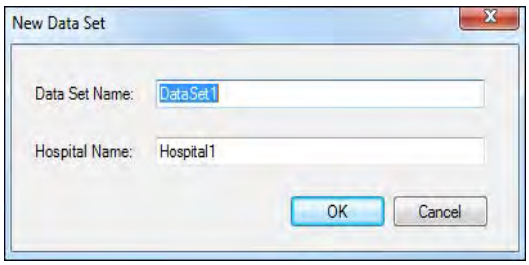
Creating a Data Set

This procedure describes how to create a data set in the Guardrails™ Editor software.

1. In the menu bar, click **File** > **New**.

   The New Data Set dialog box appears.

2. Enter up to 20 case-sensitive characters for the **Data Set Name**.



NOTE:
The data set name that is displayed on PCU is distinct from the data set filename on your computer.

3. Enter up to 40 case-sensitive characters for the **Hospital Name**.

4. To save the information, click **OK**.

   NOTE:

   - The data set name appears in the upper-left corner of the PCU display when the data set is transferred. It is recommended that each time a new version of the data set is released, a new data set name be created by adding a unique identifier (for example, Mission Hospital-A or Mission Hospital v2) to the data set name.
   - If a released data set from a previous version of the Guardrails™ Editor software is opened and saved without any edits, the data set remains in released status. If the data set is edited, the status of the data set is reverted to draft.

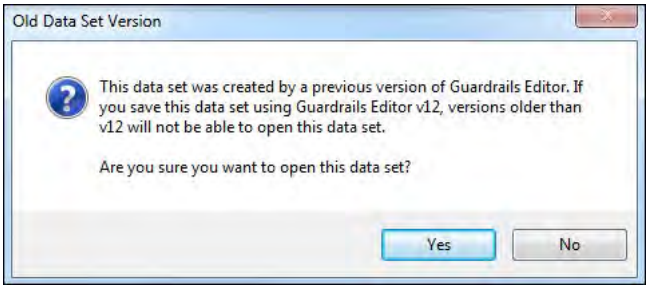
Opening, Closing, or Saving a Data Set

Use the following guidelines to open, close, or save a data set from the main menu bar.

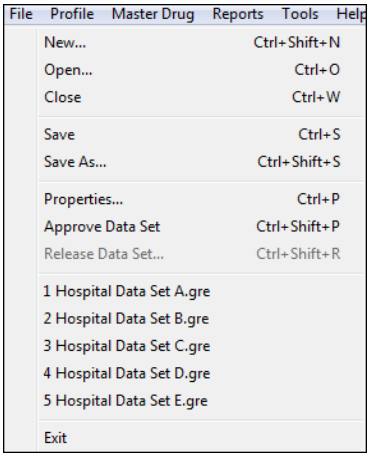
Opening a Data Set

NOTE:

- In the event of a computer-system crash, this software attempts to recover the version of the file that it had in memory before the crash occurred.
- It is recommended that a backup copy of the Guardrails™ file be created after any major changes. A copy of the file should be saved to a different location, such as a shared network drive or a thumb drive. If no file is available, consult the hospital's IT department for a backed up network drive.

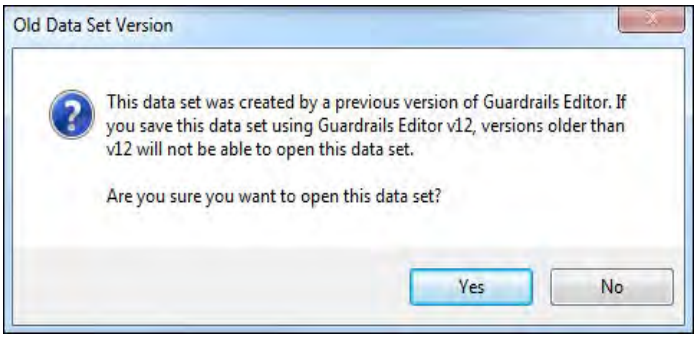


1. Click  , press **Ctrl+O**, or click **File** > **Open**.



2. When you click **File** > **Open**, the Open dialog box appears, allowing you to select or browse for a data set file. If there is already a data set open with unsaved changes, you are prompted to save the changes before it closes.

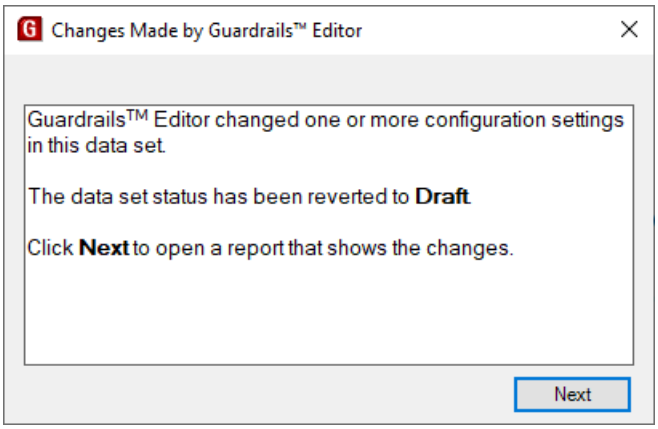
   NOTE:
   If you save a data set that was created in Guardrails™ Editor version 9.33.1 or earlier with version 12.1.3, it can no longer be opened in previous versions of the software.



Changes Made by the BD Alaris™ Guardrails™ Editor

In some cases, the Guardrails™ Editor will make changes to a prior version of a data set or detect incomplete entries when the data set is opened in Guardrails™ Editor version 12.1.3.

If this applies to your data set, the following screen displays:



- Click **Next** to open a Microsoft™ Word report that lists the changes made in the data set or incomplete data set entries detected by Guardrails™ Editor v12.1.3. This is called the Data Set Changes Report.

The report will generate each time a data set is opened until all incomplete data set entries are resolved. You can print and save this report.

The data set status is changed to **Draft** if the prior version of the data set was not in **Draft** status.

Incomplete Data Set Entries also populate in the Error Summary. For instructions on how to access the Error Summary, refer to *Tools Menu on page 20* or *Error Summary on page 188*.

Data Set Changes Report

The Data Set Changes Report may include two sections: Data Set Changes and Incomplete Data Set Entries. The Data Set Changes section includes features or functionalities that have been disabled or new requirements added into the software. The Incomplete Data Set Entries section includes entries now considered invalid or incomplete within the software. The report includes the profile and configuration or section affected plus the action or pending action needed. Below are the items that may be included in your report:

Data Set Changes

Action	Description
SpO_2 Module Disabled	SpO_2 module and all configuration settings have been disabled and no longer compatible. This may impact PCA Pause Protocol Settings.
Multidose Disabled	Configuration is removed.
Concentration Limits Enabled	Concentration Limits are required and now enabled for Continuous/Bolus and PCA infusion that have Units Only concentration (custom concentration) selected.
Syringe Option Disabled	The Astra Zeneca 50 mL, IVAC 50 mL, Covidien Monoject™ 3 mL, 6 mL, and 20 mL, Terumo™ 3 mL, 5 mL, 20 mL, 30 mL, and 60 mL, and IMS 30 mL Prefill syringe master list favorites have been disabled and are no longer compatible.

Incomplete Data Set Entries

Pending Action	Description
Incomplete Concentration Limits	Continuous/Bolus or PCA setups that include a Units Only concentration (custom concentration) that require a hard minimum and soft maximum concentration limits.
Concentration Limits are outside of the range that can be programmed on the pump	The Guardrails™ Editor software aligns the Concentration Limit units with the Dosing units for Continuous/Bolus drug setups using a Units Only concentration (custom concentration). On the Alaris device, the clinician will program the concentration based on the Units Only concentration (custom concentration) unit. When the Dosing Units are not the same as the Units Only concentration (custom concentration) unit, the Guardrails™ Editor software will not allow you to enter a concentration limit that is outside the range of what can be programmed on the Alaris device.

BD Alaris™ Guardrails™ Editor

Data Set Changes Report

University Hospital – Data Set

Data Set Changes

Profile Name	Configuration / Section	Action
N/A	Options	SpO2 Module disabled
Critical Care	Shared Infusion Settings (Pump & Syringe)	Multidose Disabled. Previous Callback setting was "None"
Critical Care	SpO2 Module	SpO2 Module settings disabled
Critical Care	PCA Module	PCA Pause Protocol support switched from "Both" to "EtCO2"
Critical Care	Continuous/Bolus Library	Concentration Limits enabled on the following drug setups: Alteplase (vascular) / Non-weight based HYDROmorphone / Non-weight based
Critical Care	PCA Library	Concentration Limits enabled on the following drug setups: morphine / High Dose

Incomplete Data Set Entries

Profile Name	Configuration / Section	Pending Action
Critical Care	Continuous/Bolus Library	Incomplete Concentration Limits on the following drug setups: abciximab / PCI / Weight based Alteplase (vascular) / Non-weight based HYDROmorphone / Non-weight based
Critical Care	Continuous/Bolus Library	Concentration Limits are outside of the range that can be programmed on the pump on the following drug setups: NORepinephrine / Non-weight based
Critical Care	PCA Library	Incomplete Concentration Limits on the following drug setups: morphine / High Dose
PEDIATRICS	Continuous/Bolus Library	Incomplete Concentration Limits on the following drug setups: pantoprazole / Non-weight based

Sample Hospital - 08/31/2020 15:13
Sample Hospital - 026dbe1ce-D

Page 3 of 3

Closing an Open Data Set

1. Click **File** > **Close**, or click the close box in the upper-right corner of the window.

Saving the Open Data Set

1. Click **File** > **Save**.

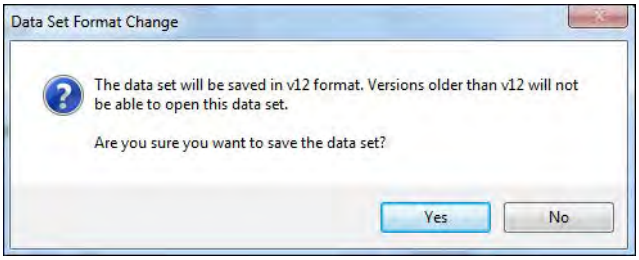
   An icon with the data set name appears in the folder location where the data set was saved. Data set files must be saved with the extension *.gre* or they are not visible in the software.

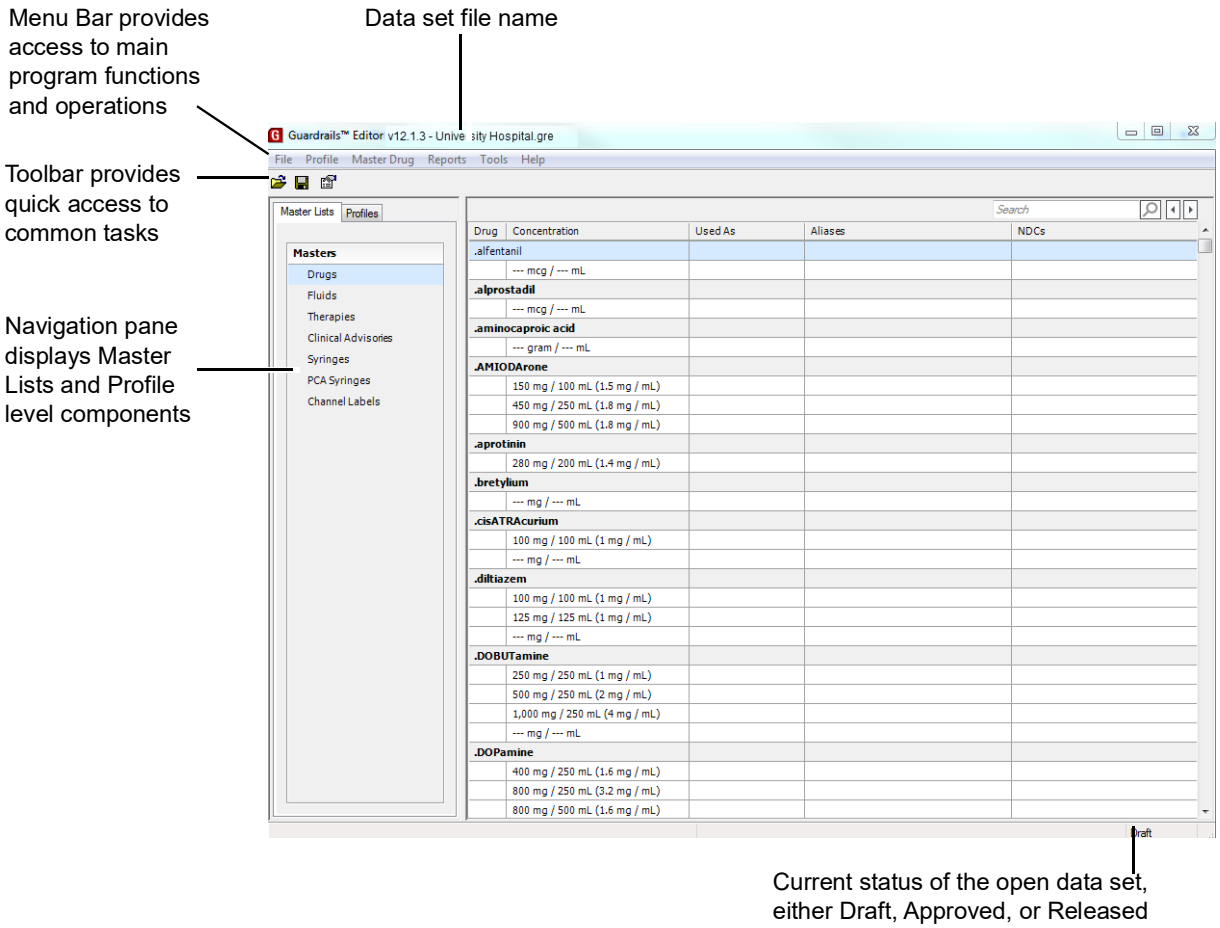
Saving an Open Data Set with a Different File Name or Earlier Version

1. Click **File** > **Save As**.

   NOTE:

   - Use the **Save As** option to save the new v12 data set while maintaining a copy of the original version data set.
   - If you save a data set using Guardrails™ Editor v12, you cannot open it in versions earlier than v12 of the Guardrails™ Editor.

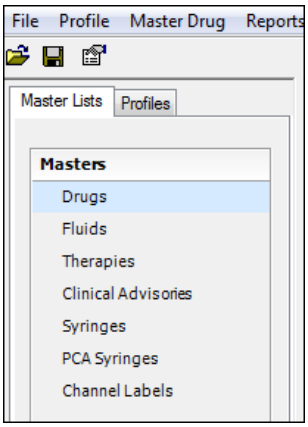



Menu Bar provides access to main program functions and operations
Data set file name
Toolbar provides quick access to common tasks
Navigation pane displays Master Lists and Profile level components
Guardrails™ Editor v12.1.3 - Unive sity Hospital.gre
File Profile Master Drug Reports Tools Help
Master Lists Profiles
Masters
Drugs
Fluids
Therapies
Clinical Advisories
Syringes
PCA Syringes
Channel Labels
Search
Drug Concentration Used As Aliases NDCs
.alfentanil
--- mcg / --- mL
.alprostadil
--- mcg / --- mL
.aminocaproic acid
--- gram / --- mL
.AMIODArone
150 mg / 100 mL (1.5 mg / mL)
450 mg / 250 mL (1.8 mg / mL)
900 mg / 500 mL (1.8 mg / mL)
.aprotinin
280 mg / 200 mL (1.4 mg / mL)
.bretylium
--- mg / --- mL
.cisATRAcurium
100 mg / 100 mL (1 mg / mL)
--- mg / --- mL
.diltiazem
100 mg / 100 mL (1 mg / mL)
125 mg / 125 mL (1 mg / mL)
--- mg / --- mL
.DOBUTamine
250 mg / 250 mL (1 mg / mL)
500 mg / 250 mL (2 mg / mL)
1,000 mg / 250 mL (4 mg / mL)
--- mg / --- mL
.DOPamine
400 mg / 250 mL (1.6 mg / mL)
800 mg / 250 mL (3.2 mg / mL)
800 mg / 500 mL (1.6 mg / mL)
Draft
Current status of the open data set, either Draft, Approved, or Released

Working with the Navigation Pane

The navigation pane provides access to the main sections of this software.

Tabs	Description
Master Lists	Create and edit the data set master lists using the options on this tab.
Profiles	Add up to 30 unique profiles, edit the profile drug and fluid libraries, set device configurations, and select profile channel labels for the profiles using the options on this tab.



NOTE:

- If specific modules are not enabled in the BD Alaris™ System tab in the Guardrails™ Editor Tools/ Options menu, the module does not appear on the drug library screens or navigation pane.
- Modules can be enabled any time during or after data set development.
- When you make the Pump Module or the Syringe Module unavailable in the Guardrails™ Editor, it is only unavailable in the Guardrails™ Editor software, the modules are still available for use in No Guardrails™-Basic Infusion with default configurations when attached to a PCU.

Special Characters

This software does not allow entry of the following characters:

[‘] [“] [^] [`]

Navigating the BD Alaris™ Guardrails™ Editor Software

This procedure describes how to navigate the Guardrails™ Editor software.

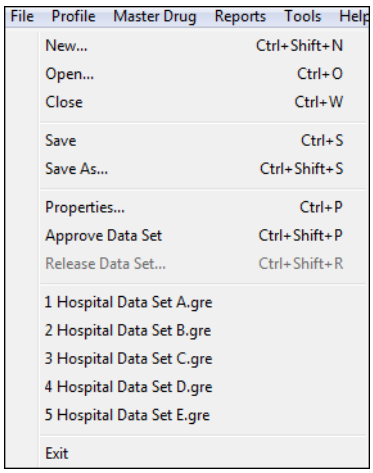
Menu Bar

The main software functions are available from pull-down menus on the main menu bar.

File Menu

Use this menu to:

- Create a new data set
- Open an existing data set
- Close a data set
- Save a data set with an existing name
- Save a data set with a new name
- View the properties (data set status) of an open data set
- Approve or release a data set
- Select a recently opened data set
- Exit the application

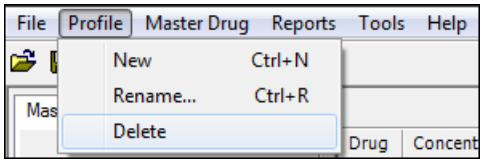


Profile Menu

Use this menu to:

- Create a new profile
- Rename an existing profile
- Delete a profile

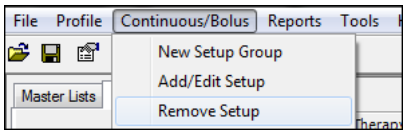
If the program has reached its maximum of 30 profiles, the **New** command is unavailable.



Dynamic Menu

The variable menus appear on the menu bar when an item is selected in the navigation pane. The options on the variable menus are specific to the navigation pane item selected.

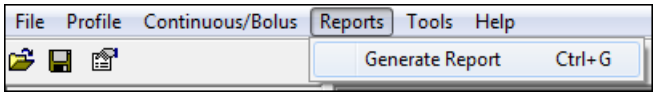
In the following example, the user selected the **Continuous/Bolus** drug library on the **Profiles** tab.



NOTE:
Many variable menu functions can also be accessed directly from the dialog boxes.

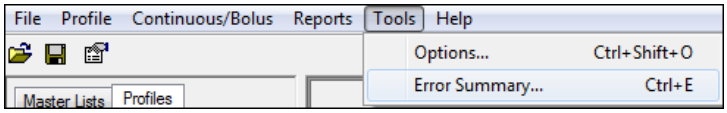
Reports Menu

Use this menu to generate a variety of reports.



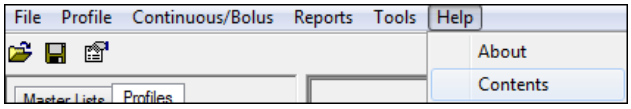
Tools Menu

Use this menu to access the **Options** dialog box, which provides settings for security, archiving, and the BD Alaris™ System module types to display in Guardrails™ Editor and to view the **Error Summary**.



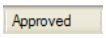
Help Menu

Use this menu to check the version of your software or find information in the Help.



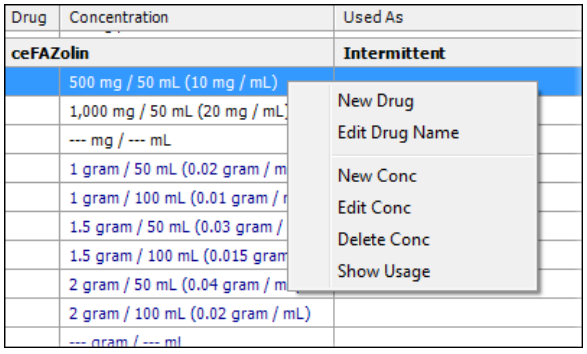
Dialog Box Controls and Information

Most dialog boxes in this software include **OK** and **Cancel** buttons. Some also have an **Apply** button.

Control	Description
OK	Accept the changes made and close the dialog box. Proceed to the next program activity.
Cancel	Cancel the changes made and close the dialog box. Return to the previous program activity.
Apply	Commit any changes made to the data set, and keep the current dialog box open for more entries.
	The exclamation symbol appears next to any field where you have entered an out-of-range, missing, or other invalid value. Tool tips appear when you place the cursor over the exclamation symbol. You cannot accept or commit changes by clicking **OK** or **Apply** until these fields have been resolved. You can click **Cancel**.
	The counter at the bottom of Master Therapies, Master Channel Labels, Master Clinical Advisories, Profile Drug Libraries, and Channel Label Library dialog boxes indicates how many entries of a certain type have been entered.
	Current status of the open data set, either Draft, Approved, or Released.

Displaying Menus and Options

Right-click shortcuts can be used on many of the screen items to open shortcut menus. Right-click items in tables in the main display to view edit screens for that item.



NOTE:
A comma is automatically inserted as you type in values above 999.9 in all fields except Alias, National Drug Code (NDC), and PCA Module security codes.

Getting Help

The online help can be used as a reference to complete many program activities.

1. In the main menu bar, click **Help** > **Contents** to open the Help.
2. Click the **Contents** tab to view the Table of Contents for the Help.

Icon	Description
	Click this icon to open a main topic and see the subtopics in a section.
	Click this icon to close a main topic.
	Click this icon to review topic information.

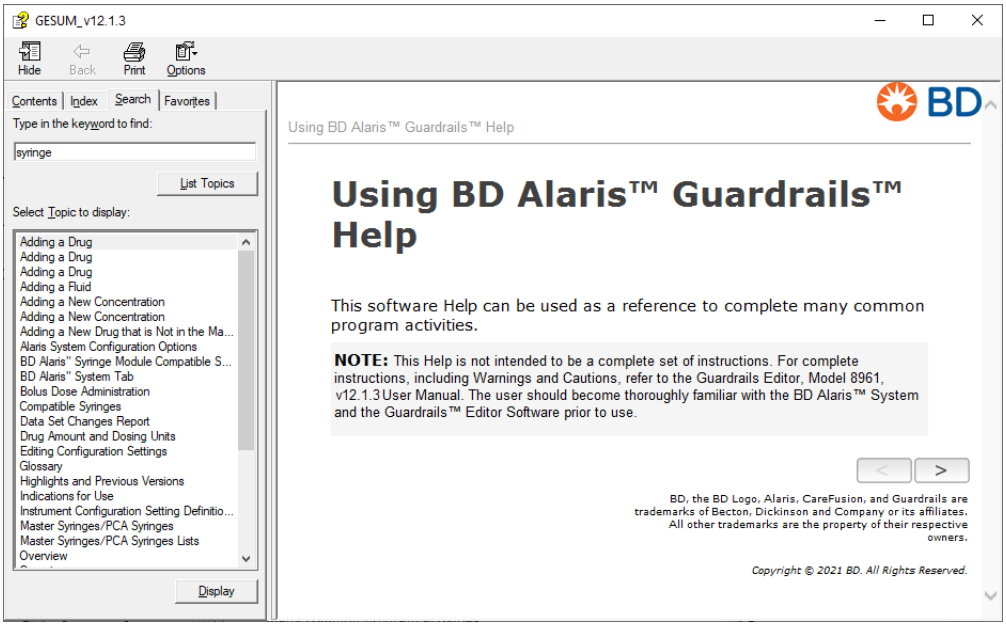
Other Help Controls

Other help controls for the Guardrails™ Editor software are as follows:

Icon	Description
	Hide the Table of Contents. If you hide the Table of Contents, the Show button appears. Click **Show** to display the Table of Contents.
	Show the Table of Contents. If you Show the Table of Contents, the Hide button appears. Click Hide to hide the Table of Contents
	Move back one page.
	Print the page that is currently displayed.
	Click to access the Options menu, which provides Hide Tabs, Back, Forward, Home, Stop, Refresh, Internet Options, Print, and Search Highlight Off commands.

Using the Search Feature:

1. Click **Search**.

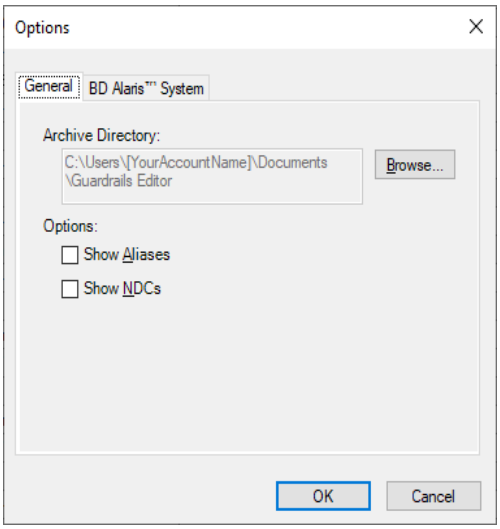


2. Enter a keyword, and click **List Topics**.
3. When the topics are listed, double-click a topic to view it in the main Help window.

Setting User Options

This procedure describes how to set user options in the Guardrails Editor software.

1. In the menu bar, click **Tools** > **Options**.
   The Options dialog box appears.



The Options dialog box includes the following tabs:

Tab	Description
General	Determine the location of released data sets and enable/ disable Aliases and NDCs.
BD Alaris™ System	Customize which module types display in the navigation pane and the application.

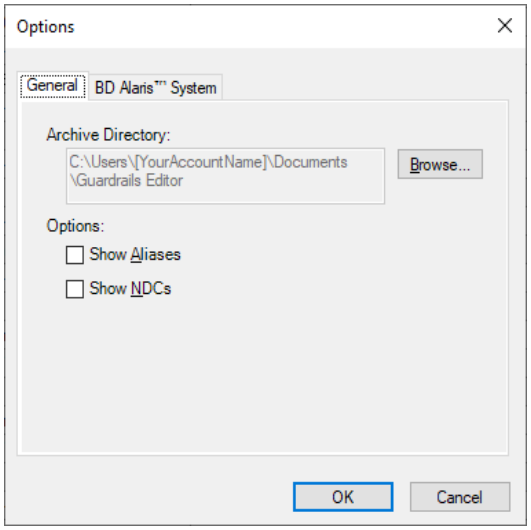
General Tab

The Archive Directory is used as the location for archiving released data sets.

This software is installed with a default location of `C:\Documents and Settings\<logon name>\My Documents\Guardrails Editor`.

1. To search for and set a new folder location, click **Browse**.

   NOTE:
   When a draft data set is changed to *Released* status, it automatically is exported to the specified location.



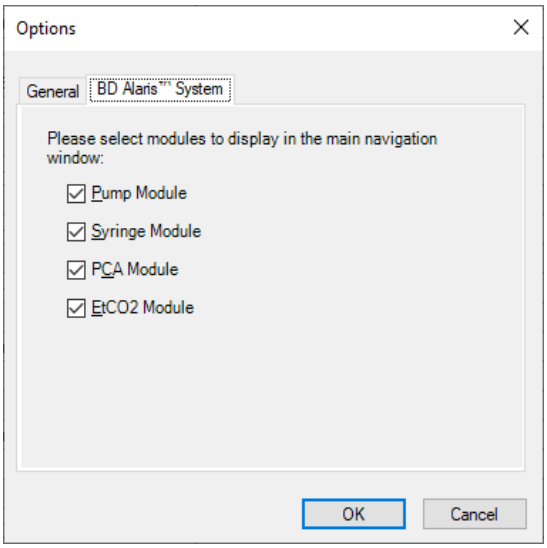
2. To turn aliases on for use in master drugs and fluids lists, select **Show Aliases**.
3. To turn NDCs on for use in the master drug and fluid lists, select **Show NDCs**.

   If you are using aliases or NDCs, see *Master Drug List – Aliases and NDCs on page 195* for more information.
4. To confirm changes, click **OK**.

BD Alaris™ System Tab

The BD Alaris™ System tab is used to select the modules to display in the main navigation window. The default setting has all modules selected.

1. Clear the check box next to a module name so that the module is not displayed.



2. To confirm changes, click **OK**.

NOTE:

- This software defaults to showing all modules as active.
- If modules are not enabled in the BD Alaris™ System tab in the Options menu, the module does not appear on drug library screens, navigation pane, configuration sections, or reports. Modules can be enabled at any time during or after data set development.
- Modules are enabled automatically when a data set is opened that currently has those modules programmed.
- The Pump Module, Syringe Module, and PCA Module cannot be disabled if there are any entries in their drug libraries. In this case, the options to disable these modules appear grayed-out in the Tools/ Options menu.
- For purposes of this manual, all modules are enabled in User Options, with other example screens reflecting this.
- When you make the Pump or Syringe Module(s) unavailable in the Guardrails™ Editor, it is only unavailable in the Guardrails™ Editor software, the modules are still available for use in No Guardrails™ -Basic Infusion with default configurations when attached to a PCU.

Checking the Installed Software Version

NOTE:
The software version number and UDI number depicted in all screenshots are representative only. Follow the steps in *Identifying the Unique Device Identification (UDI) Information* below, to determine your software version and UDI number.

This procedure describes how to check for the installed version of the Guardrails™ Editor software.

1. In the menu bar, click **Help** > **About**.

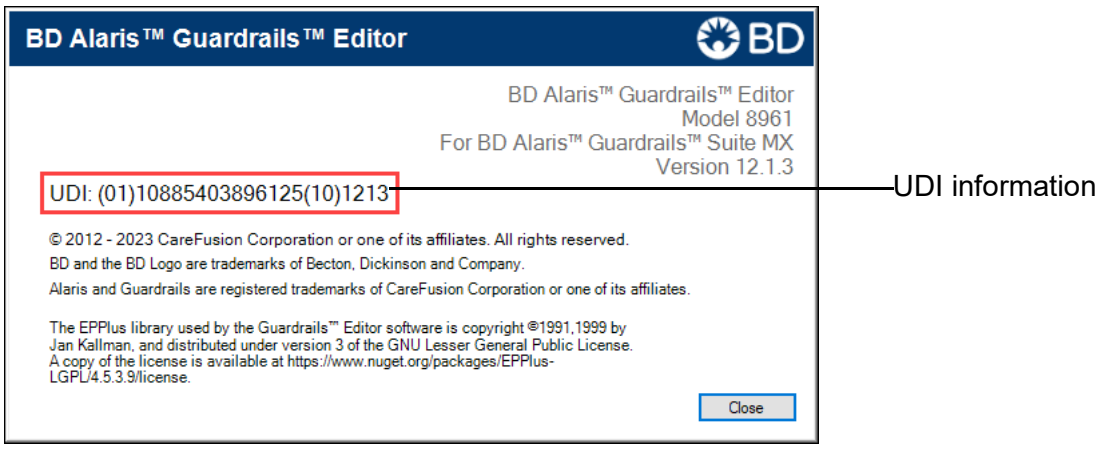
   The About dialog box appears, displaying the software version, UDI, and copyright information.

Identifying the Unique Device Identification (UDI) Information

This procedure describes how to find the UDI number.

1. In the menu bar, click **Help** > **About**.

   The About dialog box appears, displaying the UDI information.

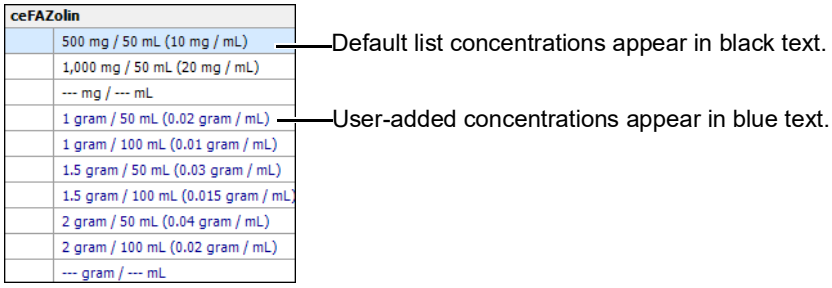


Chapter 3
Master Drug Lists

This section contains the following topics:

Overview

The first step in using this software is to create master drug lists for continuous/bolus, PCA, and intermittent drugs by adding drug names and concentrations to the data set. A default list containing continuous/bolus, PCA, and intermittent master drugs and concentrations is provided.



You can add, edit, or remove new drugs using the master drug lists.You can make case changes to the names of drugs in the default list, but you cannot edit the names or remove them from the default list.

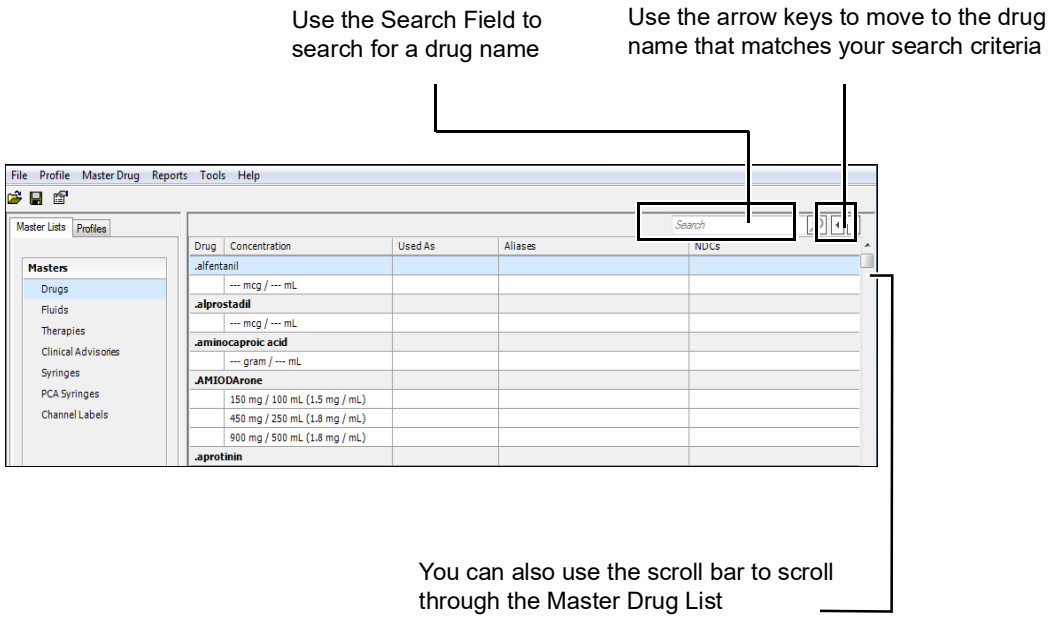
This software can store an unlimited number of master drug names and concentration entries, depending on available disk space.

Drug names must be unique within the data set master drug lists. You cannot have the same drug name in both the master drug list and the master fluids list.

Displaying a Master Drug List

1. In the navigation pane, click the **Master Lists** tab and then click **Drugs**.

   The Master Drug List appears in the right pane with the drug names listed in alphabetical order.



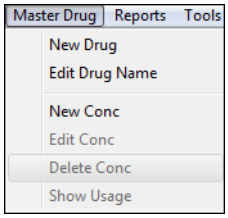
Selecting a Drug Using the Search Function:

1. Type a drug name or the initial characters of the drug name in the search field.
2. Press **Enter** or click  .

   The selected drug name is highlighted in yellow.
3. Use the left and right arrow to move to the next or previous drug that matches your search criteria.

Creating a New Drug

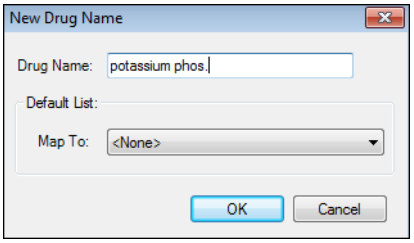
You can create, edit, or rename a drug entry by right-clicking the drug name or concentration in the master drug list and selecting an action from the shortcut menu. You can also select these commands from the Master Drugs menu.



NOTE:
You cannot edit or delete drugs or concentrations from the default drug list. Only case changes are allowed to the drug names.

1. Click **New Drug**.
2. In the New Drug Name dialog box, enter the **Drug Name**, using up to 20 characters, and click **OK**.

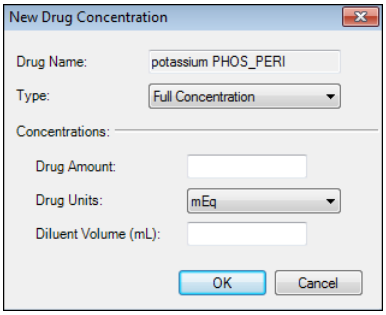
   As an option for future use, you can select a drug name to map to from the *Map To* list, if desired. The default is *None*. If you choose a drug to map to, its concentrations are copied from the default list to the new drug name.



3. In the New Drug Concentration dialog box, select the type of concentration from the **Type** list.

Field	Description
Full Concentration	The Drug Amount, Drug Units, and Diluent Volume (mL) values.
Units Only	A concentration that includes drug units without predefined drug amount and diluent volume values. The clinician enters these values when initiating an infusion on the BD Alaris™ System. Only one Units Only concentration (custom concentration) selection is allowed per setup.
Volume (mL only)	Drug as volume (only applies for a PCA drug).

NOTE:
Not all drug concentrations can be added to the PCA drug library.



4. Enter a **Drug Amount** (Full Concentration only).
5. Select the **Drug Units** from the list (excluding Volume (mL only) (PCA)).
6. Enter a **Diluent Volume** (Full Concentration only) and click **OK**.

   The drug is added to the master drug list, with the concentration listed on a separate line. The drug amount/mL is listed in parentheses ( ).

Adding a New Concentration for an Existing Drug

Use this procedure to add a new concentration for a drug in the Master Drug List.

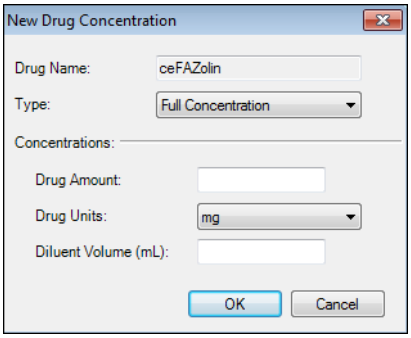
1. In the Master Drug List, right-click the desired drug and click **New Conc**.

   The New Drug Concentration dialog box opens displaying the name of the selected drug and the current drug units.

2. Select the type of concentration from the **Type** list.

Field	Description
Full Concentration	The Drug Amount, Drug Units, and Diluent Volume (mL) values.
Units Only	A concentration that includes drug units without predefined drug amount and diluent volume values. The clinician enters these values when initiating an infusion on the BD Alaris™ System. Only one Units Only concentration (custom concentration) selection is allowed per setup.
Volume (mL only)	Drug as volume (only applies for a PCA drug).

NOTE:
Depending on your selection, some or all of the concentration values (Drug Amount and Diluent Volume) requires values to be entered.



3. Enter a **Drug Amount**.
4. Enter the **Diluent Volume** and click **OK**.

   Concentration is listed on a separate line in the Master Drug List.

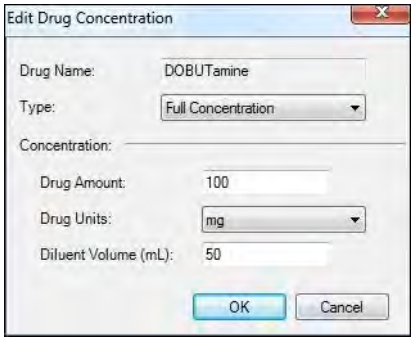
Editing a Drug Concentration

This section applies to user-added concentrations only. You cannot edit concentrations from the default list.

1. Right-click the drug concentration that you want to update, and click **Edit Conc**.

   The Edit Drug Concentration dialog box opens, displaying the name and concentration of the selected drug.

2. Change the editable fields, as necessary.



3. To confirm your changes, click **OK**.

   The Concentration Edit Confirmation dialog box opens, displaying a list of profiles containing this drug and concentration.

   The selected drug and/or concentration is removed from all listed profiles. For information on using this updated concentration in a Profile, see *Adding a New Concentration for an Existing Drug on page 31*.

4. To save your changes, click **OK**.

   The modified concentration is entered in the Master Drug List.

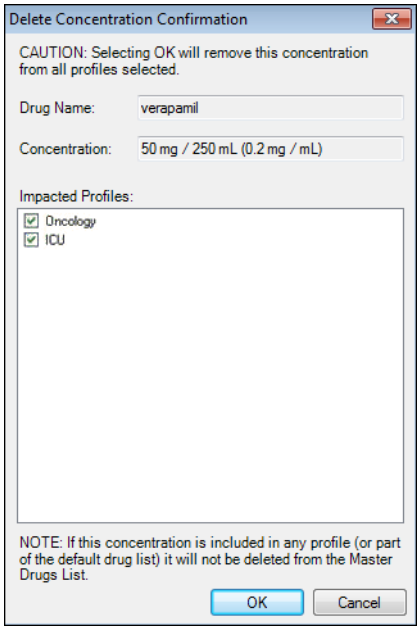
Deleting a Drug Concentration

A concentration cannot be deleted from the default Master Drug List, but it can be deleted from a profile setup by clicking Delete Concentration.

To Delete a Drug Concentration:

1. In the Master Drug List, right-click the applicable drug concentration and click **Delete Conc**.

   The Delete Concentration Confirmation dialog box appears, displaying a list of profiles containing this drug and concentration. All Impacted Profiles are selected.



2. Clear the check box for any profile that you do *not* want to delete this drug and/or concentration.
3. To confirm deletion, click **OK**.

NOTE:
If all profile boxes are selected, a default drug and concentration is removed from the profiles but remains in the master drug list. Only drugs and concentrations added by the user can be permanently removed from the master drug list. If the concentration remains in any profile (at least one check box cleared), it remains in the master drug list.

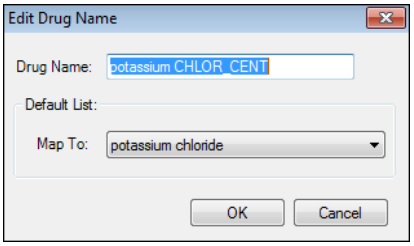
Renaming a Drug

This procedure describes how to rename a drug in the Guardrails™ Editor software.

NOTE:
Changing the name of a drug modifies all instances of the drug name in all profiles containing it. Only the names of user-added drugs can be changed. User-added drug names appear as blue text.

To Change the Name of a Drug:

1. In the displayed Master Drug List, right-click the applicable drug and click **Edit Drug Name**.
   The Edit Drug Name dialog box opens with the current drug name displayed.



2. Revise the drug name and click **OK**.
   The Rename Confirmation dialog box appears listing affected Profiles.
3. To accept and update all Profiles, click **OK**.

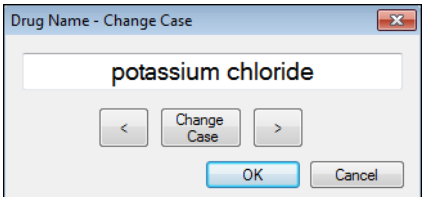
Changing the Case of a Drug Name

Drug names in the default master drug list cannot be renamed. Only the case can be adjusted on drugs in the default master drug list (for example, MORphine can be changed to morphine). The default drug names appear as black text.

NOTE:
Changing the case modifies all instances of the drug name in all profiles containing it. Only the names of user-added drugs can be changed. The user-added drug names appear as blue text.

1. In the Master Drug List, right-click the applicable drug and click **Edit Drug Name**.

   The Drug Name – The Change Case dialog box appears with the current drug name displayed.



2. Highlight (click and drag) the text that you want to modify.

   The text case changes when you release the mouse button. Alternatively, use the left and right arrow buttons to move the cursor along with the Change Case button to toggle the case.

3. To confirm the case change, click **OK**.

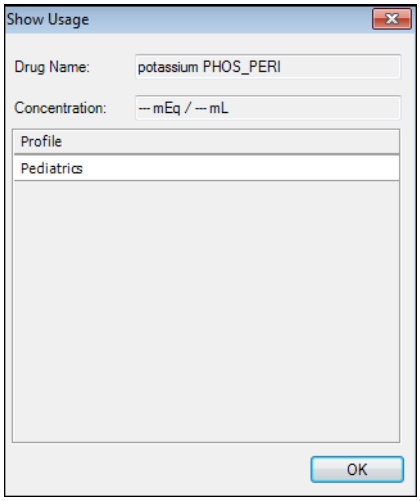
   The Rename Confirmation dialog box appears listing the affected profiles.

4. To accept and update all profiles, click **OK**.

Showing Usage

The following procedure describes how to view profiles in which a concentration is used.

1. In the displayed Master Drug List, right-click the applicable drug concentration and click **Show Usage**. The Show Usage dialog box appears listing the profiles in which the concentration is used.



2. To close the Show Usage dialog box, click **OK**.

Chapter 4
Master Fluids List

This section contains the following topics:

Overview

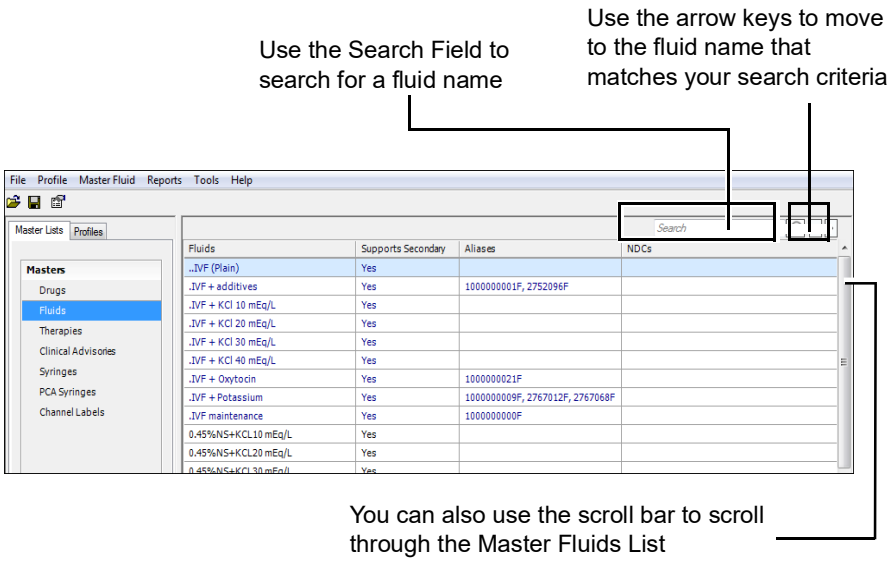
This software includes a set of default fluids in the master fluids list. You can add, edit, or delete new fluid names to meet your hospital's requirements. You cannot change or delete the names from the default Fluids list.

NOTE:
Default master fluids appear as black text. User-added fluid names appear in blue text.

Displaying the Master Fluids List:

1. Click **Fluids** on the Master Lists tab.

   The Master Fluids List appears in the right pane, in alphabetical order. Numeric values appear before alphabetical values.



Selecting a Fluid Using the Search Function:

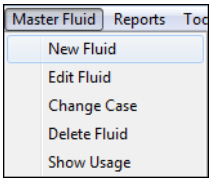
1. Type a fluid name or the initial characters of the fluid name in the search field.
2. Press **Enter** or click  .

   The selected fluid name is highlighted in yellow.
3. Use the left and right arrow to move to the next or previous fluid that matches your search criteria.

Creating a Fluid

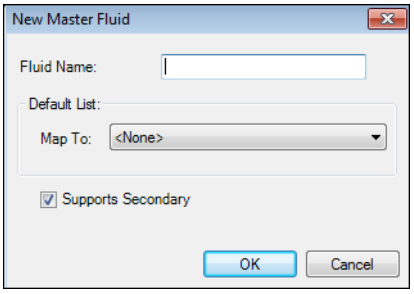
This procedure describes how to create a fluid in the Guardrails™ Editor software.

1. On the Master Lists tab, click **Fluids**.
2. If the required fluid is not listed, right-click in the main display area and select **New Fluid**.



   The New Master Fluid dialog box appears.

3. Enter a name for the fluid (up to 20 characters).



4. If desired, select a fluid in the default list to which to map.
5. Select or clear the **Supports Secondary** check box based on the ability for a secondary infusion to be given while this primary fluid is infusing.

   NOTE:
   The Master List is the only place where you can edit this setting.

6. Click **OK**.

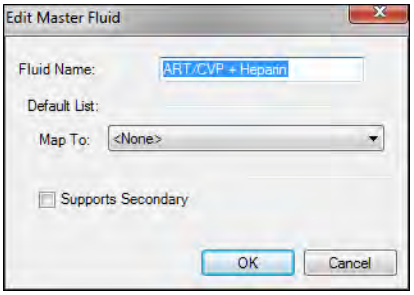
Editing a Fluid

Only user-added fluid names can be edited. A fluid name case can be changed in the default fluids list. You can also enable or disable Supports Secondary for all fluids by selecting or clearing the check box.

1. In the Master Fluids List, right-click the row of the Fluid, and click **Edit Fluid**.

   The Edit Master Fluid dialog box appears.

2. In the Fluid Name field, update the **Fluid Name**, select or clear the **Supports Secondary** check box as required, and click **OK**.



   The Edit Fluid Confirmation dialog box appears listing the impacted profiles.

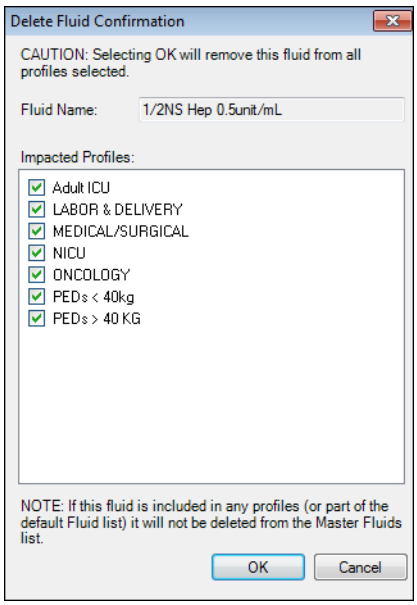
3. To accept and update all profiles, click **OK**.

   The Master Fluids List shows the edited fluid.

Deleting a Fluid

This section applies to user-added fluids only. You cannot delete fluids from the default Fluids list.In the Master Fluids List, right-click the row of the fluid, and click **Delete Fluid**.

1. The Delete Fluid Confirmation dialog box appears.



2. Clear the check box for any Profile for which you do *not* want to delete this fluid.Clear the check box for any Profile for which you do *not* want to delete this fluid.
3. To confirm deletion, click **OK**.

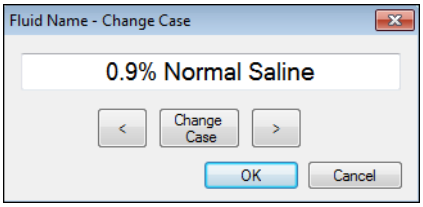
NOTE:
If all profile boxes are selected, a default fluid is removed from the profiles but remains in the master drug list. Only fluids added by the user can be permanently removed from the master drug list. If the fluid remains in any profile (at least one check box cleared), it remains in the master drug list.

Changing the Case of a Fluid Name

You can only change the case (and/or enable or disable supports secondary) of fluid names in the default Master Fluids List. You cannot otherwise edit or delete names of fluids in the default list.

1. In the Master Fluids List, right-click the row of the Fluid, and click **Change Case**.

   The Fluid Name – Change Case dialog box appears.



2. Click and drag over the text to be changed to highlight it.

   The text changes case when you release the mouse button. Alternatively, use the left and right arrow buttons to move the cursor and the Change Case button to toggle the case.

3. To confirm the name change, click **OK**.

   The Rename Confirmation dialog box appears listing impacted Profiles.

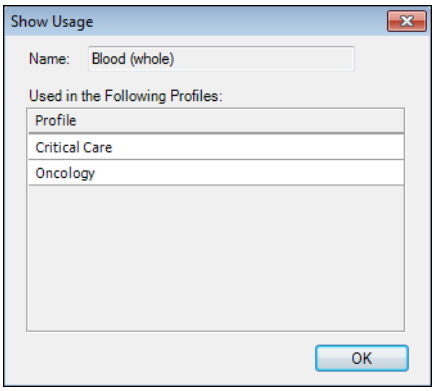
4. To accept and update all Profiles, click **OK**.

Showing Usage

The following procedure describes how to view profiles in which a fluid is used.

1. In the displayed Master Fluids List, right-click the desired Fluid and click **Show Usage**.

   The Show Usage dialog box appears listing the Profiles in which the Fluid is used.



2. To close the Show Usage dialog box, click **OK**.

Chapter 5
Master Therapies List

This section contains the following topics:

Overview

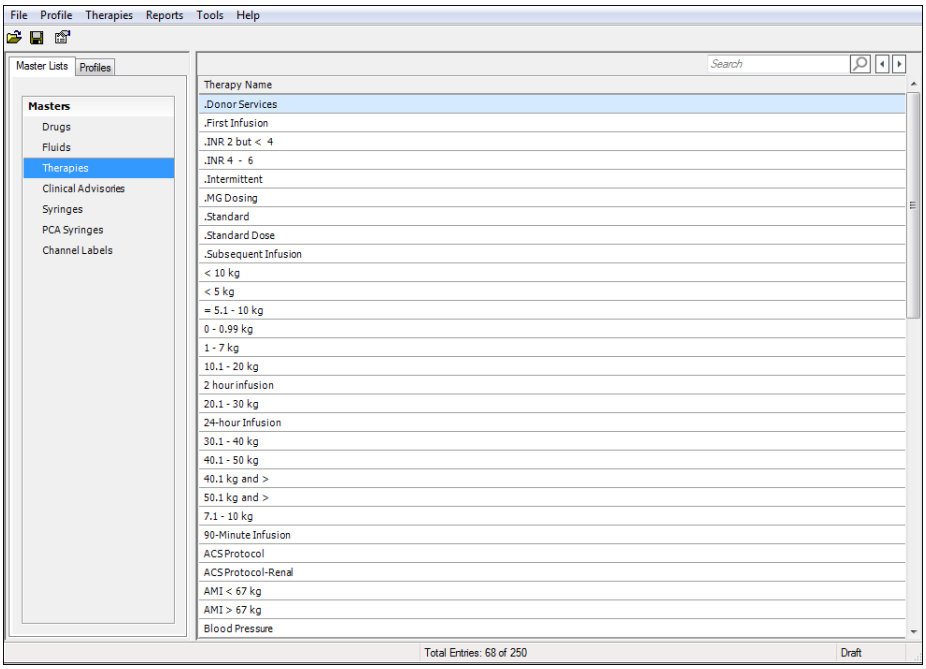
This software includes a set of default therapies in the master therapies list. You can add new therapies and edit or delete default therapies to meet your hospital's requirements. You can create up to 250 unique Therapy names. Therapy names appear in alphanumerical order.

Therapies are an optional hospital-defined or clinical indication for delivery of an infusion. Different limits can be defined for the same medication with different therapeutic indications. Therapies provide the ability for the health care facility to protect a medication that is dosed in different ways with limits appropriate for each entry. (For example: peripheral versus central, weekly versus Q3-week protocols.)

Displaying the Master Therapies List:

1. Click **Therapies** on the Master Lists tab of the navigation pane.

   The Master Therapies List appears.



Selecting a Therapy Using the Search Function:

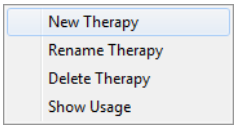
1. Type a therapy name or the initial characters of the therapy name in the search field.
2. Press **Enter** or click  .

   The selected therapy name is highlighted in yellow.
3. Use the left and right arrow to move to the next or previous therapy that matches your search criteria.

Creating a Therapy

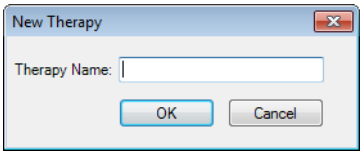
This procedure describes how to create a therapy in the Guardrails™ Editor software.

1. On the Master Lists tab, click **Therapies**.
2. If the required therapy is not listed, right-click in the main display area, and click **New Therapy**.



   The New Therapy dialog box appears.

3. Enter a name for the therapy (up to 20 characters) and click **OK**.



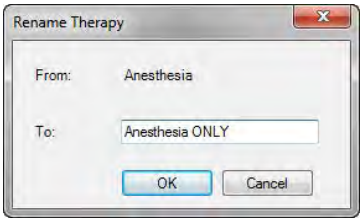
   The Master Therapies List shows the new therapy name.

NOTE:
A counter at the bottom of the list shows the total number of therapies in the master therapies list.

Renaming a Therapy

This procedure describes how to rename a therapy in the Guardrails™ Editor software.

1. In the Therapies Master List, right-click the therapy name, and select **Rename Therapy**.
   The Rename Therapy dialog box appears.
2. Update the therapy name and click **OK**.



   The Edit Therapy dialog box appears listing the impacted profiles.

3. To accept and update all profiles, click **OK**.
   The Master Therapy List shows the updated therapy.

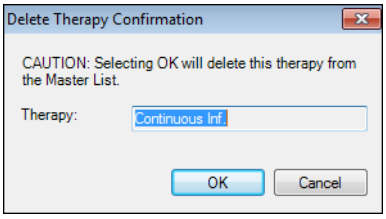
Deleting a Therapy

The Guardrails™ Editor software does not allow you to delete a therapy if it is being used by any drug setup.

1. In the Master Therapies List, right-click the therapy name, and select **Delete Therapy**.

   The Delete Therapy Confirmation dialog box appears.

2. Click **OK** to confirm the deletion.



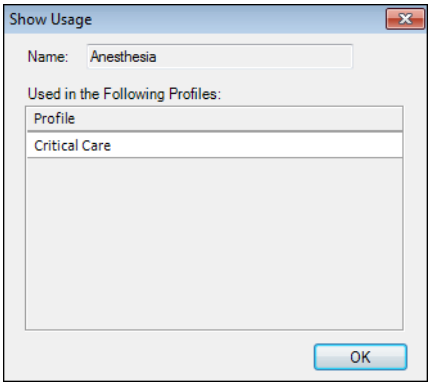
NOTE
If a therapy is in use, it cannot be deleted.

Showing Usage

The following procedure describes how to view profiles in which a therapy is used.

1. In the Master Therapies List right-click the desired therapy, and select **Show Usage.**

   The Show Usage dialog box appears listing the profiles in which the therapy is used.



2. To close the Show Usage dialog box, click **OK**.

Chapter 6
Master Clinical Advisory List

This section contains the following topics:

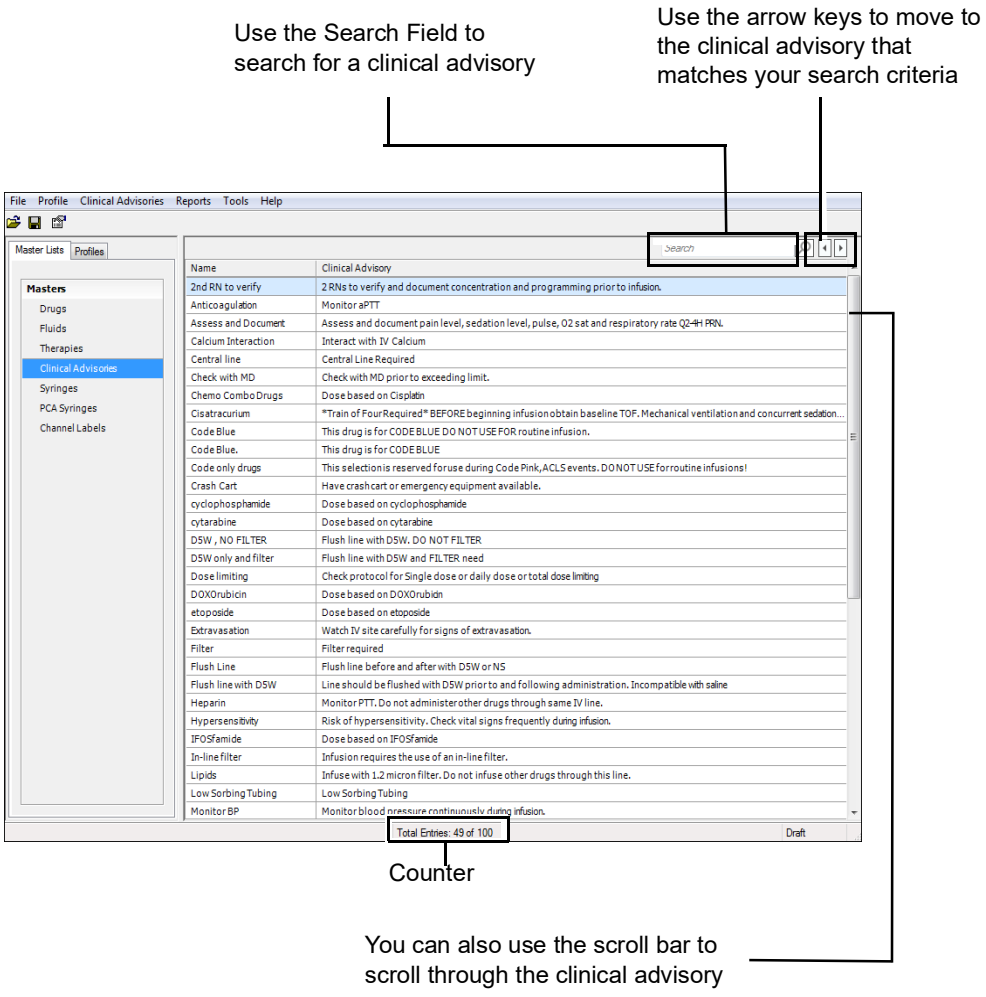
Overview

This software includes a set of default clinical advisory messages. You can add, edit, or delete these standard messages to meet your hospital's clinical requirements.

This software can store a total of 100 clinical advisories in the master clinical advisory list. Later, you can associate clinical advisories from the master clinical advisory list with specific drugs within the profiles developed for your hospital. Each drug or fluid setup can have only one clinical advisory.

Clinical advisories do not appear on the PCU when it is in Anesthesia Mode.

Clinical advisories can be created, edited, and deleted from the data set at the master advisory list level. The main display lists the current advisories.



NOTE:
The counter at the bottom of the dialog box indicates how many clinical advisories are in the master list.

Selecting a Clinical Advisory Using the Search Function:

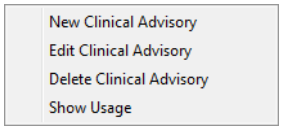
1. In the search field, type a clinical advisory name or the initial characters of any word within the name or clinical advisory text.
2. Press **Enter** or click  .

   The selected clinical advisory name is highlighted in yellow. The system searches within both the name and the clinical advisory text.
3. Use the left and right arrow to move to the next or previous clinical advisory that matches your search criteria.

Creating a Clinical Advisory

The new advisory option is disabled if 100 clinical advisories have already been entered.

1. On the Master Lists tab, click **Clinical Advisories**.
2. Make sure that the advisory is not listed (does not already exist).
3. Right-click the Clinical Advisories Master List, and select **New Clinical Advisory**.



   The New Clinical Advisory dialog box appears.
4. Enter a name for the clinical advisory (up to 20 characters).
5. Enter advisory text in the upper part of the clinical advisory text area.

   Enter text line by line as you want it to appear on the PCU display screen.
6. Click **OK**.

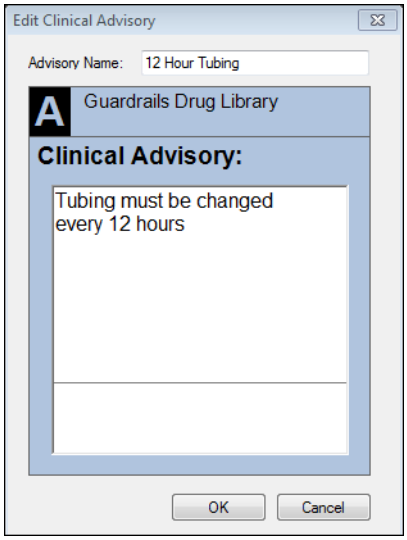
   The Master Clinical Advisory List shows the new clinical advisory.

NOTE:
Because the PCU display screen uses a variable width font, the number of characters allowed on each line of the clinical advisory message will vary. The total number of characters for all eight lines will vary from 112 to 200 characters.

Editing a Clinical Advisory

This procedure describes how to edit a clinical advisory in the Guardrails™ Editor software.

1. On the Master Lists tab, click **Clinical Advisories**.
2. Right-click a clinical advisory and click **Edit Clinical Advisory**.
3. In the Edit Clinical Advisory dialog box, update the advisory name and/or advisory text, and click **OK**.



The Edit Clinical Advisory Confirmation dialog box appears showing the impacted profiles.

4. Click one of the following:

Button	Function
Update	Update all listed profiles.
Remove	Remove the clinical advisory from all listed profiles.
Cancel	Close the dialog box without taking any action.

The master clinical advisory list shows the edited advisory.

Deleting a Clinical Advisory

Use this procedure to delete a clinical advisory from the master clinical advisory list.

NOTE:
The selected clinical advisory will be deleted from *all* profiles. To remove an advisory from individual profiles, see *Working with Clinical Advisories in Drug or Fluid Libraries on page 149*.

1. On the Master Lists tab, click **Clinical Advisories**.
2. Right-click a clinical advisory, and click **Delete Clinical Advisory**.

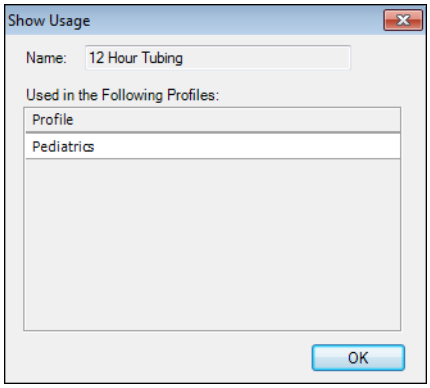
   The Delete Clinical Advisory Confirmation dialog box appears displaying the impacted profiles.
3. To confirm the deletion, click **OK**.

NOTE:
A clinical advisory deletion cannot be undone after you have clicked **OK**.

Showing Clinical Advisory Usage

The following procedure describes how to view the profiles in which a clinical advisory is used.

1. In the Master Clinical Advisory List, right-click the desired advisory, and select **Show Usage**.
   The Show Usage dialog box appears listing the profiles in which the advisory is used.



2. To close the Show Usage dialog box, click **OK**.

Chapter 7
Master Syringes/PCA Syringes Lists

This section contains the following topic:

Master Syringes/PCA Syringes

This software includes a master syringes list and a master PCA syringes list to be used as favorites (defaults) on the PCU. All syringes will default to enabled status. You can select syringes most commonly used by your hospital from the master syringes list and a master PCA syringes list for display and selection on PCUs.

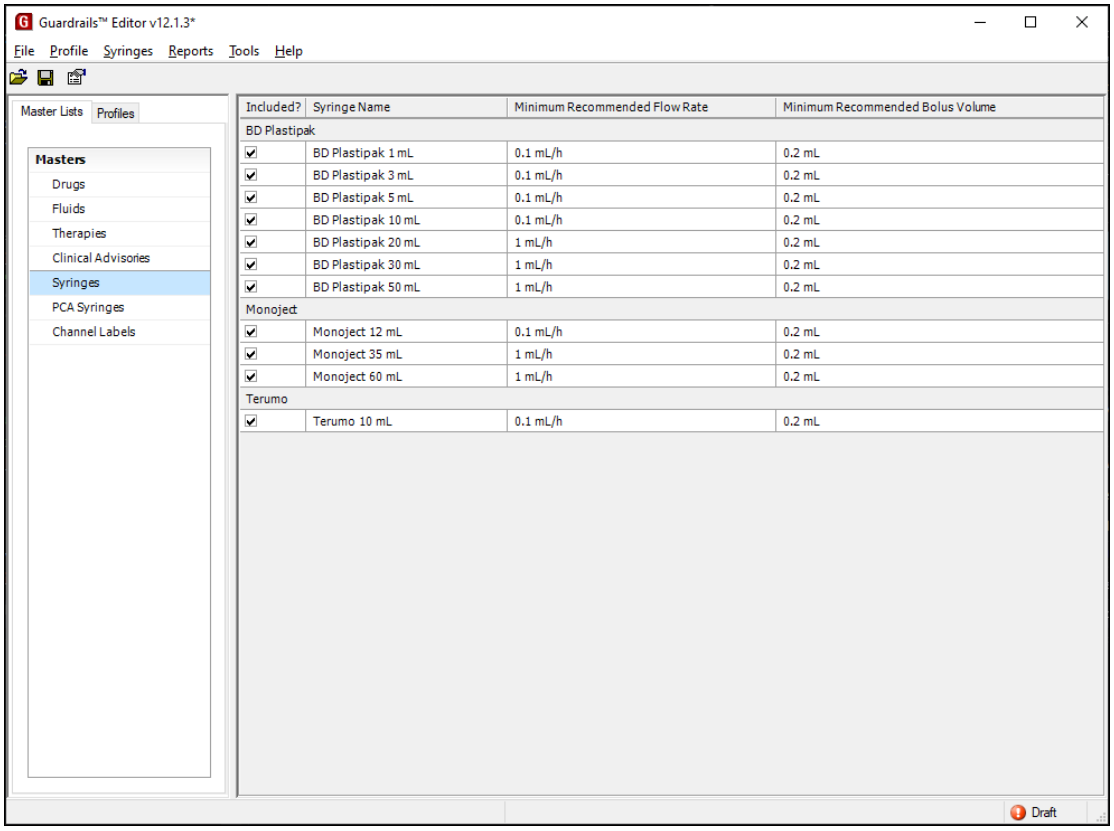
NOTE:
All available syringes outside of the favorites list can still be accessed by the clinician by pressing the **ALL SYRINGES** soft key on the BD Alaris™ PCU.

Configuring the Default Syringe Types For Your Hospital:

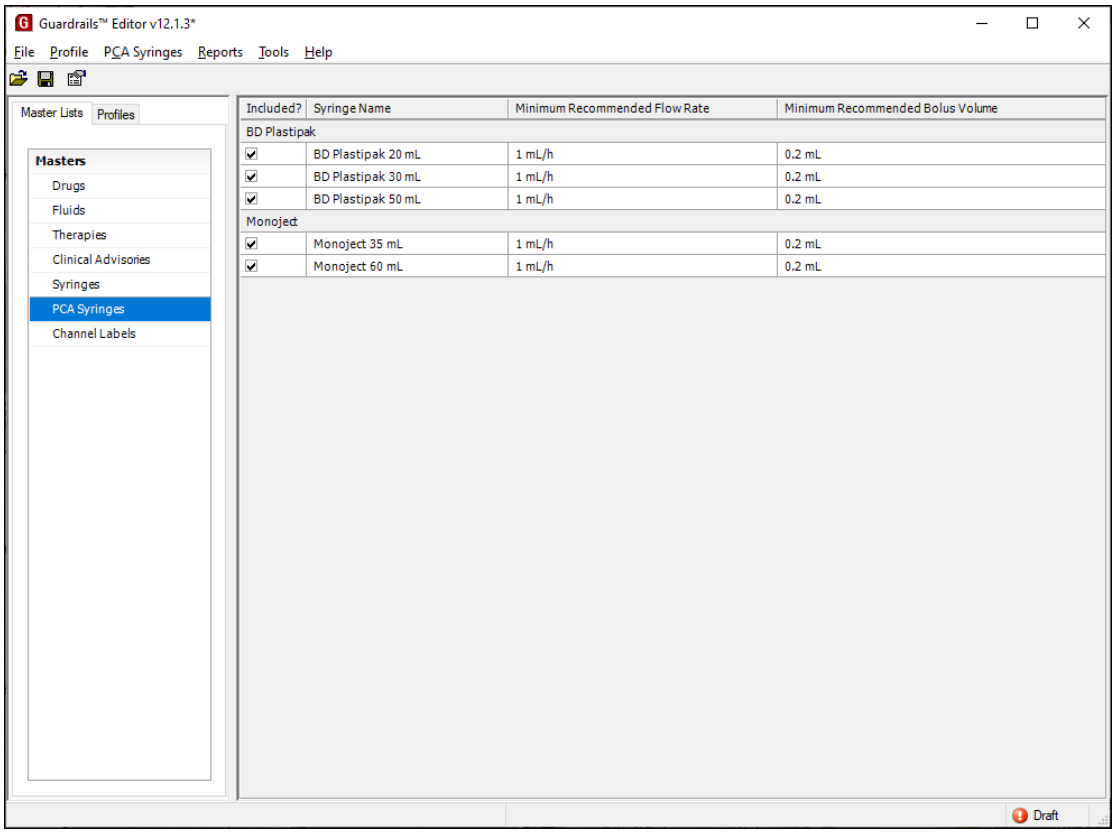
1. Select **Syringes** (for the Syringe Module) or **PCA** (for the PCA Module) from the Master Lists tab to display the list you want to edit.

   The Included Syringe List or Included PCA Syringe List is displayed.

2. Clear the check box next to a syringe name to remove it from your favorites list.



Syringes Master Lists



PCA Syringes Master Lists

Compatible Syringes

- Compatible syringe availability and model numbers vary by country. The syringes listed in the following tables may not be available in all countries. Syringe compatibility can change over time.

NOTE:

- Do not use incompatible syringe sizes and models with the Syringe Module. Use of incompatible syringes can impact pump operation resulting in inaccurate fluid delivery, delayed generation of occlusion alarms, and other potential problems (refer to the *BD Alaris™ System with Guardrails™ Suite MX User Manual*).
- Ensure that the displayed syringe manufacturer and syringe size match the installed syringe. Mismatches can impact flow rate accuracy.

WARNINGS

- **Use the smallest compatible syringe size necessary to deliver the fluid or medication. Using a larger syringe can impact pump performance, including delivery accuracy and startup time, and generation of occlusion alarms and bolus volume after occlusion. This is due to the increased friction and compliance of the syringe stopper with larger syringes. It is especially important when infusing high risk or life-sustaining medications at low infusion rates (for example, less than 5 mL/h) and very low flow rates (less than 0.5 mL/h).**
- **Avoid delivering low flow rates with larger syringes using the Syringe Module. This is of particular importance for the low, very low, and extremely low birth weight neonate. See the *Minimum Recommended Flow Rate for the Syringe Module on page 59*. Consider Syringe Module performance, recommended doses, dose volumes, and syringe size when developing drug concentration standards and data set parameters.**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 1 mL/h with syringe sizes greater than or equal to 20 mL.**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 0.1 mL/h with syringe sizes 1 mL and 3 mL.**
  - **The standard rate accuracy is the rate accuracy under standard operating conditions, which is ±5% at flow rates greater than or equal to 10% of the syringe capacity per hour; and ±10% for flow rates less than 10% of the syringe capacity per hour and greater than or equal to 0.1 mL/h (with syringe sizes less than 20 mL) or 1 mL/h (with syringe sizes greater than or equal to 20 mL).**
- **Delivering low volumes of high-risk medications with the Pump Module (particularly for neonatal populations, including low, very low, and extremely low birthweight neonates) can lead to less optimal pump performance including, but not limited to, over or under infusion and increased time to alarm for an occlusion. Consider use of the Syringe Module instead of the Pump Module using the smallest syringe size necessary for these low volumes of high-risk medications.**

WARNINGS

- **Avoid delivering low flow rates with larger syringes using the PCA Module. This is of particular importance for the low, very low, and extremely low birth weight neonate. Flow rates below 1 mL/h can cause approximately 10% over or under infusion beyond the standard rate accuracy. See the *Minimum Recommended Flow Rate for the PCA Module on page 61*. Consider PCA Module performance, recommended doses, dose volumes, and syringe size when developing drug concentration standards and data set parameters.**
  - **The standard rate accuracy is the rate accuracy under standard operating conditions, which is ± 5% at flow rates greater than or equal to 10% of the syringe capacity per hour; and ±10% for flow rates less than 10% of the syringe capacity per hour and greater than or equal to 1 mL/h.**
- **Avoid delivering an extremely small volume bolus (less than 0.2 mL) with the Syringe/PCA Module. Over or under infusion by approximately ±10% beyond the standard bolus volume accuracy can occur. Consider giving extremely small volume boluses IV push rather than with the Syringe/PCA Module bolus feature. See the *Minimum Recommended Flow Rate for the Syringe Module on page 59* and *Minimum Recommended Flow Rate for the PCA Module on page 61*. Also consider Syringe/PCA Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**
  - **The standard bolus volume accuracy is the bolus volume accuracy under standard operating conditions, which is ±10%.**
- **Avoid delivering loading bolus volumes of less than 1 mL (when the Prime Set with Syringe feature is utilized) with the Syringe Module as significant bolus volume inaccuracies can occur, resulting in under or over infusions (potentially down to 64% under infusion at 0.1 mL). Consider giving extremely small volume boluses IV push rather than with the Syringe Module bolus feature. Also consider Syringe Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**
- **Avoid delivering loading bolus volumes of less than 1 mL (when the Prime Set with Syringe feature is utilized) with the PCA Module as significant bolus volume inaccuracies can occur, resulting in under or over infusions (potentially down to 75% under infusion at 0.1 mL). Consider giving extremely small volume boluses IV push rather than with the PCA Module bolus feature. Also consider PCA Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**

BD Alaris™ Syringe Module Compatible Syringes

Medications delivered on the Syringe Module must be prepared in a syringe that accommodates the desired flow rate. The following table shows the brands for each syringe size and order number.

Compatible Syringes for the Syringe Module

Size	BD	Covidien Monoject™	Terumo™
1 mL	309628	N/A	N/A
3 mL	309657	N/A	N/A
5 mL	309646	N/A	N/A
6 mL	N/A	N/A	N/A
10 mL	300912 302995	N/A	SS-10 L (12 mL total)*
12 mL	N/A	Soft pack 1181200777 Rigid pack 8881512878	N/A
20 mL	302830	N/A	N/A
30 mL	302832	N/A	N/A
35 mL	N/A	Soft pack 1183500777 Rigid pack 8881535762 Empty barrel 8881135609	N/A
50 mL	309653	N/A	N/A
60 mL	N/A	Soft pack 1186000777 Rigid pack 8881560125	N/A
*Only available in Canada			

BD Alaris™ Syringe Module Flow Rate and Bolus Volume by Syringe Size

Refer to the table below for the recommended flow rate and bolus volume information for compatible syringes.

- For each syringe size used with the Syringe Module, the first table shows the minimum recommended flow rate to maintain flow rate accuracy within ±10%.
- For each syringe size used with the Syringe Module, the second table shows the minimum recommended bolus volumes to maintain bolus volume accuracy within ±10%.

Minimum Recommended Flow Rate for the Syringe Module

Syringe Size	Minimum Recommended Flow Rate	Minimum Flow Rate	Maximum Flow Rate
1 mL	0.1 mL/h	0.01 mL/h	30 mL/h
3 mL			100 mL/h
5 mL	0.1 mL/h	0.1 mL/h	150 mL/h
10 mL			250 mL/h
12 mL			250 mL/h
20 mL	1 mL/h	0.1 mL/h	500 mL/h
30 mL			650 mL/h
35 mL			650 mL/h
50 mL			999 mL/h
60 mL			999 mL/h

Minimum Recommended Bolus Volume for the Syringe Module Table

Syringe Size	Minimum Recommended Bolus Volume
1 mL	0.2 mL
3 mL	
5 mL	
10 mL	
12 mL	
20 mL	
30 mL	
35 mL	
50 mL	
60 mL	

Alaris™ PCA Module Compatible Syringes

Medications delivered on the PCA Module must be prepared in a compatible syringe. This table shows the brands for each syringe size and order number.

Compatible Syringes for PCA Module

Size	BD	Covidien Monoject™
20 mL	302830	N/A
30 mL	302832	N/A
35 mL	N/A	Soft pack 1183500777 Rigid pack 8881535762 Detachable plunger version, empty barrel 8881135609[†]
50 mL	309653	N/A
60 mL	N/A	Soft pack 1186000777 Rigid pack 8881560125

[†]Empty barrel only sold by BD. Detachable plunger is provided with the administration set.

Alaris™ PCA Module Flow Rate and Bolus Volume by Syringe Size

Refer to the table below for the recommended flow rate and bolus volume information for compatible syringes.

- For each syringe size used with the PCA Module, the first table shows the minimum recommended flow rate to maintain flow rate accuracy within ±10%.
- For each syringe size used with the PCA Module, the second table shows the minimum recommended bolus volumes to maintain bolus volume accuracy within ±10%.

Minimum Recommended Flow Rate for the PCA Module

Syringe Size	Minimum Recommended Flow Rate	Minimum Flow Rate	Maximum Flow Rate
20 mL	1 mL/h	0.1 mL/h	Less than 7 mL/h
30 mL			Less than 10.5 mL/h
35 mL			Less than 12.25 mL/h
50 mL			Less than 21 mL/h
60 mL			Less than 21 mL/h

Minimum Recommended Bolus Volume for the PCA Module

Syringe Size	Minimum Recommended Bolus Volume
20 mL	0.2 mL
30 mL	
35 mL	
50 mL	
60 mL	

Chapter 8
Managing Profiles

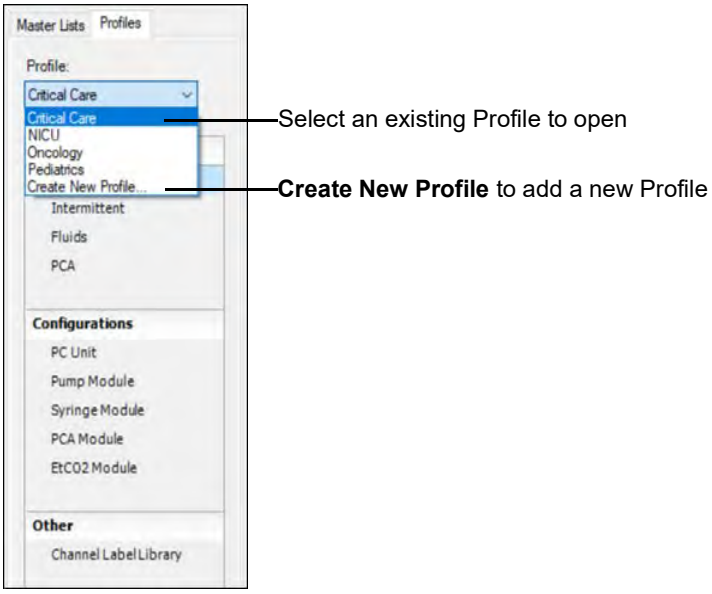
This section contains the following topics:

Overview

This software can store up to 30 care area profiles in a data set. Each profile is a unique set of configurations and best practice guidelines for IV drug delivery for a specific patient population or patient type, infusion type, or module type. The main components of a profile are the drug and fluids libraries, therapies, clinical advisories, instrument configuration settings, and channel label library.

Working with a Profile

You can create and edit profiles from the main menu bar or from the Profiles tab in the navigation pane.



The new profile will have drug libraries and configurations entries in the navigation pane for relevant module types. There will also be an entry for channel label library.

NOTE:

- If the Pump Module, Syringe Module, or PCA Module are not enabled in the BD Alaris™ System tab in Guardrails™ Editor software **Tools** > **Options** menu, the module does not appear on drug library screens. Modules can be enabled at any time during or after data set development.
- Modules that are disabled in the **Tools** > **Options** menu do not appear in the configurations list in the application or reports.
- When you make the Pump or Syringe Module(s) unavailable in the Guardrails™ Editor, it is only unavailable in the Guardrails™ Editor software, the modules are still available for use in No Guardrails™-Basic Infusion with default configurations when attached to a PCU.

You can:

- Add, delete, or rename profiles from the **Profile** menu.
- Open an existing profile from the Profile list in the navigation pane.
- Create a new profile from the Profile list.

Creating a Profile

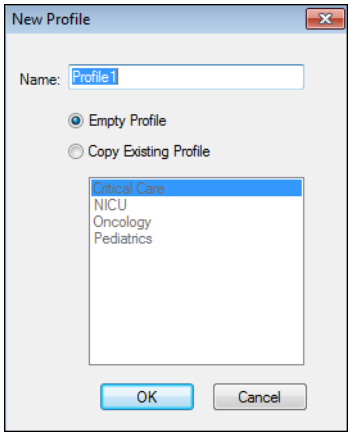
A new profile can be created from an empty profile or you can copy an existing profile and modify it.

Creating a Profile Using an Empty Profile

Use this procedure when you first set up the software, or to build a new profile in an existing data set.

1. Do one of the following:
   - In the menu bar, click **Profile** > **New**.
   - In the navigation pane, select **Create New Profile** from the profile list.

   The New Profile dialog box appears.



   Empty Profile is the default selection.

2. Enter a **New Profile Name** (up to 20 characters), and click **OK**.

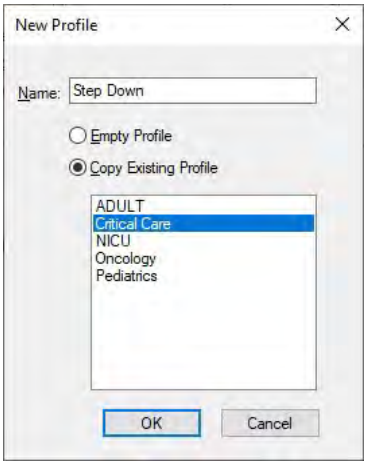
   The New Profile name appears in title bar and in the profile list in the navigation pane.

   NOTE:
   Profile names appear in alphanumerical order in the navigation pane.

Creating a Profile by Copying an Existing Profile

An alternate method for adding a new profile is to copy an existing profile in the data set and then modify it as required. This option copies the drug libraries, device configuration settings, and channel labels of the selected profile to the new profile. A unique name for the new profile must be provided.

1. Do one of the following:
   - In the menu bar, click **Profile** > **New**.
   - In the navigation pane, select **Create New Profile** from the profile list.
2. Enter the name in **New Profile Name** box.
3. Click **Copy Existing Profile**.



4. Select the profile to be copied, and click **OK**.

   The new profile name appears in the title bar and in the profile list in the navigation pane.

WARNING

When copying a setup group from one Profile to another or copying an existing Profile to create a new Profile, review all relevant drug or fluid setup group parameters, configurations, and/or the Profile name. Failure to do so may result in incorrect data set parameters on the PCU, contributing to over, under, or delayed infusions.

Assigning a Master Drug to a Profile

A drug from the master drug list can be used in the continuous/bolus and/or PCA drug library, or it can be used in the intermittent drug library. A drug *cannot* be used in both the continuous/bolus library and the Intermittent library, nor can it be used in both the PCA drug library and intermittent drug library.

After a master drug has been assigned to a drug setup in a drug library, it is not available for assignment to a different drug library drug setup in any profile. The assigned drug name is filtered out of the list.

The exception is that a drug *can* be used in both the continuous/bolus and PCA drug libraries.

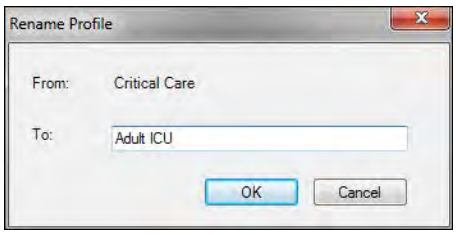
NOTE:
There is a maximum of 1500 drug or fluid setups in a single profile.

Renaming a Profile

This procedure describes how to rename a profile in the Guardrails™ Editor software.

1. Select a profile to rename from the Profile list in the navigation pane.
2. In the menu bar, click **Profile** > **Rename**.

   The Rename Profile dialog box appears.
3. Update the profile name, and click **OK** to accept the change.



Deleting a Profile

This procedure describes how to delete a profile in the Guardrails™ Editor software. The delete operation permanently deletes the profile and its corresponding drug library, instrument configurations, and channel label library. The deletion cannot be undone

1. Select a profile to delete from the Profile list in the navigation pane.
2. In the menu bar, click **Profile** > **Delete**.

3. In the confirmation message, click **Yes** to confirm the deletion.

Chapter 9
Master Channel Labels List

This section contains the following topics:

Overview

A channel label can be used to name the Pump Module or Syringe Module when a No Guardrails™-Basic Infusion is programmed. You can define up to 100 unique channel labels in each data set. Later, you can associate channel labels from the master channel labels list with specific profiles developed for your hospital

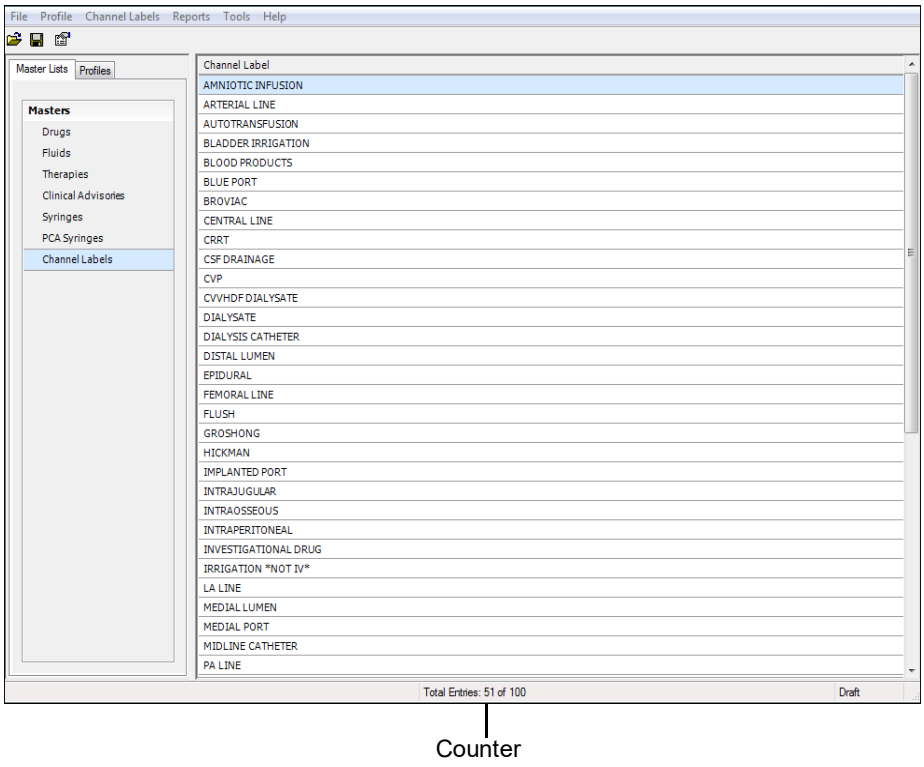
NOTE:
There is **no** Guardrails™ safety software protection with channel labels.

NOTE:
Channel labels should not include drug or fluid names. They are intended to provide a channel identifier for route of administration or type of IV line, such as epidural or distal lumen. A confirmation dialog box appears if a channel label entered is the same as the name of a drug in the master drug list or fluid name in the master fluids list. This confirmation can be overridden.

Creating a Channel Labels List

On the Master Lists tab, click **Channel Labels**. The master channel labels list appears in the main display, in alphabetical order. Numeric values are displayed before alphabetical values.

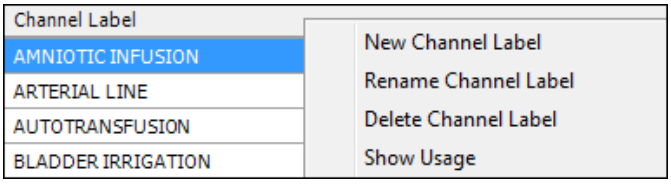
NOTE:
A counter at the bottom of the dialog box indicates how many channel labels are currently in the list.



Creating a Channel Label

This procedure describes how to create a channel label in the Guardrails™ Editor software.

1. Right-click the list of Channel Labels on the Master Channel Labels box, and click **New Channel Label**.



NOTE:
The New Channel Label button is unavailable if 100 channel labels have already been entered.

The New Channel Label dialog box appears.

2. Enter a channel label name and click **OK**.

Each channel label can be up to 20 alphanumeric characters in length.

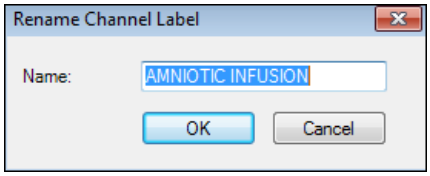
Renaming a Channel Label

This procedure describes how to rename a channel label in the Guardrails™ Editor software.

1. In the Master Channel Labels dialog box, right-click the **Channel Label** that you want to rename, and click **Rename Channel Label**.

   The Rename Channel Label dialog box appears.

2. Enter the new channel label name in the text field, and click **OK**.



   The Rename Channel Label Confirmation dialog box appears.

3. Click **Update** to confirm.

   All instances of the previous version of the label in any impacted profiles are updated with the new label.

Deleting a Channel Label

This procedure describes how to delete a channel label in the Guardrails™ Editor software.

1. In the Master Channel Labels dialog box, right-click the **Channel Label** that you want to delete, and click **Delete Channel Label**.

   The Delete Channel Label Confirmation dialog box appears, listing the profiles impacted by this change.

2. To confirm the deletion, click **OK**.

   The label is deleted from all listed profiles.

Chapter 10
Developing the Continuous/Bolus Drug Library

This section contains the following topics:

Overview

WARNING

Ensure that drug or fluid setups are entered in the correct Library (Continuous/Bolus, Intermittent, PCA and Fluids) that supports appropriate order elements. Failure to do so could result in incorrect programming leading to an over or under infusion. For example, heparin ordered with a dose unit of units/kg/hour should be entered in the Continuous/Bolus Library.

Developing a continuous/bolus drug library for the Pump Module and/or Syringe Module involves a number of optional and required steps:

- Select drugs and concentration levels from the master drug list.
- Add therapies (optional).
- Select weight-based or non-weight based drug setups.
- Select the desired infusion module, or modules, if both Pump and Syringe Modules are enabled.
- Identify drugs that are used for anesthesia only.
- Add profile-specific dosing parameters and hard limits and/or soft limits.
- Add optional initial values for certain drug-setup fields.
- Add clinical advisories to selected drugs.

NOTE:
You must set at least one minimum limit and one maximum limit. The third limit is optional.

There are expanded precision and dosing ranges for continuous/bolus drug setups, see *Highlights and Previous Versions on page 216* for more information.

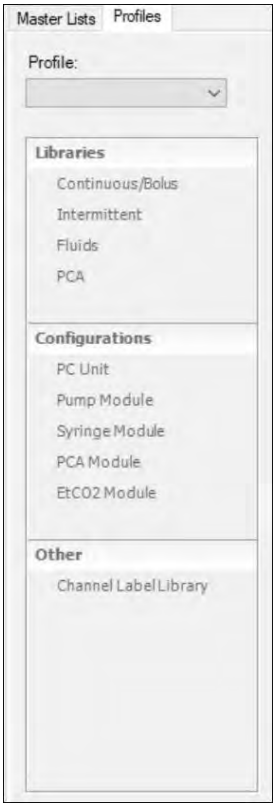
BD recommends the following customer actions to prevent potential programming errors on the Alaris System from occurring:

- Standardize using full concentrations and avoid the use of Units Only concentrations (custom concentrations) where possible, especially for all continuous/bolus and PCA infusions.
- Align pharmacy label and pump: Review how drugs, concentrations, and infusion rates are displayed in medication orders, MARs, and on pharmacy labels to ensure that they align to what the clinician will be reviewing and programming on the infusion pump.

Adding a Drug

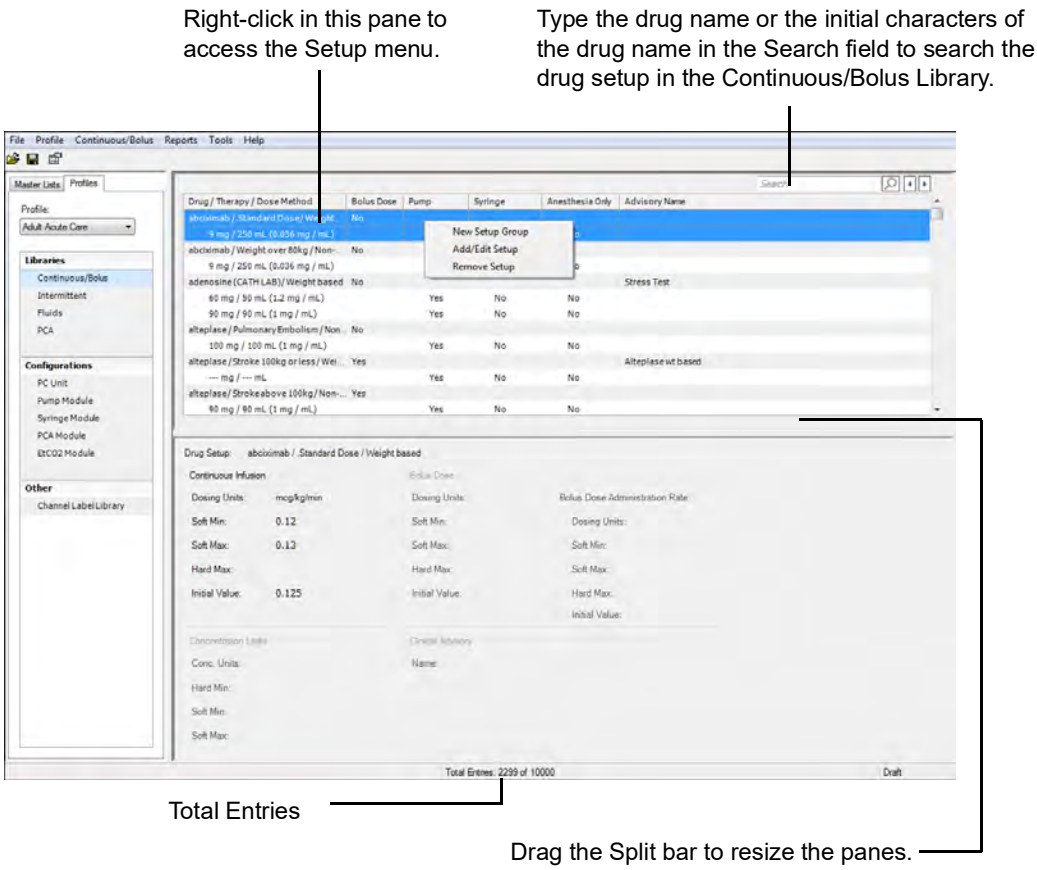
The following procedure describes how to add a drug to the continuous/bolus library.

1. Click the **Profiles** tab.
2. Select a profile from the **Profile** list in the navigation pane.



3. Select **Continuous/Bolus** in the list of libraries in the navigation pane.

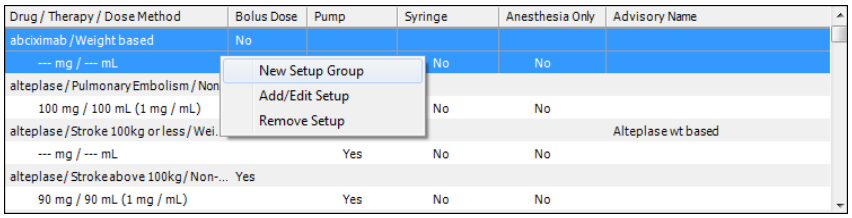
   The Continuous/Bolus Summary dialog box appears.



NOTE:

- If you are creating a new profile drug library, the main screen does not contain drugs and concentrations until you add them to the library.
- The total number of setups over all profiles combined appears at the bottom of the display.

4. Right-click in the top section of the profiles list and select **New Setup Group**.

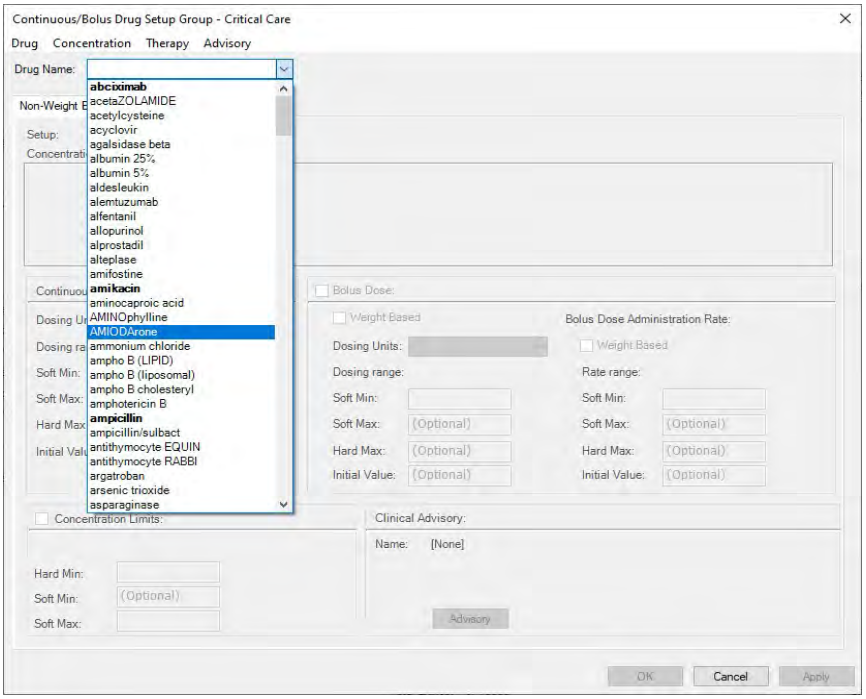


The Continuous/Bolus Drug Setup Group dialog box for the drug library you selected appears.

5. Select a **Drug Name** from the list of master drugs.

   Drug names displayed in **bold** already exist in the drug library.

   NOTE:
   There is a search feature within the Drug Name field. Place cursor in Drug Name field and type the intended drug name or the initial characters of the drug name.



   NOTE:
   If the drug does not exist in the master drug list, see *Adding a New Drug that is Not in the Master Drug List on page 89* for more information. The drug will not displayed if it already exists in the intermittent profile drug library, because it cannot appear in both libraries.

   Once a drug name is selected, the Concentrations section of the dialog box lists all current concentrations of the selected drug currently available in the master drug list and valid for continuous/bolus dose infusion.

   You can assign therapies to the new drug setup group by selecting **Therapy** > **Select** in the menu bar. For information about working with therapies in a profile, see *Assigning a Therapy on page 146*.

6. Click the **Non-Weight Based** or **Weight Based** tab to set up the desired dosing methods for this drug setup group.

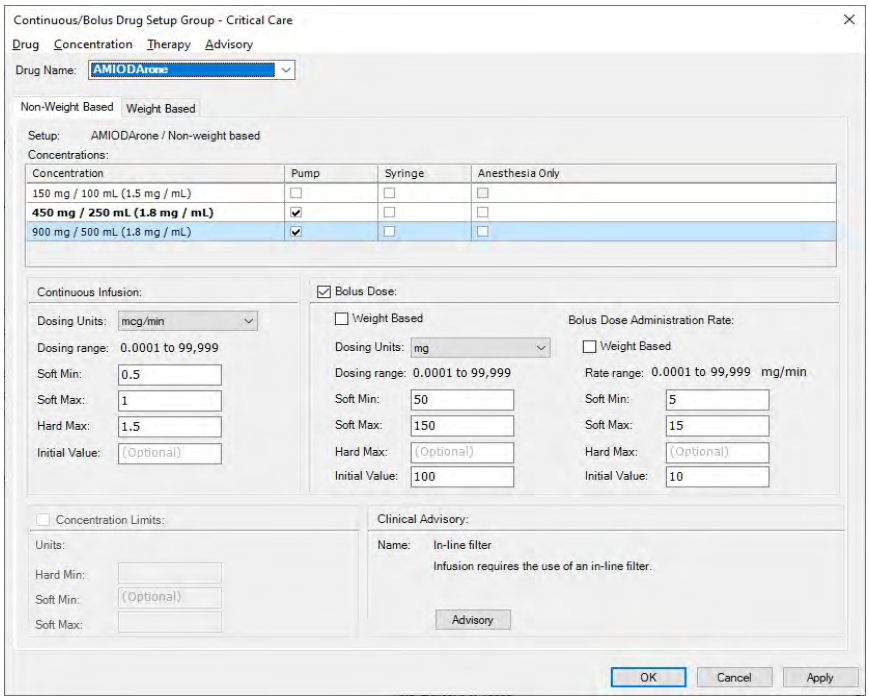
WARNINGS

- **Avoid delivering low flow rates with larger syringes using the Syringe Module. This is of particular importance for the low, very low, and extremely low birth weight neonate. See the *Minimum Recommended Flow Rate for the Syringe Module on page 59*. Consider Syringe Module performance, recommended doses, dose volumes, and syringe size when developing drug concentration standards and data set parameters.**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 1 mL/h with syringe sizes greater than or equal to 20 mL.**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 0.1 mL/h with syringe sizes 1 mL and 3 mL.**
  - **The standard rate accuracy is the rate accuracy under standard operating conditions, which is ±5% at flow rates greater than or equal to 10% of the syringe capacity per hour; and ±10% for flow rates less than 10% of the syringe capacity per hour and greater than or equal to 0.1 mL/h (with syringe sizes less than 20 mL) or 1 mL/h (with syringe sizes greater than or equal to 20 mL).**
- **Delivering low volumes of high-risk medications with the Pump Module (particularly for neonatal populations, including low, very low, and extremely low birthweight neonates) can lead to less optimal pump performance including, but not limited to, over or under infusion and increased time to alarm for an occlusion. Consider use of the Syringe Module instead of the Pump Module using the smallest syringe size necessary for these low volumes of high-risk medications.**
- **Avoid delivering extremely small volumes (less than 0.2 mL) via the Pump Module bolus feature. Over infusion and/or under infusion by 15% beyond the standard bolus volume accuracy can occur (see the *Pump Module Flow Rate Accuracy* section in the BD Alaris™ System user manual). Consider giving extremely small volume boluses IV push rather than with the Pump Module bolus feature. See the *BD Alaris™ Pump Module Bolus Duration by Bolus Volume on page 86*. Also consider Pump Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**
  - **The standard bolus volume accuracy is the bolus volume accuracy under standard operating conditions, which is +10%.**

7. Select the check box for the **Pump Module**, **Syringe Module**, or both if applicable to include this concentration in the profile.

   You must select at least one infusion module.

   If the required concentration is not in the current list, see *Adding a New Concentration on page 87* for more information.



NOTE:
If the Pump Module or Syringe Module is disabled from the Tools menu, it does not appear in the dialog box. Volume (mL only) (PCA) is not used for the continuous/bolus drug library.

8. If you want this drug and concentration to be accessible only when the BD Alaris™ System is operating in anesthesia mode, select the **Anesthesia Only** check box.

   NOTE:

   - In order to create an anesthesia only drug in a profile, Anesthesia Mode must be enabled in the PCU configuration settings section.
   - If this check box is left cleared, the drug and concentration are available for selection with the profile in anesthesia and non-anesthesia mode.
   - Enter the continuous infusion dosing units and dosing range limits.

WARNING

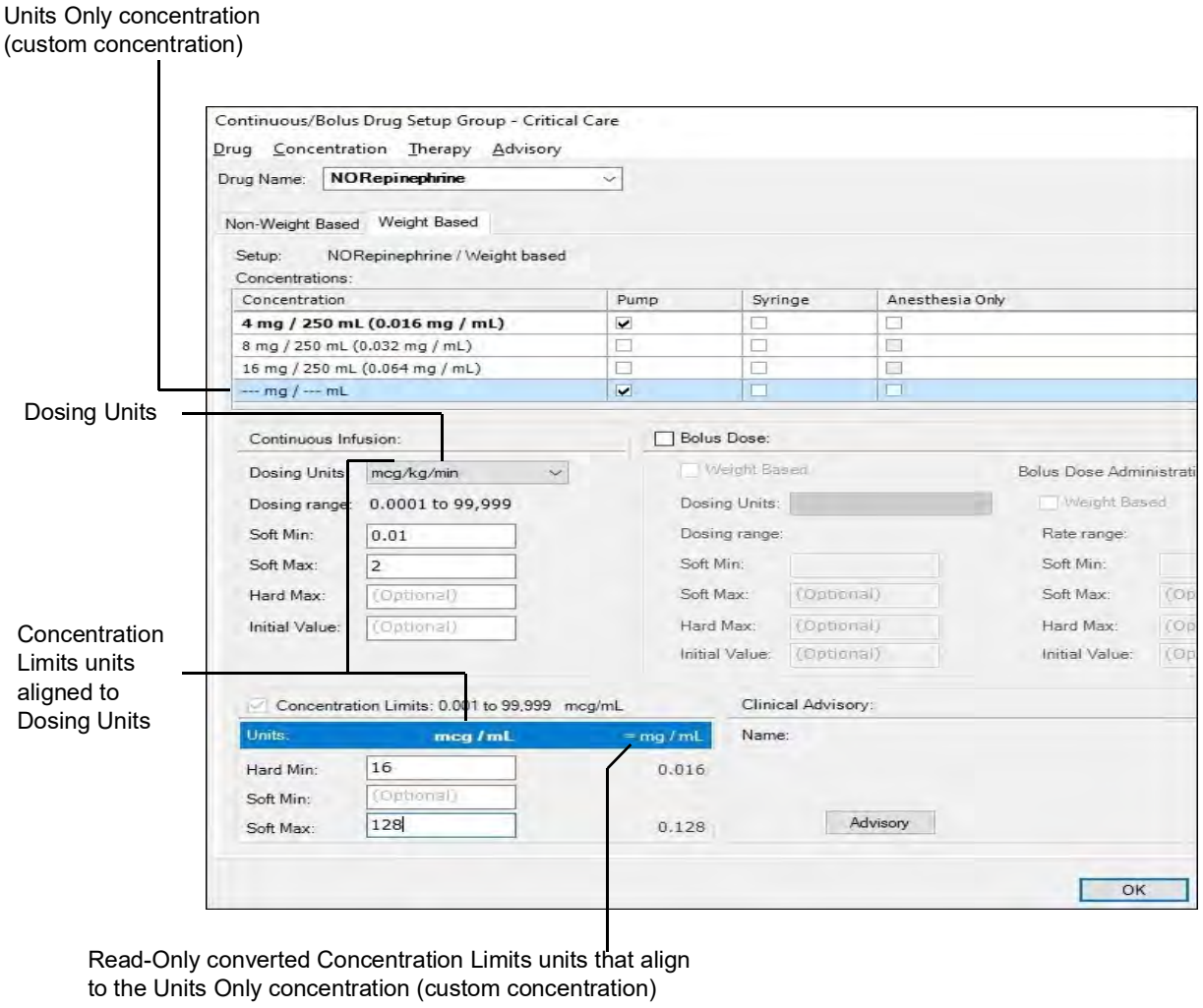
Concentration Limit Units are determined by the dosing unit selected. Verify that your concentration limit values correctly align with the associated dosing unit to avoid potential over or under infusion.

9. Enter **Concentration Limits** for drug setups with a Units Only concentration (custom concentration) selected.

   NOTE:

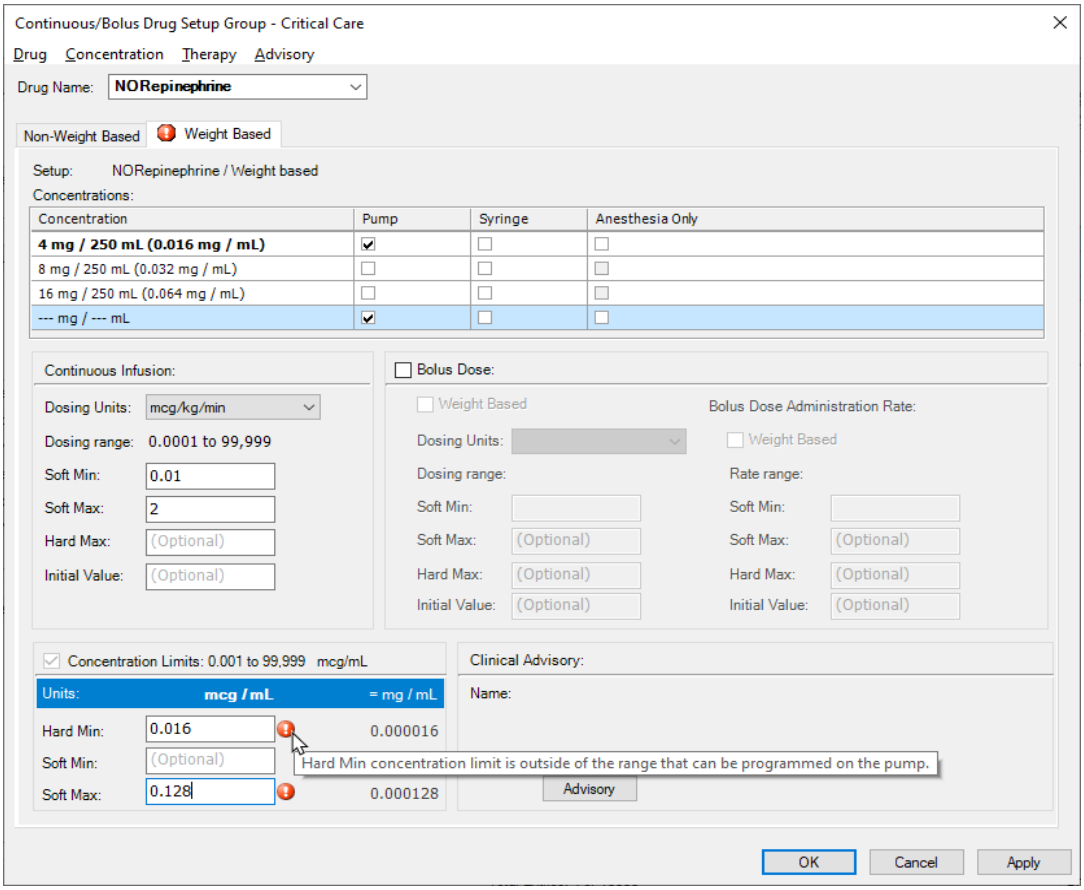
   - When programming a Units Only concentration (custom concentration) in the drug library, the Drug Amount and Diluent Volume must be entered into the infusion device by the clinician so that the resulting concentration can be used to calculate the flow rate or volume needed to deliver the prescribed dose.
   - Hard minimum concentration limits in your hospital's drug library can prevent over infusion or under infusion when a Units Only concentration (custom concentration) is programmed incorrectly at the bedside.
   - Continuous/bolus drug library setups with a selected Units Only concentration (custom concentration) require Concentration Limits, including a hard minimum and soft maximum value. Soft minimum concentration limits are optional. Concentration limits are not available for drug setups with only Full Concentrations selected.

If the concentration programmed by the clinician is...	Then the pump delivers an...
lower than the actual concentration	over infusion
higher than the actual concentration	under infusion



When the Units Only concentration (custom concentration) units differs from the Concentration Limit units, the software will highlight the Concentration Limit unit that aligns to the dosing unit. The software also provides a read-only converted value that aligns to the Units Only concentration (custom concentration) unit.

In the NORepinephrine example above, the Units Only concentration (custom concentration) is in -- mg/-- mL and the Continuous Dosing units selected are mcg/kg/min. Therefore the Concentration Limits unit are defaulted to mcg/mL due to the dosing units selected. The converted concentration is displayed to the right in mg/mL because the Units Only concentration (custom concentration) was selected in mg.



If a concentration limit value entered is outside the acceptable range capable on the Alaris System, an exclamation symbol will appear within the GRE Software. In the example above, a user entered 0.016 not realizing it was mcg/mL. This converts to 0.000016 mg/mL and would not be able to be programmed by the nurse on the device.

NOTE:
The Concentration Limits: 0.001 to 99,999 is the range of values acceptable to enter in the GRE software which in some circumstances, may differ than the allowable concentration range on the Alaris System.

10. Select the **Bolus Dose** check box, if desired, and enter the Bolus Dose and Bolus Dose Administration Rate Limits as required.

    For more information, see *Bolus Dose Administration on page 84*.

11. To attach a clinical advisory to this drug entry, click **Advisory**.

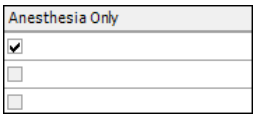
    For more information, see *Working with Clinical Advisories in Drug or Fluid Libraries on page 149*.

12. Click **Apply** to accept the entries and keep the dialog box open to add more drugs, or click **OK** to accept the entries and close the dialog box.

Anesthesia Mode

When a drug is available for Anesthesia Mode, the check box is white.

- To set an available drug as Anesthesia Only, select the available check box.



Once the check box is selected, the drug/concentration is only available when the Anesthesia Mode is enabled on the device. If the same drug needs to be available for the anesthesia and bedside clinician, two separate entries must be created. This is accomplished by using a therapy (example: Non Anesthesia and Anesthesia) or as a separate drug entry (example: Propofol ANESTHESIA).

When the device is placed into Anesthesia Mode and the clinician selects Guardrails™ Drugs, the entries marked as Anesthesia Only is displayed. The clinician using the BD Alaris™ System device in Anesthesia Mode has access to all of the drugs within the profile by using the soft key to toggle between the ANESTH DRUGS and ALL DRUGS. Entries that are set up using the Anesthesia Only option are not available to the clinician when the device is in normal mode.

NOTE:

- If an anesthesia drug is infusing and the Anesthesia Mode is disabled, the drug continues to infuse under the anesthesia entry until it is stopped and restarted using the regular profile entry.
- There are no hard limits when Anesthesia Mode is enabled.

Bolus Dose Administration

WARNINGS

- **When using the Pump Module bolus feature, avoid delivering bolus volumes that are less than 0.6 mL with durations of less than 1 minute. Over infusion from significant bolus volume inaccuracies can occur (potentially up to 45% over infusion beyond the standard bolus volume accuracy for bolus volumes less than 0.6 mL). To avoid over infusions when delivering extremely small volume boluses, consider giving boluses IV push rather than with the Pump Module bolus feature, or giving the bolus over the longest recommended duration if using the Pump Module bolus feature. See the *BD Alaris™ Pump Module Bolus Duration by Bolus Volume on page 86*. Also consider Pump Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**
  - **The standard bolus volume accuracy is the bolus volume accuracy under standard operating conditions, which is ±10%.**
- **Avoid delivering an extremely small volume bolus (less than 0.2 mL) with the Syringe Module. Over or under infusion by approximately ±10% beyond the standard bolus volume accuracy can occur. Consider giving extremely small volume boluses IV push rather than with the Syringe Module bolus feature. See the *Minimum Recommended Flow Rate for the Syringe Module on page 59*. Also consider Syringe Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**
  - **The standard bolus volume accuracy is the bolus volume accuracy under standard operating conditions, which is ±10%.**
- **Avoid delivering loading bolus volumes less than 5 mL with the Pump Module as significant bolus volume inaccuracies can occur, resulting in under or over infusions (potentially up to 50% over infusion at 0.1 mL). Consider giving small volume loading boluses IV push rather than through the Pump Module bolus feature. Also consider Pump Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**
- **Avoid delivering loading bolus volumes of less than 1 mL (when the Prime Set with Syringe feature is utilized) with the Syringe Module as significant bolus volume inaccuracies can occur, resulting in under or over infusions (potentially down to 64% under infusion at 0.1 mL). Consider giving extremely small volume boluses IV push rather than with the Syringe Module bolus feature. Also consider Syringe Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**

Bolus doses are an optional feature for drug setups in the Continuous/Bolus Library.

When enabled for a drug setup in the data set, minimum and maximum Guardrails™ limits must be entered for bolus dose and bolus dose administration rate (BDAR). Initial values are optional. The maximum limit may be either a soft or hard limit. Bolus dose and BDAR may be either non-weight based or weight-based.

A bolus dose is the drug amount to be delivered as a bolus from the continuous infusion. During the administration of the bolus, the continuous infusion stops. Once the bolus is delivered, the continuous infusion resumes.

BDAR is the drug amount per minute or drug amount per kilogram per minute. This parameter is displayed as **INFUSE AT** on the PCU's bolus dose setup display.

After the clinician enters the bolus dose and duration, an infuse at rate, or BDAR, is calculated on the PCU and compared against Guardrails™ limits. Alternatively, bolus dose duration may be calculated and prepopulated from programmed bolus dose and either the optional BDAR initial value or required maximum limit, the latter used when selecting the Rapid Bolus soft key.

The Rapid Bolus soft key is a way to deliver the bolus dose as fast as possible according to hospital best practices. When selected, the rapid bolus flow rate is calculated as the lesser of the following:

- For non-weight-based bolus dose administration rate: Rate (mL/h) = (soft max bolus dose administration rate from the data set x 60)/concentration.
- For weight-based bolus dose administration rate: Rate (mL/h) = (soft max bolus dose administration rate x 60 x patient weight)/concentration.
- Maximum rate set in the profile configuration setting or maximum physical pumping limit constrained by syringe size for the Syringe Module.

NOTE:

- If both a soft and a hard maximum bolus dose administration rate is set in the data set, the soft limit is the default.
- If only a hard bolus dose administration rate limit is established in the data set, the hard limit is the default.
- Rapid Bolus duration is prepopulated on the PCU and dependent on the programmed bolus dose value.

Low bolus dose volumes at very high flow rates using the bolus dose feature may demonstrate reduced volume accuracy characteristics.

BDAR limits in the data set may prevent the clinician from programming a rate that exceeds the performance capabilities of the BD Alaris™ System for a low bolus dose volume. It is recommended that BDAR maximum limits be entered in the data set such that resulting rapid bolus (i.e. maximum) flow rates are both clinically appropriate and lower than the maximum rate set in the profile configuration setting, in accordance with hospital best practices.

Consider doses, patient weight ranges, concentrations, resulting dose volumes and module performance characteristics as described in specific warning statements and the BD Alaris™ System User Manual when developing BDAR Guardrails™ limits.

The table below pertains to the Pump Module. For small bolus volumes, it is recommended that BDAR limits can be developed to help avoid programming values that exceed the stated flow rates and that the resulting bolus dose duration be 1 minute or greater.

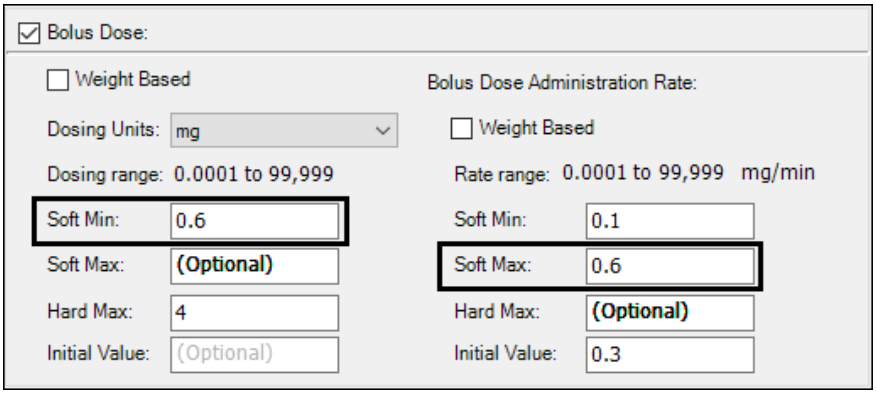
BD Alaris™ Pump Module Bolus Duration by Bolus Volume

Bolus Volume	Minimum Recommended Bolus Duration	Maximum Recommended Bolus Flow Rate (mL/h) based on BDAR
0.1 mL[1]	1 minute	6 mL/h
0.2 mL[2]		12 mL/h
0.3 mL		18 mL/h
0.4 mL		24 mL/h
0.5 mL		30 mL/h
0.6 mL		36 mL/h

1 For bolus volume of 0.1 mL, the bolus volume accuracy is ± 0.025 mL.
2 For bolus volumes greater than or equal to 0.2 mL at a bolus duration of greater than or equal to 1 minute, the bolus volume accuracy is ± 10%.

NOTE:
To help ensure that bolus doses are infused over a duration of 1 minute or greater, consider the following approach in the data set:

- Set the bolus dose soft minimum limit value equal to the BDAR maximum limit value according to hospital best practices.
- Align bolus dose and BDAR dose method (i.e. both non-weight based or both weight-based).
- For example, using a concentration of 1 mg/mL, the following bolus dose entry with a programmed dose of 0.6 mg would yield a flow rate of 36 mL/h and duration of 1 minute using the rapid bolus soft key and a flow rate of 18 mL/h and a duration of 2 minutes using prepopulated initial value. Duration would scale proportionately for larger doses.



Adding a New Concentration

Be aware of the following when adding a new concentration to the library:

- Bolus dose parameters cannot be entered until the continuous infusion settings have been entered.
- You must set at least one minimum limit and one maximum limit. The third limit value is optional.
- Edited parameter settings apply to all included concentrations.
- Initial values are optional.
- If any setting falls outside acceptable parameters or required values are not entered, the exclamation symbol appears. Move the mouse over the symbol to see which parameter is out of range or not entered.
- Duplicate drug and concentration entries are not allowed. A message box alerts you if an attempt is made to add an entry that already exists in the drug library or in the selected profile.

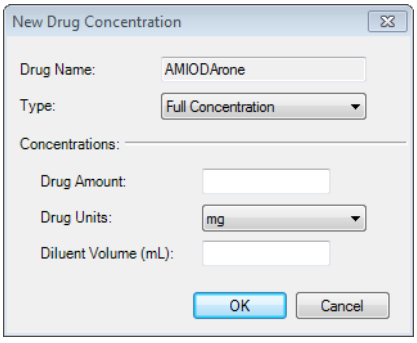
To Add a Concentration

1. In the top section of the Continuous/Bolus Summary dialog box, right-click the selected drug-setup group, and click **Add/Edit Setup**.

   The Continuous/Bolus Drug Setup Group dialog box appears displaying the selected drug-setup group.
2. Select the therapy if applicable.
3. Click the **Non-Weight Based** or **Weight Based** tab to display either the non-weight based or weight based parameters for adding a new concentration.
4. In the menu bar, click **Concentration** > **New**.

   The New Drug Concentration dialog box appears.
5. Select the type of concentration from the **Type** list.

Type	Description
Full Concentration	The Drug Amount, Drug Units, and Diluent Volume (mL) values.
Units Only	A concentration that includes drug units without predefined drug amount and diluent volume values. The clinician enters these values when initiating an infusion on the BD Alaris™ System. Only one Units Only concentration (custom concentration) selection is allowed per setup.



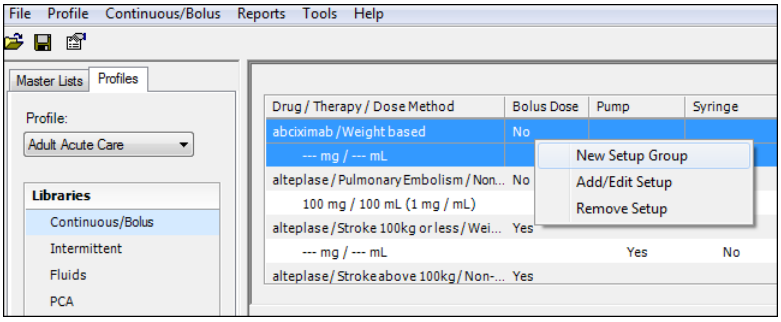
6. Enter a **Drug Amount**, applies to Full Concentration only.

7. Change the **Drug Units** using the list, if desired.
   The Drug Units default to the units previously used.
8. Enter **Diluent Volume** (applies to Full Concentration only), and click **OK**.
9. Select **Pump Module**, **Syringe Module**, or both to include the new concentration in the profile.
   You can also select Anesthesia Only.
   The new concentration is automatically updated in the master drug list.

Adding a New Drug that is Not in the Master Drug List

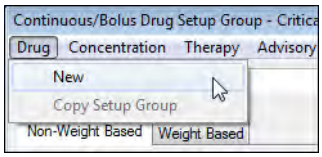
This procedure describes how to add a new drug that is not in the master drug list in the Guardrails™ Editor software.

1. In the top section of the Continuous/Bolus Summary screen, right-click and select **New Setup Group**.

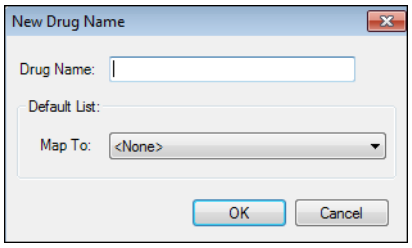


   The Continuous/Bolus Drug Setup Group dialog box appears.

2. In the menu bar, click **Drug** > **New**.



   The New Drug Name dialog box appears.



3. Enter the **Drug Name**.
4. Optionally select a drug name in the **Map To** list to copy its concentrations list.

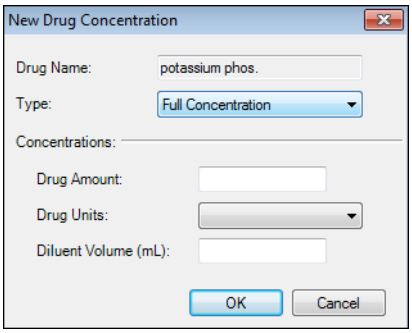
   NOTE:
   Only default master list drug names are listed.

5. To save the drug name, click **OK**.

   If you choose to copy concentrations using the **Map To** selection, you will return to the Continuous/Bolus Drug Setup dialog and you are done. If you are not copying concentrations, the New Drug Concentration window appears prompting you to add the first concentration for your new drug. Proceed to step 6.

6. Select the type of concentration from the **Type** list:

Type	Description
Full Concentration	The Drug Amount, Drug Units, and Diluent Volume (mL) values.
Units Only	A concentration that includes drug units without predefined drug amount and diluent volume values. The clinician enters these values when initiating an infusion on the BD Alaris™ System. Only one Units Only concentration (custom concentration) selection is allowed per setup.



7. Enter a **Drug Amount** (applies to Full Concentration only).
8. Select **Drug Units** from the list.
9. Enter **Diluent Volume** (in mL – applies to Full Concentration only), and click **OK**.

   The New Drug dialog box closes and the drug name and concentration is added to the master drug list.

   You can now:

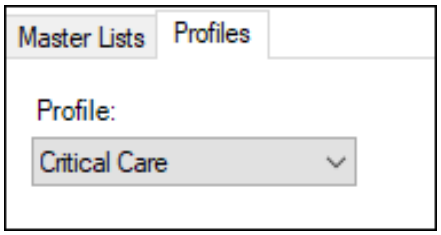
   - Select modules.
   - Add therapies.
   - Set up weight-based or non-weight-based dosing methods.
   - Enter dosing parameters.

Copying a Drug Setup Group from Another Profile

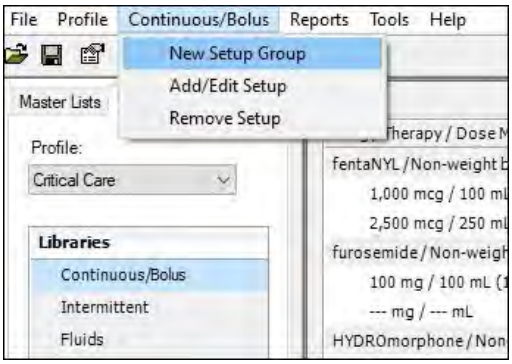
Use this procedure to copy a drug setup group to a destination profile from another profile. The destination profile is the profile to which you want to copy the drug information.

NOTE:
In the example images below, heparin is copied from the Oncology Profile to the Critical Care Profile.

1. Start in the destination Profile by selecting that profile from the Profile drop-down menu.

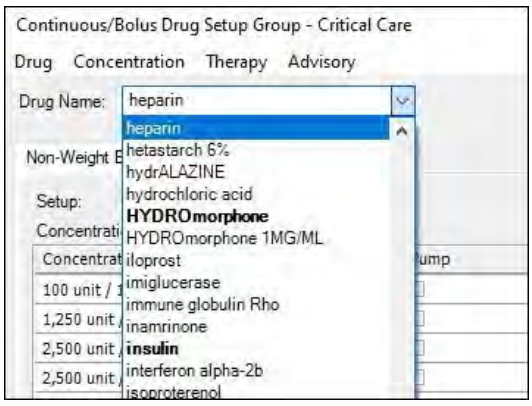


2. Click **Continuous/Bolus** > **New Setup Group** in the taskbar.

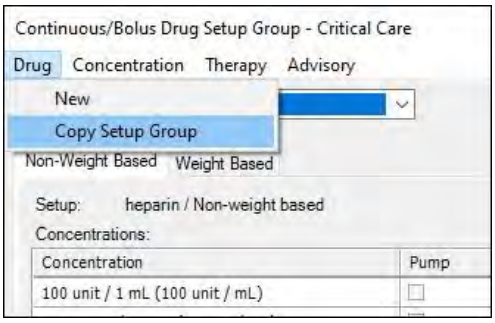


The Continuous/Bolus Drug Setup Group dialog box appears.

3. Select the drug you intend to copy from the Drug Name drop-down menu.

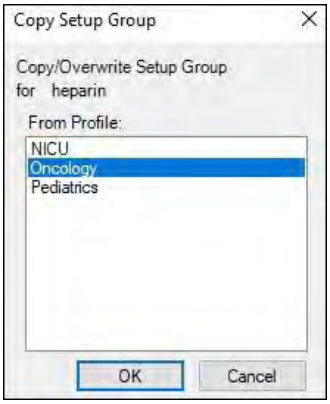


4. Click **Drug** > **Copy Setup Group** in the menu bar.



NOTE: The Copy Setup Group dialog box appears.
If the selected drug is not available in any other profile, the Copy Setup Group option is unavailable.

5. Select the profile containing the drug setup group you want to copy from and click **OK**.



The drug setup group is copied into the Continuous/Bolus drug library.

WARNING

When copying a setup group from one Profile to another or copying an existing Profile to create a new Profile, review all relevant drug or fluid setup group parameters, configurations, and the Profile name. Failure to do so may result in incorrect data set parameters on the PCU, contributing to over, under, or delayed infusions.

6. Confirm the correct parameters are shown in the drug setup window and click **OK** or **Apply.**

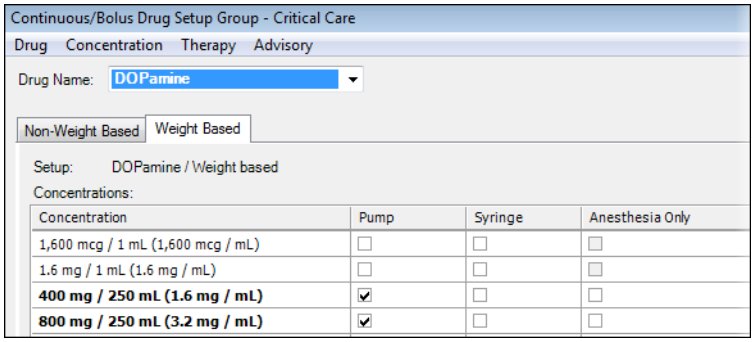
Removing a Concentration

Use this procedure to remove a drug concentration from a profile. Concentrations that are removed remain in the master drug list.

1. In the Continuous/Bolus Summary dialog box, right-click the applicable drug setup group and click **Add/Edit Setup**.

   The Continuous/Bolus Drug Setup Group dialog box appears listing all current concentrations and settings included for the drug in the profile.

2. Clear the Pump Module and/or Syringe Module check boxes for the concentration you want to remove.



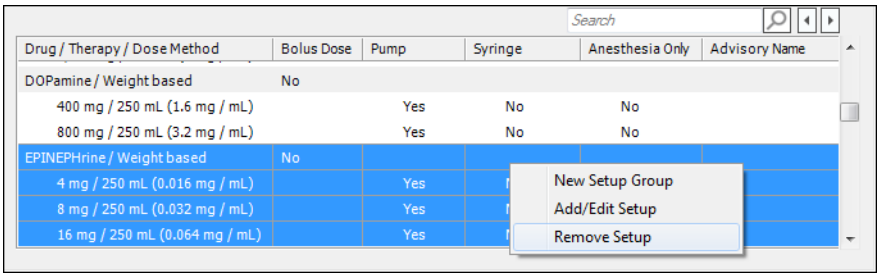
Clear the selected check boxes for any concentration you want to remove.

3. To confirm, click **OK** or **Apply**.

Removing a Drug Setup

Use this procedure to remove a drug setup and all its concentrations from a profile. The removed drug and concentrations remain in the master drug list.

1. In the Continuous/Bolus Drug Summary dialog box, right-click the drug setup that you want to remove and click **Remove Setup**.



   The Remove Setup Confirmation dialog box appears.

2. To remove the drug from the profile, click **OK**.

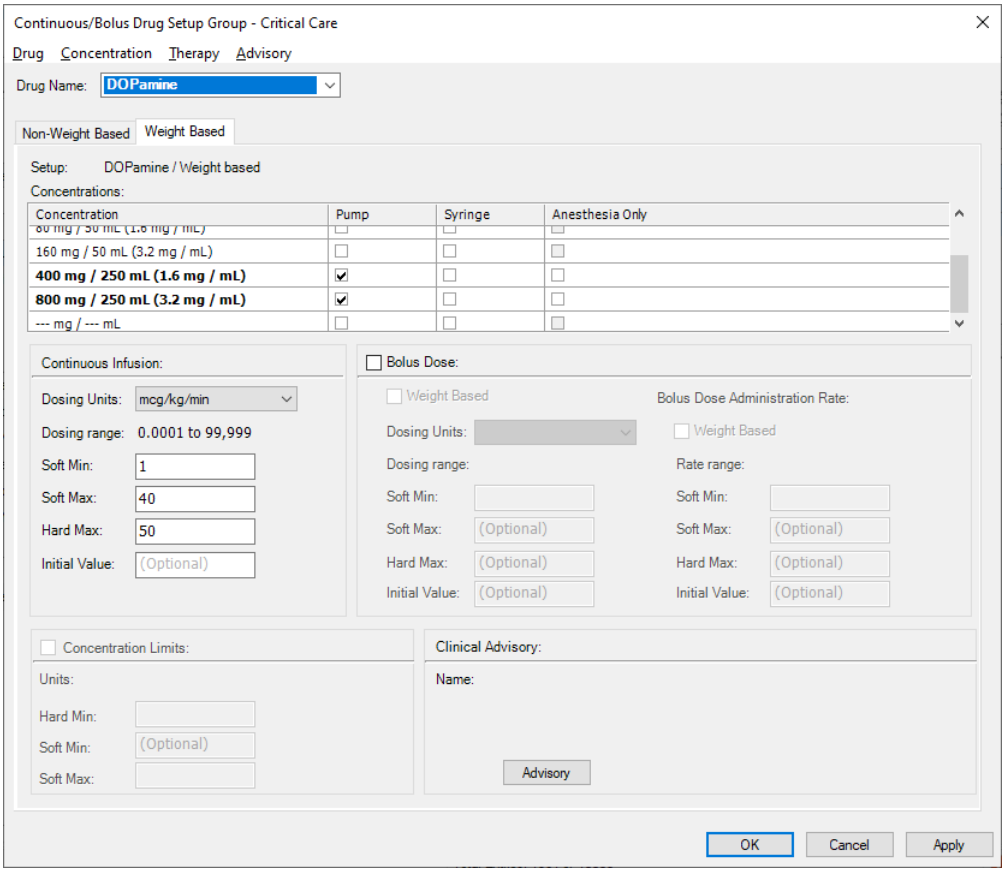
Editing Parameter Settings

This procedure describes how to edit parameter settings in the Guardrails™ Editor software.

1. In the Continuous/Bolus Summary dialog box, right-click the applicable Drug Setup group, and click **Add/Edit Setup**.

   The Continuous/Bolus Drug Setup Group dialog box appears, listing all currently included concentrations and settings for the drug in the profile.

   You can assign or reassign therapies to the drug setup group from the Therapy menu. For information about working with therapies in a profile, see *Assigning a Therapy on page 146*.



2. Click the **Non-Weight Based** or **Weight Based** tab to display the desired parameters for editing.
3. Edit any of the following continuous/bolus infusion settings:
   - Edit the **Continuous Infusion** Dosing Units.
   - Edit **Concentration Limits** as required.
   - Continuous/bolus drug library setups with a selected Units Only concentration (custom concentration) require Concentration Limits, including a hard minimum and soft maximum value. Soft minimum concentration limits are optional. Concentration limits are not available for drug setups with only Full Concentrations selected.

   See step 10: *Enter Concentration Limits for drug setups with a Units Only concentration (custom concentration) selected. on page 80*.

WARNING

Concentration Limit Units are determined by the dosing unit selected. Verify that your concentration limit values correctly align with the associated dosing unit to avoid potential over or under infusion.

NOTE:
A list of incomplete Hard Minimum Concentration Limit fields for Continuous/Bolus drug library setups with a Units Only concentration (custom concentration) selected can be generated in three ways:

Generate a Data Set Changes Report	Generate an Error Summary	Generate a Data Set Report in Microsoft™ Excel
Includes Incomplete Data Set Entries that generates in Microsoft™ Word when a prior data set version with incomplete required fields is opened in Guardrails™ Editor version 12.1.3. An updated version of this report will continue to generate upon opening the Guardrails™ Editor until the incomplete entries have been resolved. Refer to *Opening, Closing, or Saving a Data Set on page 12*.	For instructions on how to access the Error Summary, refer to *Navigating the BD Alaris™ Guardrails™ Editor Software on page 19* or *Error Summary on page 188*.	Generate a Data Set Report in Microsoft™ Excel and filter for Units Only concentrations (custom concentrations) without Hard Minimum Concentration Limits. For instructions, refer to *Filtering for Units Only Concentrations (Custom Concentrations) with No Hard Minimum Concentration Limits on page 193*.

4. Edit **Bolus Dose** and **Bolus Dose Administration Rate** Limits as required.
5. To add bolus dose parameters, select the **Bolus Dose** check box, and enter the Bolus Dose and the Bolus Dose Administration Rate Limits.
   - Edited parameter settings apply to all included concentrations.
   - Bolus dose parameters cannot be entered until the continuous infusion settings have been entered.
   - You must set at least one minimum limit and one maximum limit. The third limit value is optional.
   - Initial values are optional.
6. If any setting falls outside acceptable parameters or required values are not entered, the exclamation symbol appears. Move the mouse over the symbol to see which parameter is out of range or not entered.
7. To attach or edit a clinical advisory for this drug entry, click **Advisory**.

   For more information, see *Working with Clinical Advisories in Drug or Fluid Libraries on page 149*.
8. Click **Apply** to accept the entries and keep the dialog box open to add more drugs, or click **OK** to accept the entries and close the dialog box.

Chapter 11
Developing an Intermittent Drug Library

This section contains the following topics:

Overview

WARNING

Ensure that drug or fluid setups are entered in the correct Library (Continuous/Bolus, Intermittent, PCA and Fluids) that supports appropriate order elements. Failure to do so could result in incorrect programming leading to an over or under infusion. For example, heparin ordered with a dose unit of units/kg/hour should be entered in the Continuous/Bolus Library.

Developing an intermittent drug library for the Pump Module and/or Syringe Module involves a number of optional and required steps:

- Select a desired drug and concentration level from the master drug list.
- Add and select therapies, if used.
- Select weight-based, non-weight-based, or BSA drug setups.
- Select the desired infusion module, or modules, if both Pump Module and Syringe Module are enabled.
- Add profile-specific dosing parameters and hard and/or soft limits.
- Select availability for primary and secondary infusions.
- Add profile-specific duration limits for the selected concentrations.
- Add optional initial values for certain drug setup fields.
- Add clinical advisories to selected drugs.

BD recommends the following customer actions to prevent potential programming errors on the Alaris System from occurring:

- Standardize using full concentrations and avoid the use of Units Only concentrations (custom concentrations) where possible, especially for all continuous/bolus and PCA infusions.

Align pharmacy label and pump: Review how drugs, concentrations, and infusion rates are displayed in medication orders, MARs, and on pharmacy labels to ensure that they align to what the clinician will be reviewing and programming on the infusion pump.

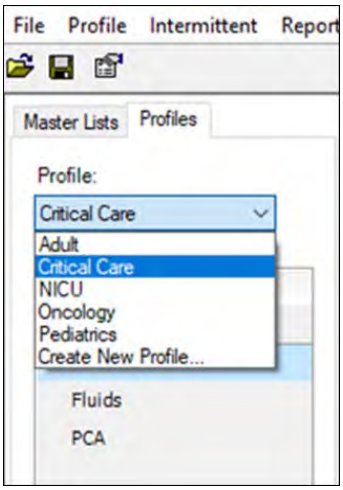
A drug name must be selected at the profile level for either the continuous/bolus and/or PCA drug library, *or* for the intermittent drug library. A drug *cannot* be used in both the continuous/bolus library and the intermittent library, nor can it be used in both the PCA drug library and intermittent drug library. Drugs listed in the continuous/bolus or PCA drug library are *not* available in the intermittent library. The **Used As** column in the Master Drug List shows how the drug, if in use, is classified.

There are expanded precision and dosing ranges for intermittent drug setups. See *Highlights and Previous Versions on page 216* for more information.

Adding a Drug

Use the following procedure to add a drug to the intermittent library.

1. Click the **Profile** tab.
2. Select a profile from the **Profiles** list in the navigation pane.

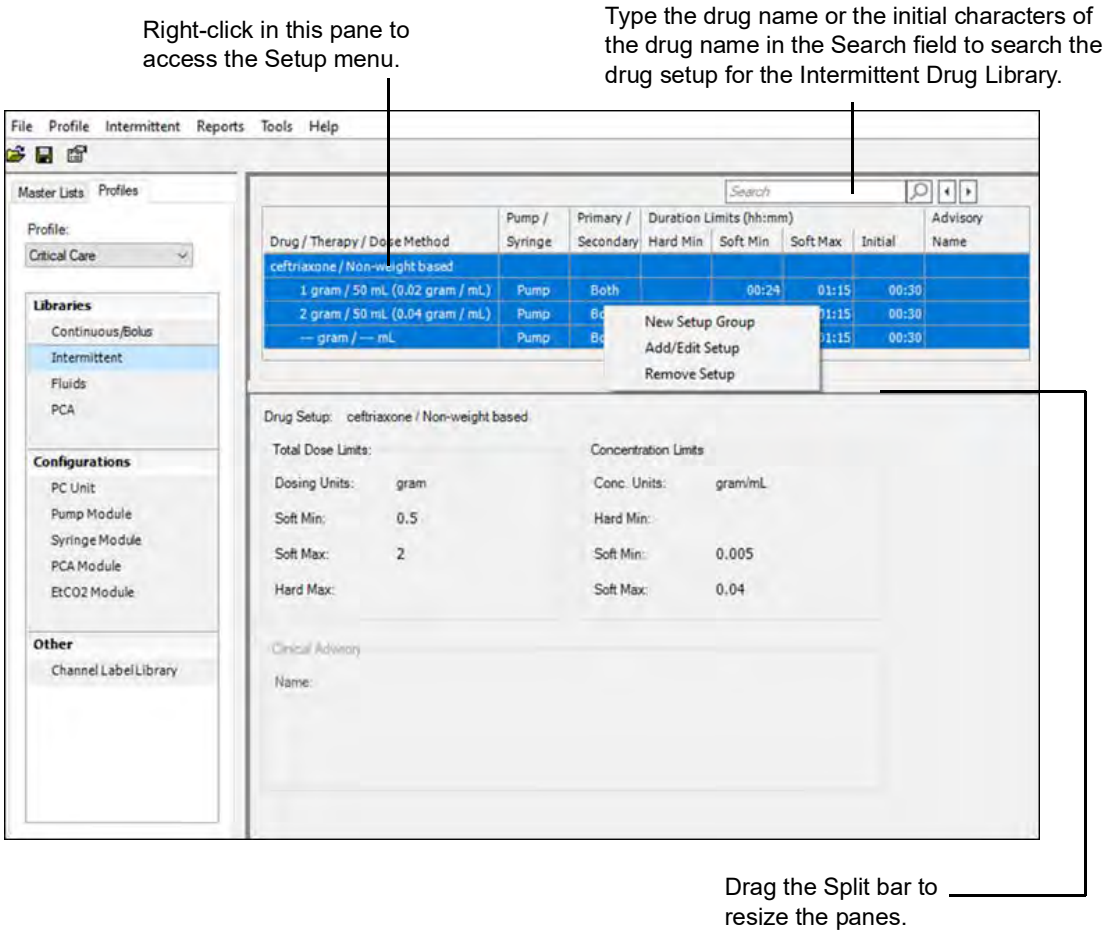


3. Select **Intermittent** in the list of libraries in the navigation pane.

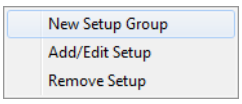
   The Intermittent Summary dialog box appears.

   NOTE:

   - If you are creating a new profile drug library, the main screen does not contain any drugs and concentrations until you add them to the library.
   - The total number of setups over all profiles combined appears at the bottom of the display.



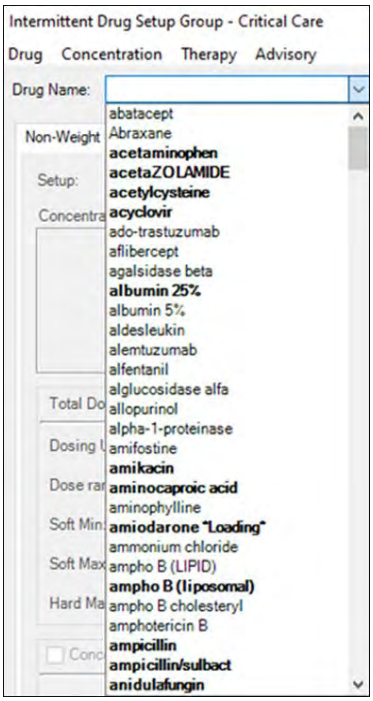
4. Right-click in the top section of the dialog box and select **New Setup Group**.



   The Intermittent Drug Setup Group dialog box appears.

5. Select a **Drug Name** from the list of master drugs. Drug names displayed in bold already exist in the drug library.

   NOTE:
   There is a search feature within the Drug Name field. Place the cursor in Drug Name field and type the intended drug name or the initial characters of the drug name.

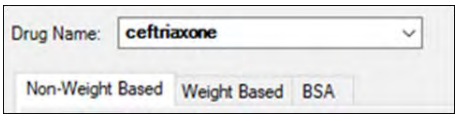


   NOTE:
   The Concentrations section of the dialog box lists all concentrations of the selected drug currently available in the master drug list and valid for intermittent dose infusion.

   NOTE:
   If the drug does *not* exist in the master drug list, see *Adding a New Drug that is Not in the Master Drug List on page 108* for more information.

   You can assign therapies to the new drug-setup group by selecting **Therapy** > **Select** in the menu bar. For information about working with therapies in a profile, see *Assigning a Therapy on page 146*.

6. Click the **Non-Weight Based**, **Weight Based,** or **BSA** tab to edit or set up the non-weight-based, weight-based, or BSA-based infusion parameters for this drug setup.



WARNINGS

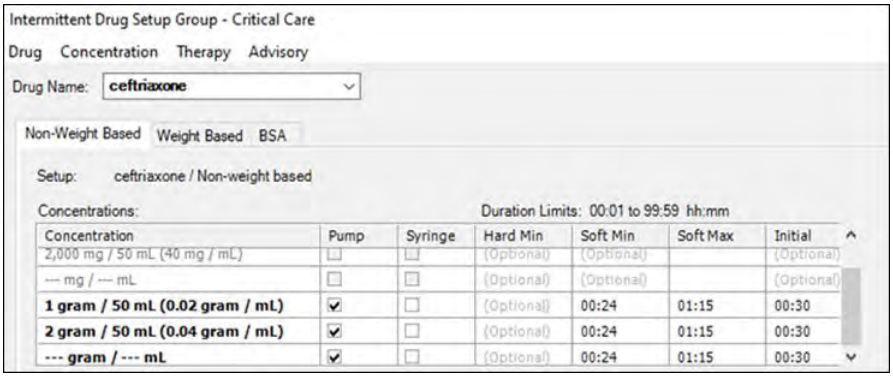
- **Avoid delivering low flow rates with larger syringes using the Syringe Module. This is of particular importance for the low, very low, and extremely low birth weight neonate. See the *Minimum Recommended Flow Rate for the Syringe Module on page 59*. Consider Syringe Module performance, recommended doses, dose volumes, and syringe size when developing drug concentration standards and data set parameters.**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 1 mL/h with syringe sizes greater than or equal to 20 mL.**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 0.1 mL/h with syringe sizes 1 mL and 3 mL.**
  - **The standard rate accuracy is the rate accuracy under standard operating conditions, which is ±5% at flow rates greater than or equal to 10% of the syringe capacity per hour; and ±10% for flow rates less than 10% of the syringe capacity per hour and greater than or equal to 0.1 mL/h (with syringe sizes less than 20 mL) or 1 mL/h (with syringe sizes greater than or equal to 20 mL).**
- **Delivering low volumes of high-risk medications with the Pump Module (particularly for neonatal populations, including low, very low, and extremely low birthweight neonates) can lead to less optimal pump performance including, but not limited to, over or under infusion and increased time to alarm for an occlusion. Consider use of the Syringe Module instead of the Pump Module using the smallest syringe size necessary for these low volumes of high-risk medications.**

7. Select the check box for the **Pump Module**, **Syringe Module**, or both if applicable to include this concentration in the profile.

   You must select at least one infusion module.

   If the required concentration is not in the current list, see *Adding a New Concentration on page 106* for more information.

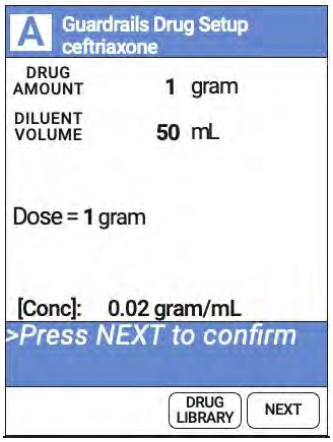
   - Total dose units default to match the concentration units selection.
   - If the Pump Module or Syringe Module is disabled from the Tools menu, it does not appear on the dialog box.
   - Volume (mL only) (PCA) is not used for the intermittent drug library.
   - Initial values are optional.
   - If any setting falls outside acceptable parameters or required values are not entered, the exclamation symbol appears. Move the mouse over the symbol to see which parameter is out of range or not entered.
   - Dosing parameters apply to all concentrations in the drug setup group. Duration limits are specific to your selected concentrations.
   - Different concentration units cannot both be selected.

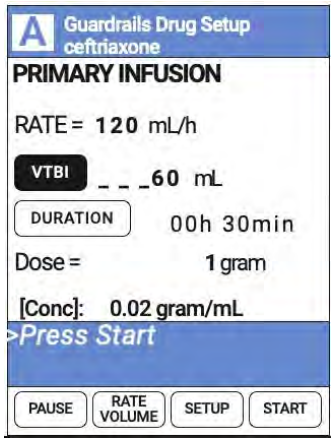


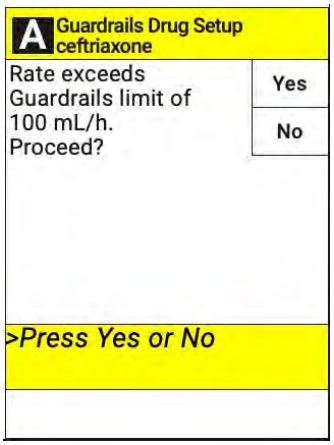
8. Enter duration limits. It is recommended that duration limits are not set the same as the initial value or intended duration time. A variance should be considered to support situations when VTBI is adjusted to a value that is different from diluent volume, such as when accounting for overfill or priming volume in order to avoid unintentionally exceeding Guardrails™ limits during clinical use. See the example below.

   Ceftriaxone 1 gram/50mL is selected with duration limits of 00:30 to 01:00 (hh:mm) and an initial value of 00:30. (See screenshots below of what the bedside clinician would view on the PCU screen during the programming process). The device calculates the Guardrails™ limits as a RATE of 50 to 100 mL/h using the diluent volume. If the bedside clinician accounts for overfill by entering a VTBI of 60 mL, the programmed rate is now 120 mL/h (60 ml over 30 minutes), which would trigger an alert on the device. If this data set entry had instead been entered as duration limits of 00:24 to 01:15 (hh:min), then the allowable RATE without an alert would be 40 to 125 mL/h.

   See the screenshots below of what the bedside clinician would view on the PCU screen in this programming process.





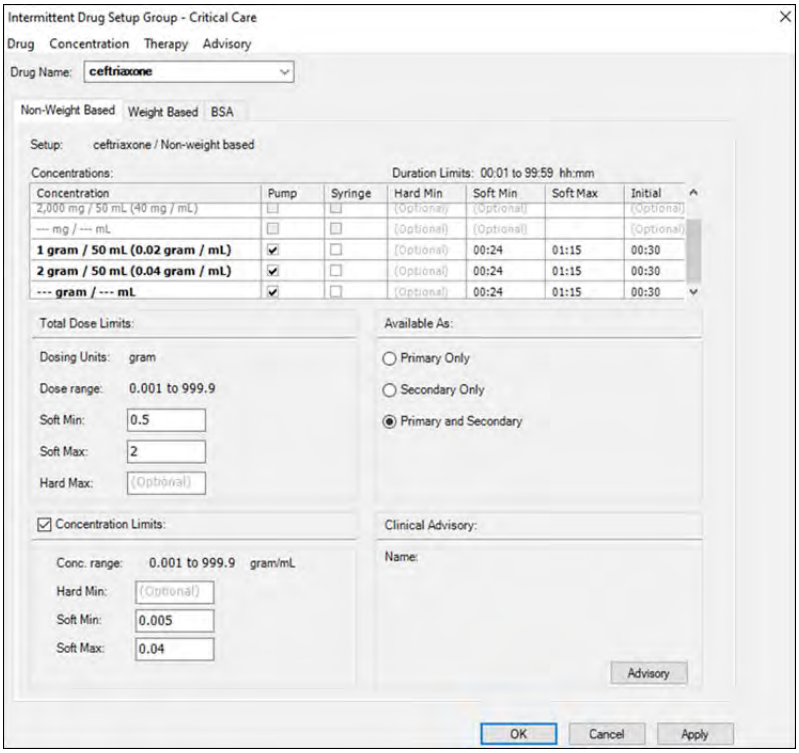


9. Select the input boxes in the **Concentrations** area of the Intermittent Drug Setup Group dialog box to enter values.

   You must set at least one minimum limit and one maximum limit. The second limit value is optional.

   You can enter numbers up to 99 in the minutes portion of the field, but they are converted to hours and minutes, where the minutes do not exceed 59, when you move the cursor to another field.

10. Enter the **Total Dose Limits**.



11. Select the **Concentration Limits** check box, if desired, for Units Only concentration (custom concentration) entries, and enter Concentration Limits.

    Concentration limit units are set based on the dosing units selected.

    NOTE:

    - An incorrect concentration entry could result in duration/rate limits that may allow the infusion to be delivered too fast or too slowly.
    - When using Units Only concentrations (custom concentrations) in the drug library, the concentration must be programmed into the infusion device by the clinician programming the infusion so it can calculate the volume needed to deliver the prescribed dose.

If the diluent volume programmed by the clinician is...	Then the pump delivers the dose...
lower than the actual diluent volume	too slow
higher than the actual diluent volume	too fast

    - Concentration limits in the Intermittent Drug Library are only available for set ups with Units Only concentrations (custom concentrations) selected. Concentration Limits are optional only in the Intermittent Drug Library.
    - Hard minimum concentration limits in your hospital's drug library can prevent over infusion or under infusion when a Units Only concentration (custom concentration) is programmed incorrectly at the bedside.

12. In the **Available As** section, choose **Primary Only**, **Secondary Only**, or **Primary and Secondary**.
13. To attach a clinical advisory to this drug entry, select **Advisory**.

    For more information, see *Working with Clinical Advisories in Drug or Fluid Libraries on page 149*.
14. Click **Apply** to accept the entries and keep the dialog box open to add more drugs, or click **OK** to accept the entries and close the dialog box.

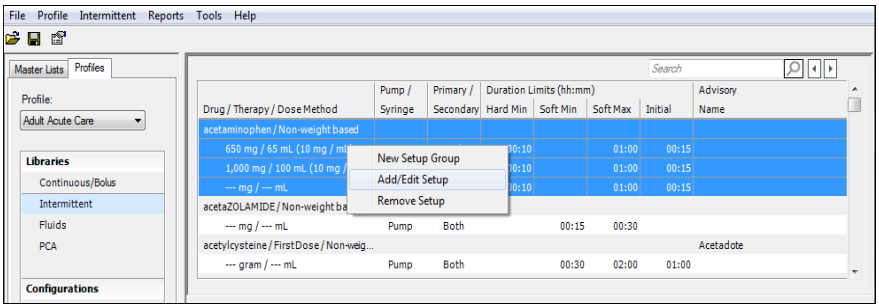
Adding a New Concentration

Duplicate drug and concentration entries are not allowed. A message box warns you if an attempt is made to add an entry that already exists in the drug library or in the selected Profile.

If any setting falls outside acceptable parameters or required values are not entered, the exclamation symbol appears. Move the mouse over the symbol to see which parameter is out of range or not entered.

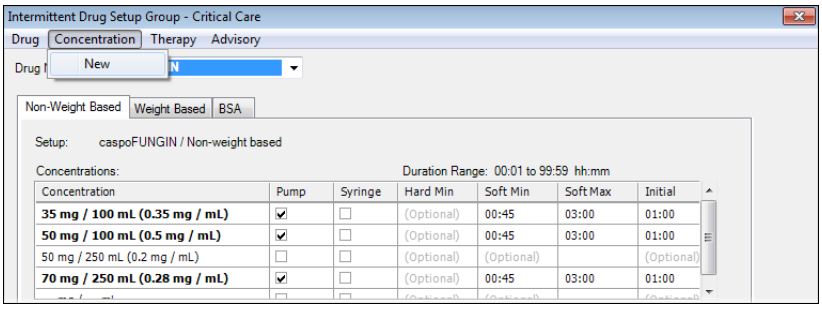
To help avoid nuisance alerts, an initial duration value should not be set at or near a hard duration limit in the intermittent Drug Library.

1. In the Intermittent Summary dialog box, right-click the applicable drug-setup group, and click **Add/Edit Setup**.



   The Intermittent Drug Setup Group dialog box appears, displaying the Drug Name and existing concentrations.

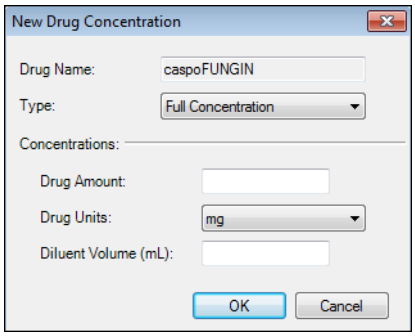
2. Select Therapies, if applicable, click the **Non-Weight Based**, **Weight Based** or **BSA (m²)** tab to display the parameters for editing.



3. In the menu bar, click **Concentration** > **New**.

   The New Drug Concentration dialog box opens.

4. Select the **Type** from the list:

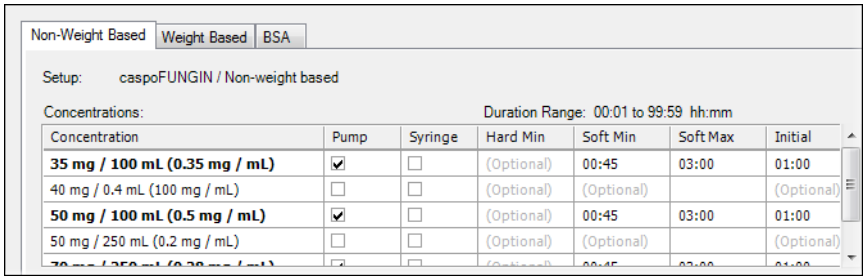


Type	Description
Full Concentration	The Drug Amount, Drug Units, and Diluent Volume (mL) values.
Units Only	A concentration that includes drug units without predefined drug amount and diluent volume values. The clinician enters these values when initiating an infusion on the BD Alaris™ System. Only one Units Only concentration (custom concentration) selection is allowed per setup.

5. Enter a **Drug Amount** (applies to Full Concentration only).
6. Change the **Drug Units** using the list (if desired).

   The Drug Units default to the units previously used.
7. Enter **Diluent Volume** (mL – applies to Full Concentration only), and click **OK**.
8. When the New Drug Concentration dialog box closes, select **Pump Module**, **Syringe Module**, or both to include the new concentration in the profile.

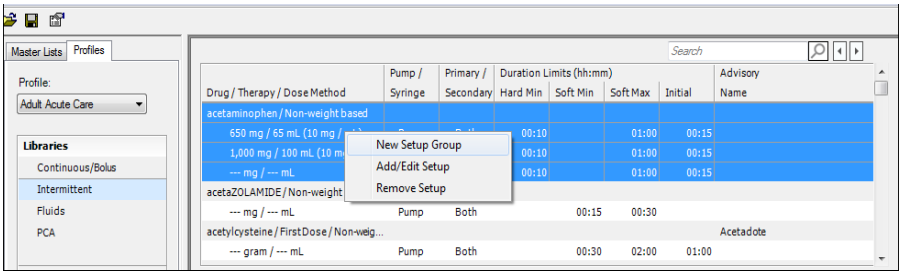
   The new concentration is automatically updated in the master drug list.



Adding a New Drug that is Not in the Master Drug List

This procedure describes how to add a new drug that is not in the master drug list in the Guardrails™ Editor software.

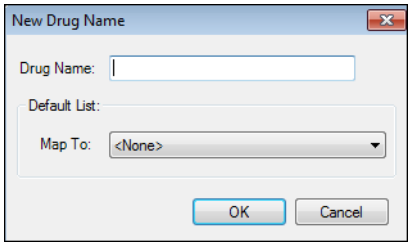
1. In the top section of the Intermittent Summary dialog box, right-click and select **New Setup Group**.



   The Intermittent Drug Setup Group dialog box appears.

2. In the menu bar, click **Drug** > **New**.

   The New Drug Name dialog box appears.



3. Enter the **Drug Name**.
4. Optionally select a drug name in the **Map To** list to copy its concentrations list.

   NOTE:
   Only default master list drug names are listed.

5. To save the drug name, click **OK**. If you choose to copy concentrations using the **Map To** selection, you will return to the Intermittent Drug Setup dialog and you are done. If you are not copying concentrations, the New Drug Concentration window appears prompting you to add the first concentration for your new drug. Proceed to step 6.

6. In the New Drug Concentration dialog box, select the **Type** from the list:

Type	Description
Full Concentration	The Drug Amount, Drug Units, and Diluent Volume (mL) values.
Units Only	A concentration that includes drug units without predefined drug amount and diluent volume values. The clinician enters these values when initiating an infusion on the BD Alaris™ System. Only one Units Only concentration (custom concentration) selection is allowed per setup.

7. Enter a **Drug Amount** (applies to Full Concentration only).
8. Select **Drug Units** from the list.
9. Enter **Diluent Volume** (mL – applies to Full Concentration only) and click **OK**.

   The New Drug Concentration dialog box closes and the drug name and concentration is added to the master drug list. You can now:

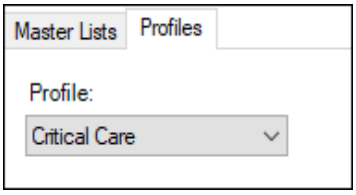
   - Select therapies, non-weight, weight, or BSA-based infusion parameters, and modules.
   - Enter duration limits and dosing parameters.

Copying a Drug Setup Group from Another Profile

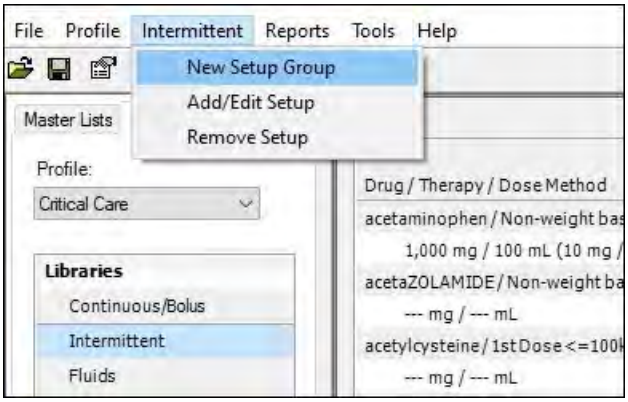
Use this procedure to copy a drug setup group to a destination profile from another profile. The destination profile is the profile to which you want to copy drug information.

NOTE:
In the example images below, gentamicin is copied from the Oncology Profile to the Critical Care Profile.

1. Start in the destination Profile by selecting that profile from the Profile drop-down menu.

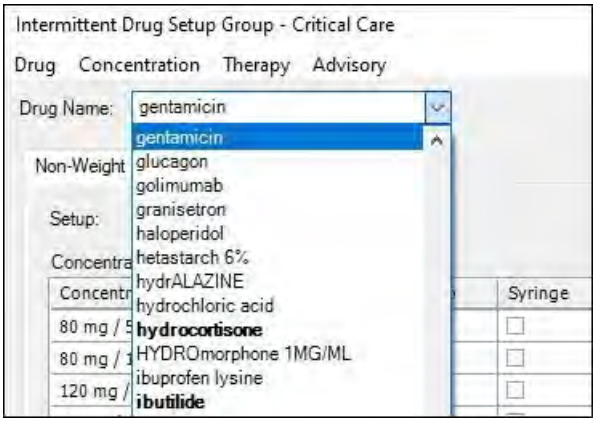


2. Click **Intermittent** > **New Setup Group** in the taskbar.

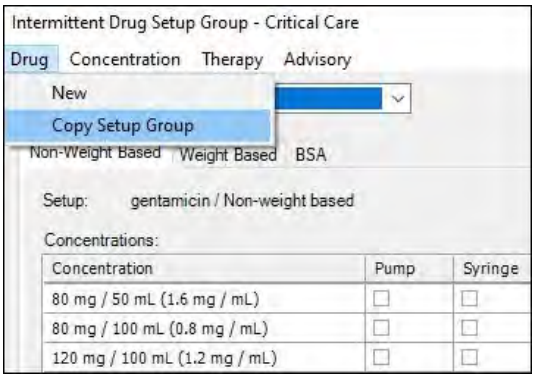


The Intermittent Drug Setup Group dialog box appears.

3. Select the drug you intend to copy from the Drug Name drop-down menu.



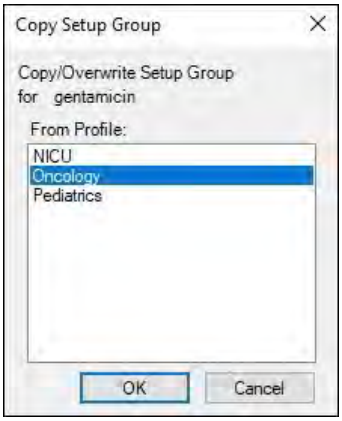
4. Click **Drug** > **Copy Setup Group** in the menu bar.



The Copy Setup Group dialog box appears.

NOTE:
If the selected drug is not available in any other profile, the Copy Setup Group option is unavailable.

5. Select the profile containing the drug setup group you want to copy from and click **OK**.



The drug setup group is copied into the Intermittent drug library.

WARNING

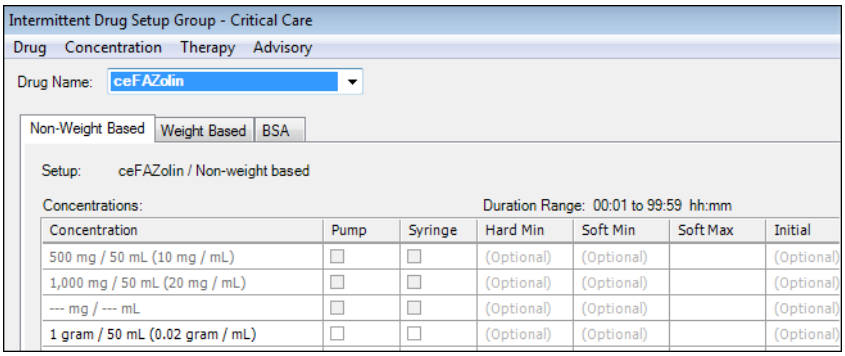
When copying a setup group from one Profile to another or copying an existing Profile to create a new Profile, review all relevant drug or fluid setup group parameters, configurations, and the Profile name. Failure to do so may result in incorrect data set parameters on the PCU, contributing to over, under, or delayed infusions.

6. Confirm the correct parameters are shown in the drug setup window and click **OK** or **Apply**

Removing a Concentration

Use this procedure to remove a drug concentration from a profile. The concentration remains in the master drug list.

1. Clear the Pump Module and/or Syringe Module check boxes on the Intermittent Drug Setup Group dialog box for the concentration you want to remove.
2. To confirm, click **OK** or **Apply**.



Removing a Drug Setup

Use this procedure to remove a drug setup and all its concentrations from a profile. The concentrations remains in the master drug list.

1. In the Intermittent Drug Library Summary dialog box, right-click the drug setup group that you want to remove, and click **Remove Setup**.

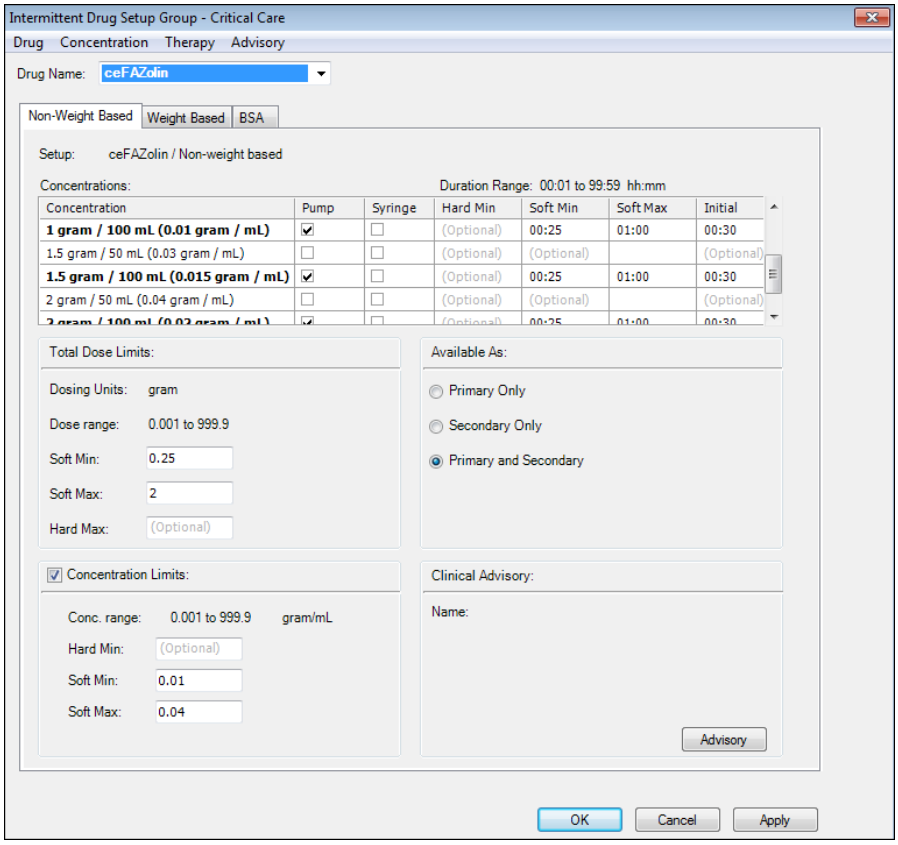
   The Remove Setup Confirmation dialog box appears.
2. To remove the drug from the profile, click **OK**.

Editing Parameter Settings

This procedure describes how to edit parameter settings in the Guardrails™ Editor software.

1. In the Intermittent Summary dialog box, select the applicable drug-setup group, right-click the selected group, and click **Add/Edit Setup**.

   The Intermittent Drug Setup Group dialog box appears listing all currently included concentrations and settings for the drug in the Profile.



   You can assign or reassign therapies to the drug setup group in the Therapy menu. For information about working with therapies in a profile, see *Assigning a Therapy on page 146*.

2. Edit any of the following intermittent infusion settings:
   - Edit duration limits for any selected concentration.

     If any setting falls outside acceptable parameters or required values are not entered, the exclamation symbol appears. Move the mouse over the symbol to see which parameter is out of range or not entered.
   - Edit the **Total Dose Limits** Dosing Units.
   - Select the **Concentration Limits** check box, for Units Only concentration (custom concentration) entries, and enter concentration limits. Best practice recommendation is to ensure hard minimum concentration limits are implemented.
   - Concentration limits are set based on the dosing units selected.
   - Each concentration has its own duration limits.

   NOTE:
   A list of incomplete Hard Minimum Concentration Limits for Intermittent drug library setups with Units Only concentrations (custom concentrations) selected can be created by generating a Data Set Report in Microsoft™ Excel and filtering for Units Only concentrations (custom concentrations) with no Hard Minimum Concentration Limits. For instructions, refer to *Filtering for Units Only Concentrations (Custom Concentrations) with No Hard Minimum Concentration Limits on page 193*.
3. Select whether the infusion is **Primary Only**, **Secondary Only**, or **Primary and Secondary** in the Available As section of the dialog box.
4. To attach or change a clinical advisory to this drug entry, click **Advisory**.

   For more information, see *Working with Clinical Advisories in Drug or Fluid Libraries on page 149*.
5. Click **Apply** to accept the entries and keep the dialog box open to add more drugs, or click **OK** to accept the entries and close the dialog box.

Chapter 12
Developing a Fluids Library

This section contains the following topics:

Overview

WARNING

Ensure that drug or fluid setups are entered in the correct Library (Continuous/Bolus, Intermittent, PCA and Fluids) that supports appropriate order elements. Failure to do so could result in incorrect programming leading to an over or under infusion. For example, heparin ordered with a dose unit of units/kg/hour should be entered in the Continuous/Bolus Library.

Developing a fluids library involves selecting a fluid from the master fluids list, selecting Therapies, setting rate limits, and adding clinical advisories to selected fluids.

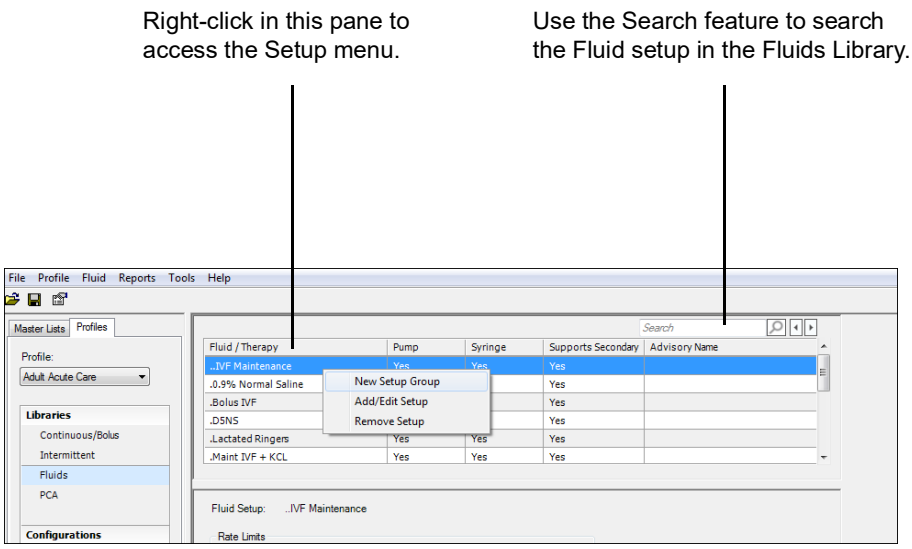
Adding a Fluid

This procedure describes how to add a fluid in the Guardrails™ Editor software.

1. Click the **Profiles** tab.
2. Select a profile from the Profile list in the navigation pane.

   NOTE:
   If you are creating a new profile fluids library, the main screen is blank until you add fluids to the library.

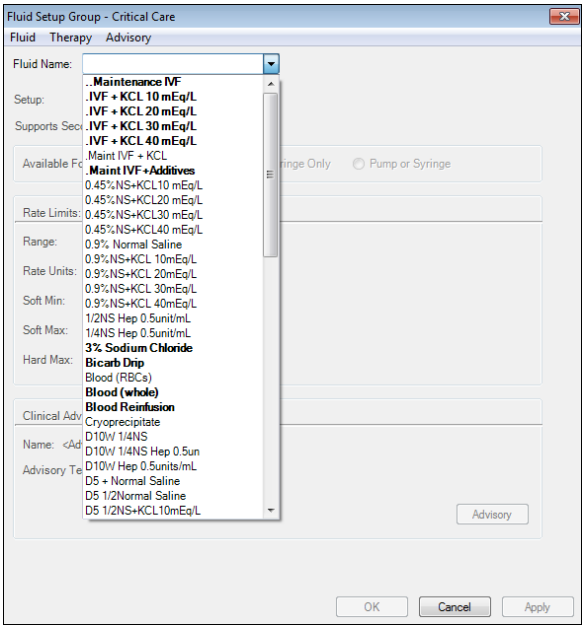
3. In the list of Libraries, click **Fluids**.
4. Right-click in the Fluids Library Summary dialog box and select **New Setup Group**.



5. In the Fluid Setup Group dialog box, select a Fluid Name from the Fluid Name list.

NOTE:
There is a search feature within the Fluid Name field. Place the cursor in the Fluid Name field and type the intended fluid name or the initial characters of the fluid name.

NOTE:
If the fluid does not exist in the master fluid list, see *Adding a New Fluid that is Not in the Master Fluid List on page 120*.

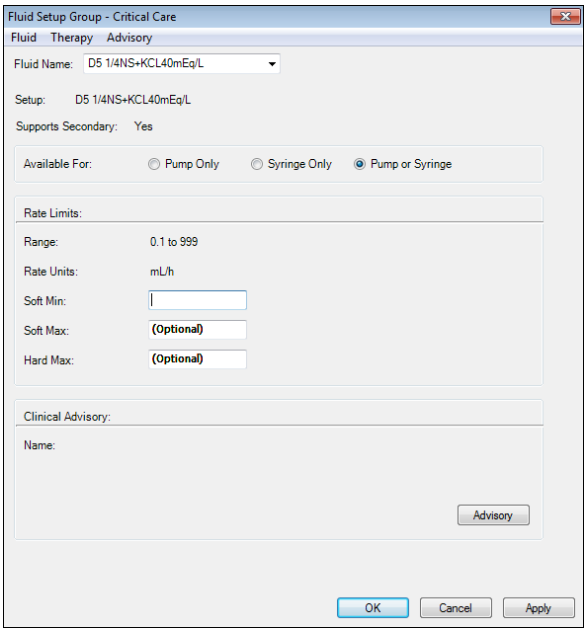


You can assign or reassign therapies to the drug-setup group in the Therapy menu. For information about working with therapies in a profile, see *Assigning a Therapy on page 146*.

WARNINGS

- **Avoid delivering low flow rates with larger syringes using the Syringe Module. This is of particular importance for the low, very low, and extremely low birth weight neonate. See the *Minimum Recommended Flow Rate for the Syringe Module on page 59*. Consider Syringe Module performance, recommended doses, dose volumes, and syringe size when developing drug concentration standards and data set parameters.**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 1 mL/h with syringe sizes greater than or equal to 20 mL.**
  - **A 10% over or under infusion beyond the standard rate accuracy can occur when using flow rates below 0.1 mL/h with syringe sizes 1 mL and 3 mL.**
  - **The standard rate accuracy is the rate accuracy under standard operating conditions, which is ±5% at flow rates greater than or equal to 10% of the syringe capacity per hour; and ±10% for flow rates less than 10% of the syringe capacity per hour and greater than or equal to 0.1 mL/h (with syringe sizes less than 20 mL) or 1 mL/h (with syringe sizes greater than or equal to 20 mL).**
- **Delivering low volumes of high-risk medications with the Pump Module (particularly for neonatal populations, including low, very low, and extremely low birthweight neonates) can lead to less optimal pump performance including, but not limited to, over or under infusion and increased time to alarm for an occlusion. Consider use of the Syringe Module instead of the Pump Module using the smallest syringe size necessary for these low volumes of high-risk medications.**

6. Select the button next to **Pump Only**, **Syringe Only**, or **Pump or Syringe** to select the valid module types for the fluid.
   - The selection defaults to Pump Module or Syringe Module.
   - If the Pump Module or Syringe Module is disabled in the profile configuration settings, the setting defaults to the enabled module and other options are unavailable.
   - If pump or syringe is selected, the maximum rate allowed on the BD Alaris™ System is the maximum rate of either the Pump Module or Syringe Module in the configuration setting.
   - Supports secondary is edited at the master fluids level.
   - Supports secondary applies to the fluid name for all profiles.

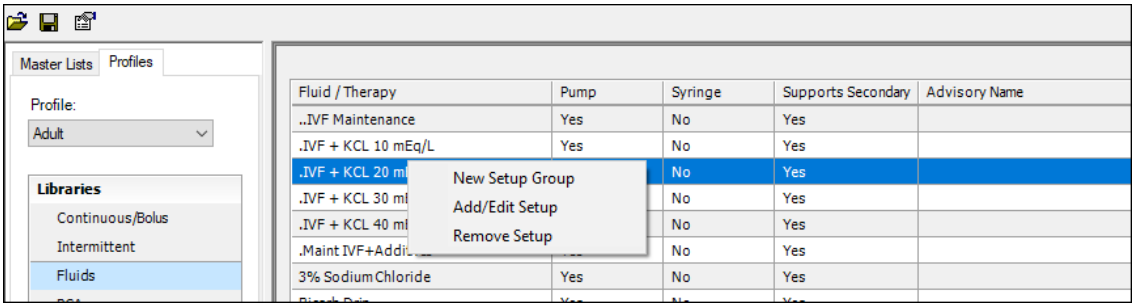


7. Enter the **Rate Limits**.
8. To attach a clinical advisory to this drug entry, click **Advisory**.
   For more information, see *Working with Clinical Advisories in Drug or Fluid Libraries on page 149*.
9. To confirm, click **OK** or **Apply**.

Adding a New Fluid that is Not in the Master Fluid List

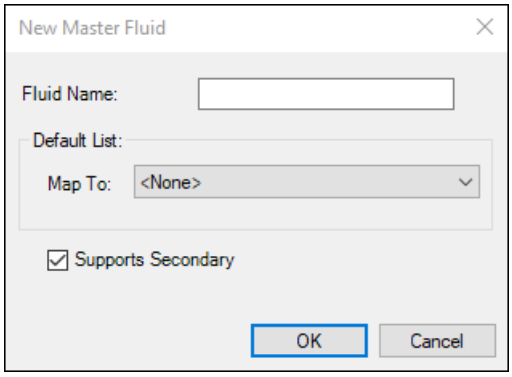
This procedure describes how to add a new fluid that is not in the master fluid list in the Guardrails™ Editor software.

1. In the top section of the Fluid Summary dialog box, right-click and select **New Setup Group**.



   The Fluid Setup Group dialog box appears.

2. In the menu bar, click **Fluid** > **New**.



   The New Master Fluid dialog box appears.

3. Enter the **Fluid Name**.
4. Select or clear the **Supports Secondary** check box based on the ability for a secondary infusion to be given while this primary fluid is infusing.

   NOTE:
   The Master List is the only place where you can edit this setting.

5. To save the fluid name, click **OK**.

   The New Master Fluid dialog box closes and the fluid name is added to the master fluid list. You can now:

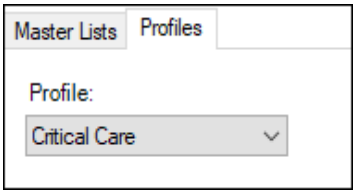
   - Select therapies, module availability, and clinical advisories.
   - Enter rate limits.

Copying a Fluid Setup Group from Another Profile

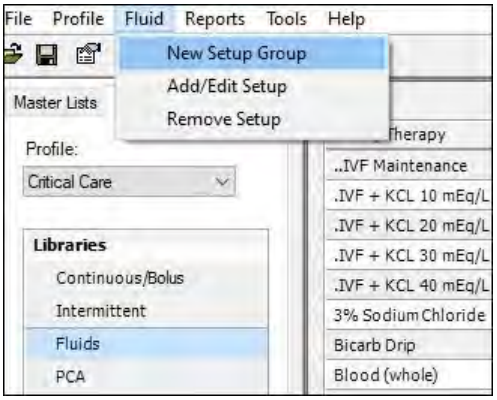
Use this procedure to copy a fluid setup group to a destination profile from another profile. The destination profile is the profile to which you want to copy fluid information.

NOTE:
In the example images below, Blood (whole) is copied from the Oncology Profile to the Critical Care Profile.

1. Start in the destination Profile by selecting that profile from the Profile drop-down menu.

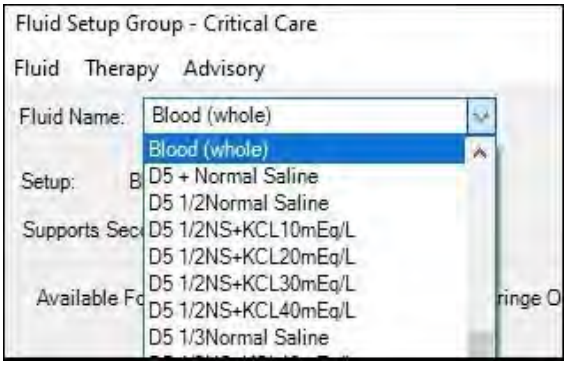


2. Click **Fluids** > **New Setup Group** in the taskbar.

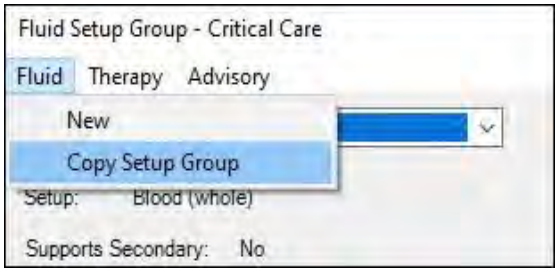


The Fluids Setup Group dialog box appears.

3. Select the fluid you intend to copy from the Fluid Name drop-down menu.



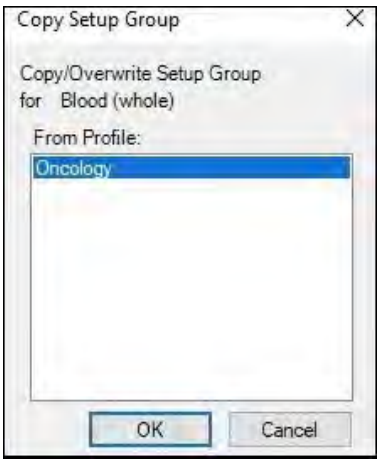
4. Click **Fluid** > **Copy Setup Group** in the menu bar.



The Copy Setup Group dialog box appears.

NOTE:
If the selected fluid is not available in any other profile, the Copy Setup Group option is unavailable.

5. Select the profile containing the fluid setup group you want to copy from and click **OK**.



The fluid setup group is now copied into the Fluid library.

WARNING

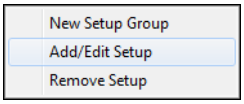
When copying a setup group from one Profile to another or copying an existing Profile to create a new Profile, review all relevant drug or fluid setup group parameters, configurations, and the Profile name. Failure to do so may result in incorrect data set parameters on the PCU, contributing to over, under, or delayed infusions.

6. Confirm the correct parameters are shown in the drug setup window and click **OK** or **Apply.**

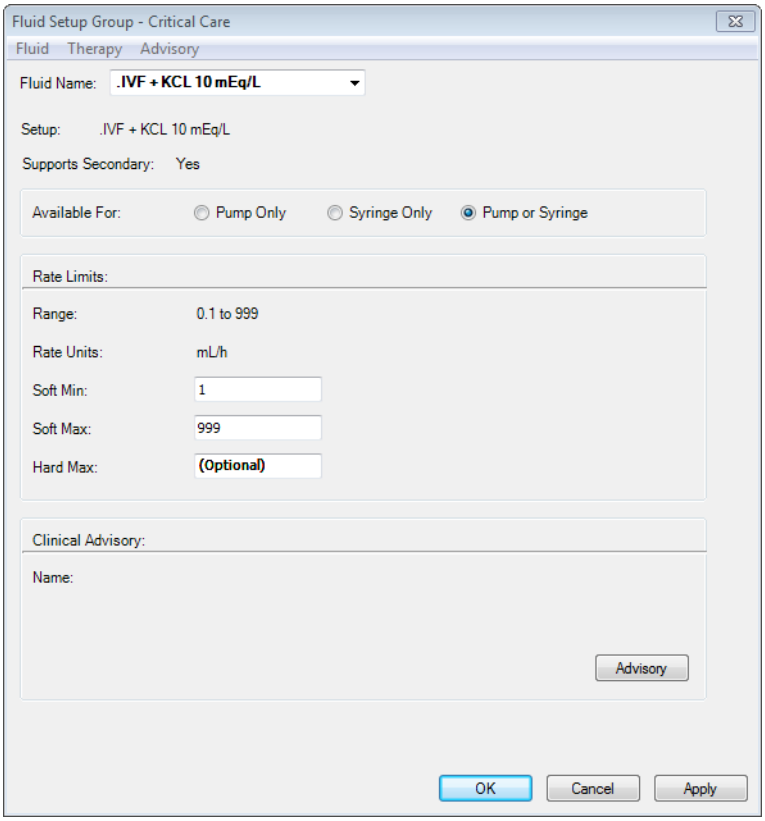
Editing Parameter Settings

This procedure describes how to edit a fluid in the Guardrails™ Editor software.

1. Right-click a fluid setup on the Fluids Library Summary dialog box, and click **Add/Edit Setup**.



The Fluid Setup Group dialog box appears.



2. Click the **Therapy** tab if applicable to edit the therapy's infusion parameters for this fluid.
3. Edit the limits as desired.
4. To confirm, click **OK** or **Apply**.

NOTE:
Supports Secondary Yes/No is edited in the master fluids list.

Removing a Fluid

This procedure describes how to remove a fluid in the Guardrails™ Editor software.

1. In the Fluids Summary dialog box, select the fluid that you want to remove, right-click the selected fluid, and click **Remove Setup**.

   The Remove Setup Confirmation dialog box appears.

To remove the drug and concentrations from the profile, click **OK**.

Chapter 13
Developing a PCA Drug Library

This section contains the following topics:

Overview

WARNING

Ensure that drug or fluid setups are entered in the correct Library (Continuous/Bolus, Intermittent, PCA and Fluids) that supports appropriate order elements. Failure to do so could result in incorrect programming leading to an over or under infusion. For example, heparin ordered with a dose unit of units/kg/hour should be entered in the Continuous/Bolus Library.

The PCA drug library allows entry of both standard concentrations and Units Only concentrations (custom concentrations) entries.

BD recommends the following customer actions to prevent potential programming errors on the Alaris System from occurring:

- Standardize using full concentrations and avoid the use of Units Only concentrations (custom concentrations) where possible, especially for all continuous/bolus and PCA infusions.
- Align pharmacy label and pump: Review how drugs, concentrations, and infusion rates are displayed in medication orders, MARs, and on pharmacy labels to ensure that they align to what the clinician will be reviewing and programming on the infusion pump.

- The Max Accumulated Dose Range is enabled/disabled in the PCA Configurations dialog box and must be configured before drugs are entered in the PCA drug library; otherwise it defaults to 4 hours.
- Max Accumulated Dose Range can be configured to 1, 2, or 4 hours. For more information, see *Editing Configuration Settings on page 160*.
- PCA pause protocols needs to be enabled in PCA configuration before it can be used. For more information, see *Editing Configuration Settings on page 160*.

Developing a drug library involves:

- Select a desired drug and concentration level from the master drug list.
- Set maximum accumulated dose ranges.
- Define the PCA dose limits and/or continuous dose limits.
- Define concentration limits, loading dose limits, or bolus dose limits.
- Add initial values.
- Add hard limits or soft limits.
- Add clinical advisories to selected drugs.

Viewing a Library

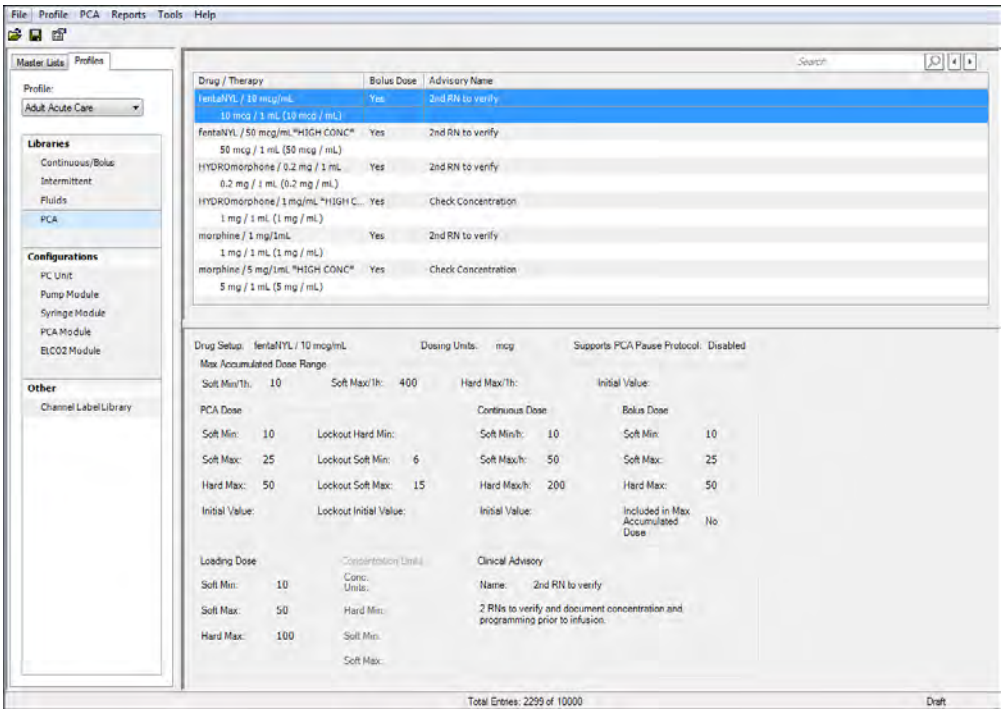
This procedure describes how to view a library in the Guardrails™ Editor software.

1. Click the **Profiles** tab.
2. Select a profile from the Profile list in the navigation pane.

   NOTE:
   If you are creating a new profile drug library, the main screen is blank until you add drugs and concentrations to the library.

3. Click **PCA** in the list of drug libraries.

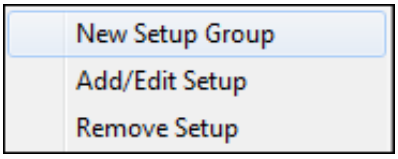
   The PCA Drug Library Summary dialog box appears.



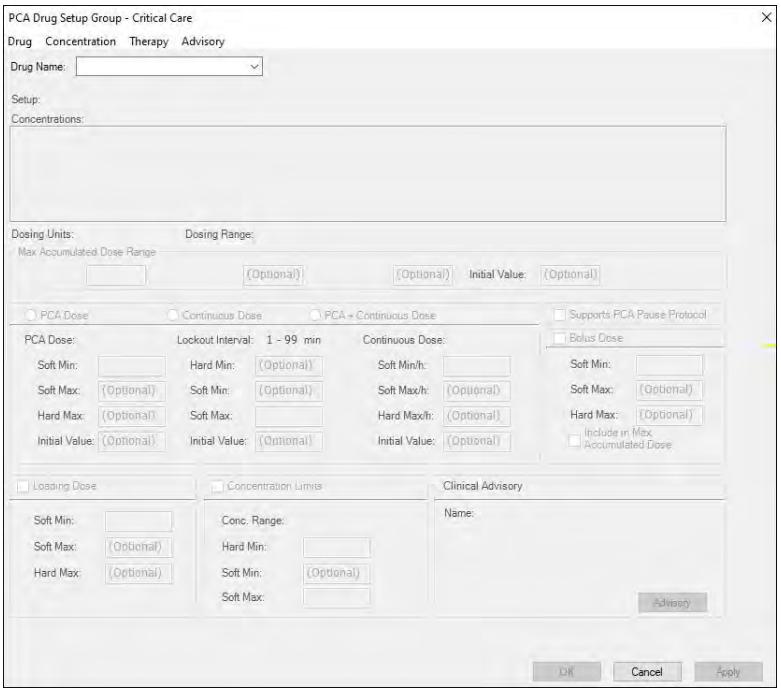
Adding a Drug

This procedure describes how to add a drug in the Guardrails™ Editor software.

1. In the PCA Summary dialog box, right-click and select **New Setup Group**.



The Drug Setup Group dialog box appears.



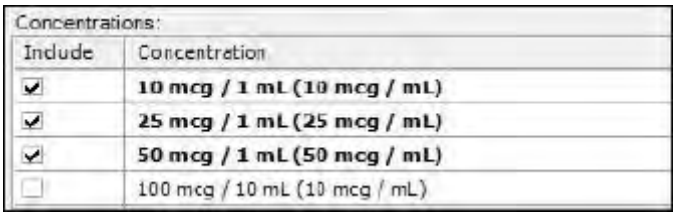
NOTE:
The subsequent example screens in this procedure zoom in on different sections of the screen shown above.

2. Select a drug from the Drug Name list to add to the Profile.

NOTE:

- There is a search feature within the Drug Name field. Place the cursor in Drug Name field and type the intended drug name or the initial characters of the drug name.
- The Drug Concentrations section lists all current concentrations of the drug currently available in the master drug list that are valid for PCA infusions. If the drug does not exist in the master drug list, see *Adding a New Drug that is Not in the Master Drug List on page 138* for more information.A drug cannot be used in both the PCA library and Intermittent library.
- You can assign Therapies to the new drug setup group by clicking **Therapy** > **Select** in the menu bar. For information about working with therapies in a profile, see *Assigning a Therapy on page 146*.

3. Select the **Include** check box next to the drug concentrations you want to include.



NOTE:
PCA drug concentration ranges are different than intermittent and continuous drug concentration ranges for the Pump and Syringe Modules. If not supported for PCA, the concentration is unavailable.

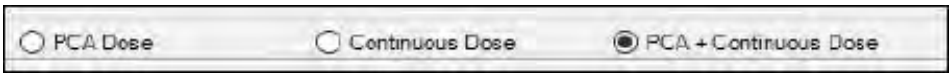
If the required concentration is not in the current list, see *Adding a New Concentration on page 136* for more information.

4. Enter the desired Maximum Accumulated Dose Range: Limits and Initial Value (optional).

NOTE:

- Edited parameter settings apply to all included concentrations.
- Maximum Accumulated Dose Range can be available in 1 hr., 2 hr., or 4 hr. intervals. This is a configuration setting adjusted in the PCA configuration settings. You cannot change this setting if drug setups are already entered. You must first delete these setups.
- You must set at least one minimum limit and one maximum limit. The third limit value is optional.
- Initial values are optional.
- If there is no accumulated dose hard maximum value in the data set, then no validation against the accumulated dose maximum occurs. The accumulated dose soft maximum is not considered the maximum for validation purposes.
- Without an accumulated dose hard maximum, the PCA dose, continuous dose, and clinician dose values can be higher than the accumulated dose soft maximum.
- If there is an accumulated dose hard maximum value in the data set, then:
  - PCA dose maximums must be less than or equal to the accumulated dose hard maximum.
  - Continuous dose maximums (adjusted to the same time-base) must be less than or equal to the accumulated dose hard maximum.
  - Clinician dose (if the check box for including in the accumulated dose has been selected) must be less than or equal to the accumulated dose hard maximum.
- If any setting falls outside acceptable parameters or required values are not entered, the exclamation symbol appears. Move the mouse over the symbol to see which parameter is out of range or not entered.

5. Click the button next to the infusion mode you want to set up: **PCA Dose**, **Continuous Dose**, or **PCA + Continuous Dose**.



NOTE:
Select the infusion mode prior to entering limits for **PCA Dose**, **Lockout Interval**, and **Continuous Dose**. If the infusion mode is changed, the limits may be erased from the entry.

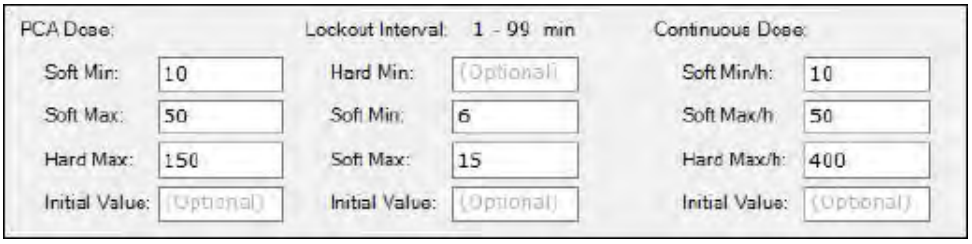
WARNINGS

- **Avoid delivering an extremely small volume bolus (less than 0.2 mL) with the PCA Module. Over or under infusion by approximately ±10% beyond the standard bolus volume accuracy can occur. Consider giving extremely small volume boluses IV push rather than with the PCA Module bolus feature. See the *Minimum Recommended Flow Rate for the PCA Module on page 61*. Also consider PCA Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**
  - **The standard bolus volume accuracy is the bolus volume accuracy under standard operating conditions, which is ±10%.**
- **Avoid delivering loading bolus volumes of less than 1 mL (when the Prime Set with Syringe feature is utilized) with the PCA Module as significant bolus volume inaccuracies can occur, resulting in under or over infusions (potentially down to 75% under infusion at 0.1 mL). Consider giving extremely small volume boluses IV push rather than with the PCA Module bolus feature. Also consider PCA Module performance, recommended doses, and dose volumes when developing drug concentration standards and data set parameters.**
- **Avoid delivering low flow rates with larger syringes using the PCA Module. This is of particular importance for the low, very low, and extremely low birth weight neonate. Flow rates below 1 mL/h can cause approximately 10% over or under infusion beyond the standard rate accuracy. See the *Minimum Recommended Flow Rate for the PCA Module on page 61*. Consider PCA Module performance, recommended doses, dose volumes, and syringe size when developing drug concentration standards and data set parameters.**
  - **The standard rate accuracy is the rate accuracy under standard operating conditions, which is ± 5% at flow rates greater than or equal to 10% of the syringe capacity per hour; and ±10% for flow rates less than 10% of the syringe capacity per hour and greater than or equal to 1 mL/h.**

CAUTION

Ensure that the correct PCA infusion mode option button is selected prior to clicking **OK** or **Apply**. Incorrect selection of PCA infusion mode within Guardrails™ Editor will impact PCA infusion mode availability on the PCU for the clinician, leading to delayed infusions.

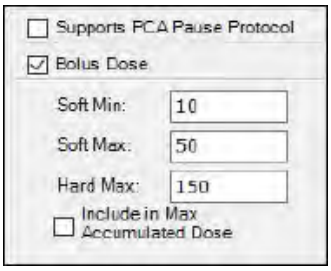
6. Enter limits for **PCA Dose**, **Lockout Interval,** and/or **Continuous Dose** if required.



NOTE:

- Dosing units available for PCA drugs are mL, mcg, and mg.
- When volume (mL only) (PCA) is selected or created in the PCA drug library, the continuous dosing units are mL/h and the loading, PCA, and bolus doses are in mL.

7. Select the **Supports PCA Pause Protocol** check box if PCA pause protocol is supported for this drug setup group.

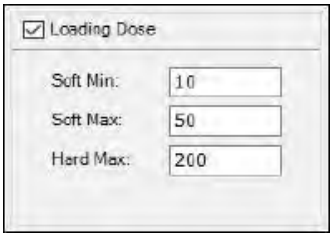


NOTE:
PCA pause protocol is enabled/disabled for $EtCO_2$ in the PCA Configurations dialog box. If it is disabled, the Supports PCA Pause Protocol check box is unavailable. For more information, see *Editing Configuration Settings on page 160*.

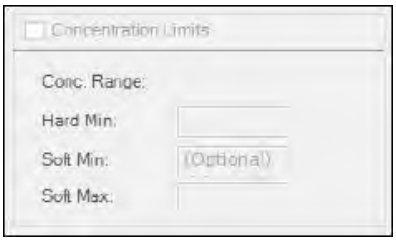
8. Select the **Bolus Dose** check box, if desired, and enter all required bolus dose limits.
9. Select the **Include in Max Accumulated Dose** check box if you want to include the bolus dose in the maximum accumulated dose.

NOTE:
The Auto-ID Module features the ability to populate programming fields such as drug amount and diluent amount by including that information in the pharmacy applied barcode label. The data set features the ability to populate initial values or typical starting values for the same parameter. Careful consideration should be given when using these features in conjunction with one another because the user may not be aware of the origin of that value.

10. Select the **Loading Dose** check box, if desired, and enter all required loading dose limits.



11. Enter **Concentration Limits** for drug setups with a Units Only concentration (custom concentration) selected.



NOTE:

- When programming a Units Only concentration (custom concentration) in the drug library, the Drug Amount and Diluent Volume must be entered into the infusion device by the clinician so that the resulting concentration can be used to calculate the flow rate or volume needed to deliver the prescribed dose.
- Hard minimum concentration limits in your hospital's drug library can prevent over infusion or under infusion when a Units Only concentration (custom concentration) is programmed incorrectly at the bedside.
- PCA drug library setups with a selected Units Only concentration (custom concentration) require Concentration Limits, including a hard minimum and soft maximum value. Soft minimum concentration limits are optional. Concentration limits are not available for drug setups with only Full Concentrations or Volume (mL only) Concentrations selected.

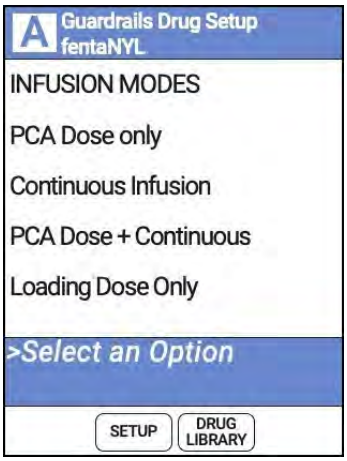
If the concentration programmed by the clinician is...	Then the pump delivers an...
lower than the actual concentration	Over infusion
higher than the actual concentration	Under infusion

12. To attach a clinical advisory to this drug entry, click **Advisory**.

    For more information, see *Working with Clinical Advisories in Drug or Fluid Libraries on page 149*.

13. Click **Apply** to accept the entries and keep the dialog box open to add more drugs, or click **OK** to accept the entries and close the dialog box.

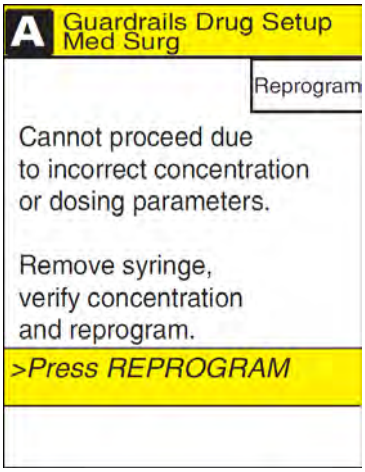
    NOTE:
    When all infusion modes are enabled within the dataset with corresponding safety limits, these infusion modes are then available at the bedside for the clinician to select from as shown in the example PCU screen below.



PCA Volume Check

To reduce the instances of programming errors, the PCA checks the total volume of all programmed PCA parameters against a percentage (35%) of the capacity of the installed syringe. A PCA infusion can only be started when the total programmed volume is less than 35% of the syringe capacity.

The PCA volume check includes one hour of continuous dose, PCA dose, bolus dose or loading dose. If the programmed volume is 35% or more of the capacity of the installed syringe during initial or subsequent programming, the clinician is presented with an alert which requires a reprogram.



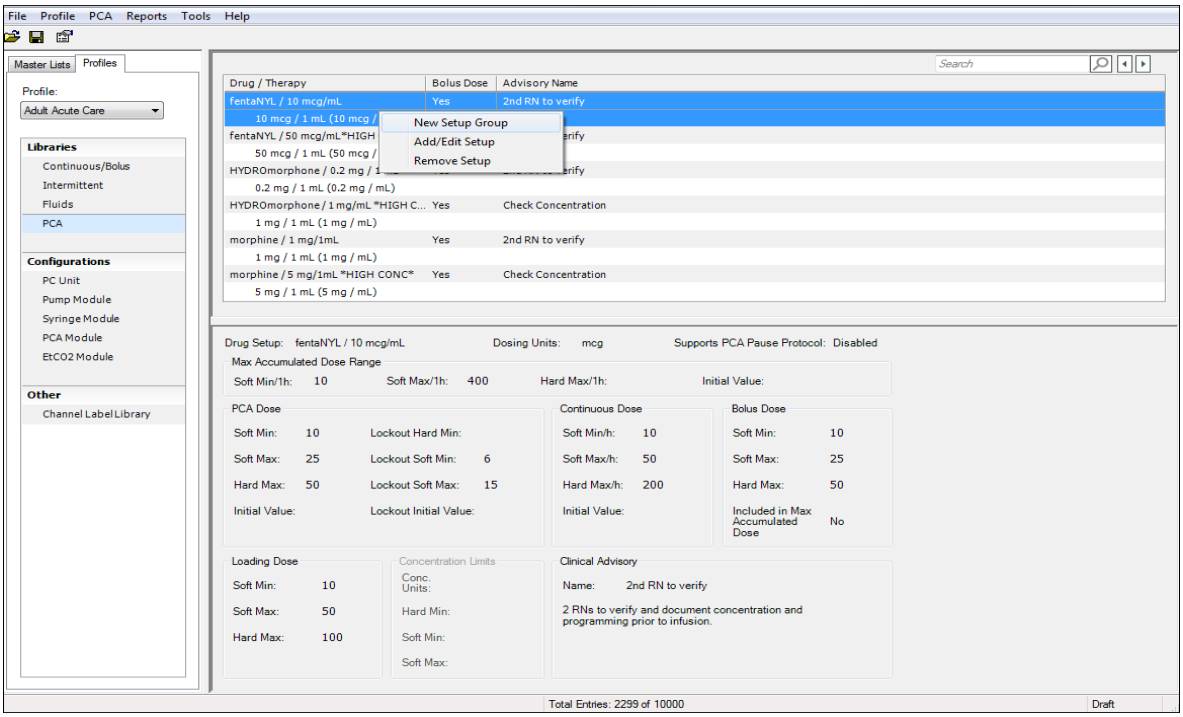
Syringe Size	35% Capacity
60 mL①	21 mL
35 mL	12.25 mL
30 mL	10.5 mL
25 mL	8.75 mL
20 mL	7 mL

① The PCA volume check for the BD® 50 mL syringe is based on a 60 mL capacity, therefore a 21 mL threshold applies.

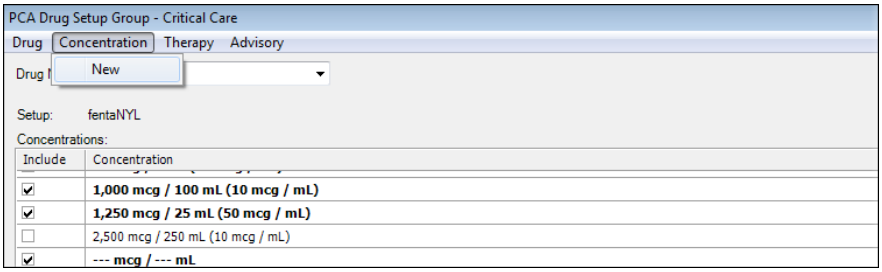
Adding a New Concentration

Duplicate drug and concentration entries are not allowed. A message box warns you if an attempt is made to add an entry that already exists in the drug library or in the selected profile.

1. In the PCA Summary dialog box, right-click the applicable drug-setup group, and click **Add/Edit Setup.**

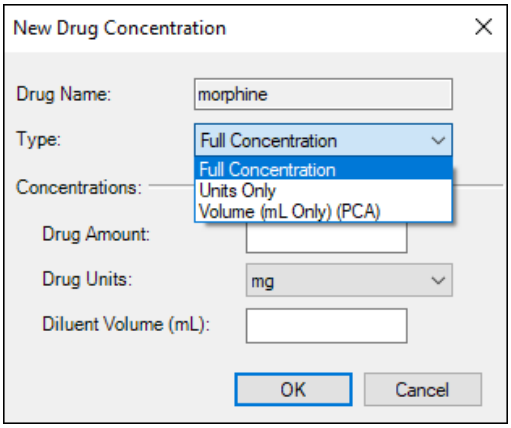


2. The PCA Drug Setup Group dialog box appears displaying the selected setup group.
3. Select **Therapy** if relevant.
4. In the menu bar, click **Concentration** > **New**.



The New Drug Concentration dialog box appears displaying the drug name and existing drug unit.

5. Select the type of concentration from the **Type** list.



Type	Description
Full Concentration	The Drug Amount, Drug Units, and Diluent Volume (mL) values.
Units Only	A concentration that includes drug units without predefined drug amount and diluent volume values. The clinician enters these values when initiating an infusion on the BD Alaris™ System. Only one Units Only concentration (custom concentration) selection is allowed per setup.
Volume (mL only) (PCA)	Volume only.

NOTE:
Depending on your selection, some or all of the concentration values (Drug Amount, Drug Units, and Diluent Volume) require entry.

6. Enter a **Drug Amount**.
7. Change the **Drug Units** using the list (if desired).
8. Enter the **Diluent Volume** (mL), and click **OK**.

   The New Concentration box is closed.
9. Select the **Include** check box in the Drug Concentrations list.

   NOTE:
   Only valid PCA concentrations are available for use. Concentrations that cannot be used are unavailable.
10. To accept the entries and close the dialog box, click **OK**.

    NOTE:
    The new concentration is automatically updated in the master drug list.

Adding a New Drug that is Not in the Master Drug List

A new drug can be added to the profile from the PCA Drug Setup Group dialog box.

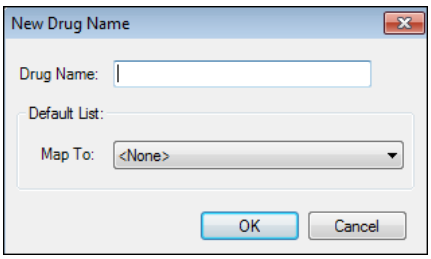
1. Right-click in the top section of the PCA Summary dialog box and select **New Setup Group**.

   The PCA Drug Setup Group dialog box appears.

2. In the menu bar, click **Drug** > **New**.

   The New Drug Name dialog box appears.

3. Enter the **Drug Name**.



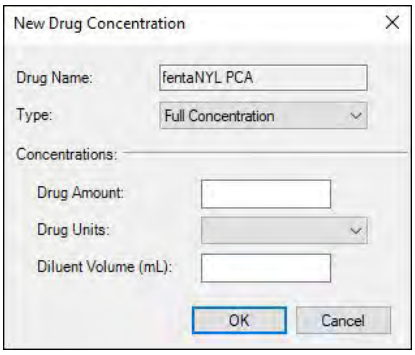
4. Optionally select a drug name in the **Map To** list to copy its concentrations list.

   Only default master list drug names are listed.

5. To save the drug name, click **OK**.

   If you choose to copy concentrations using the **Map To** selection, you will return to the PCA Drug Setup dialog and you are done.

   If you are not copying concentrations, the New Drug Concentration dialog box appears prompting you to add the first concentration for your new drug. Proceed to step 6.



6. Select the type of concentration from the **Type** list.

Type	Description
Full Concentration	The Drug Amount, Drug Units, and Diluent Volume (mL) values.
Units Only	A concentration that includes drug units without predefined drug amount and diluent volume values. The clinician enters these values when initiating an infusion on the BD Alaris™ System. Only one Units Only concentration (custom concentration) selection is allowed per setup.
Volume (mL only) (PCA)	Volume only.

NOTE:
Depending on your selection, some or all of the concentration values (Drug Amount, Drug Units, and Diluent Volume) requires values to be entered.

7. Enter a **Drug Amount**.
8. Select **Drug Units** from the list.
9. Enter **Diluent Volume** (mL) and click **OK**.

   The New Drug dialog box closes and the drug name and concentration is added to the master drug list.
10. Select the **Include** check box for the concentration desired.
11. Enter dosing ranges and limits as desired.

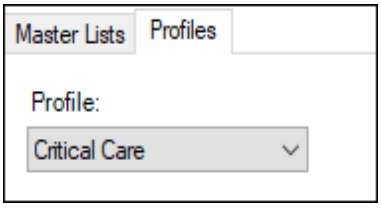
    For more information, see *Adding a Drug on page 128*.

Copying a Drug Setup Group from Another Profile

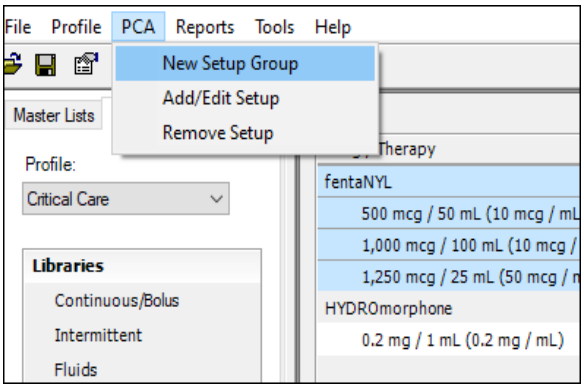
Use this procedure to copy a drug setup group to a destination profile from another profile. The destination profile is the profile to which you want to copy the drug information.

NOTE:
In the example images below, Morphine is copied from the Oncology Profile to the Critical Care Profile.

1. Start in the destination Profile by selecting that profile from the Profile drop-down menu.

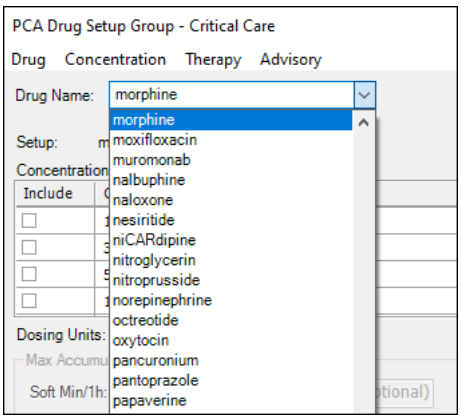


2. Click **PCA > New Setup Group** in the taskbar.

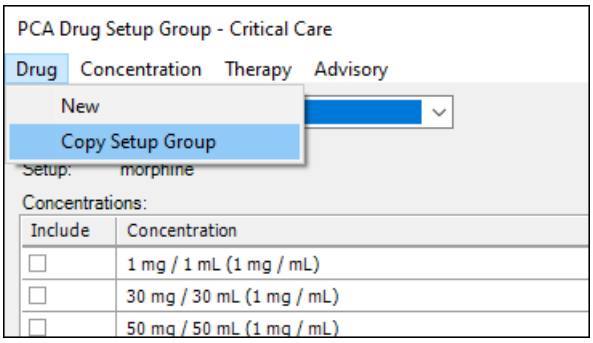


The PCA Drug Setup Group dialog box appears.

3. Select the drug you intend to copy from the Drug Name drop-down menu.



4. Click **Drug** > **Copy Setup Group** in the menu bar.

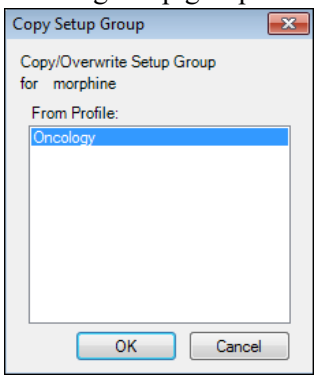


The Copy Setup Group dialog box appears.

NOTE:
If the selected drug is not available in any other profile, the Copy Setup Group option is unavailable.

5. Select the profile containing the drug setup group you want to copy from and click **OK**.

The drug setup group is now copied into the PCA drug library of the destination Profile.



WARNING

When copying a setup group from one Profile to another or copying an existing Profile to create a new Profile, review all relevant drug or fluid setup group parameters, configurations, and the Profile name. Failure to do so may result in incorrect data set parameters on the PCU, contributing to over, under, or delayed infusions.

6. Confirm the correct parameters are shown in the drug setup window and click **OK** or **Apply**.

Removing a Concentration

Use this procedure to remove a drug concentration from a profile. The concentration remains in the master drug list.

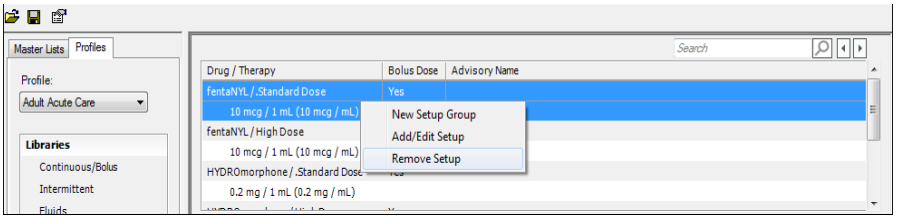
1. Right-click the applicable drug setup group in the PCA Summary dialog box and click **Add/Edit Setup**.

   The PCA Drug Setup Group box appears listing all current included concentrations and settings for the drug in the profile.
2. Clear the **Include** check box on the PCA Drug Setup Group dialog box to remove a concentration from the profile.
3. To confirm, click **OK** or **Apply**.

Removing a Drug Setup

Use this procedure to remove a drug setup and all its concentrations from a profile. The concentration remains in the master drug list.

1. Right-click the drug setup in the PCA Summary dialog box that you want to remove, and click **Remove Setup**.



   The Remove Setup Confirmation dialog box appears.
2. To remove the drug and concentrations from the profile, click **OK**.

Editing Parameter Settings

This procedure describes how to edit a drug in the Guardrails Editor software.

1. Right-click the drug setup in the PCA Summary dialog box that you want to update, and click **Add/Edit setup**.

   The PCA Drug Setup Group dialog box appears listing all current concentrations and settings for the drug in the profile.

   You can assign or reassign therapies to the drug setup in the Therapy menu. For information about working with therapies in a profile, see *Assigning a Therapy on page 146*.

2. Edit any of the following PCA settings: **Max Accumulated Dose Limits**, **PCA Dose**, **Lockout Interval**, **Continuous Dose**, **Loading Dose**, **Bolus Dose**, or **Concentration Limits**. PCA drug library setups with a selected Units Only concentration (custom concentration) require Concentration Limits, including a hard minimum and soft maximum value. Soft minimum concentration limits are optional. Concentration limits are not available for drug setups with only Full Concentrations or Volume (mL only) Concentrations selected.

NOTE:
A list of incomplete Hard Minimum Concentration Limit fields for PCA drug library setups with a Units Only concentration (custom concentration) selected can be generated in three ways:

- A Data Set Changes Report that includes Incomplete Data Set Entries generates in Microsoft™ Word when a prior data set version with incomplete required fields is opened in Guardrails™ Editor version 12.1.3. An updated version of this report will continue to generate upon opening the Guardrails™ Editor until the incomplete entries have been resolved. Refer to *Opening, Closing, or Saving a Data Set on page 12*.

Generate a Data Set Changes Report	Generate an Error Summary	Generate a Data Set Report in Microsoft™ Excel
Includes Incomplete Data Set Entries that generates in Microsoft™ Word when a prior data set version with incomplete required fields is opened in Guardrails™ Editor version 12.1.3. An updated version of this report will continue to generate upon opening the Guardrails™ Editor until the incomplete entries have been resolved. Refer to *Opening, Closing, or Saving a Data Set on page 12*.	For instructions on how to access the Error Summary, refer to *Navigating the BD Alaris™ Guardrails™ Editor Software on page 19* or *Error Summary on page 188*.	Generate a Data Set Report in Microsoft™ Excel and filter for Units Only concentrations (custom concentrations) without Hard Minimum Concentration Limits. For instructions, refer to *Filtering for Units Only Concentrations (Custom Concentrations) with No Hard Minimum Concentration Limits on page 193*.

- Generate an Error Summary. For instructions on how to access the Error Summary, refer to *Navigating the BD Alaris™ Guardrails™ Editor Software on page 19* or *Error Summary on page 188*.
- Generate a Data Set Report in Microsoft™ Excel and filter for Units Only concentrations (custom concentrations) without Hard Minimum Concentration Limits. For instructions, refer to *Filtering for Units Only Concentrations (Custom Concentrations) with No Hard Minimum Concentration Limits on page 193*.
- If any setting falls outside of acceptable parameters or required values are not entered, the exclamation symbol appears. Move the mouse over the symbol to see which parameter is out of range or not entered.

3. To attach or edit a clinical advisory for this drug entry, click **Advisory**. For more information, see *Working with Clinical Advisories in Drug or Fluid Libraries on page 149*.
4. To confirm, click **OK** or **Apply**.

NOTE:
Edited parameter settings apply to all included concentrations.

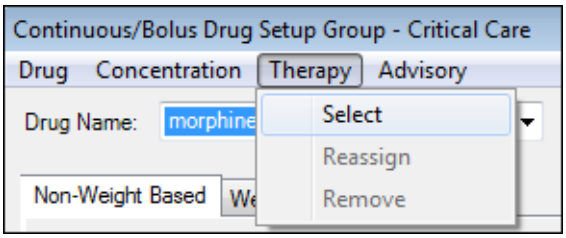
Chapter 14
Working with Therapies in Drug or Fluid Libraries

This section contains the following topics:

Assigning a Therapy

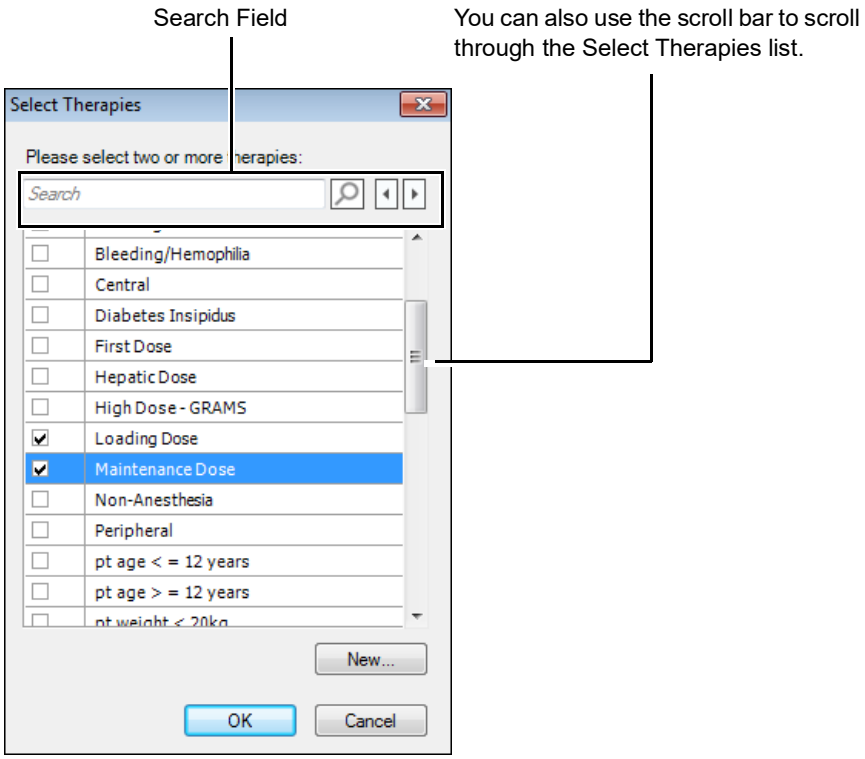
Therapies can be assigned to drug setup groups in the continuous/bolus, PCA, and intermittent profile drug libraries. They can also be assigned to fluids in the fluid library. Therapies allow different limits to be defined for the same medication with different therapeutic indications.

1. In the menu bar at the top of the Setup Group dialog box, click **Therapy** > **Select**.



   The Select Therapies dialog box appears.

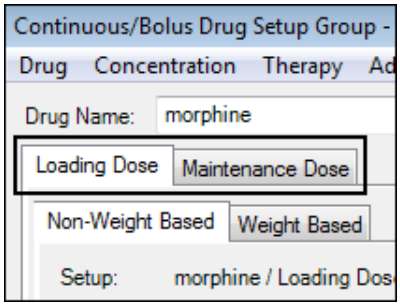
2. You can select a therapy using the scroll bar or search function (optional).
   a. Type a therapy name or the initial characters of the therapy name in the search field.
   b. Press **Enter** or click  .
      The searched for therapy name is highlighted in yellow.
   c. Use the left and right arrow to move to the next or previous therapy that matches your search criteria.
3. Select the check boxes for the therapies that you want to add.



   Drug and fluid names must have at least two therapies assigned.

4. To assign the therapies to the setup group, click **OK**.

   The Select Therapies dialog box closes and tabs containing the therapy names appear on the Setup Group screen. Click any of these tabs to select the therapy and enter appropriate parameters.

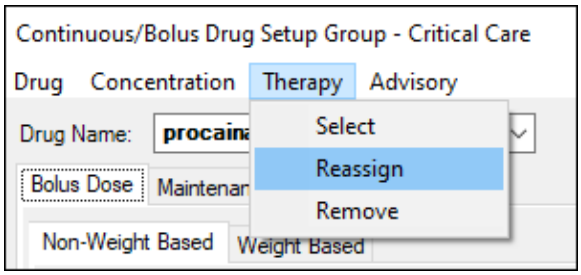


Reassigning a Therapy

Use this procedure to change the therapy names in the setup group.

NOTE:
In the example images below, a Bolus Dose therapy is reassigned to a Loading Dose therapy.

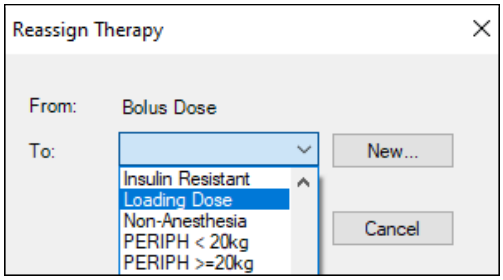
1. On the Setup Group dialog box, select the Therapy tab you want to reassign.
2. In the menu bar at the top of the Setup Group dialog box, click **Therapy** > **Reassign.**



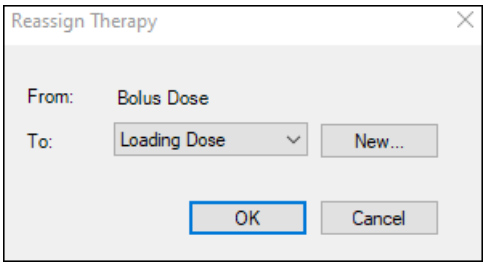
   The Reassign Therapy dialog box appears.

3. Select a therapy from the drop-down menu to change the therapy name.

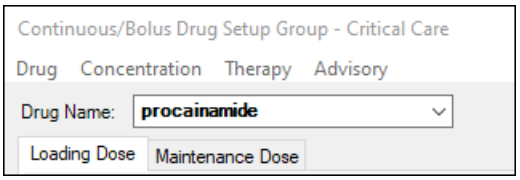
   If the reassigned therapy name is not in the drop-down menu, click **New** and enter a new **Therapy Name** in the New Therapy dialog box. Then click **OK.**



4. Click **OK** in the Reassign Therapy dialog box.



The reassigned therapy name now appears in the setup group.



Removing a Therapy

You must have at least two therapies defined in the setup group if you are utilizing therapies. If you remove one of two defined therapies, the remaining Therapy tab is removed and its associated parameters become the parameters for the setup group.

1. In the Setup Group dialog box, select the Therapy tab you want to remove.
2. In the menu bar at the top of the Setup Group dialog box, click **Therapy** > **Remove**.

   The Remove Therapy Confirmation dialog box appears.
3. Click **OK** to confirm.

Chapter 15
Working with Clinical Advisories in Drug or Fluid Libraries

This section contains the following topics:

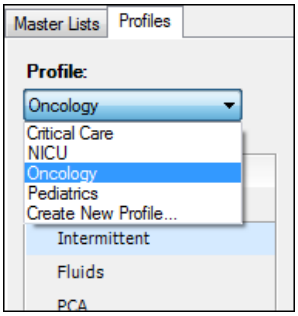
Overview

Clinical advisories are programmed text messages associated with a selected drug or fluid name that can be set to appear on the PCU display screen. Clinical advisories are created in the master clinical advisories list and can be added to or removed from a care area profile.

- A profile can only associate one clinical advisory with each drug or fluid setup.
- Clinical advisories are not displayed on the BD Alaris™ System when in the Anesthesia Mode.

To Add a Clinical Advisory to a Drug or Fluid Name:

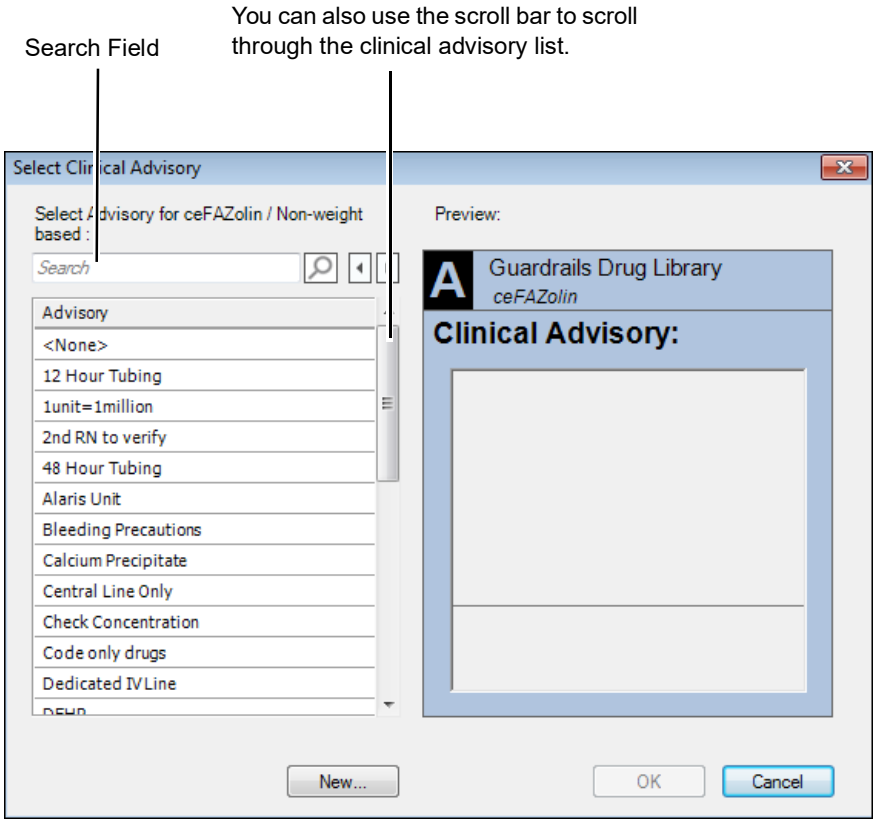
1. Click the **Profiles** tab.
2. Select a profile from the **Profile** list in the navigation pane.



3. Click **Continuous/Bolus**, **Intermittent**, **Fluids**, or **PCA** from the list of libraries in the Profiles tab.
   The relevant library summary dialog box appears.
4. Highlight the desired drug from the Library Summary dialog box.
5. Click **Add/Edit Setup** on the Setup Group dialog box.

6. Click **Advisory**.

   The Select Clinical Advisory dialog box appears.



7. Select an advisory name from the list on the left side of the dialog box. You can select a clinical advisory using the scroll bar or search function.

   a. To use the Search function, type the initial characters of any word within the clinical advisory name in the search field.

   b. Press **Enter** or click  .

      The selected clinical advisory name is highlighted in yellow. The system searches within the clinical advisory name only.

   c. Use the left and right arrow to move to the next or previous clinical advisory that matches your search criteria.

   A simulation of the PCU display screen appears in the preview window of the dialog box, showing the selected clinical advisory text.

8. Click **OK**.

   The dialog box closes and the clinical advisory appears in the clinical advisory text box on the Setup Group dialog box.

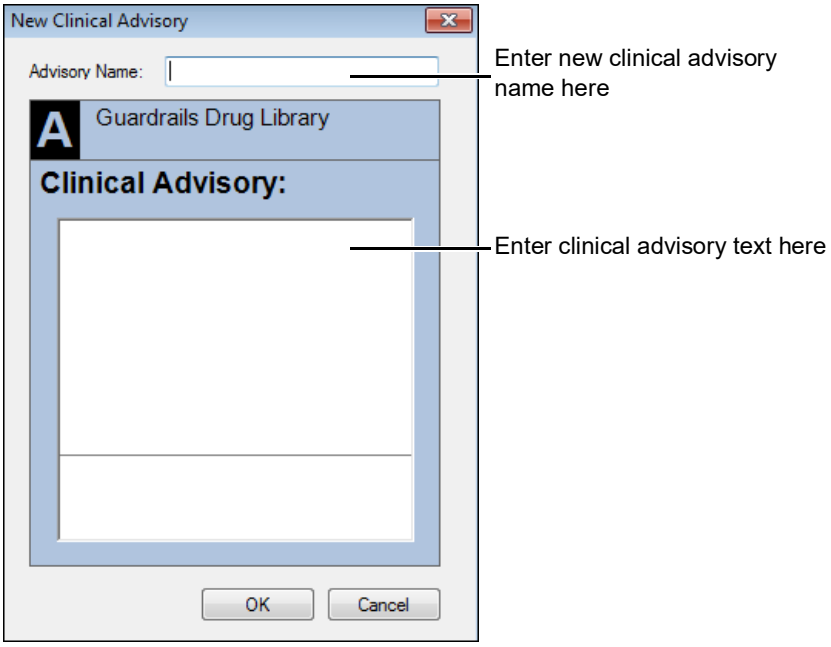
9. If the desired clinical advisory is *not* in the current master clinical advisory list, click **New**.

Creating a New Clinical Advisory for a Drug or Fluid

The New button is unavailable if 100 clinical advisories have already been entered.

1. Click **New** in the Select Clinical Advisory dialog box.

   The New Clinical Advisory dialog box appears.



2. Enter a name for the advisory (up to 20 characters).
3. Enter clinical advisory text in the text box.

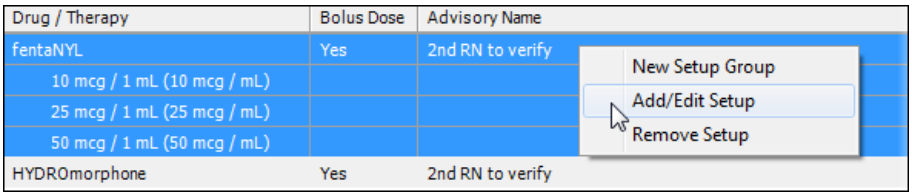
   Enter text as you want it to appear on the PCU display screen.
4. Click **OK**, and then click **OK** again to close the second dialog box.

   The dialog box closes and the clinical advisory appears in the clinical advisory text box on the Profile Drug Library dialog box.

Removing a Clinical Advisory for a Drug or Fluid

This procedure describes how to remove a clinical advisory for a drug or fluid in the Guardrails™ Editor software.

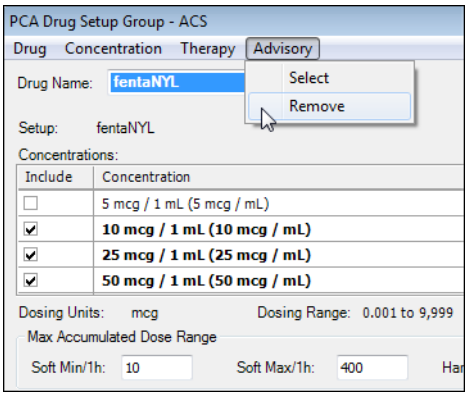
1. In the library summary dialog box, right-click on the drug or fluid for which you want to remove the clinical advisory.



2. Click **Add/Edit Setup**.

   The Setup Group dialog box appears.

3. Click **Advisory** on the menu bar.
4. Click **Remove**.



5. Click **OK**.

   The clinical advisory is removed for the selected drug or fluid.

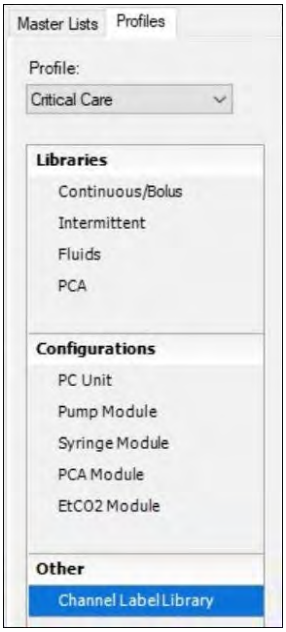
Chapter 16
Developing a Profile Channel Label Library

This section contains the following topics:

Adding or Removing a Channel Label

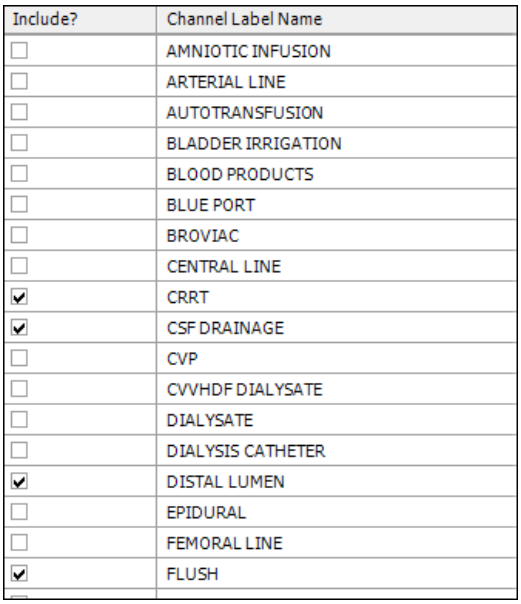
A profile channel label library is a subset of labels from the master channel label List to be used with a specific care area Profile.

1. Click the **Profiles** tab.
2. Select a profile from the **Profile** list in the navigation pane, and click **Channel Label Library**.



The current channel label library for the profile appears. The Profile Channel Label Selection page opens, listing the available channel labels.

3. Select the check box for each channel label to add to the profile.



Include?	Channel Label Name
☐	AMNIOTIC INFUSION
☐	ARTERIAL LINE
☐	AUTOTRANSFUSION
☐	BLADDER IRRIGATION
☐	BLOOD PRODUCTS
☐	BLUE PORT
☐	BROVIAC
☐	CENTRAL LINE
☑	CRRT
☑	CSF DRAINAGE
☐	CVP
☐	CVVHDF DIALYSATE
☐	DIALYSATE
☐	DIALYSIS CATHETER
☑	DISTAL LUMEN
☐	EPIDURAL
☐	FEMORAL LINE
☑	FLUSH

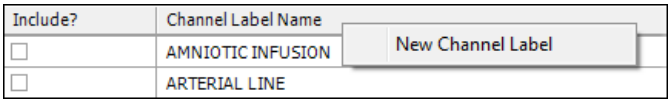
4. Clear the check box to remove a channel label from the profile.

NOTE:
Channel labels should not include drug or fluid names. They are intended to provide a channel identifier for route of administration or type of IV line, such as epidural or distal lumen. A confirmation dialog box appears if a channel label entered is the same as the name of a drug in the master drug list or fluid name in the master fluids list. This confirmation can be overridden.

Creating a Channel Label

This procedure describes how to create a channel label in the Guardrails™ Editor software.

1. Right-click the Profile Channel Label Selection dialog box, and click **New Channel Label**.



   The New Channel Label dialog box opens.

2. Enter a new channel label (up to 20 alphanumeric characters), and click **OK**.
   The new label is added to the profile and to the master channel label List.
3. To accept the changes, click **OK**.

Chapter 17
Instrument Configuration Settings

This section contains the following topics:

Overview

From this software, you can configure instrument settings for the BD Alaris™ System. Each profile can have its own set of configuration settings for each type of module.

NOTE:

- See the tables later in this section for a list of configuration default settings and definitions.
- The Pump Module and Syringe Module have some shared configuration settings listed in the Shared Infusion Settings table.
- The Syringe Module and PCA Module have some shared configuration settings listed in the Shared Infusion Settings table.

The Guardrails™ Editor has default factory instrument configuration settings that are presented when developing a new data set, when creating a new profile, or resetting a module to factory defaults. These software default settings apply to the PCU, Pump Module, Syringe Module, $EtCO_2$ Module, PCA Module, and shared module settings. These settings are editable. See below for instructions that use the Pump Module as an example.

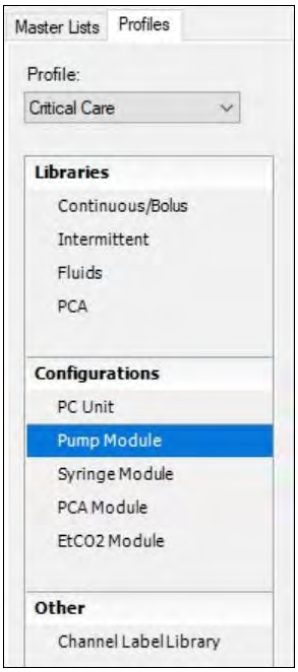
NOTE:
A new PCU is preloaded with three Profiles (Adult, Neonate, Pediatric) with applicable configuration settings (drug library not included). The preloaded profile configuration data set is named **BD Sample Configs** and provides BD recommended settings applicable to specific patient populations. Refer to *Configuration Settings* in the BD Alaris™ System user manual for a list of these configuration settings.

Editing Configuration Settings

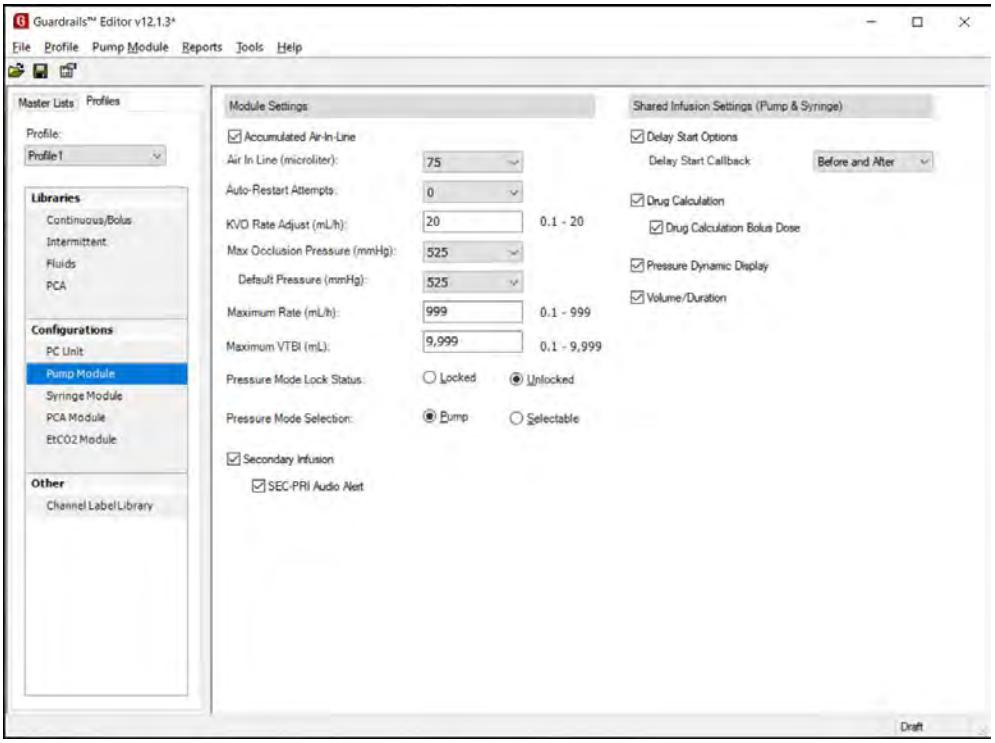
All BD Alaris™ System Modules and the PCU can be configured according to the following procedure. Each module has a unique set of parameters that can be configured.

1. Click the **Profiles** tab in the navigation pane.
2. Select a profile from the Profile list.

3. Click desired module in the Configurations list.
   The Pump Module is the selected module shown in the illustration.



The Pump Module Configuration main display lists current setting for the module.

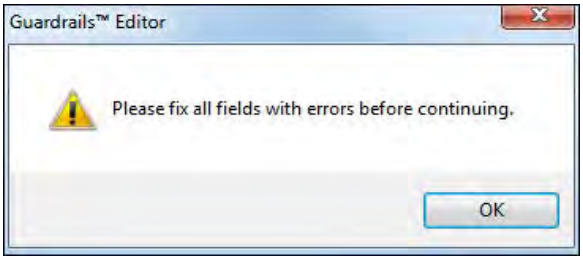


4. Make the required changes.

   The settings in the Shared Infusion Settings panel are common to both the Syringe Module and Pump Module. Any entries or changes made in this panel automatically update the same settings in the Syringe Module for this profile. The PCA Module and Syringe Module share one setting: Max. Rate.

5. Click **File** > **Save** to save configuration settings.

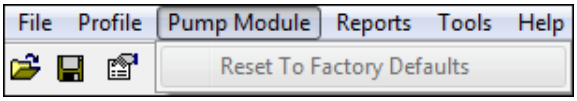
   If a setting entry falls outside acceptable parameters and you try to save the data set, close, or leave the screen, a Fix Error dialog box appears. An exclamation ❗ symbol appears next to the field or fields in error. Move the mouse over the symbol to view the error message.



Resetting All Configurations to Factory Defaults

Use the following procedure to reset this module to factory defaults.

1. In the menu bar, click the desired module and then Reset to Factory Defaults. For example, click **Pump Module** > **Reset to Factory Defaults**.



   The configuration settings are reset to factory defaults.

2. If the *Reset To Factory Defaults* option is unavailable:
   - For the PCU Module, you must remove Anesthesia Only drug concentrations in the current profile.
   - For the Pump Module, you must remove Continuous/Bolus setups in the current profile and/or disable the secondary option from Intermittent setups in the current profile (i.e. their Available As parameter must be set to Primary Only).
   - For the Syringe Module, you must remove Continuous/Bolus setups in the current profile.
   - For the PCA Module, you must remove PCA setups in the current profile.

Alaris System Configuration Options

The following Profile settings can be configured in this software. For more information, see the definitions of each setting following this set of tables.

PCU (System Configurations)

Setting	Default Value	Options
Alarm Audio Profile	Profile 1	Profile 1, 2, 3, or 4
Minimum Audio Volume	1 — Softest	1— Softest 2 3 4 5—Loudest
Default Audio Volume	5 — Loudest	1—Softest 2 3 4 5—Loudest
Anesthesia Mode	Disabled	Enabled, Disabled
Battery Meter Display	Enabled	Enabled, Disabled
Color Display (PCU 8015 Only)	Enabled	Enabled, Disabled
Key Click Audio	Enabled	Enabled, Disabled
Limit Checking	Always	Always, Smart
Max Patient BSA (m^2)	3	0.05–3 (m^2)
Max Patient Weight (Kg)	500	0.1–500 (Kg)
Patient ID Entry	Enabled	Enabled, Disabled
Preventive Maintenance Reminder	Enabled	Enabled, Disabled
Tamper Resistant	Enabled	Enabled, Disabled
Authorized User Mode	Disabled	Disabled, Enabled, Enabled with Override
No-Guardrails™, Basic Infusion Clinical Advisory	Enabled	Enabled, Disabled When Enabled, Advisory text can be edited.

NOTE:

- Profile 4 audio settings support standards compliance. Setting the Alarm Audio Profile to Profile 4 could potentially result in the BD Alaris™ System alarms sounding similar to other devices, such as respirators and monitoring services, that are compliant with the same safety standards.
- To support standards compliance the Color Display setting must also be set to Enabled.
- The BD Alaris™ User Manual cautions the user to NOT use protected health information (PHI) identifiers (for example, patient name, social security number, and so on.) for Patient ID entries.

Pump Module

Setting	Default Value	Options
Accumulated Air-in-line	Enabled	Enabled, Disabled
Air In Line (microliter)	75	50, 75, 125, 175, 250 microliters
Auto-Restart Attempts	0	0–9 attempts
Default Pressure (mmHg)	525	50–525 in 25 mmHg increments
Delay Start Options (Shared Infusion Settings - Pump & Syringe)	Enabled	Enabled, Disabled
Delay Start Callback (Shared Infusion Settings - Pump & Syringe)	Before & After	None, Before, Before & After, After
Drug Calculation (Shared Infusion Settings - Pump & Syringe)	Enabled	Enabled, Disabled
Drug Calculation Bolus Dose (Shared Infusion Settings - Pump & Syringe)	Enabled	Enabled, Disabled
KVO Rate Adjust (mL/h)	20	0.1–20 mL/h
Max Occlusion Pressure (mmHg)	525	50–525 in 25 mmHg increments
Maximum Rate (mL/h)	999	0.1–999 mL/h
Maximum VTBI (mL)	9,999	0.1–9,999 mL
Pressure Mode Lock Status	Unlocked	Locked, Unlocked
Pressure Mode Selection	Pump	Pump, Selectable
Secondary Infusion	Enabled	Enabled, Disabled
SEC-PRI Audio Alert	Enabled	Enabled, Disabled
Pressure Dynamic Display (Shared Infusion Settings - Pump & Syringe)	Enabled	Enabled, Disabled
Volume/Duration (Shared Infusion Settings - Pump & Syringe)	Enabled	Enabled, Disabled

WARNING

Ensure that air-in-line configuration settings are appropriate for the designated care area profile. Failure to do so may increase the risk of clinically significant volumes of air infusing into the patient.

Syringe Module

Setting		Default Value	Options
All Mode		Enabled	Enabled, Disabled
Auto Occlusion Pressure		Enabled	Enabled, Disabled
Back-Off After Occlusion		Enabled	Enabled, Disabled
Fast-Start		Enabled	Enabled, Disabled
KVO Option		Disabled	Enabled, Disabled
KVO Rate Adjust (mL/h)		1	0.1–2.5 mL/h
KVO Volume Adjust (%)		5	0.5–5%
Occlusion Pressure Limit with Disc (mmHg)		500	25–1,000 in 1 mmHg increments
Occlusion Pressure Limit No Disc		Med (500 mmHg)	High (800 mmHg), Med (500 mmHg), Low (200 mmHg)
Priming		Enabled	Enabled, Disabled
 WARNING **Ensure that Priming is enabled for the Syringe Module. Failure to do so prevents the clinician's ability to use the Prime Set with Syringe feature on the PCU to decrease pump mechanical slack. This can delay the infusion delivery startup time and lead to delivery inaccuracies.**			
Near End Of Infusion		Enabled	Enabled, Disabled
Continuous, Fluids, Basic		Enabled	Enabled, Disabled
	Alert time (minutes)	60	1–60 minutes before the calculated end of infusion.
Intermittent		Disabled	Enabled, Disabled
	Alert time (minutes)	15	1–15 minutes before the calculated end of infusion
NEOI Snooze (Shared Syringe and PCA Setting)		Enabled	Enabled, Disabled
Snooze Time (minutes)		15	5, 10, 15 minutes
Delay Start Options (Shared Infusion Settings - Pump and Syringe)		Enabled	Enabled, Disabled
Delay Start Callback (Shared Infusion Settings - Pump and Syringe)		Before & After	None, Before, Before & After, After

Syringe Module (Continued)

Setting	Default Value	Options
Drug Calculation (Shared Infusion Settings - Pump and Syringe)	Enabled	Enabled, Disabled
Drug Calculation Bolus Dose (Shared Infusion Settings - Pump and Syringe)	Enabled	Enabled, Disabled
Pressure Dynamic Display (Shared Infusion Settings - Pump and Syringe)	Enabled	Enabled, Disabled
Volume/Duration (Shared Infusion Settings - Pump and Syringe)	Enabled	Enabled, Disabled
Maximum Rate - mL/h (Shared Infusion Settings - PCA and Syringe)	999	0.1–999 mL/h

NOTE:
Clearing the Near End of Infusion check box disables Continuous, Fluids, Basic, Intermittent, and NEOI Snooze (if enabled).

Shared Infusion Settings (Pump and Syringe Modules)

Setting	Default Value	Options
Delay Start Options	Enabled	Enabled, Disabled
Delay Start Callback	Before & After	None, Before, Before & After, After
Drug Calculation	Enabled	Enabled, Disabled
Drug Calculation Bolus Dose	Enabled	Enabled, Disabled
Pressure Dynamic Display	Enabled	Enabled, Disabled
Volume/Duration	Enabled	Enabled, Disabled

Shared Infusion Settings (PCA and Syringe Modules)

Setting	Default Value	Options
Maximum Rate (mL/h) (Shared Syringe and PCA Settings)	999	0.1–999 mL/h
NEOI Snooze (Shared Syringe and PCA Settings)	Enabled	Enabled, Disabled

PCA Module

Setting	Default Value	Options
Bolus Delivery Rate (mL/h)	150	75–500 mL/h
Dose Request Cord (Profile)	Profile 1	Profile 1, 2, 3
Max Dose Limit	Enabled	Enabled, Disabled
Time Window (h)	1	1, 2, 4 h
Module Location Enforcement	Enabled	Enabled, Disabled
Near End of Infusion	Enabled	Enabled, Disabled
Alert Time %	5	5–25%
NEOI Snooze (Shared Syringe and PCA Setting)	Enabled	Enabled, Disabled
Snooze Time - min (Shared Syringe and PCA Setting)	15	5, 10, or 15 minutes
Pressure Limit	Med (500mmHg)	High (800mmHg), Med (500 mmHg), Low (200 mmHg)
Priming	Enabled	Enabled, Disabled
 WARNING **Ensure that Priming is enabled for the PCA Module. Failure to do so prevents the clinician's ability to use the Prime Set with Syringe feature on the PCU to decrease pump mechanical slack. This can delay the infusion delivery startup time and lead to delivery inaccuracies.**		
Security Access Level	1	1, 2, 3
Security Code	None	0000–9999
Maximum Rate (mL/h) (Shared Syringe and PCA Setting)	999	0.1–999 mL/h
PCA Pause Protocol Enabled (Available for EtCO2)	Enabled	Enabled, Disabled
Monitoring Module Attach Enforcement	Disabled	Enabled, Disabled
PCA Pause Protocol (Alarm Message)	PCA Infusion has paused due to a decline in respiratory status. Check Patient!	Select **Edit Text** to change

EtCO2 Module

Setting	Default Value	Options
Alarm Limit Type	Adult	Adult, Neonatal
EtCO2 High (mmHg)	Adult = 60 Neonatal = 60	5–99 mmHg
EtCO2 Low (mmHg)	Adult = 20 Neonatal = 20	0–98 mmHg
Respiratory Rate High (bpm)	Adult = 35 Neonatal = 80	1–150 bpm
Respiratory Rate Low (bpm)	Adult = 7 Neonatal = 18	0–149 bpm
No CO_2 Alarm (Seconds)	Adult = 30 Neonatal = 20	10–60 seconds
$FiCO_2$ High (mmHg)	8	2–99mmHg
Waveform Time Scale (Seconds)	Adult = 10 Neonatal = 5	5, 10 seconds
PCA Pause Protocol		
Resp. Rate Lower Limit (bpm)	Adult = 5 Neonatal = 14	0–149 bpm
Initial Value (bpm)	Adult = 6 Neonatal = 15	0–149 bpm

NOTE:
Although no limits are associated with the EtCO2 Module, the Guardrails™ Editor software allows you to set an initial configuration for the module. These initial settings can be changed by the clinician.

Instrument Configuration Setting Definitions

This section provides definitions of the configurable settings on the BD Alaris™ System instruments.

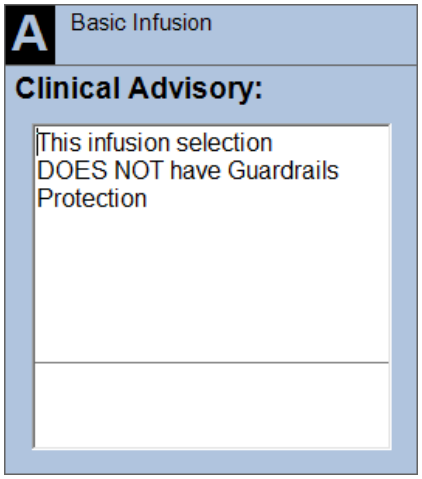
PCU Settings

Setting	Definition
Alarm Audio Profile	Four different alarm patterns can be selected to help differentiate between audio alarms in certain hospital environments. The Profile4 setting provides alarms on the PCU that support standards compliance. Select the desired alarm audio patterns. Press **Test** while the PCU is in Configuration mode to hear a sample of the selected alarm Profile.
Minimum Audio Volume	The lowest audio volume that can be used in a care area Profile. Setting 1 is the softest audio volume setting. Setting 5 is the loudest audio volume setting.
Default Audio Volume	The default audio volume when the PCU is powered on.
Anesthesia Mode	Drugs in each Profile can be set to be accessible only when the BD Alaris™ System is operating in Anesthesia Mode. When Anesthesia Mode is activated, some of the profile settings are overridden: • A channel can be paused indefinitely without an alarm. • The air-in-line associated with the profile can be set for up to 500 microliters. • All limits are set to **Soft**. • All limits are re-established for any new program changes. • Dose Checking Mode is set to **Smart**. • Valid key click audio is **Disabled**. • **Tamper Resistant** mode (panel locked) is not available. • All drug library entries are available for selection. • Bolus dose is available for drugs in the drug library that have bolus dose limits defined and generic drug calculation setup, regardless of configuration settings. • Callback audio for paused channels is permanently silenced. • Review of drug calculation setup page is omitted when restoring a stopped drug calculation. • **Clinical advisories** are not available for Anesthesia Mode and are not displayed.
Battery Meter Display	When Enabled is selected, the instrument displays the remaining battery run time calculated for the current operating conditions.
Color Display	When Enabled is selected, the instrument enables its color screen. This configuration setting does not affect instruments with a monochrome only display.

PCU Settings (Continued)

Setting	Definition
Limit Checking	Limit Checking has two selectable options: The **Always** option causes an alert to occur each time a dose limit is exceeded. The drug label on the Channel Message display provides an indicator (--- or LLL) that the infusion is beyond the current soft limit. The **Smart** option causes an initial alert to occur when a dose limit is exceeded. Subsequent programming beyond the dose limit does not receive an alert. The drug label on the Channel Message display provides an indicator (--- or LLL) that the infusion is beyond the current soft limit.
Key Click Audio	Provides an audible sound with each valid key press. Invalid key press audio is louder than Valid key press and cannot be disabled.
Max Patient BSA (m^2)	Sets maximum patient body surface area.
Max Patient Weight	Sets maximum patient weight.
Patient ID Entry	A patient ID (up to 16 characters) can be entered and displayed. • When enabled, the clinician is prompted to enter a Patient ID in the ID Entry dialog box when the conditions on the BD Alaris™ System indicate that device is being used on a new patient. • When disabled, the ID Entry dialog box is only accessible from the System Options dialog box.
Preventive Maintenance Reminder	This feature displays a reminder when the Preventive Maintenance Date for the PCU has been reached. When enabled, the Preventive Maintenance Reminder is displayed. When disabled, the Preventive Maintenance Reminder is not displayed.

PCU Settings (Continued)

Setting	Definition
Tamper Resistant	This feature provides a quick one-touch lockout of the front panel keypad for all attached modules and the PCU.
Authorized User Mode	This feature combines PCU Tamper Resist feature with Auto-ID Module. It is designed to ensure that only clinicians with a bar code on their ID badge can program the BD Alaris™ System. When Authorized User Mode is enabled in Profile configuration settings, PCU automatically enables Tamper Resist mode upon power on and 5 minutes after programming is completed. When Enabled with Override is set as a configuration setting, Authorized User Mode can be temporarily disabled (for 5 minutes) by pressing and holding Tamper Resist Switch. This may be desired for those situations when clinician's ID badge is not available. Authorized User Mode is not available when BD Alaris™ System is in Anesthesia Mode.
No Guardrails™, Basic Infusion Clinical Advisory	When enabled, a clinical advisory message appears on the PCU when Basic primary, Basic secondary, or Drug Calc is selected. This clinical advisory is used to reinforce that there is no Guardrails™ protection for the selection made. A default clinical advisory message is provided and can be edited to meet the hospital's need. The Advisory text will appear in all profiles that have this Advisory feature enabled. Because the PCU display screen uses a variable width font, the number of characters allowed on each line of the clinical advisory message will vary. The total number of characters for all eight lines will vary from 112 to 200 characters. • Press **Edit Text** to change clinical advisory message. • Press **OK** or **Cancel**. 

NOTE:

- Profile 4 audio settings support standards compliance. Setting the Alarm Audio Profile to Profile 4 could potentially result in the BD Alaris™ System alarms sounding similar to other devices, such as respirators and monitoring services that are compliant with the same safety standards.
- To support standards compliance, the Color Display setting must be set to Enabled.

Pump Module Settings

Setting	Definition
Accumulated Air-in-Line	Detects the presence of multiple air bubbles that are too small to be detected by the single bolus AIL detection limit. The volume of air that trips the accumulated air detection limit is a percentage of a specified averaging window volume that is variable based upon the current setting for single air bolus. • For the 50 microliters setting, the air volume that causes an alarm is 0.18mL (1.2mL window volume with 15% air in window volume). • For the 75 microliters setting, the air volume that causes an alarm is 1.1mL (4.4mL window volume with 25% air in window volume). • For the 125 microliters setting, the air volume that causes an alarm is 1.1mL (4.4mL window volume with 25% air in window volume). • For the 175 microliters setting, the air volume that causes an alarm is 1.1mL (4.4mL window volume with 25% air in window volume). • For the 250 microliters setting, the air volume that causes an alarm is 1.82mL (5.2mL window volume with 35% air in window volume). • When operating in Anesthesia Mode with a single bolus air-in-line limit of 500 microliters, the accumulated air detection limit is 2.73mL (7.8mL window volume with 35% air in window volume). **NOTE:** The 500 microliters limit cannot be set in the Guardrails™ Editor software and is only available when the PCU is operating in Anesthesia Mode. When **Disabled** is selected, the Accumulated AIL detection system is turned off for all pump module infusions. When **Enabled** is selected, the Accumulated AIL detection system is turned on for all pump module infusions.

Pump Module Settings (Continued)

Setting	Definition
Air-In-Line	Sets the upper limit for a single bolus of air to pass without alarm. This is the amount of air allowed to pass through the detector before an air-in-line alarm sounds. Air-in-line detection settings can be selected from a list of 5 options: 50, 75, 125, 175, or 250 microliters. The 500 microliters setting is available in Anesthesia Mode only. **WARNING** **Ensure that air-in-line configuration settings are appropriate for the designated care area profile. Failure to do so may increase the risk of clinically significant volumes of air infusing into the patient.** **NOTE:** Configuration setting considerations: • Neonate or NICU: 50 to 75 microliters. • Pediatric (One month to 21 years of age): 75 to 175 microliters. • Adult (Older than 21 years of age): 75 to 250 microliters.
Auto-Restart Attempts	The Auto-Restart feature is part of the BD Alaris™ System's Downstream Occlusion Detection system, designed to minimize nuisance patient side occlusion alarms. It allows the infusion device 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. Qualified service personnel can configure the system to allow 0–9 restart attempts within a rolling 10-minute period. If the allowable number of restarts is exceeded or if the feature is set to 0, an Occluded-Patient Side alarm occurs when the system detects downstream pressure over the pressure limit.
KVO Rate Adjust	Use this option to select the keep vein open (KVO) rate (0.1–20 mL/h allowed). This determines the rate of fluid flow after Infusion Complete has occurred.
Max Occlusion Pressure	This is the patient-side occlusion alarm threshold for the Selectable Pressure Mode. The instrument defaults to this setting when New Patient is selected. This is the maximum allowable value the user can select when in Selectable Pressure Mode. 50–525 mmHg may be selected in 25 mmHg increments.
Default Pressure	Maximum occlusion pressure default pressure. 50–525 mmHg may be selected in 25 mmHg increments and must be less than or equal to maximum occlusion pressure.
Maximum Rate	The maximum rate range is 0.1–999 mL/h. • Volumes of 0.1–99.9 mL/h may be selected in 0.1 mL increments. • Rates of 100–999 mL/h are selected in 1 mL increments.

Pump Module Settings (Continued)

Setting	Definition
Maximum VTBI	The volume-to-be-infused (VTBI) range is 0.1–9,999 mL. • Volumes of 0.1–9.99 mL may be selected in 0.01 mL increments. • Volumes of 10–999.9 mL may be selected in 0.1 mL increments. • VTBIs of 1,000–9,999 mL are selected in 1 mL increments.
Pressure Mode Lock Status	• **Locked**: Only the Default Pressure Mode selection is available to the user. • **Unlocked**: User may select either Pressure Mode.
Pressure Mode Selection	There are two pressure modes available to determine the patient-side occlusion limit. The selected mode is the default setting for the Profile: • **Pump Mode**: Where downstream occlusion alarm threshold is 525 mmHg at flow rates of 30 mL/h or greater. For rates less than 30 mL/h, the occlusion pressure is rate-dependent, to ensure rapid response to occlusions. • **Selectable Pressure Mode**: Where the downstream occlusion alarm threshold can be adjusted by the user in 25 mmHg increments from 50 mmHg up to the value set as the Profile's Maximum Occlusion Pressure
Secondary Infusion	This mode is designed to support automatic secondary infusions (piggybacking) in the same instrument channel. When the secondary VTBI reaches 0, an auditory tone is sounded, 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.
SEC-PRI Audio Alert	When **Enabled** is selected, six audio tones are sounded when the instrument transitions from Secondary to Primary mode.
Delay Start Options	This feature allows the system to be programmed to delay the start of an infusion for up to 11 hours and 59 minutes **Delay for**.
Delay Start Callback (Shared Infusion Settings - Pump & Syringe)	When programming a **Delay for** infusion, a Callback can be scheduled for that infusion. There are three types of Callback: • **Before**: Alerts when delay is completed and infusion needs to be initiated. • **After**: Alerts when delayed infusion has completed. • **Before & After:** Alerts when delay is completed and infusion needs to be initiated and when delayed infusion has completed. The default Callback (**Before & After**), or the Callback for the current Profile appear in the main display. Clinician can schedule a different callback on the Alaris System Delay Options page.

Pump Module Settings (Continued)

Setting	Definition
Drug Calculation (Shared Infusion Settings - Pump & Syringe)	The Drug Calculation mode allows one of the following: • Entry of drug dose (BD Alaris™ System calculated correct flow rate to achieve desired dose). • Entry of flow rate (BD Alaris™ System calculated corresponding drug dose).
Drug Calculation Bolus Dose (Shared Infusion Settings - Pump & Syringe)	This mode allows a bolus infusion to be programmed using either the drug library or the drug calculation feature. The bolus infusion can be programmed with or without a continuous infusion following the bolus.
Pressure Dynamic Display (Shared Infusion Settings - Pump & Syringe)	The Pressure Dynamic Display is located in the Main Display of the PCU, just below the channel status information. If enabled, it graphically displays the current patient-side occlusion pressure set point and the current patient-side operating pressure for that channel.
Volume/Duration (Shared Infusion Settings - Pump & Syringe)	The Volume/Duration infusion option allows a VTBI and duration (infusion time) to be programmed. The flow rate is automatically calculated.

Syringe Module Settings

Setting	Definition
All Mode	When **ALL** is selected as the default VTBI, the entire contents of the syringe is delivered.
Auto Occlusion Pressure	When enabled and a pressure sensing disc is in use, the Auto Pressure option is displayed in the Pressure Limit screen. Auto Pressure automatically sets the 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.
Back-Off After Occlusion	This feature is only available when the administration set in use has a pressure-sensing disc. When enabled, the motor reverses plunger movement during an occlusion until the pressure returns to preocclusion levels, automatically reducing bolus after occlusion.
Fast-Start	When Fast-Start is enabled and an administration set having a pressure sensing disc is used, the instrument runs at an increased rate when an infusion is first started, taking up any slack in the drive mechanism. The net result is that infusions start delivering fluid to the patient within a few seconds, even at very low flow rates.

Syringe Module Settings (Continued)

Setting	Definition
KVO Option	The Selectable KVO option allows some infusions to automatically switch into KVO mode upon completion. The KVO option setting cannot be changed after the instrument is powered on and a Profile selected. If the KVO feature is enabled a reserve of fluid identified by the KVO Rate Adjust is used to administer the KVO infusion. If the intent is to deliver the entire contents of the syringe, the KVO option should be disabled.
KVO Rate Adjust	This option is used to select the KVO rate (0.1–2.5 mL/h). This determines the rate of fluid flow after Infusion Complete has occurred. The KVO Rate shall be less than or equal to the Maximum Rate. **NOTE:** If flow rate is less than 0.1 mL/h with 1 mL or 3 mL syringe, the KVO rate will stay the same rate down to 0.01 mL/h.
KVO Volume Adjust	The KVO trigger volume can be configured at 0.5–5% of remaining fluid volume.
Near End Of Infusion	The near end of infusion (NEOI) option is a configurable alert that indicates that the syringe infusion is nearing a completion of the volume to be infused. The NEOI can be configured separately between continuous type infusions and intermittent infusion.
Continuous, Fluids, Basic	The NEOI option for Continuous, Fluids and Basic infusions allows an alert to be configured to sound before the infusion is completed.
Alert Time (minutes)	The NEOI alert occurs at the configured time (1–60 minutes) A separate alert time can be set between continuous and intermittent infusions.
Intermittent	The NEOI option for Intermittent infusions allows an alert to be configured to sound before the infusion is completed. When NEOI Intermittent is enabled, NEOI for Continuous is automatically enabled.
Alert Time (minutes)	The NEOI alert occurs at the configured time (1–60 minutes). A separate alert time can be set between continuous and intermittent infusions.
NEOI Snooze (Shared Syringe and PCA Setting)	Optional capability to remind users that they have silenced their Near End of Infusion.
Snooze Time — minutes (Shared Syringe and PCA Setting)	The snooze alert can be for every 5, 10, or 15 minutes.
Occlusion Pressure Limit with Disc	With pressure sensing disc, downstream occlusion alarm threshold is selectable between 25 and 1,000 mmHg, in 1 mmHg increments.
Occlusion Pressure Limit No Disc	Without pressure sensing disc, downstream occlusion alarm threshold can be set to Low (200 mmHg), Medium (500 mmHg), or High (800 mmHg)

Syringe Module Settings (Continued)

Setting	Definition
Priming	The Priming option allows a limited volume of fluid to be delivered to prime the administration set prior to being connected to a patient or after changing a syringe. When priming, a single continuous press of the **PRIME** soft key on the PCU delivers up to 2 mL of priming fluid. **WARNING** **Ensure that Priming is enabled for the Syringe Module. Failure to do so prevents the clinician's ability to use the Prime Set with Syringe feature on the PCU to decrease pump mechanical slack. This can delay the infusion delivery startup time and lead to delivery inaccuracies.**
Delay Start Options (Shared Infusion Settings - Pump & Syringe)	This feature allows the system to be programmed to delay the start of an infusion for up to 11 hours and 59 minutes **Delay for**.
Delay Start Callback (Shared Infusion Settings - Pump & Syringe)	When programming a **Delay for** infusion, a Callback can be scheduled for that infusion. There are three types of Callback: • **Before**: Alerts when delay is completed and infusion needs to be initiated. • **After**: Alerts when delayed infusion has completed. • **Before & After**: Alerts when delay is completed and infusion needs to be initiated and when delayed infusion has completed. The default Callback (**Before & After**), or the Callback for the current Profile appear in the main display. Clinician can schedule a different callback on the BD Alaris™ System Delay Options page.
Drug Calculation (Shared Infusion Settings - Pump & Syringe)	The Drug Calculation mode allows one of the following: • Entry of drug dose (BD Alaris™ System calculated correct flow rate to achieve desired dose). • Entry of flow rate (BD Alaris™ System calculated corresponding drug dose).
Drug Calculation Bolus Dose (Shared Infusion Settings - Pump & Syringe)	This mode allows a bolus infusion to be programmed using either the drug library or the drug calculation feature. The bolus infusion can be programmed with or without a continuous infusion following the bolus.

Syringe Module Settings (Continued)

Setting	Definition
Pressure Dynamic Display (Shared Infusion Settings - Pump & Syringe)	The Pressure Dynamic Display is located in the Main Display of the PCU, just below the channel status information. If enabled, it graphically displays the current patient-side occlusion pressure set point and the current patient-side operating pressure for that channel.
Volume/Duration (Shared Infusion Settings - Pump & Syringe)	The Volume/Duration infusion option allows a VTBI and duration (infusion time) to be programmed. The flow rate is automatically calculated.
Maximum Rate (Shared Infusion Settings - PCA & Syringe)	The maximum rate that can be infused. Range 0.1–999 mL/h. • 0.1–9.9 in 0.01 mL/h increments. • 10–99.9 in 0.1 mL/h increments. • 100–999 in 1 mL/h increments.

Shared Infusion Settings (Pump and Syringe Modules)

Setting	Definition
Delay Start Options	This feature allows the system to be programmed to delay the start of an infusion for up to 11 hours and 59 minutes **Delay for**.
Delay Start Callback	When programming a **Delay for** infusion, a Callback can be scheduled for that infusion. There are three types of Callback: • **Before**: Alerts when delay is completed and infusion needs to be initiated. • **After**: Alerts when delayed infusion has completed. • **Before and After:** Alerts when delay is completed and infusion needs to be initiated and when delayed infusion has completed. The default Callback (**Before & After**), or the Callback for the current Profile appear in the main display. Clinician can schedule a different callback on the BD Alaris™ System Delay Options page.
Drug Calculation	The Drug Calculation mode allows one of the following: • Entry of drug dose (BD Alaris™ System calculated correct flow rate to achieve desired dose). • Entry of flow rate (BD Alaris™ System calculated corresponding drug dose).
Drug Calculation Bolus Dose	This mode allows a bolus infusion to be programmed using either the drug library or the drug calculation feature. The bolus infusion can be programmed with or without a continuous infusion following the bolus.
Pressure Dynamic Display	The Pressure Dynamic Display is located in the Main Display of the PCU, just below the channel status information. If enabled, it graphically displays the current patient-side occlusion pressure set point and the current patient-side operating pressure for that channel.
Volume/Duration	The Volume/Duration infusion option allows a VTBI and duration (infusion time) to be programmed. The flow rate is automatically calculated.

Shared Infusion Settings (PCA and Syringe Modules)

Setting	Definition
Maximum Rate	The maximum rate that can be infused. Range 0.1–999 mL/h. • 0.1–9.9 in 0.01 mL/h increments. • 10–99.9 in 0.1 mL/h increments. • 100–999 in 1 mL/h increments.
NEOI Snooze (Shared Syringe and PCA Setting)	An optional alert that provides an audio-only tone when a Near End of Infusion alert has been previously silenced. This alert can be configured to give an audio-only tone every five, 10 or 15 minutes.

PCA Module Settings

<table>
<tr><th>Setting</th><th colspan="4">Definition</th></tr>
<tr><td>Bolus Delivery Rate (mL/h)</td><td colspan="4">The rate at which PCA, Bolus, and Loading Doses is infused.</td></tr>
<tr><td rowspan="7">Dose Request Cord (Profiles)</td><td colspan="4">Dose Request Cord Profile—The Dose Request Cord can be configured to provide both audio and visual (LED indicator) notification to the patient in response to requesting a dose.
One of these three Profiles can be selected:</td></tr>
<tr><td></td><td>Profile 1</td><td>Profile 2</td><td>Profile 3</td></tr>
<tr><td>Dose Request Cord Audio - Single Beep</td><td>Met demands only</td><td>All Demands</td><td>All Demands</td></tr>
<tr><td colspan="4">Dose request Cord LED Indicator:</td></tr>
<tr><td>PCA Available</td><td>ON</td><td>ON</td><td>OFF</td></tr>
<tr><td>PCA Delivery</td><td>ON - FLASHING</td><td>ON</td><td>OFF</td></tr>
<tr><td>Lockout Interval</td><td>OFF</td><td>ON</td><td>OFF</td></tr>
<tr><td>Max Dose Limit (Max Accumulated Dose Limit)</td><td colspan="4">Optional configuration that limits total amount of drug allowed to be delivered to the patient in a defined time period (1, 2, or 4 hours).
NOTE:
• This setting should be configured in the data set before the drug library is developed. After drugs are in the Profile PCA Drug Library, the Max Accumulated Dose Limit cannot be changed.
• This optional setting applies to all drug setups within the Profile PCA Drug Library.</td></tr>
<tr><td>Time Window (h)</td><td colspan="4">1, 2, or 4 hours</td></tr>
<tr><td>Module Location Enforcement</td><td colspan="4">Tamper resistant security feature that ensures the PCA Module is in a tamper evident position. When enabled, PCA Module must be located to the direct right of the PCU before programming an infusion.</td></tr>
</table>

PCA Module Settings (Continued)

<table>
<tr><th>Setting</th><th>Definition</th></tr>
<tr><td>Near End of Infusion (NEOI)</td><td>The NEOI option allows an audio alert to be configured based on a percentage of the syringe size.</td></tr>
<tr><td>NEOI Alert</td><td>The alert time can be set to occur when 5–25% of the syringe size is remaining.</td></tr>
<tr><td>NEOI Snooze (Shared Syringe and PCA Setting)</td><td>An optional alert that provides an audio-only tone when a NEOI alert has been previously silenced. This alert can be configured to give an audio-only tone every five, 10 or 15 minutes.</td></tr>
<tr><td>Maximum Rate (Shared Syringe and PCA Setting)</td><td>The maximum rate that can be infused. Range 0.1–999 mL/h.
• 0.1–9.9 in 0.01 mL/h increments.
• 10–99.9 in 0.1 mL/h increments.
• 100–999 in 1 mL/h increments.</td></tr>
<tr><td>Pressure Limit</td><td>Downstream occlusion alarm threshold can be set to Low (200 mmHg), Medium (500 mmHg), or High (800 mmHg).
NOTE:
Syringe variability may impact occlusion pressure sensing. The variability may reduce the device's time to alarm and/or may require that a higher alarm pressure limit be programmed.</td></tr>
<tr><td>Priming</td><td>The Priming option allows a limited volume of fluid to be delivered to prime the administration set prior to being connected to a patient or after changing a syringe. When priming, a single continuous press of the PRIME soft key delivers up to 2 mL of priming fluid.

  WARNING
Ensure that Priming is enabled for the PCA Module. Failure to do so prevents the clinician's ability to use the Prime Set with Syringe feature on the PCU to decrease pump mechanical slack. This can delay the infusion delivery startup time and lead to delivery inaccuracies.</td></tr>
<tr><td>Security Access Level</td><td>The Profile-specific 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 four-digit authorization code.
<table>
<tr><th>Security Access Level</th><th>Initial Programming</th><th>Setting Bolus Dose</th><th>Subsequent Programming</th></tr>
<tr><td>Level 1</td><td>Key</td><td>Key</td><td>Key</td></tr>
<tr><td>Level 2</td><td>Key</td><td>Code or Key</td><td>Key</td></tr>
<tr><td>Level 3</td><td>Key</td><td>Code or Key</td><td>Code or Key</td></tr>
</table></td></tr>
<tr><td>Security Code</td><td>Four-character code provided to clinicians to access the PCU for setting bolus doses and subsequent programming changes. Ability to use Profile-specific code is dependent upon the configured Security Access Level.</td></tr>
</table>

PCA Pause Protocol

Setting	Definition
PCA Pause Protocol Enabled (Available for $EtCO_2$)	PCA pause protocol can be enabled for the $EtCO_2$ Module. When PCA pause protocol is enabled, the PCA pauses upon exceeding and sustaining the PCA pause protocol alarm limits established for the $EtCO_2$ Module. Once PCA Pause Protocol is enabled, you are allowed to enter PCA/Monitoring Alarm Limits for Low Respiratory Rate and the default or initial alarm value. See $EtCO_2$ Module settings to establish the PCA pause protocol alarm limits.
Monitoring Module Attach Enforcement	This feature allows the facility to provide a notice to the user to attach the monitoring module $EtCO_2$ for the PCA pause protocol features to be enabled. When enabled, the user must attach the applicable monitoring module, or modules, prior to moving forward with PCA programming.
PCA Pause Protocol (Text Message)	This text alarm notice alerts the user that PCA infusion has paused. This default text alarm message is recommended but editable to enforce hospital protocol. The default alarm text reads: *PCA infusion has paused due to decline in respiratory status. Check patient!* The PCA Pause Protocol message on PCU displays one line for the header and has remaining 7 lines for the PCA Pause Protocol message.
Edit Text	Press this key to edit the default PCA pause protocol Alarm message text.

$EtCO_2$ Module Settings

Setting	Definition
Alarm Limit Type	Enable/Disable for Adult/Neonatal.
EtCO2 High (mmHg)	High default alarm limit for EtCO2.
EtCO2 Low (mmHg)	Low default alarm limit for EtCO2.
Respiratory Rate High	High default alarm limit for Resp. Rate.
Respiratory Rate Low	Low default alarm limit for Resp. Rate.
No CO_2 Alarm (Seconds)	The period of time no CO_2 can be detected before an alarm.
$FiCO_2$ High (mmHg)	High default alarm limit for Fraction of Inspired CO_2.
Waveform Time Scale (Seconds)	The amount of waveform time (in seconds) displayed on the EtCO2 Main display.

PCA Pause Protocol Enabled for $EtCO_2$ Module

Setting	Definition
PCA Pause Protocol	The following parameters can be set if PCA pause protocol is enabled: • **Resp. Rate Lower Limit (bpm)** — This value represents the lowest alarm value established by hospital protocol. This value is not editable by the user. • **Initial Value (bpm)** — This is the default alarm value established by hospital protocol. If this value is reached, the PCA infusion will pause and alarm. This default value must be higher than the Resp. Rate Lower Limit and is editable by the user.

Chapter 18
Data Set Status

This section contains the following topics:

Overview

A data set can exist in one of three status categories: Draft, Approved, or Released.

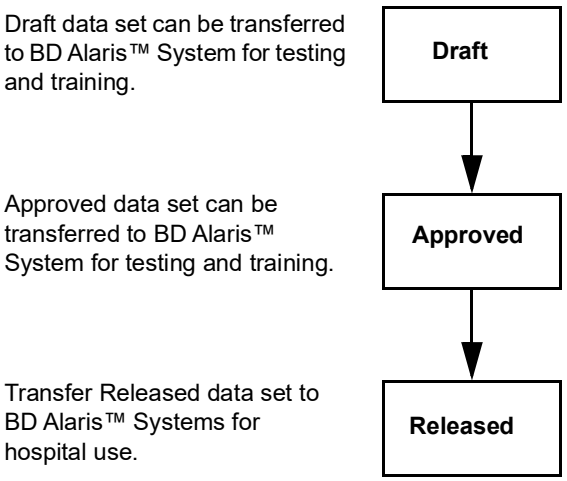
Data Set Category	Description
Draft	Not reviewed and/or approved.
Approved	Reviewed and approved.
Released	Approved and ready for use as the hospital's data set.

WARNING

Transfer only released data sets to devices that are used on patients. Data sets in draft or approved status may have unreviewed or incorrect data leading to over or under infusion and should only be used for interface testing and/or training purposes.

NOTE:
Before being released, draft or approved data sets can be transferred to the BD Alaris™ System for user interface testing or clinical training. When a data set is transferred to the Alaris system, a draft or approved data set automatically causes the PCU to display **This Device is Not for Human Use**.

Data Set Status



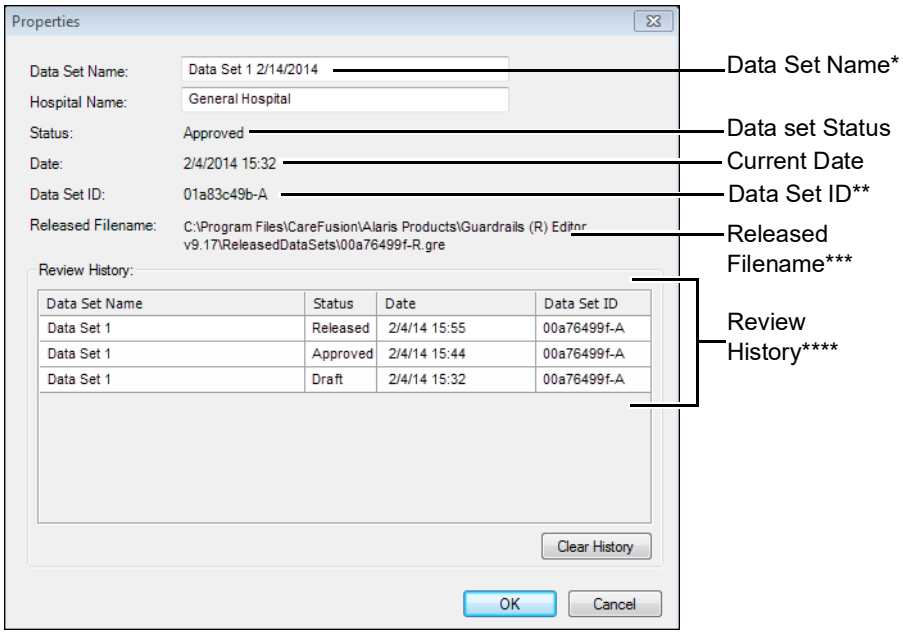
Updating Data Set Status

This procedure describes how to update data set status in the Guardrails™ Editor.

If a data set other than the current one is to be updated, click **File** > **Open** in the menu bar, and select a data set to open.

1. In the menu bar, click **File** > **Properties**.

   The Properties dialog box appears.



* The data set name appears in the upper-left corner of the PCU display when the data set is transferred.

** The Data Set ID is auto-assigned by the software when the data set is created. The ID includes a suffix of D, A, or R indicating status of Draft, Approved, or Released.

*** The Released Filename is auto-assigned and auto-saved to this location when released.

**** The Review History provides historical information about the Data Set Name, Status, Date, and the Data Set ID.

NOTE:

- The data set name that is displayed on PCU is distinct from the data set released filename and the data set filename on your computer.
- We recommend that you create a new data set name each time a new version of the data set is released by adding a unique identifier (for example, Mission Hospital-A or Mission Hospital v2).

NOTE:

- If changes are made to an approved or released data set, the data set reverts to Draft status.
- The Approval Report auto-generates when the data set status is changed to Approved.

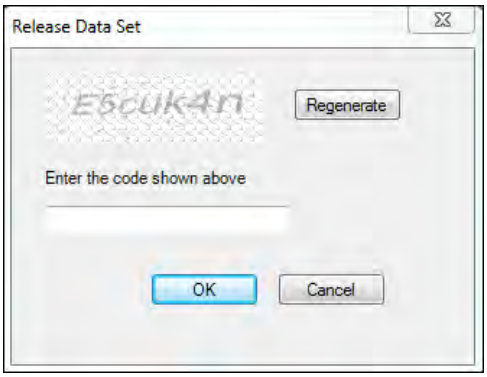
2. Edit the **Data Set Name** and **Hospital Name**, if desired and click OK.
3. To promote to Approved status, click **File** > **Approve Data Set** in the menu bar.

NOTE:

- The Data Set Approval report is generated automatically when the data set status is set to *Approved*. If the data set is approved, you can regenerate the report by selecting **Reports** > **Generate Report**. The data set approval report is generated and opens on your computer screen as an .rtf file. After the data set status is promoted to Released, this report is no longer available to generate.
- Some .rtf file editors are not able to support the formatting and graphics produced by the Guardrails™ Editor. For best results, use Microsoft™ Word.

4. To promote from Approved to Released status, click **File** > **Release Data Set** in the menu bar.

   The Release Data Set dialog box appears.



5. Enter the code displayed in the text box (case-sensitive).

   If the code appears too distorted to read, click **Regenerate** for another code.

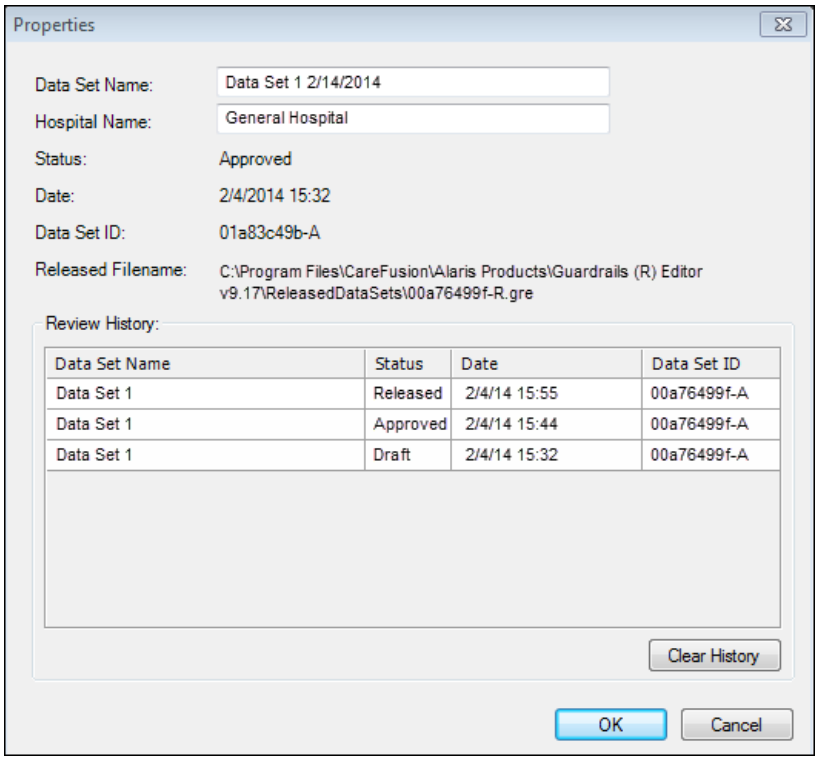
6. Click **OK**.

   The data set status is changed to Released. The released data set is automatically exported to the location entered on the Properties dialog box.

Reviewing Data Set History

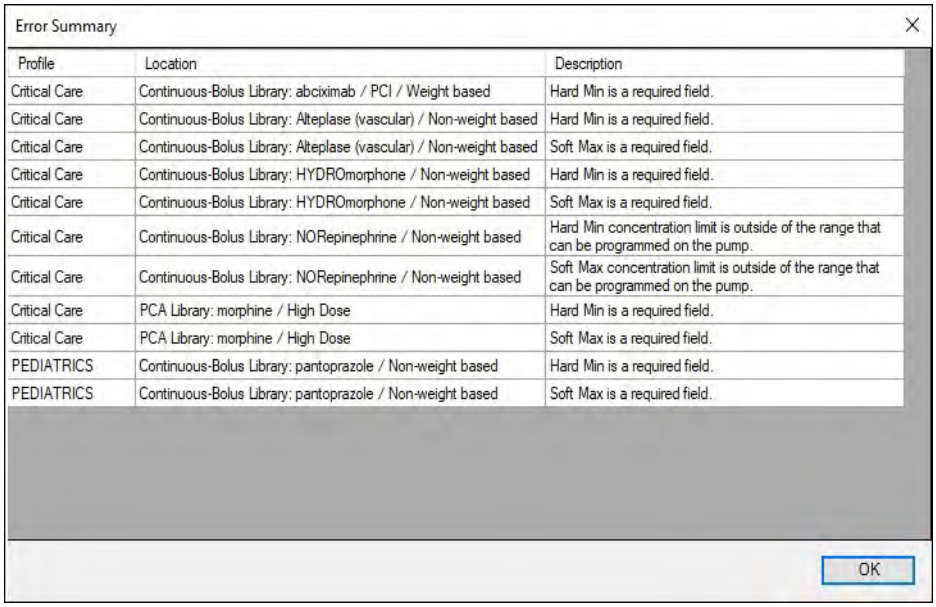
The history of changes is tracked in the Review History panel of the Properties dialog box. Previous versions do not exist in the history and can only be accessible if they have been exported and saved.

To delete the review history data and clear the display, click **Clear History** on the Data Set Review dialog box.



Error Summary

A warning icon appears next to your data set status indicator on the lower right side of the screen to indicate an error in the data set. To see a summary of errors preventing data set promotion, select **Tools** > **Error Summary**. This window can remain open while data set errors are fixed.



Chapter 19
Data Set Report

This section contains the following topics:

Overview

You can use the Guardrails™ Editor to produce reports to help manage the data set and support hospital quality initiatives. Reports can be viewed and printed.

You must have Microsoft™ Word or an RTF reader application installed to be able to view Word reports. If not, the system displays an error message.

You must have Microsoft™ Excel installed to view Excel reports, or the system displays an error message.

Word 2013 and Excel 2013 and later are supported.

See *Software Installation on page 2* for the correct Excel and Word version requirements.

NOTE:

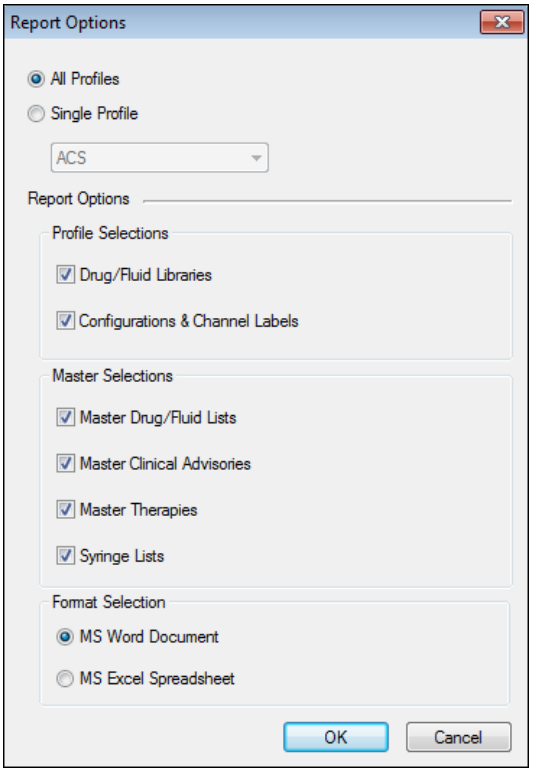
- Some RTF file editors are not able to support the formatting and graphics produced by the Guardrails™ Editor. For best results, use Microsoft™ Word. Guardrails™ Editor displays an error message if it detects that Microsoft™ Word is not installed. This occurs whether or not another RTF reader is installed.
- A Word Document report will display the commas that are inserted for values above 999.9.
- Reports available in Microsoft™ Excel can be sorted and filtered.
- The Data Set Approval report is generated automatically in Word when the data set status is set to *Approved*. If the data set status is approved, you can regenerate the report by selecting **Reports** > **Generate Report**. The data set approval report opens on your computer as an RTF file. After the data set status is promoted to Released, this report is no longer available.

Generating a Data Set Report

Selectable data set reports are available for data sets with draft, approved, or released status.

1. In the menu bar, click **Reports** > **Generate Report.**

   The Report Options dialog box appears. (User-selectable reports are not available for Approved status data sets.)



2. Select **All Profiles** or **Single Profile**.
3. If you selected **Single Profile**, select the profile from the drop-down list.
4. Under Profile Selections or Master Selections, select or clear the check boxes for the desired report sections.
5. Select the report format under Format Selection:
   - MS Word Document or MS Excel Spreadsheet
6. Click **OK**.

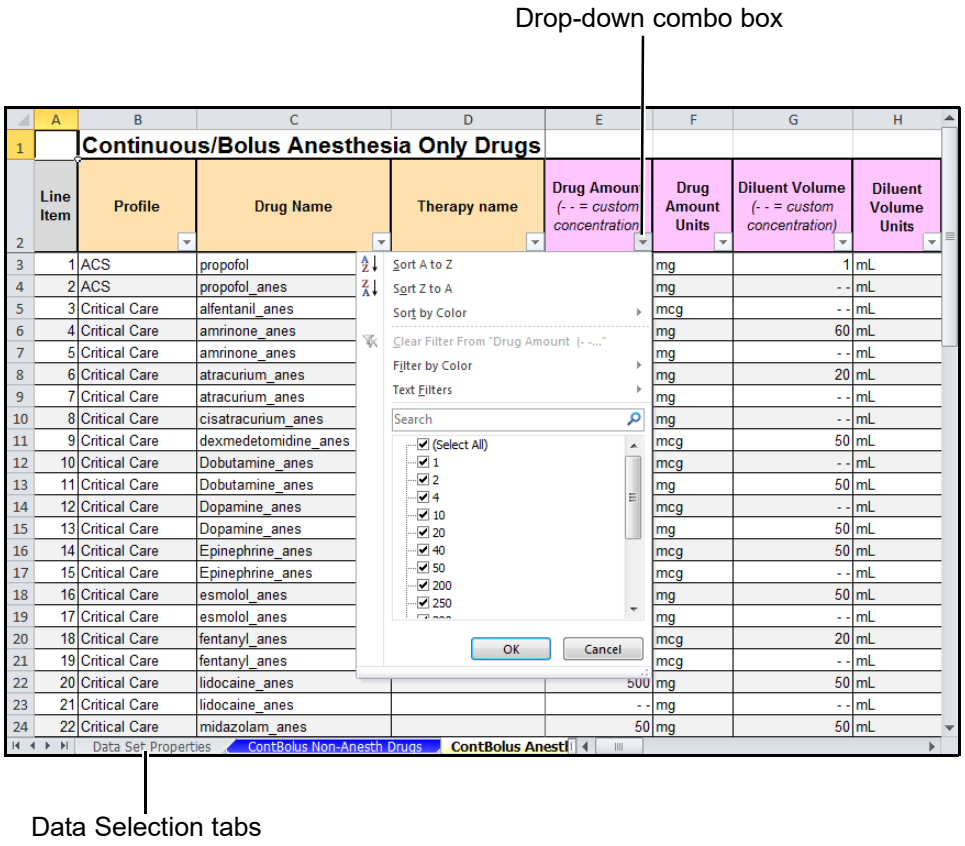
   The Generating Report dialog box shows that the report is being generated. The report is generated in a new window as a Microsoft™ Word RTF or Excel file with a unique file name.
7. View and print the file using Microsoft™ Word, an RTF application, or Excel.

NOTE:

- To avoid the possibility of printing incorrect page numbers, set Update Fields to update before printing. In Microsoft™ Word, click **Print** > **Print Preview** > **Options**. Under Printing options, select the Update fields check box.
- Once run, reports are auto-archived, which allows you to track history. In Guardrails™ Editor, go to the General tab under **Tools** > **Options** to see or set the archive location.

Excel Spreadsheet Report Example

The Excel spreadsheet report is formatted to allow data to be sorted. Colored tabs highlight the data set components. See the example below.



NOTE:
The Continuous/Bolus Non Anesthesia and Anesthesia drugs tabs will have a cell comment in the Conc Limit Units (AA) when the Units Only concentration (custom concentration) and Dosing Units have a different unit of measure.

NOTE:

- For configuration setting text: True = enabled and False = disabled.
- When formatting numbers in Excel, the use of the Use 1000 Separator(,) command is not recommended.

Filtering for Units Only Concentrations (Custom Concentrations) with No Hard Minimum Concentration Limits

Filtering for Units Only Concentrations (Custom Concentrations)

1. Select **Library** tab.
2. Select filter box for Drug Amount.
3. Clear all selections and select custom drug amount ("--").
4. Click **OK**.

Filtering for No Hard Minimum Concentrations

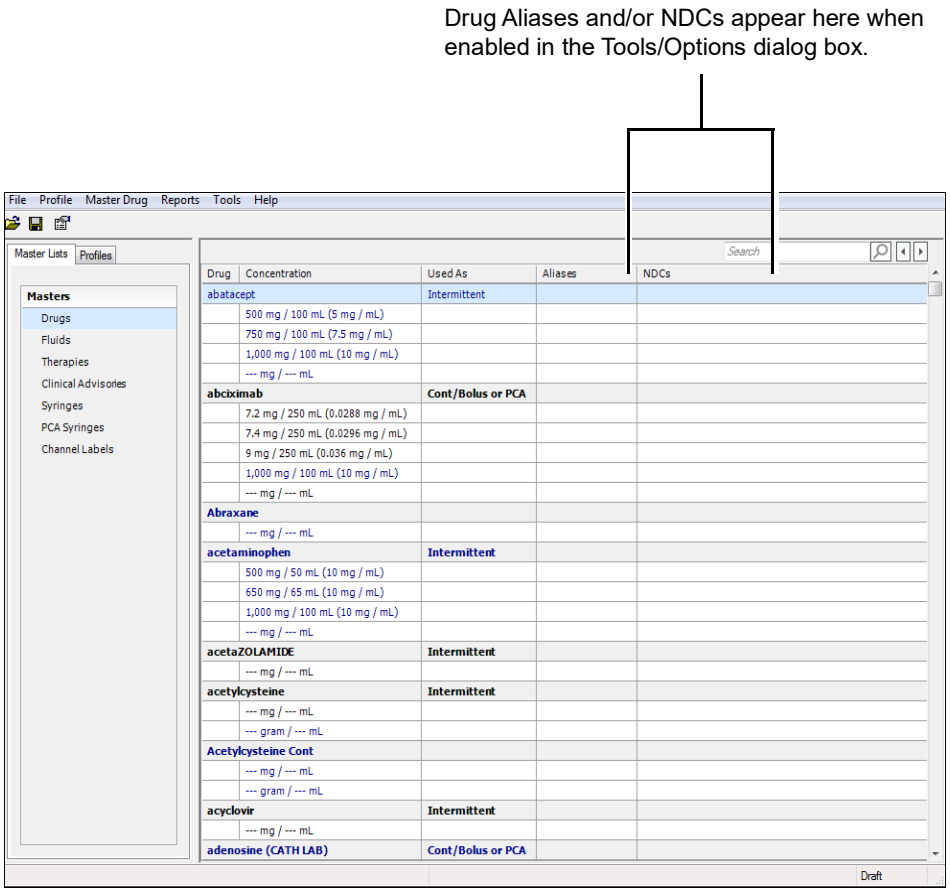
1. Scroll to the Conc. Limits Hard Min column.
2. Select the filter box.
3. Clear all selections and select **(Blanks)**.
4. Click **OK**.
5. Repeat for the other drug library tabs.

Chapter 20
Master Drug List – Aliases and NDCs

This section contains the following topics:

Overview

If Aliases and/or NDCs have been enabled in the **Tools** > **Options** menu, they can be entered in the master drug list and the master fluids list.



Type	Description
Aliases	Five entries are allowed for each drug name (1-12 characters).
NDCs	Three entries are allowed for each drug name and associated concentration (10-digits, optionally separated by two dashes). Must be unique for each concentration.

Working with Aliases and NDCs—Master Drug List

Aliases and NDCs can be added or edited when adding or editing drugs, concentrations, or fluids in the master lists.

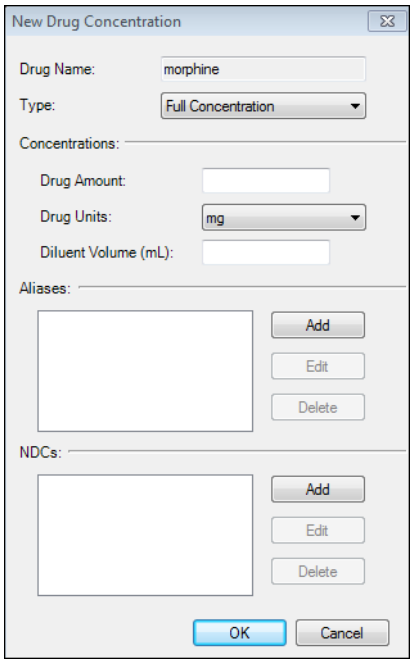
- Created, edited, or deleted from the data set at the master list level.
- Added to a new drug setup or concentration at the profile drug library level and profile fluids library level.

Adding a New Drug or Fluid with an Alias and NDCs

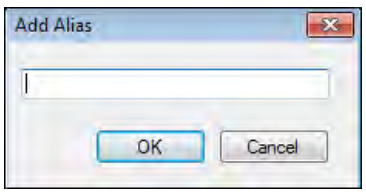
NDC must be between 1-10 digits and unique for each concentration. The 10-digit NDC code can optionally be separated by two dashes. The length of an alias must be 1-12 characters.

When enabled in the **Tools** > **Options** menu, the New Drug and New Fluid dialog boxes include blank panels for Aliases and NDCs.

1. Enter the required **Drug Name** and **Concentration** information, or add a **Fluid Name** if you are adding a Fluid.



2. Click **Add** next to the Aliases or NDCs dialog box to display the Add Alias or Add NDC dialog box.



3. Enter an Alias or NDC for this concentration, and click **OK**.

   The new Alias or NDC appears in the list in the New Drug dialog box.

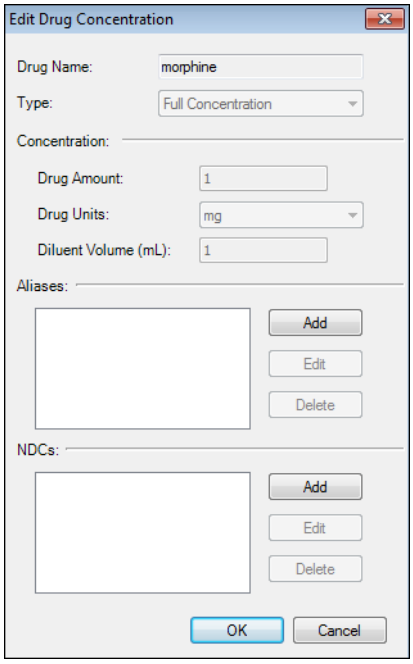
4. To add the new information and close the dialog box, click **OK**.

Adding an Alias and NDC to an Existing Drug Concentration

This procedure describes how to add an alias and NDC to an existing drug concentration in the Guardrails™ Editor software.

1. In the Drugs Master List, right-click the desired concentration and click **Edit Conc**.

   The Edit dialog box lists any current Aliases and NDCs for this concentration.



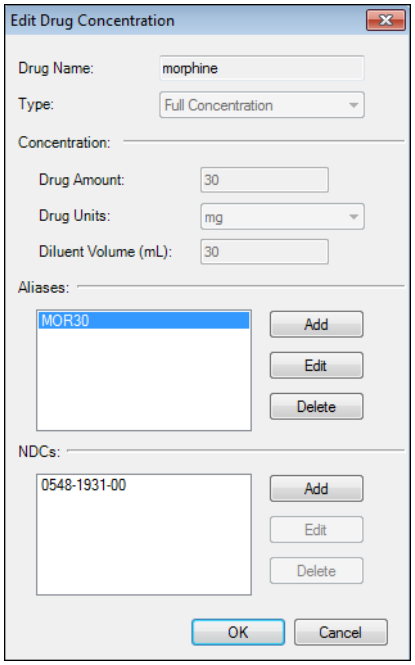
2. Click **Add** next to the Aliases or NDCs dialog box to display the Add Alias or Add NDC dialog box.
3. Enter a new Alias or NDC for this concentration, and click **OK**.

   The new Alias and NDC appears in the Aliases list in the Edit Drug Concentration dialog box.
4. Click **OK**.

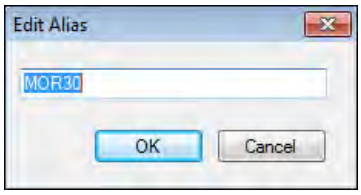
Editing an Alias or NDC

This procedure describes how to edit an alias or NDC in the Guardrails™ Editor software.

1. Select an Alias or NDC to edit.



2. Click **Edit**.
3. The Edit Alias or Edit NDC dialog box appears.



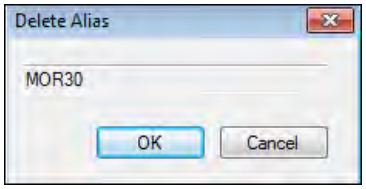
4. Edit the Alias or NDC, and click **OK**.

   The revised Alias appears in the Aliases list in the dialog box.
5. To update the master drug list and close the dialog box, click **OK**.

Deleting an Alias or NDC

This procedure describes how to delete an alias or NDC in the Guardrails™ Editor software.

1. From the Master Drug List, select **Concentration**, and select **Edit Conc**.
   The Edit Drug Concentration dialog box lists any current Aliases for this concentration.
2. Select an Alias or NDC to delete.
3. Click **Delete.**
   The Delete Alias or Delete NDC dialog box appears.



4. To delete the item from the master drug list and close the dialog box, click **OK**.
5. To close the Edit Drug Concentration dialog box, click **OK**.

Working with Aliases—Profile Drug Library

Adding an Alias or NDC While Adding a New Concentration

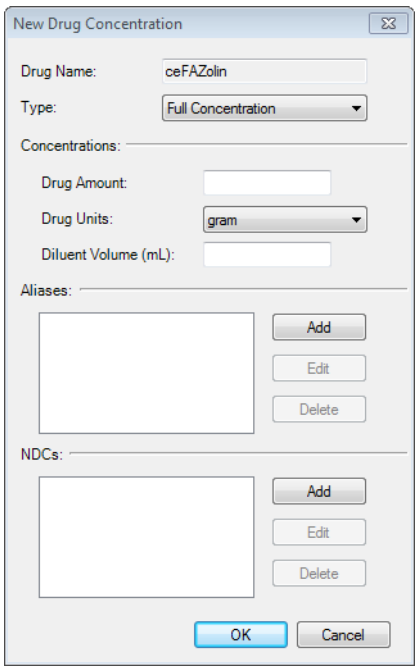
This procedure describes how to add an alias or NDC while adding a new concentration in the Guardrails™ Editor software.

1. In the Profile Drug Library, select a drug name, right-click the selected name and click **Add/Edit Setup**.

   The Setup Group dialog box appears.

2. In the menu bar, click **Concentration** > **New**.

   The New Drug Concentration dialog box appears.



3. Enter new concentration information.
4. Click **Add** next to the Aliases or NDC display box.

   The Add Alias or New NDC dialog box appears.

5. Enter a new Alias or NDC for this concentration, and click **OK**.

   The new Alias or NDC appears on the New Concentration dialog box.

6. Click **OK**.
7. To close the Setup Group dialog box, click **OK**.

Chapter 21
BD Alaris™ Guardrails™ Editor Transfer Tool

This section contains the following topics:

Overview

The Guardrails™ Editor Transfer Tool allows a data set to be transferred to the PCU. The Guardrails™ Editor Transfer Tool can be used to clear an existing data set from the PCU.

Prompt cycles every 3 seconds

NOTE:

- Draft and approved data sets can be transferred for training or clinical interface testing purposes. **This Device is Not for Human Use** displays on the PC unit screen when a draft or approved data set is loaded.
- Released data sets are only used after they are approved by the hospital and are ready for human use.

WARNING

Transfer only released data sets to devices that are used on patients. Data sets in draft or approved status may have unreviewed or incorrect data leading to over or under infusion and should only be used for interface testing and/or training purposes.

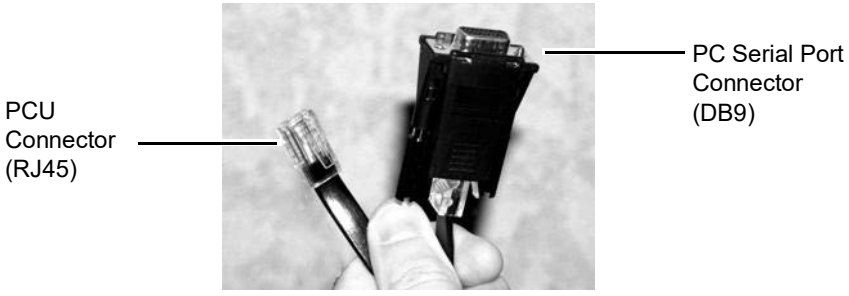
NOTE:

- If using Total Guardrails Infusions as Guardrails™ compliance measures, it is recommended that new data sets are transferred during the third through the sixth day of the month to optimize capture of infusion data.
- A transferred data set becomes active on a PCU only when the unit is power cycled and **Yes** is selected for a new patient.

Connecting a Computer to the BD Alaris™ System

This procedure describes how to connect the computer to the BD Alaris™ System in the Guardrails™ Editor software.

1. Connect the communications cable (RJ45 connector) to the communication port on the back of the PCU.
2. Connect the other end of the cable to an open serial port on the computer or a USB to serial port adapter. See *System Requirements on page 2* for information on the approved USB to serial port adapter.
3. Turn on the PCU.
4. If a data set exists in the PCU, select **New Patient**, and select a **Profile** if prompted.



Communications Cable

NOTE:
A data set cannot be transferred if the PCU is in maintenance mode.

Using the Guardrails™ Editor Transfer Tool

This section describes how to use the Guardrails™ Editor Transfer Tool in the Guardrails™ Editor software.

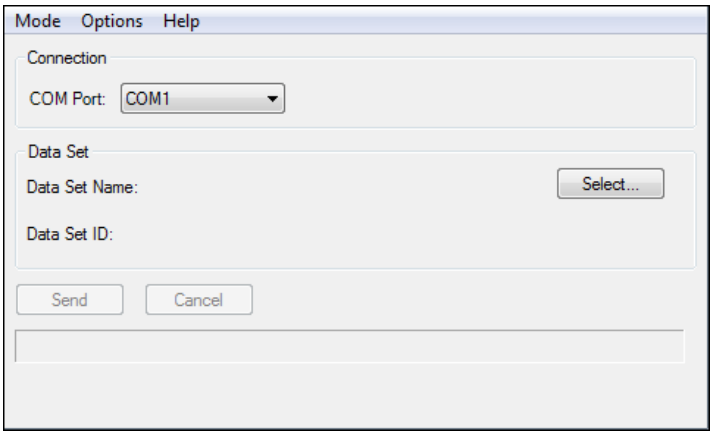
NOTE:
The transfer tool can be used to transfer data sets produced with Guardrails™ Editor v12.1.3 to PCU v12.3.1. The transfer tool can also be used to transfer older version data sets under the following conditions:

Data set version produced by Guardrails™ Editor	Transfers to PCU software version
Version 12.1.3	PCU v12.1.x and v12.3.1
Version 12.1.2	PCU v12.1.x and v12.3.1
Version 9.33	PCU v9.33, v12.1.x, and v12.3.1

Starting the Guardrails™ Editor Transfer Tool

1. Select **Start** > **All Programs** > **Alaris™ System** > **Guardrails™ Editor v12.1.3** > **Guardrails™ Editor v12.1.3 Transfer Tool**, or select the **Guardrails™ Editor v12.1.3 Transfer Tool** icon to open the Guardrails™ Editor Transfer Tool from the Windows desktop.

   The main dialog box appears.



2. From the COM Port drop-down list, select the PC COM Port to use to communicate with the PCU.

   NOTE:
   All available communication ports are displayed in ascending numerical order. If you select a port, it remains the selected port until you change it.

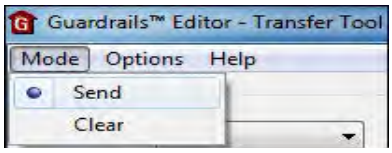
Connecting Multiple PCU

The Guardrails™ Editor Transfer Tool supports up to four PC COM ports, enabling a maximum of four PCU to be connected concurrently. To use this feature, start multiple instances of the Guardrails™ Editor Transfer Tool on the computer and assign a different available COM port to each instance.

Transferring a Data Set by Using Send Mode

The Mode menu provides two options: Send or Clear. Use the send mode when transferring a data set to the PCU.

The Guardrails™ Editor Transfer Tool is set to **Send** when the application starts.

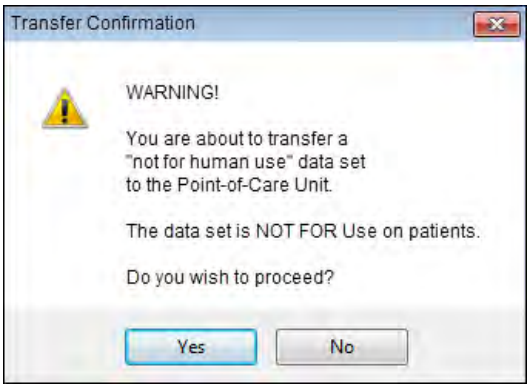


1. If the application is set to **Clear**, change it back to **Send** in the Mode menu.
2. Click **Select** to select a data set for transfer.

   The Select File dialog appears.
3. Select a **Data Set Name** from the list, or click **Browse** to browse for a data set file.

   After a data set is selected, the Data Set Name and Data Set ID appears.
4. To select the data set for transfer, click **OK**.
5. Click **Send** from the Guardrails™ Editor Transfer Tool main dialog box to begin transferring the data set to the connected PCU.

   When transferring a draft or approved (unreleased) data set, the following Transfer Confirmation warning is displayed:



6. Press **Yes** to proceed.

   A blue status bar displays during transfer and turns green when the transfer has completed successfully.

WARNING

Transfer only released data sets to devices that are used on patients. Data sets in draft or approved status may have unreviewed or incorrect data leading to over or under infusion and should only be used for interface testing and/or training purposes.

NOTE:
Larger data sets increase transfer time.

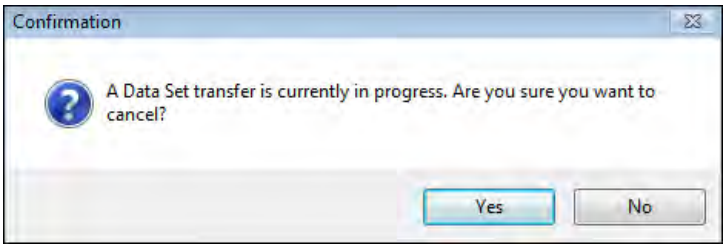
If the transfer is unsuccessful, one of the following error messages appears:

Error Condition	Error Message
Data set validation error	Data set validation error (error code)
Failed to connect	Error connecting to the device
Incompatible software version on target device	File name of the data set version is incompatible with software on connected PCU
Invalid data set format	File name is not a valid data set
Invalid data set version	File name of the data set version is incompatible with this tool
Transfer interrupted	Error sending data set

Canceling a Transfer in Progress

1. To cancel an in-progress transfer in the Guardrails™ Editor software, click **Cancel**.

   The Confirmation message box appears.



   Canceling a transfer in progress requires that the data set be transferred again to the PCU. The cancellation cannot be undone.

2. To cancel transfer, click **Yes**, or, to continue transfer, click **No**.

   If a transfer is Canceled, the Guardrails™ Editor Transfer Tool displays the status as: *Status: Transfer Canceled*.

Clearing a Data Set from the BD Alaris™ System

The current data set in the BD Alaris™ System can be deleted from the connected PCU.

1. Select **Mode** > **Clear**.

   A bullet appears next to the Clear menu option to indicate that clear data set is active.

   The Send button changes to the **Clear** button on the Guardrails™ Editor Transfer Tool dialog box.

2. Click **Clear** to begin clearing the data set from the connected PCU.

   When the data set has been cleared, the blue progress bar turns green and *Clear Successful* appears at the bottom of the dialog box.

   The cleared data set is inactive until the PCU is power cycled and New Patient is selected.

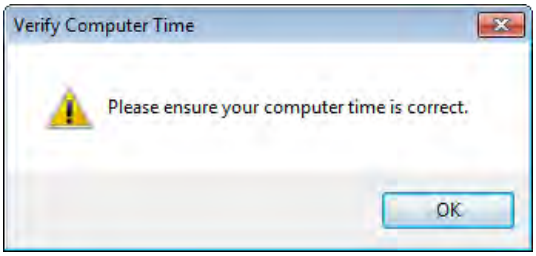
   NOTE:
   The Clear Data Set option remains active until it is turned off by selecting the **Mode** > **Send** menu item, or until the Guardrails™ Editor Transfer Tool software is restarted.

Updating the PCU's Date and Time Automatically

The date and time on the PCU can be reset automatically to the setting on the computer when the data set is transferred.

1. Select **Options** > **Auto Update Date/Time**.

   A message box prompts you to ensure that the time on the computer is correct.



   A bullet appears next to the Auto Update Date/Time menu option to indicate that the function is active.

2. Select **Options** > **Auto Update Date/Time** again to turn the feature off.

Clearing Data Sets from the Select File Dialog Box

The list of data sets in the Select File dialog box should be cleared periodically to minimize performance delays.

1. Navigate to:

   C:\Users\<<username>>\AppData\Roaming\CareFusion\Alaris Products\Transfer Tool\v12\GuardrailsCurrentUserConfig.dat

2. Delete **GuardrailsCurrentUserConfig.dat.**

Help Menu

The Guardrails™ Editor Transfer Tool Help Menu provides the following options:

Option	Description
About	Software version and copyright information.
Contents	Help for the Guardrails™ Editor Transfer Tool.

Appendix A
Drug Amount and Dosing Units

This section contains the following topic:

Drug Amount and Dosing Units

The following tables list the available drug amounts, concentration and dosing units, with valid ranges available for the BD Alaris™ System and Guardrails™ Editor software application.

Drug Amount and Continuous Dosing Units

Drug Amount		Continuous Dosing Limits		
Valid Units				
Drug Amounts Units	**Valid Range**	**Non-Wt Based**	**Wt Based**	**Valid Range**
micrograms (mcg)	0.001–99,999	nanogram/min nanogram/h nanogram/day	nanogram/kg/min nanogram/kg/h nanogram/kg/day	0.0001–99,999
		mcg/min mcg/h mcg/day	mcg/kg/min mcg/kg/h mcg/kg/day	0.0001–99,999
		mg/min mg/h mg/day	mg/kg/min mg/kg/h mg/kg/day	0.0001–99,999
milligrams (mg)	0.001–99,999	nanogram/min nanogram/h nanogram/day	nanogram/kg/min nanogram/kg/h nanogram/kg/day	0.0001–99,999
		mcg/min mcg/h mcg/day	mcg/kg/min mcg/kg/h mcg/kg/day	0.0001–99,999
		mg/min mg/h mg/day	mg/kg/min mg/kg/h mg/kg/day	0.0001–99,999
grams	0.001–999.9	mcg/min mcg/h mcg/day	mcg/kg/min mcg/kg/h mcg/kg/day	0.0001–99,999
		mg/min mg/h mg/day	mg/kg/min mg/kg/h mg/kg/day	0.0001–99,999
		gram/min gram/h gram/day	gram/kg/min gram/kg/h gram/kg/day	0.0001–999.9

Drug Amount and Continuous Dosing Units

Drug Amount		Continuous Dosing Limits		
Valid Units				
Drug Amounts Units	**Valid Range**	**Non-Wt Based**	**Wt Based**	**Valid Range**
units	0.001–99,999	milliunit/min milliunit/h milliunit/day	milliunit/kg/min milliunit/kg/h milliunit/kg/day	0.0001–99,999
		unit/min unit/h unit/day	unit/kg/min unit/kg/h unit/kg/day	0.0001–99,999
milliequivalents	0.001–999.9	mEq/min mEq/h mEq/day	mEq/kg/min mEq/kg/h mEq/kg/day	0.0001–999.9
millimoles	0.001–999.9	mmol/min mmol/h mmol/day	mmol/kg/min mmol/kg/h mmol/kg/day	0.0001–999.9

Bolus Dosing Units

	Valid Units		
Concentration	**Non-Wt Based**	**Wt Based**	**Valid Ranges**
nanogram/mL	nanogram	nanogram/kg	0.0001–99,999
mcg/mL	nanogram mcg mg	nanogram/kg mcg/kg mg/kg	0.0001–99,999
mg/mL	mcg mg	mcg/kg mg/kg	0.0001–99,999
gram/mL	mg gram	mg/kg gram/kg	0.0001–999.9
milliunit/mL	milliunit unit	milliunit/kg unit/kg	0.0001–99,999
unit/mL	milliunit unit	milliunit/kg unit/kg	0.0001–99,999
mEq/mL	mEq	mEq/kg	0.0001–999.9
mmol/mL	mmol	mmol/kg	0.0001–999.9

PCA Drug Amount Units

Concentration	PCA, Bolus and Loading Doses	Continuous Dose	Valid Ranges
mcg/mL	mcg	mcg/h	0.001–9,999
mg/ml	mg	mg/h	0.001–9,999

The dose data entry value shall be less than or equal to the installed syringe size.

Drug Amount and Intermittent Dosing Units

Non-Weight Based	Weight Based	BSA Based	Valid Range
mcg	mcg/kg	mcg/m^2	0.001–99,999
mg	mg/kg	mg/m^2	0.001–99,999
gram	gram/kg	$gram/m^2$	0.001–999.9
unit	unit/kg	$unit/m^2$	0.001–99,999
mEq	mEq/kg	mEq/m^2	0.001–999.9
mmol	mmol/kg	$mmol/m^2$	0.001–999.9

Drug Concentration Values and Units

Unit	Value
nanogram/mL	0.001–99,999
mcg/mL	0.001–99,999
mg/mL	0.001–99,999
gram/mL	0.001–999.9
milliunit/mL	0.001–99,999
unit/mL	0.001–99,999
mEq/mL	0.001–999.9
mmol/mL	0.001–999.9

Appendix B
Revision Highlights and Previous Versions

This section contains the following topic:

Highlights and Previous Versions

Version	Change
12.1.3	• Removed support for CQI software. • Updated Syringe and PCA Syringe Master Favorites List. • Added minimum recommended flow rate and minimum recommended bolus volume by syringe in Syringes and PCA Syringes Master List. • Updated factory reset values in the system configuration settings.
12.1.2	• Support for SpO_2 Module and associated configurations removed. V12.2.0 PCU software is not compatible with SpO_2 Modules. • End of life support for Windows™ 7. • Requiring hard minimum and soft maximum concentration limits for continuous and PCA infusions that utilize a Units Only concentration (custom concentration). • Data Set change report that highlights incomplete or invalid required fields. • Software updated to reinforce when Continuous/Bolus Concentration Limit Units differ from the Units Only concentration (custom concentration) unit. • IVAC 50 mL Syringe and Astra Zeneca 50mL Syringe removed from favorites list and no longer available as a Syringe Module selection. • Delay Until selection removed from delayed start option for Pump and Syringe Module.
12.1.0	• An optional clinical advisory message appears on the PCU when the following non-Guardrails™ protected modes are selected: Basic Primary, Basic Secondary, and Drug Calc infusions. • Additional air-in-line thresholds of 125 microliters and 175 microliters. • Replaced the method of requesting a password with capcha for releasing the data set. • Removed multidose configuration options. • Changed Terumo 50/60 mL syringe to Terumo 60 mL syringe in the master syringes list and master PCA syringes list.
9.33.1	• Update to display the Soft Min Concentration Limit on the summary section of the Profiles tab for Continuous, Intermittent and PCA that was not available in Guardrails™ Editor v9.33.0. This update does not affect any other version of Guardrails™ Editor.

9.33.0	• Increased drug and/or fluid setups to 10,000
	• Enhanced configurable PCU settings for Audio Alarms which added: Profile4 to Alarm Audio Profile to support standards compliance for alarms
	  • Minimum Audio Volume
	  • Default Audio Volume
	• Enhanced near end of infusion settings for Syringe Module which included:
	  • Ability to separately configure NEOI settings between continuous and intermittent infusions
	  • Optional NEOI Snooze (reminder signal)
	• Ability to separately configure NEOI settings for continuous and intermittent infusion libraries
	• Adjusted Syringe NEOI Alert Time to be based only on the configured time between 1—60 minutes.
	• Unique Device Identifier information provided in About dialog box under the Help menu

Version	Change
9.17	• A comma is automatically inserted as the user is typing in values above 999.9 in all fields except Alias, NDC, and PCA security codes. • Commas are displayed on Microsoft™ Word generated reports for values above 999.9. • A Search box feature is added to: ◦ The master lists for drugs, fluids, therapies, and clinical advisories ◦ The continuous/bolus, intermittent, fluid, and PCA summary pages ◦ The therapy and clinical advisory select page within the Profiles • The search feature within Drug Name and Fluid Name has increased the time to reset the search to two seconds.
9.9	• Ability to enter a Drug Amount with up to 3 decimal places for values between the range of 0.001 and 9.999. (Previously, only values up 0.999 could have been entered with 3 decimal places.) • Concentrations will accommodate 3 decimal places for values between the range of 0.001 and 9.999. (Previously, only values up 0.999 would have been displayed with 3 decimal places.) • The Dose field for continuous infusions, bolus doses and the bolus dose administration rate (BDAR) will now accommodate 4 decimal places for values between the range of 0.0001 and 0.9999. (Previously, 3 decimal places could have been entered for values between the range of 0.001 and 0.999.) • The Dose field for intermittent infusions will now accommodate 4 decimal places for values between the range of 0.001 and 0.9999. (Previously, 3 decimal places could have been entered for values between the range of 0.001 and 0.999.) • Ability to support continuous infusions with nanogram dosing when the Drug Amount/Diluent Volume is less than100 (one hundred) micrograms/mL. (Previously, nanogram dosing was only available if the Drug Amount/Diluent Volume was less than 10 (ten) micrograms/mL. • The Dose field for continuous and intermittent infusions will now support doses in grams up to a max of 999.9. (Previously, a max of 99.99 grams was supported.) • Continuous and intermittent drugs: Ability to enter a Drug Amount with up to 5 digits for mg and mcg units. (Previously, only 4 digits were supported.) • Ability to export a data set report in Word or Excel (previously only Word was supported) **NOTE:** For more information, see *Drug Amount Change Table on page 224*.
9.8	• Add support for Windows™ 7 Service Pack 1 • Removed support for Windows 2000. • Removed Adobe Reader as a prerequisite.
9.5	• Increased number of drug or fluid setups to 2500. • Increased number of Profiles to 30. • Increased number of clinical advisories to 100. • Increased number of Therapies to 250.
9.3	• Support for both Alaris™ System version 8 and version 9. • Updated Master Lists to reflect new Anesthesia Mode functionality.
8.3	• Error Summary feature. • Functionality added to support new PCU.

Version	Change
8.2	• Updated Report display for duration limits at 24:00 or greater. • Updated Report display from meq to mEq. • Enhanced Intermittent Drug Library to display only valid entries.
8.1	• Increased number of setups to 1500. • Increased number of Profiles to 15. • Increased number of clinical advisories to 40. • Hard and soft limits options. • Optional initial values (starting or default values). • Limit protection around intermittent infusions – includes primary and secondary infusions. • Limit protection around Fluids (mL/h). • Therapy naming and setup options for drug and Fluid libraries. • Copy and paste for Profile drug and Fluid setups. • BSA (m2) dosing method available for Intermittent Drug Library. • Weight-based and non-weight-based dosing method setup for drugs. • Additional default master lists for Fluids, Therapies, Channel Labels. • File based application for faster and more convenient programming. • Optional NDC entries for drug and Fluid list. • Show usage functionality to determine usage of master listings within each Profile and concentrations within each Profile. • Upload of draft and approved data sets for clinical user interface testing—includes automatic labeling of “This device is not for human use” on Alaris™ System display screen. • Master Syringe List selection for favorites list. • Changed management of IMS manufacturer’s prefill. • PCA pause functionality supported with new configuration settings for PCA Drug Setups. • PCA dosing ranges from tenths to thousandths.
7.x	• PCA Drug Library and Instrument Configurations. • mL/h dosing for PCA Module. • Concentration Limits for PCA and Continuous/Bolus Drug Library. • Bolus Dose Administration Rate Limits for Continuous/Bolus Dose infusion. • Millimole Dosing Units. • $EtCO_2$ Module configuration settings. • Default alarm audio volume configuration setting for PCU.
6.x	• Enhanced reporting in Microsoft™ Word format. • Save as you go data set development. • Module enable/disable for data set development. • Default Master Drugs List for newly created data sets. • Ability to clear revision history.
5.x	• Unlimited Master Drug List entries, depending on available disk space. • Up to 1000 total setups distributed across 10 Profiles. • Up to 20 unique clinical advisory messages that can be associated with Profile drug names. • Addition of Syringe Module Drug Library and Instrument Configurations • Optional Master Drug List Alias entries. • Nellcor® technology and Masimo® technology can be selected for SpO_2 module. • Optional Patient ID entry. • Data Set ID field to support drug identification when using CQI Reporter. • Help function. • Windows-based Guardrails™ Editor software application.

Version	Change
1.8.4	Updated the import/export function to support the CQI Reporter.
1.8	Added SpO_2 Configuration Tab changes to support SpO_2 module with Nellcor® technology.
1.6	• Enhanced instrument configurations for advanced features and bolus dosing settings for drug list/libraries. • Anesthesia Mode, Multi-Dose Mode, and Delay Option can be configured using the Profiles. • In addition to the ability to identify drug name, standard concentration, and standard dosing units for continuous drug infusions, bolus dose features can be enabled at the drug list level and at the drug library level. • The drug list has a limit of 375 drug names and 500 setup entries. • Nanogram unit dosing is supported—Drug Limits and continuous dosing units can be set in the data set at a Master Drug List or Profile Drug Library level, and in unit per day measurements.

Appendix C
General Information

This section contains the following topic:

Service Information

If difficulties are encountered while using the Guardrails™ Editor software, consult the following sources of information before contacting BD Technical Support:

- Readme files or package inserts accompanying the product.
- Appropriate hardware manuals (applicable BD Alaris™ System user manual or service manual and related service bulletins), if a hardware problem is suspected.

Technical Support

If the software fails to respond and the cause cannot be determined, contact a BD representative, and provide the following information:

- Description of difficulty experienced
- Message displayed at time of difficulty
- Software version

Software Return

Contact BD to obtain a return authorization number prior to shipment.

Package the software (preferably in original packaging), reference the return authorization number, and return to the closest facility.

Appendix D
Drug Amount Change Tables

This section contains the following topic:

Drug Amount Change Table

Comparison Drug Amount and Continuous Dosing Units

Drug Amount	Continuous Dosing Limits			
	Valid Units		Valid Range	
Drug Amount Units	Non-Wt Based	Wt Based	v9.8 and Lower	v9.9 and Higher
micrograms (mcg)	nanogram/min nanogram/h nanogram/day	nanogram/kg/min nanogram/kg/h nanogram/kg/day	0.001–9,999	0.0001–99,999
	mcg/min mcg/h mcg/day	mcg/kg/min mcg/kg/h mcg/kg/day	0.001–9,999	0.0001–99,999
	mg/min mg/h mg/day	mg/kg/min mg/kg/h mg/kg/day	0.001–9,999	0.0001–99,999
milligrams (mg)	nanogram/min nanogram/h nanogram/day	nanogram/kg/min nanogram/kg/h nanogram/kg/day	0.001–9,999	0.0001–99,999
	mcg/min mcg/h mcg/day	mcg/kg/min mcg/kg/h mcg/kg/day	0.001–9,999	0.0001–99,999
	mg/min mg/h mg/day	mg/kg/min mg/kg/h mg/kg/day	0.001–9,999	0.0001–99,999
grams	mcg/min mcg/h mcg/day	mcg/kg/min mcg/kg/h mcg/kg/day	0.001–9,999	0.0001–99,999
	mg/min mg/h mg/day	mg/kg/min mg/kg/h mg/kg/day	0.001–9,999	0.0001–99,999
	gram/min gram/h gram/day	gram/kg/min gram/kg/h gram/kg/day	0.001–99.99	0.0001–999.9

Comparison Drug Amount and Continuous Dosing Units

Drug Amount	Continuous Dosing Limits			
	Valid Units		Valid Range	
Drug Amount Units	Non-Wt Based	Wt Based	v9.8 and Lower	v9.9 and Higher
units	milliunit/min milliunit/h milliunit/day	milliunit/kg/min milliunit/kg/h milliunit/kg/day	0.001–99,999	0.0001–99,999
	unit/min unit/h unit/day	unit/kg/min unit/kg/h unit/kg/day	0.001–99,999	0.0001–99,999
milliequivalents	mEq/min mEq/h mEq/day	mEq/kg/min mEq/kg/h mEq/kg/day	0.001–999.9	0.0001–999.9
millimoles	mmol/min mmol/h mmol/day	mmol/kg/min mmol/kg/h mmol/kg/day	0.001–999.9	0.0001–999.9

Concentration Units (Drug Amount/mL)	Overall Concentration Range v9.9 and Higher	Concentration Ranges v9.9 and Higher	Available Dosing Units
mcg/mL	0.001 - 99,999 mcg/mL	100.0 - 99,999 mcg/mL	mcg, mg
		1.000 - 99.99 mcg/mL	nanogram, mcg, mg
		0.001 - 0.999 mcg/mL	nanogram, mcg
mg/mL	0.001 - 99,999 mg/mL	100.0 - 99,999 mg/mL	mg
		0.100 - 99.99 mg/mL	mcg, mg
		0.001 - 0.099 mg/mL	nanogram, mcg, mg
gram/mL	0.001 - 999.9 gram/mL	100.0 - 999.9 gram/mL	gram
		0.100 - 99.99 gram/mL	mg, gram
		0.001 - 0.099 gram/mL	mcg, mg, gram
unit/mL	0.001 - 99,999 unit/mL	100.0 - 99,999 unit/mL	unit
		0.001 - 99.99 unit/mL	milliunit, unit
mEq/mL	0.001 - 999.9 mEq/mL	0.001 - 999.9 mEq/mL	mEq
mmol/mL	0.001 - 999.9 mmol/mL	0.001 - 999.9 mmol/mL	mmol

Comparison Bolus Dosing Units

Concentration	Valid Units		Valid Ranges	
	Non-Wt Based	Wt Based	v9.8 and Lower	v9.9 and Higher
nanogram/mL	nanogram	nanogram/kg	0.001–9,999	0.0001–99,999
mcg/mL	nanogram mcg mg	nanogram/kg mcg/kg mg/kg	0.001–9,999	0.0001–99,999
mg/mL	mcg mg	mcg/kg mg/kg	0.001–9,999	0.0001–99,999
gram/mL	mg gram	mg/kg gram/kg	0.001–99.99	0.0001–999.9
milliunit/mL	milliunit unit	milliunit/kg unit/kg	0.001–99,999	0.0001–99,999
unit/mL	milliunit unit	milliunit/kg unit/kg	0.001–99,999	0.0001–99,999
mEq/mL	mEq	mEq/kg	0.001–999.9	0.0001–999.9
mmol/mL	mmol	mmol/kg	0.001–999.9	0.0001–999.9

Comparison PCA Drug Amount Units

Concentration	PCA, Bolus and Loading Doses	Continuous Dose	Valid Ranges *(No changes)*	
			v9.8 and Lower	v9.9 and Higher
mcg/mL	mcg	mcg/h	0.001–9,999	0.001–9,999
mg/ml	mg	mg/h	0.001–9,999	0.001–9,999

Comparison Drug Amount and Intermittent Dosing Units

Non-Weight Based	Weight Based	BSA Based	Valid Range	
			v9.8 and Lower	v9.9 and Higher
mcg	mcg/kg	mcg/m^2	0.001–9,999	0.001–99,999
mg	mg/kg	mg/m^2	0.001–9,999	0.001–99,999
gram	gram/kg	gram/m^2	0.001–99.99	0.001–999.9
unit	unit/kg	unit/m^2	0.001–99,999	0.001–99,999
mEq	mEq/kg	mEq/m^2	0.001–999.9	0.001–999.9
mmol	mmol/kg	mmol/m^2	0.001–999.9	0.001–999.9

Comparison Drug Concentration Values and Units

Unit	Value	
	v9.8 and Lower	v9.9 and Higher
nanogram/mL	0.001–9,999	0.001–99,999
mcg/mL	0.001–99,999	0.001–99,999
mg/mL	0.001–99,999	0.001–99,999
gram/mL	0.001–99.99	0.001–999.9
milliunit/mL	0.001–99,999	0.001–99,999
unit/mL	0.001–99,999	0.001–99,999
mEq/mL	0.001–999.9	0.001–999.9
mmol/mL	0.001–999.9	0.001–999.9

Precision Tables- v9.8 (and Lower) and v9.9 (and Higher) Comparison

Drug Amount Field Precision and Range		
v9.8 and Lower		
Range		Decimal Precision
Min	Max	
0.001	0.999	3
1	99.99	2
100	999.9	1
1000	99,999	0

Drug Amount Field Precision and Range		
v9.9 and Higher		
Range		Decimal Precision
Min	Max	
0.001	9.999	3
10	99.99	2
100	999.9	1
1000	99,999	0

Dose Field Precision and Range		
v9.8 and Lower		
Range		Decimal Precision
Min	Max	
0.001	0.999	3
1	99.99	2
100	999.9	1
1000	99,999	0

Dose* Field Precision and Range		
v9.17 and Higher		
Range		Decimal Precision
Min	Max	
0.0001	0.9999	4
1	9.999	3
10	99.99	2
100	999.9	1
1000	99,999	0

* Dose fields include Continuous, Bolus, BDAR

Intermittent Dose Field Precision and Range		
v9.8 and Lower		
Range		Decimal Precision
Min	Max	
0.001	0.999	3
10	99.99	2
100	999.9	1
1000	99,999	0

Intermittent Dose Field Precision and Range		
v9.17 and Higher		
Range		Decimal Precision
Min	Max	
0.001	0.9999	4
1	9.999	3
10	99.99	2
100	999.9	1
1000	99,999	0

Glossary

Auto-ID Module

A module that interacts with the PCU and contains an internal barcode image scanner and supports an optional Alaris™ Auto-ID Handheld Scanner supplied by BD.

Aliases

A drug alias is an optional alphanumeric text string associated with a drug concentration in the master drug list. A maximum of five drug aliases can be entered for each drug name in the master drug list, and each alias entry can be a maximum of 12 alphanumeric characters.

Anesthesia Mode

When the BD Alaris™ System is operating in anesthesia mode, a channel can be paused indefinitely without an alarm and the air-in-line limits can be set for up to 500 microliters. Anesthesia mode also makes it possible to have additional drugs in each profile that are only accessible when operating in anesthesia mode.

Hard limits will default to soft limits in anesthesia mode. Clinical advisories do not display in anesthesia mode.

Anesthesia Only

A drug and concentration in a continuous/bolus drug library can be set to be available only for the anesthesia mode.

BD Alaris™ System

The BD Alaris™ System consists of the PCU (PC Unit) and one or more infusion or monitoring modules - such as Pump Module, Syringe Module, PCA Module, $EtCO_2$ Module, or Auto-ID Module.

Body Surface Area (BSA)

A unit of measurement expressed in meters squared (m^2) that is estimated using mathematical calculations based on patient height and weight.

Bolus Dose

A temporary rapid increase in the rate of infusion of a drug.

Bolus Dose Administration Rate (BDAR) Limits

Limits on the rate at which a bolus dose is administered for a Pump Module or Syringe Module. Limits are established as dosing units/min or dosing units/kg/min.

Channel Label Library

A channel label library is a subset of text strings from the master channel label list that are assigned to one of the care area profiles.

Clinical Advisory

A clinical advisory is a user message that appears on the PCU when a designated drug is selected to remind the clinician of specific hospital standards of practice when programming this IV medication. A specific clinical advisory can be associated with a selected drug in any care area Profile.

NOTE:
Clinical advisories do not appear on the PCU when in anesthesia mode.

Concentration Limits

Limits on the range of concentrations that are allowed for a particular drug in a profile. Concentration limits are an optional entry. Concentration limits are available for Units Only concentration (custom concentration) entries (for example, -- mg/-- mL).

Configuration Settings

The profile-specific BD Alaris™ System operating parameters that can be customized for each module using this software.

NOTE:
Definitions of configuration settings are listed in *Instrument Configuration Setting Definitions* on page 169.

Data Set

The data set is developed using this software authoring tool and can then be electronically transferred to the BD Alaris™ System PCU using the Guardrails™ Editor Transfer Tool, BD Alaris™ Systems Manager, or BD Alaris™ System Maintenance. A data set reflects the hospital-defined best-practice guidelines for medication and fluid administration and includes drug and fluid library profiles, clinical advisories, instrument configurations, therapies, and channel labels.

Data Set ID

A unique identifier auto-assigned by this software to identify a unique data set. This ID is nine characters long.

Data Set Transfer

The process of using the Guardrails™ Editor Transfer Tool, BD Alaris™ Systems Manager, or BD Alaris™ System Maintenance to upload (transfer) a hospital-defined best practice data set from a

personal computer to a BD Alaris™ System PCU. The new data set will not become active until the PCU is power cycled and the New Patient screen is selected.

Dose Error Reduction System (DERS)

The components and functions of the BD Alaris™ System, Guardrails™ Suite MX, and hospital-defined best practice data set that aid in the prevention of infusion-related programming errors and alerts users of potential over- or under-delivery of a medication or fluid.

Dosing Units

Units of measure for delivery of a selected drug.

Drug Concentration

The drug amount units in a given diluent volume and the drug/mL amount.

Drug Library

Profile-specific list of drug names, concentrations, dosing units and dose parameters available during normal operation. May also include clinical advisories and therapy names.

Duration Limits

Hospital-established limits around duration of infusion.

$EtCO_2$ Module

End Tidal Carbon Dioxide

A monitoring module that interacts with the PCU to provide continuous, noninvasive monitoring of end-tidal carbon dioxide ($EtCO_2$), fractional inspired carbon dioxide ($FiCO_2$) and respiratory rate (RR).

NOTE:
Although no limits are associated with the $EtCO_2$ Module, the software allows users to set an initial configuration for the module.

Fluids

IV fluids (for example, TPN) and limits around rate of delivery in mL/h.

Full Concentration

Drug amount and drug units in diluent volume.

Guardrails™ Suite MX

Includes the BD Alaris™ System Maintenance, BD Alaris™ Guardrails™ Editor, and BD Alaris™ Systems Manager. The dose error reduction system (DERS) includes the components and functions of the Guardrails™ Suite MX, BD Alaris™ System, and hospital-defined best practice data set that aid in the prevention of infusion-related programming errors and alerts users of potential over- or under-delivery of medications and fluids.

Limit

A programming limit or best-practice guideline determined by hospital/health system and entered into data set. Profile-specific limits are defined for flow rate, patient weight, and maximum and minimum continuous dose for each drug in the drug library. Dose limits can be defined by hospital/health system as either hard or soft limits.

- A hard limit is a programmed limit that cannot be overridden, except in anesthesia mode.
- A soft limit is a programmed limit that can be overridden.

Hard Limit

A limit that cannot be overridden, except in anesthesia mode.

Initial Value

An optional and editable starting value for continuous/bolus, intermittent, and PCA infusion.

Intermittent Infusion

Intermittent limits for drugs around total dose and duration. Intermittent infusions can be given as primary, secondary, or primary and secondary infusions.

IV Fluid Library

An optional library consisting of limits around rate of delivery. The ability to establish limits for volumetric rate of delivery of IV fluids (mL/h).

Lockout Interval

Allows the clinician to program a pre-determined interval of time that must elapse between deliveries of PCA doses.

Master Channel Labels

Master list of hospital-defined labels that can be used to create profile-specific channel label libraries. A master channel label list has a limit of 100 entries.

Master Clinical Advisories

A master list of user messages that can be used to attach clinical advisories to drug names in the profile that will appear on the BD Alaris™ System when a designated drug is selected, except when in anesthesia mode. These messages remind the clinician of specific cautions or hospital standards of practice when programming this IV medication.

Master Drug List

Contains all of the drug names and concentrations that can be used to create profile drug libraries. The master drug list is a formulary of drugs used for IV infusions. The dot (.) before the drug name is used for drugs assigned as Anesthesia Only drugs. This allows them to appear at the top of the drug list.

Master Syringes List

Master syringes list and a master PCA syringes list contain favorites (defaults) for display on the PCU.

Max Accumulated Dose Range Limits

Total amount of drug that can be infused over a specified time period.

National Drug Code (NDC)

This is the numeric designation (10-12 digits) assigned by FDA to each drug it approves. The NDC code will be in the manufacturer applied bar code label on the medication container. NDCs can be added to the master drug or fluid list. The 10-digit NDC code can optionally be separated by two dashes.

PCA Bolus Dose

The PCA bolus dose feature enables a clinician to program an additional amount of medication after the PCA infusion has begun. The current PCA infusion will resume following the delivery of a bolus dose.

PCA Dose

The PCA dose enables a patient to self-administer a bolus infusion to be delivered at programmed lockout intervals through the dose request cord. When programmed in the PCA + Continuous mode, the continuous infusion will resume following the PCA dose.

PCA Loading Dose

The loading dose enables a clinician to program a bolus infusion prior to initiation of the PCA infusion. The loading dose may be programmed from the Infusion Modes menu or applicable PCA, PCA + Continuous or Continuous Only programming screen prior to the start of a new PCA infusion program.

PCA Module

Patient Controlled Analgesia

An infusion module that interacts with the PCU, designed for facilities that administer medications from syringes. The PCA Module supports multiple infusion types including PCA dose-only, continuous infusion, PCA dose + continuous, loading dose only, and bolus doses.

PCA Pause Protocol

An optional and hospital-configurable feature intended to align with hospital/health systems current protocol for patient monitoring during PCA therapy. When enabled, PCA infusion pauses and alarms when pre-defined monitoring values for $EtCO_2$ Module are exceeded and sustained. All device programming, data entry and validation of PCA pause parameters are performed by a trained health care professional according to hospital-defined protocol or physicians order.

PCU

The core of the BD Alaris™ system that provides a common user interface for programming infusions and monitoring.

NOTE:
Although no limits are associated with the PCU, this software allows users to set default configurations for the PCU.

Profile

A unique set of options and best-practice guidelines for a specific patient population or patient type. A profile includes:

- BD Alaris™ System configuration settings.
- A drug library, which includes drug names, concentrations, dosing units, limits and optional associated clinical advisories. Continuous/bolus and intermittent dose infusions can be set up.
- A fluids list including fluids supporting primary and secondary infusions.
- A channel label library with text (alphanumeric) labels.

Profile settings are established by hospital clinical decision-makers prior to implementation. Profile parameters are entered to create a data set, which is then transferred to the PCU.

Pump Module

An infusion module that interacts with the PCU to deliver fluids, medications and blood products. The pump module supports multiple infusion types, including fluids, primary continuous medications, and primary or secondary intermittent medications.

Setup

An entry in a profile library that includes drug or fluid name, concentrations, and limits around the infusion parameters. Setups may also include clinical advisories.

Shared Infusion Settings

Configuration settings common to both syringe and Pump Modules.

Soft Limit

A programmed limit that can be overridden.

Syringe Module

An infusion module that interacts with the PCU, designed for facilities that administer medications from syringes. The Syringe Module supports multiple infusion types including fluids, and continuous or intermittent medications.

Therapies

An optional hospital-defined therapy or clinical indication for delivery of an infusion. Different limits can be defined for the same medication with different therapeutic indications. Provides the ability for the health care facility to protect a medication that is dosed in different ways with limits appropriate for each entry. (For example: peripheral versus central, weekly versus Q 3-week protocols.)

Total Dose Limits

Hospital-established limits around total dose of infusion—used in the intermittent drug library.

Units Only Concentration (Custom Concentration)

A concentration that includes drug units without predefined drug amount and diluent volume values. These values can then be entered by the clinician during instrument setup. Units Only concentrations (custom concentrations) will appear at the bottom of the list of drug concentrations for a particular drug in the master drug list and profile drug library.

Unique Device Identification (UDI)

The UDI is a number assigned by the FDA to identify a specific medical device. The Guardrails™ software displays the UDI on the About Guardrails™ Editor screen. To learn how to access the screen, see the section titled Checking Unique Device Identification (UDI) Information.

User Types

Each computer using this software can be set up for only one user type:

- **Pharmacist users** will have access to all functions: This software (including reports), the BD Guardrails™ Editor Transfer Tool, data set and the user manual.
- **Biomed users** will only have access to the Guardrails™ Editor Transfer Tool.

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