BD Alaris™ System with Guardrails™ Suite MX, BD Alaris™ PC Unit Model 8015 Software v12.1.0

BD Alaris™ Guardrails™ Editor Model 8961 Software v12.1.0

User Manual Addendum

2019-12
DME: 10000362828-00
Part Number: P00000438

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

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

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

North America

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

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

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

United Arab Emirates

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

Southeast Asia

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

United Kingdom

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

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

Australia/New Zealand

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

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

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

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

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Chapter 1
Delay Options and Infusion Complete Alarms

Purpose of Addendum

This addendum contains supplemental information regarding:

- Programming infusions with Delay Options
- Infusion complete alarms
- Programming an infusion with a custom concentration entry
- Battery care and maintenance

See your user manual for all other information for using your BD Alaris™ system.

Delay Options Feature

When a delay option is programmed, the infusion stops when complete and no keep vein open (KVO) is delivered. It is assumed that another infusing IV line keeps the vein open until the delayed infusion begins. With firmware version 9.33 and later, there is an infusion complete alarm at the end of the delayed infusion, even with a programmed callback of none or before.

The delay options feature allows the user to schedule and program an infusion to be either:

- Delayed for up to 120 minutes, or
- Delayed until a specific time, up to 23 hours and 59 minutes

WARNING

Delay options should not be used for critical medications whose stoppage without a KVO rate have the potential to impact therapeutic dosing.

Scheduling a Callback

A delayed options callback allows the user to select an audiovisual callback alert.

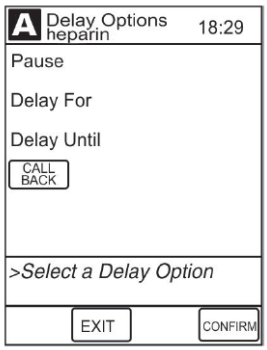
Before—Receive a callback when the delay period ends and the infusion needs to be initiated.

After—Receive a callback when the delayed infusion is completed.

Before and After—Receive a callback when the infusion needs to initiate (after delay) and again when the infusion is completed.

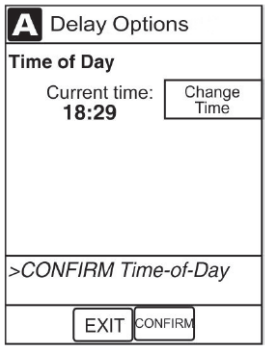
Programming a Delayed Options Infusion

1. Select the DELAY OPTIONS soft key on the BD Alaris™ PC unit.
2. Select a delay option.



3. If the delay until option is chosen, current time must be confirmed prior to programming the delay.

   NOTE:
   This will display the current time of day; it is not the time the delayed infusion will initiate. If the current time is incorrect, documentation in the electronic medical record (EMR) could be affected.



4. Enter the desired time for the infusion to start.



5. If needed, press the CALLBACK soft key to change the callback.
6. Press the CONFIRM soft key to initiate the delayed infusion and callback.

Infusion Complete Alarms

At the completion of all infusions that end with Infusion Complete or Infusion Complete/KVO, the PC unit emits an audible medium priority alarm. Clinicians should check that the current audio volume on the PC unit is appropriate prior to use on patients receiving high alert medications.

- Guardrails™ editor administrators should review the following configurable audio settings in the Editor software for each care area Profile:
  - Review the default audio volume setting and consider increasing it to the loudest audio volume setting. Setting 5 is the loudest audio volume setting.
  - For Guardrails™ editor software version 9.33 or later, review the minimum audio volume setting for each care area profile and set to the highest acceptable level.

Chapter 2
Custom Concentrations and Hard Minimum Concentration Limits

Programming an Infusion with a Custom Concentration Entry

Your hospital may choose to have a medication with an unspecified concentration entry (for example, ___mg/___ mL) in your drug library.

In this situation, the user must manually enter the DRUG AMOUNT and DILUENT VOLUME. This is called a custom concentration.

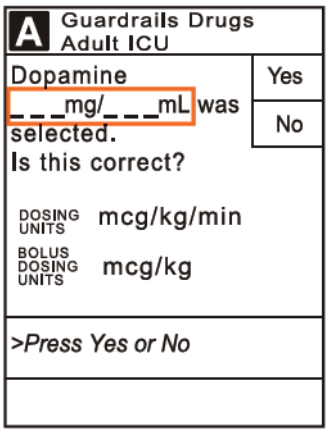
1. After selecting a medication, select the concentration.

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

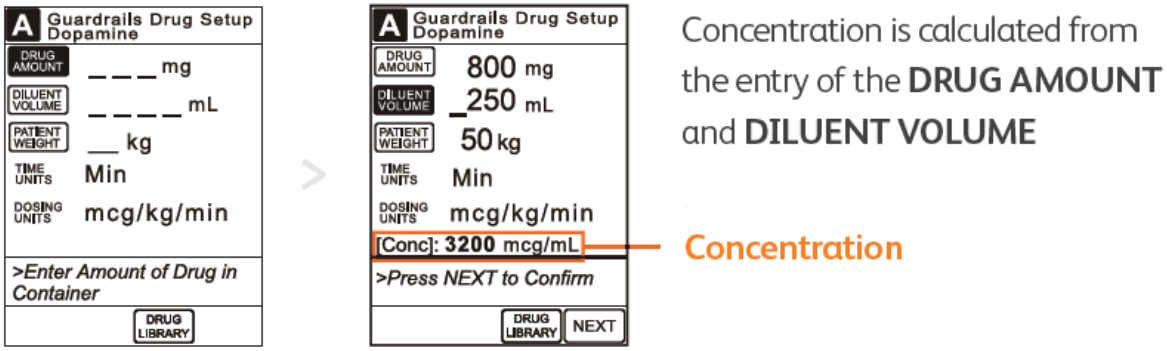
SAMPLE DRUG LABEL



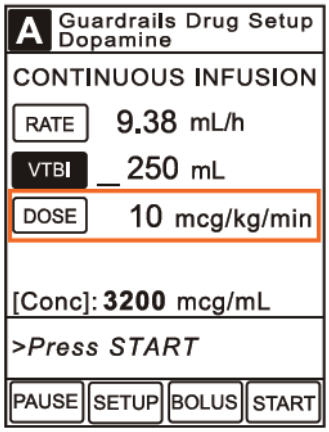
   The custom concentration entry ___mg/___mL must be selected to manually enter the ordered concentration.



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



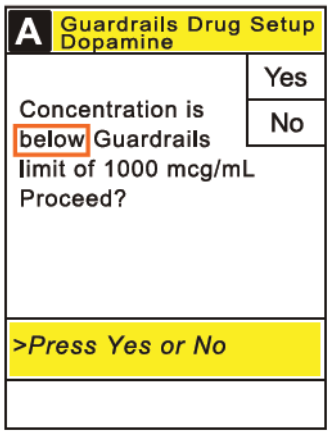
NOTE:
The DRUG AMOUNT is not the dose. The dose is entered on the next screen.



⚠ WARNING

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

3. If a concentration Guardrails™ alert is encountered during programming, to ensure accuracy, select **No** and check that the following parameters match the drug label:
   - DRUG AMOUNT
   - DILUENT VOLUME
   - [Conc] (concentration)



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

Setting Hard Minimum Concentration Limits

Hard minimum concentration limits in your hospital's data set can prevent an over-infusion when a custom concentration is programmed incorrectly at the bedside.

Example data entry errors that have the potential to cause patient harm are described below. Each scenario could be prevented by using only standard concentrations or clinically relevant hard minimum concentration limits.

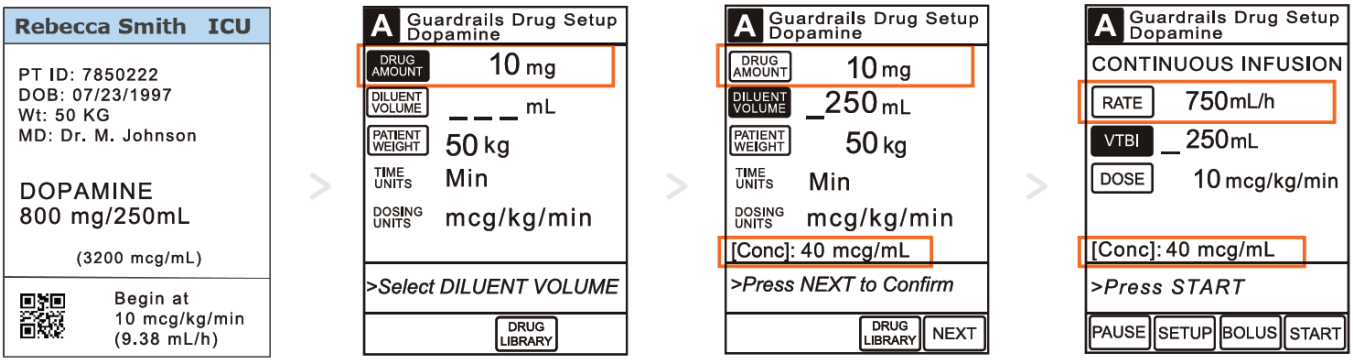
Dose as Drug Amount

Example medication order: Dopamine 800 mg/250 mL, start dose at 10 mcg/kg/min = rate 9.38 mL/h

The following screenshots show inaccurate data entry caused by substituting dose as drug amount: Dopamine 10 mg/250 mL, start a dose of 10 mcg/kg/min = rate 750 mL/h.

If programming errors are not noticed prior to pressing the START key, an over-infusion may occur.

SAMPLE DRUG LABEL



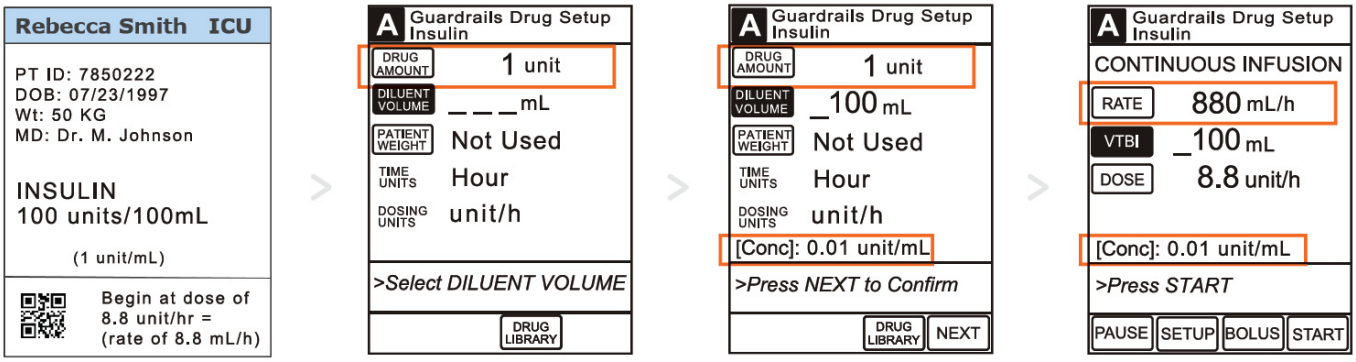
Missing Digits

Example medication order: Insulin 100 units/100 mL, start at a dose of 8.8 unit/h = rate of 8.8 mL/h

The following screenshots show inaccurate data entry caused by not entering all the digits for drug amount: Insulin 1 unit/100 mL, start a dose of 8.8 unit/h = rate 880 mL/h.

In the provided example, if programming errors are not noticed prior to pressing the START key, an over-infusion may occur.

SAMPLE DRUG LABEL



Best Practice Recommendations

BD recommends the following customer actions to prevent these errors from occurring:

- **Standardize concentrations**: Standardize concentrations and avoid the use of custom concentrations where possible, especially for all continuous/bolus and PCA infusions.
- **Hard minimum concentration limits**: If custom concentrations are unavoidable, ensure that hard minimum concentration limits are implemented.
- **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.
- **BD Alaris™ EMR Interoperability**: Recommend that ALL customers follow these recommendations regardless of whether your hospital uses EMR interoperability.
- **Implement ISMP best practices**: The Institute of Safe Medication Practice (ISMP) outlines best practices in the article *Smart Pump Custom Concentrations without Hard "Low Concentration" Alerts Can Lead to Patient Harm*[1]

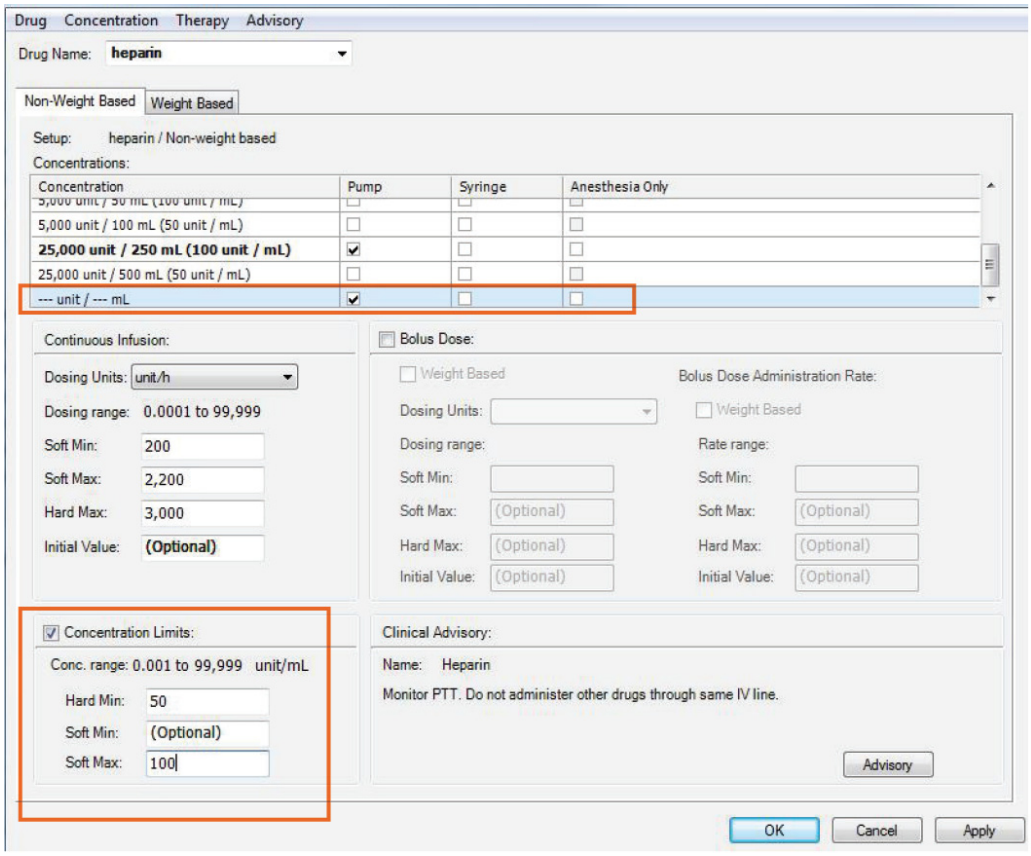
[1]Smart Pump Custom Concentrations without Hard "Low Concentration" Alerts Can Lead to Patient Harm. ISMP Web site. https://www.ismp.org/resources/smart-pump-custom-concentrations-without-hard-low-concentration-alerts-can-lead-patient. Accessed May 31, 2018.

BD Alaris™ Guardrails™ Editor Software

NOTE:
This section is applicable to Guardrails™ editor administrators only.

Custom concentration limits are available when a custom concentration is enabled within a continuous/bolus, intermittent, or PCA drug setup.

- Select the Concentration Limits check box to enable.



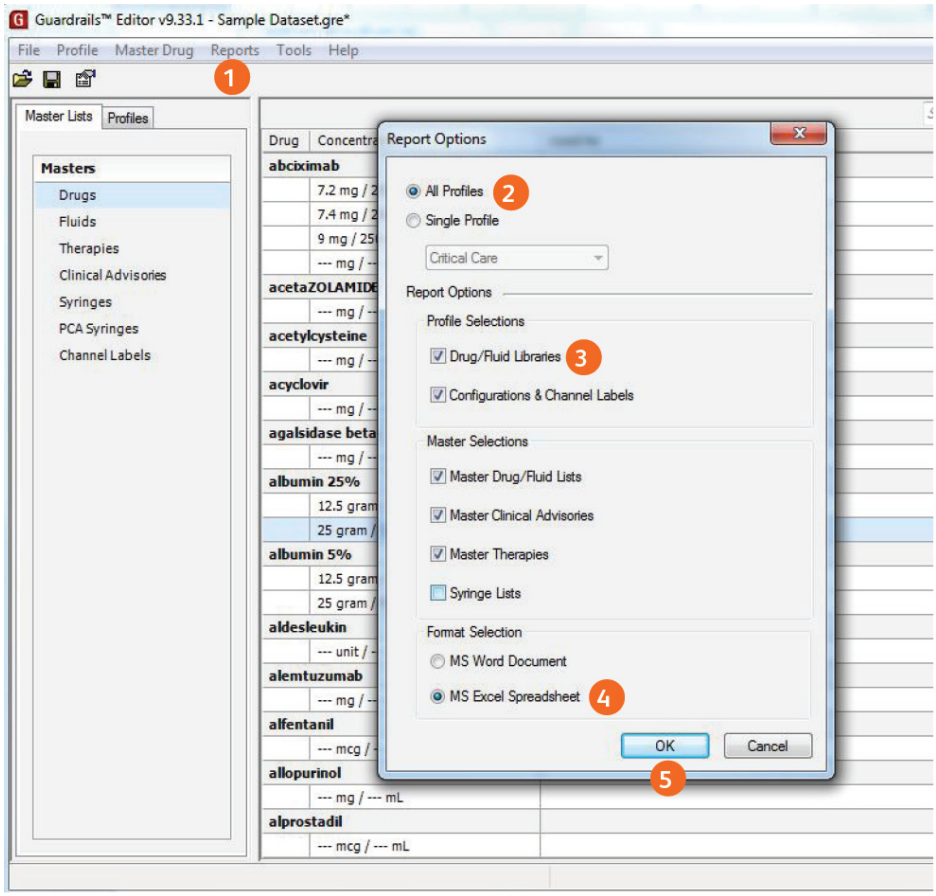
Reviewing Data Set for Custom Concentrations with No Hard Minimum Concentration Limits

To identify at-risk medication entries (continuous, bolus, PCA, and intermittents) without a set hard minimum concentration limit, do the following:

- For Guardrails™ editor versions 9.8 and earlier—manually review data set within Guardrails™ editor software or export the data set to a Microsoft Word™ document.
- For Guardrails™ editor versions 9.9 and later—utilize the Microsoft Excel™ report.

Generating an Excel Spreadsheet

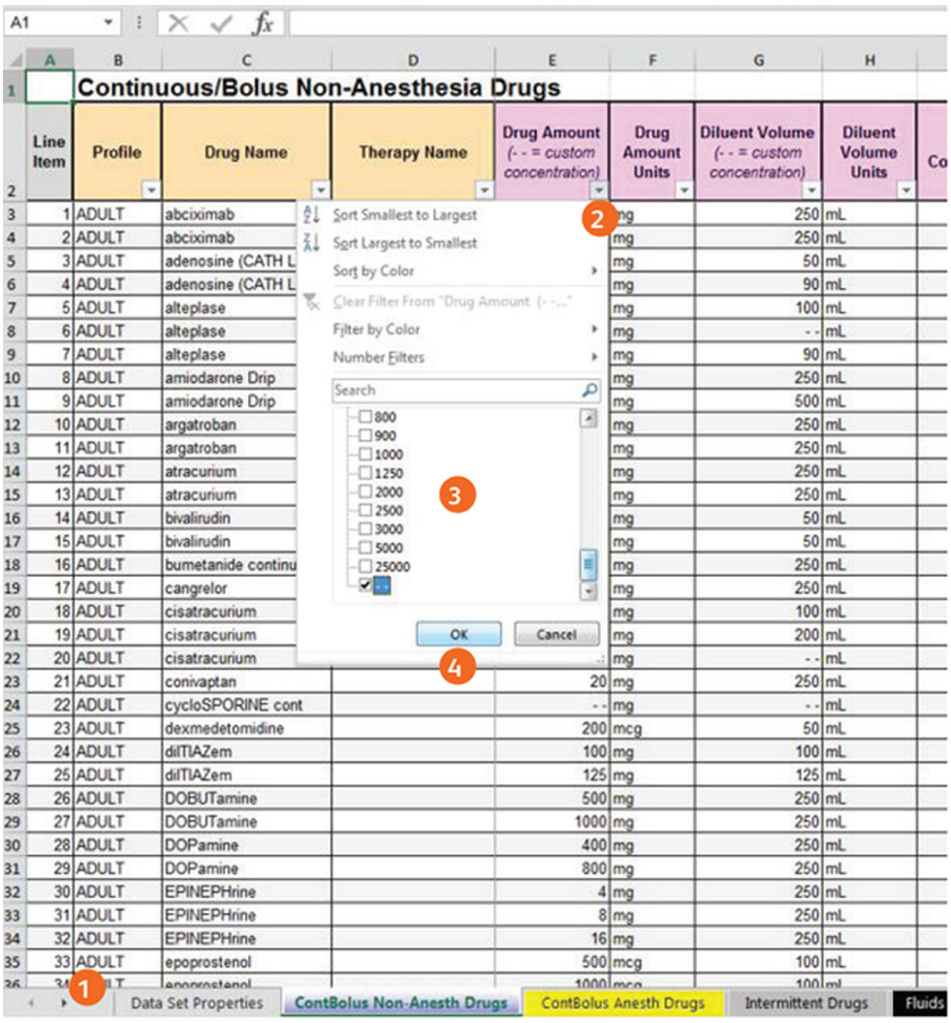
1. Select **Reports**.
2. Select **All Profiles**.
3. Select **Drug/Fluid Libraries**.
4. Select **MS Excel Spreadsheet**.
5. Click **OK**.



Filtering for Custom Concentrations with No Hard Minimum Concentration Limits

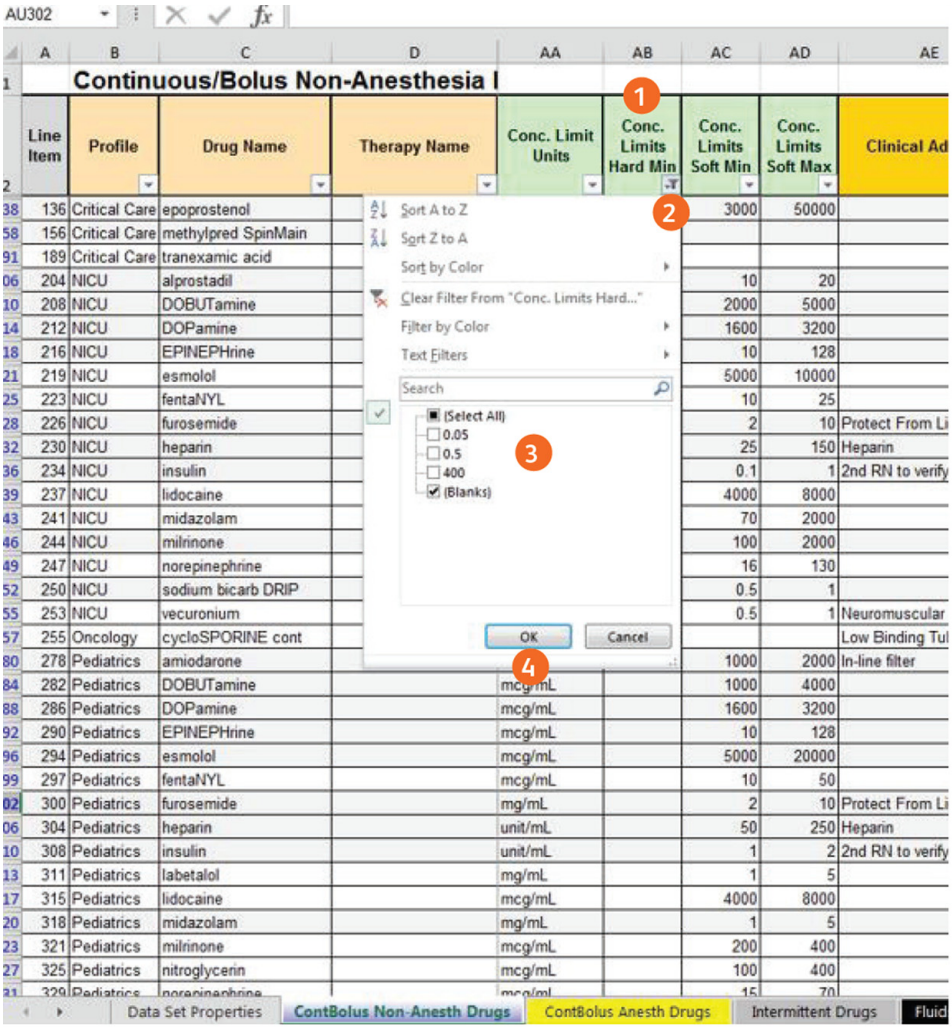
Filtering for Custom Concentrations

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 3
Battery Care and Maintenance

Battery Care and Maintenance

The battery is intended as a backup system, AC power is preferred and should be used whenever possible. If the device has been used on battery power, ensure that the battery is fully charged prior to using the device on battery power again.

To fully charge a depleted battery, connect the device to a hospital grade AC power source for 16 hours.

Biomedical engineering can refer to *Service Bulletin 592A* for more detailed battery care information.



WARNING

In certain situations, the Low Battery alarm and/or Very Low Battery alarm may not be generated when the battery power is low. In these situations, the PC unit generates a BATTERY DISCHARGE alarm and immediately suspends the infusion without any prior warning.

Accessing Documentation

For North American customers, service manuals, service bulletins, and software upgrade instructions are available through the *Customer Portal*. The following link takes you to the portal's Welcome screen: https://cp.carefusion.com/.

1. If you are registered, enter your email and password, and click **LOGIN**. If you are not registered yet, click **SIGN UP**, and follow the prompts.
2. On the BD Customer Portal home page, click **CONTENT LIBRARY**.
3. When the library page appears, select **Service bulletins and manuals** in the Content Type field to find the information you seek.

For customers outside of North America, contact BD Customer Support with Infusion Technical queries/questions at: DL-INTL-Infusion-Tech-Support@bd.com.