



CareFusion, a wholly-owned subsidiary of
Becton, Dickinson and Company (BD)
10020 Pacific Mesa Blvd
San Diego, CA 92121
1-888-876-4287 (toll-free)

www.bd.com

URGENT: Medical Device Recall Notification
AFFECTED DEVICE: BD Alaris™ System

February 4, 2020

Dear Valued BD Alaris™ System Customer:
Director of Biomedical Engineering
Director of Nursing
Director of Pharmacy
Director of Risk Management

BD is committed to providing safe and secure products to our customers given their important benefits to patient health. BD is initiating a voluntary recall to address the following issues:

- Issue 1:** Low Battery Alarm Failure
- Issue 2:** Keep Vein Open (KVO) / End of Infusion alarms priority
- Issue 3:** Use Errors related to Custom Concentration programming
- Issue 4:** KVO Rate Not Available When Using Delay Options programming

Overall Risk

The potential risks associated with these software issues have resulted in serious injury and death. Please ensure that you read this notification immediately and, in its entirety, to determine what mitigation steps to take until these software issues have been remediated. BD has assessed the potential risks associated with these issues and determined that affected products can continue to be used in accordance with the Alaris™ System with Guardrails™ Suite MX User Manual, User Manual Addendum, and this communication until they are serviced by BD with an upcoming software release. This letter provides important user actions to help mitigate the potential risks until these software issues have been remediated.

Overview of BD Actions

BD intends to address the issues described in this letter through an upcoming software release. BD will update the software for affected devices at no charge. BD will contact affected customers to initiate the scheduling process for the software update when the software becomes available. Without the software update, your devices may remain vulnerable to the potential risks associated with each issue described in this letter.

Affected Products

- BD Alaris™ System PC Unit Model 8015, software version 12.1.0
- BD Alaris™ Pump Module Model 8100, software version 12.1.0
- Alaris™ Syringe Module Model 8110, software version 12.1.0
- Alaris™ PCA Module Model 8120, software version 12.1.0

The following information provides the details of each issue, associated risks, recommended actions for each user, and BD actions for each issue.



Issue 1: Low Battery Alarm Failure

Overview of the Issue:

If the PC unit is running on battery power, a Low Battery alarm and Very Low Battery alarm should activate when 30 minutes and 5 minutes of estimated battery runtime remain. There are 2 software errors that may result in these low battery alarms not being generated before the BATTERY DISCHARGE ALARM. The BATTERY DISCHARGE ALARM will sound when the battery is depleted and the device will immediately shut down, stopping the infusion.

Potential Risk:

If the system is running on battery power and the operator is unaware of a low battery power state because low battery alarms have not been generated, the infusion may suddenly stop due to battery depletion.

High risk patient populations who are receiving life sustaining infusions are at the greatest risk of harm. For these patients, interruption of therapy can lead to serious injury or death. **BD has received five reports of serious injury that are potentially related to this issue. No reports of permanent injury or death have been attributed to this issue.**

Actions for Clinical Users:

Do not rely solely on the battery alarms to determine the status of your battery.

Whenever possible, keep the PC unit plugged into AC power. If the PC unit is disconnected from AC power and the battery is used, ensure that the PC unit is returned to AC power as soon as possible. After the device has been used on battery power, ensure that the battery is fully charged prior to using the device on battery power again.

Special care should be taken for critical infusions to ensure that AC power is used whenever possible. **Before transporting a patient (using battery power) who has a critical medication infusing, please ensure that the batteries are fully charged before the battery is used. If this is not possible, use an alternative pump that has a fully charged battery.**

Actions for Biomedical Engineering:

Follow recommended battery conditioning and maintenance per the Service Bulletin 592A. In particular, please note:

1. The battery should be replaced every 2 years by qualified service personnel.
2. The battery should be conditioned every 12 months by qualified service personnel.

Actions by BD:

BD issued a voluntary recall on Missed Low Battery Alarms and Service Bulletin 592A in November 2016. These 2 software errors will be addressed through an upcoming software release.



Issue 2: Keep Vein Open (KVO) / End of Infusion Alarms Priority

Overview of the Issue:

"KVO, End of Infusion" and "End of Infusion" alarms provide a medium priority alarm, not a high priority alarm, when the programmed Volume to be Infused (VTBI) has infused.

With the BD Alaris™ System, alerts and alarms are indicated by a combination of audible tones, visual flashing behavior, and a descriptive message on either the PC unit or scrolling module marquee.

Alarm Priority	Required User Response	Audio Characteristics	Visual Indicator
HIGH	Immediate	Profiles 1-3: Repeating sequence of 1-2 beeps followed by a 0.5 - 1.5 second pause Profile 4: Repeating sequence of 10 beeps followed by a 4 second pause	Flashing Red
MEDIUM	Prompt	Profiles 1-3: Repeating sequence of 1 beep followed by a 2 second pause Profile 4: Repeating sequence of 3 beeps followed by a 6 second pause	Flashing Yellow

Potential Risk:

The medium priority alarm setting may not be sufficient to ensure that the healthcare provider is notified that the infusion has completed (whether or not a KVO infusion rate, a non-therapeutic rate, has been programmed after the infusion).

High risk patient populations who are receiving life sustaining infusions are at the greatest risk of harm. For these patients, stopping or significantly lowering the infusion rate can lead to serious injury or death. **BD has received two reports of serious injury that are potentially related to end of infusion alarms priority. No reports of permanent injury or death have been attributed to this issue.**

Actions for Clinical Users:

Since this is a medium priority alarm, clinical users should check that the current audio volume on the BD Alaris™ PC unit is appropriate (or loud enough) for your clinical setting.

Action for Pharmacy:

Pharmacy should review the following configurable audio settings in the Guardrails™ Editor software for each care area Profile.

1. Review the Default Audio Volume setting and consider increasing it to the loudest audio volume setting. Setting 5 is the loudest audio volume setting.
2. For Editor software, review the minimum audio volume setting for each care area Profile and set to highest acceptable level.

Actions by BD:

"KVO, End of Infusion" and all "End of Infusion" alarms will be set to high priority in an upcoming software release.



Issue 3: Use Errors related to Custom Concentration Programming

Overview of the Issue:

BD is providing this medication safety information to raise awareness for the potential of data entry errors by the clinician when programming custom concentrations.

A data entry error made by the clinician when entering the DRUG AMOUNT and/or DILUENT VOLUME may result in calculated concentrations being lower or higher than the medication order causing over- or under-infusion.

The effect of this use error varies depending on whether the facility has configured Guardrails™ hard limits, soft limits or no limits for the calculated concentration.

Configuration of Concentration Limit	Effect when a Data Entry <u>Error</u> is made when programming custom concentrations
No Guardrails™ limit	Clinician can proceed without any alert.
Guardrails™ soft limit	Provides an alert notifying the clinician that the calculated concentration is above or below the Guardrails™ soft limit. The clinician may incorrectly determine that an alert below the soft limit is acceptable and therefore proceed with the infusion.
Guardrails™ hard limit	Does not allow the programmed infusion to proceed.

Consider the following two examples of programming custom concentrations, 1) an accurate programming sequence and 2) an inaccurate programming sequence that has a data entry error.

Example Medication Order: *Dopamine 800 mg/250 mL, start dose at 10 mcg/kg/min*

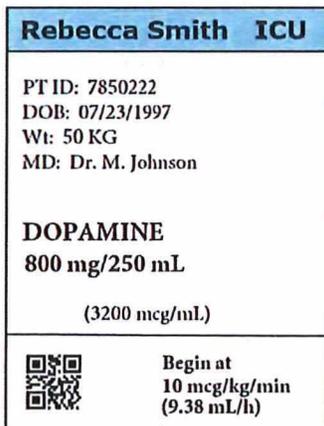


Figure 1: Example Medication Label

A. Correct Custom Concentration programming would be as follows:

If the clinician enters the following:

- 800 in the "DRUG AMOUNT" field (Figure 2)
- 250 in the "DILUENT VOLUME" field (Figure 2), which would then lead to the next programming screen to enter the dose.
- 10 in the "DOSE" field (Figure 3)

Then, when the infusion is started, the infusion would proceed correctly as ordered.



The following PC unit screen shots show accurate data entry using the example medication order: *Dopamine 800 mg/250 mL, start dose at 10 mcg/kg/min.*

A Guardrails Drug Setup Dopamine	
DRUG AMOUNT	800 mg
DILUENT VOLUME	250 mL
PATIENT WEIGHT	50 kg
TIME UNITS	min
DOSE UNITS	mcg/kg/min
[Conc]:	3200 mcg/mL
>Press NEXT to Confirm	
DRUG LIBRARY	NEXT

Figure 2. PC unit programming screen
Correct Drug Amount is entered
Correct Diluent Volume is entered
Correct Calculated Concentration is shown

A Guardrails Drug Setup Dopamine			
CONTINUOUS INFUSION			
RATE	9.38 mL/h		
VTBI	250 mL		
DOSE	10 mcg/kg/min		
[Conc]:	3200 mcg/mL		
>Press START			
PAUSE	SETUP	BOLUS	START

Figure 3. PC unit programming screen
Correct Dose is entered
Correct Calculated Concentration is shown

B. Custom Concentration programming with a data entry error by the clinician and no concentration limits in the drug library:

If the clinician enters the following:

- 10 in the "DRUG AMOUNT" field (Figure 4)
- 250 in the "DILUENT VOLUME" field, which would then lead to the next programming screen to enter the dose. (Figure 4)
- 10 in the "DOSE" field (Figure 5)

The following PC unit screen shots show incorrect data entry using the example medication order: *Dopamine 800 mg/250 mL, start at a dose of 10 mcg/kg/min*

A Guardrails Drug Setup Dopamine	
DRUG AMOUNT	10 mg
DILUENT VOLUME	250 mL
PATIENT WEIGHT	50 kg
TIME UNITS	Min
DOSE UNITS	mcg/kg/min
[Conc]:	40 mcg/mL
>Press NEXT to Confirm	
DRUG LIBRARY	NEXT

Figure 4. PC unit programming screen
INCORRECT Drug Amount is entered
Correct Diluent Volume is entered
INCORRECT Calculated Concentration is shown

A Guardrails Drug Setup Dopamine			
CONTINUOUS INFUSION			
RATE	750 mL/h		
VTBI	250 mL		
DOSE	10 mcg/kg/min		
[Conc]:	40 mcg/mL		
>Press START			
PAUSE	SETUP	BOLUS	START

Figure 5. PC unit programming screen
Correct Dose is entered
INCORRECT Calculated Concentration is shown

Then, when the infusion is started, the calculated concentration results in a calculated concentration being lower than the example medication order. In other words, the clinician has now incorrectly established a dopamine calculated concentration of **40 mcg/mL instead of 3200 mcg/mL** from incorrectly entering dose in the DRUG AMOUNT field. With the intended dose of 10 mcg/kg/min entered, the infusion **will infuse the entire 250 mL bag containing 800 mg** at 750 mL/hour over 20 minutes if no one intervenes.

Further, if Guardrails™ soft limits are configured by the facility, the clinician may receive an alert that the calculated concentration is below the Guardrails™ soft limit. The clinician may incorrectly determine that this is acceptable and therefore the clinician proceeds with the infusion.



Potential Risk:

A data entry error by the clinician when entering the DRUG AMOUNT and/or DILUENT VOLUME fields during custom concentration programming may result in over- or under- infusion.

High risk patient populations who are receiving life sustaining infusions are at the greatest risk of harm. For these patients, data entry errors can lead to serious injury or death. **BD has received one report of death and thirteen reports of serious injury that are potentially related to this issue.**

Actions for Clinical Users:

Custom concentration should only be used when the medication label does not match any of the drug concentration selections on the programming screen. *See Attachment A: Programming an Infusion with a Custom Concentration Entry.* For additional information, please refer to *Chapter 2: Custom Concentrations and Hard Minimum Concentration Limits* in the User Manual Addendum provided with your Alaris™ System.

When programming a custom concentration, clinicians should always review the medication label and program the DRUG AMOUNT and DILUENT VOLUME as indicated on the medication label. After programming the DRUG AMOUNT and DILUENT VOLUME, verify that the calculated concentration displayed at the bottom of the programming screen is correct. Clinicians should always review and confirm infusion parameters before pressing START.

Through a future software release, BD will update the Custom Concentration workflows. In the interim, BD will provide a Medication Safety program for clinical users and pharmacists, which is described below in the "BD Actions" section.

Actions for Pharmacy:

Review and implement ISMP best practices, as outlined in the article [*Smart Pump Custom Concentrations without Hard "Low Concentration" Alerts Can Lead to Patient Harm*¹](#). The following is a subset of the ISMP best practices:

- a. Standardize concentrations as much as possible for high alert IV medications. Remove custom concentration options from the drug library when a standard concentration for that drug has been established in the library.
- b. Configure both soft and hard limits for custom concentration entries in the drug library. *See Attachment B: Pharmacy quick reference guide: Hard minimum concentration limits.* For additional information, please refer to *Chapter 2: Custom Concentrations and Hard Minimum Concentration Limits* in the User Manual Addendum provided with your Alaris™ System.
- c. The Medication Administration Record (MAR) and the infusion label should present the drug and concentration (and infusion rate, if provided) in the same units and sequence required when programming the pump, with specific instructions for custom concentrations as necessary.

BD Actions:

BD will update the Custom Concentration workflow in an upcoming software release. In the interim, BD will offer an Alaris™ Medication Safety program for Custom Concentrations, including:

- a. Training for Nurse Educators, Pharmacy, Nursing, Medication Safety Officers, and Guardrails™ administrators by BD's pharmacy and clinical consultants

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



- b. Implementing best practices for Custom Concentrations
- c. Medication Safety Webinars led by BD Pharmacy and Clinical Consultants
- d. Enhanced training materials such as quick reference documents and best practice articles

Issue 4: KVO Rate Not Available When Using Delay Options programming

Overview of the Issue:

In the Alaris™ System with software version 12.1.0, the Delay Options feature allows the user to schedule and program a delayed infusion and select an audiovisual callback alert, if desired. When the user programs an infusion using Delay Options, regardless of scheduling a Callback, and when the infusion completes, no KVO rate is delivered.

Potential Risk:

In the Alaris™ System with software version 12.1.0, an infusion initiated with the Delayed Programming option, WILL appropriately sound an end of infusion alarm, but will not transition to a KVO rate at the end of the infusion. It is possible that in certain situations, the absence of a KVO rate might result in an occluded catheter. **There are no reports of serious injury or death that have been attributed to this issue.**

Actions for Clinical Users:

Do not use Delay Options when a KVO rate is required.

Actions for Pharmacy:

Pharmacy should consider disabling Delay Start Options in the Guardrails™ Editor software for care area Profiles where KVO rate is required. The default setting is set to Disabled. Disabling the Delay Start Option will remove the risks associated with this software feature. See *Attachment C: Pharmacy quick reference guide: Delay options.*

Actions by BD:

Enabling a KVO rate when using Delay Options will be addressed through an upcoming software release.

Summary Actions by BD:

BD intends to address the issues described in this letter through an upcoming software release. BD will update the software for affected devices at no charge. BD is in discussions with FDA about the release of the upcoming software version, and we will notify our customers as soon as it becomes available. BD will contact affected customers to initiate the scheduling process for the software update. Without the software upgrade, your devices may remain vulnerable to the potential risks associated with each issue described above.

BD also will offer an Alaris™ Medication Safety program for Custom Concentrations to help customers implement best practices for using custom concentrations. BD is committed to medication safety and will contact all customers to provide training and consulting on best practices for the Alaris System. BD's pharmacy and clinical consultants will support training for Nurse Educators, Pharmacy, Nursing, Medication Safety Officer, and Guardrails administrator. BD will offer clinical and technical consulting as well as training including webinars, videos, and instructions for use. BD has established a website for easy access to these resources and to support customers with this recall. Please visit www.bd.com/alaris-system-software-recall.



Contact Information:

The US Food and Drug Administration has been notified of this action. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Web: MedWatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178, or by
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

If you have any questions regarding the products, please contact:

Contact	Contact Information	Areas of Support
BD Customer Advocacy	Phone: 888-812-3266 Phone hours: 7:00am to 5:00pm PT Monday – Friday Email: customerfeedback@bd.com	Product Complaints
Training Resources	BD has established a website for easy access to training resources and to support customers with this recall. Please visit www.bd.com/alaris-system-software-recall	End-user training outlined in this notification
Clinical & Pharmacy Support Center	Phone: 858-617-1316 Phone hours: 5:00am to 5:00pm PT Monday - Friday Email: GMB-AlarisMedSafetyProgram@bd.com	Clinical or Pharmacy Related Questions
BD Recall Support Center	Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday – Friday Email: SupportCenter@bd.com	Recall Related Questions
Technical Support	Phone: 888-812-3229 Phone hours: 6:00am to 5:00pm PT, Monday – Friday Email: DL-US-INF-TechSupport@bd.com	Technical Questions

Please promptly complete and return the enclosed Customer Response Card to acknowledge receipt of this notification and the recall instructions provided in this letter and its attachments.

BD's actions are guided by our commitment to patient safety and minimizing disruption of patient care. We regret the inconvenience that may result from this recall, but we are committed to achieving the highest levels of customer satisfaction and serving your infusion product needs.

Sincerely,

Keith McLain
 Worldwide Vice President of Quality for
 Medication Management Solutions

Idal Beer, MD
 Vice President of Medical Affairs for
 Medication Management Solutions

Enclosures:

- Attachment A: Programming an Infusion with a Custom Concentration Entry
- Attachment B: Pharmacy quick reference guide: Hard minimum concentration limit
- Attachment C: Pharmacy quick reference guide: Delay options
- Attachment D: Customer Response Card

Programming an infusion with a custom concentration entry

BD Alaris™ System

Your hospital may choose to have a medication with an unspecified concentration entry (e.g., ___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.

Step 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.

Rebecca Smith ICU	
PT ID: 7850222	DOB: 07/23/1997
Wt: 50 KG	MD: Dr. M. Johnson
DOPAMINE 800 mg/250mL (3200 mcg/mL)	
Begin at 10 mcg/kg/min (9.38 mL/h)	

Figure 1—Sample drug label

No concentration entries for Dopamine match the drug label (see Figures 1 and 2).

Guardrails Drugs Adult ICU
Dopamine
400mg/250mL
___mg/___mL
>Select CONCENTRATION

Figure 2

Guardrails Drugs Adult ICU
Dopamine
___mg/___mL was selected.
Is this correct?
Yes
No
DOSING UNITS: mcg/kg/min
BOLUS DOSING UNITS: mcg/kg
>Press Yes or No

Figure 3

The custom concentration entry “___mg/___mL” must be selected to manually enter the ordered concentration (see Figure 3).

Step 2: Enter the DRUG AMOUNT and DILUENT VOLUME. Then confirm the concentration on the display matches the medication label

Guardrails Drug Setup Dopamine
DRUG AMOUNT: ___ mg
DILUENT VOLUME: ___ mL
PATIENT WEIGHT: ___ kg
TIME UNITS: Min
DOSING UNITS: mcg/kg/min
>Enter Amount of Drug in Container
DRUG LIBRARY

Figure 4

Guardrails Drug Setup Dopamine
DRUG AMOUNT: 800 mg
DILUENT VOLUME: 250 mL
PATIENT WEIGHT: 50 kg
TIME UNITS: Min
DOSING UNITS: mcg/kg/min
[Conc]: 3200 mcg/mL
>Press NEXT to Confirm
DRUG LIBRARY NEXT

Figure 5

Concentration is calculated from the entry of the **DRUG AMOUNT** and **DILUENT VOLUME** (see Figures 4 and 5).

Concentration

Note: The **DRUG AMOUNT** is not the **DOSE**. The **DOSE** is entered on the next screen (see Figure 6).

Guardrails Drug Setup Dopamine
CONTINUOUS INFUSION
RATE: 9.38 mL/h
VTBI: 250 mL
DOSE: 10 mcg/kg/min
[Conc]: 3200 mcg/mL
>Press START
PAUSE SETUP BOLUS START

Figure 6

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*).

Guardrails Drug Setup Dopamine
Concentration is below Guardrails limit of 1000 mcg/mL. Proceed?
Yes
No
>Press Yes or No

Figure 7

If a concentration Guardrails™ Safety Software alert is encountered during programming, to ensure accuracy, select **No** and check that the following parameters match the drug label (see Figure 7):

- **DRUG AMOUNT**
- **DILUENT VOLUME**
- **[Conc]** (concentration)

For product support, contact Customer Advocacy at **888.812.3266** or customerfeedback@bd.com

For technical support, contact our Technical Support Center at **866.488.1408**.

For product orders, contact Customer Order Management at **800.482.4822**.

For complete instructions, refer to the BD Alaris™ System User Manual at bd.com

BD, San Diego, CA, 92130, U.S.

bd.com



Pharmacy quick reference guide:

Hard minimum concentration limits

Your hospital may choose to have a medication with an unspecified concentration entry (e.g., ___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.

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*).

Hard minimum concentration limits in your hospital's dataset 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**

Rebecca Smith ICU
PT ID: 7850222 DOB: 07/23/1997 Wt: 50 KG MD: Dr. M. Johnson
DOPAMINE 800 mg/250mL (3200 mcg/mL)
Begin at 10 mcg/kg/min (9.38 mL/h)

Figure 1—Sample drug label

A Guardrails Drug Setup Dopamine
DRUG AMOUNT 10 mg
DILUENT VOLUME ___ mL
PATIENT WEIGHT 50 kg
TIME UNITS Min
DOSING UNITS mcg/kg/min
>Select DILUENT VOLUME
DRUG LIBRARY

Figure 2

A Guardrails Drug Setup Dopamine
DRUG AMOUNT 10 mg
DILUENT VOLUME _250 mL
PATIENT WEIGHT 50 kg
TIME UNITS Min
DOSING UNITS mcg/kg/min
[Conc]: 40 mcg/mL
>Press NEXT to Confirm
DRUG LIBRARY NEXT

Figure 3

A Guardrails Drug Setup Dopamine
CONTINUOUS INFUSION
RATE 750mL/h
VTBI _250mL
DOSE 10 mcg/kg/min
[Conc]: 40 mcg/mL
>Press START
PAUSE SETUP BOLUS START

Figure 4

In the provided example, if programming errors are not noticed prior to pressing the START key, an over-infusion would occur (see Figure 4).

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 at a dose of 8.8 unit/h = rate **880 mL/h**

Rebecca Smith ICU
PT ID: 7850222 DOB: 07/23/1997 Wt: 50 KG MD: Dr. M. Johnson
INSULIN 100 units/100mL (1 unit/mL)
Begin at dose of 8.8 unit/hr = (rate of 8.8 mL/h)

Figure 5—Sample drug label

A Guardrails Drug Setup Insulin
DRUG AMOUNT 1 unit
DILUENT VOLUME ___ mL
PATIENT WEIGHT Not Used
TIME UNITS Hour
DOSING UNITS unit/h
>Select DILUENT VOLUME
DRUG LIBRARY

Figure 6

A Guardrails Drug Setup Insulin
DRUG AMOUNT 1 unit
DILUENT VOLUME _100 mL
PATIENT WEIGHT Not Used
TIME UNITS Hour
DOSING UNITS unit/h
[Conc]: 0.01 unit/mL
>Press NEXT to Confirm
DRUG LIBRARY NEXT

Figure 7

A Guardrails Drug Setup Insulin
CONTINUOUS INFUSION
RATE 880 mL/h
VTBI _100 mL
DOSE 8.8 unit/h
[Conc]: 0.01 unit/mL
>Press START
PAUSE SETUP BOLUS START

Figure 8

In the provided example, if programming errors are not noticed prior to pressing the START key, an over-infusion would occur (see Figure 8).



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 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 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 BD Alaris™ 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

Guardrails™ Editor Software (see Figure 9)

Custom concentration limits are available when a custom concentration is enabled within a continuous/bolus, intermittent or PCA drug setup. Click the Concentration Limits checkbox to enable.

The screenshot shows the 'Guardrails Editor Software' interface for Heparin. The 'Drug Name' is 'heparin'. The 'Concentration' tab is selected. The 'Setup' is 'heparin / Non-weight based'. The 'Concentrations' table is as follows:

Concentration	Pump	Syringe	Anesthesia Only
5,000 unit / 100 mL (50 unit / mL)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25,000 unit / 250 mL (100 unit / mL)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25,000 unit / 500 mL (50 unit / mL)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--- unit / --- mL	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The 'Continuous Infusion' section has 'Dosing Units' set to 'unit/h', 'Dosing range' of '0.0001 to 99,999', 'Soft Min' of '200', 'Soft Max' of '2,200', 'Hard Max' of '3,000', and 'Initial Value' as '(Optional)'. The 'Bolus Dose' section has 'Weight Based' checked, 'Dosing Units' as a dropdown, 'Dosing range' as a dropdown, 'Soft Min' as '(Optional)', 'Soft Max' as '(Optional)', 'Hard Max' as '(Optional)', and 'Initial Value' as '(Optional)'. The 'Bolus Dose Administration Rate' section has 'Weight Based' unchecked, 'Rate range' as a dropdown, 'Soft Min' as '(Optional)', 'Soft Max' as '(Optional)', 'Hard Max' as '(Optional)', and 'Initial Value' as '(Optional)'. The 'Clinical Advisory' section has 'Name' as 'Heparin' and 'Monitor PTT. Do not administer other drugs through same IV line.' The 'Concentration Limits' section is checked, with 'Conc. range' of '0.001 to 99,999 unit/mL', 'Hard Min' of '50', 'Soft Min' as '(Optional)', and 'Soft Max' of '100'. The 'Advisory' button is visible at the bottom right.

Figure 9

Review dataset 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:

- For GRE versions 9.8 and below—manually review dataset within Guardrails™ Editor Software or export dataset to a Word document
- For GRE versions 9.9 and above—utilize the Excel report

Generate an Excel spreadsheet (see Figure 10)

- 1 Select Reports
- 2 Select All Profile
- 3 Select Drug/Fluid Libraries
- 4 Select MS Excel Spreadsheet
- 5 Click OK

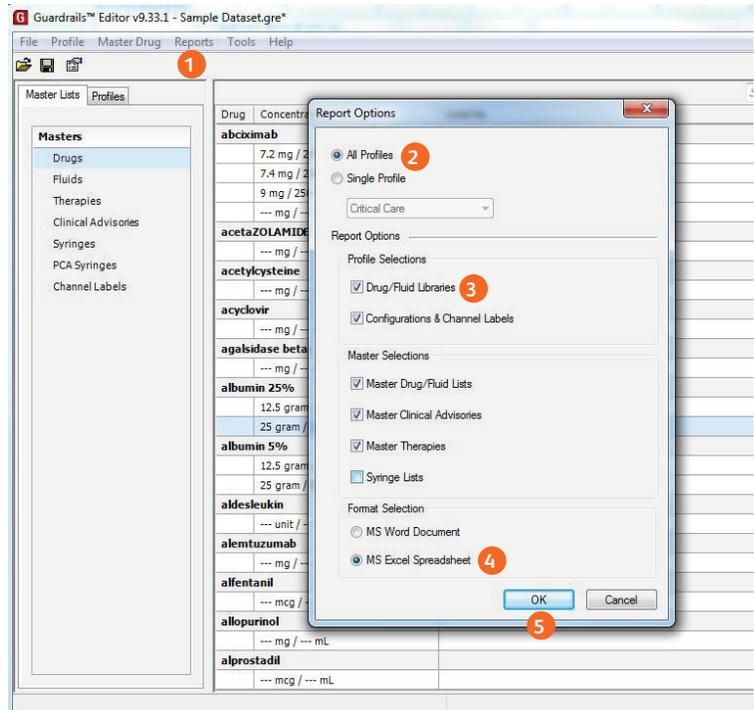


Figure 10

How to filter for custom concentrations with NO hard minimum concentration limits

Filter for custom concentrations (see Figure 11)

- 1 Select library tab
- 2 Select filter box for Drug Amount
- 3 Deselect all and select custom drug amount (“--“)
- 4 Click OK

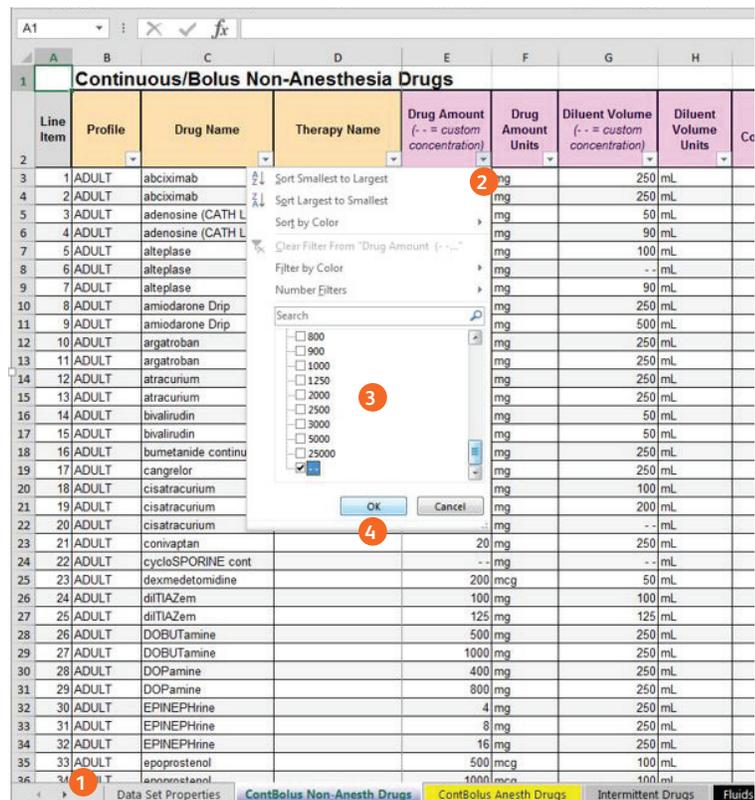


Figure 11

Filter for NO hard minimum concentrations

(see Figure 12)

- 1 Scroll to Conc. Limits Hard Min column
- 2 Select filter
- 3 Deselect all and select Blanks
- 4 Click OK
- 5 Repeat for the other drug library tabs

Line Item	Profile	Drug Name	Therapy Name	Conc. Limit Units	Conc. Limits Hard Min	Conc. Limits Soft Min	Conc. Limits Soft Max	Clinical Ad
138	Critical Care	epoprostenol				3000	5000	
158	Critical Care	methylypred SpinMain						
191	Critical Care	tranexamic acid						
206	NICU	alprostadil				10	20	
210	NICU	DOBUTamine				2000	5000	
214	NICU	DOPamine				1600	3200	
218	NICU	EPINEPHrine				10	128	
221	NICU	esmolol				5000	10000	
225	NICU	fentaNYL				10	25	
228	NICU	furosemide				2	10	Protect From Li
232	NICU	heparin				25	150	Heparin
236	NICU	insulin				0.1	1	2nd RN to verify
239	NICU	lidocaine				4000	8000	
243	NICU	midazolam				70	2000	
246	NICU	milrinone				100	2000	
249	NICU	norepinephrine				16	130	
252	NICU	sodium bicarb DRIP				0.5	1	
255	NICU	vecuronium				0.5	1	Neuromuscular
257	Oncology	cycloSPORINE cont						Low Binding Tui
280	Pediatrics	amiodarone				1000	2000	In-line filter
284	Pediatrics	DOBUTamine		mcg/mL		1000	4000	
288	Pediatrics	DOPamine		mcg/mL		1600	3200	
292	Pediatrics	EPINEPHrine		mcg/mL		10	128	
296	Pediatrics	esmolol		mcg/mL		5000	20000	
299	Pediatrics	fentaNYL		mcg/mL		10	50	
302	Pediatrics	furosemide		mg/mL		2	10	Protect From Li
306	Pediatrics	heparin		unit/mL		50	250	Heparin
310	Pediatrics	insulin		unit/mL		1	2	2nd RN to verify
313	Pediatrics	labetalol		mg/mL		1	5	
317	Pediatrics	lidocaine		mcg/mL		4000	8000	
320	Pediatrics	midazolam		mg/mL		1	5	
323	Pediatrics	milrinone		mcg/mL		200	400	
327	Pediatrics	nitroglycerin		mcg/mL		100	400	
331	Pediatrics	noraninaphthine		mcg/mL		15	70	

Figure 12

Reference

1 Smart pump custom concentrations without hard “low concentration” alerts can lead to patient harm. ISMP website. <https://www.ismp.org/resources/smart-pump-custom-concentrations-without-hard-low-concentration-alerts-can-lead-patient>. Accessed May 31, 2018.

Pharmacy quick reference guide:

Delay Options

Clinical scenario: Patient's blood sugar is 65 mg/dL and the physician orders to hold insulin drip for 45 minutes, then recheck and resume if above 80 mg/dL. Clinician sets a delay for 45 minutes with a callback BEFORE. The clinician resumes the infusion. When the infusion completes—the infusion will STOP. There is NO KVO rate and an alarm **will not** occur for device firmware versions 9.19 and earlier.

Best practice recommendation:

- Disable Delay Start Options for care area profiles that utilize continuous critical medications whose stoppage without an alarm or KVO rate have the potential to impact therapeutic dosing.
- If Delay Start is enabled—set default Delay Start Callback of “**After**” or “**Before and After**” to receive an end of infusion alarm when the infusion stops. If a callback of “None” or “Before” is selected, the end of infusion status may result in the infusion ending with NO alarm and NO KVO rate.

WARNING: Delay Options should not be used for critical medications whose stoppage without an alarm or KVO rate have the potential to impact therapeutic dosing.

Guardrails™ Editor Software: Delay Start Options configuration

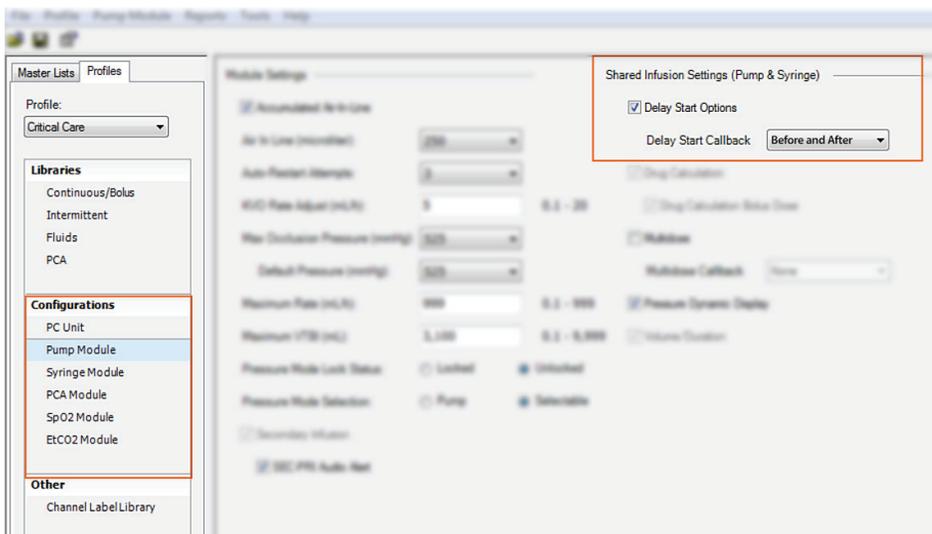
Delay Start Options is a shared infusion setting with the Pump & Syringe module for each profile.

Disable Delay Start Options—uncheck Delay Start Options checkbox

(Recommend for profiles with continuous medications whose stoppage without an alarm or KVO rate has the potential to impact therapeutic dosing.)

Adjust Delay Start default callback options—select “**After**” or “**Before and After**” from the drop-down box if Delay Start Options is enabled.

*(Selection of “**After**” or “**Before and After**” will provide an end of infusion alarm when infusion is complete.)*



BD, San Diego, CA, 92130, U.S.

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10020 Pacific Mesa Blvd.
San Diego, CA 92121
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February 2020

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