URGENT MEDICAL DEVICE RECALL
BD ALARIS SYSTEM
INFUSION PUMPS

***Total CPU/Units Identified within UHealth Inventory – (1,254)***
***Total Modules Identified within UHealth Inventory – (2,163)***

What to KNOW about the Urgent Medical Device Recall:
- BD has initiated a voluntary recall to address the following issues: by UHealth Priority
  - Issue 1: Use Errors related to Custom Concentration programming.
  - Issue 2: Low Battery Alarm Failure.
  - Issue 3: Software errors related to System Error Code 255-XX-XXX.
  - Issue 4: Keep Vein Open (KVO)/End of Infusion alarms priority.
  - Issue 5: Delay Options programming.

Recommended ACTIONS from BD Alaris until software release:
- Issue 1: Use Errors related to Custom Concentration programming.
  - Pharmacy Staff: Verify the programming matches the medication labeling.

- Issue 2: Low Battery Alarm Failure
  - Clinical Staff: Pumps should remain plugged into an outlet whenever possible.
    - ***Verify battery level prior to unplugging or transporting patients***

  - Clinical Staff: If error code appears and when safe to do so, secure another PC unit and program infusions on the new unit.
    - ***Tag and Return the affected pump to Clinical Engineering***

- Issue 4: No Keep Vein Open (KVO)/End of Infusion alarm.
  - Clinical Staff: Ensure that audio volume is set to the appropriate hearing level.

- Issue 5: Delay Options programming.
  - UHealth is currently on software Version 9.33 and the Infusion Complete Alarm is currently enabled.
  - Pharmacy Staff: Review configurable audio settings in the Guardrails Editor for each care area profiles and set to HIGH PRIORITY.
Who to CONTACT regarding Care Fusion – BD Alaris Infusion Pump Urgent Recall:

- If you have any additional questions, please contact:
  - **Arthur Thomas – Executive Director of Clinical Engineering**
    - **Phone:** 305-243-5892  |  **Email:** axt800@med.miami.edu
    - UHealth Clinical Engineering Department
  - **Nursing:**
    - Your local nurse manager
  - **Pharmacy:**
    - **Christina Vargas – Assistant Director, UHealth Towers**
      - **Phone:** 305-689-4557  |  **Email:** CVargas@med.miami.edu
    - **Diana Reyes - Assistant Director, Sylvester Cancer Center**
      - **Phone:** 305-243-2340  |  **Email:** dxr@med.miami.edu
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  - Issue 5: Delay Options programming.

ACTIONS from Clinical Engineering:
- Daily Rounds
  - Identifying Pumps which have System Error codes 255-XX-XXX
    - Contact BD Customer Advocacy and inform them of our affected pumps.
  - Sequester affected pumps and keep a log of all pumps found, which are affected by this recall.
  - Replace affected pumps as identified.
  - Returns affected pump back to BD CareFusion.
  - Weekly updates to nursing and the Uhealth Medical Systems.
  - Maintain battery conditioning and maintenance according the Original Equipment Manufacturer specification.
    - The battery should be replaced every 2 years.
    - The battery should be conditioned every 12 months.

Who to CONTACT regarding Care Fusion – BD Alaris Infusion Pump Urgent Recall:
- If you have any additional questions, please contact:
  - Arthur Thomas – Executive Director of Clinical Engineering
    - Phone: 305-243-5892 | Email: axt800@med.miami.edu
    - UHealth Clinical Engineering Department

Please Click Here for additional information: Clinical Engineering Website
What is the Delay Options feature?

The Delay Options feature allows the user to schedule and program an infusion to be delayed for up to 120 minutes, or until a specific timeframe, up to 23 hours and 59 minutes. With a delayed infusion, the system assumes another infusion is running to keep the IV line ready until the delayed infusion initiates. A delayed infusion does not revert to KVO at the end of the infusion. A delayed options callback allows the user to select an audiovisual callback alert.

One of three infusion callback types can be selected:

**Before:** Receive a callback when the delay period ends and the infusion needs to be initiated. The infusion will stop without an alarm or KVO rate for firmware versions prior to 9.33.

**After:** Receive a callback when the delayed infusion has been completed.

**Before and After:** Receive a callback when the infusion needs to initiate (after delay) and again when the infusion has been completed.

CAUTION: The system does not revert to KVO at the end of an infusion with delayed options. 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. For systems with firmware versions prior to 9.33, there is no audio alert when the delayed infusion is complete, unless the CALLBACK After or Before and After option has been programmed.

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.

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How to program a delayed options infusion:

1. Select the **Delay Options** soft key on the BD Alaris™ PC Unit.
2. Select a Delay Option (see Figure 1).
3. If the **Delay Until** option is chosen, **Current time** must be confirmed prior to programming the delay (see Figure 2).

   **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 (see Figure 3).
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.

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**Figure 1**

**Figure 2**

**Figure 3**

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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.
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.)
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.

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

![Concentration](image)

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

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)

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

BD.com

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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

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

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.*

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**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.
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](image)

**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](image)
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

Reference
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:** Software errors related to System Error Code 255-XX-XXX
**Issue 2:** Delay Options programming
**Issue 3:** Low Battery Alarm Failure
**Issue 4:** Keep Vein Open (KVO) / End of Infusion alarms priority
**Issue 5:** Use Errors related to Custom Concentration 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 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 8000, software versions 9.5 and prior
- BD Alaris™ System PC Unit Model 8015, software versions 9.33 and prior
- BD Alaris™ Pump Module Model 8100, software versions 9.33 and prior
- Alaris™ Syringe Module Model 8110, software versions 9.33 and prior
- Alaris™ PCA Module Model 8120, software versions 9.33 and prior

The following information provides the details of each issue, associated risks, recommended actions for each user, and BD actions for each issue.
Issue 1: Software Errors related to System Error Code 255-XX-XXX

Overview of the Issue:
System Error 255-XX-XXX can occur when a user selects two functions at the same time/rapid succession (less than one second) or when not following typical workflows. This results in a synchronization issue between the PC unit and the modules.

This System Error results in a non-silenceable, high priority alarm and status indicator lights on modules will flash red. The PC unit displays an error code beginning with 255 (i.e., 255-XX-XXX). Although the modules will continue as programmed, the programmed settings cannot be edited. If editing of programmed settings is critical, it may be necessary to interrupt and restart the infusion using a different PC unit.

BD issued a voluntary recall in June 2017 regarding this issue and has subsequently identified additional software errors resulting in System Error Code 255-XX-XXX.

Potential Risk:
Receiving this System Error could result in a delay to the start of an infusion. High risk patient populations who are receiving life sustaining infusions are at the greatest risk of harm. For these patients, delays in an infusion can cause serious injury or death. **BD has received nineteen 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:
If the error occurs while you are administering a critical medication(s), continue the infusion while you expedite a replacement pump if one is readily available, or restart and reprogram the PC unit.

If editing of programmed settings of the critical medications is necessary, or if your infusion can be safely stopped, then power down the PC unit by pressing the SYSTEM ON key, indicated by a red, flashing arrow. Restart the device by pressing the SYSTEM ON key, program the pump as appropriate. Infusions are not restorable and will require reprogramming.

If the System Error returns, power down the PC unit and replace it immediately. Return the PC unit to your Biomedical Engineering department for troubleshooting and log retrieval.

Please read the User Manual Addendum for software version 9.33, see attachment A. **BD has released an updated User Manual Addendum for software versions 9.33 and earlier that outlines various scenarios, steps that may result in the System Error, and tips on how to avoid the System Error.**

Actions for Biomedical Engineering:
If you have a PC unit with this System Error, please contact Customer Advocacy at the contact information listed below.

Actions by BD:
System Error 255-XX-XXX will be addressed through an upcoming software release. In the interim, **BD has released an updated User Manual Addendum for software versions 9.33 and earlier that outlines various scenarios, steps that may result in the System Error, and tips on how to avoid the System Error.**
Issue 2: Delay Options programming

Overview of the Issue:
The Delay Options feature allows the user to schedule and program a delayed infusion and select an audiovisual callback alert, if desired. Delay options programming impacts the end of an infusion as described below:

a. For Alaris System software versions 9.19 and prior: when the user schedules a Callback as ‘Before’ or ‘None’ in Delay Options, the infusion will stop without an end of infusion alarm or KVO rate.

b. For Alaris System software version 9.33 and later: when the user schedules a Callback as ‘Before’ or ‘None’ in Delay Options, there is an Infusion Complete alarm at the end of the delayed infusion but there is no KVO rate.

c. For all software versions: 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:
An infusion that stops without an End of Infusion alarm may result in an interruption of therapy. High risk patient populations who are receiving high alert IV medications are at the greatest risk of harm. For these patients, interruptions of therapy can cause serious injury or death. BD has received sixteen 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:
When programming continuous infusions for high-alert medications that require an End of Infusion alarm:

NOTE: For these instructions, the clinician must know the software version on the pump. Please see step “a” below for details regarding how to determine the software version on the pump.

a. If you are unaware of the software version for the device you are programming, follow the steps below to identify the software version:
   i. Press the OPTIONS key on the PC unit, then the PAGE DOWN soft key.
   ii. Press the Software Versions soft key to display the Software Versions menu.

b. For Alaris System software versions 9.19 and prior:
   i. Set a Callback alert of “After” or “Before and After” to receive an End of Infusion alarm.
   ii. Do not select Callback “Before” or “None”, as these selections will result in no End of Infusion alarm. Set a Callback alert of “After” or “Before and After” to receive an End of Infusion alarm. See Attachment B: Programming infusions with Delay Options.

c. For Alaris System software version 9.33 and later: No action is required for an End of Infusion alarm. There is an Infusion Complete alarm at the end of the delayed infusion, but there is no KVO rate.

d. For all software versions: 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 that include high-alert medications. 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:
Software version 9.33 was released in 2017 and enables an Infusion Complete alarm at the end of all delayed infusions. Enabling a KVO rate when using Delay Options will be addressed through an upcoming software release.

**Issue 3: 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 4: 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.

<table>
<thead>
<tr>
<th>Alarm Priority</th>
<th>Required User Response</th>
<th>Audio Characteristics</th>
<th>Visual Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>Immediate</td>
<td>Profiles 1-3: Repeating sequence of 1-2 beeps followed by a 0.5 - 1.5 second pause&lt;br&gt;Profile 4: Repeating sequence of 10 beeps followed by a 4 second pause</td>
<td>Flashing Red</td>
</tr>
<tr>
<td>MEDIUM</td>
<td>Prompt</td>
<td>Profiles 1-3: Repeating sequence of 1 beep followed by a 2 second pause&lt;br&gt;Profile 4: Repeating sequence of 3 beeps followed by a 6 second pause</td>
<td>Flashing Yellow</td>
</tr>
</tbody>
</table>

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 this issue. 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 version 9.33 and later, 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 5: 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.

<table>
<thead>
<tr>
<th>Configuration of Concentration Limit</th>
<th>Effect when a Data Entry Error is made when programming custom concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Guardrails™ limit</td>
<td>Clinician can proceed without any alert.</td>
</tr>
<tr>
<td>Guardrails™ soft limit</td>
<td>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.</td>
</tr>
<tr>
<td>Guardrails™ hard limit</td>
<td>Does not allow the programmed infusion to proceed.</td>
</tr>
</tbody>
</table>

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.**

![Correct Drug Amount](image1)
![Correct Diluent Volume](image2)
![Correct Calculated Concentration](image3)

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

![Correct Dose](image4)
![Correct Calculated Concentration](image5)

**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**

![Incorrect Drug Amount](image6)
![Incorrect Diluent Volume](image7)
![Incorrect Calculated Concentration](image8)

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

![Correct Dose](image9)
![Correct Calculated Concentration](image10)

**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 D: Programming an Infusion with a Custom Concentration Entry.*

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*. 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.


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

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

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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:

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

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: User Manual Addendum for software version 9.33
- Attachment B: Programming infusions with Delay Options
- Attachment C: Pharmacy quick reference guide: Delay options
- Attachment D: Programming an Infusion with a Custom Concentration Entry
- Attachment E: Pharmacy quick reference guide: Hard minimum concentration limit
- Attachment F: Customer Response Card