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February 10th, 2020

URGENT: FIELD SAFETY NOTICE – MMS-20-1953

BD Alaris™ System PC Unit Model 8000 and 8015

Software Upgrade

Type of Action: Advisory

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel, Nursing, Pharmacy

This letter contains important information which requires your **immediate** attention.

Dear valued Customer,

BD is undertaking a field safety corrective action for the BD Alaris™ System PC Unit Software Versions 9.33 (and lower), to inform customers of potential issues in the software. BD is finalising a software upgrade with the relevant 3rd part certification bodies that will solve the identified issues. The Field Safety Notice is intended to provide mitigation steps to take until the pump software has been remediated.

Description of the Problem

BD has identified through internal testing and customer feedback that software errors exist on the **BD Alaris™ System PC Unit Model 8000, software versions 9.5 and prio**r, and **BD Alaris™ System PC Unit Model 8015, software versions 9.33 and prior**.

The identified issues are as follows:

- **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

Each issue, the potential risks and the associated mitigation steps are listed in Attachments 1-5 of this Field Safety Notice. It is important you read these attachments carefully.

BD has assessed the potential risks associated with these issues and determined that affected products can continue to be used in accordance with the existing Alaris™ System with Guardrails™ Suite MX User Manual and this communication until BD contacts the affected sites with the upcoming software release.

Corrective Action by BD

BD intends to address the issues described in this Field Safety Notice through an upcoming software release, once it has passed the necessary regulatory approvals. 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.

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Actions Required of You (Alaris™ System PC Unit Model 8000 and 8015 Users)

1) Ensure that all the contents of this Field Safety Notice are read and understood by those within your organisation who need to be aware.

2) If you have further distributed the impacted product, please pass this notice and all the related documentation to the current user(s).

3) Until the recommended software upgrade is completed, BD recommends that BD Alaris™ System PC Unit Models 8000 and 8015 be used together with the existing User Manuals and the information contained within this Field Safety Notice.

4) Return the Customer Response Form on Page 3 to **DL-EMA-INF-Tech-Support** as soon as possible or no later than March 15th, 2020.

Should you have any questions or require assistance relating to this Field Safety Notice, please contact your local BD representative.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours sincerely,

William David
Senior Director, Quality Compliance EMEA

Attachment 1 - Issue 1: Software Errors related to System Error Code 255-XX-XXX
Attachment 2 - Issue 2: Delay Options programming
Attachment 3 - Issue 3: Low Battery Alarm Failure
Attachment 4 - Issue 4: Keep Vein Open (KVO) / End of Infusion Alarms Priority
Attachment 5 - Issue 5: Use Errors related to Custom Concentration Programming

Supplement A - User Manual Addendum for software version 9.33
Supplement B - Programming Infusions with Delay Options
Supplement C - Pharmacy Quick Reference Guide Delay Options
Supplement D - Programming an infusion with a custom concentration entry
Supplement E - Pharmacy quick reference guide Hard minimum concentration limits

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Customer Response Form – MMS-20-1953

BD Alaris™ System PC Unit Model 8000 and 8015

Please read in conjunction with Field Safety Notice MMS-20-1953 and return completed and signed form to as soon as possible or **no later than March 15th, 2020** to **DL-EMA-INF-Tech-Support.**

- **I confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

Name of Trust	
Name of Hospital/s covered by this response:	
Email Address	
Telephone Number	
Name	
Signature	
Date	

Please return your completed and signed Acknowledgement Form to: DL-EMA-INF-Tech-Support

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Attachment 1
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 field safety notice in June 2017 (RA-2017-07-01) 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 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 Supplement 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 report the complaint to BD through your normal process.

Actions by BD:
System Error 255-XX-XXX will be addressed through the 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.

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Attachment 2
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 Supplement 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 Supplement 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.

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Attachment 3
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. Also 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 field safety notice in 2016 (RA-2016-11-25) on Missed Low Battery Alarms and Service Bulletin 592A. These 2 software errors will be addressed through an upcoming software release.

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Attachment 4
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.

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 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 the upcoming software release.

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Attachment 5
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.

Configuration of Concentration Limit	Effect when a Data Entry Error 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.

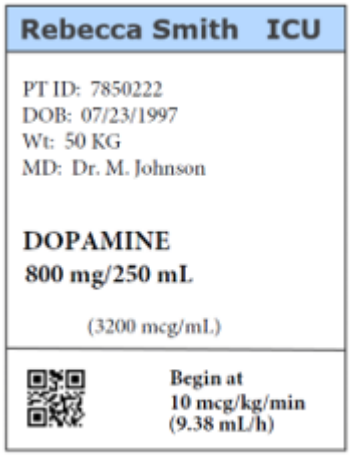

Figure 1: Example Medication Label

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.

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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*

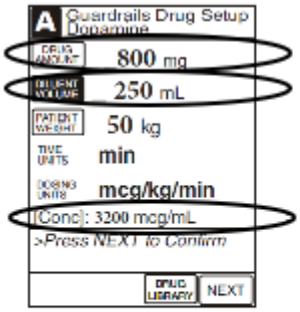

Figure 2. PC unit programming screen
Correct Drug Amount is entered
Correct Diluent Volume is entered
Correct Calculated Concentration is shown

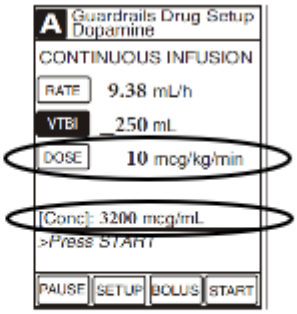

Figure 3. PC unit programming screen
Correct Dose is entered
Correct Calculated Concentration is shown

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*

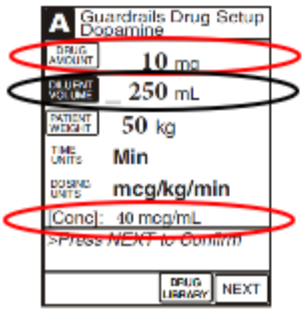

Figure 4. PC unit programming screen
INCORRECT Drug Amount is entered
Correct Diluent Volume is entered
INCORRECT Calculated Concentration is shown

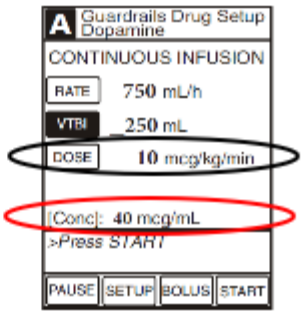

Figure 5. PC unit programming screen
Correct Dose is entered
INCORRECT Calculated Concentration is shown

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.

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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 Supplement 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 the 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 Supplement E: Pharmacy quick reference guide: Hard minimum concentration limits*.
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

[1]Smart 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