



June 30, 2020

**URGENT: FIELD SAFETY NOTICE – MMS-20-3810**

Alaris™ System PC Unit Model 8000  
Alaris™ System PC Unit Model 8015  
Alaris™ Pump Module Model 8100  
Alaris™ Syringe Module Model 8110  
Alaris™ PCA Module Model 8120  
Alaris™ EtCO2 Module Model 8300  
Alaris™ SpO2 Module Model 8210 and Model 8220

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

BD is initiating an advisory Field Action for the BD Alaris™ Infusion Pump System concerning four hardware situations **that require your attention and actions**. The four hardware situations are as follows:

- **Situation 1: Damaged Inter-Unit Interface (IUI) Connectors** – Damaged IUI connectors may lead to interruption of communication or power between PC Unit and modules. **This situation could result in an infusion that stops with an alarm on the PC Unit and an interruption of therapy or monitoring.** High-risk patient populations who are receiving high-alert IV medications are at the greatest risk of harm. For these high-risk patients, interruptions of therapy potentially can cause serious injury or death.
- **Situation 2: Broken elements on Alaris™ Pump Module platen** - A broken upper hinge post, lower hinge, and membrane frame on the Alaris™ pump module may prevent the device from delivering an accurate amount of fluid, which **may result in an over infusion, free-flow conditions, or under infusion.** High-risk patient populations who are receiving high-alert IV medications are at the greatest risk of harm. For these high-risk patients, over infusion, free-flow conditions, or under infusion of therapy potentially can cause serious injury or death.
- **Situation 3: Improperly secured PC unit Battery** - If the battery is not properly secured to the Alaris™ PC Unit that is running on battery power, the system may experience a power loss with a prolonged, non-silenceable alarm. Power loss may result in an interruption of patient therapy or monitoring. High-risk patient populations who are receiving high-alert IV medications are at the greatest risk of harm. For these high-risk patients, interruptions of therapy potentially can cause serious injury or death.
- **Situation 4: Dim Segment** - The LED display on the module may have some segments that **appear** dim, and therefore, the number may not be clearly displayed. The purpose of this display is to provide the clinicians with infusion or patient monitoring values associated with the type of module. If this dim segment is discovered during clinical use, it may cause slight user confusion or inconvenience when noticed.



## Affected Products

	Situation 1	Situation 2	Situation 3*	Situation 4
Alaris™ System PC Unit Model 8000	X		X	
Alaris™ System PC Unit Model 8015	X		X	
Alaris™ Pump Module Model 8100	X	X		X
Alaris™ Syringe Module Model 8110	X			X
Alaris™ PCA Module Model 8120	X			X
Alaris™ EtCO2 Module Model 8300	X			X
Alaris™ SpO2 Module Model 8210 and Model 8220	X			X

\*Note: Since Situation 3 affects the batteries of the PC Units, it may cause power loss to any attached module.

## Overall Risk

**The potential risks associated with these issues have resulted in serious injury and death. Please ensure that you read this notification immediately and in its entirety.** 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 the updated instructions associated with this communication.

## Overview of Customer Actions

1. Inspect the devices for the following issues in accordance with the information given in Appendix 1:
  - damaged IUI connector;
  - broken platen elements;
  - loose or missing battery screws or washers; and
  - dim LED display.

The information in Appendix 1 details each of the four issues, associated risks, actions that users should take to address each issue, and actions BD is taking to address each issue.

2. If you experience any of these issues with the device, the device should be taken out service and contact your local BD representative or distributor for replacement parts.
3. If you have further distributed the product to other organisations, please identify those users and notify them at once of this Field Action.
4. Promptly complete and return the enclosed Customer Response Card (Attachment B) to acknowledge receipt of this notification and the Field Action instructions provided in this letter and its attachments.

## Overview of BD Actions

BD is providing updated Instructions for Use, Warnings, and Cautions as part of this notice and will provide updated labeling (User Manual Addendum, Service Bulletin 630, and *Best practices for cleaning BD Alaris™ System devices* quick reference guide) from August 2020. BD also will provide accessory kits for Situations 1 and 3 to support implementation of the updated processes.

Additionally, BD will offer an expanded Alaris™ Medication Safety program to help customers implement best practices for the issues described in this recall notification. BD is committed to medication safety and will make the Alaris Medication Safety program available to all customers to



provide training and consulting on best practices for the Alaris™ System. BD will offer clinical and technical consulting as well as training including quick reference guides, videos, and instructions for use.

If you have any questions regarding the products, please contact your local BD representative.

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 Field Action, but we are committed to achieving the highest levels of customer satisfaction and serving your infusion product needs.

Sincerely,

William David  
Senior Director Quality Compliance, EMEA

**Enclosures:**

- Attachment A: Ordering Information Sheet
- Attachment B: Customer Response Card



## Appendix 1

### Situation 1: Damaged Inter-Unit Interface (IUI) Connectors

#### Affected Products:

This situation affects all serial numbers for the following products:

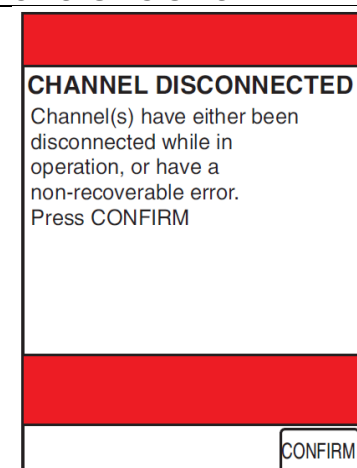
- Alaris™ System PC Unit Model 8000
- Alaris™ System PC Unit Model 8015
- Alaris™ Pump Module Model 8100
- Alaris™ Syringe Module Model 8110
- Alaris™ PCA Module Model 8120
- Alaris™ EtCO2 Module Model 8300
- Alaris™ SpO2 Module Model 8210 and Model 8220

#### Overview of the Situation:

IUI connectors provide power and communication between BD Alaris™ PC Unit and modules of the BD Alaris™ System (PC Unit, Pump Module, Syringe, PCA, and monitoring modules). **A damaged IUI may result in interruption of communication and/or power between PC unit and its connected modules.**

1. If the BD Alaris™ PC unit loses connection (i.e., power or communication) with its connected modules while the module is in use, a CHANNEL DISCONNECTED message will appear on the PC Unit (Figure 1) and an audio and visual alarm sounds.
2. Two possible scenarios can occur with the affected infusion or monitoring module(s):
  - a. **Loss of power to the PC unit results in power loss of any connected module and the PC unit will alarm. If the module loses power, the infusion or monitoring stops.**
  - b. **If the module loses communication, the module continues to infuse or monitor with a COMMUNICATION ERROR message scrolling on the module (Figure 2).** The module will continue to operate according to the programmed parameters as indicated by the green INFUSE indicator. The red ALARM indicator will flash to alert you to the error.

**Figure 1: CHANNEL DISCONNECTED message on the PC Unit**



**Figure 2: COMMUNICATION ERROR message on the module**





Damage to IUI connectors include cracked or broken pins and the presence of surface contaminants (i.e., blue or green deposits, corrosion, cleaning residue deposition). This damage may be caused by the following:

- Use of cleaning agents other than 70% Isopropyl Alcohol on the IUI connectors;
- Inadvertent exposure to cleaning agents during cleaning of the case; or
- Inadequate drying of the IUI after cleaning.

#### Potential Risk:

Interruption of communication or power could result in an infusion that stops with a PC unit alarm and may result in an interruption of therapy or monitoring. High-risk patient populations who are receiving high-alert IV medications are at the greatest risk of harm. For these high-risk patients, interruptions of therapy can cause serious injury or death.

**Between March 17, 2014, and June 15, 2020, BD has received one report of death and thirty-two reports of serious injury that may be related to this issue.**

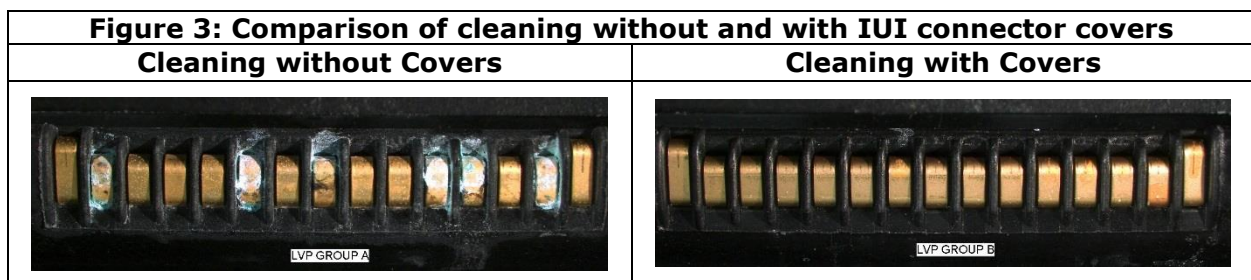
#### Actions for Clinical Users:

1. Inspect the IUI connectors on each PC unit and module prior to each use. DO NOT use a device with any damage, cracks, or surface contaminants (e.g., blue or green deposits, corrosion, and cleaning residue deposition) on the IUI connectors, or with broken IUI connector pins. If damage, deposits, residue, or corrosion is noticed, take the device out of service, and send the unit to Biomedical Engineering for repair.
2. Ensure back-up devices are readily available when infusing critical medications where interruptions could cause serious injury or death. Please also ensure that you have back-up monitoring devices (e.g., EtCO<sub>2</sub>, SpO<sub>2</sub>) that are critically important to the patient's care.
3. If the issue occurs, expedite a replacement PC unit and modules to restart the infusions and monitoring.

#### Actions for Device Cleaning Personnel:

Per the Alaris™ System User Manual, inspect the IUI connectors on each PC unit and module during the cleaning process. Devices having IUI connectors with any damage, cracks, surface contaminants (i.e., blue or green deposits, corrosion, cleaning residue deposition) (refer to Figure 3), or contact or pin damage on the IUI connectors must be taken out of service and sent to Biomedical Engineering for repair.

**BD is revising the procedure for cleaning the Alaris™ System to include the use of IUI connector covers.** BD will provide existing customers an Alaris™ System Cleaning Kit and an updated Alaris™ System User Manual Addendum from August 2020. The Alaris™ System Cleaning Kit will include IUI connector covers, cleaning brushes to clean the case and IUI connectors, and a quick reference guide. Once received, follow the updated instructions in the User Manual Addendum to clean the Alaris™ System. Failure to use IUI connector covers during cleaning can allow fluids to contact the IUI connectors and damage them over time. Examples of IUI connectors that have been cleaned without IUI connector covers and with IUI connector covers are exhibited below.



**Actions for Biomedical Engineering:**

Expedite inspection of the IUI connectors on each PC unit and module at your facility. In addition, develop a system to check the IUI connectors prior to returning a unit to use from storage or repair. Replace any IUI connector with damage, cracks, surface contaminants (i.e., blue or green deposits, corrosion, cleaning residue deposition), or contact or pin damage on the IUI connectors. Replace any missing screws. Replace female gasket if it is missing or improperly installed.

Customers can contact their local BD representative to order additional IUI connector covers (P/N 49000418 for the Universal IUI Connector Cover; P/N 49000419 for the PCA IUI Connector Cover) and cleaning brushes (P/N 49000052 for the IUI cleaning brush; P/N 49000053 for the case brush) beyond those being provided in the Alaris™ System Cleaning Kit.

**Actions by BD:**

BD is revising the procedure for cleaning the Alaris™ System to include the use of IUI connector covers. BD will provide existing customers an Alaris™ System Cleaning Kit and an updated Alaris™ System User Manual Addendum from August 2020. The Alaris™ System Cleaning Kit will include IUI connector covers, cleaning brushes to clean the case and IUI connectors, and a quick reference guide.

BD is offering an expanded Alaris Medication Safety program to help implement best practices for cleaning of the Alaris™ System devices. The program includes clinical and technical consulting and training, as well as quick reference guides and videos. Please contact your local BD representative for more information.



## Situation 2: Broken elements on Alaris™ Pump Module platen

### Affected Products

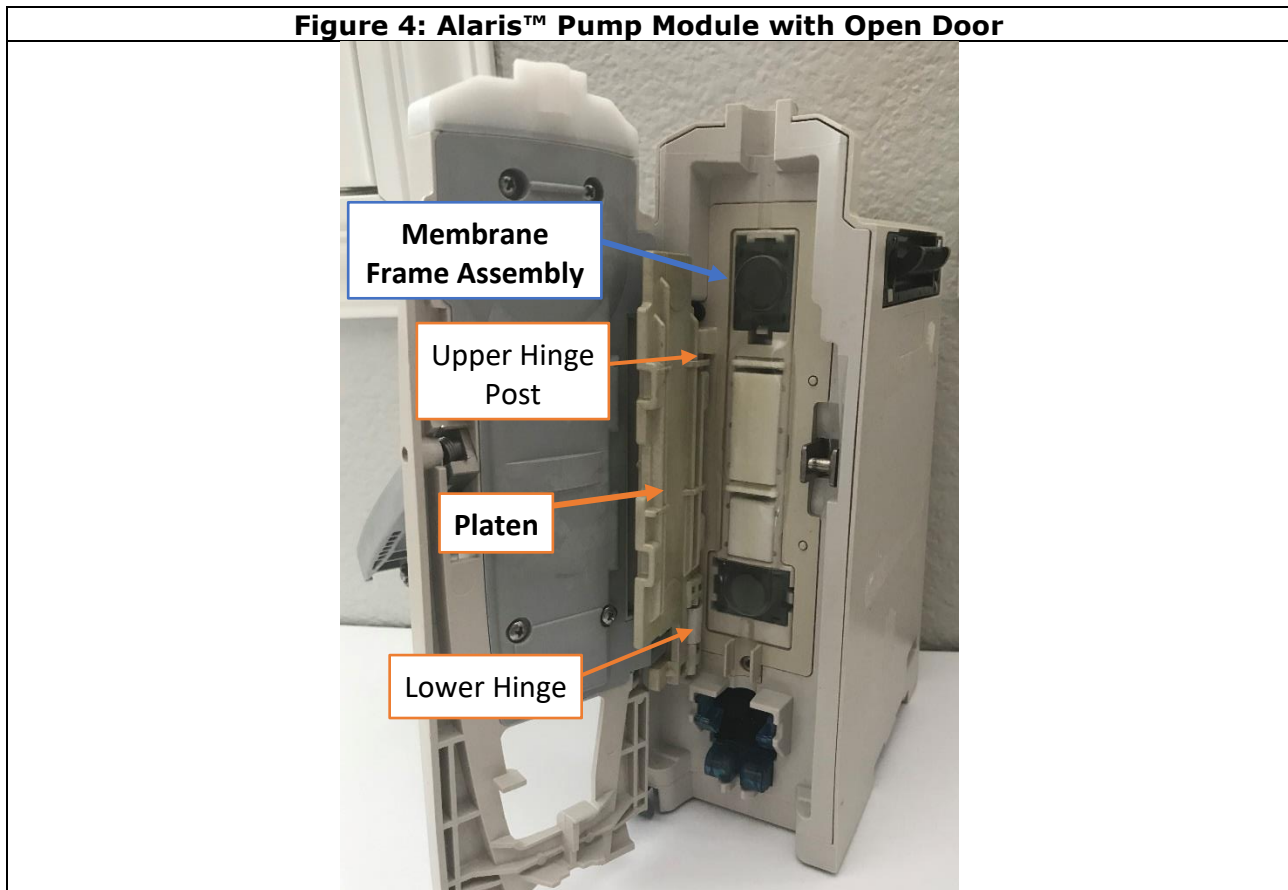
This situation affects all serial numbers for the following products:

- Alaris™ Pump Module Model 8100

### Overview of the Situation:

Based on BD's internal investigation, a broken upper hinge post, lower hinge, and/or membrane frame assembly on the Alaris™ Pump Module platen can occur when the door is forcefully closed on an object (e.g., misloaded IV administration set) or if the device is dropped. Additionally, improper use of cleaners on the membrane frame assembly can lead to cracks on the membrane frame.

**Figure 4: Alaris™ Pump Module with Open Door**



### Potential Risk:

A broken upper hinge post, lower hinge, and/or membrane frame assembly on the Alaris™ pump module may prevent the device from delivering an accurate amount of fluid, **which may result in an over infusion condition, free-flow condition, or under infusion without an alarm.** High-risk patient populations who are receiving high-alert IV medications are at the greatest risk of harm. For these high-risk patients, interruptions of therapy potentially can cause serious injury or death.

**Between March 17, 2014, and June 15, 2020, BD received thirty-one reports of serious injury that are potentially related to this issue.**



**Actions for Clinical Users:**

1. Ensure back-up devices are readily available when infusing critical medications where over-infusions, free-flow conditions, or under infusions could cause serious injury or death.
2. Follow the Alaris™ System User Manual instructions on how to properly load the administration set into the Alaris Pump Module. Please see the "Actions by BD" section below to receive additional clinical consulting and training on properly loading the administration set.
3. Be aware that this issue will not cause a pump alarm. Therefore, when beginning an infusion, and periodically during an infusion:
  - a. Check the drip chambers for both primary and secondary infusions to ensure the drip rate correlates to the intended infusion rate.
  - b. Know the expected duration of the infusion, and periodically check the amount of medication/fluid remaining in the container.If the infusion seems to be running faster or slower than expected, immediately transfer the infusion to a different Alaris™ Pump Module and send the affected module to biomedical engineering for further evaluation.
4. Should the pump module be dropped or severely jarred, immediately remove it from use and send it to biomedical engineering for further evaluation.

**Actions for Cleaning Personnel:**

Per the Alaris™ System User Manual, look for any visible external damage, such as a cracked or broken door or latch, during each cleaning. Open the door of each pump module and inspect the platen, hinges, and membrane frame for cracks or other damage. If damage is found, do not use the device and remove it from service. Send the damaged device to Biomedical Engineering for repair.

**Actions for Biomedical Engineering:**

Expedite inspection of all your Alaris™ Pump Modules for this issue. Verify that the platen upper hinge post, lower hinge, and membrane frame assembly are not broken or cracked (Figure 5). Alaris™ Pump Modules with a broken or cracked platen or membrane frame must not be used. Verify the membrane frame assembly is not loose, and that the seal is not torn. Replace any platen or membrane frame assembly that is broken, cracked or damaged. Follow the instructions in the Technical Service Manual for replacement of platen or membrane frame assembly.





**Figure 5: Broken or Cracked Platen and Membrane Frame**



Cracked Hinge on Membrane Frame

Broken Platen Post

Broken Platen Post



Broken Platen Lower Hinge Bracket



Membrane Frame Breakage

#### **Actions by BD:**

BD revised the Inspection Instructions in our Technical Service Manual to provide clarity on inspecting the pump module platen and membrane frame assembly. BD is adding the following Warning to the Alaris™ System User Manual: *To prevent a potential free-flow condition, do not use a pump module if it is damaged in any way or does not appear to be functioning as expected. Free flow condition can result in patient harm.* An updated Alaris™ System User Manual Addendum will be available from August 2020.

BD is offering an Alaris Medication Safety program to reinforce best practices for IV administration set loading. The program includes clinical consulting and training, as well as quick reference guides and videos. Please contact your local BD representative for more information.



### Situation 3: Improperly secured PC unit Battery

#### Affected Products

This situation affects all serial numbers for the following products:

- Alaris™ System PC Unit Model 8000
- Alaris™ System PC Unit Model 8015

#### Overview of the Situation:

If the battery is not properly secured to the Alaris™ PC Unit and is running on battery power, the system may experience a power loss with a prolonged, non-silenceable alarm. There are four screws and four washers that properly secure the battery to the PC unit, and power loss may occur when one or more screws or washers are loose or missing.

#### Potential Risk:

Missing or loose battery screws and/or washers that secure the battery to the PC unit may result in power loss to the entire system, including any connected modules, if the device is not plugged into AC power. Power loss may result in an interruption of patient therapy or monitoring when the device is relying solely on battery power. High-risk patient populations who are receiving high-alert IV medications are at the greatest risk of harm. For these high-risk patients, interruptions of therapy can cause serious injury or death.

**Between March 17, 2014 and June 15, 2020, BD has received one report of death that is potentially related to this issue.**

#### Actions for Clinical Users:

This situation only occurs when the device is running on battery power.

1. If this issue occurs, immediately plug the PC unit into AC power and restart the infusions.
2. Obtain a replacement PC unit as soon as possible.
3. Ensure back-up devices are readily available when infusing critical medications where interruptions could cause serious injury or death. Please also ensure that you have back-up monitoring devices (e.g., EtCO<sub>2</sub>, SpO<sub>2</sub>) that are critically important to the patient's care.

#### Actions for Cleaning Personnel:

Inspect all PC unit batteries for missing screws and washers during cleaning. Should missing screws or washers be identified, the PC unit should be sent to Biomedical Engineering for repair.

**Figure 5: Bottom of Alaris™ PC unit highlighting 2 missing screws and washers**



**Actions for Biomedical Engineering:**

Expedite the inspection of all Alaris™ PC unit batteries for loose or missing screws and washers. If loose or missing screws and washers are identified, please replace them and torque any loose screws or washers to 6 in/lb and perform battery conditioning. Refer to Service Bulletin 592A for information on battery conditioning.

If you do not have an adequate supply of battery screws and washers, please contact your local BD representative to order a package of screws and washers (P/N 49000613) at no charge.

In addition, the battery should be replaced every two (2) years by qualified service personnel using CareFusion authorized batteries.

**Actions by BD:**

**BD revised the Battery Pack Assembly procedure to add clarity for reassembly of the battery, including proper use of screws and washers.** An updated Service Bulletin will be available from August 2020. BD will provide an initial quantity of replacement screws and washers for use. Future orders for replacement batteries will include screws and washers.



## Situation 4: Dim Segment

### Affected Products

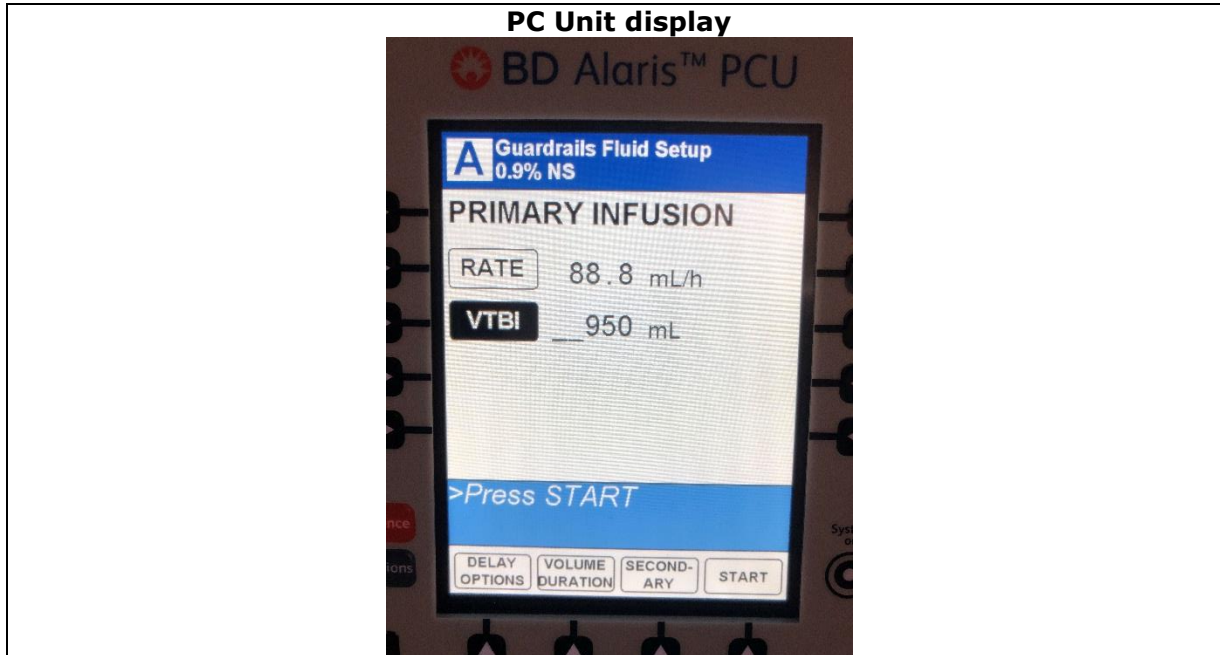
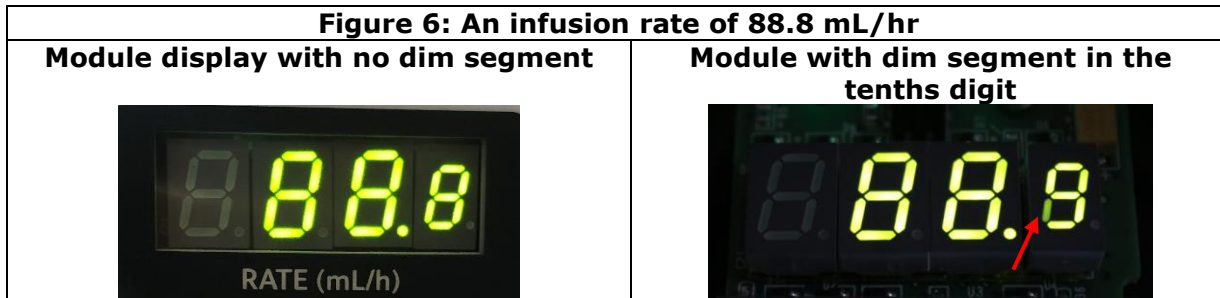
This situation affects all serial numbers for the following products:

- Alaris™ Pump Module Model 8100
- Alaris™ Syringe Module Model 8110
- Alaris™ PCA Module Model 8120
- Alaris™ EtCO2 Module Model 8300
- Alaris™ SpO2 Module Model 8210 and Model 8220

### Overview of the Situation:

The LED display on the module may have some segments that appear dim, and therefore, the number may not be clearly displayed. The programmed infusion parameters can be viewed on the PC Unit display and are not impacted by this issue.

**Figure 6: An infusion rate of 88.8 mL/hr**



### Potential Risks:

There is no impact to the infusion, which is delivered as programmed.

**Between March 17, 2014, and June 15, 2020, BD has received no reports of serious injury or death related to this issue.**

### Actions for Clinical User:



There is no change to end user workflow, as all infusion parameters and programming occur on the Alaris™ PC unit. If the end user observes a dim segment on the module, replace the module when feasible. There is no impact to the infusion.

**Actions by Biomedical Engineering:**

If the Alaris™ module has a dim segment, please contact your local BD representative to order a replacement display board (P/N TC10012952 for LVP Display Board, P/N TC10003525 for Syringe/PCA Display Board, P/N TC10008126 for EtCO2 Display Board, P/N TC10005026 for SpO2 Display Board) at no charge.

**Actions by BD:**

If the Alaris™ module has a dim segment as described in this notification, BD will provide a replacement part at no charge.



## Attachment A - BD Alaris™ System Field Safety Notice – MMS-20-3810 Ordering Information Sheet

### Alaris™ System Cleaning Kits

BD will mail one (1) Alaris™ System Cleaning Kit to the nominated contact point on Attachment B at each facility who receives this Field Safety Notice from August 2020. The Alaris™ System Cleaning Kit will include:

- 20 Universal IUI Connector Covers
- 5 PCA IUI Connector Covers
- 3 IUI Connector Cleaning Brushes
- 3 Alaris™ System Case Brushes
- 1 Best practices for cleaning BD Alaris™ System devices quick reference guide

### IUI Connector Covers & Brushes

If additional Alaris™ System Cleaning kit components are required, please contact Customer Service/local BD representative to place your order. Customers can order up to 3 packs of IUI connector covers at no charge until December 31, 2020. Please reference this Field Safety Notice (MMS-20-3810) when placing your order.

Part Number	Part Description	Package
49000418	Universal IUI Connector Covers	10 covers per pack
49000419	PCA IUI Connector Covers	5 covers per pack
49000052	IUI Cleaning Brush	1 brush
49000053	Case Brush	1 brush

### Battery Screws & Washers

If replacement battery screws and washers are required, please contact Customer Service/local BD representative to place your order. Customers can order up to 3 packs of battery screws and washers at no charge until December 31, 2020. Please reference this Field Safety Notice (MMS-20-3810) when placing your order.

Part Number	Part Description	Package
49000613	Battery Screws & Washers Replacement Kit	20 screws and 20 washers

### Display Board for Dim Segment

If a replacement display board is required, please contact Customer Service/local BD representative to place your order. BD will provide the display board at no charge. Please reference this Field Safety Notice (MMS-20-3810) when placing your order.

Part Number	Part Description	Package
TC10012952	LVP Display Board	1 display board
TC10003525	Syringe/PCA Display Board	1 display board
TC10008126	EtCO2 Display Board	1 display board
TC10005026	SpO2 Display Board	1 display board



## Customer Response Form – MMS-20-3810

**Alaris™ System PC Unit Model 8000**

**Alaris™ System PC Unit Model 8015**

**Alaris™ Pump Module Model 8100**

**Alaris™ Syringe Module Model 8110**

**Alaris™ PCA Module Model 8120**

**Alaris™ EtCO2 Module Model 8300**

**Alaris™ SpO2 Module Model 8210 and Model 8220**

Please read in conjunction with Field Safety Notice MMS-20-3810 and return the completed and signed form as soon as possible or **no later than the 27<sup>th</sup> July 2020** to <<insert fax/email address here>>.

**By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

<b>Account/Organisation Name:</b>	
<b>Department (if applicable):</b>	
<b>Address:</b>	
<b>Postcode:</b>	<b>City:</b>
<b>Contact Name:</b>	
<b>Job Title:</b>	
<b>Contact Telephone Number:</b>	<b>Contact E-mail Address:</b>
<b>Signature:</b>	<b>Date:</b>

*This form must be returned to BD before this action can be considered closed for your account.*

*To receive the Alaris™ System Cleaning Kit referred to in the Field Safety Notice, please provide a contact name and address, if different from above:*

<b>Name:</b>	<b>Email:</b>	<b>Address:</b>