Becton Dickinson (BD) CareFusion 303 Recalls Alaris System Infusion Pumps Due to Damaged Inter-Unit Interface Connectors, Loose or Missing Battery Screws and A Broken Upper and Lower Hinge Posts and Membrane Frame

The FDA has identified the occurrence of Situation 1, 2 and 3 as a Class I recall, the most serious type of recall.

Use of these devices may cause serious injuries or death. The FDA has identified the occurrence of Situation 4 as a Class II recall and use of these devices may cause temporary or medically reversible injury.

Please refer to the descriptions of each 'Situation,' below.

Recalled Product

- Alaris™ System Infusion Pump
- Models:
  - 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 8220,
  - Alaris Auto ID Module Model 8600
- Manufacturing Dates: July 1, 2004 to April 30, 2020
- Distribution Dates: July 1, 2004 to April 30, 2020
- Devices Recalled in the U.S.: total number 2,451,858
- Date Initiated by Firm: June 30, 2020

Device Use

The Alaris System is an infusion pump and vital signs monitoring system. The infusion pumps deliver fluids, medications, blood and blood products into a patient's body in controlled amounts. The pump provides fluids through an infusion tubing set into a patient's vein or through other cleared routes of administration. The system is used in adult, pediatric and neonatal care. The device is used in hospitals and other healthcare facilities

Reason for Recall

BD/CareFusion 303 is recalling the Alaris Infusion Pump System due to the following hardware situations:

- **Situation 1: Damaged Inter-Unit Interface (IUI) Connectors (Class 1 Recall)** - Damaged IUI connectors may lead to interruption of communication or power between PC Unit and modules, which could result in an infusion that stops with an alarm on the PC Unit and an interruption of therapy or monitoring.
- **Situation 2: Broken elements on Alaris™ Pump Module platen (Class 1 Recall)** - A broken upper hinge post, lower hinge, and/or 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 without an alarm.
- **Situation 3: Improperly secured PC unit Battery (Class 1 Recall)** - 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.
- **Situation 4: Dim Segment (Class 2 Recall)** - 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.

Summary of Affected Products and Reason for Recall:

Affected Product	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

Affected Product	Situation 1	Situation 2	Situation 3*	Situation 4
Alaris AutoID Module Model 8600	X			

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

The use of any of the affected products may cause serious adverse health consequences including death. There have been serious injuries and deaths reported when Situation 1, 2, or 3 occurred.

Who May be Affected

- Health care providers using the Alaris System
- Patients having infusions using the Alaris System

What to Do On

June 30, 2020, BD/CareFusion 303 issued a recall notification letter stating the Alaris pump models, issues and the following instructions:

- Inspect the devices for the following issues and follow the specific instructions for each situation as outlined in the Customer Notification:
    - Damaged Inter-Unit Interface (IUI) connectors
    - Broken elements on the Alaris Pump Module platen (for example, broken upper and lower hinge posts and/or membrane frame)
    - Improperly secured PC unit Battery (for example, loose or missing battery screws and/or washers)
    - Dim segments on the LED display
- If you experience any of these issues with the device, the device should be taken out service.
- Contact BD for replacement parts, and schedule clinical or technical consulting, as needed.
- Complete and return the enclosed Customer Response Card to BD.

Contact Information Customers with questions about this recall may contact the BD Recall Support Center at 1-888-562-6018 Monday – Friday during the hours of 7:00am to 4:00pm (Pacific Time) or by emailing SupportCenter@bd.com (mailto:SupportCenter@bd.com).

Additional Resources:

- BD CareFusion 303 Alaris Recall Notice Webpage (https://www.bd.com/en-us/support/recall-notifications/recall-notification-for-alaris-system-infusion-pump-hardware) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- BD Press Release (https://investors.bd.com/news-releases/news-release-details/bd-provides-update-previously-disclosed-recall-bd-alaris-system) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- BD CareFusion 303 Inc. Recalls Alaris System Infusion Pumps Due to Software and System Errors (/medical-devices/medical-device-recalls/becton-dickinson-bd-carefusion-303-inc-recalls-alaris-system-infusion-pumps-due-software-and-system)
- Medical Device Recall Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.