Becton Dickinson (BD) CareFusion 303 Inc. Recalls Alaris System Infusion Pumps Due to Software and System Errors

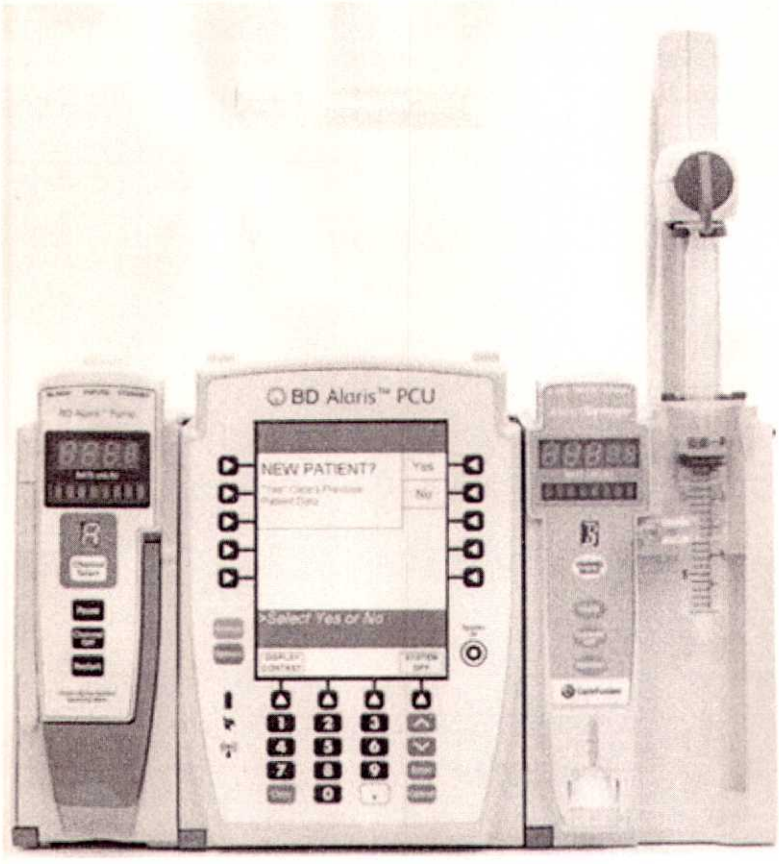
The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Alaris System Pump Modules
- Lot Numbers: All Lots of affected Models
- Model Number:
    - 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, and software version 12.1.0
    - BD Alaris™ Pump Module Model 8100, software versions 9.33 and prior, and software version 12.1.0.
    - Alaris™ Syringe Module Model 8110, software versions 9.33 and prior, and software version 12.1.0
    - Alaris™ PCA Module Model 8120, software versions 9.33 and prior, and software version 12.1.0
- Distribution Dates: Alaris PC units with software version 9.33 and older - July 2004 to October 31, 2019; Alaris PC units with software version 12.1.0 December 18, 2019 to January 23, 2020
- Devices Recalled in the U.S.: 774,000
- Date Initiated by Firm: February 4, 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.



(Source: Alaris System Instructions for Use, 510(k) K133532)

Reason for Recall

BD/CareFusion 303 is recalling the Alaris Infusion Pump System and Modules due to multiple system errors, software errors, and use-related errors.

For modules with software version 9.33 or earlier, the following issues apply:

- Software/System errors (System Error 255-xx-xxx)
- Delay options programming
- Low battery alarm failures
- Keep vein open (KVO) / "End of Infusion" alarm priority
- Use-related errors related to custom concentration programming

For modules with software version 12.1.0, the following issues apply:

- Low battery alarm failures
- Keep vein open (KVO)/ "End of Infusion" alarm priority
- Use errors related to custom concentration programming
- KVO Rate Not Available When Using Delay Options programming

These errors can lead to delay in infusion, interruption of infusion, slower than expected delivery of medication (under-infusion), and faster than expected delivery of medication (over-infusion).

There have been serious adverse health events with each of these errors. There are 55 reported injuries and one death.

Who May be Affected

- Health care providers using the Alaris System
- Patients having infusions using the Alaris System
- Biomedical Engineering Staff that manage hospital systems

What to Do

On February 4, 2020 BD/CareFusion 303 sent letters to customers, stating the Alaris pump models, issues and the following information:

- Be aware, BD/CareFusion 303 will contact all affected customers to begin the scheduling process for the software update when the software becomes available. Without the software update, the devices may remain vulnerable to the potential risk of multiple system and software errors.
- Consumers with Alaris System Infusion Pumps System Software 9.33 and earlier should follow these specific recommendations to help mitigate the potential risk of errors until the software issues have been remediated (https://www.bd.com/documents/alerts/AlarisSystem9.x_CustomerRecallPackage.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
- Consumers with Alaris System Infusion Pumps System Software 12.1.0 should follow these specific recommendations to help mitigate the potential risk of error until the software issues have been remediated (https://www.bd.com/documents/alerts/AlarisSystem12.1.0_CustomerRecallPackage.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Contact Information

Consumers with questions may contact BD by phone at (888) 562-6018, Monday through Friday between 7:00am and 4:00pm (Pacific Time) or by emailing SupportCenter@bd.com (mailto:SupportCenter@bd.com).

Additional Resources:

- BD (CareFusion 303) Recall Notice Webpage (https://www.bd.com/en-us/support/recall-notifications/recall-notification-for-alaris-system-infusion-pumps) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- BD (CareFusion 303) Recall Notice - Alaris System Infusion Pumps System Software 9.33 and earlier (https://www.bd.com/documents/alerts/AlarisSystem9.x_CustomerRecallPackage.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- BD (CareFusion 303) Recall Notice - Alaris System Infusion Pump System Software 12.1.0 (https://www.bd.com/documents/alerts/AlarisSystem12.1.0_CustomerRecallPackage.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.