CareFusion Recalls Alaris Pump Module due to an Alarm Error Which May Cause Interruption of Therapy

Note: This recall notice was updated February 10, 2017

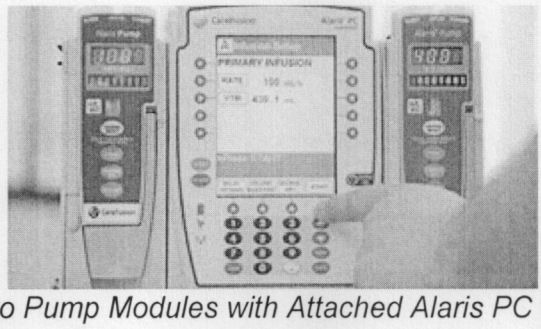
The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product

- Product Description: Alaris Pump Module (Large Volume Pump), Model No. 8100 and AIL sensor kits
- Product Numbers: 147083-102, 49000221
- Manufacturing Dates: October, 2011 to June, 2015
- Distribution Dates: October, 2011 to June, 2015
- Devices Recalled in the U.S. 349,746 units

Device Use

The Alaris Pump Module is an infusion pump that delivers fluids, such as nutrients, blood and medications, into a patient's body in controlled amounts. The syringe holds the solution, and the infusion tubing connects the syringe to the patient through intravenous or enteral access. The device is indicated for use in adults, pediatric patients, and infants and only used in hospitals and other health care facilities.



Two Pump Modules with Attached Alaris PC unit

Reason for Recall

CareFusion is recalling the Alaris Pump Module because of a faulty Air-In-Line (AIL) sensor which may generate a false alarm, and cause the syringe pump to stop supplying the infusion to the patient. If the AIL sensor is faulty, the false alarm may be repeated and require the health care provider to clear the alarm to restart the infusion. Interruption of infusion could lead to serious adverse health consequences or death.

Who May be Affected

- Health care providers using the Alaris Pump Module
- All patient groups who may be receiving infusion therapy from these pumps

What to Do

On December 2, 2016, CareFusion sent a "Medical Device Safety Notification" to affected customers. The notice instructed that if an AIL alarm occurs; the user should do the following:

1. Determine if there is air visible in the tubing that has caused the alarm to go off. If there is air visible in the line, press the "Restart" key to advance the air bubble past the sensor. Evacuate the air from the tubing according to your standard practice.
2. If no air is visible, ensure that the tubing is installed correctly in the AIL sensor. When inserting the tubing into the AIL sensor, use a fingertip and firmly push the tubing toward the back of the AIL sensor.
3. If the AIL alarms continue to reoccur on the same pump, after air has been removed from the line and the tubing has been correctly installed, the AIL sensor may be faulty. The health care provider should remove the pump from service, and notify CareFusion. If the AIL sensor needs to be replaced, CareFusion will provide replacement parts at no charge.
4. Review the AIL **tip sheet (http://pages.carefusion.com/rs/565-YXD-236/images/IF_Troubleshooting-Nuisance-Air-in-line-alarms_TS_EN.pdf)** that provides instructions on troubleshooting problematic AIL alarms.
5. Access the AIL **video (http://www.carefusion.com/our-company/video-gallery?video=5200073662001)** that provides instructions on troubleshooting problematic AIL alarms.

Contact Information

Health care professionals and consumers with questions are instructed to contact CareFusion at 888-526-6018 or **supportcenter@carefusion.com (mailto:supportcenter@carefusion.com)** with any questions related to this recall.

Date Recall Initiated

December 2, 2016

Additional Resources

- **CareFusion Press Release (http://www.carefusion.com/customer-support/alerts-and-notices/medical-device-safety-notification-for-alaris-pump-module-model-8100)**

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 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**e ither online, by regular mail or by FAX to 1-800-FDA-0178.

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