U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

CareFusion Alaris Syringe Pump Alarm Error May Cause Interruption of Therapy

Recall Class: Class I

Date Recall Initiated: July 2, 2015

Device:

- **Affected Product Codes (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=138585)**
- Alaris Syringe Pump, Model No. 8110
- Manufactured from: March 2014 to September 2014
- Distributed from: March 17, 2014 to September 30, 2014
- Devices Recalled in the U.S.: 6,458

Use: A syringe pump is a small infusion pump that delivers fluids, such as nutrients and medications, into a patient's body in controlled amounts. They are widely used in clinical settings such as hospitals, nursing homes, and in the home.

Recalling Firm:
CareFusion 303, Inc.
10020 Pacific Mesa Blvd
San Diego, CA 92121-4386

Reason for Recall:
An error in the syringe pump triggers a visual and audible alarm and causes the pump to stop supplying the infusion to the patient. Even when the user clears the error code 351.6740, the syringe pump does not respond to key presses until the product is detached and reattached to the PC unit used to program, monitor and provide power to the syringe pump. Failure of syringe module may result in a delay or interruption of therapy and can lead to serious patient injury or death.

CareFusion has received 108 reports of the issue occurring. There have been no reports of permanent injury or death.

Public Contact:
Customers can contact CareFusion Support Center at 888-562-6018, 7am-4pm PT, Monday through Friday or at **supportcenter@carefusion.com (mailto:supportcenter@carefusion.com)**.

FDA District: Los Angeles

More Information about this Recall:
The firm informed customers of the problem in a July 20, 2015 letter and indicated the company will contact all affected customers within 60 days to schedule a repair. Until the affected units can be repaired, CareFusion recommends customers take the following actions if the 351.6740 error code occurs:

1. Consider using another syringe pump.
2. Use an IV syringe push if clinically appropriate.
3. Clearly mark and sequester the Alaris Syringe pump that exhibited the channel error code.
4. Notify CareFusion Support Center at 888-562-6018 or **supportcenter@carefusion.com (mailto:supportcenter@carefusion.com)**.

Customers should establish back-up plans, in case of an infusion pump failure, that allow clinicians to obtain a working infusion pump and infusion tubing quickly.

About Class I Recalls
Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

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

Other Resources
Medical Device Recall for Alaris® Syringe Module (model 8110) Customer Notification (http://www.carefusion.com/customer-support/alerts-notices/medical-device-recall-alaris-syringe-module-8110.aspx)
(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)