Medical Devices

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CareFusion 303, Inc., Alaris Pump Module (Model 8100), Version 9.1.18 - Software May Not Properly Delay an Infusion with "Delay Until" Option or "Multidose" Feature

Recall Class: Class I

Date Recall Initiated: April 23, 2014

Product: Alaris Pump Module (Model 8100), Software Version 9.1.18

Affected Serial Numbers

The affected products were manufactured From February 6, 2014 to April 8, 2014 and distributed from February 7, 2014 through April 7, 2014.
This issue does not impact the “Delay For” Option.

Use: The Alaris Pump Model 8100 is a large volume infusion pump. It is intended for use in health care facilities that use infusion for the delivery of fluids, medicines, blood, and blood products using continuous or periodic (intermittent) delivery through various routes such as under the skin. The Alaris pump is used for adults, children, and newborns.

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

Reason for Recall:
CareFusion is recalling the Alaris Pump model 8100, version 9.1.18, because it may have a software failure where the pump module will not properly delay an infusion when the "Delay Until" option or "Multidose" feature is used. The firm received one report where the device malfunctioned when the “Delay Until” option was selected.

The software failure also causes the pump to not properly deliver a multidose infusion as expected under the following conditions:

- When the first dose is programmed to infuse when the system time is earlier than 7 pm (19:00) and a subsequent dose is intended to infuse between 19:00 and 11:59 pm (23:59); and
- When the first dose is programmed to infuse when the system time is between 19:00 and 23:59 and a subsequent dose is intended to infuse between 12 am (00:00) and 6:59 pm (18:59) the next day.

Affected customers were informed that if the infusion starts earlier or later than intended and is not immediately detected and stopped by the clinician, serious injury or death could result.

Public Contact: Use the chart below for questions and support:

CareFusion Contact	Contact Information	Areas of Support
CareFusion Support Center	Phone: 1-888-562-6018 Phone Hours: 7 am-4 pm, Pacific Time Monday-Friday Email: SupportCenter@carefusion.com	Recall Related Questions
Customer Advocacy	Phone: 1-888-812-3266 Phone Hours: 24 hours a day, 7 days a week Email: customerfeedback@carefusion.com	Adverse Events Reports
Technical Support	Phone: 1-888-812-3229 Phone Hours: 6 am -5 pm, Pacific Time Monday-Friday DL-US-INF-TechSupport@carefusion.com	Technical Questions Regarding the Alaris System

FDA District: Los Angeles District Office

More Information about this Recall:

On April 23, 2014, CareFusion sent an Urgent Medical Device Recall Notification letter to affected customers and authorized distributors.

The letter included FAQs - For External Use, Tip Sheet, and a response card. Customers were requested to promptly complete and return the Customer Response Card that was enclosed with the letter by postage-paid, self-addressed mail, fax, or email.

The letter identified the product, the problems, and the actions to be taken.

- Do NOT use the Alaris Pump module “Delay Until” option.
- Do NOT use the “Multidose” feature.

The letter also stated that the firm had identified the root cause of this issue and recommended that the previous Alaris Pump module software version 9.1.17 be installed to address this recall. CareFusion will contact all affected customers within 60 days (of the dated letter) to schedule the installation of software version 9.1.17.

As an interim guidance, customers may update their dataset to disable both Delay Options and/or Multidose across all Profiles to prevent the use of “Delay Until” option and/or “Multidose” feature. These are shared configurations with the Alaris Syringe module and if Disabled would prevent use of these features with the Alaris Syringe module as well.

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 either online, by regular mail or by FAX.

Additional Resources:

- Firm Recall Webpage

Page Last Updated: 05/20/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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