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

Hospira Plum A+ and Plum A+3 Infusion Systems Alarm Volume Failure

Recall Class: Class I

Date Recall Initiated: May 28, 2014

Devices: Plum A+ infusion pumps and Plum A+3 infusion pumps

A full list of products being recalled can be found at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=130257 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=130257)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=130256 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=130256)

Manufacturing and Distribution dates: July 2012 to May 2014

Use: An infusion pump is a medical device 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. These devices are primarily used by health care providers.

Recalling Firm: Hospira Inc.
275 N Field Dr.
Lake Forest, Illinois
60045-2579

Reason for Recall: The Plum A+ and A+3 infusion pumps have an alarm that should sound when a therapy is interrupted. Some of the alarms may fail to sound in situations that should trigger it. It is possible for a long delay before a health care professional becomes aware of the need to restore therapy.

No injuries, illnesses, or deaths associated with this defect have been reported. However, for patients receiving critical intravenous medication, there is a risk of injury resulting from this prolonged interruption in therapy.

There is the possibility of serious patient injury or death.

Public Contact: Hospira has contracted with Stericycle, Inc., in Indianapolis, IN for customer notification, response tracking, returns, effectiveness checks and destruction of product return.

Questions should be directed to Stericycle at 888-912-7350 (Monday - Friday, 8:00 AM - 5:00 PM ET).

FDA District: Chicago District Office

More Information about this Recall:
Stericycle, Inc. sent two Urgent Medical Device Correction letters dated July 2, 2014 and July 16, 2014 to customers.

The letters notified customers that Hospira would contact them regarding the completion of an audible alarm test and will replace any alarm assemblies that fail to audible alarm test.

The letter included instructions for customers to:

1. Inform potential users of this notification;
2. Complete and return the attached reply form; and,
3. If the products were further distributed, notify those accounts of this recall and ask them to contact Stericycle at 888-912-7350 (Monday - Friday, 8:00 AM - 5:00 PM ET) to receive a reply form.

Customers who further distributed the product were asked to notify their customers. Effectiveness of the communication was confirmed by phone call with direct consignees who do not respond or return the product and indirect consignees who indicate they have product on hand but do not return it. The letter was also posted on the Hospira website on July 2, 2014 and July 16, 2014.

In addition, the following safety organizations were notified:
ECRI, Noblis (RASMAS), National Recall Alert Center (NRAC), ISMP, and the Army for distribution and/or posting on their websites.

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/)** either online, by regular mail or by FAX.

Additional Resources:
Urgent Medical Device **Correction Letters (http://hospira.com/en/support_center/customer_communications/plum/index)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** were posted on the Hospira website:

- **Letter dated July 16, 2014 (http://hospira.com/Images/Letter%20Event%208785%20FA405-05%20Final%20%28C%29%282%29_81-92710_1.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Letter dated July 2, 2014 (http://hospira.com/Images/Letter%20Event%208785%20FA405-05%20Final%20v5_81-92702_1.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

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

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)

2013 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384618.htm)