Class I Medical Device Recall: Hospira Inc., GemStar Infusion System, Lithium Battery - Low Voltage

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: March 18, 2013

Product: GemStar Infusion System

All GemStar Infusion Systems are affected by this recall.

Models: 13000, 13100, 13150, 13086, 13087, 13088

Manufacturing and Distribution Dates: February 1999 through April 2013

Use:
The GemStar Infusion System is a small, lightweight, single-channeled device designed for use in the home, hospital or anywhere electronic infusion is required. The device is intended for use in intravenous, arterial, subcutaneous, short-term epidural infusion and parenteral administration of general I.V. fluids, medications, nutritional foods and blood/blood products.

Recalling Firm:
Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045-2579

Reason for Recall:

Battery failure resulting in delay/interruption of therapy and loss of data.

When the GemStar Lithium battery voltage level drops below 2.4 volts, an "11/004" error is displayed and the device is rendered inoperable. This failure mode results in a delay/interruption of therapy. Additionally, infusion settings and event history logs will be erased as a result of this device malfunction.

The severity of the clinical impact, due to the delay/interruption in therapy, is dependent upon the underlying condition of the patient and the treatment being prescribed. A delay/interruption in therapy has a worst case potential to result in a significant injury or death.

Health care professionals are advised to weigh the risk/benefit to patients associated with the use of the device when administering critical therapies.

Customers should consider the use of an alternative product, particularly in patients in which a delay/interruption in therapy could result in significant injury or death.

Public Contact: For additional information or technical assistance, contact Hospira Advanced Knowledge Center at 1-800-241-4002, option 4, 24 hours a day/7 days a week.

FDA District: Chicago District Office

Additional Recall Information:
On March 18, 2013, Stericycle, Inc., on behalf of Hospira, Inc., notified customers of the problem by UPS-delivered customer notification letter with a return reply form. Customers were asked to complete the reply form and return it to the fax number or e-mail address on the form even if they do not currently have the impacted devices.

Contact Stericycle at 1-877-907-7516 (Monday to Friday, 8 am to 5pm, Eastern Standard Time) to obtain additional copies of the reply form. For customers who have further distributed these devices, please notify your accounts who may have received these infusers and ask them to contact Stericycle to receive a reply form.

Lithium batteries that are older than three (3) years should be replaced. Contact the Hospira Advanced Knowledge Center at 1-800-241-4002, option 4, 24 hours a day/7 days a week, to determine if your battery needs to be replaced and if necessary to arrange for the return of your device to perform battery replacement.

Facilities that periodically retrieve the history logs from their GemStar Infusion System should consider retrieving them more often to reduce the amount of history log information that would be lost should this failure occur. Directions for downloading log files can be found in the GemStar System Operating Manual.

In the event that your facility's ability to administer proper care is severely impacted by this issue, Hospira will provide loaner devices.

Modification will be made to the GemStar Technical Service Manual to indicate that the useful life of the Lithium Battery is three (3) years.

For further inquiries, please contact Hospira using the additional information provided below.

Hospira Contact	**Contact Information**	**Areas of Support**
Hospira Global Complaint Management	1-800-441-4100 (M-F, 8am to 5pm, Central Standard Time) ProductComplaintsPP@hospira.com [1]	To report adverse events or product complains
Hospira Advanced Knowledge Management	1-800-241-4002, option 4 (24 hours a day/7 days a	Additional information or technical assistance

	week)	

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 [2] either online, by regular mail or by FAX.

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Links:
[1] http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/Mailto:ProductComplaintsPP@hospira.com
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm