Class I Medical Device Recall: Hospira Symbiq One and Two Channel Infuser

U.S. Food & Drug Administration

Recall Class: I

Date Recall Initiated: February 22, 2010

Products: Symbiq Infusion System

Brand Name:
Symbiq One-Channel Infuser
Symbiq Two-Channel Infuser

Model Numbers:
16026 Symbiq One-Channel Infuser
16027 Symbiq Two-Channel Infuser

The affected units were distributed from December 23, 2006 to January 22, 2010.

All lots are affected and can be found in the following List Number Configurations:

Model Number-Country/Language Code-Inventory Code	Model Number-Country/Language Code-Inventory Code
16026-04-01/03/04	16027-04-01/03/04
16026-04-51/52	16027-04-51/52
16026-04-53/54	16027-04-53/54
16026-04-79/80	16027-04-79/80
16026-04-81/82	16027-04-81/82
16026-04-83/84	16027-04-83/84
16026-04-87/88	16027-04-87/88
16026-04-89/90	16027-04-89/90
16026-13-25/26	16027-13-25/26
16026-13-53/54	16027-13-53/54
16026-27-89/90	16027-27-89/90

Use: The Symbiq One and Two-Channel Infusers are infusion pumps intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural, or irrigation routes of administration.

The systems are available as a one-channel or a two-channel infuser and may be connected to configure a three or four channel pump. The cassette-based system is powered by either AC power or can be powered by a rechargeable battery. The Symbiq Infusion Systems deliver basic therapy or advanced therapies such as multi-

step, intermittent, and inter-channel sequencing.

Recalling Firm:
Hospira, Inc.
755 Jarvis Drive
Morgan Hill, CA 95037

Reason for Recall: Hospira has identified motor encoder failures in the Symbiq pumping mechanism that causes the infuser to cease operation and exhibit an audible and visual “S321” or “S421” alarm in the One and Two-Channel infusers respectively. **Delay or interruption of therapy may result in serious injury or death in patients receiving critical therapy, pediatric patients and neonates.**

Public Contact:
Product problems should be reported at any time. Please use the chart below for questions and support.

Hospira Contact	Contact Information	Areas of Support
Dospira Global Product Safety and Complaints	1-800-441-4100- Press 1 for infusion pumps, then 1 for the Symbiq pump team then you will be connected to a live analyst (8am-5pm CST, M-F) (ProductComplaintsPP@hospira.com [1]).	To report adverse events or product complaints
Hospiral Technical Support Operations	1-800-241-4002 (8am-6pm CST, M-F)	Additional information Technical Assistance

FDA District: San Francisco

FDA Comments:
Hospira mailed an Urgent Device Field Correction to affected customers on February 22, 2010, and a Recall Notification on February 22, 2010. Information regarding additional recall actions was also provided in an updated Recall Notification letter on October 4, 2010. Links to the February 22, 2010 and October 4, 2010, letters are provided in Useful Links section below.

Hospira is taking actions to upgrade the older model MR1 motor and with a newly redesigned MR2 motor that should not exhibit this failure mode. Until Hospira can upgrade all Symbiq pumping mechanisms, corrected loaner pumps will be provided at no cost to customers for critical care areas. Until loaner or corrected pumps are in place in critical care areas, Hospira urges customers to consider an alternate method to administer therapy.

Hospira representatives will contact customers to coordinate shipment of loaner pumps. A no charge purchase order will be requested by Hospira in order to ship

corrected pumps. Upon receipt of the purchase order, Hospira will ship loaner Symbiq pumps via 2-day shipment and coordinate required technical support at no charge. Hospira requests full cooperation with recall actions in order to complete mitigations on or before December 31, 2010.

If any customer experiences S321/S421 alarms on a Symbiq pump the following steps should be performed:

- Replace the device with a loaner or corrected pump, if available.
- Remove the device from service and contact Hospira.

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 the FDA's MedWatch: The FDA Safety Information and Adverse Event Reporting Program [2] either online, by regular mail, or by FAX.

Useful Links:

- Hospira Recall Notification [3] (October 4, 2010)
- Hospira Urgent Device Field Correction [4] (February 22, 2010)
- FDA Infusion Pump Initiative [5]

SOURCE [6]

Source URL (retrieved on *12/08/2013 - 4:05am*):
http://www.mdtmag.com/news/2010/11/class-i-medical-device-recall-hospira-symbiq-one-and-two-channel-infuser?qt-video_of_the_day=0

Links:
[1] mailto://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ProductComplaintsPP@hospira.com
[2] http://www.fda.gov/Safety/MedWatch/default.htm
[3] http://www.hospira.com/Files/ClinicalBulletin/Hospira%20MR1%20Recall%20Update%20100410.pdf
[4] http://www.hospira.com/Files/ClinicalBulletin/Symbiq%20Motor%20Pole%20Clamp%20Recall%20Notification.pdf
[5] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htm
[6] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm232547.htm