Hospira Symbiq One-Channel and Two-Channel Infusers: Class I Recall - Motor Encoder Failures

FDA MedWatch

AUDIENCE: Risk Manager, Anesthesiology, Critical Care Medicine

ISSUE: FDA and Hospira notified healthcare professionals of a Class 1 recall of these infusion pump products due to motor encoder failures in the pumping mechanism that causes the infuser to cease operation. Delay or interruption of therapy may result in serious injury or death in: patients receiving critical therapy, pediatric patients, and neonates.

BACKGROUND: Symbiq Infusers are infusion pumps intended for the delivery of fluids by parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural, or irrigation routes of administration. 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 update Recall Notification letter on October 4, 2010. The affected units were distributed from December 23, 2006 to January 22, 2010.

RECOMMENDATION: 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. All lots affected can be found in the List Number Configurations in the FDA Recall Notice.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[11/04/2010 - Recall Notice [3] - FDA]

Previous Recalls:

[09/21/2010 - Recall Notice [4] - FDA]
[07/15/2010 - Recall Notice [5] - FDA]

SOURCE [6]

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http://www.ecnmag.com/news/2010/11/hospira-symbiq-one-channel-and-two-channel-infusers-class-i-recall-motor-encoder-failures

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm232547.htm
[4] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm226594.htm
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[6] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm232568.htm