From: FDA MedWatch [mailto:fda@service.govdelivery.com]
Sent: Thursday, April 22, 2010 3:25 PM
To: Reagan, Lynne
Subject: LIFEPAK 15 Monitor/Defibrillator by Physio-Control Inc.-Class I Recall

The FDA Safety Information and Adverse Event Reporting Program

LIFEPAK 15 Monitor/Defibrillator by Physio-Control Inc.

Audience: Emergency medical personnel, consumers

FDA notified healthcare professionals of a Class I recall of LIFEPAK 15 Monitor/Defibrillator manufactured and distributed between Marcy 26, 2009 and December 15, 2009. There is a potential for the device to unexpectedly:

- Power Off then On by itself.
- Power Off then NOT turn On.
- Power Off by itself requiring the operator to turn it back On.
- Stay powered On and not allow itself to be turned Off.

Healthcare professionals 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:

- Online: www.fda.gov/MedWatch/report.htm[1]
- Phone: 1-800-332-1088
- Mail: return the postage-paid FDA form 3500, which may be downloaded from the MedWatch "Download Forms[2]" page, to address on the pre-addressed form
- Fax: 1-800-FDA-0178

Read the complete MedWatch 2010 Safety summary, including a link to the Recall Notice, at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm209467.htm

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