



The FDA Safety Information and Adverse Event Reporting Program

Philips Heartstart Fr2+ Automated External Defibrillators - Recall

Audience: Fire departments, emergency medical services personnel, hospitals

Philips and FDA notified healthcare professionals of the recall of 5,400 HeartStart FR2+ automated external defibrillators (AED) due to reports of a memory chip failure which could render the AED inoperable and prevent it from delivering therapy when indicated. The AEDs are used by trained responders and designated response teams to help treat sudden cardiac arrest.

The recalled units (models M3860A and M3861A, distributed by Philips; and models M3840A and M3841A, distributed by Laerdal Medical) were manufactured between May, 2007 and January, 2008. Philips is contacting customers to arrange for the return and replacement of all the recalled AEDs and set up a page on the Philips Web site -- www.philips.com/FR2PlusAction -- with a serial number look-up tool to allow customers to find out if their FR2+ is part of this recall, as well as instructions on what to do if it is.

Read the complete MedWatch 2009 Safety summary, including a link to the firm's press release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm185179.htm>

You are encouraged to report all serious adverse events and product quality problems to FDA MedWatch at www.fda.gov/medwatch/report.htm

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