



## The Florida ESRD Network

### Philips Issues Worldwide Recall of Select Heartstart FR2+ Automated External Defibrillators

September 28, 2009 - Seattle - Philips announced today that it is voluntarily recalling approximately 5,400 HeartStart FR2+ automated external defibrillators (AEDs). This recall is being conducted due to the possibility of a memory chip failure that may render the device inoperable. Only certain HeartStart FR2+ AEDs (models M3860A and M3861A, distributed by Philips; and models M3840A and M3841A, distributed by Laerdal Medical) manufactured between May, 2007 and January, 2008 are included in the voluntary recall.

Philips has received reports of a memory chip failure in a small number of FR2+ units manufactured in 2007 and early 2008. These reported failures were detected during routine self tests, not during emergency use of the AED. Failure of this chip could render the AED inoperable and prevent it from delivering therapy when indicated, although Philips has received no reports of injury associated with this chip failure.

The AEDs affected by this recall have been distributed globally to fire departments, emergency medical services, hospitals, and other organizations. Philips is contacting customers to arrange for the return and replacement of all the recalled AEDs by sending notification letters to distributors and users. In addition, the company has set up a page on the Philips Web site 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. The Web page is [www.philips.com/FR2PlusAction](http://www.philips.com/FR2PlusAction).

Philips has notified the U.S. Food & Drug Administration (FDA) of its decision to voluntarily recall the affected product. Customers who have questions about the recall or wish to report product problems may contact HeartStart Customer Service at 1-800-263-3342.

Any adverse events experienced with the use of this product should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch Web site at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

The Florida ESRD Network (Network 7) is providing this fax blast as a Technical assistance activity for the Florida renal community.

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