



MEMORANDUM

To: Facility Manager

From: Lisle Mukai, QI Coordinator

Subject: **FDA RECALL: Philips Heartstart Fr2+ Automated External Defibrillators**

Date: October 06, 2009

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***FDA RECALL:  
Philips Heartstart Fr2+ Automated External Defibrillators (AED)***

The Network is required to distribute information regarding recalls that potentially affect ESRD facilities and/or patients. The information below was posted on October 5, 2009.

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 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.

Attached is a flyer from the Kidney Community Emergency Response Coalition (KCER) regarding this recall. Please share this information as applicable within your organizations/practices.

Thank you for your time and attention to this important patient safety issue.

Cc: Steven Preston, Project Officer, CMS RO X

**Mission Statement**

*To provide leadership and assistance to renal dialysis and transplant facilities in a manner that supports continuous improvement in patient care, outcomes, safety and satisfaction.*

October 5, 2009

***Philips Issues Worldwide Recall of Select  
Heartstart Fr2+ Automated External  
Defibrillators***



**For Immediate Release** - 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.

The HeartStart FR2+ defibrillators are used by trained responders and designated response teams to help treat sudden cardiac arrest. The device automatically analyzes the heart rhythm and determines whether a defibrillation shock is needed. If a shockable rhythm is detected, the FR2+ instructs the responder to deliver defibrillation therapy.

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)**.