



## **KCER: Kidney Community Emergency Response Coalition**

Dear ESRD Networks,

As directed by CMS, the Kidney Community Emergency Response (KCER) Coalition provides alert notices. Please share this information with your organization's stakeholders, ESRD Network (facilities, patients), your State Agency contacts, and your staff. If you have already shared this information, no duplication is necessary. These notices will also be posted on the KCER website, <http://www.kcercoalition.com/alerts.htm>.

### **Class 1 Recall: ZOLL Medical Corporation, ZOLL AED Plus Defibrillator**

**Date Recall Initiated:** February 12, 2009

**Product:** ZOLL AED Plus Defibrillator

This product was manufactured from May, 2004 through February, 2009 and distributed from May, 2004 through February 9, 2009.

**Use:** This device is used by emergency or medical personnel, by others who have completed CPR AED training courses, or the public at large. It is intended to treat patients in cardiac arrest. The device analyzes an unconscious patient's heart rhythm and instructs the user to press a button that delivers an electrical shock to the heart to restore a normal heart rhythm.

**Recalling Firm:** ZOLL Medical Corporation  
269 Mill Road  
Chelmsford, Massachusetts 01824

**Reason for Recall:** The AED failed to deliver the defibrillation energy.

**Public Contact:** The company may be contacted at 1-978-421-9655.

**FDA  
Comments:**

The company sent their distributors and customers an initial recall letter on February 12, 2009 by certified mail. This letter instructed customers to replace their batteries every three years. The company then sent their distributors and customers a follow-up recall letter on March 31, 2009 by certified mail. This letter instructed customers to download new software for their devices and to remove any battery replacement reminder labels.

ZOLL will send an email notice to all customers who included their email address as part of their contact information. ZOLL will also publish information about the recall in industry magazines.

For more information about this recall, please see the company's website at: <http://www.ZOLLAEDPlusbatteryhelp.com>

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious injury or death.

Health care professionals and consumers may report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

- Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- Regular Mail: use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)  
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- FAX: 1-800-FDA-0178

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