



The End Stage
Renal Disease
Network Of Texas

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Urgent – Deliver ASAP

TO: Facility Head Nurse
Facility Administrator

DATE: April 9, 2009

Subject: FDA MedWatch - ZOLL AED Plus Defibrillator: Recall because device may fail to deliver shock, could result in failure to resuscitate patient during sudden cardiac arrest



*The FDA Safety Information and
Adverse Event Reporting Program*

ZOLL AED Plus Defibrillator

Audience: Emergency medical personnel

ZOLL Medical Corporation and FDA notified healthcare professionals of a Class 1 recall of ZOLL AED Plus Defibrillators distributed from May, 2004 through February 9, 2009. The recall was initiated because the device may fail to deliver a defibrillation shock, which could result in failure to resuscitate a patient during treatment of sudden cardiac arrest. On February 12 and March 31, 2009, the company sent their distributors and customers recall letters with recommendations and instructions for customers on specific steps to mitigate the identified problems with this device. See the Zoll letter at link below for details.

Read the complete MedWatch 2009 Safety Summary, including links to the FDA notice and the Zoll customer letter at:

<http://www.fda.gov/medwatch/safety/2009/safety09.htm#ZOLLAEDplus>

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

Supporting Quality of Care