



ZOLL Medical Corporation
Worldwide Headquarters

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(800) 348-9011

**Urgent Medical Device Correction
AED Plus Defibrillator
Serial Numbers below X__ _200000**

ZOLL AED Plus Defibrillator May Not Deliver Therapy

February 12, 2009

We have received reports that following a long period (typically greater than four years) without use, a ZOLL® AED Plus® may prompt “change batteries” during use and fail to deliver therapy. Turning the device off completely, waiting ten seconds for the unit to re-set and then turning it back on is necessary to resume proper operation. Our investigation of this problem has determined that some batteries may develop high internal resistance that interferes with the batteries expected performance, lengthening charging time beyond specified and clinically acceptable limits.

ZOLL Medical Corporation is informing owners of all AED Plus devices with serial numbers below X__ _200000 to replace batteries that have been installed in devices for a period longer than three (3) years and at subsequent three (3) year intervals.

Required Corrective Actions

- (1) Determine the date batteries were installed in your device.**
- (2) If batteries were installed more than three (3) years ago, replace the batteries as soon as possible and add the enclosed label showing the next scheduled replacement date. Read and add the enclosed addendum incorporating this information to the administrator’s guide.**
- (3) If batteries are not more than three (3) years old, add the enclosed label completed with the next scheduled replacement date. Read and add the enclosed addendum incorporating this information to the administrator’s guide.**

Units above serial number X__ _200000 are not affected by this corrective action as they contain software that can detect this battery condition and identify when batteries require replacement. In lieu of adding the battery replacement label users may obtain this new software for their AEDs at no cost at www.ZOLLAEDPlusbatteryhelp.com

Customer Assistance

www.ZOLLAEDPlusbatteryhelp.com will be available on February 16th 2009 and will provide other technical information and support concerning this corrective action, such as help in determining battery age and ordering of replacement batteries and extra labels. We have arranged special pricing of \$39.95 per set of ten batteries inclusive of shipping that can be ordered by credit card at this site. We are offering this special pricing for customers affected today as well as for future replacements to mitigate the cost associated with a shorter than expected battery life.

We have notified the FDA and other regulatory agencies of this corrective action and expect it to be classified as a recall.

We apologize for any inconvenience this may cause you and thank you in advance for assistance in implementing this corrective action. Avoiding this problem during clinical use is our highest priority. Our 24/7 technical support numbers **1 (800) 348-9011** or **+1 (978) 421-9460** are available to assist users with any aspect of this notice.

Sincerely,

Paul Dias
VP Quality Assurance & Regulatory Affairs

Enclosures

- Battery Replacement Label(s)
- Addendum to ZOLL AED Plus Administrators Guide
- Postage Paid Business Reply Envelope

