



RECEIVED
2-17-09

ZOLL Medical Corporation

Worldwide Headquarters
269 Mill Road
Chelmsford, Massachusetts 01824-4105
U.S.A.

978 421-9655
978 421-0025 Main Fax

**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





Instructions for the Installation of New Batteries and Battery Replacement Label for the ZOLL AED Plus

Please Note: Replace the batteries in your AED Plus three years from the installation date of new batteries.

1. Ensure that the AED Plus is turned off. Open the battery compartment by removing the battery cover from the back of the unit.
2. Remove all batteries at once and dispose of old batteries properly. Place new batteries into the battery bank, observing battery polarity markings and making sure that all batteries are securely seated and properly oriented. After placing the first 5 to 9 batteries in the battery well, the INSTALL BATTERIES audio prompt reminds you to install the remaining batteries in the battery compartment.
3. After installing new batteries, press the Battery Reset Button inside the battery compartment when prompted. Pressing the button resets the battery usage indicator to full charge.
4. Close the battery compartment.
5. Turn the AED Plus over.
6. Locate battery replacement label which is included in the battery kit.
7. Write the battery replacement date on label. (Three calendar years from today's date.) Example: If today's date is (03/22/2009) the replacement date will be (03/22/2012).
8. Peel label from paper.
9. Affix label onto AED Plus below the "Status Indicator", as displayed below.

Explanation of Symbols:

 - Replace batteries on or before <date>




Place the AED Battery Replacement Label
below the AED Plus Status Indicator

REPLACE BATTERIES ON OR BEFORE:

 3/22/2012
