ZOLL Medical Corporation
Worldwide Headquarters

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

(800) 348-9011

Urgent Medical Device Correction
Follow-Up Notification

AED Plus Defibrillator
Serial Numbers below X_ _ _200000

ZOLL AED Plus Defibrillator May Not Deliver Defibrillation Shock

March 31, 2009

Dear valued customer,

You should have received a letter from ZOLL dated February 12, 2009, notifying you of a potential problem with ZOLL AED Plus Defibrillators below "X _ _ _200000". Some batteries do not work properly when used with the ZOLL AED Plus Defibrillator below the identified serial number. In addition, the version of ZOLL AED Plus Self-Test Software installed in these devices does not adequately detect defective batteries. As a result of these two issues, the ZOLL AED Plus defibrillator may fail to deliver defibrillation shocks during treatment of sudden cardiac arrest. Our investigation is not complete at this time. This letter revises and replaces recommendations in the February 12, 2009 letter.

Based on new information ZOLL now believes that the safest recommended action to assure appropriate AED Plus function is for users to update the device software.

The new software can be ordered or downloaded at no cost at www.ZOLLAEDPlusbatteryhelp.com. The website also provides other technical information and support concerning this corrective action, such as ordering of replacement batteries.

The software upgrade allows all potentially affected devices to monitor battery charging performance through periodic self-testing. If defective batteries are detected at any time prior to the recommended maximum of five years, users are prompted by the device to install fresh batteries.

If you have updated your device software as a result of our letter dated February 12, 2009, no further action is necessary.

However, if you have only replaced the batteries, and/or attached a label indicating a scheduled replacement date, you are now advised to remove the sticker and upgrade your device with the latest software version.

Field Experience

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 a defibrillation shock, which could result in failure to resuscitate a patient. In some instances turning the device off completely, waiting for at least ten seconds for the unit to re-set and then turning it back on has restored the unit's ability to deliver defibrillation therapy as intended.

Although this issue was identified through customer reports from non-clinical testing there has been one clinical event reported in which a defibrillation shock was not delivered, the patient subsequently died, and our evaluation of the device found that the batteries experienced the identified problem. At this time we have reviewed all reported patient events and found up to three additional cases in which a shock was not delivered to a patient, and the battery may have experienced the identified problem. We were informed that in one of the cases the patient subsequently died.

All AED Plus devices manufactured prior to February 12, 2009 may be affected, a total of approximately 180,000 units. It appears that the identified problem is most likely to occur with units that have been in the field for longer than 3 years, a population of approximately 80,000 units.

At this time ZOLL is not recommending the removal of any AED Plus from service. Affected units will be capable of detecting defective batteries during the self-test after the recommended software upgrade.

If the ZOLL AED Plus defibrillator shuts off or otherwise malfunctions during patient therapy, continued CPR is recommended.

Root Cause Investigation

Our investigation of this problem has determined that some batteries may over time develop high internal resistance that interferes with the batteries expected performance, lengthening charging time beyond specified and clinically acceptable limits. The lengthening of the charging time can cause the device to terminate the charge cycle resulting in a failure to deliver a defibrillation shock.

Our investigation is not complete at this time. Working with the battery manufacturer, we have not yet determined precisely what is contributing to the increase in battery resistance, but to date we have identified the following:

- The increase of internal resistance occurs after long periods of standby use. The problem is more likely to develop in batteries that have been installed in devices for over three years.
- Not all batteries experience this increase in internal resistance but it is difficult to predict which batteries will become problematic.
- The problem is not detected by an affected device's current self-test capabilities or by connecting the device to the AED Plus simulator.

The updated device software will allow more appropriate checks of battery charging performance through more rigorous self-testing, and if a defective battery is detected at any point in the maximum five-year standby life, the device will prompt the user to install fresh batteries.

Summary of Recommended User Corrective Actions

ZOLL Medical Corporation is informing owners of all AED Plus devices with serial numbers below "X_ _ _200000" to upgrade the device with new software.

(1) Obtain the new software for your AEDs at no cost at www.ZOLLAEDPlusbatteryhelp.com **and update your devices as soon as possible.**

(2) After updating your device software, change your device batteries when prompted to do so by the AED Plus. Remove any battery replacement reminder labels.

Units above serial number "X_ _ _200000" are not affected by this corrective action as they contain the updated software that can detect this battery condition and identify when batteries require replacement.

Customer Assistance

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 or confusion 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