

Patient Safety Alert

Veterans Health Administration Warning System Published by VA Central Office

AL09-17

March 24, 2009

Item: AEDPlus Public Access Automated External Defibrillators (AEDs), manufactured by Zoll.

Specific Incident: The affected defibrillators' batteries can have a shorter than expected life, expiring after three years, rather than five. When used in defibrillation, the device may verbally prompt users to "change batteries" and fail to deliver therapy. There will be no prior warning of the failure. This alert affects all AEDPlus defibrillators sold before March 2009.

General Information: The AEDPlus is distributed in many areas, both clinical and administrative. Additionally, they are distributed to VA in general, including VACO, VBA, VCA and OI&T offices.

Actions: For all affected locations that have not already done so:

1. By close of business (COB) April 3:
Staff responsible for monitoring AED status will inspect AEDPlus defibrillators to determine the date the batteries were installed. Instructions to determine age are in Attachment 1.
2. If the batteries are more than three years old,
 - a. Immediately order replacement batteries from Zoll and install them upon arrival. Battery sets cost \$39.95 each, one set is required for each AED.
 - b. When batteries are received immediately install them replacing the old batteries.

Important note: Until the batteries are replaced, **DO NOT REMOVE THE DEFIBRILLATORS FROM USE.** The remote potential for the defibrillator to fail is far outweighed far outweighed by the risk of not having the defibrillator available. Attachment 3 contains a temporary workaround submitted by Zoll in case an AED fails in use.

3. Order and install battery monitoring software on the defibrillators. This software is free, and can be either downloaded directly from the Zoll website, or ordered as a CD from Zoll. Installing the software to the defibrillator requires a computer with an active infrared (IR) port or a USB IrDA device.

4. The Patient Safety Manager shall assure that this Alert has been addressed and the action status updated on the VA's Hazardous Recalls/Alerts website upon replacement of the batteries but no later than May 30, 2009.
<http://vawww.nbc.med.va.gov/visn/recalls/index.cfm>.

Addl. Information: Additional information, including how to locate the serial number (for checking battery age) is at
<http://www.zoll.com/batteryhelp/default.html>
Also: If sites are unable to upload the battery software to the defibrillators, Zoll will provide battery expiration stickers.

Source: Manufacturer and CEOSH

Attachments

- (1) ZOLL, FAQs, including directions to identify defibrillators needing replacement batteries and work-around during an event.
- (2) Zoll Urgent medical Device Correction letter to customers.
- (3) FAQ Excerpt – Failure message and Zoll recommended work-around in case an AED fails during use.

Contact: Zoll Technical Support at (800) 348-9011 or
Paul Sherman, CEOSH 314 543- 6712

Attachment 1

ZOLL AED Plus Corrective Action CUSTOMER Questions and Answers

Q: How can I tell if my AED Plus[®] is subject to the Corrective Action?

A: Look at the unique serial number, containing letters and digits under a barcode, printed on the bottom of your AED Plus. If the last six digits are *UNDER* 200000, then your AED Plus *IS* subject to the Corrective Action. If you received your AED prior to February 14, 2009, then you will definitely find your serial number is within the range of those needing corrective action.

Q: What can be done to correct the situation?

A: You should change all ten of your batteries if your current batteries were installed more than three years ago. The questions and answers that follow will provide you with the details needed to help you correct the situation.

Q: Do I need to take action immediately?

A: In some cases, *YES!* A unit whose batteries were installed *MORE* than three years ago should have its batteries changed as soon as possible.

Q: What if I am not certain when I installed batteries in my AED Plus?

A: Check the last six digits of your serial number. If that number is *LESS* than 080000, then your AED Plus was probably installed *MORE* than three years ago and should have its batteries replaced. You may also estimate when you installed your AED Plus by determining the date your AED Plus was manufactured by interpreting the serial number as follows: Check the fourth character of its serial number to determine the *month* of manufacture using the table below.

Fourth Character	Month
A	January
B	February
C	March
D	April
E	May
F	June
G	July
H	August
I	September
J	October
K	November
L	December

You can also determine the *year* of manufacture by reading the second and third characters of the serial number, so that “02” represents 2002, “03” represents 2003, etc. For example, if your serial number begins with “X05K” then it was manufactured in November of 2005. Subtracting the manufactured date from today (ignoring any distribution lag) will yield a conservative estimate of battery age.

Q: *What if I installed the batteries in my AED Plus LESS than three years ago?*

A: Units installed less than three years ago do not need to have batteries changed immediately, but they should be replaced when the batteries reach three years. A battery replacement label should be placed on the unit indicating the next scheduled replacement date.

Q: *If my batteries were installed more than three years ago, what problem could I have?*

A: Your 123A Lithium batteries may not function properly in all cases. You could turn on your AED Plus (showing a green check in the status indicator) to start a rescue, your AED Plus could perform a rhythm analysis recommending a shock, but your 123A Lithium batteries *MAY NOT* be capable of building up the necessary charge in the time required by the AED Plus. If this happens, the AED Plus will prompt you to “Change batteries” and will NOT deliver a shock.

Q: *If I installed my AED Plus more than three years ago, how likely am I to have this problem?*

A: Our investigation shows that very few units currently installed have ever exhibited this problem. By no means should anyone *ever* hesitate to use an AED Plus, even if it has been installed for more than three years.

Q: *What causes this problem?*

A: After a long period of non-use in stand-by mode, it is possible that internal resistance can build up in the 1 23A batteries. This internal resistance might interfere with the battery set’s ability to deliver its stored charge in a timely manner.

Q: *Should such a failure occur, what would my AED Plus say?*

A: It would say, “Don’t touch patient. Analyzing.” Next it would say, “Shock advised.” Then it would say, “No shock delivered. Change batteries. Change batteries. Start CPR.”

Q: *Suppose I use my AED Plus in a rescue later today, before making any correction to it, and I experience this failure, IS THERE ANYTHING I CAN DO?*

A: YES! In the event of such a failure, you should immediately resume CPR. Power down the AED Plus by pushing the on/off button. Wait 10 seconds until the unit has time to reset, and then turn the unit back on. It will immediately begin another heart analysis. If the victim has a shockable rhythm, when the AED Plus calls for the high power needed to build-up the charge for a shock, the batteries may deliver the needed energy.

Q: *How can I prevent this kind of failure and the need to recover by turning the unit off and then back on in a rescue?*

A: Be certain to change your batteries every three years. To help you do that, if your batteries have been installed for *LESS* than three years, ZOLL is providing you with a label on which you can write in the date of your batteries' three-year anniversary and then affix below the status indicator on the AED Plus. This will help to remind you when to change the batteries. If your batteries have been installed for *MORE* than three years, you can purchase a new sleeve of ten 123A batteries directly from ZOLL along with a new label.

Q: *Should I still pay attention to the status indicator of the AED Plus?*

A: Yes. The AED Plus self-test checks the integrity of the whole unit, including pads and electronics. So you should never ignore the status indicator. But you should also check the date on which the batteries should be replaced as indicated on the label. If that date is passed, or will occur soon, you should replace all ten 123A Lithium batteries on or before that date, regardless of whether a green check is showing in the status indicator.

Q: *I bought my AED Plus expecting to replace the batteries every five years. But now I have to replace them after only three years. Is ZOLL offering any sort of assistance with battery pricing?*

A: Yes. Although all AEDs require periodic battery replacement, and no manufacturer can ever guarantee a fixed battery life, your total battery costs should be no higher under this plan. If you visit www.ZOLLAEDPlusbatteryhelp.com you can purchase batteries for \$39.95 per sleeve of ten, including shipping, (half the regular price) using a credit card. For each sleeve ordered, you will have to enter a valid AED Plus serial number.

Q: *Is there any alternative to changing my batteries every three years?*

A: Yes. If you prefer, you can upgrade the software in your AED Plus to the latest version. This new software will monitor battery condition, and if this failure occurs the red X will appear in your status indicator. At that point, of course, you should replace your batteries.

Q: So if I upgrade my AED Plus software, will I have to change my batteries every three years?

A: No. This problem condition builds slowly over time and three years is a conservative replacement interval. This new software is designed to detect high internal resistance if and when it occurs, anywhere up to five years of battery life. If, at any time during those five years, your batteries become incapable of building a high-power charge quickly enough, the software will detect this condition and alert you with beeping and a red X in your status indicator.

Q: How can I upgrade my AED Plus with the new software?

A: You will need a Personal Computer running Windows XP or Windows 2000 that is equipped with an IrDA (infrared) port. Load the ZOLL Administrative Software (ZAS) onto your PC from either the ZOLL download site, or by ordering a CD from ZOLL. To do either, visit www.ZOLLAEDPlusbatteryhelp.com.

Q: How long will it take to upgrade my AED Plus?

A: It will take about five minutes to install ZAS on your computer. Once ZAS is installed on your PC, it will take about three minutes to communicate with and upgrade your AED Plus.

Q: After I upgrade my software, will I also need to change my batteries?

A: Probably not. When ZAS installs your new software, it will immediately test the batteries. Once the upgrade is complete, if your status indicator is showing a green check, you can be certain that your batteries have no internal resistance that could interfere with the delivery of high-power to your AED Plus. The same battery test will be performed whenever you put new batteries into your AED Plus and whenever you initiate a manual self-test by holding down the on/off button for more than five seconds.

Q: What if I have a PC with no IrDA port?

A: IrDA ports with USB connectors are readily available in electronics stores everywhere. If, however, you would prefer to order directly from ZOLL, we offer a very inexpensive IrDA port device that costs only \$19.95 (including shipping to the U.S.) at the web site mentioned above.

Q: Can I upgrade more than one AED Plus with the ZAS software?

A: Yes, you can. Once you have a PC with ZAS loaded onto it and an IrDA port, you may upgrade as many AED Pluses as you wish, of course at no further cost.

Q: *Once I have upgraded my AED Plus, do I have to contact the FDA or ZOLL?*

A: You do *NOT* have to contact the FDA, but you *ARE* required to let your distributor or ZOLL know when you have updated your units. You will need to send a list of serial numbers for units upgraded and a contact name, address, and signature. ZAS makes it very easy to do this. After upgrading each unit, ZAS can generate a report showing the date, time, and serial number of the unit updated.

Q: *If I purchase another AED Plus from ZOLL in the future, will I have to upgrade it or replace batteries every three years?*

A: You will *NOT* need to apply this upgrade to any AED Plus with a serial number whose last six digits are *ABOVE* 200000, and you can expect the batteries to last up to five years in normal stand-by mode.

Attachment 2



ZOLL Medical Corporation Worldwide Headquarters

269 Mill Road

Chelmsford, Massachusetts 01824-4105
U.S.A. (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.

AL09-17

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Dias". The signature is written in a cursive style with a large, stylized initial "P".

Paul Dias
VP Quality Assurance & Regulatory Affairs

Attachment 3

Q: *Should such a failure occur, what would my AED Plus say?*

A: It would say, "Don't touch patient. Analyzing." Next it would say, "Shock advised." Then it would say, "No shock delivered. Change batteries. Change batteries. Start CPR."

Q: *Suppose I use my AED Plus in a rescue later today, before making any correction to it, and I experience this failure, IS THERE ANYTHING I CAN DO?*

A: **YES!** In the event of such a failure, you should immediately resume CPR.

Power down the AED Plus by pushing the on/off button. Wait 10 seconds until the unit has time to reset, and then turn the unit back on.

It will immediately begin another heart analysis. If the victim has a shockable rhythm, when the AED Plus calls for the high power needed to build-up the charge for a shock, the batteries may deliver the needed energy.