



# Zoll AED Plus Defibrillator

IMB Safety Notice: SN2009(13)

Circulation Date: 9<sup>th</sup> December 2009

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NOTICE

## MANUFACTURER/SUPPLIER

Zoll Medical Corporation

## TARGET GROUPS

General Practitioners  
General Public  
Community First Responder schemes  
Risk Managers  
Hospitals  
Nursing Homes  
Schools  
Sports clubs

## ISSUE

The Zoll AED Plus Defibrillator may not deliver therapy.

## BACKGROUND

Zoll received reports that following a long period without use (typically greater than four years), 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.

Zoll’s 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.

In February of this year, ZOLL Medical Corporation started to inform 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.

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](http://www.ZOLLAEDPlusbatteryhelp.com)

Four distributors have supplied the affected product in Ireland, *Pulse Medical Ltd, Heartbeat Safety Ltd, AED Direct and Medilink Services*. Zoll has been working with the distributors to ensure that the issue is communicated to all users of the product in Ireland. Zoll have been unable to confirm to the IMB that the

# S A F E T Y NOTICE

recommended actions have been completed on all devices.

## **ACTION OR RECOMMENDATIONS**

1. Ensure that the relevant personnel in your organisation are made aware of this issue.
2. Determine if you have purchased the affected serial numbers of this product, AED Plus devices with serial numbers below **X\_\_ \_200000**.
3. If you have an affected device confirm that the recommended actions have been completed:

Ensure that the date when the batteries were installed in your device has been checked.

- a. If batteries were installed more than three (3) years ago, replace the batteries as soon as possible and add the label provided by Zoll showing the next scheduled replacement date. Read and add the addendum incorporating this information to the administrator's guide that was provided by Zoll.
- b. If batteries are not more than three (3) years old, add the label provided by Zoll completed with the next scheduled replacement date. Read and add the addendum, provided by Zoll, incorporating this information to the administrator's guide.

## **ENQUIRIES**

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2

Telephone: +353-1-6764971  
Fax: +353-1-6344033  
E-mail: [vigilance@imb.ie](mailto:vigilance@imb.ie)  
Website: [www.imb.ie](http://www.imb.ie)

Enquiries should be addressed to:

### **Manufacturer:**

**Zoll Medical Corporation**  
269 Mill Road  
Chelmsford  
Massachusetts  
USA

Telephone: 00 31 651937017  
E-mail: [erozeboom@zoll.com](mailto:erozeboom@zoll.com)

# S A F E T Y

## NOTICE

### **Distributor:**

#### **Pulse Medical Ltd**

Unit 8  
Ballyboggan Road  
Glasnevin  
Dublin 11  
Ireland

Telephone: +353 1 6402615  
Fax: +353 1 8602640

#### **Heartbeat Safety Ltd.**

Unit 3  
Crookstown Business Park  
Crookstown  
Co Kildare  
Ireland

Telephone: +353 45895144  
Fax: +353 59 8623870

#### **AED Direct**

52 Clogher Road  
Co Down  
Northern Ireland

Telephone: +44 2892689604  
Fax:

#### **Medilink Services**

Link House  
81 Sydenham Road  
Belfast  
Northern Ireland

Telephone: +44 7980 603670  
Fax: