



***NOTE:** Please do not contact OFPC regarding this Manufacture's Urgent Notification. Please contact the Manufacturer or your distributor if you have any questions or concerns. Contact information is provided below.*

**Cardiac Life Products, Inc.** has requested the assistance of the Office of Fire Prevention & Control to communicate an urgent notice related to a medical device correction for certain Cardiac Science Powerheart automated external defibrillators (AEDs). Please see the Notice below.

The intent of this bulletin is to quickly share this information to as many owners of the Cardiac Science AEDs, including those who have received a donated unit. The upgraded software will make the AED unit more sensitive to identifying any resistor issues which may occur over the lifetime of the Cardiac Science Powerheart AEDs' use.

Below are listed details to help the AED owner better understand what is to be expected. The link should not take more than 15 minutes on a high speed connection. At this site, [www.cardiacscience.com/aed175](http://www.cardiacscience.com/aed175), the user will find the following information.

- o Serial number look up AED IFUs
- o Software Update Instructions
- o Customer FAQs
- o Form to order software update kit

It is important to send the update response back to Cardiac Science that the AED has been updated. This is carefully explained in the instructions.

The AED owner will need the following requirements in order to update:

- Windows XP
- Windows Vista
- Windows 7
  - A serial cable to connect the Powerheart AED to the PC. If the customer does not have the cable, they can call Cardiac Life Products, Inc., offices at 585-267-7895 or 866-710-1970 to order a cable free of charge.

**Important Points to know:**

If the Cardiac Science AED device currently operates according to the AHA/ERC 2000 Guidelines, it will change. AEDs built prior to the new Guidelines which had not been previously updated will update automatically.

If the unit currently operates according to the AHA/ERC 2005 Guidelines, it will not change.

## FAQ's

### **Should I keep my devices in service until the update is available for all other units?**

Until the update is available, Cardiac Life Products, Inc., recommends you keep your device in service and perform the tests indicated for Daily and Monthly Scheduled Maintenance as outlined in your Operator and Service manual. A copy of these procedures is available at [www.cardiacscience.com/aed175](http://www.cardiacscience.com/aed175). At this site, you may confirm if your AED is affected and register for automatic e-mail reminders to conduct scheduled maintenance.

### **What if I notice that the device's Rescue Ready indicator is red?**

If your device Rescue Ready indicator is red, you should contact technical support at 800.426.0337 (choose option 1) in the United States. Outside the US, contact Cardiac Science at +44.161.926.0011 or contact your local Cardiac Science representative, Cardiac Life Products at 866-710-1970.

### **If the chance of this error occurring is rare, why is Cardiac Science choosing to perform this update?**

Cardiac Science is committed to providing the highest quality products and services to our customers. Despite the fact that the chance of this issue occurring is rare, Cardiac Science will perform this update to further reduce the risk associated with this issue and help ensure that every device functions as intended every time.

### **How many models are affected?**

Certain automated external defibrillators (AEDs) manufactured between August 2003 and August 2009 are affected by this action. The affected models include: Powerheart 9300A, 9300C, 9300D, 9300E, 9300P, 9390A, 9390E; and CardioVive 92531, 92532, and 92533.

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President

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February 2010

**URGENT NOTICE - MEDICAL DEVICE CORRECTION**  
**Mandatory Software Update Available for**  
**Certain Cardiac Science AEDs**

Dear Customer,

Cardiac Science previously notified you that certain automated external defibrillators (AEDs) manufactured between August, 2003 and August, 2009 may experience a rare product issue, where resistors may fail and not be detected by the AEDs' periodic self-tests. If the issue were to occur, the AED may not be able to deliver therapy during a rescue attempt and may affect resuscitation of the patient. Information regarding this action can be found at [www.cardiacscience.com/aed175](http://www.cardiacscience.com/aed175).

**This is to inform you a mandatory software update for Powerheart® AED G3 Plus (9390A and 9390E) models is now available. This update enhances the AED's capability to detect the resistor issue during normal self-test procedures.**

Our records show your organization received one or more affected 9390A and 9390E models that need this software update installed as soon as possible.

**What you should do now**

The attached list shows only the affected 9390A and 9390E device(s) you received.

**If the device(s) is still in your possession:** Visit [www.cardiacscience.com/AED175](http://www.cardiacscience.com/AED175) to download and install this mandatory update. Alternatively, you may call us at 877.901.1788 or ask us from the Web site to mail you a CD and written instructions.

**Once you update your affected device(s), you must provide confirmation to Cardiac Science for each AED you update. Instructions how to do this will be provided with the update software.**

**If the device(s) is not in your possession:** Contact us at 877.901.1788 or email us [AED175@cardiacscience.com](mailto:AED175@cardiacscience.com). Then forward this letter to the person who possesses the AED. It is critical all end users with affected devices receive this information immediately.

**If you have additional models affected by this action**

If you have affected models other than the **9390A and 9390E** models covered by this notice, you will receive a separate letter once the update is available for these models. Until then, please keep your device(s) in service.

We want to remind you to continue to perform the Daily and Monthly Scheduled Maintenance as outlined in your Operator and Service manual. A copy of these procedures is available at [www.cardiacscience.com/AED175](http://www.cardiacscience.com/AED175). Checking your AED on a daily basis will confirm, in most cases, if the device is rescue ready. If at any time you determine that your AED is not rescue ready (the status indicator is red), please contact our Technical Support team at 800.426.0337 (option 1).

We apologize for any inconvenience this issue may create. If you have questions regarding this notice, contact us at 877.901.1788 or [AED175@cardiacscience.com](mailto:AED175@cardiacscience.com).

Thank you,

A handwritten signature in blue ink that reads "Bob Odell".

**Bob Odell**

*Sr. Vice President, Strategy, Design, & Operations*

