



November 2009 AED Product Field Update Frequently Asked Questions

If I have additional questions about this situation or to find out if any of my devices are affected, what can I do?

If your question is not addressed in this document, you can visit www.cardiacscience.com/aed175 to find more information or email us at aed175@cardiacscience.com. Additionally, inside the US, you can call **1-877-901-1788**. Outside the US, contact us at +44.161.926.0011, or contact your local Cardiac Science representative.

What is the issue with the component?

Certain automated external defibrillators (AEDs) manufactured between August 2003 and August 2009 may experience a rare product performance issue. These AEDs have resistors which may fail and the failure will not be detected by the device's periodic self-tests. If the performance issue were to occur, the AED may not be able to deliver therapy during a rescue attempt.

What is the chance of this component issue occurring?

The probability that this would occur in your AED is less than 0.0013%. With approximately 300,000 Cardiac Science AEDs in use, this issue contributed to a device's inability to deliver therapy in two reported occurrences over a period spanning more than six years. The probability that this would occur in your AED is remote. This issue is predicted to occur in approximately one in 75,000 devices produced before August, 2009.

What are you doing to address the issue?

By May 2010 Cardiac Science will be providing you a software update that enhances the AED's self-test capability to further reduce the risk associated with this issue. The probability you would experience this issue with your AED is remote, and Cardiac Science advises you to keep your AED in service.

Will the software update fix the issue?

The software update enhances the AED's extensive self-test capability. Enhanced self-test capability will increase the probability that the issue will be identified during the regular self-test in the rare event that the component has failed.

Should I keep my devices in service until the update is available?

Until the update is available, we recommend 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. 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 1-800-426-0337 (choose Option 1) in United States. Outside the US contact us at +44.161.926.0011, or contact your local Cardiac Science representative.

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, we 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 units 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.

How do I find out if my AED is affected?

If one or more of your AEDs were impacted by this, you will receive a written notification informing you that one or more of your devices are affected. If you have not received such notification, your product has not been impacted. You can also visit www.cardiacscience.com/aed175 to confirm if your AED is affected and register for automatic e-mail reminders to conduct scheduled maintenance.

When will the software update be available?

The software update is currently estimated to be available by May 2010.

How will I be notified of the availability of the software update?

Once the software update is available, you will be notified by mail. You can also check the status of the software update availability by visiting www.cardiacscience.com/aed175.

If I check my device's serial number at the site shown above, and it shows that my device is affected, what do I need to do?

Until the update is available, we recommend 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. The probability that this issue would occur in your AED is less than 0.0013%. In other words, the

probability of a device experiencing the issue is approximately one in 75,000. We advise you to keep your devices in service.

What if I gave/sold the affected AED(s) to another organization?

Please contact us as soon as possible. Inside the US, call **1-877-901-1788** to let us know who currently owns the device. Outside the US, contact us at +44.161.926.0011, or contact your local Cardiac Science representative.

You can also let us know by sending an email to us at aed175@cardiacscience.com.

What if I don't know where the affected AED(s) are located?

Please contact us as soon as possible. Inside the US, call **1-877-901-1788** to let us know that you don't know the location or owner of the device in question. Outside the US, please contact your local Cardiac Science representative. You can also let us know by sending an email to us at

aed175@cardiacscience.com.

Has this been addressed in forward production?

Yes, this issue has been addressed for all units produced since August, 2009.