Cardiac Science is conducting a voluntary recall of a limited number of automated external defibrillators (AEDs) manufactured between July 1, 2011 and December 30, 2011. The affected models include Powerheart 9300A, 9300E, 9300P, 9390A, and 9390E. In addition, certain CardioVive 92532 and 92533 models serviced during this time are also affected. This action is being conducted with the knowledge of the appropriate Regulatory Agencies.

The affected AEDs contain a circuit board manufactured with a component that may fail unexpectedly due to a supplier manufacturing defect. If the component were to fail during a rescue attempt, the AED may not deliver defibrillation therapy. This issue was detected at the Cardiac Science factory through our standard quality control processes. We have no reports of this issue impacting a rescue.

Cardiac Science is sending a notification letter to affected customers. This letter advises customers to return the affected AEDs to Cardiac Science for correction as quickly as possible. Cardiac Science will correct the AEDs and promptly return the device to the customers free of charge. Customers are instructed to contact us at 1.888.402.2484 (in the United States), +1.425.402.2482 (outside the United States), or at aed210@cardiacscience.com to arrange delivery of the return shipping materials.

Complete instructions will be provided with the return shipping materials. Customers should return only the affected AEDs. They should keep the battery, electrodes, and other accessories. The AEDs will be corrected at our factory and, in most cases, the same AED will be returned to the customer. We will make every effort to ship the corrected AED (via express delivery) within one business day of receipt at our factory.

Visit www.cardiacscience.com/aed210 for more information and frequently asked questions (FAQs) about AEDs affected by this corrective action.

Frequently Asked Questions

What can I do if I have questions about this situation not addressed in this document or to find out if any of my devices are affected?
If your question is not addressed in this document, you can visit www.cardiacscience.com/aed210 for more information (and to find out if your AED is affected) or e-mail us at aed210@cardiacscience.com. Additionally, you can call 1.888.402.2484 (in the United States), +1.425.402.2482 (outside the United States), or contact your local Cardiac Science representative.

What is the issue with the component?
The affected AEDs contain a circuit board manufactured with a component that may fail unexpectedly due to a supplier manufacturing defect. If the component were to fail during a rescue attempt, the AED may not deliver defibrillation therapy. We have no reports of this issue impacting a rescue.

**How was this issue discovered?**
This issue was detected at the Cardiac Science factory through our standard quality control processes. At this time, there have been no reported instances of this component failure occurring in affected devices that have been shipped.

**What models are affected?**
Certain automated external defibrillators (AEDs) manufactured between July 1, 2011 and December 30, 2011 are affected by this action. The affected models include Powerheart 9300A, 9300E, 9300P, 9390A, and 9390E. In addition, certain CardioVive 92532 and 92533 models serviced during this time are also affected.

**How do I find out if my AED is affected?**
If one or more of your AEDs are impacted, you will receive a written notification informing you that one or more of your devices are affected. You can also visit [www.cardiacscience.com/aed210](http://www.cardiacscience.com/aed210) to confirm whether your AED is affected.

**Were all AEDs manufactured during this time period affected?**
No. Some AEDs manufactured during this period of time are not affected. To confirm whether a specific serial number was affected, visit [www.cardiacscience.com/aed210](http://www.cardiacscience.com/aed210).

**How far back does this issue go?**
Based on our investigation, AEDs with the affected component were shipped between July 1, 2011 to December 30, 2011.

**Is this a required AED recall?**
Yes. Affected AEDs must be returned to the factory for correction.

**Is this a hardware issue or software issue?**
This is a hardware issue. The affected AEDs contain a circuit board manufactured with a component that may fail unexpectedly due to a supplier manufacturing defect. If the component were to fail during a rescue attempt, the AED may not deliver defibrillation therapy. This issue requires factory correction. The issue cannot be corrected by the customer.

**What do I need to do if I have an affected AED?**
You will receive a notification letter regarding the recall of affected AEDs.

1. If one or more of your AEDs is affected, please locate the AED(s) and contact Cardiac Science immediately.
2. Contact Cardiac Science at 1.888.402.2484 (in the United States), +1.425.402.2482 (outside the United States), or at [aed210@cardiacscience.com](mailto:aed210@cardiacscience.com). We will send you pre-paid priority return shipping materials to send the affected AED(s) to us, and we will correct the AED(s) at no expense to you.
3. Once you receive the return shipping materials, follow the instructions included with the shipping materials.
   - You should return only the affected AED(s) in the pre-paid return shipping materials to Cardiac Science.
   - **Remove and keep the battery, electrodes, and other accessories.**

The AED(s) will be corrected at our factory and promptly returned. We will make every effort to ship the corrected AED (via express delivery) within one business day of receipt at our factory.

**Will I have to pay anything for this recall?**
No. Cardiac Science will pay for the return shipping materials, shipping, and cost of correction.

**What do I do with my accessories/supplies?**
Please keep all accessories – including battery, electrodes, carry bags, wall cabinets, Ready Kits, etc. Do not return them with the affected AED. You can use your accessories with your AED once it is returned to you.

**What will the warranty be for the affected AED?**
The warranty will not change. It will continue to cover your product from the time you first received your AED(s).

**Will I get the same AED back that I sent to Cardiac Science?**
Yes, we will return the same AED to you in most cases. In some rare cases, we may need to send a different serial number of the same model.

**Will the affected AED operate differently during a rescue after the correction?**
If your AED currently operates according to the AHA/ERC 2010 Guidelines and is set to the factory default settings, it will not change. The correction will cause the AED to default to the AHA/ERC 2010 Guidelines and factory default settings.

**Is this issue detected in the AED’s self-test?**
Yes. If the failure is present at the time of the weekly self-test, it will be detected. If the component were to fail during a rescue attempt, the AED may not deliver defibrillation therapy so it is important for customers to return the AED to Cardiac Science for correction.

**Is this action related to any of the other field actions Cardiac Science announced in previous years?**
No, this is a completely separate action. If the AED was manufactured outside of the dates specified above, it is not affected unless **it was being serviced and returned to you between July 1, 2011 and December 30, 2011.** All customers with affected AEDs will receive a notification letter and the AED serial number will be identified as an affected AED at [www.cardiacscience.com/AED210](http://www.cardiacscience.com/AED210).

**Could AEDs affected by any other field action also be affected by this one?**
To the best of our knowledge, AEDs affected by this field action are not affected by any previous field action conducted by Cardiac Science. If you wish to verify that your AED is not affected, visit www.cardiacscience.com/AED210.

I checked my AED’s serial number at the site referenced above and my AED serial number was not found. What do I do?
You do not need to take any further action. Your AED is not affected and should be kept in service.

I own many AEDs, but only some of my AEDs are affected by this action. Do all of them need to be corrected?
No. Only the affected AEDs need to be returned to us for correction.

I own many affected AEDs. Do I need to return all of them at once?
Yes, we encourage you to return all of your affected AEDs to us as soon as possible. This will allow us to expedite the delivery of the corrected AEDs back to you. Contact us to discuss your options. We will work with you to find the best solution. You can reach us at 1.888.402.2484 (in the United States), +1.425.402.2482 (outside the United States), or at aed210@cardiacscience.com.

I am a Program Management customer with affected AEDs. What do I need to do?
Please contact us to discuss your situation. We will work with you to find the best solution. You can reach us at 1.888.402.2484 (in the United States), +1.425.402.2482 (outside the United States) or at aed210@cardiacscience.com.

How do I return my affected AED?
Detailed instructions on how to return your affected AED(s) will be sent to you with the pre-paid priority return shipping materials. Please contact us to arrange delivery of these shipping materials.

What do I do if a sudden cardiac arrest occurs during this period?
If you do not have an AED available, please provide CPR and call Emergency Medical Services immediately.

Has this been addressed in new production units?
Yes, this issue has been corrected in forward production units.

Will the FDA visit the Cardiac Science facilities or demand any further action?
We notified the FDA of this action on January 13, 2012. We will collaborate fully with the FDA to ensure our action meets the requirements of the agency.

What if I gave/sold the affected AED(s) to another organization?
Please contact us as soon as possible. Inside the U.S., call 1.888.402.2484 to let us know who currently owns the device. Outside the U.S., contact us at +1.425.402.2482 or contact your local Cardiac Science representative. You can also let us know by e-mail at aed210@cardiacscience.com. It is very important that all owners of these devices are notified immediately of this action.
What if I don’t know where the affected AED(s) are located?

Please contact us as soon as possible. Inside the U.S., call 1.888.402.2484 to let us know that you don’t know the location or owner of the device in question. Outside the U.S., contact us at +1.425.402.2482 or contact your local Cardiac Science representative. You can also let us know by e-mail at aed210@cardiacscscience.com.