



## February 2010 AED Voluntary Corrective Action Frequently Asked Questions

Cardiac Science is initiating a voluntary replacement of product after determining certain automated external defibrillators (AEDs) may not deliver therapy during a resuscitation attempt, which may lead to serious adverse events or death. Cardiac Science detected this issue through its own quality control systems and has received no complaints or reports of this problem in the field. The FDA has been informed of this situation.

These AEDs were manufactured in a way that makes them potentially susceptible to failure under certain conditions. The affected models include Powerheart 9300A, 9300E, 9300P, 9390A, and 9390E and Cardiovinne 92532 models manufactured or serviced between October 19, 2009 and January 15, 2010.

### If I have questions about this situation what can I do?

If your question is not addressed in this document, please visit [www.cardiacscience.com/AED195](http://www.cardiacscience.com/AED195) to find more information or email us at [AED195@cardiacscience.com](mailto:AED195@cardiacscience.com). Additionally, inside the US, you can call 888.402.2484. Outside the US contact us at +44.161.926.0011 or contact your local Cardiac Science representative.

### What is the issue with the affected AEDs?

AEDs manufactured or serviced between October 19, 2009 and January 15, 2010 may have a defect that makes them susceptible to failure under certain conditions.

### How do I find out if my AED is affected?

If one or more of your AEDs is affected, you will receive written notification. Within the US, we will also contact you by telephone notifying you that we have shipped you an affected AED, if we have your current contact information. Outside the US, you will receive a call from your local Cardiac Science representative. You can also check the serial number of your AED at [www.cardiacscience.com/AED195](http://www.cardiacscience.com/AED195) to verify whether your AED is affected.

### Is this action related to any of the other field actions Cardiac Science has recently announced?

No, this is a completely separate action. AEDs affected by other field actions may remain in service as long as they have not been returned for service in which case you will be notified and the AED serial number will be identified as such at [www.cardiacscience.com/AED195](http://www.cardiacscience.com/AED195).

### Could AEDs affected by any other field action also be affected by this one?

The majority of AEDs affected by this field action are not affected by any other field action. However, a small number of AEDs manufactured between October 19 and January 15, 2010 were used as replacement AEDs affected by a different field action. In addition, a very small number of AEDs that required a component replacement as part of servicing were affected. All customers who have an affected AED will be notified of this issue.

## If I have an affected AED, what do I do?

- If one or more of your AEDs is affected, please contact us at [AED195@cardiacscience.com](mailto:AED195@cardiacscience.com) to arrange for replacement(s). Additionally, inside the US, you can call 888.402.2484. Outside the US contact us at +44.161.926.0011 or contact your local Cardiac Science representative.
- Additionally, if one or more of your AEDs is affected, you will receive written notification and a follow-up telephone contact from a Cardiac Science representative.
- We will arrange to have a replacement AED shipped to your facility at no charge (in some cases, we may work in conjunction with the distributor who sold you the AED).
- Until you receive the replacement AEDs, you must remove your affected AEDs from service.

Once you have the replacement AED:

- Remove and keep all accessories from the affected AED (battery, electrodes, carry bag, ready kit, etc.).
- Install the battery from the current AED into the replacement AED.
- Use existing accessories (electrodes, carry bag, ready kit, etc.) with the replacement AED. Keep all of the electrodes from the affected AED and use them as spares. The replacement AED will be shipped with new, pre-connected electrodes.
- Place your replacement AED into service.
- Return your affected AED in the packaging provided with the replacement AED to Cardiac Science as outlined below:
- For US customers: Return the affected AED without the battery to Cardiac Science per the instructions included with the replacement AED. You will be provided pre-paid shipping labels for returning the AED.
- For international customers: Return the affected AED without the battery to the local Cardiac Science Representative who sold you the AED to ensure that it is returned to Cardiac Science.

## Is this issue caught in the AED's self test?

Yes. If the failure is present at the time of the weekly or monthly self test, it will be detected. However, because the failure may occur intermittently, we are requiring customers remove the AED from service.

## Is this a required AED exchange?

Yes. This exchange is required; your affected AED must be removed from service.

## Will I have to pay anything for this replacement?

No. Cardiac Science will send out the replacement AED at no charge. US customers will receive shipping labels and instructions for returning the affected AED to the factory. International customers should work with their local Cardiac Science representative to return the AED to the factory.

## What exactly will I receive with my new AED?

You will receive:

- A 2005 Guidelines compliant Powerheart AED model that corresponds to the model that is being replaced.
- One set of new electrodes pre-connected in the AED.

### **What do I do with my old accessories/supplies?**

Please keep all old accessories – **including battery**, pads, carry bags, wall cabinets, Ready Kits, etc. These are yours to keep. Do not return them with the affected AED. You can use your current accessories with the new AED.

### **If I check my AED's serial number at the site referenced above and it shows that my AED is not affected, what do I do?**

You do not need to take any further action. Your AED is not affected and should be left in service.

### **What if I own many AEDs, but only a subset of my AEDs is affected by this issue - do all of them need to be taken out of service and replaced?**

No. Only the affected AEDs need to be taken out of service and only these AEDs need to be replaced.

### **How do I return my affected AED?**

**For US Customers:** Detailed instructions on how to return your affected AED will be sent to you with the replacement AED.

**For International Customers:** Work with the Cardiac Science Representative who sold you the AED to ensure that it is returned to Cardiac Science.

### **Will the replacement AED operate differently during a rescue than the one I currently have in my possession?**

If your AED currently operates according to the AHA/ERC 2005 Guidelines and is set to the factory default settings, it will not change.

### **What if I gave or sold the affected AEDs to another organization?**

Please contact us as soon as possible. Inside the US, call 888.402.2484 to let us know who currently owns the AED. 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 [AED195@cardiacscience.com](mailto:AED195@cardiacscience.com).

### **What if I don't know where the affected AED is located?**

Please contact us as soon as possible. Inside the US, call 888.402.2484 to let us know that you don't know the location or owner of the AED in question. 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 [AED195@cardiacscience.com](mailto:AED195@cardiacscience.com).

### **What if there is a gap between the time I learn that one of my AEDs is affected and the time I get the replacement AED?**

If you have another AED, use it instead. We are advising customers to take the affected AEDs out of service. We will make every effort to provide a replacement AED as soon as possible. In the interim, if a sudden cardiac arrest occurs, please provide CPR and call Emergency Medical Services immediately.