



November 2009 AED Corrective Action
Replacement Devices for First Responders and
Medical Provider Facilities in Frequent Use
Environments
Customer FAQs

Which customers are receiving replacements?

Cardiac Science will provide AED replacements for first responders and medical provider facilities in frequent use environments. First responders are police, fire and ambulance services. Medical provider facilities are hospitals, medical clinics, dialysis centers and assisted living facilities.

What is considered a medical clinic?

Medical clinic includes physician offices, urgent care facilities, clinics staffed by a physician within another facility and cardiac rehabilitation clinics.

Why are these customers receiving replacements?

First responders and medical provider facilities represent professional users who are more likely to use their AEDs frequently.

The FDA has agreed with this plan, under which we will replace AEDs for these users and provide a software enhancement for all other impacted users. The FDA has issued a communication about this which may be viewed at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm191426.htm>.

Why are you modifying your previously announced action?

First responders and medical provider facilities represent professional users who are more likely to use their AEDs frequently. This may introduce a slightly higher probability of encountering a failed component during a rescue.

We determined it was appropriate to replace AEDs for these customers and settings. The software update is appropriate for all other impacted users. The FDA has agreed to this plan.

Does this resolve the FDA concerns for this action?

The FDA has reviewed this action and has agreed with the plan. The FDA has issued a communication about this which may be viewed at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm191426.htm>. We are now focusing our efforts to execute the plan quickly and effectively.

When can I expect my replacement AED?

We plan to complete replacements for first responders within the next 120 days. The replacements for medical provider facilities will be provided after that.

First responders are prioritized because they are likely to use their AEDs more frequently and use any particular AED more often.

If I am a first responder or a medical provider facility in a frequent use environment, what do I do until I receive a replacement AED?

Until you receive your replacement AED, Cardiac Science recommends that you keep your AED in service while you arrange for your replacement. Also, we urge you to perform the software update on affected AEDs in your possession until you receive your replacement AED. The software update for affected models is available for download at www.cardiacscience.com/aed175. For more information on the software update visit www.cardiacscience.com/aed175.

You will receive a notification letter, and will be contacted by a Cardiac Science representative to arrange for replacement of affected AEDs.

Will the software update fix the issue?

The software update enhances the AED's extensive self-test capability and improves detection of the component issue. This 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. If the component fails the self-test, the rescue ready indicator will turn red and the device will issue an audible alert. If this happens, Cardiac Science will repair or replace the device.

Is this a required AED replacement?

Yes. This replacement is required for first responders and medical provider facilities in frequent use environments.

Will I have to pay anything for this replacement?

No. Cardiac Science will send out the replacement AED at no charge.

What exactly will I receive with my replacement?

- A 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 your to keep. Do not return them with the affected AED. You can use your current accessories with the replacement AED.

What will the warranty be for the replacement AED?

The warranty for the replacement AED will expire at the same time as the warranty of your original AED.

Will I get the same AED back that I sent to Cardiac Science?

No, you will receive a replacement AED which will have a different serial number. You will receive a replacement Powerheart AED model that corresponds to the model that is being replaced.

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.

If I am a first responder or a medical provider facility in a frequent use environment and I already performed mandatory software update on my affected AED, will I still be receiving a replacement AED?

Yes, you will receive a replacement AED, even if the software update has been performed. You will receive an official letter from Cardiac Science first and then a call from our representative to arrange for replacement.

If I have questions about this situation not addressed in this document or to find out if any of my AEDs are affected, what can I do?

If your question is not addressed in this document, you can visit www.cardiacscience.com/aed177 to find more information or email us at aed177@cardiacscience.com. Additionally, inside the US, you can call 877.901.1788. Outside the US, contact us at +44.161.926.0011, or contact your local Cardiac Science representative.