



- THE FDA HAS ISSUED THE FOLLOWING ALERT -

## FDA IS ALERTING USERS OF CERTAIN POWERHEART AND CARDIOVIVE AUTOMATED EXTERNAL DEFIBRILLATORS THAT THESE DEVICES MAY MALFUNCTION UNEXPECTEDLY

FDA is alerting users of certain Powerheart and CardioVive automated external defibrillators that these devices may malfunction unexpectedly. This can cause a failure to deliver the electric shocks that are needed to treat sudden cardiac arrest or arrhythmias.

The manufacturer, Cardiac Science Corporation, has received multiple complaints that these devices have malfunctioned, and that their self-test features may not show that there's anything wrong. Before each use, operators are supposed to check for a green light on the front of the AED that shows the device is rescue-ready. But the light may come on even when certain electronic components inside the device have failed.

Malfunctions could cause these AEDs to interrupt ECG analysis and thus prevent shock delivery, or fail to recognize that the pads have been placed. Malfunctions could also cause interference or background noise, which could prevent the device from accurately analyzing heart rhythm and delivering a shock.

About 300,000 Cardiac Science G3 series Powerheart and CardioVive AEDs are affected by this problem worldwide. They were manufactured between August 2003 and August 2009. FDA recommends that users contact Cardiac Science Corporation immediately to arrange for repairs or replacement.

Until the company repairs or replaces the affected devices, FDA recommends that users switch to alternate AEDs if they are available, or that they consider obtaining another AED. If an alternate AED is not available, trained responders should use manual defibrillators. If a manual defibrillator is not available, responders should use the Powerheart or CardioVive AEDs, since they may still be able to deliver the necessary shock.

In the home or in public places, FDA recommends continuing to use these devices if an alternate AED is not available. That's because the consequences of not trying to defibrillate a patient outweigh the risk that the AED may fail.

The FDA is gathering more data about this situation, and as OFPC learns more, we will share any new information that might affect the use of these AEDs.

### Additional Information:

FDA MedWatch Safety Alert. Cardiac Science Corp. Powerheart and CardioVive Automated External Defibrillators: Initial Communication. November 19, 2009.

Cardiac Science Corporation website. Cardiac Science Notifies AED Customers of Nationwide Voluntary Medical Device Correction. November 13, 2009.

The FDA Recall and Safety Alert may be accessed at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=95#1>



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