



## County of Erie

CHRIS COLLINS  
COUNTY EXECUTIVE

DEPARTMENT OF HEALTH

ANTHONY J. BILLITTIER IV, M.D., FACEP  
COMMISSIONER OF HEALTH

**TO:** All E.M.S. Providers

**FROM:** Daniel Neaverth, Deputy Commissioner / E.M.S.  
Erie County Division of Emergency Medical Services

**DATE:** November 16, 2009

**SUBJECT:** Cardiac Science Automated External Defibrillator (AED) Medical Device Correction

Cardiac Science Corporation is initiating a voluntary field correction of certain Automated External Defibrillators (AEDs). The press release is available on the Food and Drug Administration website at <http://www.fda.gov/Safety/Recalls/ucm190605.htm>.

To determine if you have a unit affected by this notice, go to [www.cardiacscience.com/AED175](http://www.cardiacscience.com/AED175). Cardiac Science offers a tool using the serial number to determine if a unit is involved in the corrective action.

If you have or know any organization that has one of these units, refer them to <http://www.fda.gov/Safety/Recalls/ucm190605.htm>. This website will provide more detail on the units and corrective action proposed for the AEDs.

If you should have any questions, please contact us at the E.M.S. office at 681-6070.

Cc Anthony Billittier, IV, MD, Commissioner  
Gregory Skibitsky, Commissioner



## Cardiac Science Notifies AED Customers of Nationwide Voluntary Medical Device Correction

### Recall--Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

## Cardiac Science Notifies AED Customers of Nationwide Voluntary Medical Device Correction

FOR IMMEDIATE RELEASE -- Bothell, WA - November 13, 2009 - Cardiac Science Corporation [NASDAQ: CSCX] is initiating a voluntary field correction after it was determined certain automated external defibrillators (AEDs) may experience a rare product issue in which the AED may not be able to deliver therapy during a resuscitation attempt. Device failure may affect resuscitation of the patient, which could lead to serious adverse events or death. These AEDs have electronic components which may fail and the failure may not be detected by the device's periodic self-tests. The affected models include the Powerheart 9300A, 9300C, 9300D, 9300E, 9300P, 9390A, 9390E, and CardioVive 92531, 92532, and 92533 devices.

Cardiac Science has received a total of 64 complaints concerning four resistors within certain AEDs. Two of these complaints were associated with a failure to deliver therapy. This issue is predicted to occur in approximately one in 75,000 AEDs manufactured between August 2003 and August 2009. The company has also received 114 complaints regarding "Service Required" messages resulting from a specific relay switch failure. There have been no reported instances where this issue has resulted in an inability to deliver therapy.

Until a correction is available in May, 2010, the company strongly advises customers to check the status indicator on the front of the AED and follow the procedures documented in the materials accompanying the AED. The company advises that customers leave their AEDs in service.

"When customers choose a product from Cardiac Science, they expect outstanding reliability," said Dave Marver, president and chief executive officer. "We understand the role our products play in public health and are taking appropriate measures to further improve the performance of our products." The company has implemented more stringent testing of the components and all AEDs produced since August, 2009 are unaffected. Customers in possession of an AED that may exhibit either of these issues will be notified immediately. A software update to address the resistor issue will be available by May, 2010. This software update will enhance the AED's self-test capabilities and improve detection of the issue. In the interim, the company advises customers to keep their AEDs in service and follow the normal testing and maintenance procedures found in the Operator and Service Manual. A copy of these procedures is available at [www.cardiacscience.com/AED175](http://www.cardiacscience.com/AED175). At this site, customers may confirm if their AED is affected and register for automatic e-mail reminders to conduct

scheduled maintenance.

If the AED is not rescue ready (the indicator is red) customers should contact the company immediately at 425.402.2000 (option 1) within the United States. Outside the US contact +44.161.926.0011 or the local Cardiac Science representative. Customers can also email the company at AED175@cardiacscience.com.

#### Forward-Looking Statements

This press release contains forward-looking statements. The word "believe," "expect," "intend," "anticipate," variations of such words, and similar expressions identify forward-looking statements, but their absence does not mean that the statement is not forward-looking. Forward looking statements in this press release include, but are not limited to, predictions of AED component failure rates, the availability of software updates to improve detection of the component issue, and the effectiveness of the planned software update. These are forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Actual results and performance may vary significantly from those expressed or implied in such statements. Factors that could cause or contribute to such varying results and other risks are more fully described in the Annual Report on Form 10-K filed by Cardiac Science Corporation for the year ended December 31, 2008, as updated by subsequent quarterly reports on Form 10-Q. Cardiac Science Corporation undertakes no duty or obligation to update the information provided herein.

For more information,

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