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U.S. Department of Health and Human Services



U.S. Food and Drug Administration

**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. 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.



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**OFFICE OF
FIRE PREVENTION
& CONTROL****phone** 518.474.6746**fax** 518.474.3240**email** fire@dos.state.ny.us