



Notice Print Date (Month/Day/Year): 1/17/2012

## **URGENT - Voluntary Medical Device Recall**

Dear Valued Customer,

Cardiac Science is conducting a voluntary recall of a limited number of automated external defibrillators (AEDs) manufactured between July 1, 2011 and December 30, 2011. The affected models include Powerheart 9300A, 9300E, 9300P, 9390A, and 9390E. In addition, certain CardioVive 92532 and 92533 models serviced during this time are also affected. We are communicating this information to the appropriate national competent authorities.

The affected AEDs contain a circuit board manufactured with a component that may fail unexpectedly due to a supplier manufacturing defect. If the component were to fail during a rescue attempt, the AED may not deliver defibrillation therapy. This issue was detected at the Cardiac Science factory through our standard quality control processes. We have no reports of this issue impacting a rescue.

According to our records, your organization received one or more of the affected AEDs. We have enclosed a list of the affected AED model number(s) and serial number(s) shipped to your organization. **Please note: This action covers only those specific serial numbers in the attached list. Other AEDs you may own are not affected by this action and should remain in service.**

If you no longer have the affected devices in your possession, please forward this information to the appropriate individuals. It is imperative that all end users of these devices receive this information immediately.

### **What you should do now:**

**You should return the AED(s) to us for correction as soon as possible.** Cardiac Science will send you pre-paid priority return shipping materials and correct the AED(s) at no expense to you. Once you have located the affected AED(s), contact us by phone at +1.425.402.2482 or by e-mail at [aed210@cardiacscience.com](mailto:aed210@cardiacscience.com) to arrange delivery of the shipping materials.

Complete instructions will be provided with the shipping materials. Please return only the affected AED(s) – do not ship the battery, electrodes, and other accessories. Your AED(s) will be corrected at our factory and promptly returned to you. We will make every effort to ship the corrected AED(s) to you (via express delivery) within one business day of receipt at our factory.

Visit [www.cardiacscience.com/aed210](http://www.cardiacscience.com/aed210) for more information and frequently asked questions (FAQs) about AEDs affected by this corrective action.

**Thank you for your immediate attention to this matter.** We apologize for any inconvenience this issue may create. If you have any questions regarding this communication, please contact us by phone at +1.425.402.2482 or by e-mail at [aed210@cardiacscience.com](mailto:aed210@cardiacscience.com). You may also contact our Authorized EU Representative, MDSS GmbH, at +49 511 6262 8630 or your local Cardiac Science representative.

Thank you,

A handwritten signature in blue ink that reads "Bob Odell".

**Bob Odell**  
*Chief Operating Officer*

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