



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

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

Dear Valued Distributor,

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.

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

- 1. Please check your inventory for affected AEDs and return them to us as quickly as possible.**
- 2. If you have any affected AEDs in use at your location, return them to us as quickly as possible for correction.**

### **If you are a stocking distributor, please take these actions:**

1. For your inventory:
  - o Remove any affected AEDs from your current inventory.
  - o Contact Cardiac Science to arrange pick-up of the affected AEDs. You can reach us by phone at +1.425.402.2482 or by e-mail at [aed210@cardiacscience.com](mailto:aed210@cardiacscience.com).
  - o Your AEDs will be corrected at our factory and promptly returned to you. We will make every effort to ship the corrected AED to you (via express delivery) within one business day of receipt at our factory.
2. For your customers' inventory:
  - o Use your customer database to determine which customers received these affected AEDs.
  - o Once you have identified the affected customer:
    - Inform these customers in writing, with the attached customer letter, that a Cardiac Science representative will contact them regarding this action.
    - Provide the list of affected customers to Cardiac Science so we may contact them directly. Please contact us by phone at +1.425.402.2482 or by e-mail at [aed210@cardiacscience.com](mailto:aed210@cardiacscience.com).





**If you are a drop-ship distributor:**

Cardiac Science will contact your customers directly to correct the affected AEDs at no charge.

We will send pre-paid priority return shipping materials for customers to return their affected AEDs to our factory. Customers will be instructed to return only the affected AEDs according to the instructions enclosed with the shipping materials. They should not ship the battery, electrodes, and other accessories from the affected AEDs. The AEDs will be corrected at our factory and promptly returned to your customers. We will make every effort to ship the corrected AED to your customers (via express delivery) within one business day of receipt at our factory.

**Please note: This action covers only those specific serial numbers in the attached list. Other AEDs are not affected by this action and should remain in service.**

If you have transferred the affected devices to another distributor, please forward this information to the new distributor. It is imperative that all owners of these devices receive this communication immediately.

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

**Thank you for your immediate attention.**

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 authorised 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*

