January 13, 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. This action is being conducted with the knowledge of the appropriate Regulatory Agencies.

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.

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 at 1.888.402.2484 (in the United States), +1.425.402.2482 (outside the United States) or at 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 <u>www.cardiacscience.com/aed210</u> for more information and frequently asked questions (FAQs) about AEDs 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 at 1.888.402.2484 (in the United States) and +1.425.402.2482 (outside the United States). You may also e-mail us at aed210@cardiacscience.com.

Thank you,

Bob Odill

Bob Odell *Chief Operating Officer*

3303 Monte Villa Parkway Bothell, WA 98021-8969 Tel: 425 402 2000 Fax: 425 402 2006 Toll Free: 800 426 0337 www.cardiacscience.com QS-00625-01 Rev A, January, 2012

