Class I Medical Device Recall: Cardiac Science Powerheart, CardioVive, CardioLife; GE Responder and Responder Pro; and Nihon-Kohden Automated External Defibrillators - AEDs

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: January 13, 2012

Products:

- Cardiac Science Powerheart, CardioVive, and CardioLife Models of AEDs
- GE Responder and Responder Pro AEDs
- Nihon-Kohden AEDs

Affected Models: Powerheart 9300A, 9300E, 9300P, 9390A, and 9390E; CardioVive 92532, 92533; CardioLife 9200G and 9231; GE Responder and Responder Pro; and Nihon-Kohden AEDs

Go to Serial Number Search [1] to determine if an AED is affected by this recall. Enter one or more serial numbers, located on the back of the AED, in the box provided on the firm's webpage.

These AEDs were manufactured and distributed from July 1, 2011 through December 30, 2011.

Use: This product is used for emergency treatment of victims showing symptoms of sudden cardiac arrest who are unresponsive and not breathing.

Recalling Firm:
Cardiac Science Corporation
3303 Monte Villa Parkway
Bothell, Washington 98021

Distributors:
GE Healthcare, LLC
3000 N Grandview Blvd
Waukesha, Wisconsin 53118-1615

Nihon Kohden Corporation
1-31-4, Nishiochiai Shinjuku-ku
Tokyo, 161-8560, Japan

Reason for Recall: The affected AEDs contain a component that may fail unexpectedly due to a defect. If the component were to fail during a rescue attempt, the AED may not deliver defibrillation therapy causing serious adverse health consequences, including death. The unit's self test may not detect the failure or impending failure of the component.

Public Contact: Customers may contact the firm at 1-888-402-2484 (in the U.S.) and +1-425-402-2482 (outside the United States) or by email at aed210@cadiacscience.com [2].

FDA District: Seattle

FDA Comments: On January 13, 2012, the firm sent all affected customers an URGENT-Voluntary Medical Device Recall [3] letter. The letter describes the product, problem, and actions to be taken by the customers.

Affected customers are advised to contact the firm to arrange for delivery of shipping materials for an **immediate return** of their AEDs for repair. The affected devices will receive a hardware correction, and the same serial number device will be returned to the customer in most cases. All affected AEDs will be corrected at no charge to the customer.

Customers and distributors can also visit www.cardiacscience.com/aed210 [4] for more information about the AEDs affected by this recall (including Frequently Asked Questions).

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the MedWatch: The FDA Safety Information and Adverse Event Reporting Program [5] either online, by regular mail, by telephone, or by FAX.

Additional Information:
Firm Press Release [6]

SOURCE [7]

Source URL (retrieved on *10/23/2014 - 5:33am*):
http://www.mdtmag.com/news/2012/03/class-i-medical-device-recall-cardiac-science-powerheart-cardiovive-cardiolife-ge-responder-and-responder-pro-and-nihon-kohden-automated-external-defibrillators-aeds?qt-most_popular=0

Links:
[1] http://www.cardiacscience.com/services-support/service-announcements-and-

upgrades/aed210.php
[2] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/mailto:aed210@cadiacscience.com
[3] http://www.cardiacscience.com/assets/023/7751.pdf
[4] http://www.cardiacscience.com/aed210
[5] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
[6] http://www.cardiacscience.com/news-events/in-the-news/cardiac-science-notifies-aed-customers-of-nationwide-voluntary-medical-device-correction125612.htm
[7] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm294452.htm