Cardiac Science Automated External Defibrillators - Powerheart, Cardiovive, NK, Responder models: Class I Recall

FDA MedWatch

[UPDATED 04/27/2010] This update alerts users that Nihon Kohden (NK) and GE Responder models are also affected although they were not identified in earlier communications about this recall. In addition, Cardiac Science issued a software upgrade for the devices' self tests on 02/24/10 for the Powerheart automatic external defibrillators (Models 9390A and 9390E) and is planning on issuing a similar software upgrade for other affected devices. However, FDA's review of the updated software indicates that it detects some but not all electrical component defects.

Normally, users of these devices should always check the status indicator on the front of the external defibrillator and/or audible indicators to see whether the device is rescue-ready (green light is displayed). However, the presence of a green light on the affected devices may not reveal defective or non-working components inside the external defibrillators and give a false sense that they are in proper working order. Updated recommendations and complete list of affected models can be found in the 04/27/2010 Medical Device Update.

Cardiac Science Corporation and FDA notified healthcare professionals and consumers of a Class 1 recall of automated external defibrillators (AED). These devices may not deliver therapy during a resuscitation attempt. Defects in certain electronic components may not be detected by the device's Daily/Weekly/Monthly self-tests. These defects can cause improper functioning of the device during a rescue attempt, which may prevent resuscitation. This can lead to serious adverse health events and/or death. List of affected models includes:

- Powerheart 9300A, 9300C, 9300D, 9300E, 9300P, 9390A, 9390E
- CardioVive 92531, 92532, 92533
- NK 9200G, 9231
- Responder 2019198 and 2023440.

The affected AEDs were manufactured and distributed between August 2003 and August 2009.

[04/27/2010 - Update on Defective Cardiac Science Corporation External Defibrillators [1] - FDA]
[03/08/2010 - Recall Notice [2] - FDA]

SOURCE [3]

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http://www.ecnmag.com/news/2010/04/cardiac-science-automated-external-defibrillators-powerheart-cardiovive-nk-responder-models-class-i-recall?qt-video_of_the_day=0

Links:
[1] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm191426.htm
[2] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm203525.htm
[3] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm205165.htm