Cardiac Science Corporation issued a press release (11/13/09) alerting users of its Powerheart, and CardioVive external defibrillators of defective components and reported failures. 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. Approximately 280,000 Cardiac Science external defibrillators worldwide are potentially affected by this problem

Recall: External Defibrillator Models by Cardiac Science (April 27, 2010)

Cardiac Science Corp. has updated its November 2009 recall of automated external defibrillators (AEDs) to include additional models. The AEDs, which are used in health care facilities, public places, and in the home, may malfunction during attempts to rescue people in sudden cardiac arrest—a condition in which the heart suddenly and unexpectedly stops beating.

The risk: When cardiac arrest occurs, blood stops flowing to the brain and other vital organs, leading to death if not treated within minutes.
Normally, users of these devices should always check the status indicator on the front of the defibrillator or the audible indicators to see whether the device is rescue-ready (green light is displayed). However, a green light on the affected devices may not reveal defective or nonworking components inside the defibrillators and give a false sense that they are in proper working order.
In addition, defects in certain electronic components may not be detected by the device's daily, weekly, or monthly self-tests.
The 14 recalled models, which were manufactured and distributed between August 2003 and August 2009, are

- Powerheart models 9300A, 9300C, 9300D, 9300E, 9300P, 9390A, and 9390E
- CardioVive models 92531, 92532, and 92533
- Nihon Kohden models 9200G and 9231
- GE Responder models 2019198 and 2023440

The Powerheart and CardioVive models listed above were recalled in November 2009. But FDA has since learned that the additional Cardiac Science models listed above, marketed under the Nihon Kohden name and the GE Healthcare name as GE Responder, have similar problems.
Recommendations: Contact the company immediately to arrange for repairs or replacements of your AEDs. In the U.S., call 425-402-2000 (press option 1); outside the U.S., call +44-161-926-0011; or e-mail AED175@cardiacscience.com.

Home users and public access defibrillation programs should take the following steps while arranging for repair or replacement of their Cardiac Science AEDs:

- If an alternate AED is available, use it until the Cardiac Science's AED has been repaired or replaced, or consider obtaining another AED.
- If an alternate external defibrillator is not available, use Cardiac Science's devices if needed, as the units may still be able to deliver the necessary treatment. The consequences of not attempting to defibrillate a patient outweigh the risk that these devices may fail.

For more information, see FDA's updated communication on Cardiac Science's External Defibrillators at this link:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm191426.htm