Cardiac Science Corp. Powerheart and CardioVive Automated External Defibrillators: Initial Communication

FDA MedWatch

Cardiac Science Corporation has received multiple complaints related to defective components in these AEDs that indicate the affected devices may not deliver electric shocks and that the devices' self-test may not detect the defect in advance of their use. 300,000 Cardiac Science AEDs worldwide are potentially affected by this problem. The G3 Series devices were manufactured between August 2003 and August 2009. Affected models include the following:

- Powerheart models 9300A, 9300C, 9300D, 9300E, 9300P, 9390A, 9390E; and
- CardioVive 92531, 92532 , and 9253

Because the AED display screen and/or audible indicators may not accurately indicate whether the device is functioning properly or will function properly at time of use, FDA encourages users of the affected AEDs to follow the additional precautions provided in this communication. FDA is gathering more data about this situation to better understand its potential public health impact and will make available any new information that might affect the use of these AED devices. Prompt reporting of adverse events can help FDA identify and better understand the risks associated with medical devices. FDA encourages anyone who suspects any electronic or mechanical problem(s) with an AED to file a voluntary report [1] through MedWatch, the FDA Safety Information and Adverse Event Reporting Program.

SOURCE [2]

Source URL (retrieved on *08/28/2014 - 8:06pm*):
http://www.ecnmag.com/news/2009/11/cardiac-science-corp-powerheart-and-cardiovive-automated-external-defibrillators-initial-communication

Links:
[1] https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
[2] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm191471.htm