January 2014



Urgent Field Safety Notice G5 AED Electrode Connector

Dear Customer,

Cardiac Science has determined certain Powerheart G5 Automatic External Defibrillators (AEDs) shipped between June 21, 2012, and March 1, 2013, may have been manufactured with a defective electrode connector. Some of these G5 AEDs have been found with missing spring contacts in the Electrode Connector Assembly.

When the spring is missing, the AED may not recognize that pads have been placed on the patient during a rescue attempt. The AED voice prompts will progress until they reach the Pads placement (peeled) step. At that point, the AED will, regardless of whether pads are placed to patient's chest or not, continuously repeat "Place pads firmly onto patient's chest..." After 2 minutes, the pad placement prompting will time out and the AED will begin CPR mode. If the issue occurs, the AED may not be able to deliver therapy during a rescue attempt and may affect resuscitation of the patient. This could lead to serious adverse health events or death. The affected models include Powerheart G5S and G5A AEDs.

Our records show that your organization received one or more AEDs that could experience this issue.

What you should do now

Please check the attached list of affected devices. A Cardiac Science representative will be contacting you within the next several weeks to arrange for repair of your device. During the repair you may receive new electrode pads.

If you no longer have the device in your possession please contact us at +1.262.953.3452 or +44 161 926 0000 (United Kingdom) or via email at <u>AED1029@cardiacscience.com</u>, then forward this letter to the person now responsible for the device. German customers may contact our EU representative at +49-511-62628630 or via email at <u>vigilance@mdss.com</u>.

Until we can arrange for repair of your device(s) please keep them in service, and perform the periodic maintenance as outlined in the device Operator's Manual.

Thank you for your immediate attention.

This information has been communicated to your appropriate National Competent Authority.

Again if you have questions regarding this alert, please contact your local representative or reach us at +1.262.953.3452 (United States), +44.161.926.0000 (United Kingdom) or +49-511-62628630 (Germany). You may also email us at <u>AED1029@cardiacscience.com</u>.

Sincerely,

Beverly Magrane

Director Regulatory Compliance

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