

January 2016

URGENT: VOLUNTARY MEDICAL DEVICE RECALL

Re: **9131-001 Defibrillation Electrodes, Lot No. 141125-02**
Used in Powerheart G3 9300A, 9300E, 9300P, 9390A, and 9390E AEDs

Dear Valued Customer,

Cardiac Science has determined Powerheart G3 **defibrillation electrodes (PN 9131-001) from Lot No. 141125-02 may exhibit higher than expected electrical impedance over time. If electrode impedance becomes too high, your Powerheart G3 Automatic External Defibrillator (AED) will fail the electrode self-test performed by the AED and it will not be Rescue Ready®.** Specifically, if the AED fails the electrode self-test, the STATUS INDICATOR on the AED will be RED and the AED will beep. This is standard behavior when the impedance limit is exceeded. In order to return the AED to its RescueReady state, the high impedance electrodes require replacement.

Our records show electrodes from Lot No. 141125-02 were shipped to your facility. **The attached document includes the date(s) Lot No. 141125-02 electrodes were shipped to you, the quantity shipped, and your purchase order number if one was used.**

Defibrillation electrodes from **Lot No. 141125-02** were shipped to customers from December 26, 2014 through March 10, 2015. **The expiration date of the electrodes is 2017-06-12.** The expiration date and lot information appear on the package as indicated below.



We are not aware of any instances in which Lot No. 141125-02 electrodes failed to work at the time of a rescue. However, this field corrective action is being performed because electrodes from that lot may not meet Cardiac Science's performance specifications and may result in AED self-test failures

N7W22025 Johnson Drive
Waukesha, WI 53186
Tel: +1 262.953.3500
Fax: +1 262.798.8292
Toll Free (US Only): 800 426 0337
www.cardiacscience.com

prior to the electrode expiration date as described above. An AED with a self-test failure (i.e., not Rescue Ready®) would not be available for use in a rescue.

What you should do now

- 1) Please examine the electrodes currently installed in your AEDs and in your inventory.
- 2) Replace any electrodes from Lot No. 141125-02 with the replacement electrodes sent with this safety notification. We are asking you to replace these electrodes even if they are in an AED and the Status Indicator is GREEN.
- 3) Return the impacted electrodes to Cardiac Science per the enclosed instructions using the provided packaging and labeling.

Please provide this notification to all members of your facility who need to be made aware of it. If you no longer have Lot No. 141125-02 electrodes in your possession, then please forward this letter and replacement electrodes to the responsible person

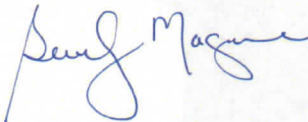
Only defibrillation electrodes from Lot No. 141125-02 are impacted. Electrodes from other manufacturing lots are not affected and should remain in service.

If you have any questions regarding this communication or need help replacing and returning the electrodes to Cardiac Science, please contact Cardiac Science Technical Support by phone **+1.877.901.1788** in the United States or **+1.608.764.7008** outside the United States or via email at a9131@cardiacscience.com.

This recall is being performed with the knowledge of the Food and Drug Administration.

Thank you for your immediate attention to this matter. We apologize for any inconvenience this issue may create and appreciate your prompt attention to this matter.

Sincerely,



Beverly Magrane
Vice President Quality Assurance and Regulatory Affairs