Urgent Medical Device Correction

Cardiac Science G3 Elite Product Family

January 21, 2020

Dear Customer,

Cardiac Science Corporation is voluntarily recalling G3 Elite AED devices. This letter describes the issue and actions that must be taken to address the problem.

We have recently received field reports of G3 Elite devices where the Rescue Ready status indicator displays red and the Service LED is illuminated. Our investigation traced the problem to a software anomaly associated with the Daylight Savings Time (DST). If the device is configured with the DST enabled, it will experience error code "0x99" after Daylight Savings. In this state, the device must be returned to Cardiac Science to clear the error, but can be used clinically if an emergency arises. We are in the process of revising the software and will make the update available free of charge in order to prevent the anomaly from occurring. We are asking customers with affected units to return their devices to Cardiac Science for update.

AFFECTED DEVICES

All **G3 Elite devices**

REQUIRED ACTIONS

Customers who have affected devices should immediately take the following steps:

(1) Alert all G3 Elite users of this problem.
(2) Locate the affected devices.
(3) A customer with an AED that has failed its self-test should remove the device from service
(4) Regardless of the self-test status, G3 Elite owners should contact the Cardiac Science Technical Support Team or your local representative to schedule an update.

We have notified the appropriate regulatory agencies of this corrective action and expect it to be classified as a recall.

We apologize for any inconvenience this may cause you and thank you in advance for assistance in implementing this corrective action. Avoiding this problem is our highest priority. Our 24/7 technical support numbers **+1.262.953.3500 or US Toll-Free +1.800.426.0337** are available to assist users with any aspect of this notice.

Sincerely,

Paul Dias
VP Quality Assurance & Regulatory Affairs

500 Burdick Parkway
Deerfield, WI 53531-9692
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Toll Free: 800 426 0337

www.cardiacscience.com
Equal Opportunity Employer – M/F/V/D

Urgent Device Corrective Action

Customer Response Form for Cardiac Science Powerheart® G3 Elite AED

Affected Models: 9790A-1002, -1010, -1014, -1031;
9790E-1002, -1005, -1010

Serial Numbers affected by this Corrective Action are listed on the following page. Please check the box next to each serial number to confirm you have located & contained the devices. Please complete this form in its entirety and return **both** pages to regulatoryteam@zoll.com

1. Customer Account Information		
Customer Account Name FLEMING MEDICAL GBP		*Account Number* 99819
Sold To Address COCANREE BUSINESS PARK, DOCK ROAD		
City LIMERICK	*Postal Code*	*Country* IRELAND
2. Customer Contact Details		
Individual completing this form (please print)	*Title*	
E-Mail Address	*Phone Number*	
3. Product Inventory Status		

☐ I have located all or some of the devices on the Serial Number list and I have indicated this by checking the box next to each serial number.

☐ Devices have been internally transferred or distributed/sold and a copy of this notification has been provided to the party in possession of the device(s). To facilitate locating the product, I am providing new contact details.

Company: _____ Address: _____

Contact Name: _____ E-mail: _____ Phone: _____

4. Ship To Address (specify your desired ship to address, if different than the address in section 1)		
		PO No. (if reqd. to receive product):
Print Name:	**Sign:**	**Date:**

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Serial Number List

Please check the box next to each serial number to confirm you have located & contained the devices.
Please complete this form in its entirety and return **both** pages to regulatoryteam@zoll.com

- ☐ 7500030
- ☐ 7500031
- ☐ 7500035
- ☐ 7500038
- ☐ 7500041
- ☐ 7500044
- ☐ 7500048
- ☐ 7500052
- ☐ 7500055
- ☐ 7500057
- ☐ 7500263

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