

## **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,

