URGENT: Medical Device Correction
ZOLL Powerheart® G5 AED Product Family
Model/ Catalog Number: G5X-XXX

February XX, 2025

CUSTOMER NAME
ADDRESS
ADDRESS

Dear Customer,

The purpose of this letter is to advise impacted customers that ZOLL is voluntarily issuing a correction for Powerheart® G5 Semi-Automatic and Automatic AEDs.

ZOLL has received 2,225 field reports involving 1,855 of these Automated External Defibrillator (AED) where after normally scheduled self-tests the AEDs have displayed Error Code (EC) 501 and cannot deliver lifesaving therapy. ZOLL is aware of one adverse event, outside of the US, where the patient ultimately expired as a result of the device failing its automated self-test due to an Error Code (EC) 501. In all of the other known instances, users have detected failed AEDs through routine inspection in time to replace the device before it is needed for a rescue.

ZOLL is communicating with users because of the potential for patient harm from a device unable to deliver lifesaving therapy if users do not notice EC 501 or other device alerts before attempted device use.

The G5 AED automatically performs self-tests to alert users of conditions that may interfere with its ability to deliver life-saving therapy. EC 501 is a specific error code that is generated during the device's automated self-test. Of the 287,917 at-risk devices in use, ZOLL is aware of 1,855 known failed devices. If the device experiences an EC 501 during its self-test it will prevent the device from delivering lifesaving therapy. Although 2,224 of the total 2,225 reported failures have been identified by users before the device is needed to support a patient rescue of victims suffering from Out-of-Hospital Cardiac Arrest (OHCA), there is a potential risk for a device self-test failed status to be missed by a user prior to needing the device for a rescue. This failure mode is likely due to exposure to humidity outside the device's published specification. Therefore, ZOLL is communicating the importance of storing at-risk devices in areas with appropriate humidity.

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These automatic self-tests have proven to be highly effective at notifying users of the presence of such conditions and prompting them to take action before the device is needed to support a patient rescue of victims suffering from OHCA. As such, it is essential that owners of these devices have programs in place to monitor the status of the device and take action when necessary.

The G5 automatically runs self-tests daily, weekly, and monthly. If the AED detects an error during the self-test, the AED should be removed from service. Please refer to Chapter 5 of G5 User's Guide or contact ZOLL's technical support to troubleshoot the AED.

The status of the Rescue Ready indicator should be monitored periodically so when failures occur the device can be repaired or replaced to minimize clinical risk. In addition, ZOLL recommends that a preventive maintenance be performed at least once a month on the device. Please refer to chapter 6 of the G5 User's Guide for a list of tests that should be performed.

BACKGROUND

AEDs are designed to perform self-tests to alert users to all manner of conditions. Some of these conditions include, but are not limited to low battery, disconnected electrodes, and other failures that might impede the device's ability to deliver therapy.

The device provides visual and audible signals of a failed self-test and gives specific error codes to assist owners in identifying the issue so that it can be addressed. It is important to monitor the status of the device and these self-tests.

Failure to monitor a device that is not ready to be used in a rescue could lead to a situation where the device is needed, but the device is unable to deliver lifesaving therapy. Adverse events can occur if the device is not ready to be used in a rescue and self-test monitoring and preventive maintenance is not being performed.

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REQUIRED ACTIONS

Customers who have AEDs should routinely:

(1) Monitor device for self-test results.
(2) For customers who experience a self-test failure, take action to resolve any alerts as soon as possible.

Customers who have at-risk devices should immediately:

(1) Communicate this notification to G5 AED users.
(2) Ensure users have a program in place that periodically monitors the status of these devices, in accordance with G5 User's Guide.
(3) EC 501 is likely due to exposure to humidity outside the device's published specification. Ensure devices are stored within the device's published specifications:
    - Temperature: 0°C to 50°C (32°F to 122°F)
    - Humidity: 10% to 95% (non-condensing)
(4) Respond to ZOLL via the customer notification form acknowledging that you have received this notice.

We have notified the appropriate regulatory agencies of this correction 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 correction. Ensuring these devices are rescue ready is our highest priority. Our 24/7 technical support number is 1 (866) 442-1011 or intlservice@zoll.com and are available to assist users with any aspect of this notice.

Sincerely,

Anne E Nadeau
Manager of Post Market Surveillance