

11th April 2025

CRITICAL PRODUCT ALERT

TGA Recall Reference Number: RC-2025-RN-00298-1 ZOLL Powerheart G5 AED Semi-Automatic and Fully Automatic AED

Dear Customer,

ZOLL Medical Australia, following agreement with the Therapeutic Goods Administration (TGA), is conducting a Safety Alert of the above G5 Semi-Automatic and Fully Automatic Defibrillators.

The potentially affected product may have been supplied to your organisation.

AFFECTED DEVICES: ZOLL Powerheart G5 AED Product Family
Model/ Catalog Number: G5X-XXX

What is the problem?

The G5 AED automatically performs self-tests to alert users of conditions that may interfere with the device's ability to deliver lifesaving 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. Error Code EC 501 is a specific error code that is generated during the device's automated self-test. The G5 automatically runs self-tests daily, weekly and monthly.

The G5 Semi-Automatic and Fully- Automatic AED, after automated normal scheduled self-tests, may experience Error Code (EC) 501, which may result in the inability for the device to deliver lifesaving therapy.

There is a potential risk 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. This failure mode (EC501) is likely due to exposure of humidity outside the device's published specifications. Investigations are ongoing.

Therefore, ZOLL is communicating the importance of monitoring devices for self-test results and ensuring devices are strowing within device's published specifications for humidity.

REQUIRED ACTIONS

Customers who have risk devices should take the following steps:

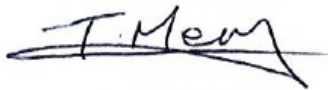
- (1) Monitor device for self-tests results.
- (2) ZOLL recommends that a preventive maintenance be performed at least once a month on the device.
- (3) If a user experiences a self-test failure, take action to resolve any alerts as soon as possible.
- (4) Ensure users have a program in place that periodically monitors the status of these device, in accordance with G5 User Guide.
- (5) EC 501 is likely due to exposure to humidity outside the device's published specifications. Ensure devices are stored:
 - a. Temperature 0°C to 50°C (32°F to 122°F)
 - b. Humidity: 10% to 95% (non-condensing)
- (6) Respond to ZOLL via the customer notification form acknowledgement, accompanied with this notification.

This action has been undertaken following consultation with the TGA.

We apologize for any inconvenience this may cause you and thank you in advance for your assistance. Avoiding any problem during clinical use is our highest priority.

For further information, please contact our 24/7 technical support team at 1800 605 555 or serviceanz@zoll.com, to assist with any aspect of this notice.

Sincerely,



Tristana Merry
Customer Quality Assurance Manager
ZOLL Medical Australia & New Zealand