



**Australian Government**

**Department of Health and Aged Care**  
Therapeutic Goods Administration

**CRITICAL PRODUCT ALERT\***

LEVEL: Hospital

CLASS: Class I

REFERENCE: RC-2025-RN-00298-1

DATE AGREED: 10/04/2025

**PRODUCT:** **ZOLL Powerheart G5 AED Semi-Automatic and Fully Automatic AED**

Multiple item numbers and serial numbers

ARTG's: 352593 & 213065

**SPONSOR:** Zoll Medical Australia Pty Ltd

**SPONSOR CONTACT INFORMATION:** 0451 373 150 - tmerry@zoll.com- Technical support team

**REASON:** The G5 AED automatically performs self-tests to alert users of conditions that may interfere with its ability to deliver lifesaving therapy. Error Code EC 501 is a specific error code that is generated during the device's automated self-test, if displayed, cannot 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 504 or other device alerts before attempted device use.

The failure mode (EC501) is likely due to exposure of humidity outside the device's published specifications.  
Investigations are ongoing.

ZOLL is communicating the importance of storing the at-risk devices in areas with appropriate humidity.

**PROPOSED CUSTOMER ACTIONS:** Customers are to:  
- Ensure the device is stored at the published specifications.  
- Monitor device for self-tests results and take actions to resolve any alerts.  
- Perform preventive maintenance on the device at least once a month.

The sponsor is expected to dispatch letters to all affected customers within two business days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods subject to this market action and have not received a notification letter.**

Product Distribution: 61 facilities nationally along with 2 private health professionals

Product export status: New Zealand

This information has been published in the TGA's searchable database,  
<https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-00298-1>

\*For further details about Market Actions, please refer to - <https://www.tga.gov.au/safety/market-actions>