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URGENT: Field Safety Notice

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

What is this Powerheart G5 notice about?

ZOLL has received field reports on the Powerheart G5 where after normally scheduled self-tests the AEDs have displayed Error Code (EC) 501 and cannot deliver lifesaving therapy. This failure mode is likely due to exposure to humidity outside the device's published specification. The field notification is intended to alert users of this specific error code, the importance of storing their device within stated environmental ranges, and to continue to visually inspect their device readiness on a periodic basis.

ZOLL Powerheart G5 End-user FAQs

Do I need to return my AED to ZOLL if it is not reporting an error?

- No, this notice is intended to provide additional information to end-users on continuous management of their AEDs and potential self-test alerts due to the storing of the AED outside of stated environmental conditions.

What action should be taken?

- Continue to visually inspect your Powerheart G5 device readiness indicator.
- Visit <https://forms.office.com/r/u5icA2mLSf> to confirm your receipt of the customer notification

Do I need to change how I inspect my Powerheart G5 device?

- No, you should continue to visually inspect your Powerheart G5 device to confirm its readiness status, the Powerheart G5 self-test is performed daily, weekly and monthly.
- Should you notice a device failure please contact ZOLL technical support for assistance: +1 (866)442-1011 or email intlservice@zoll.com

What is error code EC 501?

- EC 501 can be caused by a variety of factors, however it is likely due to exposure to humidity outside the device's published specification. ZOLL is communicating the importance of storing at-risk devices in areas with appropriate humidity.
- 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)

What happens when EC 501 is created?

- EC 501 is a specific error code that is generated during the device's automated self-test, and once it is identified by the Powerheart G5 the device will not be able to be operated clinically.

How can a user determine if a Self-test error requires ZOLL Service?

- When a Powerheart G5 Displays the Red X
 - If there IS a red indicator by the GEAR icon, then the device needs to be returned to ZOLL for servicing
 - Additionally, device will display/say:
"SERVICE REQUIRED, CONTACT TECHNICAL SUPPORT"
 - IF there is no red indicator by the GEAR icon
 - First confirm both the Intellisense pads and battery pack are within expiration;
 - Once you have completed that check and taken the necessary action you can clear the red indicator by pressing and holding both softkeys

Indicator

