



نتقدم بثقة
Moving Forward
with Confidence

رؤية عُمان
2040
Oman Vision

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 92 dated 28/4/2025 Regarding SFDA Field Safety Notice of ZOLL Powerheart® G5 AED Product Family from (mfr: ZOLL Medical Corporation).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



DSC
مركز سلامة الدواء
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

✉ @DSCPHO Email: dscpho@moh.gov.om



Circular No. 92/2025

29 -10-1446 H
28 -04-2025

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Field Safety Notice ZOLL Powerheart® G5 AED Product Family from ZOLL Medical Corporation.

Source	SFDA- Saudi Food & Drug Authority https://ade.sfda.gov.sa/Fsca/PublishDetails/346
Product	ZOLL Powerheart® G5 AED Product Family.
Manufacturer	ZOLL Medical Corporation.
Local agent	Ibn Sina Pharmacy.
The affected products	Model/ Catalog Number: G5X-XXX.
Reason	The potential for 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.
Action	<ol style="list-style-type: none">1. Customers who have AEDs should routinely:<ul style="list-style-type: none">• Monitor device for self-test results.• For customers who experience a self-test failure, take action to resolve any alerts as soon as possible.2. Customers who have at-risk devices should immediately:<ul style="list-style-type: none">• Ensure users have a program in place that periodically monitors the status of these devices, in accordance with G5 User's Guide.• 2- 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)3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi

Director General

