Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

نتقدم بثقة
Moving Forward with Confidence

رؤية عُمان 2040

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 57 **dated** 16/3/2025 **Regarding SFDA Field Safety Notice of ASSURITY™ AND ENDURITY™ PACEMAKERS. from (mfr: Abbott).**

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

ISO 9001:2015 CERTIFIED

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

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Circular No. 57 / 2025

16 -09-1446 H
16 -03-2025

Field Safety Notice of ASSURITY™ AND ENDURITY™ PACEMAKERS from Abbott.

Source	SFDA- Saudi Food & Drug Authority https://ade.sfda.gov.sa/Fsca/PublishDetails/302
Product	ASSURITY™ AND ENDURITY™ PACEMAKERS.
Manufacturer	Abbott.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	MODELS: PM1140, PM1152, PM1160, PM1162, PM1172, PM1272 PM2140, PM2152, PM2162, PM2172, PM2240, PM2272 Manufacturing date: Affected devices were manufactured between August 2019 and June 2020.
Reason	The potential for a device malfunction affecting a subset of the above pacemakers.
Action	1. Please follow "Patient Management Recommendations" in the attachment. 2. 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

سلطنة عمان - وزارة الصحة - مركز سلامة الدواء
SULTANATE OF OMAN - MINISTRY OF HEALTH
DRUG SAFETY CENTER

DSC
مركز سلامة الدواء
Drug Safety Center

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Urgent Field Safety Notice

FA-Q125-CRM-1

FOR A SUBSET OF ASSURITY™ AND ENDURITY™ PACEMAKERS

MODELS PM1140, PM1152, PM1160, PM1162, PM1172, PM1272
PM2140, PM2152, PM2162, PM2172, PM2240, PM2272

February 2025

Dear Physician or Healthcare Professional:

Abbott is informing clinicians of the potential for a device malfunction affecting a subset Assurity™ and Endurity™ pacemakers. This issue may result in incomplete mixing of epoxy during manufacturing and, with time, may permit moisture ingress into the pulse generator header, introducing a risk of interrupting device functionality. Affected devices were manufactured between August 2019 and June 2020. The specific manufacturing equipment associated with this issue is no longer in use. No affected devices remain available for implant.

There have been no reports of permanent harm to patients resulting from this issue.

The observed rate through Abbott's post market surveillance is 0.18%. The mean implant duration at time of failure is currently 3.8 years with a standard deviation of 0.6 years. Reported clinical impact has included loss of telemetry / communication, reduced battery longevity and/or premature battery depletion, and/or loss of pacing.

As Abbott records indicate you are following one or more patients implanted with a potentially affected device noted in the enclosed Device List, please reference the patient management recommendations below.

Patient Management Recommendations:

Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott Cardiac Rhythm Management (CRM's) Medical Advisory Board (MAB), Abbott provides the following guidelines:

- **Prophylactic generator replacement is not recommended** due to the low rate of occurrence of this issue. Evaluate the potential for risk in patients who are pacemaker dependent, particularly if they are unable to be reliably followed using remote monitoring.
- **Routine follow-up should remain as per standard of care.** Enroll patients on Merlin.net when possible, and consider increasing the frequency of scheduled interrogations in patients with non-RF enabled pacemakers. Review device function, including measured battery voltage, any unexpected change in battery consumption, and connectivity status on Merlin.net where available.
- **Prompt replacement for devices that demonstrate unexpected depletion to ERI/EOS, trigger an EPI notification,** or demonstrate one of the clinical impacts listed above. As always, timing of replacements should be appropriate for the patient's underlying clinical condition.

Additional Information:

EPI (Electronics Performance Indicator) Description: the EPI tool assists in patient management in patients followed with Merlin.net. The EPI tool supplements remote monitoring, analyzing transmitted data available on Merlin.net to identify abnormal electrical system behavior resulting from loss of hermeticity. The EPI tool is an Abbott surveillance process that reviews data from all devices within this affected population communicating with Merlin.net. If an EPI signal is detected, Abbott will notify the clinic using the email contact information in Merlin.net. Please ensure your clinic contact information in Merlin.net is current.

As an additional resource, a device lookup tool has been made available at https://www.cardiovascular.abbott/int/en/hcp/product-advisories/pacemaker-safety-lookup-2025.html and can aid you or your practice in confirming impact for those patients you are following.

This communication is also located at: https://www.cardiovascular.abbott/int/en/hcp/product-advisories.html.

Please complete and return the attached Acknowledgement Form.

Abbott is notifying all applicable regulatory agencies about this matter. Please share this notification with others in your organization and follow-up centers, as appropriate.

Adverse reactions or quality problems experienced may be reported directly to Abbott. Should you have any questions about this notice, please contact your local Abbott Representative. In addition, please work with your Abbott Representative to return any explanted devices to Abbott for product evaluation and analysis.

We sincerely apologize for any difficulties or inconvenience that this may cause. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for assisting us with this process.

Sincerely,

Robert Blunt

Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management