February 18, 2025

Canadian Heart Rhythm Society
Device Committee

ADVISORY: Abbott Medical Device Recall

Subset of ASSURITY™ AND ENDURITY™ PACEMAKERS

MODELS PM1160, PM1172, PM1272, PM2172, PM2240, PM2272

Nature of the Advisory:

During post market surveillance, Abbott has observed malfunctions in a subset of the above devices manufactured between August 2019 and June 2020 in a specific manufacturing plant with equipment that is no longer in use. The issue is related to an intermittent incomplete mixing of epoxy, which may result in moisture ingress into the pulse generator header in some devices. This may result in loss of telemetry or communication with the device, loss of pacing, reduced battery longevity, and a shortened Elective Replacement Indication (ERI) to End of Service (EOS) time.

Scope of the problem:

To date, a subset of 54,000 devices have been identified as being susceptible to this issue. Approximately 900 of these devices were implanted in Canada. The rate of affected malfunction in these devices is estimated to be **0.18%**. Of the 97 devices identified with this anomaly worldwide, 4 were identified in Canada.

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

The mean time from implant to anomalous behaviour has been identified to be **3.8 years post implant**.

The Abbott remote monitoring system (MERLIN.NET) checks for ERI status every week. The EPI (Electronics Performance Indicator) tool supplements remote monitoring, analyzing transmitted data available on Merlin.net to identify abnormal electrical system behavior resulting from loss of hermeticity.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue.
- Patients should be followed according to their usual schedule, remotely or in person.
    - Consider increasing the frequency of scheduled interrogations in patients with non-RF enabled pacemakers.
- All patients should be enrolled on the MERLIN.NET home monitoring system, where possible. This recommendation applies to all patients with CIEDs, but is especially important in this advisory patient group
- Prompt generator replacement should be performed in cases where unexpected depletion to ERI/EOS, devices that trigger an EPI notification, or where there is a loss of telemetry / communication (e.g. inability to interrogate the device or to transmit data)
    - Pacemaker-dependent patients should be **admitted to hospital and their pacemaker replacement performed promptly**
    - Non-pacemaker dependent patients should undergo replacement **within 1 week.**
- Prophylactic device generator replacement is not recommended given the low rate of occurrence.
    - Prophylactic device generator replacement may be considered for individuals with a device affected by this advisory and who are at high-risk of harm (i.e. pacemaker dependent AND who are unable to be reliably followed using remote monitoring, those planning to undertake planned prolonged travel, or those living remote from medical facilities)

The CHRS device committee may update these recommendations should more data become available

CHRS Device Committee

Jason Andrade, MD, FRCPC (Chair, Device Committee)
François Philippon, MD, FRCPC, FHRS, FCCS (Past chair, Device Committee)
Derek Exner, MD, FRCPC, FHRS
Clarence Khoo, MD, FRCPC
Jaime Manlucu, MD, FRCPC
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Larry Sterns, MD, FRCPC, FHRS, FCCS

Voluntary Medical Device Recall
Urgent

FOR A SUBSET OF ASSURITY™ AND ENDURITY™ PACEMAKERS

MODELS PM1160, PM1172, PM1272, PM2172, PM2240, PM2272

February 2025

Dear Physician or Healthcare Professional:

Abbott is informing clinicians of the potential for a device malfunction affecting a subset of 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.

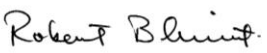
This communication is also located at: https://www.cardiovascular.abbott/int/en/hcp/product-advisories.html.

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 your local Abbott Representative. 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
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Abbott Cardiac Rhythm Management