Urgent Field Safety Notice

FA-Q323-CRM-6

FOR A SUBSET OF ASSURITY™ AND ENDURITY™ PACEMAKERS

MODELS PM2152, PM2162, PM2172, PM2272

October 2023

Dear Physician or Healthcare Professional:

Summary:

Abbott is informing clinicians of the potential for device malfunction due to a manufacturing issue which may affect a limited subset of 455 Assurity™ and Endurity™ pacemakers. The issue has been associated with interrupted functionality such as loss of pacing, reduced battery longevity, reverting to back-up mode, loss of telemetry / communication, and/or shortened duration between Elective Replacement Indicator (ERI) and End of Service (EOS).

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

Abbott's product performance surveillance processes have identified nine (9) devices affected by a manufacturing process variation within a single piece of equipment resulting in the potential for moisture ingress into the pulse generator. Reported clinical symptoms ranged from no patient clinical signs to transient patient symptoms (discomfort, dizziness, dyspnea, arrhythmia). The affected devices were manufactured between August 2018 and November 2019. The equipment which led to this issue is no longer part of the device manufacturing.

The potentially affected devices were distributed in Germany, France, the United Kingdom, Spain, and Italy. The potential rate of any permanent patient harm is estimated to be 0.2%. Based on data reviews, the functionality interruption may occur within a week from the last transmission date listed in Merlin.net.

Patient Management Recommendations:

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

- **Consider generator replacement for patients at risk for significant symptoms or harm if pacemaker malfunction were to occur.**
- **When possible, monitor patients using Merlin.net** to benefit from compliance and alert monitoring, including Electronics Performance Indicator (EPI – see description below), between routine device checks. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring, which provides daily monitoring of ERI alerts and includes monitoring of the safety notification population by the EPI tool.
- **Prompt replacement for devices that receive an EPI notification, or reach ERI/EOS,** or experience one of the clinical impacts listed above, unless particular patient circumstances preclude this.

EPI (Electronics Performance Indicator) Description:

The EPI tool assists in patient management in patients followed with Merlin.net. The EPI tool supplements ERI using data available on Merlin.net to identify abnormal electrical system behavior resulting from loss of hermeticity due to moisture ingress. 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.

Additional Information:

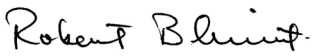
As an additional resource, a device lookup tool has been made available at https://www.cardiovascular.abbott/int/en/hcp/product-advisories/pacemaker-equipment-lookup.html and can aid you or your practice in confirming impact for those patients you are following.

Abbott has notified all applicable regulatory agencies about this matter. Please share this notification with others in your organization, 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,



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