

**Date: March 16, 2021**

**Canadian Heart Rhythm Society**

**Device Committee**

**ADVISORY: Abbott Medical Device Recall**

**ASSURITY™ AND ENDURITY™ PACEMAKERS**

**MODELS PM1160, PM1172, PM1240, PM1272,**

**PM2160, PM2172, PM2240, PM2260, PM2272**

**Nature of the Advisory:**

During post market surveillance, Abbott has observed malfunctions in a subset of the above devices manufactured between 2015 and 2018 in a specific manufacturing plant 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 reduced battery longevity, loss of telemetry or communication with the device, loss of pacing and a shortened Elective Replacement Indication (ERI) to End of Service (EOS) time.

**Scope of the problem:**

To date, a subset of 95 000 devices are identified as being susceptible to this issue and approximately 500 devices were implanted in Canada. Of the 135 devices identified so far with this anomaly worldwide, there have been no identified serious adverse clinical events. The median duration of this failure occurring is **3.5 years post implant, with a range from 1.6-5 years**. The failure rate in these devices is estimated to be **0.049%**. The average time of progression from ERI until EOS has averaged **17 days**. However, the shortest ERI to EOS time observed was **1 day**.

The Abbott remote monitoring system (MERLIN.NET) checks for ERI status every week. A system modification/update will automatically change this monitoring to everyday check for the affected devices.

**Response of the CHRS Device Committee:**

* As part of this formal advisory, we recommend that patients be notified about this issue
* No prophylactic replacement is recommended at this stage
* Patients should be followed according to their usual schedule, remotely or in person
* 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
* In cases where unexpected ERI is reached or inability to interrogate the device or to transmit data is encountered, replacement should be performed:
	+ Pacemaker-dependent patients should be **admitted to hospital and their pacemaker replacement performed promptly**
	+ In non-pacemaker dependent patients, replacement should be planned **in ≤ 1 week**.
* Prophylactic device generator replacement is not recommended, but may be considered in certain high-risk individuals and discuss with patients as part of the decision-making process (e.g., pacemaker dependent patients where there is an inability to use the MERLIN.NET system, those planning to undertake planned prolonged travel, or those living remote from medical facilities). One should keep in mind the very low risk of failure when assessing the risks and benefits of an early generator change.
* The CHRS device committee may update these recommendations should more data become available

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