

September 23, 2011 **Advisory Response Notification**



Canadian Heart Rhythm Society Device Advisory Committee

Re: St. Jude Medical Dual Chamber (Accent) and CRT-P (Anthem) Devices

Dear CHRS Device Committee Members,

Class of Advisory: Class II

Urgency of Advisory: Elective

Nature of the Advisory: This advisory describes the potential for a low lead impedance measurement reported in certain St. Jude pacemakers. The pacemakers affected include: Accent DR dual models PM 2112, PM 2212 and the Anthem CRT-P models PM3112, PM3212. The algorithm to measure lead impedance in these devices utilizes an automatic daily Pacing Lead Impedance (PLI) circuit. A dedicated capacitor is involved in this measurement. There is a potential for a small amount of charge to build and be stored on these capacitors, resulting in a faulty report of a low impedance. This may result in a device alert trigger, a transmission of an alert via Merlin.net or be noted as an alert at the next clinic followup.

Scope of the Problem: This is reported to occur at a very low rate in the Accent DR pacemakers but is a higher rate in the Anthem CRT-P devices. There are 152 000 Accent DR pacemakers in circulation worldwide, 0.01% of these have been reported to have this issue. Of 14 000 Anthem CRT-P devices worldwide, 1.6% have been reported with this. The reason behind the higher occurrence in CRT-P devices, is that the shorter AV and VV intervals results in the potential for fewer PLI pulses, and the potential for charge to be stored on the capacitor. In Canada, there are 1350 Accent DR pacemakers and 150 Anthem CRT-P devices in circulation. One report has been from an Anthem CRT-P device. There have been a few reports worldwide of either a pulse generator or a lead erroneously replaced due this issue.

Response of the Canadian Heart Rhythm Society

Recommendations:

1. The CHRS-DC feels that patients may be informed of this issue at their next routine clinic visit.
2. A software upgrade will be available in the next few weeks that will address this issue. Until that is available, if this condition occurs, the lead should be evaluated with usual maneuvers to detect a lead problem, recognizing that the measurement may be due to this mechanism and that the lead may be intact. Each case will need to be considered on an individual basis, as to whether this is a lead issue, or an abnormal measurement as described in this advisory.
3. The CHRS-DC does not recommend early device replacement for this issue.

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