

## April 5, 2011 Advisory Response Notification



### Canadian Heart Rhythm Society Device Advisory Committee

Re: Dual Chamber Pacemakers with Measurement Lock-up ERI

Dear CHRS Device Committee Members,

**Class of Advisory:** Class II

**Urgency of Advisory:** Elective

**Nature of the Advisory:** This advisory describes a rare measurement lock-up issue in Medtronic Dual Chamber Pacemakers, including: Kappa 600, 700, 800, 900, EnPulse, Adapta, Versa, Sensia, Relia, and Vitatron Models E50A1, E60A1, and G70A1. If this lock-up were to occur, it results in the device triggering ERI, as the battery voltage is falsely read as zero. The ERI trigger results in reversion to VVI pacing at 65 bpm. This is identified at the time of interrogation, as the battery voltage and remaining longevity measurements appear blank.

**Scope of the Problem:** This is reported to occur at a very low rate and is estimated to be affect 1/18000 devices. There is no loss of pacing output prior to correction of this problem and no impact on battery longevity.

### 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 year that will address this issue. Until that is available, if this condition occurs, the device may be reset through a specifically configured programmer (software to be obtained through your Medtronic representative).
3. The CHRS-DC does not recommend early device replacement for this issue.

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