February 11, 2010 **Advisory Notification/Response**

Canadian Heart Rhythm Society Device Advisory Committee (CHRS DAC)

Re: Two issues related to the battery have recently been reported in the Medtronic EnRhythm® and EnRhythm MRI™ pacemakers. The first issue relates to the battery voltage measured at the time of interrogation, which can be lower than the one measured by the device on a daily basis. This does not have any impact on the function of the device. A second issue relates to battery behaviour as the device nears the elective replacement indicator (ERI) >9 years post implant. These issues resulting from an increase in battery impedance and lithium depletion, do not pose any current risk for loss of device function. However, if the planned software update is not implemented, there is a potential risk of loss of pacing output in a small percentage of devices. There have been no clinical events to date, and a software update that will be submitted to regulators in the near future will eliminate future risk.

Class of Advisory: Class II

Urgency of Advisory: Routine

Nature of the Advisory:

First Issue: The battery voltage at device interrogation may be lower than the battery voltage tracked by the device. This issue does not pose any current risk of loss of function, nor does it indicate that there is an issue with the battery. The root cause for this observation has been found to be a higher battery resistance.

Second Issue: Rapid battery depletion may occur as these devices approach ERI due to a greater than expected rate of lithium depletion (component of the battery). This has not been observed to date and is not expected to occur within the next 4 years (approximately 9 years post-implant; market release for these devices was in 2005).

Scope of the Problem: The first issue has been reported in 62 out of 110 000 devices (0.056%) worldwide; in Canada 9 cases have been reported out of 2000 (0.45%). It is unlikely that there will be any failure due to the second issue. Medtronic Inc. has developed a solution to both these issues by creating a software update that will make adjustments to the battery voltage that is reported upon interrogation, to avoid any confusion regarding the ambulatory battery voltage, and shift the battery voltage curve to an earlier point at which ERI will be reached. This will result in a 10-15% loss in battery

longevity for these devices, but entirely eliminate the risk of failure. Without implementation of the software update, there is a potential risk of loss of device functionality in 0.08% of devices, six years post implant. This software update will be available from Medtronic Inc. in mid-2010.

Response of the Canadian Heart Rhythm Society

Recommendations:

1. The CHRS DAC does not feel that early patient notification by letter is necessary for this advisory as there is no recognized risk of failure at this time. Communication for this advisory may occur at the time of the next followup visit.
2. The CHRS DAC agrees with the manufacturer's independent safety board's recommendation that no increased followup is necessary for these devices.
3. The CHRS DAC does not recommend that these devices be replaced prematurely for any given patient conditions (such as pacemaker dependence) as the anticipated software update will correct the observed issues.
4. The CHRS DAC recommends prompt dissemination of the software update to prevent potential device malfunction.