May 5th, 2010 **Advisory Response Notification**

Canadian Heart Rhythm Society
Société canadienne de rythmologie

Canadian Heart Rhythm Society Device Advisory Committee

Re: Medtronic Consulta CRTD, Secura VR/DR, Maximo II CRTD and Maximo II VR/DR ICD advisory. Delay or loss of high voltage therapies may occur subsequent to the rare circumstance of 3 "simultaneous" events, which can be corrected with an anticipated software release.

Dear CHRS DAC Committee Members,

Class of Advisory: CHRS Class 1 (further details below)

Urgency of Advisory: Semi-urgent

Nature of the Advisory: ICD generator, software related.

Delay or loss of high voltage therapies will occur subsequent to the rare circumstance of 3 events within a few msec of each other: end of charge time, battery voltage measurement at charge end, and VT/VF self-termination resulting in aborted therapy. The probability of all three of these conditions being met is estimated at 1:27,000 patient years. ATP therapies remain available until 3 consecutive failed charge attempts occur and an alert is initiated. Subsequent ATP and high voltage therapies would be unavailable. If a long charge time during capacitor reform is detected due to this problem, an alert would be triggered. This behavior has been observed most often in the context of defibrillation threshold testing. Software to correct the potential problem is expected to be approved by Health Canada by May 7th, 2010. This software update can only be implemented during an in person device clinic visit, and not by remote monitoring.

Scope of the Problem: Medtronic has noted 5 affected cases out of an estimated 144,000 worldwide devices, one of which occurred in Canada. There have been 2,982 devices registered in Canada as of Apr 27th, 2010, and 2,916 patients are considered active implants.

Response of the Canadian Heart Rhythm Society

Recommendations:

1. *CHRS encourages physicians to promptly notify patients with potentially affected ICDs of this issue, being careful to emphasize the extremely low rate of failure and the role of patient alerts in detecting possible malfunction. A sample notification letter is available at www.chrsonline.ca. It is possible that patients may have heard about this issue in the lay press and will require reassurance.*
2. *CHRS recognizes that the risk of high voltage failure is extremely low, and that corrective software will be available as soon as possible. Thus the remote risk of an adverse outcome is considerably lower than any corrective action involving generator replacement, which should not be considered with respect to this advisory unless there is evidence of malfunction.*
3. *CHRS encourages each centre to schedule follow-up visits and perform the manufacturer's recommended software update in affected patients as rapidly as possible, targeting completion within one month of software availability in the majority of patients, and within 3 months in all patients.*

Andrew Krahn
CHRS Device Advisory Committee Chair

akrahn@uwo.ca

Important Links Related to the Advisory:

Canadian Heart Rhythm Society Website: Device Advisory and Recall Section
http://www.chrsonline.ca/members/advisories.htm

Medtronic Site including Physician Letter:
http://www.medtronic.com/product-advisories/physician/
http://www.medtronic.com/crm/performance

Health Canada site including Physician Letter:
http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/index-eng.php

Appendix regarding advisory processing by the CHRS DAC

Advisories are divided in 2 classes depending on the gravity of the consequence to the patient of the potential device malfunction. The CHRS term "Class I Advisory" applies when device or lead replacement should be considered because of the reasonable probability that the malfunction or potential malfunction could result in death or significant harm to the patient. The term "Class II advisory" applies when the advisory involves non-life threatening malfunctions or potential malfunctions. This classification system has been intentionally simplified, and is consistent with the "recall" classification of Health Canada and the Heart Rhythm Society's classification. When a device advisory is released, it is directed to the attention of the Committee Chair, or a Working Group member if the Chair is unavailable. Depending on the urgency and scope of the advisory, communication is via e-mail, fax or telephone. The Chair has the responsibility to classify the advisory as Urgent requiring response within 2 business days, semi-urgent requiring response within 5-10 working days, or routine requiring response within 20 working days. The required urgency of a response depends on both the number of potential patients affected and the actual threat to the patient (i.e. premature battery depletion, abrupt failure, inappropriate ICD shocks, etc.). Committee members discuss advisories by e-mail, and when needed, a conference call lead by the Chair is used to arrive at a consensus regarding recommendations. Recommendations are drafted and circulated by e-mail to the entire Committee and require response within a finite period determined by the urgency of the advisory. Consensus recommendations are forwarded to the CHRS executive and made available to all implant and follow-up centers in Canada by e-mail and posted on the CHRS website (www.chrsonline.ca).