

September 9th, 2009

Advisory Notification/Response



Canadian Heart Rhythm Society Device Advisory Committee (CHRS DAC)

Re: Subset of Concerto® CRT-D and Virtuoso® Series ICD that may not meet expected device longevity due to gradually increasing current drain caused by low voltage capacitor degradation. This would present clinically as devices reaching the Recommended Replacement Time (RRT) earlier than projected. No patient has experienced a clinical event as a result of this issue.

Class of Advisory: Class II

Urgency of Advisory: Semi-Urgent

Nature of the Advisory: This advisory stems from observed premature battery depletion due to increasing current drain caused by low voltage capacitor degradation. Battery depletion is gradual, and not abrupt. Concerto® and Virtuoso® devices in the affected subset were manufactured primarily in 2006, and can be traced to a specific subset of low voltage capacitors. To date, there have been no related confirmed failures in Concerto® and Virtuoso® devices outside of this subset. This issue may present in the affected devices as reaching the Recommended Replacement Time earlier than projected. Affected devices have demonstrated ~60% of anticipated longevity at RRT, with a wide range that has been as low as 25%. This issue does not compromise device functionality or affect therapy delivery. Medtronic has received no reports of death or injury attributed to this issue. Based on information from returned devices, Medtronic expects that affected devices will continue to provide at least three months of normal device function between RRT and End of Service (EOS), as described in device labeling.

Scope of the Problem: This advisory affects ~2.6% of all Concerto® CRT-D and Virtuoso® Series ICD devices implanted, or approximately 212 devices in Canada and 6,300 worldwide, out of a total of 245,000 devices.

Response of the Canadian Heart Rhythm Society

Recommendations:

1. The CHRS DAC encourages physicians to notify patients with potentially affected devices of this issue, being careful to emphasize the surveillance nature of the advisory. The CHRS DAC recommends that Physicians and Hospitals/Clinics communicate the nature of the advisory to all affected patients within 30 days, focusing initially on more urgent contact with patients closer to the recommended replacement time. A sample notification letter is available at www.chronline.ca (online September 10th, 2009). Some patients may hear about this issue in the lay press and will require reassurance.
2. The CHRS DAC agrees with the manufacturer's independent safety board's recommendation to perform routine follow-up sessions of the affected devices at least every three months in accordance with product labeling. For centers that normally perform follow-up every 6 months according to Canadian guidelines (Gillis AM et al, Can J Cardiol 2003;19(1):21-37), follow-up frequency should be

- increased to every 3 months, or remote monitoring should be employed to automatically notify the clinician when the device reaches RRT. Given the potential for accelerated battery depletion, a determination of RRT at a regular 3-month check or by remote monitoring should prompt a timely replacement. This replacement should be carried out in a scheduled (non-emergent) fashion, but should generally take place within one month after the RRT determination.
3. The manufacturer will provide each implanting centre with a list of affected patients who were implanted at that centre. They will also make efforts to provide centers that provide follow-up only a list of affected patients that they follow. However, these lists are unlikely to be perfectly comprehensive because of patient mobility over time. Both implanting and follow-up centers are encouraged to cross reference the lists provided with their own databases, and to work with peer centers across the country to ensure that every affected patient is accounted for.
 4. Physicians should verify that the Low Battery Voltage RRT alert is programmed to “On-High.” This provides an audible, alternating tone when the device reaches RRT. These devices are shipped with this alert programmed nominally to “On-High.”
 5. Physicians should consider utilizing remote monitoring in all potentially affected patients through CareLink.
 6. The CHRS DAC recognizes that affected patients and their Physicians may choose to proceed with early ICD replacement because of potential concern of unpredictable failure. Given the recognized risk of device replacement (5% complications) and gradual nature of the observed current drain, the CHRS DAC encourages individualized decision-making that would favor deferring replacement until the generator reaches Recommended Replacement Time (RRT).



Andrew Krahn
CHRS DAC Chair
akrahn@uwo.ca

Appendix regarding advisory processing by the CHRS DAC (Can J Cardiol. 2009 Jul;25(7):403-5)

Advisories are divided in 2 classes depending on the gravity of the consequence to the patient of the potential device malfunction. The term “Class I Advisory” applies when device 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 is consistent with the “recall” classification of Health Canada. 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).

Important Links Related to the Concerto/Virtuoso 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>

CHRS DAC Summary for www.chrsonline.ca