



**CHRS Device Advisory Committee**  
**Boston Scientific High Voltage Generator Advisory**  
**Original Product Update June 2007, Reclassified as Advisory May 2008**

**Brief Summary:** At the mid battery life of high voltage devices, there is an increase in charge time that can occur because of normal impedance increases in the battery that does not reflect battery depletion. The affected Boston Scientific devices have a greater increase in charge time/impedance than normal, which triggers elective replacement indicators (ERI) or end of life (EOL) alerts, and should undergo generator replacement. This affects specific models of the Vitality and Contak family of Boston Scientific devices. This affects from 1-10% of models implanted before July 2006, and less than 1% in those implanted thereafter. There are an estimated 567 such devices that have been implanted in Canada. There are no reports of adverse outcomes to patients to date in Canada or elsewhere. This advisory is classified as routine.

In November 2007, the United States Food and Drug Administration (FDA) classified a portion of this communication (devices typically implanted prior to July 2005) as a Class II product recall. With the classification, FDA has not required any further action be taken by Boston Scientific or its customers. The FDA has also stated that prophylactic explant of these devices prior to ERI is not recommended.

Health Canada's Therapeutic Products Directorate (TPD) has recently classified the March 10, 2007 *Product Update* (devices typically implanted prior to July 2005) as a product recall under the current Canadian Medical Device Regulations (SOR/98-282). To date, the TPD also has not required any further action be taken by Boston Scientific or its customers.

**Quote from Product Update:** "Devices that have triggered charge time-based ERI or EOL during mid-life have several months, and in most cases more than one year of remaining battery voltage and capacity, which allows the devices in this pattern to continue to provide brady and LV pacing and maximum energy shocks. However, if ERI or EOL is triggered, device replacement should be scheduled."

**Response of the Canadian Heart Rhythm Society**

The Canadian Heart Rhythm Society (CHRS) is dedicated to the safety of our patients, to best practices and to the development of open, transparent processes.

While we are reassured that the risk posed by this particular defect is low, we believe that timely communication and assessment of patients is essential to addressing potential concern. We believe that physicians and patients have the right to know about these defects in a timely way, so that individualized decision-making can be undertaken by the doctor and his/her patient with all of the relevant information in hand.

1. *CHRS encourages physicians to notify patients with potentially affected devices of this issue, being careful to emphasize the low rate of failure due to this defect and the ability to detect and correct the problem with generator replacement once an ERI alert has been detected. Some patients may have heard about this issue in the lay press and will require reassurance. Some centers may choose to contact patients prior to their next scheduled visit. A sample letter of notification has been posted on [www.chrsonline.com](http://www.chrsonline.com)*
2. *CHRS recognizes that for most patients, the incremental risk of early generator replacement would be expected to be less than the risk of either markedly prolonged charge times or potential high voltage output failure. As a result, generator replacement is generally recommended when an ERI or EOL alert has been detected. This may not be the case for all patients, such as the patient with significant surgical risk and infrequent device use. Decisions regarding replacement should be individualized.*
3. *CHRS encourages each centre to schedule follow-up visits according to Canadian guidelines (Gillis AM et al, *Can J Cardiol* 2003;19(1):21-37) or manufacturers recommendations at their discretion, since there is no evidence that increased follow-up will alter patient outcome in this situation.*