

Instructions Regarding St. Jude Epic, Atlas and Convert ICDs



Dear ICD patient,

This letter is regarding a potential problem with your implanted defibrillator (ICD).

On January 16th, 2008 St. Jude Medical, the manufacturer of your ICD, made us aware that there is a very small chance (8 in 143,000 patients worldwide) that a problem could develop in how your ICD senses your heart beat. There have been no adverse patient events reported to date. In the rare cases where a potential problem was found, simple reprogramming of the device with updated software has resolved the issue.

The CHRS Device Advisory Committee has considered this an elective Class II advisory (meaning that this issue involves a non-life threatening potential malfunction), and has recommended the following:

1. Patients should be contacted by their local ICD clinic based on the policy of the local clinic in notifying patients regarding non-urgent device advisories.
2. Patients should attend their local ICD clinic for their next scheduled visit to have their device reprogrammed. Attending the clinic earlier is not necessary, but may be preferred by some patients after discussion with their local ICD clinic.
3. ICD clinics should obtain the updated software and reprogram their patient's ICDs as recommended by St. Jude Medical.

If you have further questions, please contact your local ICD clinic. Information about Device Advisories and the Canadian Heart Rhythm Society is available at www.chrsonline.ca.

Sincerely,



Andrew Krahn, Chair for the
Device Advisory Committee
Canadian Heart Rhythm Society