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Canadian Heart Rhythm Society
Device Advisory Committee
Medtronic Kappa Longevity Summary
This is not an Advisory

Dear CHRS DAC Committee Members,

There has been some recent concern about the generator battery status reliability of the Medtronic Kappa 700 series, and we have been doing some work over the winter. An informal survey has determined that there does not appear to be any systematic collection of failures by serial number. We have been working with Medtronic to develop an update for their customers to outline end of life behavior and the role of the various longevity estimates in managing frequency of follow-up and timing of generator replacement. This Product Education Brief has been finalized, and is currently being distributed widely to implant and follow-up centers. Our thanks go to Ratika Parkash and Jennifer Fraser for their efforts in this area.

There are over 12,000 devices implanted in Canada. There is a known issue with interconnect wire fractures internal to the pacemaker leading to rare abrupt failure that occurs primarily with submuscular devices, but also very rarely with subcutaneous devices. This was the subject of a previous advisory in 2002. According to the Medtronic Product Performance Report, the Kappa 700 DR device survival is 99.6% at 105 months (excluding normal battery depletion). The primary failure mechanisms are fracture or separations of internal interconnect wires.

The longevity calculator provides a range of remaining time to Elective Replacement Indicator (ERI, not EOL). Approximately 5% of patients will reach ERI sooner than the lower end of this range due to battery variation. Thus a patient presenting with abrupt failure well before the ERI estimate is likely to have had an interconnect wire fracture or separation, or other mechanism of failure rather than unexpected battery depletion.

Tables C-6 through C-10 of the Medtronic Kappa 700 Pacemaker Reference Manual provides projected estimates regarding the number of months remaining free from erratic pacing based upon the mode of operation prior to ERI tripping. The approved labeling indicates that the device must be replaced within 3 months once ERI is set and verified.

Additional parameters that should be assessed when considering this are the battery impedance and the magnet rate, which do not appear to be systematically assessed in most clinics in Canada that we spoke to. When the battery impedance has increased (some clinics use >3000 ohms) and/or the magnet rate is 65, these are signs of ERI and suggest scheduling replacement, particularly in dependent patients. ERI is tripped in one of two ways: 1) when the battery voltage is less than 2.5V, or 2) by a combined cell impedance of 3000 ohms and a voltage of less than 2.59V. Once the reversion to ERI

(VVI pacing) happens, there may be a temporary increase in cell voltage due to a reduced demand in battery load when going to VVI pacing. Therefore, it would seem prudent to book elective replacement as these values are being approached. Once ERI is reached, patients will pace in VVI mode at 65 bpm, which may result in symptoms, again supporting a strategy of early replacement. At most output settings, at least 95% of pacemakers will continue to function normally for at least 3 months after RRT/ERI is set. At the end of 3 months, erratic pacing may occur.

Predicting the time of RRT/ERI in order to schedule timely replacement is important, particularly in pacemaker dependent patients. This may be done by paying attention to the cell voltage and to the battery impedance. Some clinics change follow-up interval frequency to monthly or bi-monthly when cell impedance approaches 2700 ohms and/or battery voltage is 2.64 volts. In many centers, autothreshold is turned off in patients with stable thresholds approaching EOS. It should be noted that Capture Management measures daily thresholds and adapts pacing outputs to adequately maintain programmed safety margins while providing the lowest possible outputs. Once ERI triggers, Capture Management is automatically turned OFF. When turned off automatically at RRT, output will remain at the output Capture Management has programmed when RRT is tripped.

Recommendations:

- a. All forms of longevity markers (longevity calculator, battery voltage and impedance, magnet rate) should be used to guide decisions to increase follow-up frequency or replace devices. A fall in magnet rate (85 to 65) indicates the need for replacement.
- b. Replace device within 90 days of reaching RRT
- c. Consider increasing follow up frequency when the lower limit of the longevity calculator is less than 12 months, or battery impedance is 2600 and cell voltage is 2.6, especially for dependent patients
- d. Consider shutting Capture Management off as RRT approaches

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