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EnRhythm® and EnRhythm MRI™ SureScan Pacemaker

Patient Management Recommendations Update

August 2011

Dear Doctor,

In February 2010, we informed you of two specific battery issues with EnRhythm pacemakers that were subsequently addressed by a software update released in the Fall of 2010. As part of our ongoing vigilance efforts, we are providing a summary of the most recent performance data along with patient management recommendations developed with the Independent Physician Quality Panel's guidance.

Background

The battery issues communicated in February 2010 and subsequent software update are summarized in the table below. When a device receives the software update, if battery impedance is greater than the new ERI threshold ERI will be triggered shortly thereafter. Therefore, clinicians may observe an ERI/EOL indicator at the next patient follow-up. When ERI is triggered by battery impedance, additional battery capacity remains and can support device function at ERI parameters for at least one year. Medtronic is not aware of any reports of loss of therapy due to this issue.

As a reminder, when ERI is triggered, EnRhythm devices revert to VVI pacing at 65 ppm at the programmed output settings. EOL is declared 90 days after ERI or at a battery voltage of 2.69V, whichever comes sooner.

Battery Issue	Software Update
Battery voltage could decrease sooner than expected due to a slightly increased rate of lithium depletion	Changed ERI battery voltage threshold from 2.59V to 2.81V to ensure 90 days of therapy from ERI to EOL
Higher than expected battery impedance	Added a secondary ERI trigger based on battery impedance. This new criteria will identify devices with increased battery impedance before device performance is impacted. If triggered, displayed battery voltage is reset to 2.81 V to ensure alignment with ERI battery voltage threshold

Updated Performance Information

We now have access to battery impedance and ERI performance on more than 5000 EnRhythm devices that have received the EnRhythm software update. Our modeling based on these data shows that approximately 6-10% of devices will reach ERI within 5 years post-implant. Consistent with our previous communications, we continue to expect average device longevity to be reduced by approximately 10 –15%, with the expected average longevity remaining at 8.5 to 10.5 years, depending on device settings.[1]

Updated Patient Management Recommendations

After consultation with Medtronic's Independent Physician Quality Panel, we recommend:

- Performing a device follow-up within 90 days after the software download to identify devices that triggered ERI shortly after the software update. Patients that received the software update more than 3 months ago should also be scheduled for a follow-up to identify whether their device has triggered ERI due to battery impedance. Subsequent follow up can be performed per standard practice. During programmer

[1] The 8.5 year estimate represents a high use scenario (DDD, 100% pacing in atrium and ventricle with 3.0V output in both chambers). The 10.5 year estimate represents MVP function ON (AAI(R)<=>DDD(R) 50% pacing in atrium and 5% pacing in ventricle with 3.0V output in both chambers. Projections are based on modeling and not actual field returns, due to limited availability of implant experience beyond 6 years. Field performance will continue to be monitored and modeling updated to reflect actual data.

interrogation of a device at ERI, there is a slight possibility a transient drop in pacing amplitude could occur. If this is noted, either remove the programmer head or temporarily program to a higher output voltage.

- If an unanticipated ERI/EOL is declared, it is likely due to battery impedance. In such cases, additional battery capacity remains and can support device function at ERI parameters for at least one year. However, when ERI or EOL (typically 90 days after ERI) declaration is seen, schedule device replacement.

We regret any difficulties this may cause you and your patients. If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative on 01923 212 213 or contact Medtronic Directo Technical Services at 08702 403 304.

Yours sincerely

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