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February 11, 2010.

To:
DIRECTOR OF MEDICAL DEVICE BUREAU
MINISTRY OF HEALTH MALAYSIA
Level 5, No. 26, Boulevard Plot 3C4,
Precinct 3,
Federal Government Administration Centre,
62675 Putrajaya,
Malaysia

Dear Sir,

MEDICAL DEVICE CORRECTION: EnRhythm® Pacemakers.

This letter is to inform you on the medical device correction being carried out by Medtronic on two specific battery issues with EnRhythm® Pacemakers.

The communication letters are sent to the respective physicians and the Hospitals/Institutions where the affected lots of the products have been distributed. The letter is as attached, to provide further insights into this field action.

Do consult us should you require additional information.

Yours Sincerely,

Debra Anne Anthony Peter
REGULATORY AFFAIRS SPECIALIST
MEDTRONIC INTERNATIONAL, LTD.

Attachment: Customer Communication Letter

Medtronic International, Ltd.
Singapore Branch
49 Changi South Avenue 2
Singapore 486056
www.medtronic.com

Tel: 65-6436 5000
Fax: 65-6776 6355

IMPORTANT: MEDICAL DEVICE CORRECTION

EnRhythm® Pacemakers

February 2010

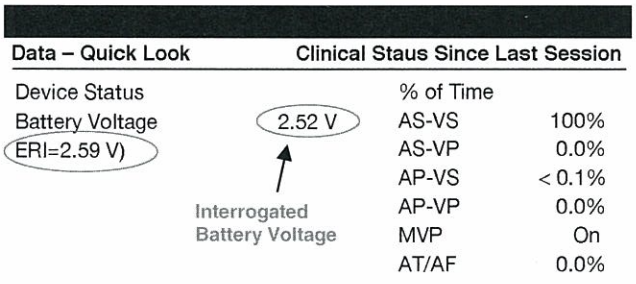
Dear Doctor,

We are informing you of two specific battery issues with EnRhythm® pacemakers that will be addressed by a Medtronic software update available mid-2010. EnRhythm devices were commercially released in 2005, and these devices have been implanted for less than 5 years.

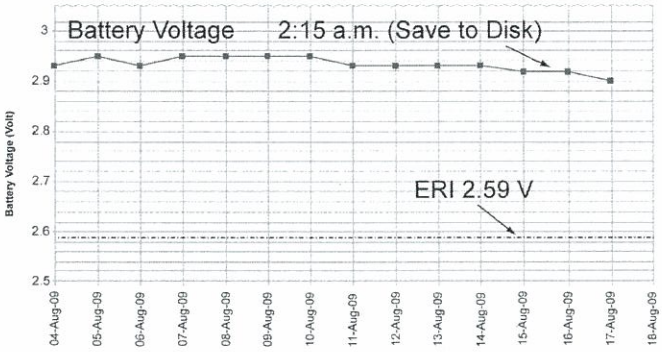
First Issue

Medtronic has received 62 reports (out of approximately 110,000 devices worldwide) indicating that the battery voltage at device interrogation was lower than the battery voltage that is tracked by the device to provide data for the elective replacement indicator (ERI) notification. The lower voltage measurement has caused confusion and occasionally has resulted in unnecessary explants.

Medtronic's investigation has shown that none of these reports has resulted in loss of therapy. Importantly, the ERI notification, which uses the nightly battery measurement, is unaffected and accurate. Medtronic has identified the root cause as higher than expected battery resistance.



Example of interrogated battery voltage lower than ERI, but no ERI notification triggered



Example of nightly voltage trend above ERI – stored to device memory but not visible to user

Medtronic's internal testing has shown that there is no current risk for compromised therapy delivery. If the software update referenced above is not implemented, there will be a potential risk of loss of device functionality in a small percent (less than 0.08% six years post implant) of devices. The software update will eliminate this risk.

Medtronic recommends physicians continue to use the ERI notification to determine time for device replacement. At this time, no other action, reprogramming or change in the frequency of follow-up is recommended.

Second Issue

Through internal accelerated testing, Medtronic has identified a second issue that projects battery voltage could decrease sooner than expected due to a slightly increased rate of lithium depletion. This issue has not been clinically observed and is not expected to occur for another 4 years (approximately 9 years post-implant). If the software update referenced above is not implemented, there may be a potential risk for loss of therapy at or near ERI in a small number of devices. The software will eliminate this issue by changing ERI criteria.

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Summary

The software update will eliminate any potential future risk of the two battery issues described above by changing the ERI criteria. This update will reduce longevity of these devices by approximately 10-15%, but the expected average longevity will still be 8.5 to 10.5 years depending on device settings[1]. At this time, no other action, reprogramming or change in the frequency of patient follow-up is recommended. Your Medtronic representative will notify you when the software update is available.

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 or Medtronic Technical Services.

Sincerely,

Shamik Dasgupta

Business Director
Medtronic Cardiac Rhythm Disease Management
South Asia and ASEAN

Medtronic encourages health care professionals and consumers to report any serious adverse affects with the use of any our products to their local Medtronic Representative.

[1] The 8.5 year estimate represents a high use scenario (DDD, 100% pacing in atrium and ventricle with 3.0 V output in both chambers). The 10.5 year estimate represents a typical use scenario for a sinus node dysfunction patient with the MVP function ON (AAI(R)<=> DDD(R), 50% pacing in atrium and 5% pacing in ventricle with 3.0 V output in both chambers).