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April 05, 2011.

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,

IMPORTANT MEDICAL DEVICE CORRECTION:
Dual Chamber Models of Pacemakers: Kappa 600, 700, 800, 900, EnPulse, Adapta, Versa, Sensia <Relia, Vitatron Models E50A1, E60A1, and G70A1>

This letter is to inform you of a medical device correction which is being communicated to the healthcare professionals. The information is being rolled out together with the Performance Note that describes the rare measurement lock-up issue that impacts the Medtronic Dual Chamber pacemakers listed above.

The scope of this field action impacts on the local market and we have located the impacted units and are notifying the relevant customers on this field action.

Please find the attached copy of the physician communication letter and the Performance Note 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.

Encl: Customer Communication Letter & Performance Note

IMPORTANT: MEDICAL DEVICE CORRECTION

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<Relia, Vitatron Models E50A1, E60A1, and G70A1>

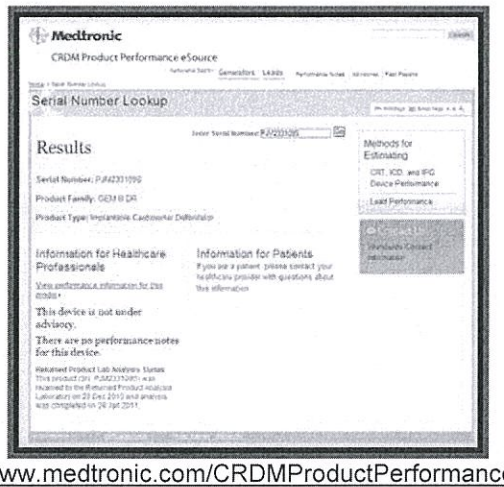
April 2011

Dear Doctor,

Attached is a Performance Note that explains a rare measurement lock-up condition that may (at a rate of approximately 1 in 18,000 devices) inappropriately trigger ERI/RRT in the Medtronic Dual Chamber Pacemakers listed above. This is caused by a random lock-up of the measurement system hardware that may result in an incorrect battery voltage reading of zero. **This issue does NOT impact battery longevity and does NOT require device explant. Currently, the device can be reset to normal operation by a Medtronic representative.** Reset devices are no more likely to experience a recurrence of this issue. In late 2011, pending regulatory approval, Medtronic is planning to release a programmer software update that will allow the clinician to reset the device.

Medtronic has received 101 reports worldwide of this issue out of an estimated 1.8 million devices. Seventy devices have been explanted due to this issue, with most explants occurring prior to Medtronic's development of a method to reset devices.

Updated CRDM Product Performance Website
Medtronic has consolidated our product performance data with the vision of creating a primary reference tool for performance updates. With our technical services staff, this resource will help guide clinicians in managing their patients. This website www.medtronic.com/CRDMProductPerformance will provide survival curves, longevity tables, performance notes and advisories based on device model and serial number (Serial Number Lookup). In addition, clinicians will be able to check the progress of analysis of a returned device. The website will be available in April.



www.medtronic.com/CRDMProductPerformance

If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services at 800-505-4636.

Sincerely,

Shamik Dasgupta
2011.04.04
14:44:54 +08'00'

Medtronic Cardiac Rhythm Disease Management

Performance Note

Dual Chamber Pacemakers with Measurement Lock-up ERI

Kappa 600, 700, 800, 900, EnPulse, Adapta, Versa, Sensia, Relia, and Vitatron Models E50A1, E60A1, and G70A1

Purpose of this Information

This Performance Note describes a rare measurement lock-up issue that impacts the Medtronic **Dual Chamber** pacemakers listed above. If this measurement lock-up occurs, the device will trigger a false Elective Replacement Indicator (ERI). A reset is available to clear this condition and there is no need to explant the device. This issue does not impact battery longevity.

Background

If this rare measurement lock-up occurs in the pacemaker, it causes the device to read a value of zero for battery voltage. After four measurements of zero, the device will trigger ERI and revert to a VVI pacing mode at 65 bpm. There is no loss of ventricular pacing and the output voltage will remain the same.

The issue can be uniquely identified using the programmer or via CareLink transmission; the battery voltage measurements and remaining longevity will appear as blank values. Medtronic has developed a method for clearing the ERI condition through the use of a specially configured programmer. There is no impact to the device functionality or longevity after this reset is complete.

Example

Two examples of images from the Medtronic 2090 programmer are shown below. Example 1 shows what a normal ERI condition looks like. Example 2 shows what will be displayed if the ERI is triggered due to the measurement lock-up condition.

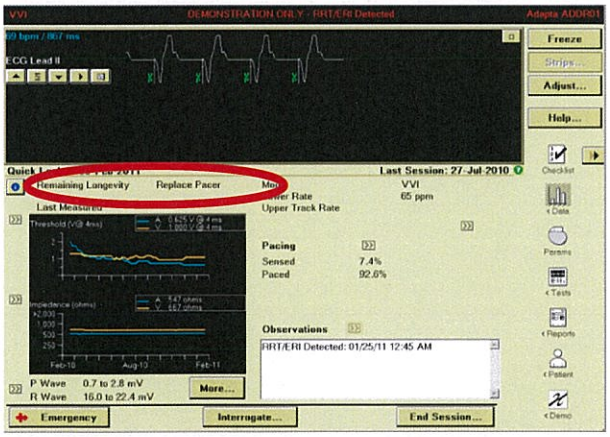
A device that has experienced a measurement lock-up ERI will present ALL of the following symptoms:

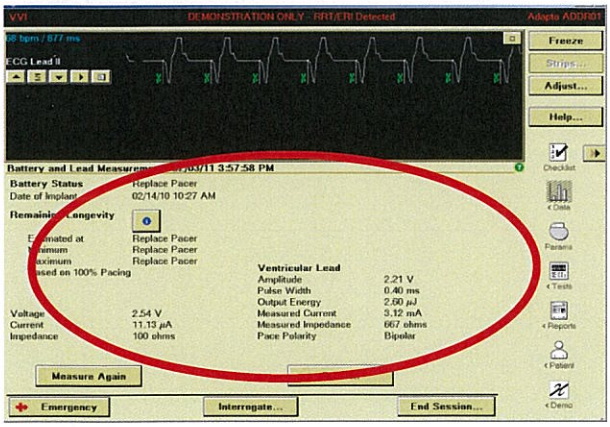
- Device declaring ERI/RRT
- Remaining Longevity = <Blank> on the programmer (and CareLink where available)
- Battery Voltage = <Blank> on the programmer (and CareLink where available)
- If the user attempts to take a Battery and Lead Measurement, a pop up window will indicate that it cannot estimate remaining battery life.

Recommendation

This condition can be reset and does not require device explant. If this measurement lock-up occurs, obtain a save-to-disk file and contact Medtronic Brady Technical Services at 1-800-505-4636 for assistance. Reset devices are no more likely to experience a recurrence of this issue.

Example 1–Programmer Screen for Typical Pacemaker at ERI





Example 2 – Programmer Screen for Measurement Lock-up ERI