To:
Danish Medicines Agency
Medical Devices
Axel Heides Gade 1
DK-2300 Copenhagen S, Denmark

Medtronic Ref.: FA507
Your ref: LMST2011040682

16 January 2012

Dear Mrs Jespersen

The purpose of this letter is to provide you with an update of the above mentioned Field Safety Corrective Action.

In April 2011 we informed you of a potential ERI Lock-Up issue with Dual Chamber pacemakers (FA507). This issue will be addressed via following software updates:

- Model: SW003 v 7.3: Adapta, Versa, Sensia
- Model: SW010 v7.3: Relia
- Model: VSF20 v1.2: Vitatron Series E and G

The software update will allow the physician to clear the ERI immediately should the ERI lock-up occur. A service tool continues to be available through Medtronic Technical Services to clear this condition on Kappa and EnPulse devices.

Following development and regulatory approval of the updates, we are now proceeding with their distribution in the field. Medtronic field representatives will install the programmer software updates on the model 2090 Physician Programmers.

The attached Dear Physician Cover Letter and addendum, informing the physicians of the changes resulting from these updates, will be delivered to the affected centers.

The software distribution will start on 17 January 2012 and will be completed by 21 September 2012.

If you would need more information about this notification, please do not hesitate to contact me.

Sincerely,

Åse Ek
Nordic RA Manager

Enclosures: Dear Physician Cover Letter
Dual Chamber Pacemakers ERI Lock-Up Addendum

Software Updates Now Available

Medtronic reference: FA507

January 2012

Dear Physician,

Medtronic is now releasing programmer software updates to address the Dual Chamber Pacemaker ERI Lock-Up issue that was initially communicated in April 2011 via Medtronic reference FA507:

- **ERI Lock-Up software** - SW003 v 7.3 (Adapta, Versa, Sensia); SW010 v7.3 (Relia) and VSF20 v1.2 (Vitatron Series E and G). Please refer to attached addendum.

Additionally Medtronic is including the following seven (7) software updates in this software bundle:

- **Advisa Clinical Devices Battery Issue** - 9995 v7.4
- **Updated Longevity Estimator:** Consulta, Ensura, Advisa - 9995 v7.4
- **Medtronic Desktop Enhancements** - BOSS Desktop 2.5
- **Vitatron Desktop Enhancements** - VSH02 v 2.3
- **Reveal XT-DX** - SW007 v7.1 (Carry forward release of Reveal FULL VIEW software)
- **EnRhythm** - 9987 v7.2 and **EnRhythm MRI** - SW005 v7.3 (Carry forward release of FA453, Phase II software)

Your Medtronic representative will assist you with installing the software on your 2090 programmer.

We apologize for the inconvenience this may cause to you. If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative <insert local contact>.

Sincerely,

Country BU Manager

Attachment: FA507 - Dual Chamber Pacemakers ERI Lock-Up Addendum

Dual Chamber Pacemakers – ERI Lock-Up issue

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

Addendum

Medtronic Reference: FA507

January 2012

Dear Physician,

Programmer software is now available to detect a rare measurement lock-up ERI that can occur in Adapta, Versa, Sensia, Relia, and Vitatron Series E and G devices, as communicated in April 2011. This programmer update will allow the clinician to clear the ERI immediately should the ERI lock-up occur.

- This software update will reside on the programmer and will not be installed on the patient's device.
- Once the programmer has the new software installed, if an inappropriate measurement lock-up ERI is present it will be detected and you will be prompted to **Clear** the ERI.
- After the inappropriate ERI has been reset, the battery voltage field will display "Not Available" until the next scheduled measurement cycle (within 3 hours).
- Some device parameters are disabled during ERI. Following an ERI reset, review device parameters and reprogram to clinician specifications.
- Medtronic Representatives are currently updating programmers with software SW003 v7.3 (Adapta, Versa, Sensia), SW010 v7.3 (Relia) and VSF20 v1.2 (Vitatron Series E and G).
- A service tool continues to be available through Medtronic Technical Services to clear this condition on Kappa and EnPulse devices. To obtain the service tool, contact Technical Services at [insert contact info].

We regret any difficulties this may cause you and your patients. If you have questions please contact your Medtronic field representative, at [insert contact info].

Sincerely,

Country BU Manager

[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).