



Medtronic

Urgent Field Safety Notice

Model 8870 Software Application Card used in the 8840 N'Vision™ Clinician Programmer

SynchroMed Implantable Infusion System Therapy: Erroneous Replace by Date and
Premature Reservoir Alarm

Deep Brain, Spinal Cord and Peripheral Nerve Stimulation Therapies: Loss of
Stimulation and Over Stimulation

XX October 2013

Medtronic Reference: FA581

Dear Healthcare Professional,

This letter provides important safety information regarding the 8870 Software Application Card used by your programmer and is intended to advise you that the card is being updated. The updated version of the software card includes applications that impact SynchroMed Drug Infusion systems, Deep Brain Stimulation, Spinal Cord Stimulation and Peripheral Nerve stimulation devices, and will address each of the issues as noted below. Your Medtronic representative will assist you in installing this new software version BBR/01.

1. SYNCHROMED DRUG INFUSION THERAPY

Products affected: SynchroMed II® pump model 8637

Description of the issues:

Erroneous Replace by Date: The updated software corrects the issue previously communicated in Medtronic's March 2012 Field Safety Notice titled *Potential Display of Incorrect "Schedule to Replace the Pump By" Date for the SynchroMed II Pump* (Medtronic ref. FA535). In some circumstances after a pump's Elective Replacement Indicator (ERI) has occurred, the "Schedule to replace the pump by" date may be incorrectly displayed as a series of question marks (??/??/????), or as a date greater than 90 days from the ERI date, potentially leading to the pump reaching End of Service (EOS) prior to replacement.

As of September 12, 2013, there have been 15 reports of this occurring. If a pump reaches end of service prior to replacement, the patient may experience the return of underlying symptoms and/or withdrawal symptoms.

Premature Reservoir Alarm: The updated software corrects the potential for premature low and empty reservoir alarms. These premature alarms are due to an incorrect calculation within the 8840 programmer software. The majority of these alarms occur within the clinic immediately following an interrogation. As of September 12, 2013, Medtronic has received 85 reports of a premature alarm in implanted devices.

Therapy is not affected and the pumps' calculated residual volume is correctly displayed on the 8840 programmer even if this issue occurs. However, the only impact to patients is the potential for earlier than necessary refill appointments.

To date, there have been no patient-related, serious adverse events reported due to these issues.

Recommendations:

- Medtronic does **not** recommend prophylactic explant of devices because these issues are addressed automatically and non-invasively with this software card update.
- Until the software application card is updated to version BBR/01 in your programmer:
 - You may continue to use the present software card.
 - As identified in the March 2012 notification regarding the Erroneous Replace by Date:
 - Continue the normal follow up schedule, and monitor the estimated number of months until Elective Replacement Indicator (ERI).
 - Follow labeled recommendations for pump replacement within 90 days of ERI declaration.
 - In the case of a low or empty reservoir alarm:
 - Review the calculated residual volume displayed on the 8840 programmer to assess if the alarm is premature.

2. DEEP BRAIN, SPINAL CORD AND PERIPHERAL NERVE STIMULATION THERAPIES

Products affected:

- Activa[®] PC, Activa[®] RC and Activa[®] SC implantable deep brain stimulator models 37601, 37602, 37603, 37612
- RestoreUltra[®] and RestoreSensor[®] implantable spinal cord and peripheral nerve stimulator models 37712, 37714

Description of the issues:

Loss of Programmed Stimulation: Unexpected loss of stimulation may occur under the following specific conditions:

- Switching Between Groups with Multiple Programs: Switching from a group with two programs to a group with three or four programs where a non-negative contact is shared within the programmed groups.

OR

- Creating Program Groups: (For Activa SC only): When a second program is created for the first time within the device.

The patient programmer or clinician programmer will not indicate a loss of therapy, even though stimulation output will not be delivered to the electrodes.

As of September 12, 2013, this issue has been reported for a total of twenty-one (21) devices (10 DBS, 11 SCS). In all cases of temporary loss of stimulation, therapy was restored with the Physician Recharge Mode (PRM) of the Implantable Neurostimulator Recharger (INSR).

Over Stimulation or Stimulation in the Wrong Area: (NOTE: *Activa SC – Models 37602 / 37603 are not affected by this issue.*) Under a specific set of conditions, typically related to device recovery from an over discharge, there is a potential for over stimulation or stimulation directed to a lead electrode other than what was intended. The conditions leading to this issue are:

- 1) Device reaches a power on reset (POR) state. A POR may be detected during interrogation with the patient or physician programmer. The patient will experience loss of therapy if a POR occurs.

AND

- 2) 'Therapy OFF' command is sent (by patient programmer, INSR, or 'THERAPY-STOP' button on the 8840 clinician programmer) to device while the device is making an automatic periodic battery measurement.

As of September 12, 2013, Medtronic has received thirty-seven (37) reports associated with this issue. All of these reported events have been for spinal cord (SCS) and peripheral nerve stimulation devices. There have been no reports associated with deep brain stimulation (DBS).

To date, there have been no patient-related, serious adverse events reported due to these issues.

Recommendations:

Medtronic does **not** recommend prophylactic explant of devices because these issues can be addressed non-invasively by the clinician using an 8840 clinician programmer or an Implantable Neurostimulator Recharger using the Physician Recharge Mode.

Loss of Stimulation Output: The model 8870 Software Application Card used by your programmer is being updated to version BBR/01 by your Medtronic field representative. Interrogating your patient's device with the updated software version will automatically update the implanted device software and reduce the probability that a loss of stimulation output will occur. Individual patient needs and/or programmed parameters (i.e. number of programs) may determine whether patients should have their device software updated before their normally scheduled visit.

Over Stimulation or Stimulation in the lead electrode other than what was intended: To significantly reduce the likelihood that this issue will occur, patients should avoid over discharge. If a rechargeable device becomes over discharged, please contact your Medtronic representative or Technical Support International West on +31 (0)45 566 8844 to resolve the POR and reduce the likelihood of over stimulation. If inappropriate stimulation does occur, it can be terminated using either a 8840 Clinician Programmer or in the case of a rechargeable device, by using an Implantable Neurostimulator Recharger and employing the Physician Recharge Mode.

After the software update to version BBR/01, any previous version of the model 8870 Software Application Card should no longer be used and can be returned to Medtronic to ensure only the most up-to-date version is available for use in your practice. Your local Medtronic representative will assist with this software card update.

The Competent Authority of your country has been informed of this action.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

We regret any difficulties this may cause you and your patients. We are committed to continuing to improve our product performance and services to enable you to manage your patients in a safe and effective manner. You can access product performance information at: <http://professional.medtronic.com>. If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative.

Sincerely,