Urgent: Medical Device Correction

Model 8870 Software Application Card used in the 8840 N'Vision™ Clinician Programmer
For SynchroMed Implantable Infusion System Therapy

Dear Customer,

This letter is to inform you that the model 8870 software application card used by your programmer is being updated to version AAR/01 by your Medtronic field representative. This card includes applications for Neuromodulation SynchroMed Infusion systems, deep brain stimulation, and spinal cord stimulation devices. With respect to the SynchroMed II® pump, the update will automatically correct the following two issues when your patient comes in for their next scheduled visit. There have been no reports of deaths or life threatening injuries associated with these issues.

**Erroneous Replace by Date:** The updated software corrects the issue previously communicated in Medtronic’s March 2012 Medical Device Correction titled *Potential Display of Incorrect "Schedule to Replace the Pump By" Date for the SynchroMed II Pump* ([http://professional.medtronic.com/sync2date](http://professional.medtronic.com/sync2date)). 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.

**Recommendations:**

- Medtronic does **not** recommend prophylactic explant of devices because these issues are addressed automatically and noninvasively with this software card update.
- Until the software application card is updated to version AAR/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.
- After the software update to version AAR/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.
**Additional Information:**
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](http://professional.medtronic.com). If you have questions, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am - 6pm CST. Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services and to FDA’s MedWatch Program ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)). Electronic copies of this letter can be accessed at [http://professional.medtronic.com/iddadvisories](http://professional.medtronic.com/iddadvisories).

Sincerely,

[Signature]

Mike Crader  
Vice President Quality  
Medtronic Neuromodulation