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.