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Urgent Field Safety Notice

Updated Model 8870 Software Application Card for RestoreUltra® SureScan MRI (model 97712) and RestoreSensor® SureScan MRI (model 97714)

Spinal Cord Stimulation Therapy: Loss of Stimulation

July 2014

Medtronic Reference: FA581 follow-up communication

Dear Healthcare Professional,

This letter provides important safety information regarding the 8870 Software Application Card used with your physician programmer (model 8840), and is intended to advise you that the current software card is being replaced with a newer version. The new card version BBR/02, will resolve the issue described below. Note that stimulators manufactured after 31 July 2013 are not affected by this issue.

SPINAL CORD AND PERIPHERAL NERVE STIMULATION THERAPIES

Products affected:
RestoreUltra® SureScan MRI (model 97712) and RestoreSensor® SureScan MRI (model 97714) implantable spinal cord stimulators with model serial numbers less than 700904H.

Description of the issue:
Loss of Programmed Stimulation: Unexpected loss of stimulation may occur under the following specific condition:

- 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

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 February 14, 2014, this issue had been reported for a total of twenty-three (23) devices (13 DBS, 10 SCS), this includes both: devices in scope for this software update (BBR/02) and devices in scope for the previous update (BBR/01). In all cases of temporary loss of stimulation, therapy was restored with the Physician Recharge Mode (PRM) of the Implantable Neurostimulator Recharger (INSR).

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.

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Loss of Stimulation Output: The model 8870 Software Application Card used by your programmer was updated to version BBR/01 by your Medtronic field representative earlier this year or at the end of last year. Upgrading to version BBR/02 adds the ability to address the two pain stimulators models listed above. 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.

It is recommended that all programmers within your practice will be updated to version BBR/02, and we request that previous versions are returned to Medtronic. Use of older versions of the model 8870 Software Application Card (BBQ/01 and earlier) after a device has been interrogated with the updated software may cause system compatibility issues. Your local Medtronic representative will assist with this software card update.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been informed of this action.

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

Please be sure that only BBR/02 cards are in use within your practice. 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.

Yours sincerely,

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