Urgent Field Safety Notice

Model 8870 Application card versions NNA and NNB_01 used with model 8840 N'Vision Clinician Programmer

Software upgrade

March 2009

Medtronic reference: FA426

Dear InterStim[™] or Enterra[™] Therapy Healthcare Provider,

This letter accompanies an upgrade for your Model 8870 software application card (used with the model 8840 N'Vision[®] Clinician Programmer) and Model 3037 iCon[®] Patient Programmers (InterStim Therapy). The Model 8870 Software Application Cards NNA and NNB version 01 (NNB_01) have been superseded by NNB version 02 (NNB_02).

To ensure the most current version of software is used, Medtronic will replace any outdated Model 8870 software application cards with version NNB_02.

Impact to InterStim Therapy: The Model 8870 NNB_02 upgrade contains software and labeling upgrades to correct the following InterStim Therapy-related issues with the NNB_01 card:

- Post-implant, a false LOW battery alert could be displayed when interrogating an InterStim INS Model 3023 with an N'Vision Clinician Programmer, or with an InterStim iCon Patient Programmer.
- Pre-implant, a lower than expected battery capacity estimate could be displayed when interrogating an InterStim II INS Model 3058 with an N'Vision Clinician Programmer.

These issues were previously communicated to clinicians using InterStim in a letter dated July 2007. In addition to addressing the issues above, the NNB_02 application card also contains additional enhancements for the InterStim Therapy (see Appendix A).

Impact to Enterra Therapy: This upgrade only contains a non-safety related enhancement for the Enterra Therapy (see Appendix A). However, the NNB card is shared by both InterStim and Enterra therapies. As such, it is necessary to upgrade all application cards regardless of therapy.

Clinician Actions:

Once your Medtronic Representative has upgraded your Model 8870 card to version NNB_02:

- <u>Upgrade iCon Patient Programmers (InterStim Therapy)</u> iCon Patient Programmers are upgraded by performing an iConSync[®] (see Appendix B). An iConSync should be performed at the patient's next office visit. However, if any InterStim (Model 3023) patients have previously experienced a false LOW battery alert, please schedule an office visit and perform an iConSync as soon as possible to prevent further false LOW battery alerts.
- <u>Additional N'Vision Clinician Programmers</u> Contact your Medtronic sales representative if you become aware of other N'Vision Clinician Programmers at other clinic locations or with third party home health care providers.
- <u>No additional training is required</u> Please contact your Medtronic sales representative at <insert local contact> with any questions or concerns.

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

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

For additional information, please contact your Medtronic Representative or Medtronic Neuromodulation Technical Services at {add local phone number}.

Sincerely,

Enclosures: Appendix A: List of Upgrades and Additional Enhancements Appendix B: iConSync Instructions (InterStim Therapy)

Appendix A: List of Upgrades and Additional Enhancements

Below are the specific changes that were included in the Model 8870 NNB version 02 software application card release.

InterStim[™] (Model 3023) & InterStim[™] II (Model 3058)

Upgrades to correct issues communicated in July 2007:

- Software upgrade corrects InterStim INS Model 3023 false LOW battery alert.
- Upgrade to InterStim Programming Guide (p. 5-2) instructs clinicians how to verify neurostimulator battery status prior to implant. Programming Guide also provides clarification on InterStim II INS Model 3058 battery capacity estimates.

Additional Enhancements:

- Add patient's name to the session report file name in the Session Data Manager screen.
- Change default pulse width to 210 µsec (from 450 µsec) during Electrode Impedance Measurements and Therapy Measurements to simplify comparisons to previous impedance measurement results.
- Streamline process for performing or skipping iConSync.
- Prevent potential temporary overstimulation during amplitude resolution adjustments.
- Allow clinician to fix incorrectly entered serial numbers.
- Update Medtronic SpeedStart Library to reflect commonly used settings.
- Prevent occasional incomplete card copying during 8870 card data transfers.
- Eliminate unwanted beeping when a new screen is shown.

Enterra[™] (Model 3116)

 Enhancement prevents occasional incomplete card copying during 8870 card data transfers.

Appendix B: iConSync Instructions (InterStim[™] Therapy) Reference: Downloading Programmed Settings, pages 6-65 to 6-67 of the InterStim Model 8870 Programming Guide for Software Version B

iConSync is a wireless telemetry feature that associates a patient programmer with the clinician programmer and allows communication between the patient programmer and the clinician programmer.

iConSync is performed in the beginning and at the end of the programming session. Please refer to pages 6-62 to 6-64 of the InterStim Model 8870 Programming Guide for Software Version B.

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	InterStim® - B (Demo) 🖾 🗙	
	€ 1 8. 200 B	
	iConSync [™] (25)	
	To iConSync™:	
	① Turn InterStim iCon™ Programmer on.	
	Alian IR ports on N'Vision	
(Programmer and InterStim iCon Programmer.	
	Press Cancel to skip iConSync and start in Reduced iCon Mode. Press Exit to end session.	
	Cancel Exit	
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N'Vision Clinician Programmer iConSync screen



Aligning Infra Red ports on N'Vision and iCon programmers

In case you never performed an iConSync before, the screens on your N'Vision Clinician Programmer and on your patient iCon Patient Programmer will be slightly different once the iConSync is performed.



Key changes to the N'Vision Clinician Programmer screens:

Stim Settings Screen after an iConSync



Stim Settings Screen without iConSync



For complete description of the screens please refer to the InterStim Model 8870 Programming Guide for Software Version B for the N'Vision Clinician Programmer screens.

Key changes to the iCon Patient Programmer screens:



iCon main screen after an iConSync



iCon main screen if iConSync was never performed

For complete description of the screens please refer to the InterStim iCon Model 3037 Patient Programmer User Manual for the iCon Patient Programmer screens