

Medical Device Correction
Model 8870 Software Application Card Used In The 8840 N'Vision™ Clinician Programmer
For SynchroMed Therapy



February 2009

Dear Healthcare Provider,

This letter provides important information regarding changes to the programming software used in SynchroMed® Infusion System. Medtronic has received reports of both overdose and underdose that were the result of errors in the programming use of SynchroMed implantable infusion pumps. These errors were most commonly associated with:

- Priming Bolus Programming
- Bridge Bolus Programming

Pump programming errors that result in overdose and underdose can lead to serious patient injury including death.

Medtronic has made some modifications to the Model 8870 Software Application Card used in the Model 8840 N'Vision™ Clinician Programmer. This update provides improved user interface features to help reduce pump programming errors. The Model 8870 versions AAG and AAJ software cards are being replaced by version AAH or newer.

The user interface enhancements affect how clinicians interact with SynchroMed® II and SynchroMed® EL programming applications. It is important to note that these changes are related to user interface and do not affect the core functions of the software applications. The specific changes are highlighted in Appendix A. If you have questions regarding the software update, please contact your local Medtronic Representative or Medtronic Technical Services at 1-800-707-0933.

Medtronic wants to ensure that customers are always using the most current version of programmer software. Your local Medtronic representatives will assist with this software exchange and provide training on the use of the new programming features. During the exchange, any previous version 8870 cards will be returned to Medtronic to assure you have only the most up to date version in use in your practice. Data on cards returned to Medtronic as part of this exchange will be handled in a manner compliant to HIPAA Privacy Rules.

Medtronic appreciates your continued support and remains committed to delivering quality products and services to help you help your patients. Thank you for your attention to this new update for your 8840 programmer. For additional information, please contact your Medtronic Representative or Medtronic Neuromodulation Technical Services at 1-800-707-0933. This telephone number is staffed 24 hours a day for any product or clinical questions.

Sincerely,

A handwritten signature in black ink that reads "George Aram".

George Aram
Vice President, Quality
Medtronic Neuromodulation

Medical Device Correction

Model 8870 Software Application Card Used In The 8840 N'Vision™ Clinician Programmer For SynchroMed Therapy

Appendix A

Below are the specific changes that were made to the existing 8840 pump programmer software applications that affect the user experience.

SynchroMed II

- Bridge bolus screens and navigation direct the user to perform the bridge bolus operation, based on drug parameter changes.
- Priming bolus screens and navigation direct the user to perform the correct priming bolus operation, based on location of drug in path.
- Summary of total dose provided prior to pump update.
- Summary of percent dose increase or decrease provided prior to pump update.
- Additional notation for “micro” was added. mL/mcg is now in addition to $\mu\text{L}/\mu\text{g}$ in the Units drop down list.
- Catheter length input is checked against typical range. User is alerted if entry is outside this range.
- Enhancements for patient activated dosing behavior.
- Alarm notification at initial interrogation.
- Warning message displayed in the event of incomplete telemetry.

SynchroMed EL

- Bridge bolus screens and navigation direct the user to perform the bridge bolus operation, based on drug parameter changes.
- Priming bolus screens and navigation direct the user to perform the correct priming bolus operation, based on location of drug in path.
- Summary of total dose provided prior to pump update.
- Summary of percent dose increase or decrease provided prior to pump update.
- Additional notation for “micro” was added. mL/mcg is now in addition to $\mu\text{L}/\mu\text{g}$ in the Units drop down list.
- Change drop-down selection from “Single Bolus” to “Single Bolus + Stopped Pump” to better describe pump function.
- Actual bolus type is shown at next interrogation.
- Catheter volume stored in pump memory.