

Urgent Field Safety Notice Update SynchroMed® II Programmable Pump

Update to Model 8870 Software Application Card used in the 8840 N'Vision™ Clinician Programmer and SynchroMed® Infusion System Labeling for Priming Bolus

December 2016

Medtronic reference: FA573 Phase II

This letter is a follow up to the June 2013 communication (refer to the attached copy of that letter for a full description of the issue and potential risks) regarding the SynchroMed II priming bolus function and to inform you that Medtronic is updating the Model 8870 software application card (to version BBU01) as well as the SynchroMed® Infusion System labeling to address the issue. The SynchroMed priming bolus function is intended to quickly advance drug from the pump reservoir to the catheter tip to allow for therapy initiation while the patient remains under medical supervision.

The updated 8870 software card mitigates the potential for clinically relevant effects of over-delivery of unintended drug, such as respiratory depression, loss of consciousness, or death, during the full system priming bolus procedure. The therapy applications on the software card for deep brain stimulation and spinal cord stimulation remain unchanged.

This letter provides a description of the software change, description of labeling changes, 8870 Software Card Recommendations and New Priming Bolus Recommendations.

Description of Software Change

The software update will change the value displayed on the 8840 programmer for the SynchroMed II pump tubing volume from 0.199 ml to **0.140 ml** (see picture). The tubing volume is used to calculate the total volume of a full system priming bolus. This volume change does not alter the procedural steps or the other calculations required to program a priming bolus.

Over delivery of drug during priming bolus has the potential to lead to overdose symptoms in some patients. This software change mitigates the potential for unintended over-delivery of drug while still ensuring prompt therapy initiation. However, there continues to be a potential for underdose symptoms to present for a period of time after the completion of the full system priming bolus. This potential for underdose symptoms occurs when a high concentration of drug solution is used at a low total therapeutic daily dose. Therefore, do not increase the programmed daily dose within the first 48 hours following a full system prime.

The screenshot shows the 'SynchroMed II B Infusion Bolus' software interface. The 'Tubing Volume' field is highlighted with a red arrow pointing to the value '0.140 mL'. Other fields include 'Catheter Volume' (0.251 mL), 'Total Prime Volume' (mL), 'Drug' (MORPHINE), 'Bolus Dose' (µL), and 'Bolus Duration' (h:m). The 'Current Pump Settings' section shows 'Infusion Mode' (1 B) and 'Minimum Rate' (6.0 µL/day).

New tubing volume value of **0.140 ml**, replaces previous value of 0.199 ml

Description of Labeling Changes

The SynchroMed® II Infusion System Manuals were updated for the priming bolus function. A reference booklet, titled *Important Labeling Updates Related to Priming Bolus with the SynchroMed® II Infusion System*, was created to provide information on the updated manual content. This reference booklet is included as Attachment 1.

8870 Software Card Recommendations

- Continue to use the current software card and its displayed tubing volume until your Medtronic Representative has exchanged the current card with the new software card (new version is BBU01).



New Priming Bolus Recommendations

New guidelines regarding priming bolus are listed below. Reference Attachment 1 for a complete list of labeling changes related to priming bolus as used on SynchroMed II Infusion Pumps.

- For a full system priming bolus: Based on the therapeutic index of the drug and the sensitivity of the patient, some individuals may need additional monitoring until the delivered drug reaches the intended concentration. Do not increase the programmed daily dose within the first 48 hours following a priming bolus as the delivered drug may not have reached the intended concentration during this time.
- For a full system priming bolus: Priming bolus default parameters have been carefully selected based on extensive modeling and testing. To ensure optimal initiation of therapy, modifications to these values are not recommended.
- The priming bolus function has not been characterized during intravascular administration of floxuridine (FUDR) and methotrexate; therefore dosing within the first 24 hours might be variable.

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. If you have questions, please contact your Medtronic Representative.

Sincerely,

Attachments:

- Important Labeling Updates Related to Priming Bolus with the SynchroMed® II Infusion System
- June 2013 – Urgent Field Safety Notice SynchroMed® Implantable Infusion Pump Priming Bolus