Urgent Field Safety Notice

Potential Display of Incorrect "Schedule to Replace the Pump By" Date for the SynchroMed® II Pump

IMPORTANT MEDICAL DEVICE INFORMATION

Medtronic ref : FA535

March 2012

Dear Healthcare Professional,

The purpose of this communication is to provide you with important information regarding the "Schedule to replace the pump by" date displayed on the Model 8840 N'Vision® physician programmer and printed reports, for the Model 8637 SynchroMed® II implantable drug infusion pump.

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. (See Figure 1)

- For an erroneous date to be displayed, the intended "Schedule to replace the pump by" date must occur on the first day of a month.
- **The display of an erroneous date DOES NOT impact pump function or alarms,** and the pump will continue to operate for 90 days* as described in product labeling until EOS is declared.

Background:
Upon reaching ERI, the SynchroMed II pump is designed to sound a non-critical single-tone alarm and continue to deliver drug therapy for 90 days*. Once ERI has occurred, interrogation of the SynchroMed II pump with the physician programmer will display the "Schedule to replace the pump by" date. Ninety (90) days* after ERI, the critical two-tone alarm sounds, which indicates EOS and the cessation of therapy delivery.

Clinical Manifestations:
Medtronic has confirmed that an algorithm used in the Model 8870 application card software has resulted in nine (9) occurrences of an incorrectly displayed "Schedule to replace the pump by" date. It is estimated that there are more than 140,000 SynchroMed II pump implants worldwide. A patient with a pump reaching EOS prior to replacement may experience the return of underlying symptoms and/or withdrawal symptoms. Intrathecal baclofen patients could experience baclofen withdrawal syndrome, which can be life threatening.

No adverse events have been reported for eight (8) of the confirmed cases, and one Intrathecal Baclofen Therapy (ITB) patient experienced decreased therapeutic effect with increased spasticity due to the pump reaching EOS prior to replacement. Refer to the product labeling for the drug being administered for information pertaining to discontinuation of drug delivery.

Recommendations:

- **Continue normal follow up schedule, and monitor the estimated number of months until ERI.** This information can be found on the Pump Status screen, the Alarms screen, and

in the Session or Print Reports (see Figure 2). myPTM® Model 8835 also indicates if the pump has reached ERI (Pump Alarm Screen, code 8615).

- **Follow labeled recommendations for pump replacement within 90 days* of ERI declaration.** To determine the ERI date, review the Pump Status screen and the Alarms screen (see Figure 3).

*A minimum of 90 days at rates up to 1.5 mL/day, between ERI activation and EOS, per device labeling.

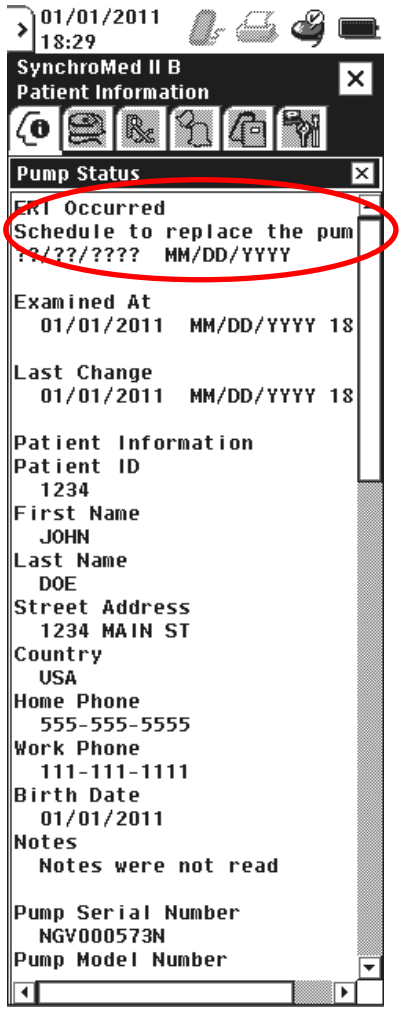
The Competent Authority of your country has been informed of this action.

We regret any difficulties this may cause you and your patients. If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative or Medtronic Technical Services at <xxxxx>

Sincerely,

Country BU Manager

Figure 1. Display of Incorrect “Schedule to Replace the Pump By” Date



Note: This example shows the incorrect date being displayed as “??/??/????”. It’s also possible for the incorrect date to be displayed as a date in the format “MM/DD/YYYY”.

Figure 2. Display of “Estimated ERI”

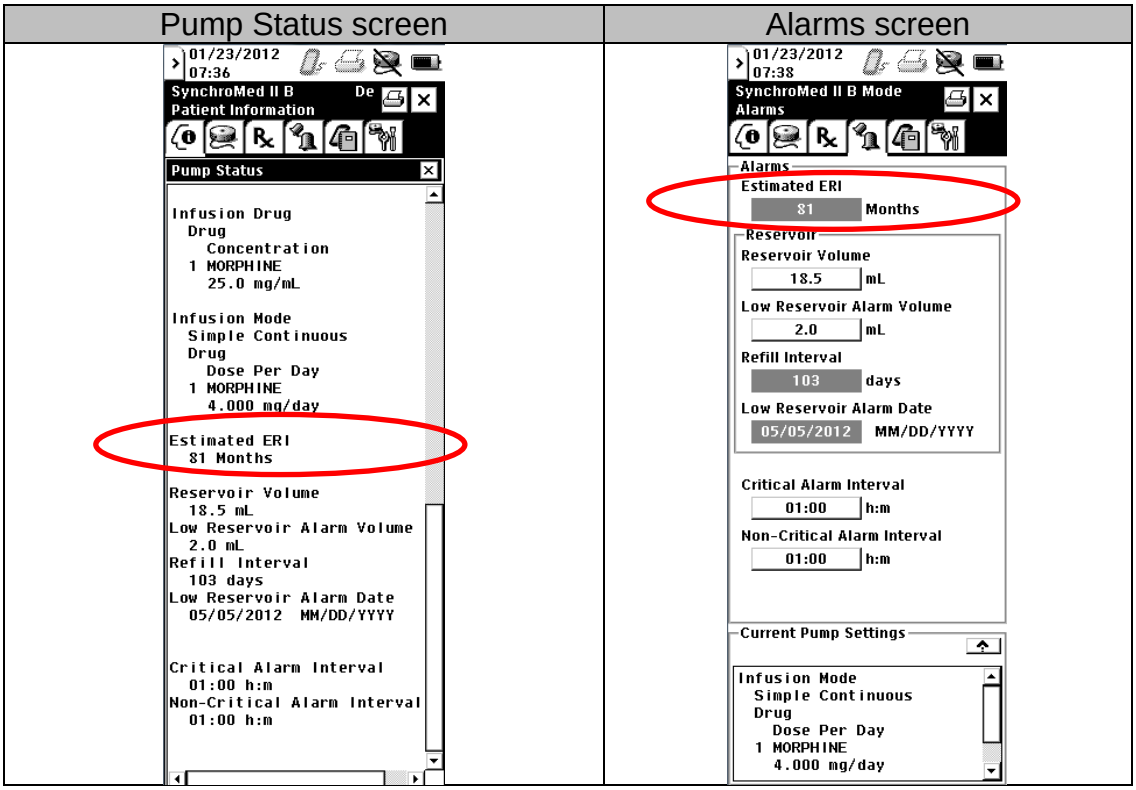


Figure 3. Display of “ERI Occurred”