Medtronic

Urgent Field Safety Notice Update

SynchroMed® II Implantable Drug Infusion Pump

Update to 2011 Notification, for Pumps Manufactured through June 2011

April 2017

Medtronic reference: FA760

Dear Healthcare Professional,

This notice provides an update to information previously communicated to physicians in July 2011 regarding the failure rate for reduced battery performance in Medtronic Model 8637 SynchroMed® II pumps manufactured through June 2011 (Medtronic reference FA522). This notice reinforces previously communicated patient management recommendations related to this issue. This notification does not apply to SynchroMed II devices currently being distributed or implanted or to any devices manufactured after June 2011. In Europe, Middle East and Africa Medtronic started distribution of SynchroMed II pumps with a new battery design that resolved this issue, in April 2011.

In July 2011, Medtronic issued a notification regarding the potential for sudden loss of therapy due to reduced battery performance from the formation of a resistive film in a small percentage of SynchroMed II pumps. Note: affected pumps were manufactured through June 2011; therefore, at this time all affected devices have been implanted at least 5 years.

The following website can be used to identify whether a pump may be affected by this issue based on its serial number: http://synchromed2battery.medtronic.com

Nature of the Device Issue:
For pumps manufactured through June 2011, reduced battery performance may be caused by the formation of a resistive film within the battery. This issue may result in Low Battery Reset (critical alarm), premature Elective Replacement Indicator (non-critical alarm), or premature End of Service (critical alarm). For affected pumps, the minimum timeframe of 90 days between Elective Replacement Indicator and End of Service may also be reduced.

Potential Severity of the Issue:
A patient with a pump exhibiting reduced battery performance may experience return of underlying symptoms and/or withdrawal symptoms. Patients receiving intrathecal baclofen therapy are at risk for baclofen withdrawal syndrome, which can lead to a life-threatening condition if not promptly and effectively treated. The July 2011 letter communicated that one patient death had been attributed to this issue, and it was determined to be due to baclofen withdrawal syndrome; there have been no additional deaths directly attributed to this issue. For potential severity of withdrawal information on other drugs, please refer to the product labeling for the drug being administered. Patients with pumps experiencing Low Battery Reset or premature Elective Replacement Indicator due to this issue will require surgical revision to replace or remove their pump.

Scope:
Model 8637 SynchroMed II pumps with batteries manufactured prior to the battery design change implemented in 2011.

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Updated Failure Rate Information[1]:

- **Pumps manufactured From March 2005 through December 2010:**
  0.13% cumulative probability for pump failure due to this issue (upper bound of 0.16%) at 72 months after implant. This rate remains within the failure rate upper bound of 0.2% that was reported in 2011.
- **Pumps manufactured with the previous battery design from January 2011 through June 2011**:
  3.17% cumulative probability for pump failure due to this issue (upper bound of 3.67%) at 72 months after implant. This failure rate exceeds the upper bound estimate of 0.2% that was reported in 2011.

Recommendations:

Medtronic does not recommend prophylactic replacement of SynchroMed II pumps with the prior battery design because of the estimated low occurrence rates, the presence of pump alarms, and the risks associated with replacement surgery. This position has been reviewed and is supported by an experienced external physician panel. However, appropriate consideration should be given to individual patient medical needs. When the critical or non-critical alarms noted below occur, Medtronic strongly recommends that replacement surgery be scheduled as soon as possible for these patients.

Refer to the enclosed *Pump Event Information* for: 1) a description of Low Battery Reset (critical alarm), Elective Replacement Indicator (non-critical alarm), and End of Service (critical alarm), and 2) screenshots depicting how events are displayed and reported with the N'Vision Model 8840 clinician programmer.

If Low Battery Reset (critical alarm) Occurs: **Replacement surgery should be scheduled as soon as possible.** Although you may be able to reprogram the pump, the issue may reoccur *at any time*. Alternative medical management should be considered if appropriate.

If premature Elective Replacement Indicator (non-critical alarm) or End of Service (critical alarm) occurs: **Replacement surgery should be scheduled as soon as possible.** In the case of premature Elective Replacement Indicator, the minimum timeframe of 90 days between Elective Replacement Indicator and End of Service may be reduced due to this battery issue. The date for scheduled replacement of the pump that is displayed on the Model 8840 N'Vision clinician programmer may not be accurate for those pumps experiencing reduced battery performance. Alternative medical management should be considered if appropriate. Elective Replacement Indicator may be considered premature if it occurs sooner than expected based on implant duration and flow rate.

Contact your Medtronic representative for assistance in determining if an Elective Replacement Indicator message can be considered premature.

Ongoing Patient Management Recommendations:

- Increase the critical alarm frequency to improve the probability of early identification of a Low Battery Reset (critical alarm) condition. Medtronic recommends changing the critical alarm interval frequency to sound every 10 minutes. Refer to the enclosed *Alarm Information* sheet for details.
- Remind patients, their caregivers, and your appropriate staff members to be alert for pump alarms. At implant or follow-up visits, perform an alarm test to provide an opportunity for patients and caregivers to hear and differentiate between the critical and non-critical pump alarms. Refer to the enclosed *Alarm Information* sheet for details. The alarm can be demonstrated with the 8840 Clinician Programmer or by using the following website:

  http://www.medtronic.com/us-en/patients/treatments-therapies/drug-pump-severe-spasticity/living-with/safety-pump-alarms.html

- Reinforce information on the signs and symptoms of withdrawal due to therapy cessation with patients and caregivers, and emphasize the importance of contacting their provider immediately.

[1] In addition, the July 2011 letter reported failure rates for pumps manufactured prior to March 2005; however, this population is beyond functional life of the device. These pumps are no longer in service.

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- Inform patients and caregivers about the importance of keeping their pump refill appointments and contacting their physician immediately if their pump alarm sounds or if they notice a change in symptoms. Remind patients to always carry their patient identification card.

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

Please share this notification with others in your organization as appropriate. In case of any questions related to this Urgent Field Safety Notice Update, contact your Medtronic Representative at <XXXX>.

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.

Sincerely,

Enclosures

1. Alarm Information Sheet
2. Pump Event Information

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Pump Event Information

SynchroMed® II Battery Performance

Event		What it means	Type of Alarm	Therapeutic Effect
Low Battery Reset	LBR	LBR occurs when battery voltage momentarily drops below 1.975 volts. If the voltage drop causes any data loss or corruption in pump memory, a *safe state** event will be triggered, resulting in infusion at the *minimum rate mode* of 6 microliters/day (0.006 milliliters/day) rather than the previously programmed rate. Although you may be able to reprogram the pump, the issue may reoccur *at any time.*	Critical	If safe state is triggered, the pump will go into minimum rate mode: 6 microliters/day (0.006 milliliters/day) rather than the previously programmed rate. The minimum rate mode in effect during a pump *safe state* is non-therapeutic and can result in loss of drug effect and drug withdrawal.
Elective Replacement Indicator	ERI	ERI activates when the pump nears the end of its service life (EOS). At ERI, the pump continues to infuse at the programmed rate.	Non-Critical	A normal pump will operate for a minimum of 90 days at rates up to 1.5 mL/day prior to EOS. In the case of premature ERI**, the minimum timeframe of 90 days between ERI and EOS may be reduced. This means that the date for scheduled replacement of the pump that is displayed on the N'Vision® Model 8840 clinician programmer may not be accurate.
End Of Service	EOS	EOS activation indicates the pump has reached the end of its service life. At EOS, the pump permanently stops infusing, but telemetry is available until the pump battery is depleted.	Critical	Pump will permanently stop delivering drug.

* Note: *safe state* does not mean a clinically safe rate of infusion. The minimum rate mode in effect during a pump *safe state* is non-therapeutic and can result in loss of drug effect and/or drug withdrawal. Patients receiving intrathecal baclofen therapy are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not promptly and effectively treated.

** Note: ERI may be considered premature if it occurs sooner than expected based on implant duration and flow rate. Contact Medtronic Technical Services (1-800-707-0933) for assistance determining if an ERI message can be considered premature.

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Low Battery Reset

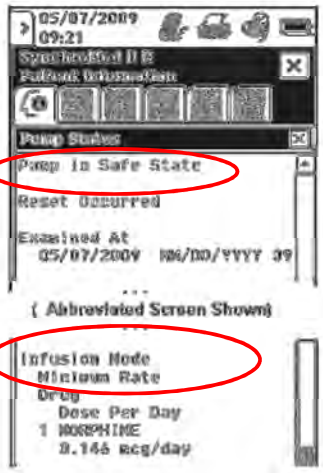
8840 N'Vision Programmer Screen

[Attention Dialog Box]

8840 Dialog Box –

Notification for reset to *safe state*

[Pump Status Screen]

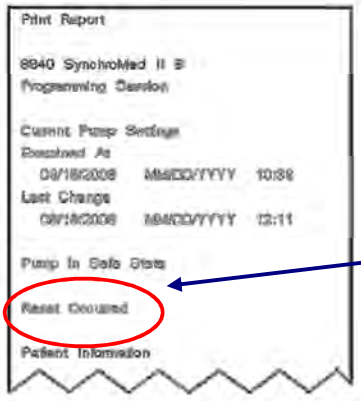


8840 Pump Status –

Shows pump in *safe state*, and Infusion mode at "Minimum Rate"

8840 N'Vision Programmer Printouts

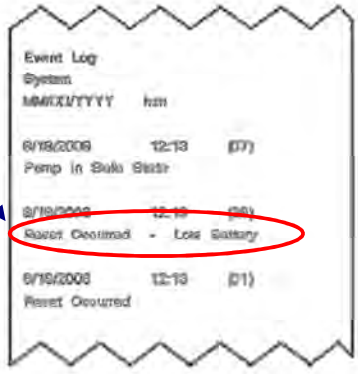
[Print Report]



Print Report --
Shows "Reset Occurred"

Event Log --
Specifies it was a Low Battery Reset

[Event Log]



Safe state does not mean a clinically safe rate of infusion. The minimum rate mode in effect during a pump *safe state* is non-therapeutic and can result in loss of drug effect and/or drug withdrawal.

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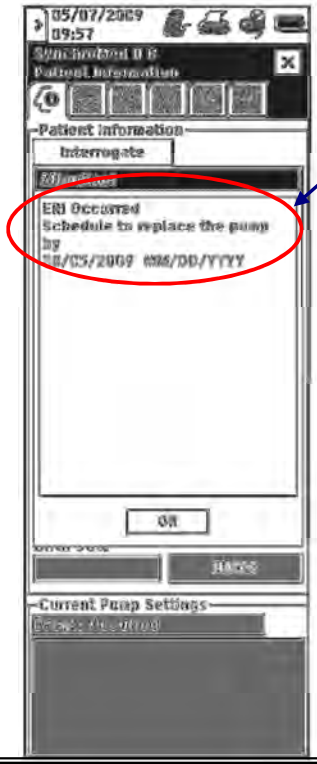
Elective Replacement Indicator

8840 N'Vision Programmer Screen

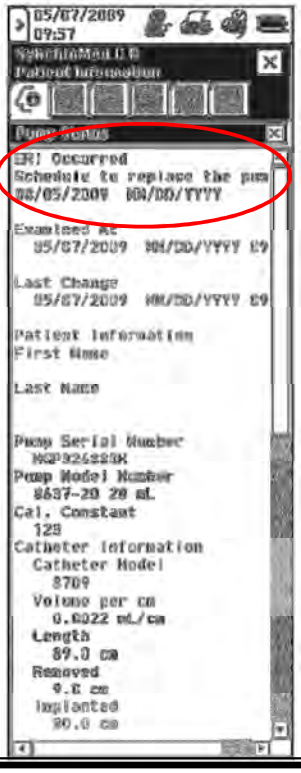
[Attention Dialog Box]



8840 Dialog Box –

Notification of ERI with calculated 90 day replacement date

[Pump Status Screen]

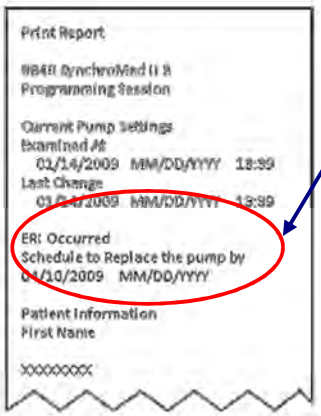


8840 Pump Status –

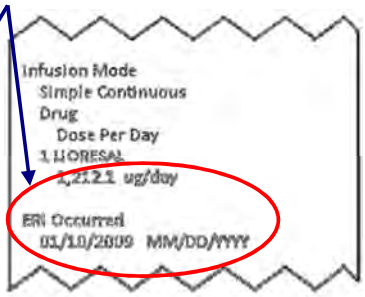
Shows ERI Occurred, and calculated 90 day window to EOS

8840 N'Vision Programmer Printouts

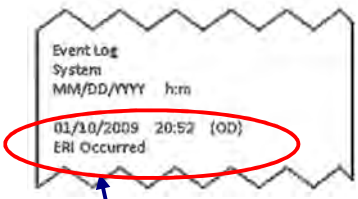
[Print Report]



Print Report --
Shows ERI Occurred, and calculated 90 day window to EOS



[Event Log]



Event Log --
Specifies ERI Occurred

The minimum timeframe of 90 days between ERI and EOS may be reduced in an affected pump; therefore the scheduled replacement date displayed on the *Print Report* may not be accurate.

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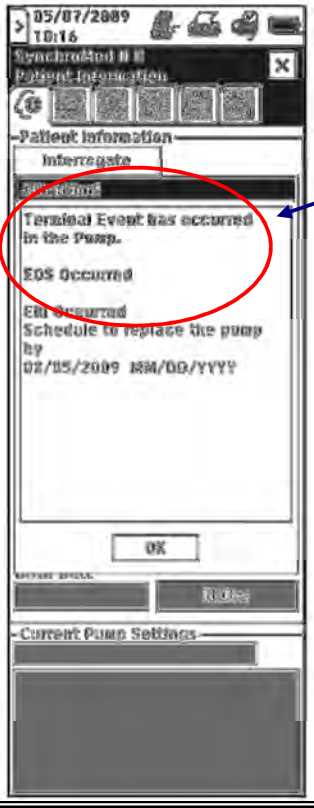
End of Service

8840 N'Vision Programmer Screen

[Attention Dialog Box]



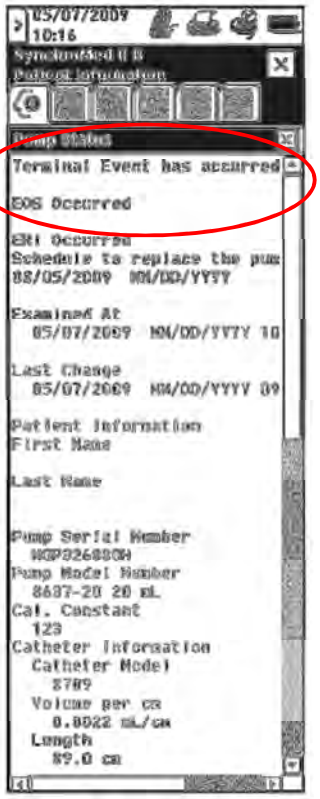
8840 Dialog Box –

Notification for *Terminal Event* and *EOS Occurred*

8840 Pump Status –

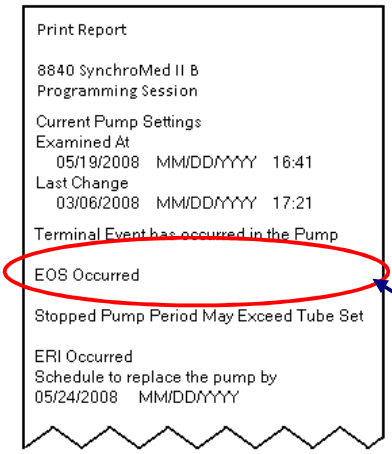
Notification for *Terminal Event* and *EOS Occurred*

[Pump Status Screen]



8840 N'Vision Programmer Printouts

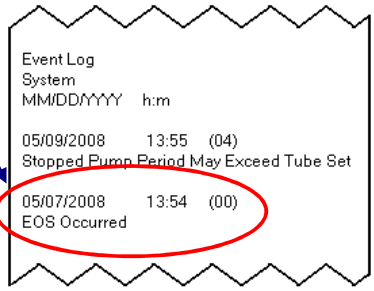
[Print Report]



Event Log **--**
Shows Date that the EOS event was triggered

Print Report **--**
Shows EOS Occurred

[Event Log]



At EOS, the pump stops infusing drug. This will result in loss of drug effect and/or potentially drug withdrawal. Telemetry is available until the pump battery is depleted.

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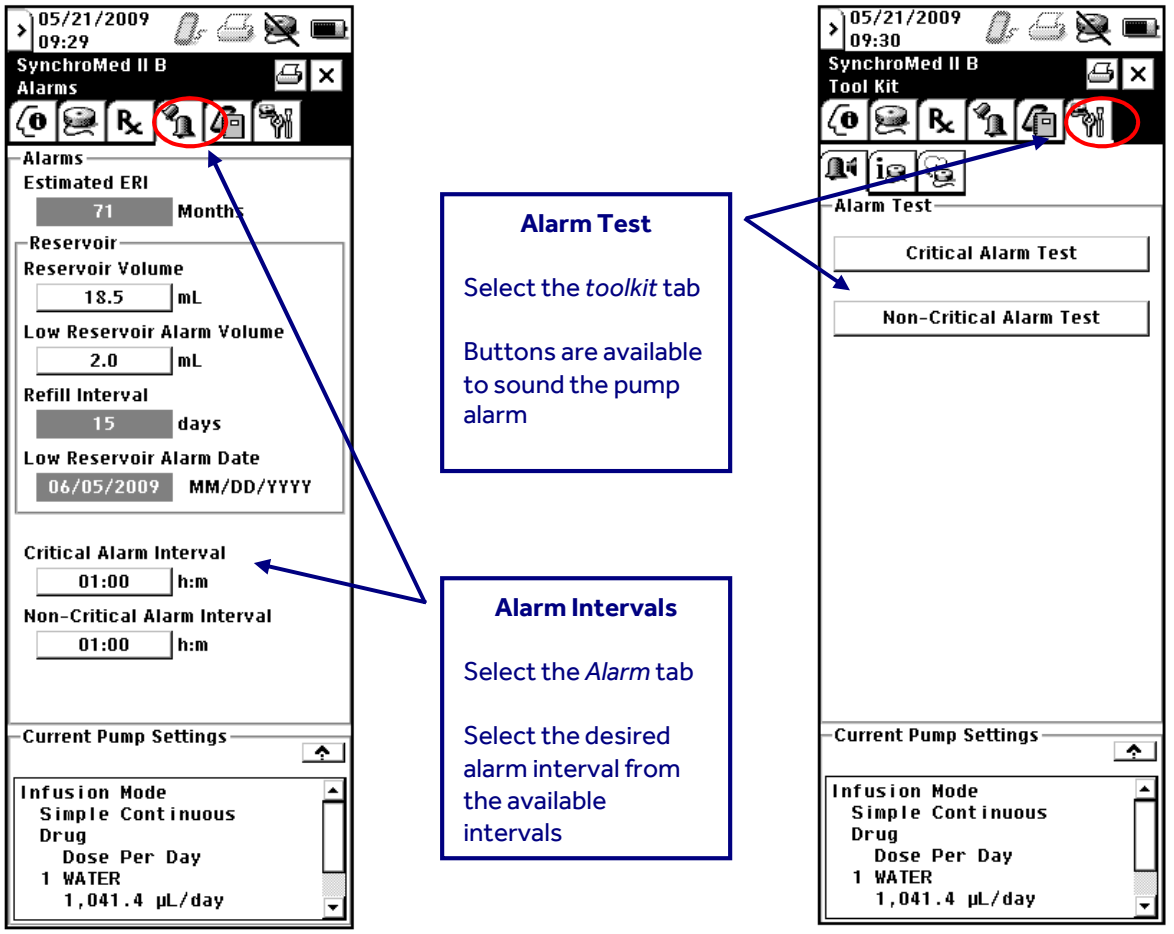
Alarm Information Sheet

SynchroMed® II Battery Performance

N'Vision® Model 8840 Clinician Programmer Screens



The pump has two different alarms, a **critical** (two tone) alarm and a **non-critical** (single tone) alarm.

Alarm Type	Alarm Sound	Alarm Meaning	Available Intervals
Critical	Two tone	Pump has stopped or will stop soon; immediate physician attention is needed	10 minute increments from 10 minutes to 2 hours
Non-critical	Single tone	Not as urgent; prompt physician attention is needed	1 hour increments from 1 to 6 hours