Medtronic

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www.medtronic.com

April 2017

Dear Healthcare Professional,

# *Battery Performance of the Model 8637 SynchroMed® II Implantable Drug Infusion Pump*

**Update to 2011 Notification, for Pumps Manufactured through June 2011**

Medtronic International Ltd, in consultation with the Health Sciences Authority (HSA), is issuing this letter to provide 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. This notice reinforces previously communicated patient managementk recommendations related to this issue. This notification does not apply to SynchroMed II devices currently supplied or to any previously implanted devices manufactured after June 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. In August 2011, Medtronic began distributing pumps with a new battery design that resolved this issue.

## Description of issue:

For pumps manufactured through June 2011, reduced battery performance is 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.

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.

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## Updated Information on the Issue:

Model 8637 SynchroMed II pumps with batteries manufactured prior to the design change in July 2011.

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 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.

## Advisory to Healthcare Professionals

***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.

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[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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***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.

***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.
- 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.

## Reporting of Adverse Event

Inform Medtronic Neuromodulation Technical Services if a battery performance issue is suspected. As always, Medtronic requests you return any explanted products to Medtronic Returned Products Analysis. If you have questions please contact your Medtronic field representative. This important patient management information is also available at http://professional.medtronic.com/pt/neuro/idd/ind/product-advisories.

Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to your local Clinical Representative Mr. Jason Ee at +65 9835 7526, Email: jason.ee@medtronic.com, Fax: +65-6776 6355. Alternatively, healthcare professionals may report the adverse events to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report

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online at www.hsa.gov.sg/ae_online. Events that are reported to Medtronic International Ltd will be investigated and subsequently reported to HSA.

Sincerely,

[redacted]

Yours Sincerely,
Shirley Loh
Marketing Director

Enclosures:

- *Appendix 1: Pump Event Information*
- *Appendix 2: Alarm Information Sheet*
- *Appendix 3 :Physician Reply Form*

CC: Chairman Medical Board and relevant Head of Department

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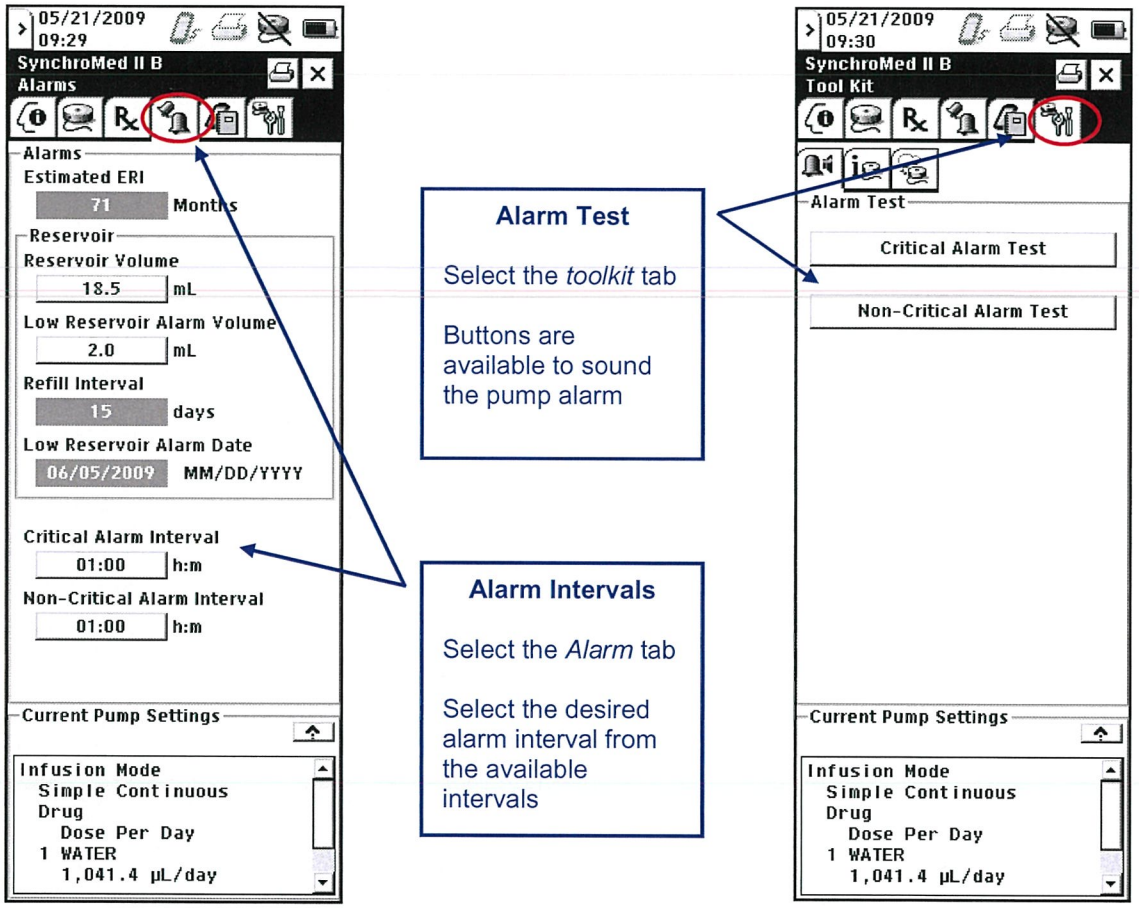
# Appendix 1: Alarm Information Sheet

## 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 |

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# Appendix 2: 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.<br><br>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.<br><br>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.<br><br>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]

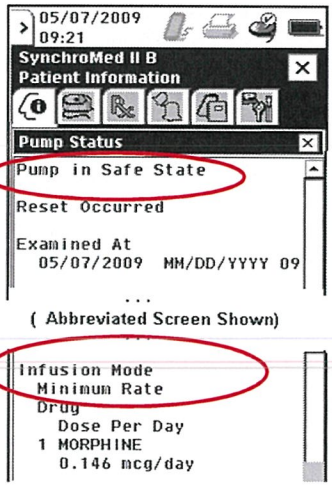

**8840 Dialog Box –**

Notification for reset to *safe state*

**8840 Pump Status –**

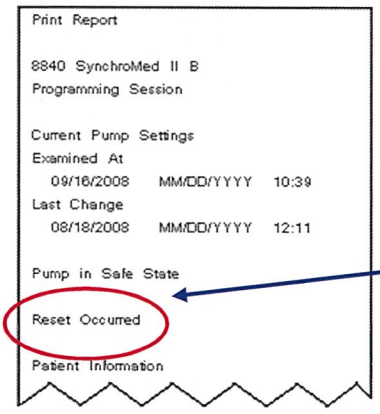
Shows pump in *safe state*, and Infusion mode at "Minimum Rate"

### [Pump Status Screen]




## 8840 N'Vision Programmer Printouts

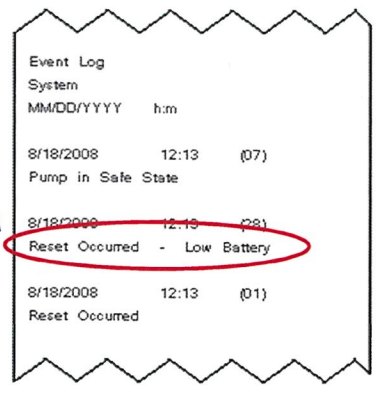
### [Print Report]




***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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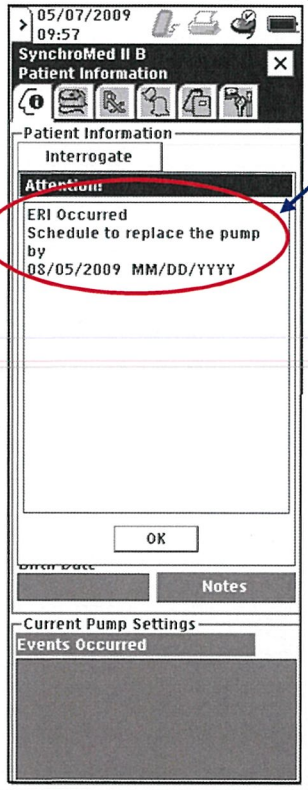
# Elective Replacement Indicator

## 8840 N'Vision Programmer Screen

### [Attention Dialog Box]



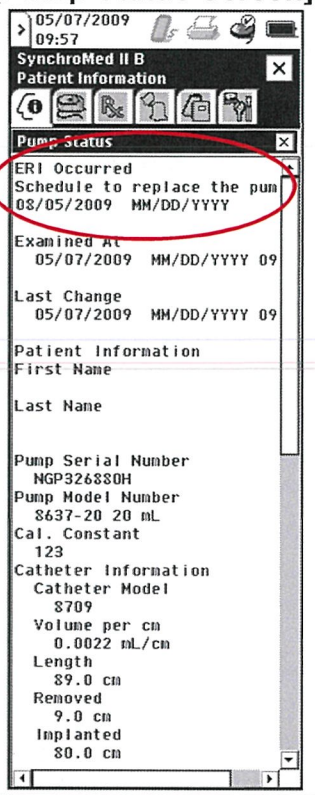

**8840 Dialog Box –**

Notification of ERI with calculated 90 day replacement date

**8840 Pump Status –**

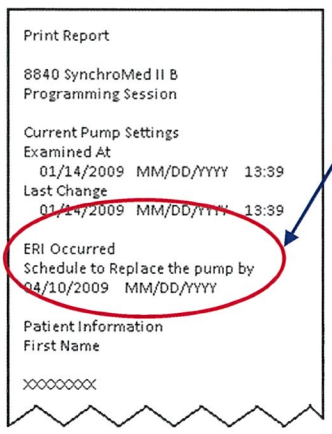
Shows ERI Occurred, and calculated 90 day window to EOS

### [Pump Status Screen]

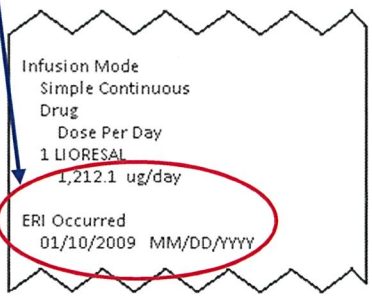



## 8840 N'Vision Programmer Printouts

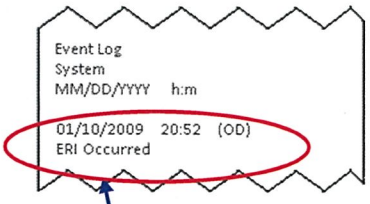
### [Print Report]




***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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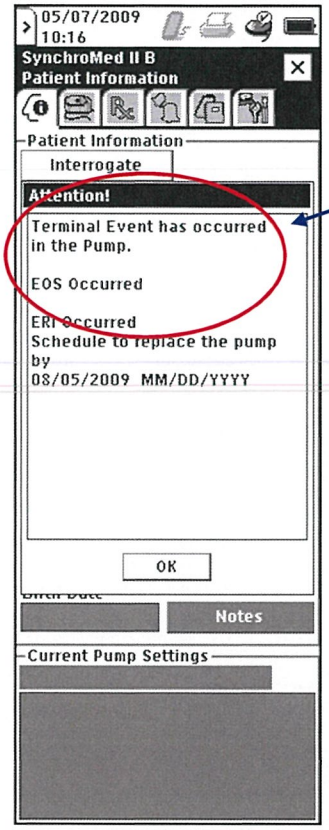
# End of Service

## 8840 N'Vision Programmer Screen

### [Attention Dialog Box]



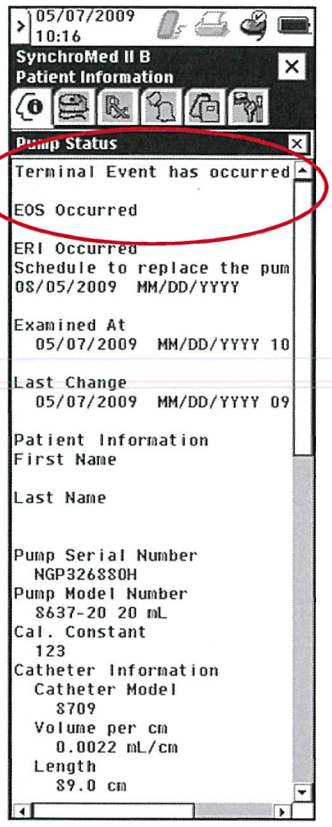

**8840 Dialog Box –**

Notification for *Terminal Event* and *EOS Occurred*

**8840 Pump Status –**

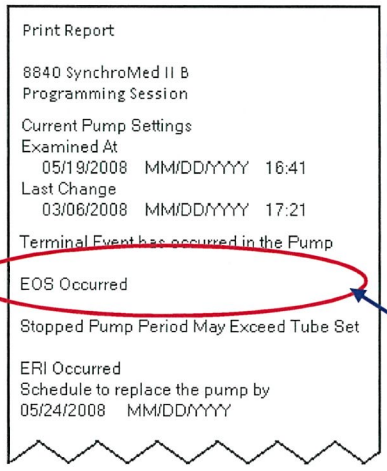
Notification for *Terminal Event* and *EOS Occurred*

### [Pump Status Screen]




## 8840 N'Vision Programmer Printouts

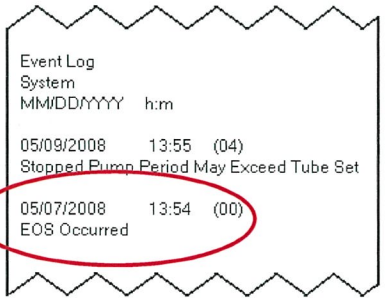
### [Print Report]




***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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# Appendix 3: PHYSICIAN / HCP REPLY FORM

## Important information regarding Battery Performance of the Model 8637 SynchroMed® II Implantable Drug Infusion Pump

April 2017

Dear Physician / Healthcare Professional,

According to our records, you are currently the managing physician for patients implanted with SynchroMed® II Implantable Drug Infusion Pump which was manufactured prior to August 2011.

Medtronic requires confirmation that you have received and understand the attached information regarding the SynchroMed® II Implantable Drug Infusion Pump device correction.

_____ _____

*Confirm physician name (please print)* *Facility Name and Stamp (please print)*

_____ _____

*Physician signature and stamp* *Date*

*Please sign and date this form and return it to Medtronic immediately, providing any corrections to your contact information. Thank you.*

Return this form (keep a copy for your records) to:

**POSTAL MAIL:**
Medtronic International Ltd., 49 Changi South Avenue 2, Singapore 486056

**FAX:**
+65 6776 6355