Urgent Medical Device Correction
SynchroMed® Implantable Infusion Pump Internal Shorting

Dear Healthcare Professional,

The purpose of this communication is to provide safety information and patient management recommendations related to the potential for electrical shorting internal to the SynchroMed infusion pump.

Nature of Device Issue:
Within the SynchroMed pump, feedthroughs are components that provide an electrically insulated path for current to flow from the electronic circuitry to the motor. An electrical short can occur when ions from the drug solution and humidity permeate through the drug pathway tubing inside the pump and interact with the feedthrough over time. An electrical short circuit in a feedthrough may present as a motor stall or low battery reset/alarm and lead to a loss of or reduction in therapy which may result in the return of underlying symptoms and/or withdrawal symptoms.

Scope and Likelihood of Issue:
All SynchroMed II and SynchroMed EL pumps can potentially be affected by this issue at any time throughout the life of the device, regardless of drugs used in the pump. The SynchroMed EL has been discontinued and based on Medtronic data, at least 90% of the remaining actively implanted SynchroMed EL pumps are near expected end of service.

Medtronic has assessed reports of internal feedthrough shorting in the SynchroMed II pump since its release in 2004. There have been 380 relevant product events from approximately 181,400 pump implants worldwide. Medtronic’s analysis of returned products and reports data shows the cumulative failure probability for internal feedthrough shorting to be approximately 0.28% at 48 months and 0.69% at 84 months post implant.

Severity:
SynchroMed pump internal feedthrough shorts can lead to a loss of or reduction in therapy which may result in a 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. Surgical revision to replace or remove the pumps may be required for patients with pumps experiencing repeated motor stalls, Low Battery Resets (with or without Safe State), or a premature Elective Replacement Indicator.

How to Identify Pumps Potentially Affected:
For SynchroMed II, this issue may be exhibited as one or more of the following:

- Repeated motor stalls with recovery listed in the pump event log, not associated with temporary exposure to a magnetic field (e.g. MRI).
- Multiple “Reset - Low Battery” errors (critical alarm) listed in the pump event log. After a reset, the pump may change to “Safe State”. While in Safe State, the pump does not deliver at a therapeutic rate.
- Premature Elective Replacement Indicator (non-critical alarm), which is one that occurs sooner than expected based on implant duration and flow rate.

For SynchroMed EL, this issue may be exhibited as one or both of the following:

- Motor Stall as determined by rotor study
- Low battery alarm
Recommendations:
Medtronic does not recommend prophylactic replacement of SynchroMed II or SynchroMed EL pumps due to the estimated low occurrence rate, the presence of pump alarms, and the risks associated with replacement surgery. However, appropriate consideration should be given to individual patient needs.

If repeated short duration motor stalls, Low Battery Resets (with or without Safe State), or a premature Elective Replacement Indicator occur, replacement surgery should be scheduled for therapy continuation. Alternative medical management should be considered if appropriate.

Ongoing Patient Management Recommendations:
- Continue to monitor patients closely for the return of baseline symptoms. A return of baseline symptoms may potentially indicate pump failure.
- Inform patients about the importance of keeping their pump refill appointments and contacting their physician immediately if the pump alarm sounds or if they notice a change or return of symptoms. Remind patients to always carry their patient identification card.
- Reinforce with patients and caregivers information on the signs and symptoms of withdrawal due to therapy cessation, and the importance of contacting their healthcare provider immediately if the identified signs and symptoms appear.
- The SynchroMed II pump is designed with both critical and non-critical alarms.
  - Increase the critical alarm interval frequency. The critical alarm interval frequency may be changed to sound every 10 minutes.
  - 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.
  - For patients with a Personal Therapy Manager (PTM), if there is an active alarm, the PTM will show an alarm code when a bolus is attempted.
  - Retrieve and check logs for critical alarm events when interrogating the SynchroMed II pump. Note that a motor stall with recovery is expected in the event log when the pump is exposed to a strong magnetic field, such as during an MRI. Medtronic Technical Services may be contacted for further assistance evaluating critical alarm events on logs.
- For the SynchroMed EL pump:
  - Remind patients, their caregivers, and your appropriate staff members to be alert for the low battery pump alarm.
  - For suspected motor stalls, perform a rotor study to confirm or rule out a motor stall.

Additional Information:
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. You can access product performance information at: http://professional.medtronic.com. If you have questions, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am - 6pm CST. Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services and to FDA’s MedWatch Program (www.fda.gov/medwatch).

Sincerely,

Mike Crader
Vice President Quality
Medtronic Neuromodulation

Enclosures: Pump Event and Alarm Information
### Pump Event Log Information

**SynchroMed® II**

<table>
<thead>
<tr>
<th>Event</th>
<th>What it means</th>
<th>Type of Alarm</th>
<th>Therapeutic Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motor Stall</td>
<td>The SynchroMed II pump detects motor stall and motor stall recovery. Motor stall events are recorded in the pump event log and can be reviewed using the clinician programmer. A motor stall will also cause the pump alarm to sound (two tone alarm). Intermittent motor stalls can be a precursor to a permanent motor stall.</td>
<td>Critical</td>
<td>Intermittent or permanent pump motor stalls may be reported as a loss of or change in therapy. Therapy changes could potentially result in serious injury and/or death.</td>
</tr>
<tr>
<td>Low Battery Reset</td>
<td>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.</td>
<td>Critical</td>
<td>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.</td>
</tr>
<tr>
<td>Elective Replacement Indicator</td>
<td>ERI activates when the pump nears the end of its service life (EOS). At ERI, the pump continues to infuse at the programmed rate.</td>
<td>Non-Critical</td>
<td>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.</td>
</tr>
</tbody>
</table>

* 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.
Motor Stall

Interrogate the pump using the clinician programmer and select the check box to download event logs (see Figure 1).

- If the event log states “Motor Stall Occurred” and “Motor Stall Recovery Occurred”, normal function of the pump has returned (see Figure 2).
- If the event log states “Motor Stall Occurred” and does not state “Motor Stall Recovery Occurred”, there is a motor stall which may be due to the feedthrough shorting issue. Contact Medtronic Technical services for further troubleshooting.

Intermittent or permanent pump motor stalls may be reported as a loss of or change in therapy. Therapy changes could potentially result in serious injury and/or death.
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”

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**8840 N’Vision Programmer Printouts**

- **[Print Report]**
  - Event Log -- Specifies it was a Low Battery Reset

- **[Event Log]**
  - Print Report -- Shows “Reset Occurred”

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*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.
Elective Replacement Indicator

8840 N’Vision Programmer Screen

[Attention Dialog Box]

8840 Dialog Box – Notification of ERI with calculated 90 day replacement date

[Event Log]

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 if feedthrough shorting occurs; therefore the scheduled replacement date displayed on the Print Report may not be accurate.
The pump has two different alarms, a **critical** (dual tone) alarm and a **non-critical** (single tone) alarm.

<table>
<thead>
<tr>
<th>Alarm Type</th>
<th>Alarm Sound</th>
<th>Alarm Meaning</th>
<th>Available Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Dual tone</td>
<td>Pump has stopped or will stop soon; immediate physician attention is needed</td>
<td>10 minute increments from 10 minutes to 2 hours</td>
</tr>
<tr>
<td>Non-critical</td>
<td>Single tone</td>
<td>Not as urgent; prompt physician attention is needed</td>
<td>1 hour increments from 1 to 6 hours</td>
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