Urgent: Medical Device Correction

Model 8637 SynchroMed® II Implantable Drug Infusion Pump
Battery Performance

Dear Healthcare Professional:

This letter provides important safety information and patient management recommendations related to the potential for reduced battery performance in a small percentage of Medtronic Model 8637 SynchroMed® II pumps with batteries manufactured during two distinct time periods prior to April 2005.

Nature of the Device Issue:
As part of ongoing analysis of returned explanted product, Medtronic has confirmed that reduced battery performance resulted in eight (8) occurrences of Low Battery Reset between 47 to 56 months implant duration, and one (1) occurrence of premature Elective Replacement Indicator (ERI) at 54 months implant duration. Of the eight (8) reports of Low Battery Reset (critical alarm), seven (7) were confirmed to have occurred when a bolus was given during priming or flex programming, which places additional demand on the battery. The single report of premature ERI (non-critical alarm) occurred during simple continuous drug delivery. Analysis of these pumps showed that the alarms were functional.

While root cause has not yet been fully identified, the issue involves formation of a film within the battery that impacts resistance and, therefore, battery voltage. Affected pumps may exhibit Low Battery Reset (critical alarm), premature ERI (non-critical alarm), or premature End of Service (critical alarm). Note that, for affected pumps, the minimum timeframe of 90 days between ERI and End of Service (EOS) may also be reduced. Bench test data to date show this reduced battery performance issue presenting as early as 42 months. Refer to the enclosed Pump Event Information for a description of Low Battery Reset, ERI, and EOS, along with how the Medtronic N’Vision® Model 8840 clinician programmer displays these events.

This issue could manifest itself clinically as a return of underlying symptoms and/or withdrawal symptoms. Furthermore, there may be the potential for complications due to withdrawal.

Scope:
Medtronic estimates that up to 312 (2.1 %) of approximately 14,852 SynchroMed II pumps worldwide may be at risk for this issue. Based on statistical analysis of the 9 returned devices, the cumulative probability for pump failure due to this issue is estimated to be 0.3% at 5 years post implant. Pumps in the affected population are those with batteries manufactured from April 2002 through July 2002, and from August 2003 through March 2005. The inclusion of a pump in the affected population does not necessarily mean that the pump will be impacted by this issue. For additional detail on SynchroMed II failure rates and survival analyses, refer to the enclosed Pump Survival document.

The enclosed Physician Patient Detail Report(s) identifies your patients who, according to our records, are implanted with a pump from the affected population. The following website can be used to identify (based on pump serial number) whether a specific SynchroMed II pump is potentially affected by this battery performance issue: http://synchromed2battery.medtronic.com.

Medtronic continues to monitor post market performance and analyze bench test data related to pumps already implanted as well as those currently being manufactured and distributed in order to determine whether any other populations may be impacted by this issue.
Potential Severity of the Issue:
Of the nine (9) confirmed events patients experienced return of underlying symptoms, withdrawal symptoms, and all have undergone surgical revision to replace or remove their pump. No patient deaths have been associated with these events. Complications associated with drug withdrawal are possible. Patients receiving intrathecal baclofen therapy (i.e., Lioresal® Intrathecal) are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not promptly and effectively treated. For information on other drugs, please refer to the product labeling for the drug being administered.

Recommendations:
Medtronic does not recommend prophylactic replacement of SynchroMed II pumps because of the estimated low occurrence rate, 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 critical or non-critical alarms occur, Medtronic strongly recommends prompt medical attention.

Refer to the enclosed Pump Event Information for a description of how the Low Battery Reset (critical alarm), ERI (non-critical alarm), and EOS (critical alarm), 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 an affected pump, the issue may reoccur at any time. Alternative medical management should be considered if appropriate. Please note that Low Battery Reset is not specific to this issue and can occur for other reasons. Regardless of the reason, occurrence of Low Battery Reset in a pump should prompt a pump replacement.

If premature ERI (non-critical alarm) or EOS (critical alarm) Occurs: Replacement surgery should be scheduled as soon as possible. In the case of premature ERI, the minimum timeframe of 90 days between ERI and EOS 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 pumps within the affected group due to the reduced battery performance issue. Alternative medical management should be considered if appropriate. 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.

Ongoing Patient Management Recommendations:

- Increase the critical alarm frequency for the potentially affected population to improve the probability of early identification of a Low Battery Reset (critical alarm) condition. The critical alarm interval frequency can be set to sound as frequently as every 10 minutes. Refer to the enclosed Alarm Information sheet for details.
- Remind patients, their caregivers, and your appropriate staff members to listen 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.
- Reinforce with patients and caregivers information on the signs and symptoms of withdrawal due to therapy cessation.

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Lioresal® is a registered trademark of Novartis Pharmaceuticals Corp.
• Refer to the enclosed Lioresal® Intrathecal (Baclofen Injection) Emergency Procedures sheet for patient management recommendations associated with baclofen withdrawal. Patients receiving intrathecal baclofen therapy (i.e. Lioresal® Intrathecal) are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not promptly and effectively treated.

• Inform patients 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.

• A sample patient informational letter is attached for your convenience, should you choose to use it.

Additional Information:
The US Food and Drug Administration (FDA) has been made aware of this SynchroMed II pump issue. Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services at 1-800-707-0933 and FDA’s MedWatch Program (www.fda.gov/medwatch).

We are committed to answering your questions and keeping you informed. Medtronic continues to investigate this issue and will provide you with an update if our recommendations change.

Refer to the enclosed Warranty and Replacement Cost Information for details on device warranty and medical expenses.

As always, Medtronic requests you return any explanted products to Medtronic Returned Products Analysis. If you have questions please contact your Medtronic field representative, or contact Medtronic Neuromodulation Technical Services at 1-800-707-0933. This important patient management information is also available at http://www.professional.medtronic.com under the heading Product Advisories.

Sincerely,

George Aram
Vice President Quality
Medtronic Neuromodulation

Enclosures:
• Pump Event Information
• Pump Survival
• Alarm Information Sheet
• Lioresal Emergency Procedures Sheet
• Sample Patient Letter
• Physician Patient Detail Report(s)
• Physician Reply Card
• Warranty and Replacement Cost Information