

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL09-24

August 6, 2009

- Item:** Medtronic SynchroMed II Implantable Drug Infusion Pump;
Models: 8637-20 and 8637-40.
- Specific Incident:** Medtronic issued an Urgent Medical Device Correction "Model 8637 SynchroMed II Implantable Drug Infusion Pump Battery Performance" in July 2009 (Attachment 1). Medtronic has documented eight reduced battery performance (low battery reset: a critical alarm) occurrences and one occurrence of premature elective replacement indicator (ERI: a non-critical alarm). The devices affected were manufactured from April 2002 through July 2002 and from August 2003 through March 2005.
- Of the nine confirmed events, all patients have experienced return of underlying symptoms and/or 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 become life threatening if not promptly and effectively treated. See Attachment # 5 for additional information.
- Additional Information:** Pump Event Information can be found in Attachment 2, Pump Survival data is in Attachment 3, details of the Alarm Information Sheet are in Attachment 4, Warranty & Cost Information are in Attachment 6, and the web site for serial number inquiry is in Attachment 7.
- Actions:**
1. By close of business (COB) August 07, 2009, the **Facility Director (or designee)** will ensure that all applicable Surgical, Medical and Pharmacy staff are made aware of this safety risk.
 2. By COB August 12, 2009, the **Surgical and Medical** staff must identify all affected patients and implement both of the following steps 2a and 2b. **Pharmacists** must implement step 2c. **Pain Management** staff must implement step 2d.

- a. Review the manufacturers letter (Attachment 1).
 - b. Review the *Physician Patient Detail Report* mailed July 7, 2009, from Medtronic listing their patients with an affected device to implement Action # 3 below. If you have not received the report, please contact Andrew Rennie at Medtronic Neuromodulation via email at andrew.j.rennie@medtronic.com. If necessary, Network (VISN) Patient Safety Officers (PSOs) should contact Tom Bauld at NCPS to access the list of affected patients.
 - c. **Pharmacists** shall review patient records for all patients receiving intrathecal baclofen, (Lioresal[®] Intrathecal) the most critical medication administered by the pump. This may also help to identify patients with Medtronic SynchroMed II pumps affected by this Alert that had been implanted at a non-VA facility. The list of identified patients shall be given to the physician writing the medication order so the physician can implement Action # 3 below.
 - d. **Pain Management staff and/or the Chief of Staff's office staff** shall attempt to identify those patients with pumps that are fee based to outside providers.
3. By COB August 18, 2009, **physicians/caregivers or designees** must contact affected patients and offer an appointment prior to August 18, 2009 and encourage the patient to come in for corrective action which includes the Patient Management Recommendations a) through d) contained in the manufacturer's letter (Attachment 1) and reproduced below. Documentation of the actions shall be placed in the patient's record.

Patient Management Recommendations:

- a. 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 *Alarm Information* sheet for details (Attachment 4).
- b. 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 *Alarm Information* sheet (Attachment 4) for details.

- c. Reinforce with patients and caregivers information on the signs and symptoms of withdrawal due to therapy cessation. Refer to the *Lioresal[®] Intrathecal (Baclofen Injection) Emergency Procedures* sheet (Attachment 5) 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.
 - d. 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.
4. By COB August 20, 2009, the **Patient Safety Manager** shall document the status of this Patient Safety Alert on the VHA Hazardous Recalls/Alerts website.
vaww.nbc.med.va.gov/visn/recalls/index.cfm.

Source: Medtronic

Attachments:

1. Urgent Medical Device Correction July 2009
2. Pump Event Information
3. Pump Survival
4. Alarm Information Sheet
5. Lioresal Emergency Procedure Sheet
6. Warranty and replacement Cost Information
7. Hyperlink and Device Identification Web Page

Contacts: Andrew Rennie, Medtronic Neuromodulation Quality Assurance: (763) 526-9738 or
Medtronic Technical Services: (800) 707-0933 or
Tom Bauld, VA National Center for Patient Safety (NCPS): (734) 930-5890



July 2009

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.

Attachment 1 Urgent: Medical Device Correction (cont)

July 2009

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 treated¹. 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.

¹ For complete product information refer to the Lioresal[®] Intrathecal (baclofen injection) Package Insert, Copyright Medtronic Inc. 2002
<http://www.medtronic.com/physician/itb/disclosure-package-insert.html> Lioresal[®] is a registered trademark of Novartis Pharmaceuticals Corp.

Attachment 1 Urgent: Medical Device Correction (cont)

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*



Pump Event Information

SynchroMed® II Battery Performance

Event		What it means	Type of Alarm	Therapeutic Effect
Low Battery Reset	LBR	<p>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 <i>safe state</i>* event will be triggered, resulting in infusion at the <i>minimum rate mode</i> of 6 microliters/day (0.006 milliliters/day) rather than the previously programmed rate.</p> <p><i>Although you may be able to reprogram the pump, the issue may reoccur at any time.</i></p>	Critical	<p>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.</p> <p>The minimum rate mode in effect during a pump <i>safe state</i> is non-therapeutic and can result in loss of drug effect and drug withdrawal.</p>
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	<p>A normal pump will operate for a minimum of 90 days at rates up to 1.5 mL/day prior to EOS.</p> <p><i>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.</i></p>
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.

** 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.



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]

Event Log --
Specifies it was a Low Battery Reset

Print Report --
Shows "Reset Occurred"

[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.



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.



End of Service

8840 N'Vision Programmer Screen

[Attention Dialog Box]

05/07/2009 10:16
SynchroMed II B
Patient Information
Interrogate
Attention!
Terminal Event has occurred in the Pump.
EOS Occurred
ERI Occurred
Schedule to replace the pump by 08/05/2009 MM/DD/YYYY

OK

[Pump Status Screen]

05/07/2009 10:16
SynchroMed II B
Patient Information
Pump Status
Terminal Event has occurred
EOS Occurred
ERI Occurred
Schedule to replace the pump 08/05/2009 MM/DD/YYYY
Examined At 05/07/2009 MM/DD/YYYY 10
Last Change 05/07/2009 MM/DD/YYYY 09
Patient Information
First Name
Last Name
Pump Serial Number NGP326880H
Pump Model Number 8637-20 20 mL
Cal. Constant 123
Catheter Information
Catheter Model 8709
Volume per cm 0.0022 mL/cm
Length 89.0 cm

8840 Dialog Box –
Notification for *Terminal Event* and *EOS Occurred*

8840 Pump Status –
Notification for *Terminal Event* and *EOS Occurred*

8840 N'Vision Programmer Printouts

[Print Report]

Print Report
8840 SynchroMed II B
Programming Session
Current Pump Settings
Examined At 05/19/2008 MM/DD/YYYY 16:41
Last Change 03/06/2008 MM/DD/YYYY 17:21
Terminal Event has occurred in the Pump
EOS Occurred
Stopped Pump Period May Exceed Tube Set
ERI Occurred
Schedule to replace the pump by 05/24/2008 MM/DD/YYYY

[Event Log]

Event Log
System
MM/DD/YYYY h:m
05/09/2008 13:55 (04)
Stopped Pump Period May Exceed Tube Set
**05/07/2008 13:54 (00)
EOS Occurred**

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

Print Report –
Shows EOS Occurred

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.



Pump Survival

SynchroMed® II Battery Performance

SYNCHROMED II PUMPS IN THE AFFECTED POPULATION

The graphs identified as *Figure 1* and *Figure 2* show cumulative survival probability for SynchroMed II pumps within the affected population of devices. These graphs were generated using US device registration and returned product analysis data.

Figure 1 shows the cumulative survival probability from this battery performance issue by length of implant time. As shown on the graph, within the affected population, SynchroMed II pumps show 99.7% survival from the battery performance issue 60 months post implant.

Figure 2 shows the cumulative survival probability from *all* failure modes by length of implant time. As shown on the graph, within the affected population, SynchroMed II pumps show 98.6% survival from all failure modes 60 months post implant.

Figure 1
Affected Population – Battery Issue Only
SynchroMed II Survival - Battery Performance

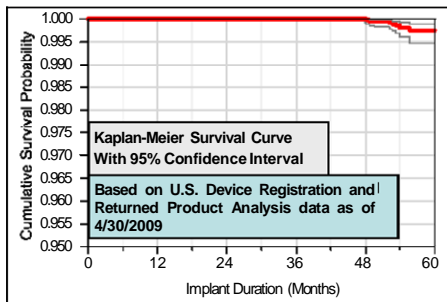
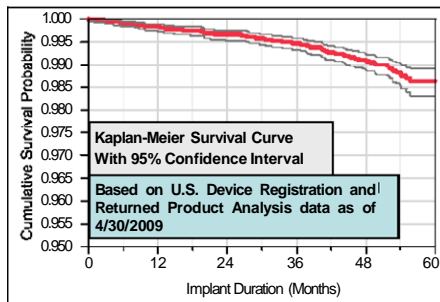


Figure 2
Affected Population – All Failure Modes
SynchroMed II Survival - All Failure Modes



SynchroMed® II pumps within the affected population continue to perform within reliability expectations.



Alarm Information Sheet

SynchroMed® II Battery Performance

N'Vision® Model 8840 Clinician Programmer Screens

Alarm Test

Select the *toolkit* tab

Buttons are available to sound the pump alarm

Alarm Intervals

Select the *Alarm* tab

Select the desired alarm interval from the available intervals

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

Alarm Type	Alarm Sound	Alarm Meaning	Available Intervals
Critical	Dual 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

Attachment 5 Lioresal Emergency Procedures Sheet

Lioresal® Intrathecal Underdose/ Withdrawal

In the U.S. emergency technical support is available 24 hours/day for clinicians managing patients with Medtronic SynchroMed® Infusion System implants: 800 707 0933. In other world areas contact your Medtronic representative.

EMERGENCY PROCEDURE

Symptoms of Underdose

Pruritus, hypotension, paresthesias, fever, and altered mental state.

Symptoms of Intrathecal Baclofen Withdrawal

High fever, altered mental status, exaggerated rebound spasticity and muscle rigidity that in rare cases has advanced to rhabdomyolysis, multiple organ system failure and death. The condition may resemble autonomic dysreflexia, sepsis, malignant hyperthermia, and neuroleptic-malignant syndrome.

Medtronic SynchroMed Infusion System

The SynchroMed Infusion System consists of an implantable programmable pump, intraspinal catheter and pump programmer. The pump is implanted in the lower abdomen and dispenses medication from its reservoir through the catheter to the intrathecal or epidural space. Some pumps are equipped with a catheter access port that bypasses the pump reservoir, permitting direct catheter access to the intrathecal or epidural space.

Suggested Treatment for Intrathecal Baclofen Underdose/Withdrawal

Initiate life-sustaining measures if indicated.

If a patient receiving ITB TherapySM (Intrathecal Baclofen Therapy) presents with the signs and symptoms suggestive of baclofen withdrawal (above), the following approach is consistent with that suggested by a panel of therapy-experienced clinicians convened to explore this issue: **1**

1. Immediately contact a physician experienced in ITB Therapy, preferably the physician managing the therapy for the patient in question; follow the recommendations of this physician. This step is important even if the patient's signs and symptoms seem mild.
2. If an ITB Therapy physician is unavailable, consider instituting one or more of the following options, unless otherwise contraindicated:
 - high-dose oral* or enteral baclofen
 - restoration of intrathecal baclofen infusion
 - intravenous benzodiazepines by continuous or intermittent infusion, titrating the dosage until the desired therapeutic effect is achieved

*Note: Oral baclofen should not be relied upon as the sole treatment for intrathecal baclofen withdrawal syndrome.

Report incident to Medtronic, Inc. In the U.S. call 1-800-707-0933. In other world areas contact your Medtronic representative.

The physician experienced with ITB Therapy should expeditiously attempt device troubleshooting. This may include, but is not limited to:

- interrogation of the pump status using the Medtronic pump programmer
- radiologic examination of the pump and catheter system
- a pump refill procedure with the appropriate concentration of baclofen
- system troubleshooting procedures to determine the cause of ITB Therapy interruption
- surgical repair, revision, or replacement of system components

Baclofen withdrawal has been identified during post-approval use of Lioresal® Intrathecal (baclofen injection). Because this reaction is reported spontaneously from a population of uncertain size, it is not possible to reliably estimate the frequency.

Abrupt withdrawal of intrathecal baclofen, regardless of the cause, has, in rare cases, resulted in a life-threatening syndrome that included high fever, altered mental status, exaggerated rebound spasticity and muscle rigidity that progressed to rhabdomyolysis, multiple organ-system failure, and death.

All patients receiving ITB Therapy are potentially at risk. Some clinical characteristics of the advanced intrathecal baclofen withdrawal syndrome may resemble autonomic dysreflexia, or infection (sepsis), malignant hyperthermia, neuroleptic-malignant syndrome, and other conditions associated with a hypermetabolic state or widespread rhabdomyolysis. **A rapid and accurate diagnosis is important in an emergency room or intensive care setting before initiating treatment in order to prevent the potentially life-threatening central nervous and systemic effects of intrathecal baclofen withdrawal.**

Contact Information

ITB TherapySM Physician

Name:

Phone:

City:

State:

Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.

¹Coffey RJ, Edgar TS, Francisco GE, et al. Abrupt withdrawal from intrathecal baclofen: recognition and management of a potentially life-threatening syndrome. *Arch Phys Med Rehabil*: Vol. 83. June, 2002. pp735-41
Lioresal® is a registered trademark of Novartis Pharmaceuticals Corporation.



UC200303503aEN NP5676aEN PN221500-101

Attachment 5 Lioresal Emergency Procedures Sheet (cont)

Lioresal® Intrathecal Overdose

In the U.S. emergency technical support is available 24 hours/day for clinicians managing patients with Medtronic SynchroMed® Infusion System implants: 800 707 0933. In other world areas contact your Medtronic representative.

EMERGENCY PROCEDURE

Symptoms of Overdose

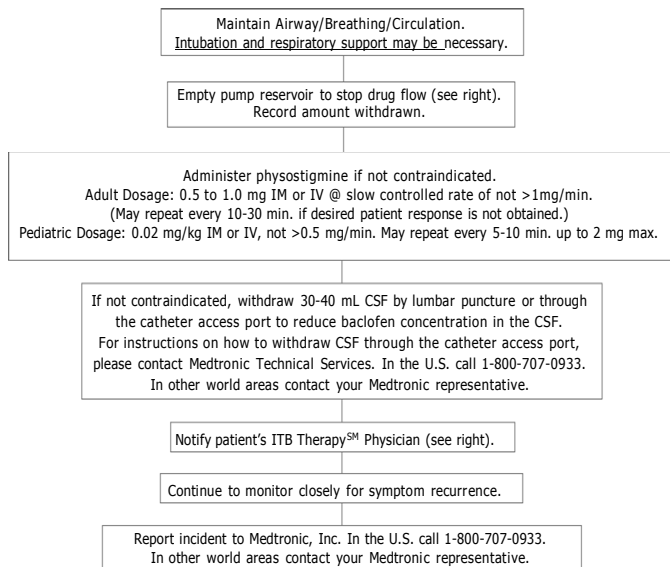
Drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia and loss of consciousness progressing to coma.

There is no specific antidote for treating overdoses of Lioresal® Intrathecal (baclofen injection). However, anecdotal reports suggest that intravenous physostigmine may reverse central side effects, notably drowsiness and respiratory depression.²

Medtronic SynchroMed Infusion System

The SynchroMed Infusion System consists of an implantable programmable pump, intraspinal catheter and pump programmer. The pump is implanted in the lower abdomen and dispenses medication from its reservoir through the catheter to the intrathecal or epidural space. Some pumps are equipped with a catheter access port that bypasses the pump reservoir, permitting direct catheter access to the intrathecal or epidural space.

Suggested Treatment for Intrathecal Baclofen Overdose

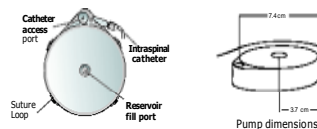


Medtronic SynchroMed Pump Descriptions

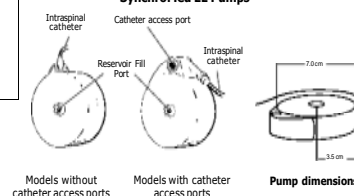
Pump Name	Model	Catheter Access Port?	Reservoir Size
SynchroMed II	8637-40	Yes, funnel-shaped	40 mL
SynchroMed II	8637-20	Yes, funnel-shaped	20 mL
SynchroMed EL	8627-18, 8627L-18*	Yes, screened	18 mL
SynchroMed EL	8627-10, 8627L-10*	Yes, screened	10 mL
SynchroMed EL	8626-18, 8626L-18*	No	18 mL
SynchroMed EL	8626-10, 8626L-10*	No	10 mL
SynchroMed	8618-18, 8618L-18*	Yes, not screened	18 mL
SynchroMed	8617-18, 8617L-18*	Yes, screened	18 mL
SynchroMed	8617-10	Yes, screened	10 mL
SynchroMed	8616-18	No	18 mL
SynchroMed	8616-10	No	10 mL

*L=pump contains suture loops

SynchroMed II Pumps



SynchroMed EL Pumps



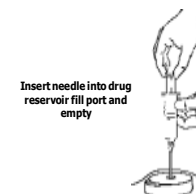
Emergency Procedure to Empty the Pump Reservoir

Equipment:

- 22-gauge or smaller needle (1.5 in./3.8 cm or 2 in./5.1 cm)
- 20 mL luer-lock syringe
- antiseptic agent

1. Locate the pump (right or left abdomen) by palpation. Pump diameter is approximately 3 in./7 cm. The reservoir fill port is located in the CENTER of the pump.

1. Prepare injection site by cleansing area using an antiseptic agent; allow skin to dry.
2. Locate reservoir fill port and insert needle through skin. Enter the port's septum until the needle touches the metal needle stop. If you encounter resistance during needle insertion, reassess placement. Do not force the needle; use of excessive force may damage the needle.
3. Withdraw fluid from reservoir using negative pressure. Empty reservoir until large air bubbles are apparent in syringe.
4. Maintain negative pressure while removing needle and attached syringe together from port septum and skin.
5. Record amount of fluid emptied from reservoir in patient chart.



Contact Information

ITB TherapySM Physician

Name: _____ Phone: _____
City: _____ State: _____

Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.
Müller-Schwefe G., Penn R.D. Physostigmine in the treatment of intrathecal baclofen overdose: report of three cases. *J Neurosurg.* August, 1989; 71:273-5.
Lioresal® is a registered trademark of Novartis Pharmaceuticals Corporation.



UC20030503aENNP5678aENPN21500-101



Warranty and Replacement Cost Information

SynchroMed II Battery Performance

SUPPLEMENTAL LIMITED WARRANTY

Pump Replacement for U.S. Patients

SynchroMed® II Battery Performance

A. This Supplemental Limited Warranty is incorporated in and made part of the Limited Warranty issued with Medtronic SynchroMed II Implantable Infusion Pump Models 8637-20 and 8637-40 (hereinafter collectively referred to as "Pump"). Subject to the conditions in Section B below:

(1) Should the Pump fail within six years after the date of the Pump's implant to function due to reduced battery performance, as confirmed by Medtronic by returned product analysis, and be replaced with a functionally comparable Medtronic pump (a "Replacement Pump"), Medtronic will issue to the purchaser of the Replacement Pump a pro-rated credit against such purchase in an amount equal to a percentage of the net invoiced price of the Replacement Pump (the "Purchase Price"), as follows:

<u>Implant Duration of Explanted Pump</u>	Credit
4 years or less	100% of Purchase Price
4 years and 1 day to 5 years	50% of Purchase Price
5 years and 1 day to 6 years	25% of Purchase Price

(2) For purposes of this Supplemental Limited Warranty, "reduced battery performance" means the formation of a film within the Pump battery that impacts resistance and, therefore, battery voltage.

B. To qualify for this Supplemental Limited Warranty, these conditions must be met:

- (1) The explanted Pump serial number must be included on Medtronic's list of affected devices.
- (2) The explanted Pump must have been implanted prior to its "Use By" date.
- (3) All device registration materials must have been completed and returned to Medtronic within thirty (30) days of implant of the original Pump and of the Replacement Pump, respectively.
- (4) The explanted Pump must be returned to Medtronic within thirty (30) days of explant and shall be the property of Medtronic.
- (5) The use of medication with the explanted Pump must have been in accordance with the technical manual shipped with the Pump.
- (6) The patient must have received the explanted Pump and the Replacement Pump in the U.S.

C. This Supplemental Limited Warranty is limited to its express terms. In particular:

- (1) Except as expressly provided by this or any other applicable Supplemental Limited Warranty, no provision of the Limited Warranty is amended or modified.
- (2) Pump battery cell depletion is normal and expected and will occur with time. The batteries have a specified capacity that may deplete at different rates depending on usage. Normal battery cell depletion is not considered to be a defect in materials or workmanship.



Warranty and Replacement Cost Information

SynchroMed II Battery Performance

- (3) Except as expressly provided by the Limited Warranty or any applicable Supplemental Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE PUMP TO FUNCTION WITHIN NORMAL TOLERANCES WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.
- (4) This Supplemental Limited Warranty is made only to the patient in whom the Pump was implanted. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO SUCH EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE CIRCUMSTANCES SPECIFIED ABOVE. THE LIMITED WARRANTY AND ANY APPLICABLE SUPPLEMENTAL LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDIES AVAILABLE TO ANY PERSON.
- (5) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part of the term of this Supplemental Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Supplemental Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Supplemental Limited Warranty did not contain the particular part or term held to be invalid. This Supplemental Limited Warranty gives the patient specific legal rights. The patient may also have other rights which vary from state to state.
- (6) No person has any authority to bind Medtronic to any representation, condition, or warranty, except the Limited Warranty and any applicable Supplemental Limited Warranty.

This Supplemental Limited Warranty is provided by Medtronic, Inc., 710 Parkway, Minneapolis, Minnesota 55432. It applies only within the United States.

Attachment 6 Warranty Replacement Cost Information (cont)



Warranty and Replacement Cost Information

**SynchroMed II Battery Performance SUPPLEMENTAL LIMITED WARRANTY
Unreimbursed Expenses for U.S. Patients
SynchroMed® II Battery Performance**

D. This Supplemental Limited Warranty is incorporated in and made part of the Limited Warranty issued with Medtronic SynchroMed II Implantable Infusion Pump Models 8637-20 and 8637-40 (hereinafter collectively referred to as "Pump"). Subject to the conditions in Section B below:

- (1) Should the Pump fail to function due to reduced battery performance, as confirmed by Medtronic by returned product analysis, Medtronic will pay, for the benefit of the patient, up to one thousand dollars (\$1,000.00) of reasonable and customary, unreimbursed expenses incurred in connection with surgical procedures taken to explant the Pump.
- (2) For purposes of this Supplemental Limited Warranty, "reduced battery performance" means the formation of a film within the Pump battery that impacts resistance and, therefore, battery voltage.

E. To qualify for this Supplemental Limited Warranty, these conditions must be met:

- (2) The Pump serial number must be included on Medtronic's list of affected devices.
- (3) The Pump must have been implanted prior to its "Use By" date.
- (4) The explanted Pump must be returned to Medtronic within thirty (30) days of explant and shall be the property of Medtronic.
- (5) The use of medication with the Pump must have been in accordance with the technical manual shipped with the Pump.
- (6) This coverage applies for expenses that remain after the patient's medical bills have been submitted to and paid by insurance or other medical expense plan, provided such expenses are adequately documented with receipts or other documentation acceptable to Medtronic.
- (7) The patient must have received the Pump in the U.S.

F. This Supplemental Limited Warranty is limited to its express terms. In particular:

- (7) Except as expressly provided by this or any other applicable Supplemental Limited Warranty, no provision of the Limited Warranty is amended or modified.
- (8) Pump battery cell depletion is normal and expected and will occur with time. The batteries have a specified capacity that may deplete at different rates depending on usage. Normal battery cell depletion is not considered to be a defect in materials or workmanship.
- (9) Except as expressly provided by the Limited Warranty or any applicable Supplemental Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE PUMP TO FUNCTION WITHIN NORMAL TOLERANCES WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

Attachment 6 Warranty Replacement Cost Information (cont)



Warranty and Replacement Cost Information

SynchroMed II Battery Performance

- (10) This Supplemental Limited Warranty is made only to the patient in whom the Pump was implanted. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO SUCH EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE CIRCUMSTANCES SPECIFIED ABOVE. THE LIMITED WARRANTY AND ANY APPLICABLE SUPPLEMENTAL LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDIES AVAILABLE TO ANY PERSON.
- (11) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part of the term of this Supplemental Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Supplemental Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Supplemental Limited Warranty did not contain the particular part or term held to be invalid. This Supplemental Limited Warranty gives the patient specific legal rights. The patient may also have other rights which vary from state to state.
- (1 2) No person has any authority to bind Medtronic to any representation, condition, or warranty, except the Limited Warranty and any applicable Supplemental Limited Warranty.
- (13) This Supplemental Limited Warranty is provided by Medtronic, Inc., 710 Parkway, Minneapolis, Minnesota 55432. It applies only within the United States.

Attachment 7 Hyperlink and Device Identification Web Page

<http://synchronomed2battery.medtronic.com>

You Have Just Entered The
Device Identification Web Page
Synchronomed® II Battery Performance

Urgent: Medical Device Correction

Dated July 2009

You may use this web page to determine whether a specific Medtronic Synchronomed II pump is part of the affected population of devices that are potentially at risk for reduced battery performance as described in Medtronic's physician letter dated July 2009.

Models 8637-20, 8637-40

Enter serial number into search function box: Example: NGV123456H	<input type="text"/>	<input type="button" value="Search"/>	Note: Serial number must be entered accurately and exactly or search will not work properly.
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To determine whether any Medtronic Synchronomed II pump is within the affected population for the Battery Performance issue:

1. Type the serial number of the Medtronic device in the search box above. The serial number must be typed in accurately and exactly in the format shown in the example - with three alpha characters followed by six numeric digits and one alpha character. Do not include any spaces. Example: NGV123456H
2. If the serial number falls within the population of pumps that are potentially at risk for the battery performance issue, the serial number will appear in a box and will state that *"the serial number you entered is in the affected population of devices"*.
NOTE: The inclusion of a pump in the affected population does not necessarily mean that the pump will be impacted by the issue. Refer to Medtronic's physician letter dated July 2009 for Medtronic's patient management recommendations.
3. If the serial number does not fall within the affected population, the serial number will appear in a box and will state that *"the serial number you entered is not in the affected population of devices"*.

Note: To obtain accurate and reliable results, you must enter the serial number accurately. If you have questions about the results of your search or the use of this web page, please contact your Medtronic representative.