August 2008

Urgent Field Safety Notice

Important Information on Potential MRI Effects

SynchroMed EL (Models 8626, 8627) and SynchroMed II (Model 8637) implantable infusion pumps

Medtronic reference: FA403

Dear Healthcare Professional,

This letter contains important safety information regarding MRI (magnetic resonance imaging) effects on the SynchroMed EL (Models 8626, 8627) and SynchroMed II (Model 8637) implantable infusion pumps.

As stated in our product labeling, the magnetic field of an MRI will temporarily stop the rotor of the pump motor and suspend drug infusion for the duration of MRI exposure for all SynchroMed pumps. The pump should resume normal operation when removed from the MRI magnetic field; however, new information has been identified related to the following MRI effects:

- There is the potential for a delay in the return of proper drug infusion after an MRI (this affects all SynchroMed pumps).
- There is the potential for a delay in the logging of motor stall events after an MRI (this only affects SynchroMed II pumps).

Please carefully review the new safety information below related to MRI effects on SynchroMed pumps. Medtronic is in the process of updating the product labeling with this information. and once this is complete, will be sending pump patients updated identification cards with information on how to obtain MRI safety information.

Severity of the Issues:

- We have received nine reports of a delay in return of proper pump infusion after MRI, relatively evenly distributed from 2005 to present. The reported occurrence rate for this issue is 0.014 % of all pumps sold worldwide. These nine reported events indicate that the delay in proper pump infusion after MRI ranged from two to 24 hours. No deaths or permanent patient injuries have been reported due to this pump MRI effect. Patients reported either no symptoms, or a return of underlying symptoms with this issue. Complications associated with drug withdrawal are possible, but have not been reported to date. Patients receiving intrathecal baclofen therapy (e.g. Lioresal® Intrathecal) are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively[1]. For information on other drugs, please refer to the product labeling for the drug being administered.

- We have received 70 reports of a delay in the logging of motor stall events after MRI, relatively evenly distributed from 2005 to present. The reported occurrence rate for this issue is 0.11 % of all pumps sold worldwide. No deaths or permanent patient injuries have been reported due to this pump MRI effect. There has been one report of device explant related to this event logging issue. When this logging delay occurs, there is the potential that the pump may indicate that it ceased drug delivery for an extended period of time, when in fact it had recovered drug infusion normally. The patient risk for this issue is the potential for unnecessary surgery, along with the associated surgical

[1] For complete product information refer to the Lioresal® Intrathecal (baclofen injection) Package Insert.

risks if the managing physician were to believe the pump was not infusing properly based on the event logs. If the device event log shows an extended motor stall during the post MRI interrogation, the patient should be carefully evaluated with respect to the signs and symptoms of therapy cessation. Additionally, the pump reservoir volume can be measured and compared to the expected volume to assess whether there has been a significant therapy disruption.

Patient Management Recommendations:

Review the enclosed *New Information Regarding Potential MRI Effects* document in order to fully understand the new information related to potential effects of MRI exposure on the SynchroMed pump.

Prior to MRI Scan Procedure:

As stated in the product labeling, prior to MRI, the physician should determine if the patient could safely be deprived of drug delivery during the MRI procedure. If the patient cannot be safely deprived of drug delivery, medical supervision and alternative delivery methods for the drug can be used during the time required for the MRI scan.

Following MRI Scan Procedure:;

A patient's pump must be interrogated after MRI exposure in order to confirm proper pump functionality.

- Patients implanted with SynchroMed EL pumps:
  - As stated in the product labeling, the SynchroMed EL pump does not detect or alarm for motor stalls.
  - A clinician should confirm a SynchroMed EL pump has resumed proper infusion after an MRI by performing a pump roller study (refer to the enclosed document for instructions on performing a pump roller study). If a pump roller study can not be performed, patients must be closely monitored for return of underlying symptoms to confirm the pump has resumed proper infusion after an MRI.
  - A clinician must interrogate the SynchroMed EL pump after an MRI scan to determine if electromagnetic interference impacted the pump programming. If interrogation shows that the MRI scan caused a "Pump Memory Error" the clinician must reprogram the pump in order for proper infusion to resume.

- Patients implanted with SynchroMed II pumps:
  - Physicians must confirm that therapy has properly resumed after MRI exposure by interrogating the pump with the clinician programmer. For detailed stall detection and interrogation information, refer to the attached *Post MRI Interrogation Guidelines.*
    - Detection of a motor stall, recording of the motor stall in the pump event log, and the audible motor stall alarm will all typically occur within 20 minutes of MRI exposure (for pumps programmed to deliver at least 0.048 ml/day).
    - Detection of motor stall *recovery* and recording of the recovery in the pump event log will typically occur within 20 minutes of the removal of the pump from the magnetic field of the MRI (for pumps programmed to deliver at least 0.048 ml/day).

Detection of a *motor stall* and detection of *motor stall recovery* may each take up to 90 minutes if the pump is programmed to minimum rate mode (0.006 ml/day).

- In some cases, the SynchroMed II pump event log may not register motor stall recovery until after the pump has been interrogated a second time due to the effect of Electromagnetic Interference (EMI) on the pump.
- Medtronic does not recommend programming the SynchroMed II pump to "stopped pump mode" prior to an MRI because of the possibility of an increased delay in the detection of an extended motor stall.
- If EMI from the MRI scan caused a change to “safe state” the clinician must reprogram the pump in order for prescribed drug infusion to resume. “Safe state” is a special mode used by the pump following certain errors to suspend therapeutic drug delivery until the error can be evaluated or corrected with the clinician programmer. While in “safe state”, the pump will infuse at the minimum rate of 0.006 ml/day. This is accompanied by an audible critical alarm and an event log entry that documents the pump has entered “safe state”.

Additional Resources:
For additional information and/or updates, please contact your Medtronic field representative at, [countries to edit] or contact Medtronic European Technical Services at (+31-45) 566 8849. This important patient management information is also available on www.medtronicconnect.com, under the heading “Advisories – Implantable Infusion Systems”.

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

Nothing is more important to Medtronic than patient safety. We are committed to answering your questions and keeping you informed. Please maintain a copy of this notification in your files.

Enclosures: New Information Regarding Potential MRI Effects - SynchroMed EL and SynchroMed II
Post MRI Interrogation Guidelines - SynchroMed II
Roller Study Procedure - SynchroMed EL

Sincerely,

Country Manager or Country BU Manager

New Information Regarding Potential MRI Effects

New Information	SynchroMed EL	SynchroMed II
Delay in Return of Proper Infusion after an MRI	X	X
Event Logging Delay		X
Time Required for Stall & Recovery Detection		X

Delay in Return of Proper Infusion after an MRI

Exposure to the MRI magnetic field may cause the motor gears within the pump to bind temporarily without permanent damage. This is caused by the potential for backward rotation of the pump rotor magnet when it aligns with the MRI magnetic field. This temporary binding may delay the return of proper infusion after the pump is removed from the MRI magnetic field.

Delay in Logging of Motor Stall Events (Event Logging Delay)

The SynchroMed II pump checks for motor stall and motor stall recovery. These stall and recovery events are logged in the memory of the device. In some cases, electromagnetic interference (EMI) from the MRI may cause the pump to switch into the telemetry mode. 'Telemetry mode' is a special state in which the pump is able to communicate with the clinical programmer. While in this state, the pump infuses normally; however, some error logging and the audible alarm for motor stall are suspended. If the pump switches into telemetry mode due to EMI, the pump resumes drug delivery after leaving the MRI magnetic field; however, pump motor stall and motor stall recovery detection function is not active until the post MRI pump interrogation ends telemetry mode. Please note that due to this issue, if the interrogation is not performed upon completion of the MRI scan or shortly thereafter as indicated in the labeling, review of the pump logs may indicate that the pump ceased drug delivery for an extended period of time, when in fact it had recovered normally. In this scenario, you may receive an erroneous “stopped pump period may exceed tube set” error message.

Delay in Logging of Motor Stall Events (Time Required for Stall & Recovery Detection)

The SynchroMed II pump audibly alarms (two-tone) in the event of a motor stall. For pumps programmed to deliver at least 0.048 ml/day, the motor stall detection (with audible alarm) should occur within 20 minutes of exposure to the MRI magnetic field. Stall recovery detection should occur within 20 minutes of exiting the MRI magnetic field. Please note that the slower the programmed delivery rate is, the longer it may take for the stall detection algorithm to log motor stall and/or motor recovery (both the detection of a motor stall and detection of motor stall recovery may each take up to 90 minutes if the pump is programmed to minimum rate mode (0.006 ml/day)).

SynchroMed II - Post MRI Pump Interrogation Guidelines

For pumps programmed to deliver at least 0.048 ml/day, post MRI interrogation will typically confirm that proper pump functionality has resumed within 20 minutes of completion of the MRI procedure. The following pump interrogation guidelines should be used to determine whether the pump has resumed proper function.

1. At least 20 minutes after completing MRI exposure, 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).
2. If event log **does not** show stall and recovery, wait 20 minutes after the initial interrogation, re-interrogate the pump using the clinician programmer, and review the event logs again. (This will address the potential for event logging delays due to Electromagnetic Interference (EMI) from the MRI magnetic field.
    - If the event log states "Motor Stall Occurred" and **<u>does not</u>** state "Motor Stall Recovery Occurred", there is a potential for an extended motor stall due to gear binding. Contact Medtronic Technical services for further troubleshooting.
    - In all other cases, the pump has resumed its normal operation.

Figure 1

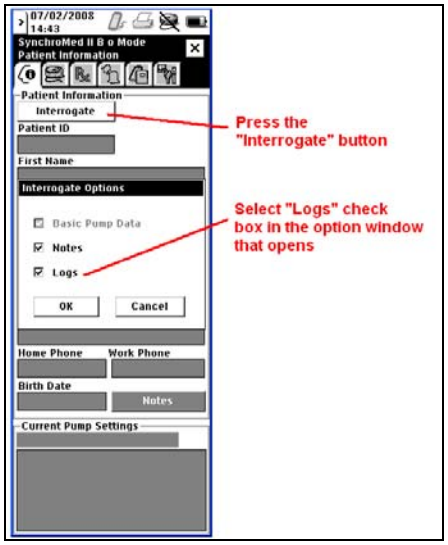
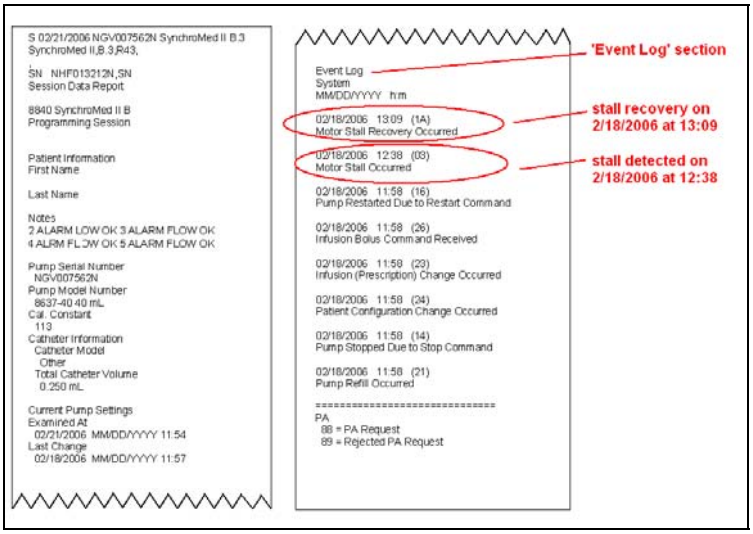


Figure 2



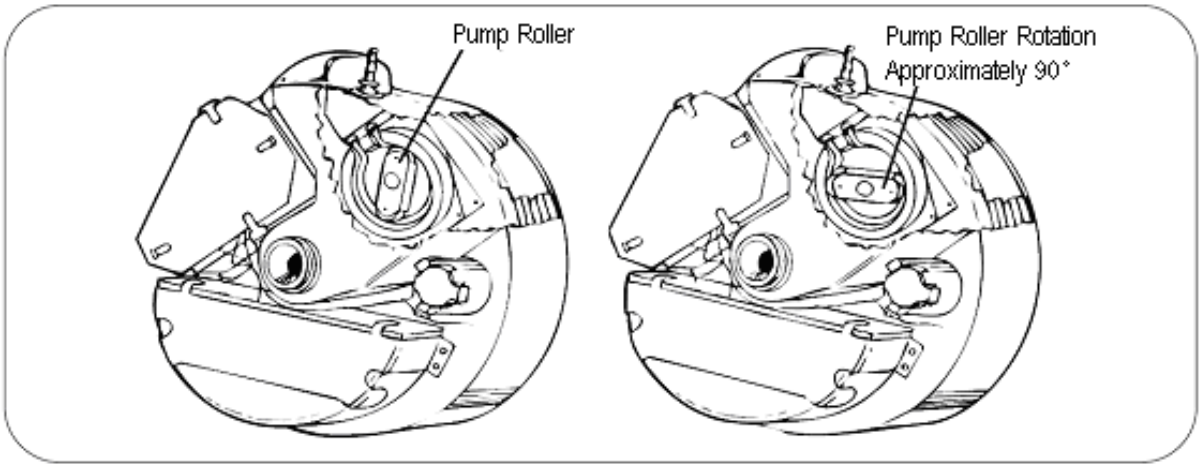
SynchroMed®
Important Information on Potential MRI Effects

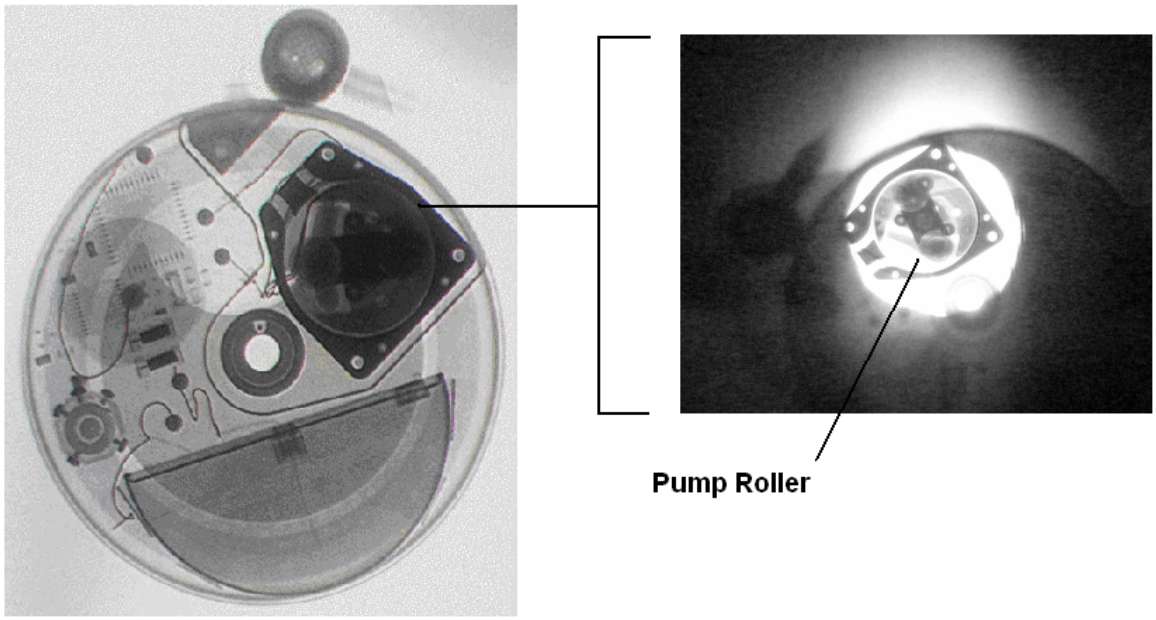
Roller Study Procedure

Roller Study Procedure – SynchroMed EL

To confirm pump function, conduct a roller study using this procedure. Review the following procedure carefully before beginning:

1. X-ray the pump to determine the location of the pump roller (overexposing the film will make the roller more visible). Several attempts may be necessary to visualize the roller.





2. Only use a Medtronic catheter access port (CAP) kit to access the catheter access port septum.

3. Calculate the amount of a bolus in microliters (µL) that will move the roller approximately 90°. Use the formula below.

a.	**Determine the calibration constant from the Pump Status Screen of the programmer or patient's *Implanted Device Identification* card.**
b.	**Divide 1800 by the calibration constant.** The result is the volume in µL required to move the roller approximately 90°. 1800 ÷ Cal Constant = _____µL
c.	To obtain the bolus dose expressed in the present metrology, **multiply the formula's result (in µL) by the concentration, and divide by 1000.** $\frac{\text{µL x (drug concentration)}}{\text{1000 µL/mL}}$ = Dose in Present Metrology

WARNING

A significant amount of drug may be present in the catheter access port and catheter. Failure to remove the drug during catheter access port injections can result in clinically significant or fatal drug overdose.

4. If the calculated bolus could cause an overdose, aspirate approximately 1-2 mL of fluid from the catheter access port to ensure removal of drug from the catheter access port and catheter.

5. Program a single bolus using the calculated dose to run for approximately 1 minute. The pump will operate for approximately 1 minute to deliver a bolus that will turn the roller approximately 90°.

6. X-ray the pump and determine the new position of the pump's roller. The pump's roller should have moved approximately 90°. Alternatively, fluoroscopy can be used to visualize the pump as it moves to its new position.

7. If there is no roller movement, the device may be stalled. Make copies of the pump status after update printout and the x-rays, then contact Medtronic, Inc. or your local Medtronic Representative.

8. Subsequent to a pump roller study, the appropriate priming bolus must be performed per the implant manual to advance the drug to the catheter tip.

   NOTE: If drug was aspirated from the CAP prior to the roller study, both the volume of drug that was aspirated from the CAP and the roller study bolus should be taken into consideration when performing the priming bolus.

WARNING

Programming a bolus could lead to drug overdose. Therefore, caution must be used when calculating and programming all bolus doses.