Urgent: Medical Device Correction

Important Information on Potential MRI Effects
SynchroMed® Pump Models Affected: 8626, 8627, and 8637

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 risks if the managing physician were to believe the pump was not infusing properly based on the

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
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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.

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.

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.
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- 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, or contact Medtronic Neuromodulation Technical Services at 1-800-707-0933. This important patient management information is also available on www.medtronicconnect.com, under the heading “Advisories – Implantable Infusion Systems.”

Report any malfunction or adverse event related to this device to:

Medtronic Neuromodulation Technical Services: 1-800-707-0933
And
FDA’s MedWatch Program:
  ▪ Phone: 1-800-FDA-1088
  ▪ Fax: 1-800-FDA-0178
  ▪ Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
  ▪ Internet: www.fda.gov/medwatch

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.

Sincerely,

George Aram
Vice President Quality
Medtronic Neuromodulation

Enclosures:
- Dear Healthcare Professional Letter
- Roller Study Procedure
- Post MRI Interrogation Guidelines
- New Information Regarding Potential MRI Effects