

MRI

MAGNETIC RESONANCE IMAGING

TARGETED DRUG DELIVERY TECHNICAL SERVICES

Medtronic

The information in this document applies to the following Medtronic device models:

SynchroMed II – model numbers 8637-20 and 8637-40

SynchroMed EL – model numbers beginning with 8626 and 8627

IsoMed – model numbers beginning with 8472

Reference: Information for prescribers (includes MRI eligibility information) – MA09758A050, pages 4, 26-35 (Appendix B: Magnetic Resonance Imaging)

For complete manuals and other documents for these and other Medtronic products please visit: www.emanuals.medtronic.com

To contact a local Medtronic representative, please call 1-800-633-8766

For telephone technical support please contact Medtronic Targeted Drug Delivery Technical Services at: 1-800-707-0933



Appendix B: Magnetic Resonance Imaging 26

Introduction 26

MRI information for Model 8637-20 and 8637-40 SynchroMed II pumps 26

MRI information for Model 8626 and 8627 SynchroMed EL pumps 30

MRI information for Model 8472 IsoMed pump 34

Information for prescribers (includes MRI eligibility information)

!USA Rx only

CE0123

Appendix B: Magnetic Resonance Imaging

Introduction

Read the appropriate pump section in this appendix before performing a magnetic resonance imaging (MRI) examination on a patient implanted with a Medtronic pump.

Note: For SynchroMed Pump Models 8615, 8616, 8617 and 8618, refer to the MRI information for the SynchroMed EL Pump.

For further information or questions, contact:

- US only: Medtronic Technical Services at 1-800-707-0933.
- Outside US: Your local representative using the phone numbers listed inside the back cover.

Also, please review "Electromagnetic interference" on page 13, Table 1: "Potential effects of EMI from devices or procedures" on page 15, and "Appendix A: Electromagnetic interference" on page 23.

Before any medical procedure is begun, patients must always inform any health care personnel that they have an implanted drug infusion system and share this information about MRI with them.

The most restrictive MRI exposure requirements must be used if the patient has multiple active medical device implants. Contact the appropriate device manufacturers if you have questions. If you are unclear what implants may be present, perform an x-ray to determine implant type and location.

MRI information for Model 8637-20 and 8637-40 SynchroMed II pumps



MR Conditional: If the patient is implanted with a Medtronic SynchroMed II pump, MRI examinations of the entire body may be safely performed under the following conditions:

- 1.5-Tesla (T) and 3T horizontal closed bore
- Maximum spatial gradient of 19T/m (1900 gauss/cm)
- Maximum gradient slew rate: 200 T/m/s
- Maximum RF field intensity: First level controlled operating mode defined in IEC 60601-2-33

SynchroMed II pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

Temporary motor stall and stall recovery

The magnetic field of the MRI scanner will temporarily stop the rotor of the SynchroMed II pump motor and suspend drug infusion for the duration of the MRI exposure. The pump should resume normal operation upon termination of MRI exposure; however, there is the potential for an extended delay in pump recovery after exiting the MRI magnetic field because 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. While extended delays in pump recovery are unlikely, reports have indicated that there is the potential for a delay of 2 to 24 hours to return to proper drug infusion after completion of an MRI scan.

Warning: Patients receiving intrathecal baclofen therapy (eg, 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. For complete product information, refer to the Lioresal Intrathecal (baclofen injection) Package Insert. For information on other drugs, please refer to the product labeling for the drug being administered.

Time required for stall and recovery detection

The SynchroMed II pump detects motor stall and motor stall recovery. 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.

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). The slower the programmed delivery rate, the longer it may take for the stall detection algorithm to log motor stall and motor stall recovery. 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. 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).

Potential for delay in logging motor stall events

In some cases, electromagnetic interference (EMI) from an MRI scan can interfere with normal event logging. If this occurs, it 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 clinician 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 (refer to "Post-MRI examination review"). Due to this issue, if the interrogation is not performed upon completion of the MRI scan or shortly thereafter, 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.

Note: 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 on the pump.

Potential for permanent motor stall

90° alignment of an implanted pump with the z axis (Figure 1) of 1.5-T and 3.0-T horizontal, closed-bore magnetic resonance imaging (MRI) scanners can cause MRI-

induced demagnetization of the internal pump motor magnets, which can result in permanent, nonrecoverable stoppage of the pump. This is due to the orientation of the pump with respect to the magnetic field of a horizontal, closed-bore MRI system. SynchroMed II pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

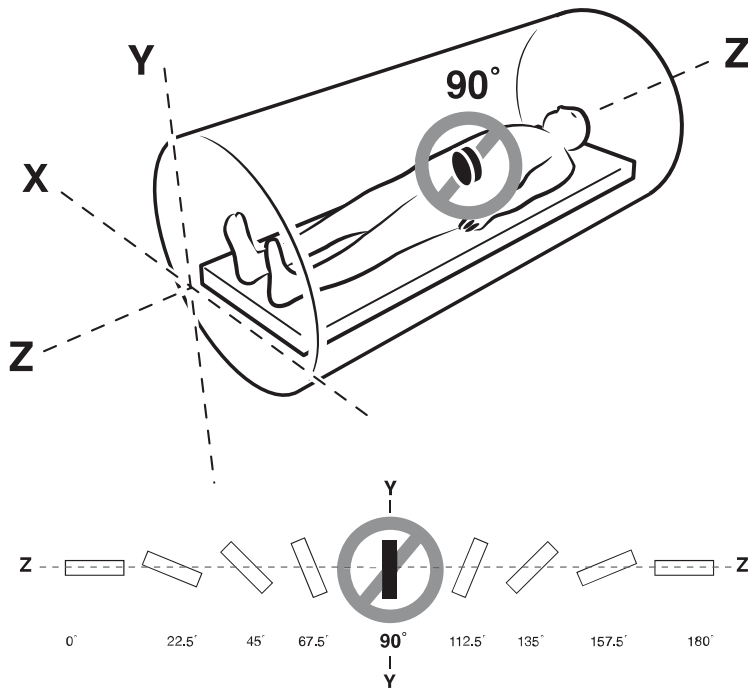


Figure 1. Pump positions in relation to z-axis MRI orientations

Note: If the pump face is oriented at 90° to the z axis, the refill port would be facing towards the patient's feet or head.

Preparation for the MRI examination

Prior to MRI, confirm the pump is not oriented 90° with respect to the z axis of the MRI scanner (see Figure 1). Also, determine if the patient implanted with a SynchroMed II pump can safely be deprived of drug delivery. If the patient cannot be safely deprived of drug delivery, alternative delivery methods for the drug can be used during the time required for the MRI scan. If there is concern that depriving the patient of drug delivery

may be unsafe for the patient during the MRI procedure, medical supervision should be provided while the MRI is conducted.

Post-MRI examination review

Upon completion of the MRI scan, or shortly thereafter, confirm that therapy has properly resumed by interrogating the SynchroMed II pump with the clinician programmer. For pumps programmed to deliver at least 0.048 mL/day, the detection of the motor stall should occur within 20 minutes of MRI exposure. Detection of the 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 MRI magnetic field.

Note: Both the detection of the motor stall and detection of the motor stall recovery may each take up to 90 minutes if the pump is programmed to minimum rate mode (0.006 mL/day). In the unlikely event that electromagnetic interference from the MRI scan causes a change to "safe state", the pump will automatically switch to minimum rate mode (infusion at 0.006 mL/day). The pump must be reprogrammed in order for proper infusion to resume.

The following pump interrogation guidelines should be used to determine whether the pump has resumed proper function (refer to the SynchroMed II Programming Guide for information about how to interrogate the pump and view event logs).

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. If the event log states "Motor Stall Occurred" and "Motor Stall Recovery Occurred", normal function of the pump has returned.
2. If event log **does not** show stall and recovery, wait 20 minutes after the initial interrogation, reinterrogate 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 from the MRI magnetic field.)
 - If the event log states "Motor Stall Occurred" and **does not** state "Motor Stall Recovery Occurred", there is a potential for an extended motor stall due to temporary gear binding. Contact:
 - US only: Medtronic Technical Services at 1-800-707-0933.
 - Outside US: Your local representative using the phone numbers listed inside the back cover.
 - In all other cases, the pump has resumed its normal operation.

Additional safety and diagnostic issues

Testing on the SynchroMed II pump has established the following with regard to other MRI safety and diagnostic issues:

- **Tissue heating adjacent to implant during MRI scans**
Heating—Presence of the pump can potentially cause an increase of local temperatures in tissues near the pump. Active torso scanning durations exceeding 30 minutes increase the risk of heating. If the patient indicates discomfort at any time during an MRI, the MRI procedures should be stopped or the intensity (ie, gradient, RF) of the scan sequence should be reduced. Following the MRI recommendations in this manual will minimize risk of tissue heating.
- **Peripheral nerve stimulation during MRI scans**

Time-varying gradient magnetic fields—Presence of the pump may potentially cause an increase of the induced electric field in tissues near the pump.

In the unlikely event that the patient reports stimulation during the scan, the proper procedure is the same as for patients without implants—stop the MRI scan and adjust the scan parameters to reduce the potential for nerve stimulation.

▪ **Static magnetic field**

For magnetic fields up to 3.0 T, the magnetic force and torque on the pump will be less than the force and torque due to gravity. The patient may experience a slight tugging sensation at the pump implant site. An elastic garment or wrap may prevent the pump from moving and reduce the sensation the patient may experience.

▪ **Image distortion**

The pump contains components that will cause image distortion and image dropout in areas around the pump. The severity of image artifact is dependent on the MR pulse sequence used. Images of the head or lower extremities should be largely unaffected.

Note: Medtronic catheters have a non-magnetic metallic tip which can also cause image artifact near the catheter tip and should be taken into consideration when evaluating images of this area.

Minimizing image distortion—Careful choice of pulse sequence parameters and location of the angle and location of the imaging plane may minimize MR image artifact; however, the reduction in image distortion obtained by adjustment of pulse sequence parameters will usually be at a cost in signal-to-noise ratio. The following general principles should be followed:

- Use imaging sequences with stronger gradients for both slice and read encoding directions. Employ higher bandwidth for both radio-frequency pulse and data sampling.
- Choose an orientation for read-out axis that minimizes the appearance of in-plane distortion.
- Use spin echo or gradient echo MR imaging sequences with a relatively high data sampling bandwidth.
- Use shorter echo time for gradient echo technique, whenever possible.
- Be aware that the actual imaging slice shape can be curved in space due to the presence of the field disturbance of the pump (as stated above).
- Identify the location of the implant in the patient, and when possible, orient all imaging slices away from the implanted pump.

MRI information for Model 8626 and 8627 SynchroMed EL pumps

SynchroMed EL pump performance has not been established for greater than 3.0-Tesla (T) horizontal, closed-bore MRI scanners. SynchroMed EL pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

Temporary motor stall and stall recovery

The magnetic field of the MRI scanner will temporarily stop the rotor of the SynchroMed EL pump motor and suspend drug infusion for the duration of the MRI exposure. The pump should resume normal operation upon termination of MRI exposure; however, there

is the potential for an extended delay in pump recovery after exiting the MRI magnetic field because 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. While extended delays in pump recovery are unlikely, reports have indicated that there is the potential for a delay of 2 to 24 hours to return to proper drug infusion after completion of an MRI scan.

Warning: Patients receiving intrathecal baclofen therapy (eg, 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. For complete product information, refer to the Lioresal Intrathecal (baclofen injection) Package Insert. For information on other drugs, please refer to the product labeling for the drug being administered.

Potential for permanent motor stall

90° alignment of an implanted pump with the z axis (Figure 2) of 1.5-T and 3.0-T horizontal, closed-bore magnetic resonance imaging (MRI) scanners can cause MRI-induced demagnetization of the internal pump motor magnets, which can result in permanent, nonrecoverable stoppage of the pump. This is due to the orientation of the pump with respect to the magnetic field of a horizontal, closed-bore MRI system. SynchroMed EL pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

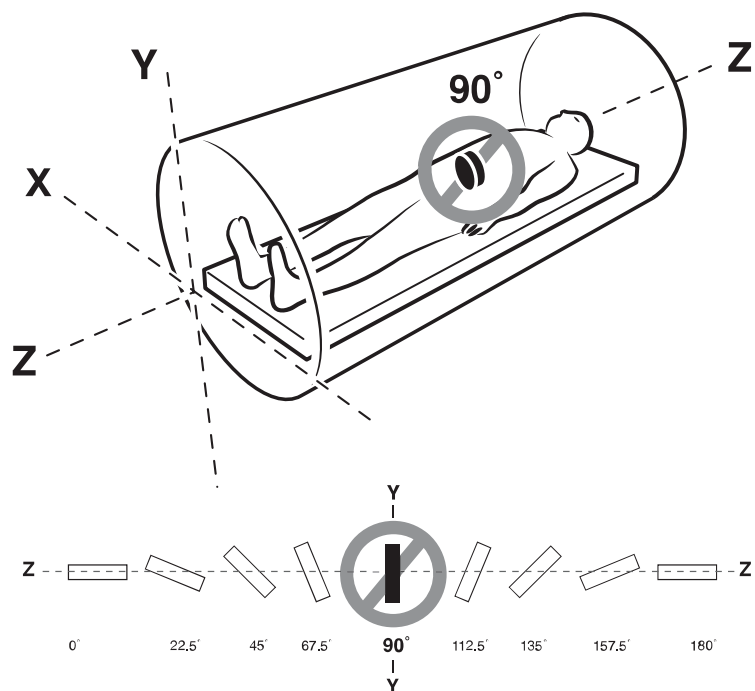


Figure 2. Pump positions in relation to z-axis MRI orientations

Note: If the pump face is oriented at 90° to the z axis, the refill port would be facing towards the patient's feet or head.

Preparation for the MRI examination

Prior to MRI, the physician should ensure the pump is not oriented 90° with respect to the z axis of the MRI scanner (see Figure 2). The physician should also determine if the patient implanted with a SynchroMed EL pump can safely be deprived of drug delivery. If the patient cannot be safely deprived of drug delivery, alternative delivery methods for the drug can be used during the time required for the MRI scan. If there is concern that depriving the patient of drug delivery may be unsafe for the patient during the MRI procedure, medical supervision should be provided while the MRI is conducted.

Note: Prior to the MRI scan, confirm that the pump program settings are documented in case reprogramming is required after the scan.

Post-MRI examination review

Upon completion of the MRI scan, or shortly thereafter, the SynchroMed EL pump must be interrogated using the clinician programmer in order to confirm that electromagnetic interference from the MRI has not affected the pump status. If interrogation using the clinician programmer shows that a "Pump Memory Error" occurred, the physician must reprogram the pump in order for proper drug infusion to resume. A Pump Memory Error Alarm (double tone) will accompany a Pump Memory Error. If this occurs, notify:

- US only: Medtronic Technical Services at 1-800-707-0933.
- Outside US: Your local representative using the phone numbers listed inside the back cover.

The SynchroMed EL pump does not detect or alarm for motor stalls. A physician should confirm a SynchroMed EL pump has resumed proper drug infusion after an MRI by performing a pump roller study. If a pump roller study cannot be performed, patients must be closely monitored for return of underlying symptoms to confirm the pump has resumed proper drug infusion after an MRI. The duration of monitoring depends on the drug and the delivery rate. Consult the patient's providing physician for likely time period for return of symptoms in the event of a pump stoppage.

Additional safety and diagnostic issues

Testing on the SynchroMed EL pump has established the following with regard to other MRI safety and diagnostic issues:

▪ **Tissue heating adjacent to implant during MRI scans**

Specific absorption rate (SAR)—Presence of the pump can potentially cause an increase of the local temperature in tissues near the pump.

During a 20-minute pulse sequence in a 1.5-T GE Signa scanner with a whole-body average SAR of 1 W/kg, a temperature increase of 1 °C in a static phantom was observed near the pump implanted in the "abdomen" of the phantom. The 20-minute scan time is representative of a typical imaging session. Implanting the pump more lateral to the midline of the abdomen may result in greater temperature increases in tissues near the pump.

Testing in a 3.0-T GE Signa scanner using transmit-receive RF body coil (at an MR system reported whole body averaged SAR of 3.0 W/kg and a spacial peak SAR of 5.9 W/kg) resulted in maximum heating of 1.7 °C for the SynchroMed EL pump.

In the unlikely event that the patient experiences uncomfortable warmth near the pump, the MRI scan should be stopped and the scan parameters adjusted to reduce the SAR to comfortable levels.

▪ **Peripheral nerve stimulation during MRI scans**

Time-varying gradient magnetic fields—Presence of the pump may potentially cause a two-fold increase of the induced electric field in tissues near the pump. With the pump implanted in the abdomen, using pulse sequences that have dB/dt up to 20 T/s, the measured induced electric field near the pump is below the threshold necessary to cause stimulation.

In the unlikely event that the patient reports stimulation during the scan, the proper procedure is the same as for patients without implants—stop the MRI scan and adjust the scan parameters to reduce the potential for nerve stimulation.

▪ **Static magnetic field**

For magnetic fields up to 3.0 T, the magnetic force and torque on the pump will be less than the force and torque due to gravity. The patient may experience a slight tugging sensation at the pump implant site. An elastic garment or wrap will prevent the pump from moving and reduce the sensation the patient may experience.

- **Image distortion**

The pump contains ferromagnetic components that will cause image distortion and image dropout in areas around the pump. The severity of image artifact is dependent on the MR pulse sequence used. For spin echo pulse sequences, the area of significant image artifact may be 20 to 25 cm across. Images of the head or lower extremities should be largely unaffected.

Minimizing image distortion—Careful choice of pulse sequence parameters and location of the angle and location of the imaging plane may minimize MR image artifact; however, the reduction in image distortion obtained by adjustment of pulse sequence parameters will usually be at a cost in signal-to-noise ratio. The following general principles should be followed:

- Use imaging sequences with stronger gradients for both slice and read encoding directions. Employ higher bandwidth for both radio-frequency pulse and data sampling.
- Choose an orientation for read-out axis that minimizes the appearance of in-plane distortion.
- Use spin echo or gradient echo MR imaging sequences with a relatively high data sampling bandwidth.
- Use shorter echo time for gradient echo technique, whenever possible.
- Be aware that the actual imaging slice shape can be curved in space due to the presence of the field disturbance of the pump (as stated above).
- Identify the location of the implant in the patient, and when possible, orient all imaging slices away from the implanted pump.

MRI information for Model 8472 IsoMed pump

IsoMed pump performance has not been established in >1.5-Tesla (T) magnetic resonance scanners. Patients should not have magnetic resonance imaging (MRI) using >1.5-T scanners.

Exposure of IsoMed pumps to MRI fields of 1.5 T has demonstrated no impact on pump performance and a limited effect on the quality of the diagnostic information.

Testing on the IsoMed pump has established the following with regard to MRI safety and diagnostic issues:

- **Tissue heating adjacent to implant during MRI scans**

Specific absorption rate (SAR)—Presence of the pump can potentially cause a two-fold increase of the local temperature rise in tissues near the pump.

During a 20-minute pulse sequence in a 1.5-T GE Signa scanner with a whole-body average SAR of 1 W/kg, a temperature rise of 1 °C in a static phantom was observed near the pump implanted in the “abdomen” of the phantom. The temperature rise in a static phantom represents a worst case for physiological temperature rise and the 20-

minute scan time is representative of a typical imaging session. Implanting the pump in other locations may result in higher temperature rises in tissues near the pump.

In the unlikely event that the patient experiences uncomfortable warmth near the pump, the MRI scan should be stopped and the scan parameters adjusted to reduce the SAR to comfortable levels.

- **Peripheral nerve stimulation during MRI scans**

Time-varying gradient magnetic fields—Presence of the pump may potentially cause a two-fold increase of the induced electric field in tissues near the pump. With the pump implanted in the abdomen, using pulse sequences that have dB/dt up to 20 T/s, the measured induced electric field near the pump is below the threshold necessary to cause stimulation.

In the unlikely event that the patient reports stimulation during the scan, the proper procedure is the same as for patients without implants—stop the MRI scan and adjust the scan parameters to reduce the potential for nerve stimulation.

- **Static magnetic field**

For magnetic fields up to 1.5 T, the magnetic force and torque on the pump will be less than the force and torque due to gravity.

In the unlikely event that the patient reports a slight tugging sensation at the pump implant site, an elastic garment or wrap may be used to prevent the pump from moving and reduce the sensation the patient may experience.

- **Image distortion**

The IsoMed pump will cause image dropout on MRI images in the region surrounding the pump. The extent of image artifact depends on the pulse sequence chosen with gradient echo sequences generally causing the most image dropout. Spin echo sequences will cause image dropout in a region approximately 50% larger than the pump itself, about 12 cm across, but with little image distortion or artifact beyond that region.

Minimizing image distortion—MRI image artifact may be minimized by careful choice of pulse sequence parameters and location of the angle and location of the imaging plane. However, the reduction in image distortion obtained by adjustment of pulse sequence parameters will usually be at a cost in signal-to-noise ratio. These general principles should be followed:

- Use imaging sequences with stronger gradients for both slice and read encoding directions. Employ higher bandwidth for both radio-frequency pulse and data sampling.
- Choose an orientation for read-out axis that minimizes the appearance of in-plane distortion.
- Use spin echo or gradient echo MR imaging sequences with a relatively high data sampling bandwidth.
- Use shorter echo time for gradient echo technique, whenever possible.
- Be aware that the actual imaging slice shape can be curved in space due to the presence of the field disturbance of the pump (as stated above).
- Identify the location of the implant in the patient, and when possible, orient all imaging slices away from the implanted pump.



Manufacturer

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

www.medtronic.com
Tel. 1-763-505-5000
Toll-free 1-800-328-0810
Fax 1-763-505-1000



* M A 0 9 7 5 8 A 0 5 0 *

© Medtronic, Inc. 2017
All Rights Reserved

MA09758A050