

Medtronic

MRI guidelines for Medtronic
implantable infusion systems

8667

8637

8472

Instructions for use

Rx only

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.



Magnetic Resonance (MR) Conditional



MR Unsafe

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Introduction

Read the appropriate pump section in this manual before performing a magnetic resonance imaging (MRI) examination on a patient implanted with a Medtronic pump. For information about how other forms of electromagnetic interference can affect the pump, see the Implantable infusion systems information for prescribers manual.

Contact a Medtronic representative if you have any questions about the information in this manual. In the US, contact Medtronic Technical Services at 1-800-707-0933.

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.

Obtain the latest MRI guidelines labeling

Always obtain the latest MRI guidelines. Refer to the contact information at the back of this manual, or go to www.medtronic.com/mri.

Copies of these MRI guidelines may not be the most up-to-date version available if not received directly from the website or in another manner from Medtronic the same day of the patient's MRI appointment.

Multiple implanted devices

If the patient has multiple medical devices implanted, use the most restrictive MRI exposure requirements of the medical devices implanted. 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.

Inactive pump models

Some older SynchroMed™ pump models may still be implanted in patients long after their batteries have been depleted and drug delivery has ceased. These include the Model 8626 and 8627 SynchroMed EL pumps, the Models 8615, 8616, 8617, and 8618 SynchroMed pumps, and inactive Model 8637 SynchroMed II pumps.

For MRI safety and diagnostic information related to all inactive models, refer to the Model 8626 and 8627 SynchroMed EL pumps and the Models 8615, 8616, 8617, and 8618 SynchroMed pumps section on page 15.

Schedule MRI

To schedule an MRI for a patient with an implanted Medtronic infusion system:

- Identify the model number for the implanted Medtronic pump.
- For MRI scheduling purposes only, see Table 1 to determine potential MRI scan-type eligibility.
- If the pump model number is not known, ask the patient to look for the pump model number on the Medtronic patient ID card, check with the pump clinician, or contact Medtronic Technical Services at 1-800-707-0933.

Prior to the MRI appointment, remind patients to do the following:

- Consult with the clinician who manages their infusion system
- Bring their pump patient ID card to the MRI appointment
- Inform the MRI clinician that they have an implanted device



External devices are MR Unsafe in the scanner (magnet) room – Do not allow the following Medtronic external control devices into the MRI scanner (magnet) room. These devices are MR **Unsafe**:

- Patient control devices (for example, patient programmer, patient handset, or communicator)
- Clinician programmer and communicator

Table 1. MRI scan-type eligibility

Pump	MRI equipment	Possible scan locations
SynchroMed II: 8637-20, 8637-40 SynchroMed III: 8667-20, 8667-40	1.5-T or 3-T	Entire body (head, torso, extremities)
IsoMed: 8472	1.5-T	Entire body (head, torso, extremities)
SynchroMed EL: 8626, 8627 SynchroMed: 8615, 8616, 8617, 8618	1.5-T or 3-T	Entire body (head, torso, extremities)

Minimizing image distortion

The following information applies to all pump models.

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 8637-20 and 8637-40 SynchroMed™ II pumps and Model 8667-20 and 8667-40 SynchroMed III pumps



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

- 1.5-Tesla (T) and 3-T horizontal cylindrical system for hydrogen imaging
- Radio-frequency (RF) coil: Any type
- Maximum spatial field gradient of 19T/m (1900 gauss/cm)
- Maximum gradient slew rate: 200 T/m/s or less per axis
- Maximum RF field intensity: First Level Controlled Operating Mode
- Active scan time: The risk of heating increases for active torso scanning durations over 30 minutes

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

Temporary motor stall and stall recovery

The magnetic field of the MRI scanner will temporarily stop the rotor of the SynchroMed II or SynchroMed III 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 up 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

SynchroMed II and SynchroMed III pumps detect motor stall and motor stall recovery. Medtronic does not recommend programming the SynchroMed II or SynchroMed III 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).

8637 SynchroMed II pumps only: Ensuring normal pump operation after MRI scans

Always interrogate the pump after an MRI scan in order to ensure the pump has resumed normal operation. If an interrogation is not performed, and the pump does not resume drug delivery after leaving the MRI examination, a patient may experience a return of underlying symptoms, clinically significant or life threatening drug withdrawal symptoms or underdose.

In some cases, electromagnetic interference (EMI) from an MRI scan may cause the pump to switch into a state in which the pump is waiting for communication (interrogation) with the programmer. While in this state, the pump may infuse normally; however, some error logging and all audible alarms are suspended. Due to this issue, pump interrogation is required after the MRI scan to accurately log both the motor stall and motor stall recovery events and ensure the pump has resumed normal operation.

If the interrogation is not performed, review of the pump logs may indicate that the pump ceased drug delivery for an extended period of time, when in fact it may have recovered normally. In this scenario, you may receive an erroneous stopped pump error message. See the "Post-MRI examination review" section for pump interrogation guidelines.

Potential for permanent motor stall

90° alignment of an implanted pump with the z axis (Figure 1) of 1.5-T and 3-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 and SynchroMed III pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

Note: Bench testing indicates that damage to SynchroMed II and SynchroMed III pumps can occur; however, pump implantation requirements and patient orientation in a horizontal, closed-bore MRI system make this potential damage clinically unlikely.

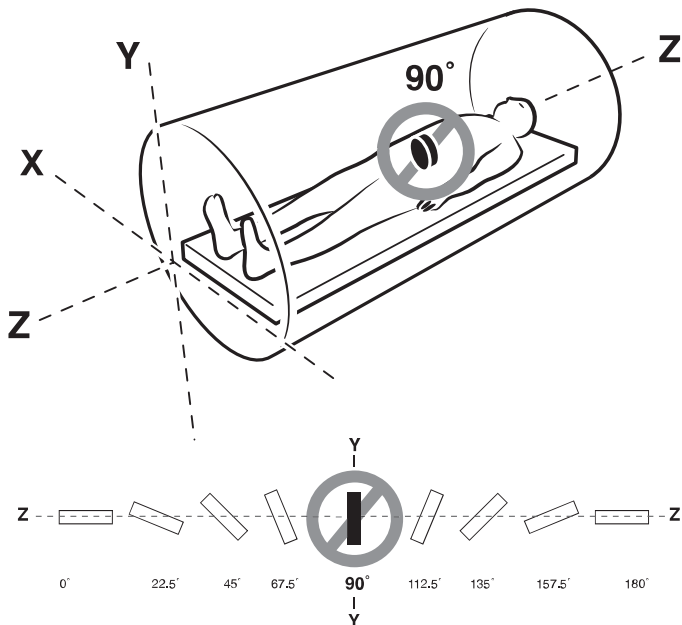


Figure 1. Pump positions in relation to z-axis MRI orientations

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). Palpate the pump to determine the orientation. The pump diameter is about 87.5 mm (3.4 inches) including the catheter access port. If the pump face is oriented at 90° to the z axis, do not initiate the MRI scan. Also, determine if the patient implanted with a SynchroMed II or SynchroMed III 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

Wait a minimum of 20 minutes after completion of the MRI scan to confirm that therapy has properly resumed by interrogating the SynchroMed II or SynchroMed III 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.

The following pump interrogation guidelines should be used for the clinician programmer to determine whether the pump has resumed proper function (refer to the SynchroMed 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 to review the event logs. If the event log states "Critical Alarm - Pump Motor Stall Occurred" and "Pump Motor Stall Recovery", 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 "Critical Alarm - Pump Motor Stall Occurred" and **does not** state "Pump Motor Stall Recovery", there is a potential for an extended delay in pump recovery from a motor stall due to temporary gear binding. Contact Medtronic Technical Services in the US at 1-800-707-0933.
 - In all other cases, the pump has resumed its normal operation.
3. If event log **does not** show stall and recovery, and the pump is programmed to minimum rate mode (0.006 mL/day), wait 90 minutes after the initial interrogation, reinterrogate the pump using the clinician programmer, and review the event logs again.

Note—SynchroMed II pumps only: This will address the potential for 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 with a clinician programmer in order for proper infusion to resume.

MRI information for the Model 8472 IsoMed pump

IsoMed pump performance has only been established in 1.5-Tesla (T) magnetic resonance scanners. Patients should not have magnetic resonance imaging (MRI) using 3-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**
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 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. 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.

MRI information for Model 8626 and 8627 SynchroMed EL pumps and the Models 8615, 8616, 8617, and 8618 SynchroMed pumps

Safety and diagnostic issues

Testing 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 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-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**

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 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.

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