



Medtronic

SYNCHROMED[®]

ISOMED[®]

Implantable infusion systems

Information for prescribers

USA Rx only



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Refer to the Indications, Drug Stability, and Emergency Procedures reference manual for indications and related information.

Refer to the device implant manual for device description, package contents, device specifications, and instructions for use.

Refer to the appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures.

Contraindications

Pump implantation - Implantation of the pump is contraindicated:

- in the presence of infection, unless indicated for osteomyelitis.
- when the pump cannot be implanted 2.5 cm or less from the surface of the skin.
- in patients whose body size is not sufficient to accept pump bulk and weight.

Intrathecal catheterization - Intrathecal catheterization is contraindicated:

- in the presence of known or suspected meningitis, ventriculitis, skin infection, bacteremia, and septicemia.
- in the presence of spinal anomalies that may complicate the implantation and fixation of a catheter for drug delivery.

Vascular catheterization - Vascular catheterization is contraindicated in the presence of known or suspected infection, bacteremia, and septicemia.

Drugs - Contraindications relating to the use of the prescribed drug must be observed.

Drugs with preservatives - Drugs with preservatives are contraindicated when known to damage the SynchroMed Infusion System (eg, sodium metabisulfite).

Blood sampling (vascular applications) - Blood sampling or aspiration through the catheter access port is contraindicated in vascular applications.

Catheter access port kits - Medtronic catheter access port kits are contraindicated for all refill procedures.

Low pH - Drug formulations with pH ≤ 3 are known to damage the SynchroMed Infusion System and are contraindicated.

Refill kits - Medtronic refill kits are contraindicated for all catheter access port procedures.

Warnings

User instructions - Comply with all product instructions for initial preparation and filling, implantation, programming (if applicable), refilling, and accessing the catheter access port (if present) of the pump. Failure to comply with all instructions can lead to technical errors or improper use of implanted infusion pumps and result in additional surgical procedures, a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose.

Alcohol contact - Do not expose the catheter components to alcohol or solutions containing alcohol. Alcohol can damage the components. Component damage can result in drug or spinal fluid leakage into surrounding tissue and tissue damage or a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose. Damage to the components can require surgery to repair or replace the components.

Advancing drug to catheter tip (intraspinal applications) - For intraspinal applications, do not inject drug directly into the catheter or through the catheter access port to advance drug to the catheter tip. Injecting through the catheter access port or injecting directly into the catheter to advance drug to the catheter tip can result in a clinically significant or fatal drug overdose.

Catheter aspiration (intraspinal applications) - During intraspinal applications, before injecting fluids through the catheter access port, aspirate approximately 1 to 2 mL from the catheter (unless contraindicated). A significant amount of drug may be present in the catheter access port and catheter, and failure to remove the drug during catheter access port injections can result in a clinically significant or fatal drug overdose.

Catheter aspiration (vascular applications) - During vascular applications, do not aspirate blood through the catheter access port or catheter. Blood sampling or aspiration through the catheter access port is contraindicated in vascular applications. Residual blood from aspiration or blood sampling can occlude the catheter or pump and inhibit drug delivery, resulting in a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose, and require surgical revision or replacement.

Coagulopathies - Assess patients for intrathecal catheter implantation to assure that risks for increased or uncontrolled bleeding are not present and/or are managed optimally. Physicians should specifically investigate the following:

- Anatomical factors at or near the implant site (eg, vascular abnormalities, neoplasms, or other abnormalities)
- Underlying disorders of the coagulation cascade, platelet function, or platelet count (eg, hemophilia, Von Willebrand's disease, liver disease, or other medical conditions)
- The administration of any antiplatelet or anticoagulant medication (eg, aspirin, Clopidogrel Bisulfate, NSAIDs) in the preoperative or perioperative period
- Use of nutritional supplements (eg, St. John's Wort) that can impact coagulation

Any of those conditions or drugs could place a patient at an increased risk for intraoperative or postoperative bleeding.

The decision to proceed with implant rests on stratification of risks and benefits in a particular patient. The risks and benefits of any patient management strategy, such as discontinuing anticoagulation medication during screening and the surgical procedure, should be discussed with patients and their caregivers.

Contrast medium - When injecting contrast medium into the intraspinal space, use ONLY contrast medium indicated for intraspinal use. Using nonindicated contrast media can result in adverse events including, but not limited to, extreme pain, cramps, seizures, and death. Inject contrast medium through the catheter access port only.

Drug first use - Do not use high-concentration drugs the first time a drug is used because of the unknown therapeutic window. Using high-concentration drugs in this case could result in a clinically significant or fatal drug overdose.

Drug incompatibility - Use only drugs or fluids indicated for use with the Medtronic Infusion System. Do not use:

- drugs or fluids that may contain preservatives, antimicrobials, or antioxidants or that exhibit chemical properties (such as pH ≤ 3) that are not compatible with the infusion system.
- drugs or fluids that may break down over time and produce degradation products that are not compatible with the infusion system (eg, diamorphine and diacetylmorphine).
- drugs or drug mixtures that may precipitate in the pump and inhibit pump flow or occlude the catheter (eg, greater than approved concentrations).

Nonindicated formulations (including drugs not indicated for use with the SynchroMed Infusion System, admixtures, compounded drugs, and unapproved drug concentrations) are not approved for use or tested with the infusion system. Use of nonindicated drugs or fluids can result in increased risks to the patient, damage to the infusion system requiring surgical replacement, and a loss or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Drug quality - Do not use a drug if sterility is questionable or if the drug is cloudy or contains visible particulates. Using such a drug may cause infection or component occlusion that inhibits drug delivery, resulting in a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose, and require surgical revision or replacement.

Inflammatory mass at the catheter tip (symptoms) - An inflammatory mass that can result in serious neurological impairment, including paralysis, could occur at the tip of the implanted catheter. Patients on intraspinal opioid therapy should be monitored carefully at each visit for any new neurological signs or symptoms.

Physicians should routinely monitor patients receiving **opioids** for the following prodromal clinical signs or symptoms of inflammatory mass:

- Change in the character, quality, or intensity of pain
- Reports of new radicular pain, especially at or near the dermatomal level of the catheter tip
- Frequent or large escalations of the daily drug dose are required to maintain the analgesic effect
- Dose escalations alleviate increasing pain only temporarily

To prevent possible permanent neurological injury, physicians should immediately evaluate patients who develop the following signs or symptoms:

- New or different sensory symptoms (eg, numbness, tingling, burning, hyperesthesia, hyperalgesia)
- New, occasional, or intermittent bowel or bladder sphincter dysfunction
- New motor weakness, change in gait, or difficulty walking
- Any neurological symptoms or signs that differ from baseline (eg, reflex changes)

Physicians should routinely monitor patients receiving **intrathecal baclofen** as a sole agent for the following prodromal clinical signs or symptoms of inflammatory mass:

- Change in the character, quality, or intensity of spasticity
- Frequent or large escalations of the daily drug dose are required to maintain the antispastic effect
- Rapid dose escalations alleviate the increasing spasticity only temporarily

Incidence of reports of Inflammatory mass in pain patients: An analysis of reports to Medtronic from 1996 through September 2007 indicates an incidence of 0.49% (1 in 200 chance) of inflammatory mass in patients ever implanted with an infusion system for the treatment of pain. The actual incidence is likely to be higher due to under reporting, but the extent of under reporting is currently unknown. Some reported cases occurred within six months, while others occurred as long as ten or more years after starting opioid therapy.

The risk of inflammatory mass occurrence appears to be cumulative over time and increases with higher concentrations of opioids. Literature reports and preclinical studies have shown that inflammatory mass has been associated with a wide range of doses and concentrations of opioids. No dose and/or concentration of morphine sulfate can be considered completely free of risk from inflammatory mass. Current available information does not definitively exclude other possible contributing factors such as other infusates, catheter design, or material.

Incidence of reports of inflammatory mass in spasticity patients: An analysis of reports to Medtronic from 1996 through September 2007 indicates an incidence of 0.05% (1 in 2,000 chance) of inflammatory mass in patients ever implanted with an infusion system for the treatment of spasticity. Many of these reports involved opioids/baclofen admixtures and pharmacy compounded baclofen. There were 15 reports of inflammatory mass involving intrathecal baclofen as a sole agent over this 10-year period.

Physicians managing patients on ITB TherapySM (Intrathecal Baclofen Therapy) should use their medical judgment regarding the most appropriate monitoring specific to their patients' medical needs to identify prodromal clinical signs and symptoms for inflammatory mass, especially for a change in the character, quality, or intensity of spasticity. Patients receiving pharmacy-compounded drugs or baclofen admixtures that include opioids should also be monitored per the recommendations noted above for opioids.

Refer to "Adverse events summary" on page 14 for more information on recognition, treatment, and mitigation of inflammatory mass.

Intraspinal therapy - For intraspinal therapy, use ONLY a preservative-free sterile solution indicated for intraspinal use. Nonindicated fluids containing preservatives or endotoxins can be neurotoxic in intraspinal applications. Using nonindicated fluids can result in adverse events including, but not limited to, extreme pain, cramps, seizures, and death.

Physician training

Drug information - Refer to the appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures. Refer to the appropriate drug labeling for specific drug underdose or overdose symptoms and methods of management. Failure to refer to the drug labeling can result in inappropriate patient selection and management, inadequate therapy, intolerable side effects, or a clinically significant or fatal drug underdose or overdose. Consider the possibility of a drug error if the patient experiences unusual side effects. Failure to do so can result in misdiagnosis of patient symptoms.

Implantation and system management - Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the infusion system and must be in compliance with procedures described in the appropriate technical instructions. Inadequate training or failure to follow instructions can require surgical revision or replacement, and result in a clinically significant or fatal drug underdose or overdose.

Prescribing - Physicians must be familiar with the drug stability information listed in the Indications, Drug Stability, and Emergency Procedures manual and must understand the dose relationship to drug concentration and flow rate before prescribing an infusion system. Failure to understand the relationships between concentration, flow rate, dose, and drug stability can result in a clinically significant or fatal drug underdose or overdose.

Patient activities and information

Activities involving exposure to high altitudes - Patients who live or travel at high altitudes are exposed to lower air pressures. With continued exposure to lower air pressure, the flow rate of the pump may increase and then stabilize at the higher flow rate. In those circumstances where a potential increase in flow rate may pose a risk for a patient, the infusion prescription can be adjusted to offset the higher flow rate. In rare instances, while the patient is exposed to lower pressures, exposure to lower pressures can cause:

- the flow rate of the SynchroMed II Pump to exceed the programmed flow rate by more than 14.5%.
- the flow rate of the SynchroMed EL Pump to exceed the programmed flow rate by more than 15%.
- the flow rate of the IsoMed Pump to exceed the expected flow rate by more than 25%.

Changes in drug concentration or pump programming can be considered for patients who will be exposed to lower pressures.

Activities involving exposure to high temperatures - Patients should avoid using hot tubs, hot showers, steam rooms, saunas, or tanning beds where the temperature is greater than 39 °C (102 °F). The flow rate of the pump will vary with body temperature. The flow rate increases as the temperature increases. A significant increase in temperature can result in overinfusion and a clinically significant or fatal drug overdose.

Activities requiring excessive twisting or stretching - Patients should avoid activities that put undue stress on the implanted components of the infusion system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can damage or dislodge components and require surgical revision or replacement. These activities can also kink or occlude the catheter, resulting in a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Component manipulation by patient (twiddler's syndrome) - Patients should avoid manipulating or rubbing the pump or catheter through the skin. Manipulation can cause skin erosion, component damage, catheter disconnection, kinking, or dislodgement and result in drug or CSF leakage into surrounding tissue and tissue damage or a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose, and can require surgical revision or replacement.

Manipulation may also cause pump inversion, making it impossible to refill the pump.

Drug interaction and side effects - Inform patients of the appropriate warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention, including prodromal signs and symptoms of inflammatory mass. Failure to recognize the signs and symptoms and to seek appropriate medical intervention can result in serious patient injury or death.

Drug underdose/overdose - Inform patients of the signs and symptoms of a drug underdose and overdose. Failure to recognize these signs and symptoms and to seek appropriate medical intervention can result in serious patient injury or death.

Elective Replacement Indicator (SynchroMed II Pump) - Inform patients that the SynchroMed II Pump has an Elective Replacement Indicator (ERI) that sounds when the

pump is nearing End of Service (EOS). When the ERI sounds, patients must contact their physician to schedule a pump replacement. If the pump is not replaced after the ERI sounds, the pump will reach EOS after 90 days and the pump will stop. A stopped pump results in loss of therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Long-term catheter damage - Inform patients that the catheter is subject to wear. Over time, the component may fail and require surgical revision or replacement. Component failure can result in drug or CSF leakage into surrounding tissue and tissue damage or a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose or overdose.

Low battery alarm (SynchroMed EL Pump) - Inform patients that the SynchroMed EL pump has a low battery alarm that sounds when the pump battery is nearing depletion (the pump End of Service or EOS). When a pump alarm sounds, patients must contact their physician to determine the reason for the alarm, and if necessary, schedule a pump replacement. If the pump is not replaced shortly after the low battery alarm sounds, the battery may become completely depleted, causing the pump to stop. A stopped pump results in loss of therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Medical procedures - Patients should always inform health care professionals that they have an implanted pump before undergoing medical tests or procedures. Failure to inform health care professionals can result in procedural delays, patient injury, component damage that requires surgical revision or replacement, or a clinically significant or fatal underdose or overdose.

Patient travel - Patients should notify their clinicians of any travel plans. Clinicians need this information to coordinate patient care and pump refills and help prevent a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Refill - Patients must return to the clinic for refills at the prescribed times. Failure to return to the clinic for refills at the prescribed times can result in the actual flow rate of the pump being less than expected, resulting in a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose. Failure to return at the prescribed times can also damage the pump, requiring surgical replacement.

Scuba diving or hyperbaric chambers - Patients should not dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters of water (or above 2.0 ATA) could damage the pump, requiring surgical replacement. To minimize damage to the pump when hyperbaric treatment is required, fill the pump to capacity using the appropriate refill kit and maintain the current infusion prescription prior to exposure to hyperbaric conditions. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their physician. As pressure increases, pump flow decreases. Continuing to increase the pressure will eventually result in a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Electromagnetic interference

Electromagnetic interference - Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with pump function. The programmable pumps include features that provide protection from electromagnetic interference. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a pump; however, sources of strong electromagnetic interference can result in the following:

- **Patient injury**, from heating of the implanted pump resulting in damage to surrounding tissue.
- **System damage**, from electrical or mechanical effects that can cause inappropriate device responses or loss of device function, resulting in loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug overdose or underdose.
- **Operational changes to the pump**, from strong magnets temporarily or permanently stopping the pump motor or electrical interference causing a pump memory error, resulting in loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose. In the case of a pump memory error or a change to "safe state," reprogramming by a clinician is required.
- **Changes in flow rate**, from warming of the implanted pump, resulting in overinfusion and a clinically significant or fatal drug overdose.

Refer to Table 1 on page 10 and "Appendix A: Electromagnetic interference" on page 18 for information on sources of EMI, the effect of EMI on the patient and the infusion system, and instructions on how to reduce the risk from EMI.

For information about the effects of EMI on programming, refer to "Telemetry signal disruption from EMI" on page 13.

For information about the effects of magnetic resonance imaging (MRI) on pump performance, refer to "Appendix B: Magnetic Resonance Imaging" on page 20.

Table 1. Potential effects of EMI from devices or procedures

Device or procedure	Patient injury	System damage ^a	Operational changes ^a	Change in flow rate	For guidelines
Bone growth stimulators			X		page 18
Defibrillation/ cardioversion		X			page 18
Diathermy	X			X	page 18
Electromagnetic field devices: (eg, arc welding, power stations)			X		page 18
High-output ultrasonics / lithotripsy		X			page 19
Laser procedures				X	page 19
Magnetic resonance imaging (MRI)	X	X	X ^b	X	page 20
Psychotherapeutic procedures			X	X	page 19
Radiation therapy		X			page 19
Radio-frequency (RF)/ microwave ablation			X	X	page 19
Theft detector			X		page 19
Therapeutic magnets			X		page 19

^a Applies to SynchroMed, SynchroMed EL, and SynchroMed II Pumps only.

^b Bench testing indicates that damage to SynchroMed EL and SynchroMed II Pumps can occur; however, pump implantation requirements and patient orientation in a horizontal, closed-bore MRI system make this potential damage clinically unlikely. There has been no reported permanent damage to SynchroMed EL or SynchroMed II Pumps due to clinical 1.5- or 3.0-Tesla (T) MRI exposure.

Precautions

Storage

Component packaging - Before shipment the components in the sterile package were sterilized by the process indicated on the package label. Do not use or implant a component if the following circumstances have occurred:

- The storage package or sterile seal has been pierced or altered because component sterility cannot be guaranteed and infection may occur.
- The component shows signs of damage because the component may not function properly.
- The use-by date has expired because component sterility cannot be guaranteed and infection may occur; also, device battery longevity may be reduced and may require early replacement.

Pump resterilization - Do not resterilize the pump. The pump is sterilized prior to shipment. Do not steam or flash autoclave the pump. At high temperatures, the pump can explode, resulting in equipment damage or personal injury.

Single use only - Do not reuse any component. Components are intended for single use only. Reusing components can result in inadequate therapy and an increased risk of infection.

Storage temperature: catheters - Do not store or transport the catheter and accessories above 57 °C (135 °F) or below -34 °C (-30 °F). Temperatures outside this range can damage components.

Storage temperature: kits and accessories - Do not store or transport the kit device components or accessories above 57 °C (135 °F) or below -34 °C (-30 °F). Temperatures outside this range can damage device components.

Storage temperature: pumps - Do not store or transport the pump above 43 °C (110 °F) or below 5 °C (40 °F). Temperatures outside this range can damage components.

System implant

Catheter access port kit components - The appropriate Medtronic catheter access port kit **MUST** be used during all catheter access port procedures for Medtronic implantable infusion pumps. Using components other than Medtronic components or a kit other than the appropriate catheter access port kit can damage Medtronic components, requiring surgical revision or replacement, and allow drug leakage into surrounding tissue, resulting in tissue damage or loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Catheter patency (vascular applications) - When using a nonheparinized solution in vascular applications, flush the catheter through the catheter access port after every use and/or at a minimum of once per month to maintain the patency of the catheter. Failure to maintain catheter patency increases the likelihood of a catheter occlusion that can inhibit drug delivery, resulting in a loss of or change in therapy, which may lead to a return of underlying symptoms. If catheter occlusion is suspected, follow the instructions for clearing a catheter occlusion in the catheter access port kit manual.

For programmable pumps, continuous modes are recommended for vascular applications to maintain catheter patency. Because of insufficient flow through the catheter to maintain catheter patency, bolus modes are not recommended for vascular applications, except under conditions of close supervision.

Cerebrospinal fluid leak - For patients prone to cerebrospinal fluid (CSF) leaks, consider special procedures, such as a blood patch, to minimize the potential for CSF leaks. CSF leaks can cause seromas and severe spinal headaches.

Compatibility, all components - Follow these guidelines when selecting system components:

- **Medtronic components:** For proper therapy, use only components that are compatible with the appropriate indication.
- **Non-Medtronic components:** No claims of safety, efficacy, or compatibility are made with regard to the use of non-Medtronic components with Medtronic components. Refer to the non-Medtronic documentation for information.

Component handling - Handle the implantable components of this system with extreme care. These components may be damaged by excessive traction or sharp instruments, requiring surgical replacement. Refer to the appropriate implant manual for additional instructions.

Pump location - Select a location in the lower abdomen that is:

- away from bony structures (eg, 3 to 4 cm) to minimize discomfort at the pump site.
- away from areas of restriction or pressure to minimize the potential for skin erosion and patient discomfort.

For programmable pumps, select a location that is also:

- a minimum of 20 cm away from another programmable device to minimize telemetry interference and incorrect or incomplete programming.
- in an area accessible to the patient for proper operation of a patient control device (if applicable).

In the pediatric population, care must be taken to select an appropriate location by taking into consideration:

- available body mass.
- presence of ostomies.
- growth and development.

Refill kit components - The appropriate Medtronic refill kit **MUST** be used during all refill procedures for Medtronic implantable infusion pumps. Using components other than Medtronic components or a kit other than the appropriate refill kit can damage Medtronic components, requiring surgical revision or replacement, and allow drug leakage into surrounding tissue, resulting in tissue damage or loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Replacement surgery - Patient management should be increased following pump or catheter replacement to ensure quick response to any signs of underdose or overdose.

Therapy discontinuance - If therapy is discontinued for an extended period, fill the pump reservoir with preservative-free saline in intraspinal applications or with the appropriate

heparinized solution (if not contraindicated) in vascular applications. For programmable pumps, program the pump to infuse at the minimum flow rate. Refill the pump as needed to ensure the pump always contains fluid in the reservoir and fluid pathway. Stopping the pump for extended periods or allowing the pump reservoir to empty completely can damage the system and require surgical replacement.

Vesicant/cytotoxic drugs at implant - Do not spill or leak vesicant or cytotoxic drug into adjacent tissue during pump procedures. Spillage or leakage of vesicant drug into adjacent tissue can result in significant local tissue damage. If the drug to be used is a vesicant or has the potential to cause local tissue damage, do not put the drug into the pump until after implantation. Fill the pump and catheter with saline (a heparinized solution may be used if not contraindicated) instead of the drug.

Clinician programming

Clinician programmer interaction with a cochlear implant - When the patient has a cochlear implant, minimize or eliminate the potential for unintended audible clicks during telemetry by keeping the external portion of the cochlear system as far from the programming head as possible or by turning off the cochlear implant during programming.

Clinician programmer interaction with flammable atmospheres - The programmer is not certified for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the programmer near flammable atmospheres are unknown.

Clinician programmer interaction with other active implanted devices - When a patient has a programmable pump and another active implanted device (eg, pacemaker, defibrillator, neurostimulator):

- the radio-frequency (RF) signal used to program either device can reset or reprogram the other device.
- the magnet in a cardiac programmer may temporarily stop the pump.

To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed parameters of each device before the patient is discharged from the hospital and after each programming session of either device (or as soon as possible after these times).

Also, inform patients to contact their physician immediately if they experience symptoms that could be related to either device or to the medical condition treated by either device.

Telemetry signal disruption from EMI - Do not attempt telemetry near equipment that may generate electromagnetic interference (EMI). EMI can interfere with programmer telemetry. If EMI disrupts programming, move the programmer away from the likely source of EMI. Examples of sources of EMI are magnetic resonance imaging (MRI), lithotripsy, computer monitors, cellular telephones, motorized wheelchairs, x-ray equipment, and other monitoring equipment. Interrupting telemetry can result in incorrect or incomplete programming.

Component disposal

When explanting a device (eg, replacement, cessation of therapy, or postmortem), or when disposing of accessories, follow these guidelines:

- If possible, return the explanted device with completed paperwork to Medtronic for analysis and disposal. See the back cover for the mailing addresses.
- To allow for device analysis, do not autoclave the device or expose the device to ultrasonic cleaners.
- Dispose of any unreturned components according to local environmental regulations; in some countries, explanting a battery-powered implantable device is mandatory.
 - Do not incinerate or cremate the device because it may explode if subjected to these temperatures.
 - Do not reuse any implantable device or implantable accessory after exposure to body tissues or fluids because the functionality of the component cannot be guaranteed.

Individualization of Treatment

Best results are achieved when the patient is fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities. Maximum benefits from the infusion system require long-term postsurgical management.

Use only preservative-free drugs approved for use in the SynchroMed Infusion System and follow the recommended doses in the approved drug labeling. The risk of inflammatory mass occurrence appears to be cumulative over time and increases with higher concentrations of opioids, therefore the lowest effective dose and concentration of opioids is recommended.

Adverse events summary

Adverse events summary - The implantation of an infusion system for intraspinal or intravascular delivery involves risks that are similar to other spinal or vascular procedures. In addition to those normally associated with surgery, implantation or use of an infusion system includes, but is not limited to, the following risks:

- Pocket seroma, hematoma, erosion, or infection
- Infection
- Pump inversion (“flipping”)
- Placement of the catheter in intrathecal applications may expose patients to risks of postlumbar puncture (spinal headache), CSF leak and CSF subcutaneous collection or rare central nervous system (CNS) pressure-related problems, radiculitis, arachnoiditis, bleeding, spinal cord damage, or meningitis
- Placement of the catheter in intravascular applications may expose patients to risks of arterial thrombosis, hemorrhage and exsanguination, stroke, organ failure, or death
- Inflammatory mass could result in neurological impairment, including paralysis

System-related complications

- End of device service life or component failure, requiring surgical replacement
- Component failure, resulting in loss of therapy or inability to program the pump
- Catheter damage, dislodgement, migration, disconnection, kinking or occlusion, fibrosis, or hygroma, resulting in tissue damage or a loss of or change in therapy, or other potentially serious adverse health consequences.

Procedure-related complications

- Pump implanted upside down
- Improper handling of components before, during, or after implantation
- Reservoir contamination
- Improper injection through the catheter access port
- Injection into the pocket or subcutaneous tissue
- Activation of the reservoir valve (if present)
- Overpressurization of the reservoir
- Programming error
- Detached catheter tip or catheter fragment(s) in the intrathecal space:
 - Residual catheter fragments may migrate, including rarely into the intracranial cavity, potentially resulting in serious adverse health consequences that may require surgical removal.
 - Residual catheter fragments in the CSF may compromise antibiotic effectiveness in the presence of a concomitant CSF infection

Drug-related complications

- Local or systemic drug toxicity and related side effects
- Inflammatory mass formation at the tip of the implanted catheter particularly in patients who receive intraspinal morphine or other opioid drugs

Recognition of inflammatory mass

For patients receiving intrathecal opioids, the following **prodromal**, or **warning** signs or symptoms may occur before the onset of more severe neurological impairment:

- Change in the character, quality, or intensity of pain
- New radicular pain, especially at or near the dermatomal level of the catheter tip
- Frequent or large escalations of the daily drug dose are required to maintain the analgesic effect
- Dose escalations alleviate the increasing pain only temporarily

For patients receiving intrathecal baclofen as a sole agent, the following **prodromal**, or **warning** signs or symptoms may occur before the onset of more severe neurological impairment¹:

- Change in the character, quality, or intensity of spasticity

¹ Based on three case reports of patients from Murphy and Deer, respectively - Murphy PM, Skouvaklis DE, Amadeo RJJ et al. *Intrathecal Catheter Granuloma Associated with Isolated Baclofen Infusion*, *Anesthesia Analgesia* 2007; 102:848-852. Deer TR, Raso LJ, Garten TG. *Inflammatory Mass of an Intrathecal Catheter in Patients Receiving Baclofen as a Sole Agent: A Report of Two Cases and a Review of the Identification and Treatment of the Complication*. *Pain Medicine* 2007; 8(3):259-262.

- Frequent or large escalations of the daily drug dose are required to maintain the antispastic effect
- Rapid dose escalations alleviate the increasing spasticity only temporarily

All patients on intraspinal opioid therapy should be monitored carefully at each visit for any new neurological signs or symptoms, including:

- New or different sensory symptoms (eg, numbness, tingling, burning, hyperesthesia, hyperalgesia)
- New, occasional, or intermittent bowel or bladder sphincter dysfunction
- New motor weakness, change in gait, or difficulty walking
- Any neurological symptom or sign that differs from baseline (eg, reflex changes)

In patients with new neurological signs or symptoms, consider neurosurgical consultation and the prompt performance of an imaging procedure (eg, MRI with and without contrast or CT myelogram) to confirm or rule out the diagnosis of an inflammatory mass.

Treatment of inflammatory mass

Timely treatment may minimize, or help to avert permanent neurological injury.

If an inflammatory mass is detected early in its clinical course, a decrease or discontinuation of opioid delivery into the mass may cause it to shrink or disappear without the need for surgical removal.

Note: Refer to the emergency procedures included in the technical manual packaged with the refill kit for information on emptying the pump. Stopping the pump for more than a few days can cause the rotor to stall permanently. If therapy is to be discontinued for an extended period of time, the pump should be filled with preservative-free saline and programmed to run at the minimum rate of 0.048 mL/day.

Depending upon an individual patient's clinical condition, intraspinal therapy may be continued after one of the following interventions:

- Withdraw the catheter to a level below the inflammatory mass.
- Remove the involved catheter and replace it with a new catheter positioned below the inflammatory mass.
- Disconnect the involved catheter from the connector (two-piece catheter), or transect the involved catheter above the level of the lumbodorsal fascia (one-piece catheter) leaving the intraspinal catheter segment undisturbed. Ligate the exposed end of involved catheter to prevent CSF loss. Implant a new catheter with its tip below the inflammatory mass, and connect the new catheter to the proximal (pump) catheter segment.

Prompt open surgical removal of the mass or decompression of the spinal canal should be considered in patients who have a significant or progressive neurological deficit.

Mitigation of inflammatory mass

Intraspinal therapy should be administered to achieve adequate clinical response for as long as possible at the lowest effective dose and concentration.

For the treatment of pain patients, whenever medically possible, the tip of the intraspinal catheter should be placed in the lumbar thecal sac, below the conus medullaris. Lumbar

placement may lessen the neurological consequences if an inflammatory mass develops.

Patients who receive intraspinal opioid therapy should be monitored carefully at each visit for any new clinical and neurological signs or symptoms.

Patient Counseling Information

Physicians should provide patients with information about:

- the components of the infusion system: catheter and pump.
- where the components are implanted in the body.
- instructions for using the infusion system.
- the indications, contraindications, warnings, and precautions for the infusion system.
- inflammatory mass and the related prodromal clinical symptoms.
- their therapy.

Physicians should also instruct patients to:

- always inform any health care personnel that they have an implanted infusion system before any procedure is begun.
- contact their physician if they notice any unusual symptoms or signs.
- read the patient manual.
- avoid use of concomitant drugs without medical supervision.

Appendix A: Electromagnetic interference

Please review "Electromagnetic interference" on page 9 and Table 1: "Potential effects of EMI from devices or procedures" on page 10.

Before any medical procedure is begun, patients should always inform any health care personnel that they have an implanted infusion system and share this information about EMI with them. The potential for the following effects results from an interaction of the infusion system and equipment—even when both are working properly.

Warnings

EMI from the following medical procedures or equipment may damage the device, interfere with device operation, or cause harm to the patient. If these procedures are required, follow the guidelines below:

Diathermy - Avoid using shortwave (RF) diathermy within 30 cm of the pump or catheter. Energy from diathermy can produce a significant increase in temperature in the area of the pump and continue to heat the tissue in a localized area because the pump can retain heat. If overheated, a pump can overinfuse the drug, potentially causing a drug overdose. The effects of other types of diathermy (microwave, ultrasound, etc) on the pump are unknown.

Magnetic Resonance Imaging - Refer to "Appendix B: Magnetic Resonance Imaging" on page 20.

Precautions

EMI from the following equipment is unlikely to affect the infusion system if the guidelines below are followed:

Bone growth stimulators - Keep external magnetic field bone growth stimulator coils 45 cm away from the infusion system. After using either an implantable or external bone growth stimulator, ensure the infusion system is working as intended.

Defibrillation or cardioversion - When a patient is in ventricular or atrial fibrillation, the first consideration is patient survival. Testing indicates defibrillation is unlikely to damage the pump; however, after defibrillation, confirm the pump is functioning as intended.

Electromagnetic field devices - Testing indicates that the pump motor will stop while exposed to magnetic fields of 57 gauss or more at a distance of 5 cm or less. Less powerful magnets at closer distances may also stop the pump. Magnetic fields of 10 gauss or less will generally not affect the pump. Patients should exercise care and avoid prolonged exposure to the following equipment or environments:

- Electric arc welding equipment
- High-voltage areas (safe if outside the fenced area)
- Magnets, degaussing equipment, or other equipment that generates strong magnetic fields
- Microwave communication transmitters (safe if outside the fenced area)
- Television and radio transmitting towers (safe if outside the fenced area)

If patients suspect that prolonged exposure to equipment is interfering with pump function, they should do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.
3. Inform the equipment owner or operator of the occurrence.

If the above actions do not resolve the effects of the interference, or the patients suspect that their therapy has been affected by exposure to EMI, they should contact their physician.

High-output ultrasonics or lithotripsy - Use of high-output ultrasonic devices, such as electrohydraulic lithotriptors, is not recommended for patients who have an implanted pump. If lithotripsy must be used, do not focus the beam within 15 cm of the pump.

Laser procedures - Keep the laser directed away from the infusion system.

Psychotherapeutic procedures - Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (eg, electroconvulsive therapy, transcranial magnetic stimulation) in patients who have an implanted infusion system. Induced electrical currents may cause heating of the pump, resulting in overinfusion and a clinically significant or fatal drug overdose.

Radiation therapy - Do not direct high radiation sources such as cobalt 60 or gamma radiation at the pump. If radiation therapy is required near the pump, place lead shielding over the pump to help prevent radiation damage.

Radio-frequency or microwave ablation - Safety has not been established for radio-frequency (RF) or microwave ablation in patients who have an implanted infusion system. Induced electrical currents may cause heating of the pump, resulting in overinfusion and a clinically significant or fatal drug overdose.

Theft detectors and security screening devices - When patients approach theft detector and security screening devices (such as those found in airports, libraries, and some department stores), they should not linger near or lean on the security screening device.

Therapeutic magnets (eg, magnetic mattresses, blankets, wrist wraps, elbow wraps) - Keep the magnet at least 25 cm away from the pump. Magnetic fields of 10 gauss or less will generally not affect the pump.

Notes

Household items - Most household appliances and equipment, if working properly and grounded properly, will not interfere with the infusion system.

Other medical procedures - EMI from the following medical procedures is unlikely to affect the infusion system:

- Computerized axial tomography (CT or CAT) scans
- Diagnostic ultrasound (eg, carotid scan, doppler studies)

Note: To minimize potential image distortion, keep the transducer 15 cm away from the infusion system.

- Diagnostic x-rays or fluoroscopy
- Electrocautery
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans

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 9, Table 1: "Potential effects of EMI from devices or procedures" on page 10, and "Appendix A: Electromagnetic interference" on page 18.

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.

MRI information for SynchroMed II pump

SynchroMed II pump performance has not been established for greater than 3.0-Tesla (T) horizontal, closed-bore MRI scanners. 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.

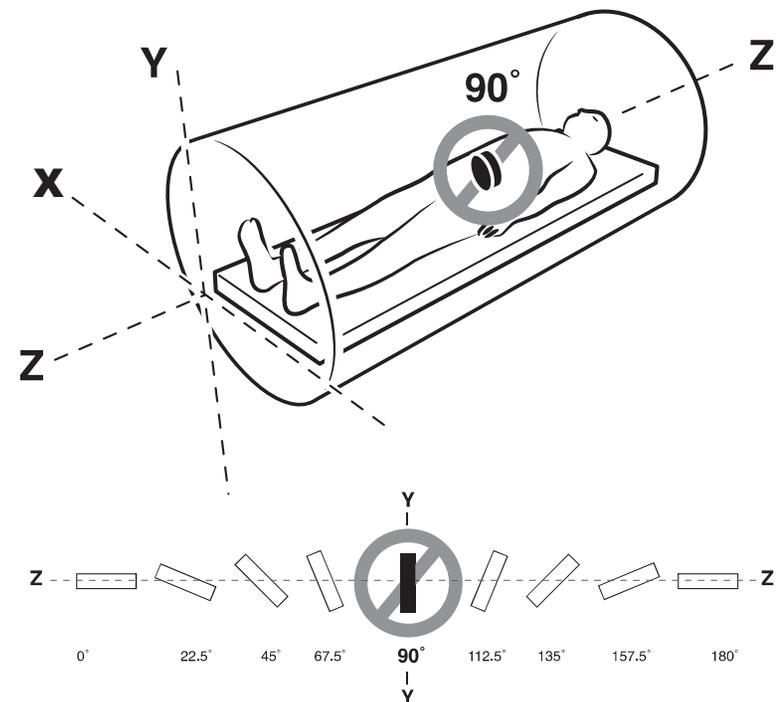


Figure 1. Pump positions in relation to z-axis MRI orientations

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, the physician should ensure the pump is not oriented 90° with respect to the z axis of the MRI scanner (see Figure 1). The physician should 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, the physician must 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**

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 2.7 °C for the SynchroMed II 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 SynchroMed EL pump

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.

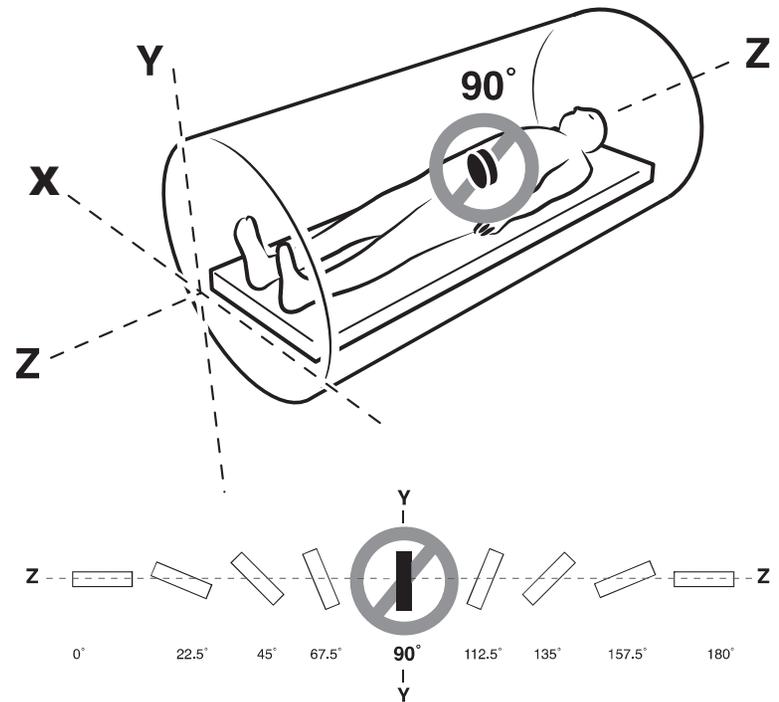


Figure 2. Pump positions in relation to z-axis MRI orientations

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 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.

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