



Medtronic

SynchroMed[®] II Infusion system patient manual

8637



I USA Rx only



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Label symbols

Explanation of symbols on products and packaging.
Refer to the appropriate product to see symbols that apply.



Conformité Européenne (European Conformity).
This symbol means that the device fully complies with AEMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.



For USA audiences only



Manufacturer



Authorized representative in the European community

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Glossary

Catheter – A thin, flexible tube that connects to your pump. The pump delivers medication through the catheter to a specific site in your body where it can have the best effect.

Catheter access port – Sometimes used for diagnostic purposes, the port on your pump used to send medications or sterile solutions directly into your catheter, without going through your pump.

Caution – A statement describing actions that could result in damage to or improper functioning of a device.

Clinician programmer – A device your doctor or nurse uses to adjust the amount of medication your pump delivers. The programmer communicates with your pump using radio waves.

Diathermy – A medical treatment applied to the outside of the body that delivers energy into the body. Three types of energy that can be used are shortwave, microwave, and ultrasound. Depending on the power level used, diathermy devices may or may not produce heat within the body. This treatment is typically used to relieve pain, stiffness and muscle spasms, reduce joint contractures, reduce swelling and pain after surgery, and promote wound healing.

Dose – The amount of drug or fluid given.

Electromagnetic interference (EMI) – A strong field of energy near electrical or magnetic devices that could prevent the pump from functioning properly.

Flow rate – The amount of fluid the pump delivers during a certain period.

Inflammatory mass – A growing collection of inflammatory cells at the tip of the implanted catheter that could result in serious neurological impairment, including paralysis.

Infusion system – Consists of a clinician programmer and an implanted pump and catheter. The implanted pump and catheter deliver medication to a specific site in your body where it can have the best effect.

Lithotripsy – Crushing of a calculus within the urinary system or gall bladder, followed by the washing out of the fragments. Lithotripsy may be performed surgically or by noninvasive methods, such as laser or shock waves.

Precaution – See caution.

Programming – When the clinician programmer sends communication signals to your pump.

Pump – The round, metal device that stores and delivers your medication.

Pump reservoir – The cavity inside your pump where the medication is stored.

Reservoir fill port – The port in the center of your pump that your doctor or nurse uses to fill your pump. A special needle is inserted through the skin into the septum to fill your pump.

Septum – The self-sealing, rubber part of the pump reservoir fill port or catheter access port. A needle is inserted through the septum during pump refills.

Therapy – Treatment of a disease or condition. When infusion therapy is prescribed, an infusion system is used to deliver drugs or fluids to a specific site.

Warning – A statement describing an action or situation that could harm the patient.



1 Introduction

About this manual

This manual provides you with the following:

- A glossary is included at the beginning of the manual
- Information on your patient identification card
- Purpose of the infusion system and when an infusion system should not be used
- Description of the therapy and system components
- Description of warnings, precautions, and patient activities related to your implanted system
- Description of how your implanted system works to manage your symptoms
- What to expect as you recover from surgery
- Answers to common questions
- The appendix provides more information about electromagnetic interference

Ask your doctor or nurse to explain anything that is unclear.



Patient identification card

When you leave the hospital, your doctor will give you a patient identification card. This card supplies information about you, your pump, and your doctor. Carry this card with you at all times. If you move, change doctors, or lose your card, contact Medtronic for a replacement. Refer to the list of Medtronic contacts at the end of this manual.

c A temporary identification card will be provided at the hospital. After Medtronic receives your implant registration from the hospital, you will receive a permanent identification card.

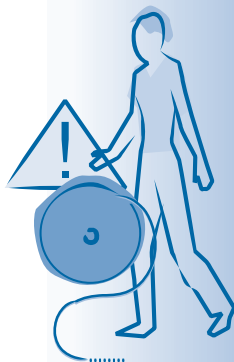


2 System and therapy information

Purpose of the infusion system (indications)

The SynchroMed II Infusion System is indicated when patient therapy requires the long-term infusion of drugs or fluids.

Your pump is only approved for use with specific drugs. If you have any questions about the drug in your pump, ask your doctor.



Your infusion system

The infusion system continuously delivers medication to a specific location in your body where it can have the best effect. Your doctor or nurse programs your pump to deliver a constant rate or different rates throughout the day.

A typical infusion system consists of two implanted components: a pump and a catheter (Figure 2.1).

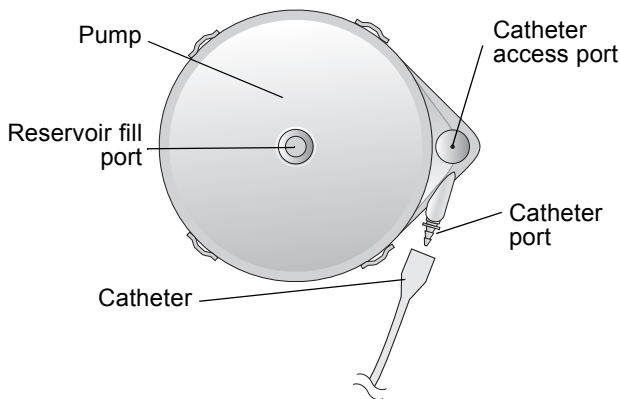


Figure 2.1 Your infusion system.

Pump – The pump is a battery-powered device that stores your medication and delivers prescribed amounts of medication into your body. A microprocessor in the pump controls the rate at which the pump delivers medication.

In the center of the pump is a reservoir fill port. In the middle of the port is a self-sealing, rubber septum. To refill your pump, a needle is inserted through your skin and through the septum. The medication is stored inside the pump in the pump reservoir.

Your pump also has a catheter access port. Your doctor can use the catheter access port to send medications or sterile solutions directly into your catheter, without going through your pump. Your

doctor may also use the catheter access port for some diagnostic purposes, such as testing to make sure medication is able to flow through the length of the catheter.

Catheter – The catheter is a thin flexible tube that connects to the pump at the catheter port. The pump delivers medication through the catheter to a specific site in your body where it can have the best effect.

Contraindications (when the infusion system should not be implanted)

The infusion system should not be implanted if:

- you have an infection, meningitis, ventriculitis, skin infection, bacteremia, or septicemia.
- the pump cannot be implanted 2.5 cm (1 in) or less from the surface of the skin.
- you do not have sufficient body size to accept the pump bulk and weight.
- you have spinal anomalies that complicate placement of the catheter for spinal applications.

Risks and benefits

Benefits

Infusion systems are typically used when more traditional therapies are considered ineffective or inappropriate. In the case of chronic pain, infusion systems are commonly used when oral, intravenous, or topical medications fail to provide enough pain relief or cause uncomfortable side effects. For chemotherapy, infusion systems are commonly used when non-direct delivery of medication (delivery not directed to a specific site or organ) is less effective or causes uncomfortable side effects.

Infusion systems are also used when alternative therapies such as an external pump with a catheter through the skin, or injections directly into the spine or internal organ are not effective enough or are uncomfortable for the patient.

Your doctor will tell you why this infusion system has been recommended for you. Your doctor will discuss with you any questions you may have about your therapy or how the system works.

Risks of surgery

Implanting an infusion system has risks similar to other surgical procedures, including pain or infection at the implant site after surgery.

Implanting an infusion system that will deliver drug to your spine has risks similar to spinal procedures, including:

- Bruising
- Bleeding
- Swelling
- Infection
- Spinal fluid leak
- Headache
- Paralysis

Implanting an infusion system that will deliver drug into an artery or vein has risks including:

- Blood clots
- Bleeding and loss of blood
- Stroke
- Organ failure
- Death

Possible system complications

Possible system complications listed below can result in tissue damage or a loss of or change in therapy, which might lead to a return of underlying symptoms, drug withdrawal symptoms, serious injury, or death and might require surgery to replace or remove the

pump, catheter, or catheter fragment. These complications include:

- The pump, catheter, or catheter fragment could migrate within the body or erode through the skin.
- There could be undesirable changes in therapy, possibly related to cellular changes around the tip of the catheter.
- An inflammatory mass that could result in serious neurological impairment, including paralysis.
- The catheter could leak, tear, or become disconnected, resulting in delivery of medication into the area under the skin where the pump is implanted or along the catheter path.
- The catheter could kink or become blocked resulting in no delivery of medication.
- The pump could stop because it has reached end of service life or because of a component failure.

Warnings

System and therapy

Drug interaction and side effects – Talk to your doctor about warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention. Failure to recognize these signs and symptoms and to seek medical attention can result in serious injury or death.

Drug underdose/overdose – Talk to your doctor about signs and symptoms of a drug underdose and overdose each time your pump is refilled or your pump settings are changed. Failure to recognize these signs and symptoms and to seek medical attention can result in serious injury or death.

Elective Replacement Indicator – Your SynchroMed II pump has an Elective Replacement Indicator (ERI) alarm. This alarm sounds when your pump is nearing End of Service (EOS). When the ERI alarm sounds, contact your doctor to schedule a pump replacement. If the pump is not replaced after the ERI alarm sounds, the pump will continue to operate for a while, but will stop after 90 days. A stopped pump results in a loss of therapy that can lead to serious injury or death.

Electromagnetic interference – Electromagnetic interference (EMI) is a field of energy (electrical, magnetic, or a combination of both) made by equipment found in the home, work, medical, or public environments. The pump has built-in features to protect it from EMI made by other equipment. Most of the magnetic and electrical devices normally encountered are unlikely to affect your pump; however, sources of strong electromagnetic interference can result in the following effects:

- **Patient injury**, from heating of the implanted pump and damage to surrounding tissue.

- **System damage**, from electrical or mechanical effects, resulting in loss of or change in therapy that can lead to serious injury or death.
- **Operational changes to the pump**, from strong magnets temporarily or permanently stopping the pump or electrical interference causing a pump memory error, resulting in loss of or change in therapy that can lead to serious injury or death, and in the case of a pump memory error, requiring reprogramming by your doctor to confirm the pump is working properly.
- **Change in flow rate**, from warming of the implanted pump, resulting in overinfusion and serious injury or death.

Refer to Table 2.1, on page 24 and “Appendix: Electromagnetic interference (EMI)” on page 45 for information on the sources of EMI, the effect of EMI on you and your infusion system, and instructions on how to reduce the risk from EMI.

Table 2.1 Potential effects of EMI from devices or procedures

Device or procedure	Patient injury	System damage	Operational changes	Change in flow rate	For guidelines
Bone growth stimulators			✓		page 49
Defibrillation/cardioversion		✓			page 49
Diathermy	✓			✓	page 46
Electromagnetic field devices (eg, arc welding, power stations)			✓		page 49
High-output ultrasonics/lithotripsy		✓			page 50
Laser procedures				✓	page 50
Magnetic resonance imaging (MRI)	✓	✓ ^a	✓	✓	page 47
Psychotherapeutic procedures			✓	✓	page 51
Radiation therapy		✓			page 51
Radio-frequency (RF)/microwave ablation			✓	✓	page 51

Table 2.1 Potential effects of EMI from devices or procedures (Continued)

Device or procedure	Patient injury	System damage	Operational changes	Change in flow rate	For guidelines
Theft detectors and security screening devices			✓		page 51
Therapeutic magnets			✓		page 51

^a Testing indicates that damage to SynchroMed II pumps can occur; however, this is extremely unlikely because of the location and position of your pump during an MRI scan.

Inflammatory mass at intraspinal catheter tip – An inflammatory mass that can result in serious neurological impairment, including paralysis, can occur at the tip of the implanted catheter.

If you are on intraspinal opioid therapy, you should be monitored carefully at each doctor visit for any new neurological signs or symptoms. Your doctor should routinely monitor you for the following signs or symptoms of inflammatory mass:

- Change in the character, quality, or intensity of your pain
- Unfamiliar or new pain, especially at or near the catheter tip
- Need for frequent or large increases of your daily drug dose to maintain the same effect
- Dose increases relieve your increasing pain only temporarily

To prevent possible permanent neurological injury, your doctor should immediately evaluate you if you develop the following signs or symptoms:

- New or different sensory symptoms (eg, numbness, tingling, burning, hyperesthesia [increased sensitivity to touch], hyperalgesia [increased sensitivity to pain])
- New, occasional, or intermittent bowel or bladder problems

- New motor weakness, change in gait, or difficulty walking
- Any neurological symptoms or signs that differ from normal (eg, change in reflexes)

If you are on ITB TherapySM (Intrathecal Baclofen Therapy), you should be monitored carefully at each doctor visit for any new neurological signs or symptoms. Your doctor should routinely monitor you for the following signs or symptoms of inflammatory mass:

- Change in the character, quality, or intensity of your spasticity
- Need for frequent or large increases of your daily drug dose to maintain the same effect
- Dose increases relieve your increasing spasticity only temporarily

Long-term catheter damage – 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 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.

Medical procedures – Always tell healthcare professionals that you have an implanted pump before

undergoing medical tests or procedures. Failure to tell healthcare professionals can result in procedural delays, damage to the implanted system that requires surgery to repair or replace the system, serious injury, or death.

Patient activities

Activities involving exposure to high altitudes –

Before engaging in activities at high altitudes (such as airline flights, hiking or skiing in the mountains), discuss the effects of low pressure with your doctor. 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 stay at the higher flow rate. If your doctor determines that such an increase in flow rate might pose an undue risk to you, your doctor can adjust your prescription to offset the higher flow rate.

In rare instances, exposure to lower pressures can cause the flow rate of the pump to exceed the programmed flow rate by more than 14.5% while the patient is exposed to the lower pressures. The infusion prescription can be changed for patients who will be exposed to lower pressures.

Activities involving exposure to high

temperatures – If the temperature of a hot tub, hot shower, steam room, sauna, or tanning bed is greater than 39 °C (102 °F), you should not use it. The flow

rate of the pump will vary with body temperature. The flow rate increases as the temperature increases. If the increase is significant, the pump can deliver too much medication. This may lead to serious injury or death.

Activities requiring excessive twisting or stretching – Avoid activities that put undue stress on the implanted components of your infusion system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can damage the components or cause the catheter to dislodge. This can require surgery to repair or replace the components. The catheter could also become kinked or blocked. Catheter disconnection and kinking can result in drug or spinal fluid leakage into tissue and tissue damage, or a loss of or change in therapy that can lead to serious injury or death.

Component manipulation (Twiddler’s syndrome) – Do not manipulate or rub the pump or catheter through the skin; this is sometimes called “Twiddler’s syndrome.” Manipulation can cause skin erosion, component damage, catheter disconnection, kinking, or dislodgement. Damage to the components of your infusion system can require surgery to repair or replace the components. Catheter disconnection and kinking can result in drug or spinal fluid leakage into tissue and tissue damage, or a loss of or change in therapy that can lead to serious injury or death.

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

Patient travel – Notify your doctors or nurses of any travel plans. They need this information to coordinate your care and pump refills, and help prevent a loss of or change in therapy that could lead to serious injury or death.

Refill – 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 that can lead to serious injury or death. Failure to return at the prescribed times can also damage the pump and require surgery to replace the pump.

Scuba diving or hyperbaric chambers – Do not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) could damage the pump, requiring surgery to replace the pump. To minimize damage to the pump when hyperbaric treatment is required, your doctor should 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, discuss the effects of high pressure with your doctor. As pressure increases, pump flow decreases. Continuing

to increase the pressure will eventually result in a change in therapy that could lead to serious injury or death.

Precautions

Clinician programmer interaction with a cochlear implant – If you have a cochlear implant, the external portion of the cochlear system should be kept as far away as possible from the clinician programmer or the cochlear implant should be turned OFF during programming to prevent unintended audible clicks.

Clinician programmer interaction with other active implanted devices – If you have a pump and another active implanted device (eg, pacemaker, defibrillator, neurostimulator):

- the radio-frequency 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, doctors or nurses familiar with each device should check the programmed settings of each device before you are sent home from the hospital and after either device is programmed (or as soon as possible after these times).

Contact your doctor immediately if you notice symptoms that could be related to either device or to the medical condition treated by that device.

Patient counseling information

Your doctor should tell you about:

- the components of your infusion system and where they are located in your body.
- any instructions you need to know about using your infusion system.
- the indications, contraindications, warnings, and precautions for the infusion system.
- the risk of inflammatory mass and recognizing the symptoms of inflammatory mass.
- your therapy.
- informing any health care personnel that you have an implanted infusion system before any procedure is begun.
- contacting your doctor if you notice any unusual symptoms or signs.
- the importance of reading this manual.

Patient management

Best results are achieved when you are 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.

Be attentive to any signs or symptoms of drug underdose or overdose, especially associated with any changes in pump programming or drug refills.

How your infusion system works

Your medication is stored in a reservoir inside the pump. The pump moves the medication from the pump reservoir, through the catheter, to the infusion site (Figure 2.2).

Your doctor or nurse programs your pump to automatically deliver the medication at specific amounts and times.

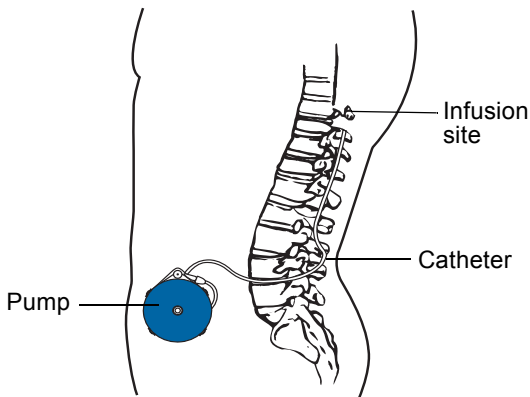


Figure 2.2 Implanted infusion system.

To program the pump, a clinician programmer is used to send prescribed therapy settings to your pump. If needed, your doctor or nurse uses the clinician programmer to change your therapy settings at follow-up visits.

Also at scheduled follow-up visits, your doctor or nurse refills your pump by inserting a needle into the reservoir fill port and injecting the medication into the pump reservoir.

Recovery and care

As you recover from surgery and live with your infusion system, make sure your caregivers are

familiar with the information in this recovery and care section.

Recovering from surgery

It takes several weeks to heal from surgery. It is normal to feel some discomfort from the incision(s) and to have some pain at the implant site for 2 to 6 weeks.

Your doctor may also prescribe physical therapy or medication to help manage your pain. Always follow your doctor's instructions.

Avoid activities where you must bend, stretch, or twist your body; these movements can move your catheter and affect your therapy.

Avoid the following activities during recovery:

- Lying on your stomach
- Reaching over your head
- Turning from side to side
- Bending forward, backward, or from side to side
- Lifting more than 2.3 kilograms (5 pounds)

As you begin to feel better, you should be able to return to many activities, such as:

- Bathing or showering
- Sexual activity

- Working at home or at your business
- Hobbies or activities, such as walking, gardening, cycling, or swimming
- Traveling

Remember that returning to your daily activities should make you feel better, not worse.

Note: As you adjust to life with better symptom management, you may want to try activities that you could not perform before your surgery. Discuss your activity level with your doctor.

Follow-up visits

Your doctor or nurse will schedule follow-up visits at regular intervals. At a follow-up visit, they refill your pump and check your system to make sure you are receiving the most appropriate therapy. The follow-up visits may be scheduled from once a week to several times per year.

Refill dates are based on:

- the amount of medication your pump holds.
- the rate at which your pump delivers medication.
- the number of dosing changes required by your treatment plan.
- the concentration of the medication you are receiving.

During a typical follow-up visit, the pump is refilled by inserting a needle through your skin and injecting new medication into your pump. Your doctor or nurse also checks your pump and, if necessary, adjusts your prescription. Speak with your doctor or nurse about the signs and symptoms of drug underdose or overdose.

When to call your doctor or nurse

You should contact your doctor or nurse if any of the following events occur:

- You notice any signs or symptoms of drug underdose or overdose.
- You have pain, redness, or swelling at the incision(s) later than 6 weeks after surgery.
- Your system is not working properly.
- You are not getting enough symptom relief.
- You hear an alarm from the pump.
- You notice any unusual reaction to a specific medication you are receiving.
- You notice any side effects that your doctor has not discussed with you.
- You notice any significant change in your therapy.

- You have new or different sensory symptoms (eg, numbness, tingling, burning, hyperesthesia [increased sensitivity to touch]) or a return of spasticity.
- You have new, occasional, or intermittent bowel or bladder problems.
- You have new motor weakness, change in gait, or difficulty walking.
- You have any neurological symptoms or signs that differ from normal.

What to do if you hear an alarm?

Your pump has alarms that sound when:

- the pump needs to be refilled.
- the pump needs to be replaced.
- there is a problem with the pump.

The alarm signals a critical or noncritical event in your infusion system.

- A critical alarm is a 3-second, dual-tone alarm. A critical alarm means that therapy will stop soon.
- A noncritical alarm is a single-tone alarm. A noncritical alarm requires a doctor or nurse's attention but does not mean that therapy will necessarily stop soon.

If an alarm sounds, call your doctor or nurse as soon as possible.

Common questions

How long will the pump battery last?

The battery should last about 6–7 years, depending on how much medication the pump has to deliver.

Can the pump battery be recharged?

No.

When would the pump or catheter need to be replaced?

Your doctor or nurse uses a clinician programmer to check the pump battery charge level. When the battery starts to run down, your doctor will schedule a pump replacement.

Pumps may also need to be replaced if the pump has mechanical problems or there are complications with the catheter.

Repairing or replacing a pump or catheter requires surgery.

How large is the pump?

The pump is round. It is approximately 8.8 cm (3.5 in) wide, and 2.5 cm (1.0 in) thick.

Will the pump show through my clothes?

Depending on your body build, the pump may appear as a bulge under the skin. However, your doctor will try to place the pump in an area that is most comfortable and cosmetically acceptable.

Will my system limit my activities?

Generally, no—you should be able to resume your normal daily activities. However, be sure to consult your doctor or nurse before undertaking any particularly strenuous activities. For more information, see “Patient activities” on page 28.

Does the pump make any noise?

No, unless an alarm is sounding.

Will a microwave oven interfere with my pump?

No.

Will there be any problems when I pass through theft detectors and security screening devices?

Your pump may set off the metal detector. Show your patient identification card to security personnel.

Will I be able to take hot baths or showers?

Talk with your doctor or nurse to find out if you may shower immediately following surgery. You should not soak in a hot bath until after your stitches are removed and your incisions are healed. After the incisions are

healed, a hot bath that is less than 39 °C (102 °F) does not affect your pump.

Can I use a hot tub, sauna, steam room, or tanning bed?

Do not use a hot tub, steam room, sauna, or tanning bed where the temperature is greater than 39 °C (102 °F). The pressure in the pump reservoir is sensitive to temperature. At higher temperatures, the pressure in the pump reservoir increases. If the increase is significant, the pressure can cause the pump to deliver too much medication. This may lead to a drug overdose.

Can I travel?

Notify your clinic of your travel plans. Your doctor will determine if you need to schedule an appointment to evaluate your prescription or refill your pump before you leave. If you will need a refill while you are traveling, your doctor must refer you to a doctor who can refill your pump. Referral arrangements may take several weeks or more.

Will the infusion system cure my condition?

The infusion system will not eliminate the primary source of your condition or cure your disease. It will help you manage your symptoms and may allow you to participate in some activities that you were unable to before. The infusion system may be one of several therapies your doctor uses to treat your condition.

Will I be able to stop taking other medications once I have the infusion system?

Your doctor will determine if you need to take other medications.

Can I drive a motor vehicle?

Ask your doctor to provide information about how your prescribed medication may affect your ability to drive.

Pump disposal

The pump should be removed before burial or cremation. In some countries, removal of battery-powered implantable devices is mandatory before burial because of environmental concerns. Also, the pump should be removed before cremation because the cremation process causes the battery to explode. Explanted devices should not be resterilized or reimplanted.

Declaration of conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment and Directive 90/385/EEC on Active Implantable Medical Devices.

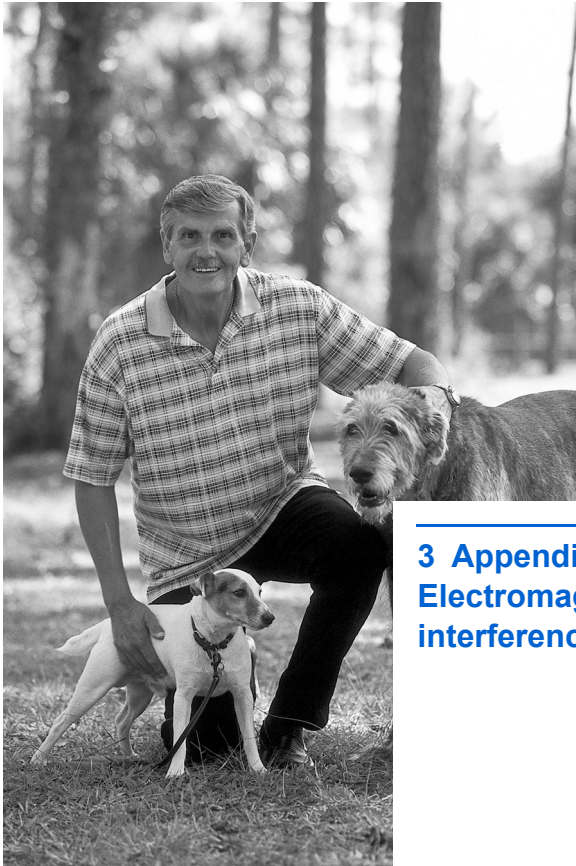
For additional information, contact Medtronic at the telephone numbers and addresses provided at the back of this manual.

Specifications

Table 2.2 Infusion system material specifications

Component	Material
	Typical materials in contact with human tissue or drug path ^a
Pump	Titanium
	Silicone
	Polyvinylidene fluoride
Catheter	Silicone

^a For a complete list of materials in contact with human tissue or drug path, contact your doctor or nurse.



3 Appendix: Electromagnetic interference (EMI)

Please review “Electromagnetic interference” on page 22, and Table 2.1 on page 24 for additional information.

Before any medical procedure is begun, always inform any healthcare personnel that you have an implanted infusion system and share this information about EMI with them.

Warnings

EMI from the following medical procedures or equipment may damage the device, interfere with device operation, or cause you harm. If the procedure or equipment is required, the guidelines below must be followed:

Diathermy – Shortwave diathermy should not be used within 30 cm (12 in) 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 around the pump because the pump can retain heat. If overheated, the pump can deliver more than the prescribed amount of drug, potentially causing a drug overdose. The effects of other types of diathermy (microwave, ultrasound, etc.) on the pump are unknown.



Magnetic resonance imaging – Pump performance has not been established for magnetic resonance imaging (MRI) scanners at fields greater than 3.0 T (Tesla). Patients with pumps should not have an MRI using greater than 3.0 T scanners. Testing has only been done on horizontal, closed-bore MRI scanners. Other MRI scanners, such as open-sided and standing MRIs, have not been tested. You should inform the doctor who manages your pump if you are going to have an MRI. Your doctor will recommend whether or not an MRI is appropriate for you.

The MRI will cause your pump to temporarily stop and suspend drug delivery during the MRI. The MRI may also cause your SynchroMed II pump to temporarily sound an alarm. The pump should resume normal operation after the MRI is complete; however, in some cases this may take up to 24 hours. It is normal to hear the 3-tone alarm until the pump resumes normal operation. The effects of temporary suspension of medication will depend on the medication used in your pump. Your doctor will determine if alternative delivery methods for the drug should be used during the time required for the MRI and if medical supervision should be provided while the MRI is conducted. Your doctor must check your pump after the MRI to confirm your pump is still working properly. A pump motor stoppage can result in the return of your underlying symptoms and drug withdrawal.

During an MRI scan, the front of your pump (the side with the refill port), should not directly face your head or feet as shown in Figure 3.1. This pump position could result in permanent damage. Testing indicates that damage to the SynchroMed II pumps can occur; however, this is extremely unlikely because of the location and position of your pump during an MRI scan.

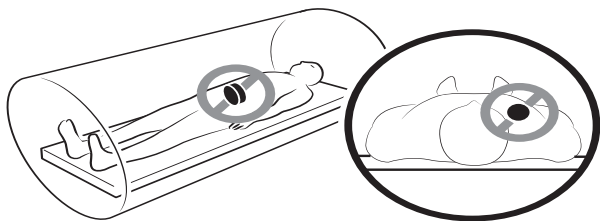


Figure 3.1 Incorrect pump positioning for an MRI.

During an MRI, you may notice a warming sensation around the pump or feel a tingling sensation. If the warming or tingling sensation is uncomfortable to you, the MRI should be stopped and the settings adjusted to reduce or eliminate the sensation.

During an MRI, you may also notice a slight tugging sensation at the pump. An elastic garment or wrap will reduce the tugging sensation.

Additionally, the metal in the pump may cause the MRI image to be distorted in the area around the pump.

The MRI should be adjusted to minimize the image distortion.

Precautions

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

Bone growth stimulators – The coils of the external magnetic field bone growth stimulator should be kept 45 cm (18 in) away from the infusion system. After using either an implantable or external bone growth stimulator, your doctor should ensure the infusion system is working as intended.

Defibrillation or cardioversion – When you are in ventricular or atrial fibrillation, the first consideration should be your survival. Testing indicates external defibrillation is unlikely to damage the pump; however, after external defibrillation, your doctor should confirm that the pump is working 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 (2 in) 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. 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 you suspect that prolonged exposure to equipment is interfering with the pump, you 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 you suspect that your therapy is not the same after exposure to EMI, you should contact your doctor.

High-output ultrasonics or lithotripsy – Use of high-output ultrasonic devices or lithotripsy is not recommended if you have an implanted pump. If lithotripsy must be used, the beam must not be focused within 15 cm (6 in) of the pump.

Laser procedures – The laser should be 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 serious injury or death.

Radiation therapy – High radiation sources, such as cobalt 60 or gamma radiation, should not be directed at the pump. If radiation therapy is required near the pump, lead shielding should be placed over the pump to help prevent radiation damage to the pump.

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 serious injury or death.

Theft detectors and security screening devices – When approaching theft detectors and security screening devices (such as those found in airports, libraries, and some department stores) do not linger near or lean on the security screening device.

Therapeutic magnets (eg, magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep therapeutic magnets at least 25 cm (10 in) 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 your infusion system:

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

Note: To minimize potential image distortion, the transducer must be kept 15 cm (6 in) away from the infusion system.

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

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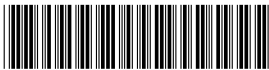
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