Medtronic

Medical Procedure and EMI Warnings, Precautions, and Guidance

for implanted pacemakers and defibrillators

Manual for Health Care Professionals

Contents

1 Introduction

This manual is for physicians and other health care professionals who treat patients who have the following Medtronic implanted cardiac devices:

- Pacemakers, including cardiac resynchronization therapy pacemakers (CRT-P)
- Cardioverter defibrillators (ICD), including cardiac resynchronization therapy defibrillators (CRT-D)

Note: The warnings, precautions, and guidance in this manual do not apply to patients who have leadless transcatheter cardiac devices or implantable cardiac monitors.

To view or download this manual online, see the Medtronic eManuals website at www.medtronic.com/manuals.

Chapter 2 provides a short overview of electromagnetic interference (EMI).

Chapter 3 describes the most common device responses to electromagnetic interference (EMI).

Chapter 4 provides EMI guidelines for clinicians to discuss with their patients.

Chapter 5 provides guidance for the perioperative care of patients with implanted devices for medical procedures.

Chapter 6 provides information related to EMI for health care professionals who perform medical procedures on patients with Medtronic implanted cardiac device systems, in consultation with patient cardiologists. This section provides warnings, precautions, and guidance for medical therapies and diagnostic procedures that present potential risk to the patient or to the operation or physical integrity of the Medtronic system. Some common medical procedures that pose no risk for EMI are also listed. This chapter also includes technical and procedural information for the application of a Medtronic Model 9466 patient magnet. The patient magnet can mitigate the effects of EMI on an implanted device. Use of the patient magnet is suggested for a number of the medical therapies and diagnostic procedures described in this chapter.

Chapter 7 provides precautions and other information related to EMI that is helpful to patients in their daily living. Health care professionals can review the information with their patients and use it as a reference for post-implant consultations.

For guidance on medical procedures or potential EMI scenarios that are not documented in this manual, customers can contact the following Medtronic resources:

- Customers in the USA can contact Medtronic Technical Services at +1 800 505 4636 for pacemakers and CRT-Ps or +1 800 723 6243 for ICDs and CRT-Ds. You can also submit questions to tshelp@medtronic.com or to your Medtronic representative.
- Customers outside of the USA can contact a Medtronic representative.

2 Overview of electromagnetic interference (EMI)

This chapter details the types of EMI and lists the electromagnetic field intensity limits for Medtronic implanted pacemakers and ICDs.

2.1 Types of EMI

Medtronic pacemakers and ICDs comply with standards for testing of implanted cardiac devices in the presence of EMI. These devices operate properly when a patient is exposed to the electromagnetic fields commonly encountered at work, at home, or in other environments. Medtronic advises patients, their clinicians, and their employers to consult with each other to consider EMI safety before the patient returns to work after receiving a pacemaker or an ICD.

Note: See Section 2.2, “Applicable standards for safety and electromagnetic compatibility”, page 5 for more information.

There are 3 principal types of EMI:

- **Conducted interference** occurs when the patient is in direct contact with the electrical source. The greatest risk occurs from poorly maintained or ungrounded electrical equipment or items. Patients with an implanted pacemaker or ICD must avoid conducted current.
- **Radiated fields** are signals propagated through the air. They can induce current that is detectable by an implanted pacemaker or ICD. Common sources of these fields include high-voltage power lines, radio transmission towers, or two-way wireless communication equipment.
- **Static magnetic fields** are produced by permanent magnets or direct current (DC) electro-magnets. Permanent magnets are the most common type of magnet in consumer products.

See Chapter 3, “Device responses to EMI”, page 5 for details on how EMI affects implanted pacemakers and ICDs.

2.2 Applicable standards for safety and electromagnetic compatibility

Medtronic pacemakers and ICDs conform to the following industry standards for active implantable medical devices for safety and electromagnetic compatibility:

- ANSI/AAMI/ISO 14117
- EN 45502-1
- EN 45502-2-1
- EN 45502-2-2
- ISO 14708-1
- ISO 14708-2
- ISO 14708-6

3 Device responses to EMI

This chapter describes the most common device responses to electromagnetic interference (EMI).

Potential EMI impact on implanted pacemakers and ICDs – Table 1 describes the potential impact of EMI on implanted pacemakers and ICDs.

Note: If you remove the source of EMI or if the patient moves away from or turns off the source of EMI, the implanted cardiac device resumes normal operation.

Table 1. Potential EMI impact on implanted pacemakers and ICDs

EMI source	Potential impact on a pacemaker	Potential impact on an ICD
Conducted interference; radiated electric / magnetic fields	Inhibition of pacing therapy[a]; noise reversion[b]; high-rate pacing[c]	Inhibition of pacing therapy[a]; suspension of tachyarrhythmia detection, and suspension of therapy[d]; high-rate pacing[c]; delivery of inappropriate high-voltage therapy
Static magnetic fields (direct current)	Asynchronous pacing[e]; suspension of tachyarrhythmia detection, and suspension of anti-tachyarrhythmia pacing therapy[f]	Suspension of tachyarrhythmia detection which will prevent tachyarrhythmia therapy delivery[d,g]

[a] EMI oversensing can cause both pacemakers and ICDs to provide insufficient pacing support. If pacing therapy is inhibited, pacemaker-dependent patients can be deprived of adequate cardiac output.

[b] See Section 3.3, “Reversion”, page 6 for more information.

[c] Application of pacing therapy at an excessive rate such that it causes symptoms or compromised cardiac hemodynamics.
[d] Inadequate tachyarrhythmia therapy (failure to provide anti-tachyarrhythmia pacing, cardioversion, or defibrillation therapy).
[e] Pacemakers will switch their operating mode and rate in the presence of a strong magnet. For pacemakers that have not reached recommended replacement time (RRT) or elective replacement indication (ERI), the device will operate in VVI mode with a pacing rate of 85 min^{-1}. For pacemakers that have reached RRT or ERI, the pacemaker will revert to VVI mode with a pacing rate of 65 min^{-1} in the presence of a strong magnet. Asynchronous pacing can cause an arrhythmia induction.
[f] Tachyarrhythmia detection and anti-tachyarrhythmia pacing therapy are available in some models of pacemakers. Exposure to static magnetic fields can result in inadequate tachyarrhythmia therapy.
[g] Static magnetic fields do not affect pacing in ICDs.

3.1 Oversensing

Oversensing is the most common consequence of device overexposure to EMI. Oversensing occurs when a device detects EMI in addition to intrinsic cardiac signals. Several factors can trigger oversensing, such as the duration of EMI exposure or the path of the electrical or magnetic current.

Inappropriate sensing of tachyarrhythmias – Some medical procedures use equipment that can create EMI that an implanted pacemaker or ICD does not filter out but interprets as a rapid heart rate. If this interference persists, it can meet the criteria for tachyarrhythmia detection for which the device can deliver inappropriate tachyarrhythmia therapy.

Inhibition of pacing and cardiac resynchronization therapy – Oversensing can inhibit pacing or cardiac resynchronization therapy in pacemakers and ICDs. If a patient is pacemaker-dependent, prolonged pacing inhibition can cause hemodynamic instability.

3.2 Device reset

Device reset, also known as a power on reset (POR) or an electrical reset, is a recovery response to an unexpected device event. Device reset is a rare response to EMI or to ambient radiation. A device reset can also occur in response to the direct exposure to some types of therapeutic ionizing radiation.

Device reset settings are safe for most patients, but they can be therapeutically suboptimal. Perform the following steps if an implanted device reports a device reset:

1. Schedule an immediate clinic appointment with your patient.
2. Restore the patient's parameter values for pacing, arrhythmia detection, and arrhythmia therapy with a Medtronic programmer or a Medtronic device manager.
3. Download the saved device data file according to the procedure provided in the instructions for use for your Medtronic programmer or Medtronic device manager. This file includes the device memory image that Medtronic uses to analyze the device.
4. Contact Medtronic Technical Services for further guidance.

3.3 Reversion

Reversion, also known as noise reversion, initiates asynchronous pacing in the presence of strong EMI. It minimizes the effect of EMI that can inhibit pacing. During reversion, a pacemaker responds as follows:

- Pacing occurs at the sensor-indicated rate for all rate responsive modes (excludes VVIR and VDIR).
- Pacing occurs at the programmed lower rate for all non-rate responsive modes (includes VVIR and VDIR).

The device resumes normal operation when the EMI source is removed.

4 General guidelines for patients in the presence of EMI

Advise patients to observe the following general guidelines in the presence of EMI:

- Area restrictions – consult with your clinician before entering an area where signs are posted that warn persons with an implanted pacemaker or ICD.
- Symptoms of EMI – if you become dizzy or feel rapid or irregular heartbeats while using an electrical item, release whatever you are touching or move away from the item. The implanted cardiac device should immediately return to normal operation. If symptoms do not improve when you move away from the item, notify your clinician. If you have an ICD and you receive a therapy shock while using an electrical item, release the item or move away from it, then notify your clinician.
- Proper grounding of electrical items – To avoid interference from electrical current that can leak from improperly grounded electrical items and pass through the body, observe the following precautions:
  - Confirm that all electrical items are properly wired and grounded.
  - Confirm that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

5 Perioperative management of patients with implanted pacemakers or ICDs

Perioperative care of a patient with an implanted pacemaker or an implanted ICD requires thorough communication between the procedure team and the device team. The procedure team includes the clinicians who perform the medical procedure. The device team includes the clinicians who monitor the device function. The device team leader is an electrophysiologist, a cardiologist, an anesthesiologist, or a surgeon with expertise in device management. If the patient's device team is not available, a resident device team can evaluate the patient and provide recommendations to the procedure team.

Observe these general precautions:

- The perioperative management of devices must consider the health of the patient, the type of device, and the procedure.
- The procedure team informs the device team of the type of procedure and any sources for EMI.
- The device team gives the procedure team a prescription for the perioperative management of the patient in consideration of the potential to the device for EMI. For most patients, the prescription can be made from a review of records maintained by the device clinic. Consult with device specialists if clinic records are not available.

6 Warnings and precautions for medical procedures and equipment

This chapter describes the potential for EMI from medical procedures and equipment to patients with a Medtronic implanted pacemaker or a Medtronic implanted ICD.

Table 2. Acceptability of medical equipment and procedures for patients with an implanted pacemaker or an implanted ICD

Acceptability	Acceptability criteria
Acceptable	The equipment and procedure have a low potential for EMI with an implanted device, and they are safe if the equipment is in proper working condition and used as intended.
Acceptable with precautions	The equipment and procedure have some potential for EMI with an implanted device. You can mitigate the effects of the EMI if the equipment is in proper working condition and used as intended, and if you follow the precautions in this document.
Not recommended	The equipment and procedure have a high potential for EMI with an implanted device, and they are not safe. You cannot mitigate the effects of the EMI.

Note: The off-label use of any medical equipment or procedure described in this document voids these acceptability criteria.

6.1 Medical procedures and equipment that require warnings, precautions, and guidance for health care professionals

This section describes medical procedures and equipment that require precautions for patients with a Medtronic implanted pacemaker or ICD:

- A pacemaker can be a single-chamber VR pacemaker, a dual-chamber DR pacemaker, or a CRT-P.
- An ICD can be a single-chamber VR ICD, a dual-chamber DR ICD, or a CRT-D.

For a list of commonly performed medical procedures that are acceptable without precautions for patients with implanted cardiac devices, see Section 6.2, “Medical procedures and devices that are acceptable for patients with implanted pacemakers and ICDs”, page 21.

Ablation

Cryogenic ablation – Acceptable. Cryogenic ablation is indicated for the treatment of atrial fibrillation. This procedure creates lesions in the cardiac tissue near the pulmonary veins with cryothermal energy (pressurized liquid nitrous oxide).

Radiofrequency (RF) or microwave ablation – Acceptable with precautions. RF or microwave ablation is a surgical technique in which energy creates heat to destroy cells. Common types of ablation include, but are not limited to, intracardiac ablation and endometrial ablation.

RF or microwave ablation used for cardiac device patients can result in, but is not limited to, ventricular tachyarrhythmias, oversensing, unintended tissue damage, or unintended device function.

Observe the following precautions when you administer RF or microwave ablation to a patient with an implanted pacemaker or ICD:

- Make sure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Consider using at least 2 methods to monitor the patient during ablation. These methods can include arterial pressure display, ECG, manual monitoring of patient rhythm (taking pulse), ear or finger pulse oximetry, or Doppler pulse detection.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Ablation	
Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Acupuncture, alternating current (AC)

Acceptable with precautions. AC acupuncture, also known as electroacupuncture, passes a small electrical current between pairs of acupuncture needles.

AC acupuncture introduces electrical current into the body that can cause oversensing in a pacemaker or an ICD. Patients should consult with their clinicians to determine if their cardiac condition allows them to undergo exposure to AC acupuncture.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Bone growth stimulators

A bone growth stimulator provides supplemental therapy to promote bone healing. There are 3 types of bone growth stimulators:

Stimulator that introduces direct current (DC) into the body – Acceptable. A DC bone growth stimulator generates insufficient EMI to affect an implanted pacemaker or an ICD.

Stimulator that introduces alternating current (AC) into the body – Acceptable with precautions. An AC bone growth stimulator uses electrodes to introduce electrical current into the body. There is a potential for EMI with an implanted pacemaker or ICD with the electrodes attached to the torso. When the electrodes are attached to an extremity, the stimulator generates insufficient EMI to affect an implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Stimulator that produces an alternating magnetic field – Acceptable with precautions. This bone growth stimulator delivers a short, high-intensity pulse to a coil in an insulated cuff to produce a therapeutic magnetic field. This therapy does not introduce conducted current into the body. When the insulated cuff is on a patient’s leg, the stimulator generates insufficient EMI to affect an implanted pacemaker or ICD. However, when the insulated cuff is on a patient’s wrist or arm, maintain a 30 cm (12 in) distance between the cuff and the implanted pacemaker or ICD.

Bone scan

Bone scans are used to diagnose and evaluate bone diseases and conditions. There are 3 types of bone scans.

X-ray bone scan (skeletal scintigraphy) – Acceptable. An x-ray bone scan uses small amounts of a radiopharmaceutical to show contrast between abnormal and healthy bone tissue. An x-ray bone scan generates insufficient EMI to affect an implanted pacemaker or ICD.

Ultrasound bone scan (sonography or musculoskeletal ultrasound) – Acceptable. An ultrasound bone scan uses a transducer to transmit high-frequency sound waves to create an image of bone tissue. An ultrasound bone scan generates insufficient EMI to affect an implanted pacemaker or ICD.

Bone densitometry (dual-energy x-ray absorptiometry – DEXA) – Acceptable with precautions. Bone densitometry is an enhanced form of x-ray technology used to measure bone density. It uses a small dose of ionizing radiation to produce images used to diagnose osteoporosis and to assess patient risk for developing fractures. These images are usually of the lower spine and the pelvis.

The accumulated dose of radiation from DEXA is insufficient to damage or interfere with the operation of an implanted pacemaker or ICD. However, do not allow an implanted pacemaker or ICD to undergo direct exposure to the radiation beam.

Capsule endoscopy

Contact Medtronic Technical Services. Capsule endoscopy, also known as *video capsule endoscopy*, uses an ingestible digital camera that captures a video record of the patient's digestive tract. The camera is in a capsule with light-emitting diodes, a battery, and a transmitter. Transmission of the video data occurs in short bursts of radiofrequency energy, approximately 2 per s, for an 8-hour diagnostic period.

Note: Contact Medtronic Technical Services to confirm that your capsule endoscopy system is safe for your patient.

Central venous access catheter

Acceptable with precautions. Also known as a central line or a central venous line, a central venous access catheter is placed into a large vein or into the heart. It administers medication or fluids that cannot be taken orally or that can harm a smaller peripheral vein.

If transvenous leads are acute (within 30 days of implant), verify that they are actively fixed in the endocardium. Confirm lead fixation with an x-ray or through a review of the stored device lead impedance and short interval count data (if available). If a lead has dislodged, do not insert a central venous access catheter into the patient's heart.

Observe these precautions when you insert the guide wire of a central venous access catheter into the heart of a patient who has an implanted pacemaker or ICD:

- The presence of a guide wire can trigger an arrhythmia in the patient, independent of the implanted cardiac device.
- Contact between a guide wire and sensing electrodes can cause inappropriate pacing or oversensing in an implanted cardiac device.
- Contact between a guide wire and a coil can cause inappropriate shock or an electrical short in an implanted ICD.

To mitigate the potential effects of a central venous access catheter, consider the following procedures if patient condition allows:

Central venous access catheter

Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Dental equipment

Acceptable with precautions. Dental procedures that use equipment such as apex locators, ultrasonic scalers, drills, and pulp testers, pose no potential for EMI with an implanted pacemaker or ICD.

Accessories, such as office pillows or headrests, can contain magnets that can affect sensing or initiate asynchronous pacing in an implanted pacemaker or ICD. Keep an implanted pacemaker or ICD at least 15 cm (6 in) from these magnets.

Note: See “Electrosurgery” for guidance with electrosurgery used in periodontal surgery.

Diagnostic radiology (CT scans, fluoroscopy, mammograms, x-rays)

Diagnostic radiology includes the following procedures: computerized axial tomography (CT or CAT scan), fluoroscopy, mammograms, and x-rays.

Normally, the accumulated dose of radiation from diagnostic radiology is insufficient to damage an implanted pacemaker or ICD. If the implanted pacemaker or ICD is not directly in the radiation beam, there is no potential for EMI, except where noted here.

CT scan – Acceptable with precautions. Oversensing can occur only when the implanted pacemaker or ICD is directly in the CT scan beam.

Pacemakers	If the device is in the CT scan beam for more than 4 s, see Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	If the device is in the CT scan beam for more than 4 s, see Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Fluoroscopy at < 1 cGy/min – Acceptable. Fluoroscopy at < 1 cGy/min generates insufficient EMI to affect an implanted pacemaker or ICD.

Fluoroscopy at ≥ 1 cGy/min – Not recommended. EMI from fluoroscopy at ≥ 1 cGy/min can cause oversensing in an implanted pacemaker or ICD.

Mammography – Acceptable. Mammography generates insufficient EMI to affect an implanted pacemaker or ICD.

X-ray – Acceptable. X-rays generate insufficient EMI to affect an implanted pacemaker or ICD.

Diagnostic ultrasound

Acceptable. Diagnostic ultrasound is an imaging technique that visualizes muscles and internal organs, their size, structures, and motion, as well as any pathological lesions. It can also monitor a fetus, and it can detect and measure blood flow. Diagnostic ultrasound generates insufficient EMI to affect an implanted pacemaker or ICD. For precautions about therapeutic ultrasound, see “Diathermy (3 types)”.

Diathermy (3 types)

Diathermy involves the therapeutic heating of body tissues. There are 3 types of diathermy: shortwave diathermy, microwave diathermy, and ultrasonic diathermy, also known as therapeutic ultrasound. Shortwave diathermy or microwave diathermy can cause serious injury, or they can damage an implanted pacemaker or ICD. Do not use shortwave diathermy or microwave diathermy. Ultrasonic diathermy is acceptable, with precautions.

Shortwave diathermy – Not recommended. Shortwave diathermy can cause serious patient injury. It can damage an implanted pacemaker or ICD. Do not perform shortwave diathermy on patients who have an implanted pacemaker or ICD.

Microwave diathermy – Not recommended. Microwave diathermy can cause serious patient injury. It can damage an implanted pacemaker or ICD. Do not perform microwave diathermy on patients who have an implanted pacemaker or ICD.

Therapeutic ultrasound – Acceptable with precautions. Therapeutic ultrasound (including physiotherapy, high intensity therapeutic ultrasound, and high intensity focused ultrasound) uses ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Therapeutic ultrasound does not produce EMI fields capable of inducing significant energy levels in pacing leads; however, the mechanical energy can physically damage internal device components.

Therapeutic ultrasound is acceptable with a minimum separation distance of 15 cm (6 in) between the applicator and the implanted device and lead system. Also, point the ultrasonic beam away from the device and lead system.

EECP (enhanced external counterpulsation therapy)

Acceptable with precautions. EECP is a noninvasive outpatient therapy for treatment of angina. It uses inflatable cuffs to compress the blood vessels in the lower limbs to increase blood flow to the heart. If the rate response feature of an implanted pacemaker or an implanted ICD is programmed to On, the pacing rate can increase if the implanted device detects EECP-induced vibration.

Consider programming an implanted pacemaker or an implanted ICD to a non-rate-responsive pacing mode before you administer EECP.

Enteral magnetic navigation

Acceptable with precautions. Enteral magnetic navigation allows a clinician to steer catheter-based diagnostic and therapeutic devices throughout the digestive system.

An enteral magnetic navigation procedure can initiate asynchronous pacing in a pacemaker or suspend tachyarrhythmia detection in an ICD.

To mitigate the effects of oversensing EMI during an enteral magnetic navigation procedure, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

ECT (electroconvulsive therapy)

Acceptable with precautions. ECT, also known as electroshock therapy, provides relief from psychiatric illnesses. ECT delivers a measured electrical pulse to induce a seizure that can last for several minutes. The electrical current that this procedure introduces into the body can affect an implanted pacemaker or an implanted ICD. Clinicians who administer ECT to patients with an implanted pacemaker or an implanted ICD should consult with their cardiologists to evaluate the potential for EMI.

A pacemaker or an ICD will respond in the following ways during a typical 1 to 2 s ECT electrical pulse:

Pacemakers	The electrical pulse can inhibit pacing for 1 to 2 s. If the rate response feature is programmed to On, the pacing rate can increase during the seizure period. If an ECT electrical pulse is longer than 8 s, reversion can occur.
ICDs	An ICD will inhibit pacing for the duration of the electrical pulse. If the rate response feature is programmed to On, the pacing rate can increase during the seizure period. The potential is low that an ICD will deliver a shock during a 1 to 2 s electrical pulse. If an ECT electrical pulse is longer than 8 s, an ICD can deliver a shock.

EMG (electromyography)

Acceptable. EMG records muscle response to electrical stimuli during muscle rest and during muscle contraction. It helps to diagnose a number of muscular or neuromuscular conditions.

EMG is typically administered with an NCS (nerve conduction study), where an NCS measures nerve response to electrical stimuli. See “NCS (nerve conduction study)” for more information and precautions.

There are 2 types of EMG:

- **sEMG**: surface electromyography. sEMG delivers electrical stimuli to a single patch electrode or to an array of patch electrodes attached via a skin adhesive over the tested muscle.
- **NEMG**: needle electromyography. NEMG delivers electrical stimuli to a single needle electrode or to an array of needle electrodes inserted into the tested muscle.

EMG is acceptable for patients with an implanted pacemaker or ICD.

Electrolysis

Acceptable with precautions. Electrolysis permanently removes hair by inserting an electrified needle (AC or DC) into the hair follicle. Electrolysis introduces electrical current into the body, which can cause oversensing. Patients should consult with their clinicians to determine if their cardiac condition allows them to undergo electrolysis.

To mitigate the effects of EMI during electrolysis, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Electrosurgery

Acceptable with precautions. Electrosurgery (including electrocautery, argon plasma coagulation, electrosurgical cautery, advanced energy surgical technology, and hyfrecator) uses an electric probe to control bleeding, cut tissue, or remove unwanted tissue. Electrosurgery performed on patients with an implanted pacemaker or ICD can result in, but is not limited to, the following complications:

- Potential pacing interruption during and up to 5 s immediately after exposure to electrosurgery.
- Oversensing.
- Unintended tissue damage.
- Tachyarrhythmias.
- Lead or device damage.
- Device malfunction.

If electrosurgery is required, consider the following precautions:

- Ensure that temporary pacing and defibrillation equipment is immediately available.
- If possible, use a bipolar electrosurgery system or advanced energy surgical technology. If a unipolar electrosurgery system is used, position the return electrode patch so that the electrical current pathway passes no closer than 15 cm (6 in) from the device and leads. Contact Medtronic Technical Services for further guidance with unipolar electrosurgery.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.
- Always monitor the patient during electrosurgery. If the ECG tracing is not clear due to interference, manually monitor the patient's rhythm (take pulse); alternatively, monitor by some other means such as ear or finger pulse oximetry, Doppler pulse detection, or arterial pressure display.

To mitigate the effects of oversensing during electrosurgery, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, "How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet", page 22.
ICDs	See Section 6.4, "How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet", page 23.

External defibrillation and cardioversion

Acceptable with precautions. External defibrillation and cardioversion are therapies that deliver an electrical shock to the heart to convert an abnormal heart rhythm to a normal rhythm.

Medtronic pacemakers and ICDs are designed to withstand exposure to external defibrillation and cardioversion. While damage to an implanted pacemaker or ICD from an external shock is rare, the probability increases with increased energy levels. These procedures can also temporarily or permanently elevate pacing thresholds or temporarily or permanently damage the myocardium.

Follow these precautions when you deliver external defibrillation or cardioversion:

- Use the lowest clinically appropriate energy.
- Position the patches or paddles at least15 cm (6 in) from the implanted pacemaker or ICD.
- Use a Medtronic programmer or a Medtronic device manager to evaluate the implanted pacemaker or ICD if you deliver external defibrillation or cardioversion.

Hearing aids and cochlear implants, in ear or hardwired

Acceptable. Hearing aids or cochlear implants worn in the ear or hardwired to an acoustical detector have no potential for EMI with an implanted pacemaker or ICD.

Hearing aids with transmitting loop antenna

Acceptable with precautions. A hearing aid with a transmitting loop antenna, worn around the neck, radiates a magnetic field that is coupled with the T-coil in the earpiece. Advise patients to keep the loop antenna at least 15 cm (6 in) from an implanted pacemaker or ICD.

If the loop antenna is closer than 15 cm (6 in) to a pacemaker or ICD, there is a potential for pacemaker reversion, pacing inhibition, or ICD shock.

Advise patients to reposition the loop antenna to the shoulder opposite the implant site. If that is not possible, advise patients to use an alternative transmitting antenna that can be worn at least 15 cm (6 in) from the implant site.

Note: This precaution also applies to transmitting loop antennae attached to audio equipment.

Note: Bluetooth hearing aids without a transmitting loop antenna are acceptable.

Hyperbaric therapy (including hyperbaric oxygen therapy, or HBOT)

Acceptable with precautions. Hyperbaric therapy is the medical use of air or 100% oxygen at a higher pressure than atmospheric pressure. Hyperbaric therapy treats several conditions, including decompression sickness, carbon monoxide poisoning, serious infections, and persistent wounds. Hyperbaric therapies with pressures exceeding 4.0 ATA, approximately 30 m (100 ft) of seawater, can affect the function of or damage an implanted pacemaker or ICD. To avoid or mitigate risks to an implanted pacemaker or ICD, do not expose patients to pressures exceeding 4.0 ATA.

Interferential current therapy

Acceptable with precautions. Physical therapists use interferential current therapy to relieve pain and to promote soft-tissue healing. If interferential current therapy is administered on the torso, it introduces an electrical current that can affect an implanted pacemaker or ICD. Patients should consult with their clinicians to determine if their cardiac condition allows them to undergo interferential current therapy.

Note: The potential is low for a pacemaker or an ICD to detect interferential current therapy when it is administered to the extremities.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Lithotripsy

Acceptable with precautions. Lithotripsy uses mechanical shock waves to break up kidney stones or gallbladder stones. Lithotripsy can damage an implanted pacemaker or ICD if it is at the focal point of the lithotripter beam. Keep the focal point of the lithotripter beam at least 2.5 cm (1 in) away from the implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Lithotripsy	
Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Magnetic resonance imaging (MRI)

A Medtronic implanted pacemaker, ICD, or lead is either **MR Conditional** or **MR Unsafe**.

Use any of the following resources to confirm if a pacemaker, an ICD, or a lead is MR Conditional or MR Unsafe:

- See the Medtronic MR Conditional Product Search for Cardiac Devices at www.medtronic.com/mrc.
- See the Medtronic MRI Resource Library at http://manuals.medtronic.com/manuals/mri/region.
- If you are in the USA, you can call +1 877 674 7677 for MRI technical consultation.
- If you are outside of the USA, you can contact a Medtronic representative for MRI technical consultation.

Patients with an implanted pacemaker system or an implanted ICD system (implanted device, implanted leads, and any abandoned leads) that is **MR Conditional** can undergo an MRI scan under specified conditions. For details, refer to the MRI technical manual for the pacemaker or ICD, or contact the listed Medtronic resources.

An implanted pacemaker system or ICD system (implanted device, implanted leads, and any abandoned leads) is **MR Unsafe** if any system component or item poses unacceptable risks to the patient, medical staff or other persons within the MR environment. Patients with an implanted pacemaker system or ICD system that is MR Unsafe cannot undergo an MRI scan. An MRI scan on a patient with an MR Unsafe system can result in serious patient injury or induction of tachyarrhythmias. An MRI scan on an MR Unsafe system can damage or impact the function of the implanted pacemaker system or the implanted ICD system.

MET (microcurrent electrical therapy)

Not recommended. MET is an in-home treatment for acute, chronic, and postoperative or post-traumatic pain. MET delivers an electrical current that can affect an implanted pacemaker or ICD, depending on where MET is applied to the body.

The potential is low that an implanted pacemaker or ICD will detect an MET pulse if the pulse is applied to the cranium or extremities. However, if MET is applied to the torso, it can inhibit pacing in a pacemaker or an ICD, or it can cause pacemaker reversion or ICD shock. Because MET is marketed for use in the home, its misapplication cannot be anticipated. MET, therefore, has a high potential to affect an implanted pacemaker or ICD.

NCS (nerve conduction study)

Acceptable with precautions. An NCS, also known as a nerve conduction velocity (NCV) test, records the speed that an electrical pulse is conducted through a nerve. This study can determine nerve damage or nerve destruction that causes abnormal muscle response. An NCS delivers mild electrical pulses between 2 patch electrodes. These electrodes are attached over the tested nerve with a conductive skin adhesive. One electrode delivers the pulse, and the other electrode records the pulse and calculates its speed along the tested nerve.

An NCS is typically administered with EMG (electromyography), where EMG measures muscle response to electrical stimuli. See “EMG (electromyography)” for more information.

NCS (nerve conduction study)

Test 1: manual test – During a manual NCS, the clinician applies discretionary electrical pulses. If an implanted pacemaker or ICD detects a pulse, it can inhibit pacing for 1 to 2 s. If the clinician separates pulses by > 10 s, the inhibited pacing does not cause symptoms in most patients. If it is necessary to apply pulses more frequently than once every 10 s, the implanted pacemaker or ICD can mistake the therapy for oversensing. However, if both NCS electrodes are on the same extremity and not on the torso, the pulses are unlikely to affect an implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during a manual NCS, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, "How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet", page 22.
ICDs	See Section 6.4, "How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet", page 23.

Type 2: automated test – An automated NCS applies a programmed sequence of pulses to a nerve that can affect an implanted pacemaker or ICD.

In an automated NCS, the pulse sequence is sent from the sending patch electrode to the receiving patch electrode at a rate of 2 to 5 pulses/s for 250 pulses. If an implanted pacemaker or ICD detects the pulse sequence, there is the potential for pacemaker reversion or pacing inhibition, or for an inappropriate ICD shock. However, if both NCS electrodes are on the same extremity and not on the torso, the pulses are unlikely to affect an implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during an automated NCS, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, "How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet", page 22.
ICDs	See Section 6.4, "How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet", page 23.

Ocular procedures

A patient must remain motionless during critical junctures of an ocular procedure. A cardiac event or implanted cardiac device therapy that is delivered during an ocular procedure can cause a patient to move and sustain injury to the eye.

Pacemakers – Acceptable. Ocular procedures are acceptable for patients with pacemakers.

ICDs (monitored patients) – Acceptable with precautions. Suspend tachyarrhythmia detection with a Medtronic patient magnet (see Section 6.4, "How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet", page 23), a Medtronic programmer, or a Medtronic device manager. If appropriate for the patient, program the ICD to an asynchronous pacing mode. Remove the magnet or restore ICD parameters with the programmer or the device manager after completing the ocular procedure.

ICDs (unmonitored patients) – Not recommended. A cardiac event or a device therapy delivered during an ocular procedure can cause a patient to move and sustain trauma to the eye. It is more important that the patient receive the appropriate arrhythmia therapy if needed. Therefore, the occurrence of VT or VF in an unmonitored ICD patient with tachyarrhythmia detection suspended would result in unexpected patient motion and, potentially, sudden cardiac death.

PEMF (pulsed electromagnetic field therapy)

Not recommended. PEMF generates a pulsed magnetic field that can cause serious injury, induction of tachyarrhythmias, or implanted system malfunction or damage. Patients with an implanted pacemaker or ICD should not use PEMF devices or therapies.

PET (positron emission tomography) / SPECT (single photon emission computed tomography)

Acceptable. PET and SPECT are noninvasive nuclear imaging technologies. They scan radioactive tracers injected into the bloodstream to produce three-dimensional images.

PET and SPECT generate insufficient EMI to affect an implanted pacemaker or an implanted ICD.

RFID (radiofrequency identification devices)

Acceptable with precautions. RFID is an autoidentification technology used to decrease cost and improve patient safety, particularly in an operating room. Wireless technology used in this setting has the potential to interfere with implanted pacemakers and ICDs. EMI from RFID technology depends on distance and frequency of the RF source. It is stronger at lower frequencies and at closer distances, and it peaks with direct contact between an RFID reader and an RFID tag. Do not place an RFID tag within 30 cm (12 in) of an implanted pacemaker or ICD.

If an RFID tag is placed more than 30 cm (12 in) from an implanted pacemaker or ICD, the generated EMI is insufficient to interfere with the device.

Standard autoidentification systems, like systems used in consumer merchandising, present a low potential for EMI with an implanted pacemaker or ICD.

Stereotaxis

Acceptable with precautions. Stereotaxis allows clinicians to steer catheter-based diagnostic and therapeutic devices throughout the body by using magnetic navigation. During a stereotaxis procedure, the magnetic field can initiate magnet mode (asynchronous pacing) in a pacemaker or suspend tachyarrhythmia detection in an ICD. The implanted pacemaker or ICD resumes normal programmed operation after the stereotaxis procedure.

Clinicians should consult with cardiologists to determine if a stereotaxis procedure is safe for their patients with an implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Therapeutic radiation (radiosurgery and radiotherapy)

Radiosurgery – Acceptable with precautions. Also known as stereotactic radiosurgery, radiosurgery delivers intense doses of radiation from a linear accelerator to destroy tumors with submillimeter precision.

Do not subject an implanted pacemaker or ICD to direct radiosurgery exposure. Accumulated radiation dosage must not exceed 500 cGy.

Radiotherapy – Acceptable with precautions. Radiotherapy is a cancer treatment that uses radiation to control cell growth and destroy tumors. Types of radiotherapy include high-energy photon radiation and proton beam therapy (PBT).

Do not subject an implanted pacemaker or ICD to direct radiotherapy exposure. Accumulated radiation dosage must not exceed 500 cGy.

Note: Contact your Medtronic representative for additional guidance to monitor the implanted pacemaker or ICD during radiosurgery or radiotherapy.

Pacemaker and ICD shielding and radiation modeling – Discuss a shielding plan with the radiation oncologist and physicist responsible for treating the patient. The plan includes modeling of the radiation to be absorbed by the implanted pacemaker or ICD — the accumulated radiation dosage must not exceed 500 cGy.

Pacemaker and ICD repositioning – If the modeling of the radiation indicates that the accumulated radiation dosage will be > 500 cGy, consider repositioning the implanted pacemaker or ICD. If you must reposition the implanted pacemaker or ICD, use lead extenders to implant the device in an alternate location. If possible, implant the pacemaker or ICD in its original location after you deliver the therapy.

Pacemaker and ICD interference from radiosurgery or radiotherapy – If a patient undergoes radiosurgery or radiotherapy, an implanted pacemaker or ICD can sense direct or scattered radiation as cardiac activity for the duration of the procedure. Average dose rates at the pacemaker or ICD of less than 1 cGy/min are unlikely to produce pacemaker or ICD interference. Decreasing the dose rate (for example, by increasing the distance between the beam and the implanted pacemaker or ICD) decreases the potential for interference.

The programmer or device manager can detect pacemaker or ICD interference during the initial therapy, shown as unexpected activity in the programmer marker channel or the device manager event markers. If interference does not occur, it is unlikely to occur during future treatments with the same therapy.

Note: Interrogate the implanted pacemaker or ICD to evaluate it following radiosurgery or radiotherapy.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, “How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet”, page 22.
ICDs	See Section 6.4, “How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet”, page 23.

Device reset following radiation – A device reset (also called an electrical reset) does not indicate damage to the implanted pacemaker or ICD; however, a reset requires device interrogation. In rare cases, a device reset can occur several days following exposure to radiation.

Report a device reset to Medtronic Technical Services. Download the device data file with your programmer’s save-to-media function and include it with your report. This file contains the device memory image.

Therapeutic radiation (radiosurgery and radiotherapy)

How to evaluate a pacemaker or ICD for a device reset – If an implanted pacemaker or ICD has had a device reset, a device reset warning message displays immediately upon interrogation. Reprogram the device to restore normal operation.

Inform your Medtronic representative if your patient's device has reset.

Pacemaker or ICD damage from radiosurgery or radiotherapy – Radiation can affect electronic circuitry, so an accumulated radiation dosage of > 500 cGy can damage an implanted pacemaker or ICD. However, radiation damage is sometimes not immediately apparent. If a patient requires radiosurgery or radiotherapy from any source, do not expose an implanted pacemaker or ICD to an accumulated radiation dosage that exceeds the recommended limit. Record and monitor the accumulated radiation dosage to implanted devices for patients who undergo multiple radiosurgeries or courses of radiation treatment.

Tests have shown damage to implanted Medtronic pacemakers and ICDs with accumulated radiation dosage > 500 cGy. Medtronic therefore cannot predict the operation of implanted pacemakers and ICDs that have withstood radiation overdose. Monitor devices exposed to radiation overdose after each radiosurgery or radiotherapy treatment and consider them for replacement. Consider an augmented follow-up schedule following the completion of all procedures.

TENS (transcutaneous electrical nerve stimulation)

Not recommended. TENS (including NMES – neuromuscular electrical stimulation) is a pain control technique that uses electrical impulses passed through the skin to stimulate nerves. A TENS device is not recommended for in-home use by cardiac device patients due to a potential for oversensing, inappropriate therapy, inhibition of pacing, or asynchronous pacing. If a TENS device is determined to be medically necessary, contact a Medtronic representative for more information.

Tissue expanders with magnetic aiming guides

Not recommended. Tissue expanders are used by plastic surgeons to prepare for reconstructive breast surgery. Some tissue expanders incorporate magnets to direct a needle that is used to fill the expander with fluid. These magnets are often close enough to initiate magnet mode in a pacemaker or suspend tachyarrhythmia detection in an ICD.

Do not use tissue expanders with magnetic aiming guides on patients with pacemakers or ICDs. Instead, use tissue expanders that do not have magnetic aiming guides.

TMS (transcranial magnetic stimulation)

Acceptable with precautions. TMS is a treatment that provides relief from major depressive disorder. TMS therapy delivers rapid magnetic pulses over an extended period to stimulate nerve cells in areas of the brain thought to control mood. TMS produces an effect similar to electroconvulsive therapy but with minimal side effects. The magnetic current that TMS introduces into the body can affect an implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See Section 6.3, "How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet", page 22.
ICDs	See Section 6.4, "How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet", page 23.

TUNA (transurethral needle ablation), TUMT (transurethral microwave therapy), and TURP (transurethral resection of the prostate)
Acceptable with precautions. TUNA, TUMT, and TURP are surgical procedures that treat urinary symptoms caused by benign prostatic hyperplasia (BPH). These procedures use precisely focused energy to ablate prostate tissue. Patients with implanted cardiac devices can conditionally undergo procedures that use a TUNA, TUMT, or TURP system. To avoid affecting an implanted pacemaker or ICD when performing a TUNA, TUMT, or TURP procedure, position the return electrode on the lower back or lower extremity at least 15 cm (6 in) away from the implanted pacemaker or ICD.

Virtual colonoscopy (CT scan)
Acceptable with precautions. This procedure diagnoses colon and bowel disease, including polyps, diverticulosis, and cancer. The procedure is performed with a CAT scan. See “Diagnostic radiology” for more information on this procedure.

Virtual colonoscopy (MRI)
Acceptable with precautions. This procedure diagnoses colon and bowel disease, including polyps, diverticulosis, and cancer. As this procedure is performed with an MRI, it can only be performed on patients with implanted cardiac devices and leads that are MR Conditional. See magnetic resonance imaging (MRI) for more information.

6.2 Medical procedures and devices that are acceptable for patients with implanted pacemakers and ICDs

The following medical procedures and devices, when in proper working condition and used as intended, generate insufficient EMI to affect an implanted pacemaker or an ICD.

Acceptable procedures and devices for patients with implanted pacemakers and ICDs	
Acupuncture, direct current (DC)	DC acupuncture is safe for patients with an implanted pacemaker or ICD.
Colonoscopy	Diagnostic colonoscopy is safe for patients with an implanted pacemaker or ICD.
Digital infrared thermal imaging (DITI)	Digital infrared thermal imaging is an imaging technique. It monitors the infrared radiation that the skin surface emits. It uses a passive device that does not introduce electrical current into the body.
Dysphagia treatment devices	Dysphagia treatment devices apply neuromuscular electrical stimulation to the throat to treat swallowing disorders.
Echocardiography	Echocardiography uses diagnostic ultrasound to examine the heart.
Electrocardiography (ECG)	Electrocardiography senses the electrical activity of the heart.
Electroencephalography (EEG)	Electroencephalography detects electrical activity in the brain.
Electronystagmography (ENG)	Electronystagmography is a diagnostic test that uses passive electrodes on the head to record involuntary movements of the eye caused by nystagmus. This test helps to diagnose the causes of vertigo, dizziness, or balance disorders.

Acceptable procedures and devices for patients with implanted pacemakers and ICDs	
Esophageal pH test	An esophageal pH test measures and records esophageal pH to assess for gastroesophageal reflux disease. The test works by temporarily attaching a small capsule to the wall of the esophagus to measure pH levels. The capsule transmits data to a receiver that the patient wears on a belt.
Iontophoresis	Transdermal drug delivery via iontophoresis (also known as electromotive drug administration – EMDA) relies on delivering a small level of localized DC current.
Laser surgery	Laser (light energy only) is safe for patients with an implanted pacemaker or ICD. See the precautions for performing electrocautery if you plan to combine laser surgery with electrocautery.
Motion sickness relief band	A motion sickness relief band prevents motion sickness. This device delivers a small electrical pulse at the wrist area.
Photodynamic therapy (PDT)	Photodynamic therapy is a cancer treatment that uses a drug, called a photosensitizer or photosensitizing agent. The photosensitizing agent interacts with a specific wavelength of light to produce a form of oxygen that kills nearby cells.
Sleep apnea therapy — CPAP machine	CPAP (continuous positive airway pressure) keeps airways open in patients with moderate to severe obstructive sleep apnea. If the CPAP mask uses magnetic clips, keep the magnets at least 15 cm (6 in) from the implanted pacemaker or ICD.

6.3 How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet

All Medtronic pacemakers, including all MR Conditional and MR Unsafe models, enter "magnet operation" with the application of a magnet. During magnet operation, a pacemaker paces in an asynchronous mode at either 85 min^{-1} or 65 min^{-1}, depending upon whether the pacemaker battery voltage is above or below its elective replacement threshold. Sensing is suspended during asynchronous pacing to prevent pacing inhibition by EMI.

Note: As an alternative, you can program asynchronous pacing during a telemetry session with a Medtronic programmer or with a Medtronic device manager. If telemetry is established with an implanted pacemaker, a Medtronic Model 9466 patient magnet will not initiate magnet operation.

Note: Tap the [End Now] button to end a programmer session with a Kappa, EnPulse, Adapta, Versa, Sensia, or Relia pacemaker. If you do not tap the [End Now] button, a 1-hour period must elapse before you can initiate asynchronous pacing with a Medtronic Model 9466 patient magnet.

Review pacemaker labeling, available at www.medtronic.com/manuals, for information on specific pacemaker response to a Medtronic magnet.

6.3.1 Magnet application procedure

If appropriate for the patient, perform the following steps to initiate asynchronous pacing in an implanted pacemaker with a Medtronic Model 9466 patient magnet:

1. Locate the implanted pacemaker by gently feeling for the device under the skin. The typical location is in the left or right pectoral area.
2. Place the patient magnet directly over the pacemaker. This action initiates asynchronous pacing in the device.
3. To return the pacemaker to its programmed operation, remove the patient magnet.

6.3.2 Magnet operation in a pacemaker

When you position a Medtronic Model 9466 patient magnet over a pacemaker, magnet operation implements the following changes:

- Single-chamber atrial pacing modes switch to AOO asynchronous pacing.
- Single-chamber ventricular pacing modes switch to VOO asynchronous pacing.
- Dual-chamber pacing modes, including MVP modes, switch to DOO asynchronous pacing.
- The pacing rate switches to 85 min^{-1} (700 ms) if the pacemaker has not reached Recommended Replacement Time (RRT).
- The pacing rate switches to 65 min^{-1} (920 ms) if an RRT indicator or a device reset has occurred.
- Tachyarrhythmia detection, available in some models, is suspended.

When you remove the patient magnet, the pacemaker resumes operation as programmed.

Note: Some pacemakers deliver the first 3 paces in magnet operation at 100 min^{-1}, followed by 85 min^{-1}.

Note: Magnet operation does not occur if telemetry is established between the pacemaker and a Medtronic programmer or a Medtronic device manager, or if the MRI SureScan feature is programmed to On.

6.4 How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet

All Medtronic ICDs, including all MR Conditional and MR Unsafe models, enter “magnet operation” with the application of a magnet. In magnet operation, an ICD sounds a steady magnet alert tone, suspends tachyarrhythmia detection, and suspends therapy delivery. With magnet application, suspension of tachyarrhythmia detection and suspension of therapy delivery prevent inappropriate shock therapy.

Review ICD labeling, available at www.medtronic.com/manuals, for information on specific ICD model response to a Medtronic Model 9466 patient magnet.

Warning: An ICD suspends tachyarrhythmia detection and therapy delivery while the patient magnet is in place. A patient magnet does not affect bradycardia pacing in an ICD. Remove the magnet to restore the ICD to its programmed operation.

See Section 6.4.3, “How to program asynchronous pacing in an ICD”, page 24 for additional information.

Warning: To ensure the availability of needed tachyarrhythmia therapy, the patient should not carry, store, or leave the patient magnet positioned over the ICD. The patient should be careful to avoid sources of electromagnetic interference (EMI) while applying the patient magnet.

6.4.1 Magnet application procedure

1. To suspend tachyarrhythmia detection and therapies, place the patient magnet over the ICD.
2. To resume tachyarrhythmia detection and therapies, remove the patient magnet from the ICD.

Note: You can also suspend and resume tachyarrhythmia detection and therapies with a Medtronic programmer or a Medtronic device manager.

6.4.2 ICD device tones

There are 2 types of ICD or CRT-D tones, the magnet tone, and the patient alert tone.

Magnet tone – The magnet tone is a steady tone. It sounds when an ICD or CRT-D senses a magnetic field. If a patient hears a magnet tone, instruct them to look for a magnetic object on them or near them. If a patient is ambulatory when they hear the tone, instruct them to move away from the magnetic source, or to move to a different location if they cannot identify the magnetic source.

Patient alert tone – The patient alert tone is either a beeping tone or an alternating high/low tone. If a patient alert tone is programmed to On, the tone sounds when its related alert is triggered. The patient alert tone continues to sound as scheduled, either once every 4 hours or once every 24 hours, until you interrogate the device. A patient alert tone will also sound if an alert is in effect and the ICD or CRT-D senses a magnetic field. Tell your patient to contact you if they hear a patient alert tone.

If you hear an alert tone when you apply a Medtronic Model 9466 patient magnet, interrogate the ICD or CRT-D for alert conditions, for device errors, or for a device reset.

Note: ICD or CRT-D tones sound in the presence of EMI that includes a magnetic field.

Note: Magnets are designed into many consumer products, including clothing and clothing accessories. Patients may not be aware of these magnets because they can be difficult to locate. If a patient is unsure if a product has a magnet, the patient can contact the product manufacturer for further information. Patients can also search consumer products with a ferrous metal object, such as a paper clip, to see if any magnets attract it.

6.4.3 How to program asynchronous pacing in an ICD

Some medical procedures and therapies generate enough EMI to inhibit pacing in an ICD. If your ICD patient is pacemaker-dependent, use a Medtronic programmer or Medtronic device manager to program an asynchronous pacing mode (AOO, VOO, or DOO).

Note: A Medtronic Model 9466 patient magnet will not initiate asynchronous pacing in a Medtronic ICD.

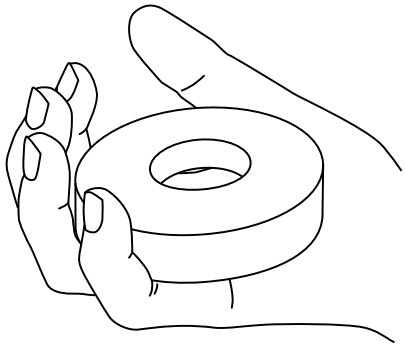
When you have finished the medical procedure or therapy, use a Medtronic programmer or Medtronic device manager to restore device parameters.

6.5 Medtronic Model 9466 patient magnet

Table 3. Model 9466 patient magnet specifications

Shape	ring
Size	
Diameter	75 mm (3 in)
Thickness	16 mm (5/8 in)
Materials	ferrous alloys, coated with epoxy
Minimum field strength	90 gauss, at 40 mm (1.5 in) from magnet surface

Figure 1. Model 9466 patient magnet



Patient magnet storage and handling – Observe the following precautions when storing and handling the Medtronic Model 9466 patient magnet:

- The patient magnet can damage some electronic devices if it is stored too close to those devices.
- Keep the patient magnet at least 15 cm (6 in) from electronic devices and recordings: VCRs, televisions, and videotapes; bank cards and credit cards, cordless telephones and mobile telephones, computers, diskettes, calculators, and similar devices.
- Keep the patient magnet at least 5 cm (2 in) from wristwatches and clocks.
- If soiled, the patient magnet can be wiped clean with a soft cloth or a sponge, or it can be washed with a non-abrasive cleanser. The patient magnet is not damaged by being submerged in water.

7 Warnings, precautions, and guidance for EMI for patients with an implanted pacemaker or ICD

This chapter provides guidance for you to share with your patients to help them remain safe in or near environments and devices that can generate EMI.

7.1 Items with no distance restriction from an implanted pacemaker or ICD

The following table represents items that, when used as intended and in good working condition, have no distance restriction from an implanted pacemaker or ICD.

Table 4. Examples of household items with no distance restriction for EMI interference

Bed, adjustable	Garage door opener, remote control	Medical alert necklace or pendant
Battery charger for household batteries	GPS (global positioning system)	Microwave oven
Blender / food processor	Guitar, electric	Radio, AM/FM
Bluetooth technology	Hair shaver / trimmer, battery powered[a]	Refrigerator
Can opener	Hair straightener	Remote control, infrared, for CD/DVD player, television, and so on.
CD/DVD/DVR player or recorder, without speakers	Heart rate monitor, chest band	Residential power line
Clothes iron	Heating pad	Satellite dish, receiving

Table 4. Examples of household items with no distance restriction for EMI interference (continued)

Curling iron	Home security system, infrared or ultrasonic	Sauna, electric
Digital music player (for example, iPod)	Hot tub[b]	Smart scale that measures body mass index (BMI)[c]
Dishwasher	House arrest anklet[d]	Stove, kitchen[e]
Electric blanket or electric mattress pad	Ionized bracelet	Swimming pool[b]
Electronic weight scale	Kiln, 115-120 V AC or 220-240 V AC	Television[f]
Flashlight	Massage bed / chair / pad	Toaster

[a] Compare to hair shaver / trimmer in Table 9, page 28.
[b] Hot tub and swimming pool must be properly grounded.
[c] Contact Medtronic Technical Services for a list of acceptable BMI scales.
[d] Compare to house arrest bracelet. See Table 7, page 27.
[e] 60 cm (24 in) distance restriction from induction cooktops.
[f] Maintain a 15 cm (6 in) distance from television speakers.

Table 5. Examples of professional and vocational items with no distance restriction for EMI interference

Anti-theft detection pedestals / electronic article surveillance equipment for retail loss prevention[a]	Diesel engines	Office printer
Automobiles, electric[b]	Facsimile (fax) machine	Photocopier / copy machine
Automobiles, hybrid[c]	Hooded hair dryer, salon[d]	Pager, receiver only
Barcode scanner	Laser level, battery operated	Soldering iron[e]
Calipers, battery powered	Office calculator	Stud finder, battery operated

[a] Safe when walking between the pedestals at normal walking speed. Do not linger near the detection equipment.
[b] 30 cm (12 in) distance from electric automobile battery charger.
[c] Compare to hybrid automobiles in Section 7.3.1, “Vehicles with engines fueled by gasoline or petrol”, page 29.
[d] Compare to hair dryer, handheld in Table 7, page 27.
[e] Compare to soldering gun; see Table 12, page 29.

Table 6. Examples of recreational items with no distance restriction for EMI interference

Casino slot machine	Motorcycle vest, heated	Tanning booth, electrostatic
Electric golf cart[a]	Tanning bed	

[a] Maintain a 15 cm (6 in) distance from battery.

7.2 Items with a 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

The following table represents items that, when used as intended and in good working condition, have a 15 cm (6 in) distance restriction from an implanted pacemaker or ICD.

Table 7. Examples of household items with 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

Air filter, ionized	Magnet, small	Static electricity generator, "plasma ball"[a]
Amateur radio, ham radio, and marine radio, < 3 W, from antenna	Magnetic back brace or belt	Stereo speakers, from magnet
Canine shock collar for electric pet containment fence, including remote control and base with antenna	Magnetic cover for tablet computer	Television audio headset, from transmitter near television
Clasp, magnetic	Magnetic chair pad	Tools, battery powered
Electric guitar speakers	Magnetic therapy products	Tools, small electric, from motor
Electric kitchen appliances, handheld	Massager, handheld	Toothbrush, electric, from charging base
Exercise bicycle, wheel magnet	Model cars, airplanes, video drones — remote controlled, from controller antenna	Toy train, electric, from transformer and rails
Hair dryer, handheld[b]	Refrigerator door, from magnetic closure strip	Treadmill, from electric motor
Home security system, microwave, from transmitter	Sewing machine or serger, from motor	Ultrasonic or radio frequency pest control device
House arrest bracelet[c]	Smart meter (used by utility companies)	Vacuum cleaner, from motor

[a] Do not touch this item.
[b] Compare to hooded hair dryer, salon in Table 5, page 26.
[c] Compare to house arrest anklet; see Table 4, page 25.

Table 8. Examples of household wireless electronic devices with 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

Activity band or wearable fitness monitor, if device contains magnets	Earbuds, wireless (from magnet)	Remote control, radiofrequency (RF), for CD/DVD player, television, and so on
Cellular adaptor for laptop computer	eReader	Remote keyless entry and remote car starter key fob
Computer keyboard, wireless	Gaming console and controllers	Radiofrequency (RF) wireless charger
Computer: personal, laptop, or tablet	Headphones, from magnets	Smart watch
Cordless telephone, < 3 W, from antenna and base station[a]	Network router	Wi-Fi or cellular modem, from transmitter/receiver
CD/DVD/DVR player and recorder with speakers	Qi inductive mobile telephone charger	

[a] See also cordless telephone, 3 to 15 W, in Table 11, page 28

Caution: Do not carry a wireless device in a pocket or in a shoulder bag near a pacemaker or an ICD.

Table 9. Examples of professional and vocational items with 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

Badge (name tag) with magnetic clasp	OnStar Technology, from antenna	Tools, handheld battery powered, from battery
Badge (security) with externally activated electronic circuit	Pager, 2-way, ≤ 3 W, from antenna	Tools, handheld electric, from motor
Citizens band (CB) radio, ≤ 3 W, from antenna	Personal scooter / electric grocery cart, from battery	Security badge wall scanner
Cordless microphone, from transmitter	Piconet wireless computer connector, from antenna	Tattoo machine
Extractor wand, for automobile mechanics	Portable radio (walkie-talkie), ≤ 3 W, from antenna	Telephone headset, cordless
Hair shaver / trimmer, corded[a]	—	—

[a] Compare to hair shaver / trimmer, battery powered in Table 4.

Mobile telephones
Keep mobile telephones, cellular telephones, or smartphones at least 15 cm (6 in) from an implanted pacemaker or ICD.
Keep magnetic accessories for mobile telephones at least 15 cm (6 in) from an implanted pacemaker or ICD. Accessories with magnets can include wireless earbuds, plug-in earbuds, or cases with magnetic clasps.

Table 10. Sample of recreational items with 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

Bingo wand	Golf cart, electric, from battery	Marine radio, < 3 W, from antenna
Disney MagicBand reader[a]	Laser tag, from magnet or transmitter in some vests	

[a] No distance restriction for Disney MagicBand.

7.3 Items with a 30 cm (12 in) distance restriction from an implanted pacemaker or ICD

The following table represents items that, when used as intended and in good working condition, have a 30 cm (12 in) distance restriction from an implanted pacemaker or ICD.

Table 11. Examples of household items with 30 cm (12 in) distance restriction from an implanted pacemaker or ICD

Amateur radio, cordless telephone[a], ham radio, or 2-way portable radio, 3 to 15 W, from antenna and base station	Automobile battery charger / charging station for electric automobiles	Lawn and garden tools powered by gasoline / petrol, from ignition system (for example, backpack leaf blowers, snow blowers, chainsaws)
Automobile battery charger for gasoline engines	Electrical transformer / transformer box, residential	

[a] Compare to cordless telephone, < 3 W, in Table 8, page 27.

Table 12. Examples of professional and vocational items with 30 cm (12 in) distance restriction from an implanted pacemaker or ICD

Cattle prod / stock prod, from electrodes	Marine radio, 3 to 15 W, from antenna	Transmitters, portable 3 to 15 W, from antenna
Degausser / demagnetizer	Pagers, 2-way, 3 to 15 W, from antenna	UPS (uninterruptible power source – commercial power failure back-up system) up to 200 A
Generators, electric, portable AC/DC, up to 20 kW	Soldering gun[a]	

[a] Compare to soldering iron, see Table 5, page 26.

7.3.1 Vehicles with engines fueled by gasoline or petrol

Observe the following precautions when using vehicles fueled with gasoline / petrol:

- Do not repair or perform maintenance work on an engine while it is running or when its ignition switch is on. Repair or perform maintenance work on an engine when both the engine and its ignition switch are off.
- Maintain a 30 cm (12 in) distance between the implanted cardiac device and an engine that is running or that has its ignition switch turned on.

Note: Diesel engines are safe for patients with an implanted pacemaker or ICD.

Table 13. Examples of vehicles with gasoline / petrol engines with a 30 cm (12 in) distance restriction from an implanted pacemaker or ICD

All-terrain vehicle (ATV)	Equipment / vehicles used for agriculture or construction	Motorcycle
Automobile / hybrid automobile[a]	Forklift – also fueled by propane or natural gas	Snowmobile or snow machine
Boat motor	Jet ski	Truck / lorry

[a] Automobile / hybrid automobile have no distance restriction for drivers or passengers.

7.4 Items with a 60 cm (24 in) distance restriction from an implanted pacemaker or ICD

The following table represents items that, when used as intended and in good working condition, have a 60 cm (24 in) distance restriction from an implanted pacemaker or ICD.

Table 14. Examples of items with a 60 cm (24 in) distance restriction from an implanted pacemaker or ICD

Household items	
Amateur radio, ham radio, or walkie-talkie, 15 to 30 W, from antenna	Stove, induction cooktop
Jumper cables, during use	Residential satellite dish, 2-way
Professional and vocational items	
Anti-theft tag deactivator	GPS survey equipment
Bench-mounted / free-standing tools with motors ≤ 400 horsepower	Radio transmitters, vehicle-mounted, 15 to 30 W – from antenna

Table 14. Examples of items with a 60 cm (24 in) distance restriction from an implanted pacemaker or ICD (continued)

Household items	
Forklift, battery powered, from motor	Welding equipment with less than 160 A (see Section 7.4.1, “Welding safety precautions”, page 30)
Recreational items	
Beach comber / metal detector, from detector head	Marine radio, single side band, 20–25 W, from antenna

7.4.1 Welding safety precautions

Patients must observe the follow precautions with welding equipment at currents less than 160 A. (It is not recommended that patients work with welding equipment at currents greater than 160 A.)

- Work in a dry area with dry gloves and shoes.
- Maintain a 60 cm (24 in) distance between the welding arc and the implanted device.
- Keep the welding cables close together and as far as possible from the implanted device. Place the welding unit approximately 150 cm (5 ft) from the work area.
- Connect the ground clamp to the metal as close to the point of welding as possible. Arrange the work area so that if the handle and rod are dropped, they will not contact the metal being welded.
- Wait several seconds between attempts when having difficulty starting a weld.
- Work in an area that offers firm footing and room for movement.
- Work with an informed person who understands these precautions.
- The patient must immediately stop welding and step away from the area if the patient becomes light-headed or dizzy, or if an implanted ICD delivers a shock.

Note: Aprons or vests will not effectively shield a pacemaker or an ICD from EMI generated by welding equipment.

7.5 Items with low potential for EMI at extended distances from an implanted pacemaker or ICD

The following table lists communications items that have low potential for EMI when used as intended and in good working condition. These items are safe for patients when their antennae are at, or greater than, the listed distance from an implanted pacemaker or ICD.

Note: These distances assume free space and an unobstructed line-of-sight.

Table 15. Items with low potential for EMI at extended distances from an implanted pacemaker or ICD

Communications	
1 m (3 ft)	2-way portable radio, from antenna – 30 to 50 W.
2 m (6 ft)	2-way portable radio, from antenna – 50 to 125 W.
3 m (9 ft)	Amateur radio, ham radio, marine radio, or 2-way portable radio, from antenna – 125 to 250 W. Cellular tower – ≤ 250 W. Commercial broadcast towers – 125 to 250 W. For transmitters with power levels > 250 W, avoid restricted areas that contain the antenna.
4 m (12 ft)	Amateur or ham radio, from antenna – 250 to 500 W.

Table 15. Items with low potential for EMI at extended distances from an implanted pacemaker or ICD (continued)

Communications	
6 m (20 ft)	Amateur or ham radio, from antenna – 500 to 1000 W.
9 m (30 ft)	Amateur or ham radio, from antenna – 1000 to 2000 W.

7.6 Items and environments with special considerations for EMI for patients with implanted pacemakers and ICDs

The information in this section discusses electrical equipment and environments that generate EMI that can affect an implanted pacemaker or ICD. Share this information with patients who work with this equipment or in these environments, or who can encounter these sources of EMI. Contact Medtronic Technical Services for additional guidance regarding these environments.

Industrial equipment – The following industrial equipment and environments include high-voltage current, magnetic fields, or other EMI sources that can affect device operation. Patients may need to avoid using or working near the following categories of industrial equipment. Medtronic recommends that the employers of patients with pacemakers or ICDs consult with clinicians before their employees return to work in these environments.

- Electric furnaces used in the manufacturing of steel
- Induction heating equipment and induction furnaces, such as kilns
- Industrial magnets such as those used in surface grinding and electromagnetic cranes
- Dielectric heaters to heat plastic and dry glue in furniture manufacturing
- Electric arc and resistance welding equipment operating at greater than 160 A (see Section 7.4, “Items with a 60 cm (24 in) distance restriction from an implanted pacemaker or ICD”, page 29 for guidance with welding equipment operating at less than 160 A)
- Broadcasting antennas for AM, FM, shortwave radio, and TV stations
- Microwave transmitters
- Power plants, power generators, and transmission power lines
  Note: Lower-voltage distribution power lines for homes and businesses are unlikely to affect implanted cardiac devices.

Anti-theft and security systems

Anti-theft systems – Anti-theft systems are unlikely to affect an implanted pacemaker or ICD. However, as a precaution, do not linger near or lean against these systems. Walk past or through them at a normal pace. If you experience symptoms, move away from the equipment. After you move away from the equipment, the device resumes its previous state of operation.

Security systems – Metal detectors (walk-through archways and handheld wands) and full-body imaging scanners (millimeter wave scanners, three-dimensional imaging scanners, or backscatter full body scanners) are unlikely to affect an implanted pacemaker or ICD. These detectors and scanners are common in airports, courthouses, and other high-security facilities.

When you encounter security systems, observe the following guidelines:

- Always carry your cardiac device ID card. If your cardiac device sets off a metal detector or a security system, your card is helpful for security staff.
- To minimize the risk of temporary interference with your implanted pacemaker or ICD while going through the security screening process, do not touch metal surfaces around any screening equipment.
- Do not stop or linger in a walk-through archway; simply walk through the archway at a normal pace.
- If a handheld wand is used, ask the security operator not to hold it over or wave it back and forth over your implanted pacemaker or ICD.
- If you have concerns about security screening methods, show your cardiac device ID card to the security operator, request alternative screening, and then follow the security operator’s instructions.

Shock from an electrical outlet (110 V / 220 V)
A momentary shock from an electrical outlet can inhibit pacing in a pacemaker or an ICD. A momentary shock can reset some parameters to their nominal values. Any parameter changes that occur can be reprogrammed during an office visit. There is a low risk of permanent damage to a pacemaker or an ICD from a momentary shock from an electrical outlet. A prolonged shock greater than 8 s can inhibit pacing in a pacemaker or an ICD, or it can cause delivery of a shock in an ICD. A prolonged external shock greater than 2 s can cause reversion in a pacemaker. There is a low risk of permanent damage to a pacemaker, ICD, or leads from a prolonged shock from an electrical outlet.

7.7 Non-EMI environments with special consideration for patients with implanted pacemakers and ICDs

This section includes important information to share with patients about home or work environments that can affect an implanted pacemaker or ICD. Contact Medtronic Technical Services for additional guidance regarding these environments.

Air travel
Air travel in a pressurized cabin is safe for patients with an implanted pacemaker or ICD.

High altitude environments and activities
Medtronic implantable pacemakers and ICDs can withstand air pressure levels equivalent to an altitude limit of 6,000 m (20,000 ft). The following activities are safe for patients with an implanted pacemaker or ICD: • Hiking, trekking, skiing or vehicle travel up to the altitude limit. • Camping or extended stays up to the altitude limit.

Rifles, shotguns
Patients should consult their physician for advice and limitations for the use of rifles and shotguns. A rifle or shotgun should be used on the shoulder that is opposite from the implant location.

Scuba diving, recreational diving
Medtronic implantable pacemakers and ICDs are rated for pressure levels up to 4.0 ATA (atmospheres absolute). 4.0 ATA is approximate to a seawater depth of 30 m (100 ft).

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

EC REP

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
+31 45 566 8000

Canada
Medtronic of Canada Ltd
99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
+1 905 460 3800

Technical manuals
www.medtronic.com/manuals

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