Medtronic

Medical Procedures and EMI Precautions

for MR Conditional Implantable Cardiac Defibrillators

Manual for Health Care Professionals

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

1 Medical procedures and EMI precautions

1.1 Introduction

This manual is intended for physicians and other health care professionals who treat patients who have an implanted Medtronic cardiac defibrillator (ICD). To view this manual online, to download it, or to see the latest list of device models to which this manual pertains, refer to the Medtronic Manual Library at www.medtronic.com/manuals.

Section 1.2 of this document is useful to health care professionals who perform medical procedures on patients with Medtronic cardiac pacing systems and who consult with the patients' cardiologists. This section provides warnings, precautions, and guidance related to medical therapies and diagnostic procedures that may cause serious injury to a patient, interfere with the system, or permanently damage the system. Some common medical procedures that pose no risk are also listed.

Section 1.3 provides precautions and other information related to electromagnetic interference (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 additional guidance on medical procedures or potential EMI scenarios you are concerned about that are not addressed in this manual, customers can contact the following resources:

- Customers in the United States can contact Medtronic Technical Services at +1 800 723 4636. You may also submit questions to tshelp@Medtronic.com or your Medtronic representative.
- Customers outside of the United States can contact a Medtronic representative.

1.2 Warnings, precautions, and guidance for clinicians performing medical procedures on cardiac device patients

Ablation (RF ablation or microwave ablation) – Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation used in cardiac device patients may result in, but is not limited to, induced ventricular tachyarrhythmias, oversensing, unintended tissue damage, device damage, or device malfunction. Pulse-modulated ablation systems may pose higher risk for induced ventricular tachyarrhythmias. Medtronic cardiac devices are designed to withstand exposure to ablation energy. To mitigate risks, observe the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the return electrode patch so that the electrical current pathway does not pass through or near the device and lead system.
- Always monitor the patient during ablation with at least two separate methods, such as arterial pressure display, ECG, manual monitoring of the patient's rhythm (taking pulse) or monitor by some other means such as ear or finger pulse oximetry, or Doppler pulse detection.

To avoid or mitigate the effects of oversensing, consider the following precautions:

- Suspend tachyarrhythmia detection by using a magnet or a programmer. If a programmer is used and ablation causes a device reset, the cardiac device resumes detection. After the ablation procedure, remove the magnet or restore device parameters.
- If appropriate for the patient, program the device to an asynchronous pacing mode (for example, DOO). After the ablation procedure, restore device parameters.

Capsule endoscopy, pH capsule procedures – Capsule endoscopy is a procedure in which a capsule containing a tiny camera is swallowed by the patient to take pictures of the patient's digestive tract. Capsule endoscopy and pH capsule procedures should pose no risk of electromagnetic interference.

Dental procedures – Dental equipment, such as ultrasonic scalers, drills, and pulp testers, poses no risk of electromagnetic interference. Keep a cardiac device at least 15 cm (6 in) away from magnets, such as magnets found in dental office pillow headrests.

Diagnostic radiology (CT scans, fluoroscopy, mammograms, x-rays) – Diagnostic radiology refers to the following medical procedures:

- Computerized axial tomography (CT or CAT scan)
- Fluoroscopy (an x-ray procedure that makes it possible to see internal organs in motion by producing a video image)
- Mammograms
- X-rays (radiography, such as chest x-rays)

Normally, the accumulated dose from diagnostic radiology is not sufficient to damage the device. If the device is not directly exposed to the radiation beam, no risk of interference with device operation occurs. However, if the device is directly in a CT scan beam, see the following precautions in "CT scan". Similar interference may be observed for some forms of high-intensity fluoroscopy.

CT scan – A CT scan is a computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image. If the device is not directly in the CT scan beam, the device is not affected. If the device is directly in the CT scan beam, oversensing may occur for the duration of time the device is in the beam. If the device will be in the beam for longer than 4 s, to avoid or mitigate the effects of oversensing, consider the following precautions:

- Suspend tachyarrhythmia detection by using a magnet or a programmer. After completing the CT scan, remove the magnet or restore device parameters.
- If appropriate for the patient, program the device to an asynchronous pacing mode (for example, DOO). After completing the CT scan, restore device parameters.

Diagnostic ultrasound – Diagnostic ultrasound is an imaging technique that is used to visualize muscles and internal organs, their size, structures, and motion as well as any pathological lesions. It also is used for fetal monitoring and to detect and measure blood flow. Diagnostic ultrasound, such as echocardiogram, poses no risk of electromagnetic interference. For precautions about therapeutic ultrasound, see "Diathermy treatment (including therapeutic ultrasound)".

Diathermy treatment (including therapeutic ultrasound) – Diathermy is a treatment that involves the therapeutic heating of body tissues. Diathermy treatments include high frequency, short wave, microwave, and therapeutic ultrasound. Except for therapeutic ultrasound, do not use diathermy treatments on cardiac device patients. Diathermy treatments may result in serious injury or damage to an implanted device and lead system. Therapeutic ultrasound (including physiotherapy, high intensity therapeutic ultrasound, and high intensity focused ultrasound), is the use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Therapeutic ultrasound is acceptable if treatment is performed with a minimum separation distance of 15 cm (6 in) between the applicator and the implanted device and lead system, as long as the ultrasonic beam is pointing away from the device and lead system.

Electrolysis – Electrolysis is the permanent removal of hair by using an electrified needle (AC or DC) that is inserted into the hair follicle. Electrolysis introduces electrical current into the body, which may cause oversensing. Evaluate any possible risks associated with oversensing with the patient's medical condition. To avoid or mitigate the effects of oversensing, consider the following precautions:

- Suspend tachyarrhythmia detection by using a magnet or a programmer. After completing electrolysis, remove the magnet or restore device parameters.
- If appropriate for the patient, program the device to an asynchronous pacing mode (for example, DOO). After completing electrolysis, restore device parameters.

Electrosurgery – Electrosurgery (including electrocautery, electrosurgical cautery, Medtronic Advanced Energy surgical incision technology, and hyfrecator) is a process in which an electric probe is used to control bleeding, to cut tissue, or to remove unwanted tissue. Electrosurgery used on cardiac device patients may result in, but is not limited to, oversensing, unintended tissue damage, tachyarrhythmias, device damage, or device malfunction. If electrosurgery cannot be avoided, consider the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.

- Use a bipolar electrosurgery system or Medtronic Advanced Energy surgical incision technology, if possible. If a unipolar electrosurgery system is used, position the return electrode patch so that the electrical current pathway does not pass through or within 15 cm (6 in) of the device and lead system.
- Do not apply unipolar electrosurgery within 15 cm (6 in) of the device and lead system.
- 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 avoid or mitigate the effects of oversensing, consider the following precautions:

- Suspend tachyarrhythmia detection by using a magnet or a programmer. If a programmer is used and electrosurgery causes a device reset, the cardiac device resumes detection. After completing electrosurgery, remove the magnet or restore device parameters.
- If appropriate for the patient, program the device to an asynchronous pacing mode (for example, DOO). After completing electrosurgery, restore device parameters.

External defibrillation and cardioversion – 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 cardiac devices are designed to withstand exposure to external defibrillation and cardioversion. While damage to an implanted system from an external shock is rare, the probability increases with increased energy levels. These procedures may also temporarily or permanently elevate pacing thresholds or temporarily or permanently damage the myocardium. If external defibrillation or cardioversion are required, consider the following precautions:

- Use the lowest clinically appropriate energy.
- Position the patches or paddles no closer than 15 cm (6 in) to the device.
- Position the patches or paddles perpendicular to the device and lead system.
- If an external defibrillation or cardioversion is delivered within 15 cm (6 in) of the device, use a Medtronic programmer to evaluate the device and lead system.

Hyperbaric therapy (including hyperbaric oxygen therapy, or HBOT) – Hyperbaric therapy is the medical use of air or 100% oxygen at a higher pressure than atmospheric pressure. Hyperbaric therapies with pressures exceeding 4.0 ATA, approximately 30 m (100 ft) of seawater, may affect device function or cause device damage. To avoid or mitigate risks, do not expose implanted devices to pressures exceeding 4.0 ATA.

Lithotripsy – Lithotripsy is a medical procedure that uses mechanical shock waves to break up kidney or gallbladder stones. If the device is at the focal point of the lithotripter beam, lithotripsy may permanently damage the device. If lithotripsy is required, keep the focal point of the lithotripter beam a minimum distance of 2.5 cm (1 in) away from the device. To avoid or mitigate the effects of oversensing, consider the following precautions:

- Suspend tachyarrhythmia detection by using a magnet or a programmer. After completing lithotripsy treatment, remove the magnet or restore device parameters.
- If appropriate for the patient, program the device to an asynchronous pacing mode (for example, DOO). After completing lithotripsy treatment, restore device parameters.

Magnetic resonance imaging (MRI) – An MRI is a type of medical imaging that uses magnetic fields to create an internal view of the body. If certain criteria are met and the warnings and precautions provided by Medtronic are followed, patients with an MR Conditional device and lead system are able to undergo an MRI scan; for details, refer to the MRI Technical Manual that Medtronic provides for an MR Conditional device.

Radiotherapy – Radiotherapy is a cancer treatment that uses radiation to control cell growth. When performing radiotherapy, take precautions to avoid oversensing, device damage, and device operational errors, as described in the following sections:

- Oversensing – If the patient undergoes radiotherapy treatment and the average dose rate at the device exceeds 1 cGy/min, the device may inappropriately sense direct or scattered radiation as cardiac activity for the duration of the procedure. To avoid or mitigate the effects of oversensing, consider these precautions:
  - Suspend tachyarrhythmia detection by using a magnet or a programmer. After completing radiotherapy treatment, remove the magnet or restore device parameters.

  - If appropriate for the patient, program the device to an asynchronous pacing mode (for example, DOO). After completing radiotherapy treatment, restore device parameters.
- Device damage – Exposing the device to high doses of direct or scattered radiation from any source that results in an accumulated dose greater than 500 cGy may damage the device. Damage may not be immediately apparent. If a patient requires radiation therapy from any source, do not expose the device to radiation that exceeds an accumulated dose of 500 cGy. For patients who are undergoing multiple radiation treatments, consider the accumulated dose to the device from previous exposures.
  Note: Normally, the accumulated dose from diagnostic radiology is not sufficient to damage the device. See "Diagnostic radiology" for precautions.
- Device operational errors – Exposing the device to scattered neutrons may cause electrical reset of the device, errors in device functionality, errors in diagnostic data, or loss of diagnostic data. To help reduce the chance of electrical reset due to neutron exposure, deliver radiotherapy treatment by using photon beam energies less than or equal to 10 MV. The use of conventional x-ray shielding during radiotherapy does not protect the device from the effects of neutrons. If photon beam energies exceed 10 MV, Medtronic recommends interrogating the device immediately after radiotherapy treatment. An electrical reset requires reprogramming of device parameters. Electron beam treatments that do not produce neutrons do not cause electrical reset of the device.

Stereotaxis – Stereotaxis is a catheter navigation platform that allows clinicians to steer catheter-based diagnostic and therapeutic devices throughout the body by using magnetic navigation. During a stereotaxis procedure, the magnetic field may activate the magnet detection sensor in the implanted device, which suspends tachyarrhythmia detection in an ICD, or reverts pacing to asynchronous in a pacemaker. The device resumes normal programmed operation after the procedure.

Transcutaneous electrical nerve stimulation (TENS) – TENS (including neuromuscular electrical stimulation or NMES) 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.

Transurethral needle ablation (TUNA) and Transurethral Microwave Therapy (TUMT) – TUNA and TUMT are surgical procedures used for benign prostatic hyperplasia (BPH) in which precisely focused energy is used to ablate prostate tissue. Patients with implanted cardiac devices may conditionally undergo procedures that use a TUNA or TUMT system. To avoid affecting cardiac device function when performing a TUNA or TUMT procedure, position the return electrode on the lower back or lower extremity at least 15 cm (6 in) away from the implanted device and lead system.

1.3 Warnings, precautions, and guidance related to electromagnetic interference (EMI) for cardiac device patients

Many cardiac device patients resume their normal daily activities after full recovery from surgery. However, there may be certain situations that patients need to avoid. Because a cardiac device is designed to sense the electrical activity of the heart, the device may sense a strong electromagnetic energy field outside of the body and deliver a therapy that is not needed or withhold a therapy that is needed. The following sections provide important information to share with patients about electrical equipment or environments that may cause interference with their implanted cardiac device. If you have any questions or concerns about EMI, contact a Medtronic representative.

General EMI guidelines for patients – Patients should observe the following general guidelines regarding EMI:

- Area restrictions – Before entering an area where signs are posted prohibiting persons with an implanted cardiac device, such as a pacemaker or ICD, consult with your doctor.
- 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 cardiac device should immediately return to normal operation. If symptoms do not improve when you move away from the item, consult with your doctor. 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 consult with your doctor.

- Proper grounding of electrical items – To avoid interference from electrical current that may leak from improperly grounded electrical items and pass through the body, observe the following precautions:
  - Make sure that all electrical items are properly wired and grounded.
  - Make sure that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

Wireless communication devices – Wireless communication devices include transmitters that can affect cardiac devices. When using wireless communication devices, keep them at least 15 cm (6 in) away from your cardiac device. Do not carry the wireless communication device in a pocket over the device or in a shoulder bag near the device.

The following items are examples of such devices:

- Handheld cellular, mobile, smartphones, or cordless telephones (wireless telephones);
- Wireless-enabled devices and accessories such as laptop or tablet computers, keyboards; network routers; MP3 players; eReaders; gaming consoles; televisions and remote controls; DVD/DVR players; wearable fitness monitors; smart watches; headsets, headphones, and earbuds
- Remote keyless entry and remote car starter devices
- Remote controller of radio-controlled toys
- Two-way walkie-talkies (less than 3 watts)

Household and hobby items with motors or magnets and other items that cause EMI – Household and hobby items that have motors or magnets or that generate electromagnetic energy fields could interfere with a cardiac device. Keep a cardiac device at least 15 cm (6 in) away from the following items:

- Handheld kitchen appliances, such as electric mixers
- Sewing machines and sergers
- Personal care items, such handheld hair dryers, electric shavers, electric or ultrasonic toothbrushes (base charger), or back massagers
- Items that contain magnets, such as bingo wands, mechanic's extractor wands, magnetic bracelets, magnetic clasps, magnetic chair pads, speakers, or earphones

The following household and hobby items require special precautions:

- Boat motors – Keep a cardiac device at least 30 cm (12 in) away from electric trolling motors or gasoline-powered boat motors.
- Electronic body fat scale – Using this type of scale is not recommended for cardiac device patients because it passes electricity through the body and can interfere with the device.
- Electronic pet fences or invisible fences – Keep a cardiac device at least 15 cm (6 in) away from the collar, remote control, and indoor antenna of electronic pet fences or invisible fences.
- Recreational handheld metal detectors – Keep a cardiac device at least 60 cm (24 in) away from the detector end.
- Home-use electric kilns – Keep a cardiac device at least 60 cm (24 in) away from home-use electric kilns.
- Induction cook tops – An induction cook top uses an alternating magnetic field to generate heat. Keep a cardiac device at least 60 cm (24 in) away from the heating zone when the induction cook top is turned on.
- Magnetic mattress pads or pillows – Items containing magnets can interfere with the normal operation of a cardiac device if they are within 15 cm (6 in) of the device. Avoid using magnetic mattress pads or pillows because they cannot easily be kept away from the device.
- Portable electric generators up to 20 kW – Keep a cardiac device at least 30 cm (12 in) away from portable electric generators.
- UPS (uninterruptible power source) up to 200 A – Keep a cardiac device at least 30 cm (12 in) away from a UPS.

Home power tools – Most home power tools should not affect cardiac devices. Consider the following common-sense guidelines:

- Keep all equipment in good working order to avoid electrical shock.
- Be certain that plug-in tools are properly grounded (or double insulated). Using a ground fault interrupter outlet is a good safety measure (this inexpensive device prevents a sustained electrical shock).

Some home power tools could affect cardiac device operation. Consider the following guidelines to reduce the possibility of interference:

- Electric yard and handheld power tools (plug-in and cordless) – Keep a cardiac device at least 15 cm (6 in) away from such tools.
- Soldering guns and demagnetizers – Keep a cardiac device at least 30 cm (12 in) away from these tools.
- Gasoline-powered tools and gasoline-powered yard equipment – Keep a cardiac device at least 30 cm (12 in) away from components of the ignition system. Turn off the motor before making adjustments.
- Car engine repair – Turn off car engines before making any adjustments. When the engine is running, keep a cardiac device at least 30 cm (12 in) away from components of the ignition system.

Industrial equipment – After recovering from implant surgery, you likely will be able to return to work, school, or daily routine. However, if you will be using or working near high-voltage equipment, sources of high electrical current, magnetic fields, or other EMI sources that may affect device operation, consult with your doctor. You may need to avoid using, or working near, the following types of industrial equipment:

- Electric furnaces used in the manufacturing of steel
- Induction heating equipment and induction furnaces, such as kilns
- Industrial magnets or large magnets, such as those used in surface grinding and electromagnetic cranes
- Dielectric heaters used in industry to heat plastic and dry glue in furniture manufacturing
- Electric arc and resistance welding equipment
- Broadcasting antennas of AM, FM, shortwave radio, and TV stations
- Microwave transmitters. Note that microwave ovens are unlikely to affect cardiac devices.
- Power plants, large generators, and transmission lines. Note that lower voltage distribution lines for homes and businesses are unlikely to affect cardiac devices.

Radio transmitters – Determining a safe distance between the antenna of a radio transmitter and a cardiac device depends on many factors such as transmitter power, frequency, and the antenna type. If the transmitter power is high or if the antenna cannot be directed away from a cardiac device, you may need to stay farther away from the antenna. Refer to the following guidelines for different types of radio transmitters:

- Two-way radio transmitter (less than 3 W) – Keep a cardiac device at least 15 cm (6 in) away from the antenna.
- Portable transmitter (3 to 15 W) – Keep a cardiac device at least 30 cm (12 in) away from the antenna.
- Commercial and government vehicle-mounted transmitters (15 to 30 W) – Keep a cardiac device at least 60 cm (24 in) away from the antenna.
- Other transmitters (125 to 250 W) – Keep a cardiac device at least 2.75 m (9 ft) away from the antenna. For transmitters with power levels higher than 250 W, avoid restricted areas containing the antenna.

Security systems – When passing through security systems, follow these precautions:

- Electronic antitheft systems, such as in a store or library, and point-of-entry control systems, such as gates or readers that include radio frequency identification equipment – These systems should not affect a cardiac device, but as a precaution, do not linger near or lean against such systems. Simply walk through these systems at a normal pace. If you are near an electronic antitheft or entry control system and experience symptoms, promptly move away from the equipment. After you move away from the equipment, the cardiac device resumes its previous state of operation.
- Airport, courthouse, and jail security systems – Given the short duration of security screening, it is unlikely that metal detectors (walk-through archways and handheld wands) and full body imaging scanners (also called millimeter wave scanners and three-dimensional imaging scanners) in airports, courthouses, and jails will affect a cardiac device. When encountering these security systems, follow these guidelines:
  - Always carry your cardiac device ID card. If a cardiac device sets off a metal detector or security system, show your ID card to the security operator.
  - Minimize the risk of temporary interference with your cardiac device while going through the security screening process by not touching 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 cardiac device.
  - 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.

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