



Medtronic

Answers to Questions about Implantable Cardiac Devices

Electromagnetic Compatibility Guide

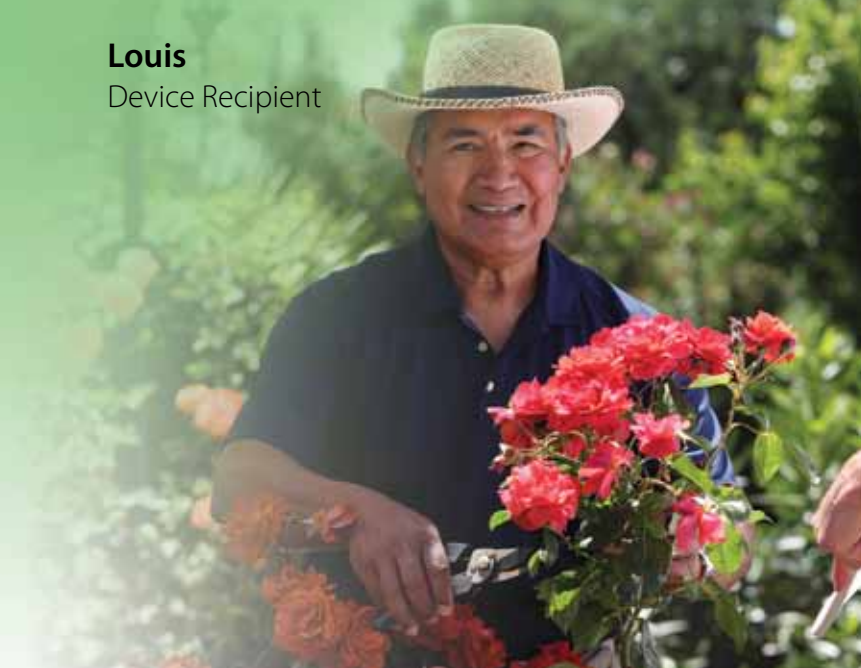


Helping you lead a fuller life.

This booklet is designed to provide answers to questions you may have related to living with an implanted heart device.

If you have specific questions regarding dental or medical procedures, please ask your doctor or nurse. You can also call Medtronic Patient Services toll-free at 1 (800) 551-5544, x41835 (8:00 a.m. to 5:00 p.m., Monday – Friday, Central time) with non-medical questions.

Louis
Device Recipient



What you should know about electromagnetic compatibility (EMC)

Medtronic heart devices are built with protective shields, so the majority of items that you use or come into contact with will not affect the normal operation of your implanted heart device. However, items that generate or use electricity, or transmit wireless signals – such as a portable generator, power drill, or cell phone – have electromagnetic fields around them. Some of these fields may affect the normal operation of your heart device. Electromagnetic compatibility is the relationship between these electromagnetic fields and your heart device.

How items may affect your heart device

If the electromagnetic fields surrounding an item are too close to your implanted heart device – and your heart device happens to detect these fields – this may temporarily affect the normal function of your heart device. This same effect may also occur if the item being touched is not in good working order or properly wired, causing electrical current to flow into your body.

In either situation, this may temporarily cause your heart device to deliver a therapy that is not needed or withhold a therapy that is needed. For this reason, we recommend you only use items that are in good working condition. In addition, we recommend you maintain a minimum distance between certain items and your implanted heart device. This will help to avoid any temporary effect on your heart device.

What to do if you think an item is affecting your heart device

If you feel dizzy, lightheaded, a change in heart rate, or receive a shock while using an item, simply release whatever you're touching or move away from it. Any temporary effect is unlikely to cause reprogramming or damage to your heart device. Your heart device is designed to return to normal operation. Of course, if your symptoms continue or do not improve, contact your doctor as soon as possible.

Answers to the most commonly asked questions

We've organized this guide to make it helpful and convenient for you to find the answers you're looking for. It's divided into four main categories:

1. Household and Hobby Items
2. Tools and Industrial Equipment
3. Communications and Office Equipment
4. Medical and Dental Procedures

Each category is broken into sections, ranging from no known risk to special considerations, which provides you with the recommended minimum distance for the items or products listed. If the item you're looking for isn't on the list or you have a specific question about an item, contact Medtronic Patient Services at 1 (800) 551-5544, ext. 41835.

Household and Hobby Items

Most household and hobby items are unlikely to affect your heart device when the items are in good working condition, used as intended, and the recommended distances are maintained. For items that transmit power through an antenna, it is recommended that you follow the noted distances between the antenna and your implanted heart device.

No Known Risk

If the item is used as intended and in good working condition, there is no known risk:

- Battery Charger – for household batteries
- Casino Slot Machine
- CD/DVD/VHS Player or Recorder
- Dishwasher
- Electric Blanket

- Electric Guitar
- Garage Door Opener
- Heating Pad
- Hot Tub
- Ionized Air Filter
- Iron
- Kitchen Appliances – small and large (blender, can opener, refrigerator, stove, toaster)
- Massage Chair/Pad
- Medical Alert Necklace
- Microwave Oven
- Remote Control (CD, DVD Player, TV, VHS)
- Salon Hair Dryer
- Shaver – battery powered
- Tanning Bed
- TV
- Electronic Weight Scale
- Low Voltage Residential Power Lines

Minimal Risk

Maintain at least a 6-inch distance between the item and your heart device:

- Electric Grocery Cart/Golf Cart – from motor
- Electric Kitchen Appliances – hand-held (electric mixer or knife)
- Electric Shaver – corded
- Electric Toothbrush Charging Base

- Ultrasonic Pest Controller
- Hair Dryer – hand-held
- Magnetic Therapy Products
- Radio-Controlled Items – from antenna
- Sewing Machine/Serger – from motor
- Small Magnet (household magnet)
- Speakers
- Treadmill – from motor
- Vacuum Cleaner – from motor
- Hand-held Back Massager

Special Considerations

Maintain at least the recommended distance between the item and your heart device:

12-Inch Distance

- Car/Motorcycle – from components of ignition system
- Electric Fence

- Electric Pet Containment Fence – from buried wire and indoor antenna
- Transformer Box (green box in yard)

2-Foot Distance

- Beach Comber Metal Detector – from search head
- Induction Cooktop Stove

Not Recommended

- Ab Stimulator
- Electronic Body Fat Scale
- Magnetic Mattress Pad/Pillow

Tools and Industrial Equipment

It is important that your power tools and/or equipment be in good working order and properly wired (three-prong plug, if applicable) and used as intended by the manufacturer of the product. It is recommended that corded electrical items be plugged into a safety outlet device called a ground fault circuit interrupter (GFCI or GFI).

No Known Risk	Minimal Risk	Special Considerations
<p>If the item is used as intended and in good working condition, there is no known risk:</p> <ul style="list-style-type: none">• Calipers – battery powered• Flashlight – battery powered• Laser Level• Soldering Iron• Stud Finder	<p>Maintain at least a 6-inch distance between the item and your heart device:</p> <ul style="list-style-type: none">• Circular Saw – skill saw• Drills – battery and electric powered• Grinder (hand-held)• Hedge Trimmer – electric powered• Lawn Mower – electric powered• Leaf Blower – electric powered <ul style="list-style-type: none">• Reciprocating Saw (Sawzall®)• Router• Sander• Screwdriver – battery powered• Soldering Gun• Weed Whacker – electric powered• Electric Chainsaw	<p>Maintain at least the recommended distance between the item and your heart device:</p> <p>12-Inch Distance</p> <ul style="list-style-type: none">• Car Battery Charger – 100 amps or less• Gasoline Ignition Systems – from components of ignition system <ul style="list-style-type: none">• Gasoline Powered Tools – from components of ignition system (lawn mower, snowblower, weed whacker, chainsaw)• Generators – 20 kW or less <p>2-Foot Distance</p> <ul style="list-style-type: none">• Bench Mounted/Free Standing Tools – for motors 400 horsepower or less (air compressor, drill presses, grinder, pressure washer, table saw)• Jumper Cables• Welding Equipment (with currents under 160 amps, see page 9) <p>Not Recommended</p> <ul style="list-style-type: none">• Welding Equipment (with currents over 160 amps, see page 9)

Communications and Office Equipment

Guidelines for safe operation of communications and office equipment include such factors as transmitting power, frequency, and antenna type. For items that transmit wireless signals through an antenna, it is recommended that you follow the noted distances between the antenna and your implanted heart device.

No Known Risk	Minimal Risk	Special Considerations
<p>If the item is used as intended and in good working condition, there is no known risk:</p> <ul style="list-style-type: none">• Copy Machine• Desktop/Laptop Computer• Fax Machine• Global Positioning System (GPS)• Pager – receiver only <ul style="list-style-type: none">• Printer• Scanner• Radio AM/FM• Digital Music player (iPod®) – non-transmitting• Infrared Scanner	<p>Maintain at least a 6-inch distance between the item and your heart device:</p> <ul style="list-style-type: none">• Amateur Radio, Ham Radio, Marine Radio, Walkie Talkie – 3 watts or less – from antenna• Cellular Phone – 3 watts or less – from antenna <ul style="list-style-type: none">• Home Wireless Electronics – from antenna• Cordless Headphone Sending Unit (i.e., TV Ears®)• OnStar™ Technology – from antenna• Security Badge Wall Scanner• Wireless Communication devices (computers, headsets, modems, routers, smartphones, Bluetooth®)• Electronic Reader/Reading devices• Electronic Tablets (i.e., iPad®)• Wireless Controllers (Video Game Consoles)• Digital Music Player (iPod) – transmitting• Remote Keyless Entry• Remote Car Starter• Smart Meter (utility companies)	<p>Maintain at least the recommended distance between the item and your heart device:</p> <p>12-Inch Distance</p> <ul style="list-style-type: none">• Amateur Radio, Ham Radio, Marine Radio, Walkie Talkie – between 3-15 watts – from antenna <ul style="list-style-type: none">• Citizens Band (CB) Radio – 5 watts or less – from antenna• Uninterrupted Power Source (UPS) <p>2-Foot Distance</p> <ul style="list-style-type: none">• Amateur Radio, Ham Radio, Marine Radio, Walkie Talkie – between 15-30 watts – from antenna

Medical and Dental Procedures

Many medical procedures will not affect your heart device; however, certain medical procedures can result in serious injury, damage to your heart device, or device malfunction. Before undergoing any medical procedure, it is recommended that you advise your treating doctor or dentist that you have an implanted heart device and consult with your heart doctor to evaluate any possible associated risk.

Acceptable

If the item is used as intended and in good working condition, there is no known risk:

- Acupuncture – no electrical stimulus
- Bone Density Test (x-ray)
- Bone Density Ultrasound – on heel or hand
- Capsule Endoscopy

- Dental Drills
- Dental Ultrasonic Scaler/Cleaner
- Diagnostic Ultrasound (Echocardiogram)
- Diagnostic x-rays (fluoroscopy)
- Electrocardiogram (ECG/EKG)
- Hearing Aid (in or behind ear)
- Heart Rate Monitor
- Laser Surgery
- Mammography
- Positron Emission Tomography (PET Scan)
- PH Capsules
- Sleep Apnea Machine

Acceptable with Precautions

Inform your treating physician that you have a heart device implanted and/or consult with your heart doctor/clinic.

- Medical procedures that require some precautions:
- Ablation (specifically, microwave ablation and radiofrequency ablation)
 - Acupuncture with electrical stimulus

 - Computerized axial tomography (CT or CAT) scan
 - Electrolysis
 - Electrosurgery and other procedures that use an electric probe to control bleeding, cut tissue, or remove tissue
 - External defibrillation, AED, and elective cardioversion
 - Hyperbaric Oxygen Therapy (HBOT)
 - Lithotripsy
 - Radiotherapy (including high-energy radiation therapy)
 - Stereotaxis
 - Therapeutic ultrasound
 - Transcutaneous Electrical Nerve Stimulation (TENS), including neuro muscular electrical stimulation (NMES)
 - Transmitting loop for digital hearing aid
 - Transurethral needle ablation (Medtronic TUNA® therapy)
 - Muscle Stimulators and other devices sending current into your body

Not Recommended

- Diathermy (high frequency, short wave, and microwave)
- MRI (if device not MR-Conditional. Present your heart device identification card to your physician to determine if your heart device is MR-Conditional, which may allow access to an MRI scan – see page 7)

Activities and Intimacy

The goal is for you to lead a normal life as soon as possible. Here are suggested precautions to follow during your recovery period. Your physician will provide you with specific directions based on your current medical condition and history.

Q: What activities can I resume?

A: Generally, your device will not keep you from most activities and hobbies (e.g., bowling, golfing, playing tennis, gardening, fishing, etc.).

Q: Will I be able to return to work?

A: Most patients are able to return to work after device implant. You and your doctor will make this decision. The timing will depend on many things, including the type of work you do.

Q: Will my ICD deliver a shock during intimacy or daily activities?

A: It is rare. Your ICD is programmed to allow your heart to normally rise without treatment shocks being delivered. Your device should only deliver a shock when your heart rate meets the specific criteria programmed by your heart doctor. If you receive a shock during intimacy or other activities, contact your physician. Your doctor will then determine the cause of the shock and may also make

adjustments in the programming of your heart device.

Q: Will I be able to resume sexual activity?

A: Intimacy is a normal part of life. We understand patients resume sexual activity when they feel comfortable. However, if you have a question, it may be helpful to have a conversation with your doctor.

If in doubt about an activity, always discuss with your doctor or nurse.

MRIs

Q: Are heart devices MR-compatible?

A: Currently, most heart devices are not considered safe in an MRI environment because the MRI could change the settings and/or temporarily affect the normal operation of the heart device. Medtronic has a pacemaker system* which is FDA-approved for use in the MRI environment. This pacemaker system has a unique design, developed so that under specific conditions, patients may safely undergo MRI scans.

Talk to your doctor about the pacemaker options available to you, including a device that may allow you access to an MRI in the future.

Q: What if my device is not FDA-approved for use in the MRI environment?

A: Medtronic does not recommend the use of an MRI scan if your device is not FDA-approved for use in the MRI environment. Your physician should discuss all potential benefits and risks with you.

Q: What if my doctor strongly recommends an MRI scan?

A: Your doctor should discuss all potential benefits and risks of an MRI scan with you. Present your ID card to the doctor recommending the MRI scan. This card will advise them to contact your attending heart doctor. If needed, your doctor can seek more information from a Medtronic representative.

Q: If I had an MRI scan, did this affect my heart device?

A: Your doctor can determine if there is an effect on your heart device. If you did not see your doctor after an MRI scan, contact your doctor.

* The Revo MRI® SureScan® pacing system is MR Conditional designed to allow patients to undergo MRI under the specified conditions for use. A complete system, consisting of a Medtronic MRI SureScan IPG implanted with two CapSureFix MRI® SureScan leads, is required for use in the MRI environment.

Anti-Theft Detectors and Airport Security Systems

Q: Can I go through store anti-theft detectors?

A: Yes. *Anti-theft detectors* in stores and libraries generate electromagnetic fields that can “sense” embedded “tags” on merchandise. It may be possible, under unique circumstances, for these fields to temporarily affect the operation of your heart device. Significant effects from interference are unlikely if you pass “normally” through the detectors. It is recommended that you:

- Be aware of anti-theft detectors
- Walk through at a “normal” walking speed
- Don’t linger close to the detection system equipment. If you are near an anti-theft system and feel symptoms, promptly move away from the equipment. Your heart device will resume its previous state of operation when you move away from the equipment.

Q: Can I go through security systems such as those found in airports and courthouses?

A: Given the short duration of security screening, it is unlikely that your Medtronic heart device will be affected by metal detectors (walk-through archways and hand-held wands) or full-body imaging scanners (also called millimeter wave scanners and 3D imaging scanners) such as those found in airports, courthouses, and jails. The metal case of your heart device could set off a metal detector. To minimize the risk of temporary interference with your heart device while going through the security screening process, avoid 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 hand-held wand is used, ask the security operator not to hold it over your heart device and not to wave it back and forth over your heart device. You may also request a hand search as an alternative. If you have concerns about these security screening methods, show your device ID card, request alternative screening, and then follow the instructions of the security personnel.

Household Magnets

Q: Do magnets affect pacemakers and implantable defibrillators?

A: Even though most electromagnetic fields in the home environment will rarely affect the function of a pacemaker or implantable defibrillator, it is recommended you keep any item containing magnets away (at least 6 inches/15 centimeters) from your pacemaker or implantable defibrillator.

The reason for this is because there is a small magnetically activated switch built into the electronics of pacemakers and implantable defibrillators. This internal switch is designed to close when a magnet of enough strength is placed over it.

When the internal switch is closed in the pacemaker, the pacemaker paces the heart at a continuous pre-set rate (which could be different than the rate your doctor programmed).

When the internal switch is closed in an implantable defibrillator, it prevents it from delivering treatment therapies.

You may not always know if an item has a magnet in it. However, if you use household items as they are intended, and they are properly maintained, they should have no effect on your heart device. This includes microwaves, kitchen appliances, cordless phones, radios, televisions, video games,

CD players, hair dryers, electric shavers, electric toothbrushes, electric blankets, leaf blowers, lawn mowers, garage door openers, computers, and small shop tools.

If you mistakenly place a magnet too close to your heart device, simply move the item away.

Removing the magnet returns the pacemaker or implantable defibrillator back to its previous, normal programming.

The use of magnetic mattress pads and pillows is not recommended since it would be difficult to keep a 6-inch (15 centimeter) separation from your heart device.

Welding and Chainsaws

Q: I read in my patient manual that I should avoid welding. Why?

A: Unlike most other household power tools, welding with currents above 160 amps may have a higher tendency to temporarily affect the normal function of your pacemaker or implantable defibrillator.

Q: What if I may need to use a welder?

A: It is recommended you avoid using welding currents above 160 amps.

Follow the safety precautions below to minimize the risk of interfering with your heart device while welding with currents under 160 amps.

Welding Safety Precautions

- Limit welding to currents less than 160 amps
- Work in a dry area with dry gloves and shoes
- Maintain a 2-foot (60 centimeter) distance between the welding arc and heart device
- Keep the welding cables close together and as far away as possible from your heart device. Place the welding unit approximately 5 feet from the work area.
- Connect the ground clamp to the metal as close to the point of welding as possible. Arrange the work so the handle and rod will not contact the metal being welded if they are accidentally dropped.
- Wait several seconds between attempts when having difficulty starting a weld
- Work in an area that offers firm footing and plenty of room for movement

- Work with an informed person who understands these suggestions
- Immediately stop welding and step away from the area if you start feeling lightheaded, dizzy, or you believe your implantable defibrillator has delivered a shock

Since welding equipment may temporarily affect the normal operation of your heart device, any decision you make to use this equipment should be made in consultation with your heart doctor. Your doctor can advise you as to the degree of risk these responses pose for your medical condition.

Aprons or vests will not effectively shield your pacemaker or implantable defibrillator from the electromagnetic energy generated by welding equipment.

Q: I read in my patient manual that I should avoid using a chainsaw. Why?

A: The electromagnetic energy generated by a chainsaw is similar to other electric and gasoline powered tools. If electromagnetic interference occurs with your heart device and you experience symptoms such as becoming dizzy or lightheaded, a running chainsaw may present a higher risk of injury to you than other power tools.

Q: What if I may need to use a chainsaw?

A: You may need to use a chainsaw from time to time. Follow the safety precautions below to minimize the risk of interfering with your heart device while using a chainsaw.

Chainsaw Safety Precautions

- Maintain a 6-inch distance between the motor of an electric chainsaw and your heart device. Also, be sure the equipment is properly grounded.
- Maintain a 12-inch distance between the components of the ignition system of a gas-powered chainsaw and your heart device. Also, it is better to use one that is built with the spark plug located away from the hand grips.
- Immediately stop cutting and turn off your chainsaw if you start feeling lightheaded, dizzy, or you believe your implantable defibrillator has delivered a shock
- Do not work on the engine while it is running
- Do not touch the coil, distributor, or spark plug cables of a running engine

Educational services for patients

Medtronic Patient Services

If you have a Medtronic cardiac device and want to learn more or have questions about living with an implanted heart device, please contact Medtronic Patient Services at 1 (800) 551-5544, ext. 41835. Our Patient Services Specialists are available to assist you, Monday-Friday from 8:00 a.m. to 5:00 p.m. Central time.

If you would like to submit questions, suggestions, or requests to us online, you can use the online form provided at www.medtronic.com/corporate/contact.jsp

Medtronic.com

The Medtronic website includes in-depth information on heart conditions and treatment options for patients and their caregivers. Our interactive website allows you to take assessments, view video, read patient stories, and link to other resources. Visit us online at www.medtronic.com.

www.medtronic.com

World Headquarters

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Patient Services

Medtronic, Inc.
8200 Coral Sea St. NE MVS14
Mounds View, MN 55112

Patient toll-free line:
1 (800) 551-5544
Fax: (763) 367-5809
8:00 am to 5:00 pm CT Mon.-Fri.



Additional Device Information

An implantable pacemaker system relieves symptoms of heart rhythm disturbances. They do this by restoring normal heart rates. A normal heart rate provides your body with the proper amount of blood circulation. The pacemaker system is intended for patients who need rate-adaptive pacing or chronic pacing or for patients who may benefit from synchronizing the pumping of the heart chambers.

An implantable cardioverter defibrillator (ICD) system delivers therapies to treat patients with heart rhythm disorders or who are at significant risk of developing heart rhythm disorders. An ICD is placed inside your body and works automatically.

An implantable CRT pacemaker system relieves symptoms of heart rhythm disturbances. They do this by restoring normal heart rates. A normal heart rate provides your body with the proper amount of blood circulation. The pacemaker system is intended for patients who need rate-adaptive pacing or chronic pacing or for patients who may benefit from synchronizing the pumping of the heart chambers.

A cardiac resynchronization therapy (CRT) implantable cardioverter defibrillator (ICD) system delivers therapies to treat patients who may benefit from synchronizing the

pumping of the heart chambers. A CRT ICD also delivers therapies to treat patients with heart rhythm disorders or who are at significant risk of developing heart rhythm disorders. A CRT ICD is placed inside your body and works automatically.

Risks associated with these implantable device systems include, but are not limited to, infection at the surgical site and/or sensitivity to the device material, failure to deliver therapy when it is needed, or receiving extra therapy when it is not needed. After receiving an implantable device system, you will have limitations with magnetic and electromagnetic radiation, electric or gas-powered appliances and tools with which you are allowed to be in contact.

Treatment with these implantable device systems is prescribed by your physician. This treatment or service is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment or service, results may vary.

For further information, please call the Medtronic toll-free number at 1 (800) 551-5544 (8:00 a.m. to 5:00 p.m., Monday–Friday, Central time) or see the Medtronic website at www.medtronic.com.