

Dear Patient,

Many individuals with a Medtronic implanted heart device (pacemaker or defibrillator) have questions about whether electrical interference from certain electrical tools, appliances, and other equipment will affect their heart device. We are providing this technical information relevant to your Medtronic implanted heart device to help you determine whether you may safely use such equipment, or safely be in an environment where such equipment is in use. There may also be other conditions about your health that may limit how you may use such equipment. Therefore, we encourage you to discuss all related factors with your physician.

Background Information

Medtronic implantable heart devices are designed to operate normally when you are in the majority of work and home environments or while using most electrical tools, appliances or other equipment. While effects are unlikely and are typically temporary, sources for potential effects to the heart device can include:

- “Conducted electric currents” flowing through the body. They are felt as an electrical shock. Sources of conducted electric currents may include:
 - Electrical equipment that is poorly maintained, improperly grounded, or connected to a faulty outlet.
 - Improper electrical safety practices such as working on “live” wires.

Low level current leaks from electrical equipment or improper wiring may be detected by a heart device even when it is not felt by the patient. If a stronger current leak is present, an electric shock from the power source is felt. Conducted currents should be avoided. Your Medtronic heart device is not likely to be damaged or reprogrammed in the event that you do receive a minor electrical shock.

- “Radiated electric/magnetic fields” are invisible energy fields that spread through space. These fields are very common in most environments. Common sources of radiated electromagnetic fields include high-voltage power lines, radio transmission towers, electric motors, cell phones, security gates, or two-way radios.
- “Static magnetic fields” are primarily created by magnets. A static magnetic field is also created around any conductor carrying direct current (DC). Common sources are permanent magnets, DC electromagnets, or certain electric motors.

A Medtronic heart device will operate normally in fields that are below the established field intensity limits. These limits (also referred to as levels of susceptibility) are listed on page 4 of this document. Limits are established by using national and international standards. These standards are developed as a result of collaboration between manufacturers, regulators, and physicians. You should contact your physician if you have exposed your heart device to fields that exceed the recommended limits and are concerned or not feeling well.

Potential Heart Device Interaction

If you are in direct contact with an electric current (conducted current), or if your Medtronic heart device senses an electromagnetic field that exceeds its established limits, the normal function of the heart device could be affected. The heart device could temporarily 1) withhold therapy that is needed, or 2) deliver therapy that is not needed (for example, a defibrillator could deliver an unnecessary shock). It is unlikely to cause damage or adjustments to the programming (settings) of your Medtronic heart device. Your heart device should return to normal operation after the interference has ceased.

If you feel dizzy, feel rapid or irregular heartbeats, or suspect your heart device is being affected, move away from the source of interference and/or turn the item off. If your symptoms continue or do not improve, contact your doctor.

General Rules

To reduce the risk of permanent or temporary effects to your implanted heart device, we recommend that you:

- Follow all established electrical safety precautions.
- Use battery powered tools, appliances, and equipment when practical.
- Protect yourself from electrical current that may leak from improperly grounded electrical items. Make sure that all electrical items are well maintained and properly grounded to avoid an electrical shock. The use of a ground-fault-interrupt [GFI] outlet is a good safety measure.
- Do not enter an area that has posted warning signs.
- Maintain the minimum distance from certain electrical tools, appliances, and other equipment as mentioned in the patient manual you received with your heart device.
- In some situations it may be best to conduct a worksite survey to measure the fields present in your work environment. Observe the maximum allowable field strengths listed in the table on page 4 of this document. Individuals doing the testing will need to know these maximum allowable field strengths in order to select appropriate test equipment and to map safe distances.

Guidelines

Determining whether you can safely use certain electrical tools, appliances or other equipment, or safely be in an environment where such equipment is in use depends on many factors. It is not possible for Medtronic to know the specific conditions which apply in your specific situation, thus Medtronic can not guarantee our information is applicable to your specific situation. Most items are safe to use, and some should be kept a minimum distance from your heart device. The following guidelines may be referenced for safe use with your implanted heart device and are some of the common questions patients have. You may be able to apply this information to other items or situations you encounter that are not referenced in this letter. Please contact Medtronic Patient Services for further assistance.

Maintain a distance of at least 6 inches between your heart device and:

- ◆ Electric powered and battery powered home and garden equipment such as hedge clippers, leaf blowers, and weed trimmers
- ◆ Electric powered and battery powered tools such as drills, circular saws, routers, sanders, and screwdrivers
- ◆ Electronic Article Surveillance (EAS) towers (located in store entrance/exit). Walk through these areas as you normally would. Do not stand or linger around the detection equipment.
- ◆ Hand-held airport security screening wands
- ◆ Soldering guns

Maintain a distance of at least 12 inches between your heart device and:

- ◆ Car battery chargers of 100 amps or less
- ◆ Portable gas or diesel generators of 20 kW (or 20 kVA) or less
- ◆ Components of gasoline ignition systems as found in gasoline powered tools and equipment including lawn mowers, snow blowers, automobiles, and gasoline/propane/compressed natural gas forklift engines while the motor is running

Maintain a distance of at least 2 feet between your heart device and:

- ◆ Electric motors that are up to 400 horsepower including those associated with bench mounted tools, air compressors, and electric powered forklifts while the motor is running
- ◆ Jumper cables (at the moment the vehicle is being started)
- ◆ Electronic Article Surveillance (EAS) deactivators (located at the registers in stores usually by the price scanners).

Radio Equipment - Determining a safe distance from the antenna of a radio transmitter depends on many factors such as transmitter power, frequency and the antenna type. The following guidelines are suggestions for safe use of radio equipment. However, if the antenna transmits in a very directional pattern, it may be necessary to maintain a farther distance from the antenna at the strongest part of the pattern.

Maintain a distance of at least 6 inches between your heart device and:

- ◆ Antennas of cellular phones, amateur radios, ham radios, walkie talkies of 3 watts or less.

Maintain a distance of at least 12 inches between your heart device and:

- ◆ Antennas of amateur radios, ham radios, marine radios, walkie talkies, citizens band (CB), of 3-15 watts

Maintain a distance of at least 2 feet between your heart device and:

- ◆ Antennas of amateur radios, ham radios, marine radios, walkie talkies of 15-30 watts

Maintain a distance of at least 3 feet between your heart device and:

- ◆ Antennas of commercial and government dispatch radio equipment of 30-50 watts

Maintain a distance of at least 6 feet between your heart device and:

- ◆ Antennas of commercial and government dispatch radio equipment of 50-125 watts

Additional Notes

- ◆ Diesel engines with mechanical injectors do not affect an implanted heart device. There are no distance precautions to maintain as they do not have an electrical ignition system.
- ◆ The use of chainsaws and welding equipment is not recommended. If required to use, you may obtain guidelines to help make these activities safer by going to our website, www.medtronic.com, or by contacting Medtronic Patient Services for guidelines (800-551-5544 x41835).
- ◆ Locations in power plants can exceed the field intensity limits and may be discussed with the plant's safety officer. Typical locations may be:
 - in the immediate vicinity of the generators (which is normally fenced off)
 - in the areas around the main power bus or transmission lines (which is normally fenced off)
 - in the area near the large pump motors associated with the turbines
 - in the area near the large positive draft motors associated with conventional power plants
 - below the transmission lines leaving a substation (which is normally fenced off)

Lastly, while Medtronic is not in a position to provide on-site environmental testing, we can serve as a resource for your physician, site surveyor, or employer to help determine the level of site evaluation or testing that may be required. Medtronic is available to assist in reviewing the results of a site survey. The decision to return to work is one that must be made by the patient, employer, and physician. We are also available to discuss any other device-related questions you may have. If we can provide further assistance, we invite you to contact us.

Regards,

CRDM Patient Services Department
Medtronic, Inc.
800-551-5544, ext. 41835

Table of Maximum Allowable Field Strengths

In cases where a worksite is being evaluated for actual leakage currents and fields, the following table lists the maximum allowable field strengths for Medtronic heart devices:

Electromagnetic Source	Maximum Allowable Field Strength
Electric Field – 50/60 Hz AC Power Frequency Sources such as: power lines, electric service panels, transformers, power plants, electrical substations	Medtronic pacemakers/defibrillators are designed to operate normally in electric fields measuring: 6,000 volts per meter
Electric Field - High Frequency 150 kHz and up Radio Frequency (RF) Sources such as: radio transmitter antennas, television transmitter antennas, cellular telephone antennas, RF welding equipment, dielectric heaters, radar	Medtronic pacemakers/defibrillators are designed to operate normally in electric fields measuring: 100 volts per meter Note: Medtronic pacemakers and defibrillators are designed to operate normally within RF levels that meet the government Maximum Permissible Exposure (MPE) limits.
Modulated Magnetic Field – 50/60 Hz AC Power Frequency Sources such as: motors, generators, transformers, metal detectors, store security gates, AC/DC welding equipment, and power tools	Medtronic pacemakers/defibrillators are designed to operate normally in modulated magnetic fields: 1 gauss (or <0.1 millitesla or <80 amps per meter) for frequencies up to 10 kilohertz (kHz)
Modulated Magnetic Field - High Frequencies above 10kHz Sources such as: radio transmitter antennas, television transmitter antennas, cellular telephone antennas, RF welding equipment, dielectric heaters, radar	Medtronic pacemakers/defibrillators are designed to operate normally in modulated magnetic fields: 1 amp per meter (or <12.5 milligauss) for frequencies greater than 10 kilohertz (kHz)
Static Magnetic Field (DC) Sources such as: permanent magnets, DC electromagnets, battery powered tools, DC welding equipment, uninterrupted power supply equipment	Medtronic pacemakers/defibrillators are designed to operate normally in static magnetic fields measuring: 5 gauss

Measuring an Electromagnetic Field

A survey or measurement of the electromagnetic fields around a source or in a work area can identify the strength of a field. Various meters can be used to survey a field, such as:

1. An extremely low frequency (ELF) meter – measures the AC electric fields at power frequency 50 Hz/60Hz
2. A radio frequency (RF) meter - measures high frequency electric fields of radio and microwave fields
3. A gauss meter - measures AC and/or DC magnetic field strengths
4. An extremely low frequency (ELF) gauss meter – measures AC magnetic field strengths at power frequencies of 50Hz/60 Hz/400Hz

In some cases, a doctor may arrange for a heart device patient to wear an ambulatory heart monitor as a means to assess his/her heart activity while in their work environment.