Electromagnetic Interference (EMI)

CRHF Technical Services Standard Letter

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The information provided in this letter is for healthcare providers and Medtronic representatives and applies to the following Medtronic device models:

Model number, model name, description (Non-MRI Conditional devices)
P1501DR ENRHYTHM®, dual chamber IPG
C2TR01 SYNCRA™ CRT-P Cardiac Resynchronization Therapy Pacemaker
C4TR01 CONSULTA® CRT-P Cardiac Resynchronization Therapy Pacemaker
C6TR01 VIVA™ CRT-P Cardiac Resynchronization Therapy Pacemaker

MRI Conditional Device Model number, model name, description
A2DR01 ADVISA DR MRI™ SURESCAN®, dual chamber IPG
A3DR01 ADVISA SR MRI™ SURESCAN®, single chamber IPG
RVDR01 REVO MRI™ SURESCAN™, dual chamber IPG
MC1VR01 Micra™ MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)

This Standard Letter addresses Warnings, precautions, and guidance related to electromagnetic interference (EMI) for the cardiac device models listed above.

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.
- 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.

Household and hobby items with motors or other items that cause EMI – Household and hobby items that have motors or items 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 as handheld hair dryers, electric shavers, electric or ultrasonic toothbrushes (base charger), or electric massagers

How to contact U.S. CRHF Technical Services:
Pacemakers: (800) 505-4636, ICDs: (800) 723-4636, Instruments: (800) 638-1991.
Email: tshelp@medtronic.com

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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 30 cm (12 in) away from the buried wire and the indoor antenna of electronic pet fences or invisible fences.
- 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.
- 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. If the UPS is operating by battery source, keep a cardiac device at least 45 cm (18 in) away.

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, to school, or to your 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:

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- Electric furnaces used in the manufacturing of steel
- Induction heating equipment and induction furnaces, such as kilns
- Dielectric heaters used in industry to heat plastic and dry glue in furniture manufacturing
- Industrial magnets or large magnets, such as those used in surface grinding and electromagnetic cranes
- 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) – These low-power devices present low risk to a cardiac device.
- 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 transmission power levels higher than 250 W, contact a Medtronic representative for more information.

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.

Labeling

ADVISA DR MRI™ SURESCAN™ A2DR01, ADVISA SR MRI™ SURESCAN™ A3SR01 Clinician Manual. Manual Document Number: M961530A001 REV. B, www.medtronic.com/manuals

ENRHYTHM® P1501DR Reference Manual. Manual Document Number: M950679A001 REV. B, www.medtronic.com/manuals

REVO MRI® SURESCAN® RVDR01 Reference Manual. Manual Document Number: M954625A001 REV. A, www.medtronic.com/manuals

SYNCRA® CRT-P C2TR01 Clinician Manual. Manual Document Number: M950693A001 REV. C, www.medtronic.com/manuals

CONSULTA® CRT-P C4TR01 Clinician Manual. Manual Document Number: M950678A001 REV. C, www.medtronic.com/manuals

VIVA™ CRT-P C6TR01 Clinician Manual. Manual Document Number: M956337A001 REV. C, www.medtronic.com/manuals

Micra™ MC1VR01 MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR) Clinician Manual. Manual Document Number: M948893A001 REV. C, www.medtronic.com/manuals

PATIENT MANAGEMENT GUIDANCE

This document is useful to health care professionals who perform medical procedures on patients with Medtronic implanted cardiac device systems and who consult with the patients' cardiologists.

Additional comments

For further information please contact the following:

- **Technical questions:** Medtronic Technical Services can answer additional questions regarding these device operations. **Device labeling:** For additional device-specific guidance**,** consult the labeling associated with the device available on the Medtronic Manual Library website at www.medtronic.com/manuals.
- **Patient questions:** Patients who have questions can contact Medtronic Heart Rhythm Patient Services at 1-800-551-5544, Option 3, email at pshelp@medtronic.com, or see www.medtronic.com/rhythms for a variety of resources.