Radiotherapy

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:

MRI Conditional Device Model number, model name, description
MC1VR01 Micra™ MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)

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, if appropriate for the patient, initiate asynchronous pacing by programming the device to an asynchronous pacing mode (for example, VOO). After completing the radiotherapy treatment, restore the 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. To limit device exposure, use appropriate shielding or other measures. For patients who are undergoing multiple radiation treatments, consider the accumulated dose to the device from previous exposures.

- 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.

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

Labeling

***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.