Medtronic Engineering the extraordinary

Radiotherapy

CRM Technical Services Standard Letter

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

Non-MRI Conditional Device Model Number, Model Name, Description	MRI Conditional Device Model Number, Model Name, Description
C6TR01 VIVA™ CRT-P Digital pacemaker with cardiac resynchronization therapy (OAE-DDDR) **P1501DR** ENRHYTHM® Dual Chamber Rate Responsive Pacemaker with RapidRead™ Telemetry (OAE-DDDR) **C2TR01** SYNCRA® CRT-P Digital pacemaker with cardiac resynchronization therapy (OOE-DDDR) **C4TR01** CONSULTA® CRT-P Digital pacemaker with cardiac resynchronization therapy (OAE-DDDR)	**RVDR01** REVO MRI ®SURESCAN ® Dual Chamber Pacemaker with SureScan® Technology (OAE-DDDR)

This Standard Letter addresses 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 implementing one of the following precautions:
  - Initiate the magnet mode (asynchronous pacing) by placing a magnet over the device. After completing radiotherapy treatment, remove the magnet.
  - 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. 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. Note: Normally, the accumulated dose from diagnostic radiology is not sufficient to damage the device.

- 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.

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.

Labeling

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

ENRHYTHM® P1501DR Reference Manual. Manual Document Number: M950679A001 REV. B, 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

REVO MRI® SURESCAN® RVDR01 Implant Manual. Manual Document Number: M954624A001 REV. A, www.medtronic.com/manuals

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

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

This information is verified for devices approved in the U.S. and may differ by country. For product-specific information on device operation and indications for use, reference the appropriate product labeling.