Medtronic Engineering the extraordinary

Diagnostic Radiology (CT scans, Fluoroscopy, Mammograms, X-rays)

CRM Technical Services Standard Letter

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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 Diagnostic radiology (CT scans, fluoroscopy, mammograms, x-rays):
Diagnostic radiology refers to the following medical procedures:

- Computed axial tomography (CT or CAT scan)
- Fluoroscopy (an x-ray procedure that makes it possible to see internal organs in motion by producing a video image)
- Mammograms
- X-rays (radiography, such as chest x-rays)

Normally, the accumulated dose from diagnostic radiology is not sufficient to damage the device. If the device is not directly exposed to the radiation beam, no risk of interference with device operation occurs. However, if the device is directly in a CT scan beam, see the following precautions in “CT scan”. Similar interference may be observed for some forms of high-intensity fluoroscopy.

CT scan – A CT scan is a computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image. If the device is not directly in the CT scan beam, the device is not affected. If the device is directly in the CT scan beam, oversensing may occur for the duration of time the device is in the beam. If the device will be in the beam for longer than 4 s, 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.
- Program the device to an asynchronous pacing mode (for example, DOO).

After completing the CT scan, remove the magnet or restore device parameters

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.

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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.