

Radiofrequency (RF) or Microwave Ablation

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

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)

MRI Conditional Device Model Number, Model Name, Description

RVDR01 REVO MRI® SURESCAN® Dual Chamber Pacemaker with SureScan® Technology (OAE-DDDR)

This Standard Letter addresses Ablation (RF ablation or microwave ablation):

Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation used in cardiac device patients may result in, but is not limited to, induced ventricular tachyarrhythmias, oversensing, unintended tissue damage, device damage, or device malfunction.

Pulse-modulated ablation systems may pose higher risk for induced ventricular tachyarrhythmias. Medtronic cardiac devices are designed to withstand exposure to ablation energy. To mitigate risks, observe the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the return electrode patch so that the electrical current pathway does not pass through or near the device and leads.
- Always monitor the patient during ablation with at least two separate methods, such as arterial pressure display, ECG, manual monitoring of the patient's rhythm (taking pulse) or monitor by some other means such as ear or finger pulse oximetry, or Doppler pulse detection.

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 the ablation procedure, remove the magnet or restore device parameters.

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

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SYNCR[®] 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

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

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.