

Stereotaxis

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:

<u>Non-MRI Conditional Device Model Number, Model Name, Description</u>
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)

<u>MRI Conditional Device Model Number, Model Name, Description</u>
RVDR01 REVO MRI® SURESCAN® Dual Chamber Pacemaker with SureScan® Technology (OAE-DDDR)

This Standard Letter addresses Stereotaxis:

Stereotaxis is a catheter navigation platform that allows clinicians to steer catheter-based diagnostic and therapeutic devices throughout the body by using magnetic navigation. During a stereotaxis procedure, the magnetic field may activate the magnet detection sensor in the implanted device, which suspends tachyarrhythmia detection. The device resumes normal programmed operation after the procedure.

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

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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.