

Diathermy (Including Therapeutic Ultrasound)

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>MRI Conditional Device Model Number, Model Name, Description</u>
MC1AVR1 Micra™ AV MR Conditional dual chamber transcatheter pacing system with SureScan™ technology (VDD)
MC1VR01 Micra™ MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)
MC2AVR1 Micra™ AV2 MR Conditional dual chamber transcatheter pacing system with SureScan™ technology (VDD)
MC2VR01 Micra™ VR2 MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)

This Standard Letter addresses Diathermy:

Diathermy involves the therapeutic heating of body tissues. There are 3 types of diathermy: shortwave diathermy, microwave diathermy, and ultrasonic diathermy, also known as therapeutic ultrasound. Shortwave diathermy or microwave diathermy can cause serious injury or can damage an implanted transcatheter pacemaker. Do not use shortwave diathermy or microwave diathermy. Ultrasonic diathermy (therapeutic ultrasound) is acceptable with precautions.

Shortwave diathermy – Not recommended. Shortwave diathermy can cause serious patient injury. It can damage an implanted transcatheter pacemaker. Do not perform shortwave diathermy on patients who have an implanted transcatheter pacemaker.

Microwave diathermy – Not recommended. Microwave diathermy can cause serious patient injury. It can damage an implanted transcatheter pacemaker. Do not perform microwave diathermy on patients who have an implanted transcatheter pacemaker.

Therapeutic ultrasound – Acceptable with precautions. Therapeutic ultrasound (including physiotherapy, high intensity therapeutic ultrasound, and high intensity focused ultrasound) uses ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Therapeutic ultrasound does not produce EMI fields capable of inducing significant energy levels; however, the mechanical energy can physically damage internal device components.

Therapeutic ultrasound is acceptable with a minimum separation distance of 15 cm (6 in) between the applicator and the implanted transcatheter pacemaker. Also, point the ultrasonic beam away from 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

Micra™ AV MC1AVR1 MR Conditional Device Manual. Manual Document Number: M042501C001 REV. A, www.medtronic.com/manuals

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Micra™ MC1VR01 MR Conditional Clinician Manual. Manual Document Number: M042502C001 REV. A, www.medtronic.com/manuals

Micra™ AV2 MC2AVR1 MR Conditional Device Manual. Manual Document Number: M019277C001 REV E. www.medtronic.com/manuals

Micra™ VR2 MC2VR01 MR Conditional Device Manual. Manual Document Number: M019292C001 REV E. 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.