

Hyperbaric Oxygen Therapy (HBOT)

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>	<u>MRI Conditional Device Model Number, Model Name, Description</u>
C6TR01 VIVA™ CRT-P Digital pacemaker with cardiac resynchronization therapy (OAE-DDDR)	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 Hyperbaric therapy (including hyperbaric oxygen therapy, or HBOT):

Hyperbaric therapy is the medical use of air or 100% oxygen at a higher pressure than atmospheric pressure. Hyperbaric therapy treats several conditions, including decompression sickness, carbon monoxide poisoning, serious infections, and persistent wounds. Hyperbaric therapies with pressures exceeding 4.0 ATA, approximately 30 m (100ft) of seawater, may affect device function or cause device damage. To avoid or mitigate risks, do not expose implanted devices to pressures exceeding 4.0 ATA.

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

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

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

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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.