

Hyperbaric therapy (Hyperbaric oxygen therapy, or HBOT)

CRHF Technical Services Standard Letter

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The information provided in this letter is for healthcare providers and Medtronic representatives and applies to the following Medtronic device models:

<u>Model number, model name, description (Non-MRI Conditional devices)</u>	<u>MRI Conditional Device Model number, model name, description</u>
C6TR01 VIVA™ CRT-P Cardiac Resynchronization Therapy Pacemaker	A2DR01 ADVISA DR MRI™ SURESCAN®, dual chamber IPG
	A3SR01 ADVISA SR MRI™ SURESCAN®, single chamber IPG
	MC1VR01 Micra™ MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)

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 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.

Labeling

ADVISA DR MRI™ SURESCAN™ A2DR01, ADVISA SR MRI™ SURESCAN™ A3SR01 Clinician Manual. Manual Document Number: M961530A001 REV. B, www.medtronic.com/manuals

VIVA™ CRT-P C6TR01 Clinician Manual. Manual Document Number: M956337A001 REV. C, www.medtronic.com/manuals

Micra™ MC1VR01 MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR). Manual Document Number: M948893A001 REV. C, 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.
- **Patient questions:** Patients who have questions can contact Medtronic Heart Rhythm Patient Services at 1-800-551-5544, Option 3, email at pshep@medtronic.com, or see www.medtronic.com/rhythms for a variety of resources.

How to contact U.S. CRHF Technical Services:
Pacemakers: (800) 505-4636, ICDs: (800) 723-4636, Instruments: (800) 638-1991.
Email: tshelp@medtronic.com

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.