Hyperbaric therapy (Hyperbaric oxygen therapy, or HBOT)

CRHF Technical Services Standard Letter

Rev. 1.0, September 2016, $\ensuremath{\textcircled{O}}$ Medtronic 2016

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

Model number, model name, description (Non-MRI Conditional devices)
P1501DR ENRHYTHM [®] , dual chamber IPG
C2TR01 SYNCRA™ CRT-P Cardiac Resynchronization Therapy Pacemaker
C4TR01 CONSULTA® CRT-P Cardiac Resynchronization Therapy Pacemaker

MRI Conditional Device Model number, model name, description RVDR01 REVO MRI[™] SURESCAN[™], dual chamber IPG

Medtronic

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

ENRHYTHM® P1501DR Reference Manual. Manual Document Number: M950679A001 REV. B, www.medtronic.com/manuals REVO MRI® SURESCAN® RVDR01 Reference Manual. Manual Document Number: M954625A001 REV. A,

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

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 <u>www.medtronic.com/manuals</u>.
- Patient questions: Patients who have questions can contact Medtronic Heart Rhythm Patient Services at 1-800-551-5544, Option 3, email at <u>pshelp@medtronic.com</u>, 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.

