Medtronic Engineering the extraordinary

Radiofrequency (RF) or Microwave Ablation

CRM Technical Services Standard Letter

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

Non MRI Conditional Device Model Name, Model Number, Description

Protecta™ XT DR **D314DRG** Digital dual chamber implantable cardioverter defibrillator (DDE-DDDR)
Protecta™ XT DR **D314DRM** Digital dual chamber implantable cardioverter defibrillator (DDE-DDDR)
Protecta™ XT CRT-D **D314TRG** Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)
Protecta™ XT CRT-D **D314TRM** Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)
Protecta™ XT VR **D314VRG** Digital single chamber implantable cardioverter defibrillator (VVE-VVIR)
Protecta™ XT VR **D314VRM** Digital single chamber implantable cardioverter defibrillator (VVE-VVIR)
Protecta™ DR **D334DRG** Digital dual chamber implantable cardioverter defibrillator (DDE-DDDR)
Protecta™ DR **D334DRM** Digital dual chamber implantable cardioverter defibrillator (DDE-DDDR)
Protecta™ CRT-D **D334TRG** Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)
Protecta™ CRT-D **D334TRM** Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)
Protecta™ VR **D334VRG** Digital single chamber implantable cardioverter defibrillator (VVE-VVIR)
Protecta™ VR **D334VRM** Digital single chamber implantable cardioverter defibrillator (VVE-VVIR)
SECURA™ DR **D204DRM** Digital dual chamber implantable cardioverter defibrillator (DDE-DDDR)
CONSULTA® CRT-D **D204TRM** Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)
SECURA™ DR **D224DRG** Digital dual chamber implantable cardioverter defibrillator (DDE-DDDR)
CONSULTA® CRT-D **D224TRK** Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)
SECURA™ VR **D224VRC** Digital single chamber implantable cardioverter defibrillator (VVE-VVIR)
VIRTUOSO® II DR **D274DRG** Digital dual chamber implantable cardioverter defibrillator (DDE-DDDR)
CONCERTO® II CRT-D **D274TRK** Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)
VIRTUOSO® II VR **D274VRC** Digital single chamber implantable cardioverter defibrillator (VVE-VVIR)
SECURA™ VR **D204VRM** Digital single chamber implantable cardioverter defibrillator (VVE-VVIR)

This Standard Letter addresses Ablation (RF ablation or Microwave ablation):
Ablation (RF ablation or microwave ablation) – Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation used in cardiac device patients may result in, but is not limited to, induced ventricular tachyarrhythmias, oversensing, unintended tissue damage, device damage, or device malfunction. Pulse-modulated ablation systems may pose higher risk for induced ventricular tachyarrhythmias. Medtronic cardiac devices are designed to withstand exposure to ablation energy. To mitigate risks, observe the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the return electrode patch so that the electrical current pathway does not pass through or near the device and leads.
- Always monitor the patient during ablation with at least two separate methods, such as arterial pressure display, ECG, manual monitoring of the patient's rhythm (taking pulse) or monitor by some other means such as ear or finger pulse oximetry, or Doppler pulse detection.

To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by implementing one of the following precautions:

- Suspend tachyarrhythmia detection by using a magnet or a programmer. If a programmer is used and ablation causes a device reset, the cardiac device resumes detection. After the ablation procedure, remove the magnet or restore device parameters.
- If appropriate for the patient, program the device to an asynchronous pacing mode (for example, DOO). After the ablation procedure, remove the magnet or restore device parameters.

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

***CONCERTO® II CRT-D D274TRK Clinician* Manual.** Manual Document Number: M950676A001 2014-02-12 REV. C, www.medtronic.com/manuals

CONSULTA® CRT-D D204TRM Clinician Manual. Manual Document Number: M950957A001 2014-02-12 REV. C, www.medtronic.com/manuals

CONSULTA® CRT-D D224TRK Clinician Manual. Manual Document Number: M950677A001 2014-02-12 REV. C, www.medtronic.com/manuals

SECURA™ DR D204DRM Clinician Manual. Manual Document Number: M950958A001 2013-04-12 REV. B, www.medtronic.com/manuals

SECURA™ DR D224DRG Clinician Manual. Manual Document Number: M950692A001 2013-04-12 REV. B, www.medtronic.com/manuals

SECURA™ VR D204VRM Clinician Manual. Manual Document Number: M928148A001 2013-04-12 REV. B, www.medtronic.com/manuals

SECURA™ VR D224VRC Clinician Manual. Manual Document Number: M928143A001 2013-04-12 REV. B, www.medtronic.com/manuals

VIRTUOSO® II DR D274DRG Clinician Manual. Manual Document Number: M950695A001 2013-04-12 REV. B, www.medtronic.com/manuals

VIRTUOSO® II VR D274VRC Clinician Manual. Manual Document Number: M932642A001 2013-04-12 REV. F, www.medtronic.com/manuals

Protecta™ XT CRT-DD314TRM Clinician Manual. Manual Document Number: M950687A001 2020-02-20 REV. D, www.medtronic.com/manuals

Protecta™ CRT-D D334TRM Clinician Manual. Manual Document Number: M950683A001 2020-02-20 REV. D, www.medtronic.com/manuals

Protecta™ XT CRT-D D314TRG Clinician Manual. Manual Document Number: M950686A001 2020-02-20 REV. D, www.medtronic.com/manuals

Protecta™ CRT-D D334TRG Clinician Manual. Manual Document Number: M950682A001 2020-02-20 REV. D, www.medtronic.com/manuals

Protecta™ XT DR D314DRM Clinician Manual. Manual Document Number: M950689A001 2020-02-20 REV. D, www.medtronic.com/manuals

Protecta™ DR D334DRM Clinician Manual. Manual Document Number: M950685A001 2020-02-20 REV. D, www.medtronic.com/manuals

Protecta™ XT DR D314DRG Clinician Manual. Manual Document Number: M950688A001 2020-02-20 REV. D, www.medtronic.com/manuals

Protecta™ DR D334DRG Clinician Manual. Manual Document Number: M950684A001 2020-02-20 REV. D, www.medtronic.com/manuals

Protecta™ XT VR D314VRM Clinician Manual. Manual Document Number: M930567A001 2020-02-20 REV. D, www.medtronic.com/manuals

Protecta™ VR D334VRM Clinician Manual. Manual Document Number: M936852A001 2020-02-20 REV. E, www.medtronic.com/manuals

Protecta™ XT VR D314VRG Clinician Manual. Manual Document Number: M930568A001 2020-02-20 REV. E, www.medtronic.com/manuals

Protecta™ VR D334VRG VA Clinician Manual. Manual Document Number: M952368A001 2020-02-20 REV. D, 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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CRM Technical Services Standard Letter

How to contact U.S. CRHF 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.