Medtronic Engineering the extraordinary

Radiotherapy

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 Radiotherapy:
Radiotherapy – Radiotherapy is a cancer treatment that uses radiation to control cell growth. When performing radiotherapy, take precautions to avoid oversensing, device damage, and device operational errors, as described in the following sections:

- Oversensing – If the patient undergoes radiotherapy treatment and the average dose rate at the device exceeds 1 cGy/min, the device may inappropriately sense direct or scattered radiation as cardiac activity for the duration of the procedure. To avoid or mitigate the effects of oversensing, consider these precautions:
  - Suspend tachyarrhythmia detection by using a magnet or a programmer. After completing radiotherapy treatment, remove the magnet or restore device parameters.
  - If appropriate for the patient, program the device to an asynchronous pacing mode (for example, DOO). After completing radiotherapy treatment, restore device parameters.
- Device damage – Exposing the device to high doses of direct or scattered radiation from any source that results in an accumulated dose greater than 500 cGy may damage the device. Damage may not be immediately apparent. If a patient requires radiation therapy from any source, do not expose the device to radiation that exceeds an accumulated dose of 500 cGy. To limit device exposure, use appropriate shielding or other measures.

For patients who are undergoing multiple radiation treatments, consider the accumulated dose to the device from previous exposures.

Note: Normally, the accumulated dose from diagnostic radiology is not sufficient to damage the device. See "Diagnostic radiology" for precautions.

- Device operational errors – Exposing the device to scattered neutrons may cause electrical reset of the device, errors in device functionality, errors in diagnostic data, or loss of diagnostic data. To help reduce the chance of electrical reset due to neutron exposure, deliver radiotherapy treatment by using photon beam energies less than or equal to 10 MV. The use of conventional x-ray shielding during radiotherapy does not protect the device from the effects of neutrons. If photon beam energies exceed 10 MV, Medtronic recommends interrogating the device immediately after radiotherapy treatment. An electrical reset requires reprogramming of device parameters. Electron beam treatments that do not produce neutrons do not cause electrical reset of 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

***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-D D314TRM 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: M936852A0012020-02-20 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

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.