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:

MRI Conditional Device Model Number, Model Name, Description
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 Radiosurgery and Radiotherapy:
Radiosurgery, also known as stereotactic radiosurgery, delivers intense doses of radiation from a linear accelerator to destroy tumors with submillimeter precision. Radiotherapy is a cancer treatment that uses radiation to control cell growth and destroy tumors. Types of radiotherapy include high-energy photon radiation and proton beam therapy (PBT). Do not subject an implanted transcatheter pacemaker to direct radiosurgery or radiotherapy exposure. Accumulated radiation dosage must not exceed 500 cGy.

Transcatheter pacemaker interference from radiosurgery or radiotherapy:
If a patient undergoes radiosurgery or radiotherapy, an implanted transcatheter pacemaker can sense direct or scattered radiation as cardiac activity for the duration of the procedure. Average dose rates at the transcatheter pacemaker of less than 1 cGy/min are unlikely to produce transcatheter pacemaker interference. Decreasing the dose rate (for example, by increasing the distance between the beam and the implanted transcatheter pacemaker) decreases the potential for interference.

To mitigate the effects of oversensing EMI during therapy, consider programming the device to an asynchronous pacing mode.

Device reset following radiation:
A device reset (also called an electrical reset) does not indicate damage to the implanted transcatheter pacemaker; however, a reset requires device interrogation. In rare cases, a device reset can occur several days following exposure to radiation. Report a device reset to Medtronic Technical Services.

Transcatheter pacemaker damage from radiosurgery or radiotherapy:
Radiation can affect electronic circuitry, so an accumulated radiation dosage of > 500 cGy can damage an implanted transcatheter pacemaker. However, radiation damage is sometimes not immediately apparent. If a patient requires radiosurgery or radiotherapy from any source, do not expose an implanted transcatheter pacemaker to an accumulated radiation dosage that exceeds the recommended limit. Record and monitor the accumulated radiation dosage to implanted devices for patients who undergo multiple radiosurgeries or courses of radiation treatment. Tests have shown damage to implanted Medtronic transcatheter pacemakers with accumulated radiation dosage > 500 cGy. Medtronic therefore cannot predict the operation of implanted transcatheter pacemakers that have withstood radiation overdose. Monitor devices exposed to radiation overdose after each radiosurgery or radiotherapy treatment and consider them for replacement. Consider an augmented follow-up schedule following the completion of all procedures.

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

***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

***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.