Medtronic Engineering the extraordinary

Diagnostic Radiology (CT scans, Fluoroscopy, Mammograms, X-rays)

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 Diagnostic radiology (CT scans, fluoroscopy, mammograms, x-rays):
Diagnostic radiology refers to the following medical procedures:

- Computed axial tomography (CT or CAT scan)
- Fluoroscopy (an x-ray procedure that makes it possible to see internal organs in motion by producing a video image)
- Mammograms
- X-rays (radiography, such as chest x-rays)

Normally, the accumulated dose of radiation from diagnostic radiology is insufficient to damage an implanted transcatheter pacemaker. If the implanted transcatheter pacemaker is not directly in the radiation beam, there is no potential for EMI, except where noted here.

CT scan – Acceptable with precautions. Oversensing can occur only when the implanted transcatheter pacemaker is directly in the CT scan beam.
Fluoroscopy at < 1 cGy/min – Acceptable. Fluoroscopy at < 1 cGy/min generates insufficient EMI to affect an implanted transcatheter pacemaker.
Fluoroscopy at ≥ 1 cGy/min – Not recommended. EMI from fluoroscopy at ≥ 1 cGy/min can cause oversensing in an implanted transcatheter pacemaker.
Mammography – Acceptable. Mammography generates insufficient EMI to affect an implanted transcatheter pacemaker.
X-ray – Acceptable. X-rays generate insufficient EMI to affect an implanted transcatheter pacemaker.

Note: An asynchronous mode will avoid or mitigate the effects of oversensing.

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.