Medtronic

Micra™ AV2 / Micra™ VR2

MRI procedural information for the Micra AV2 and Micra VR2 MR Conditional transcatheter pacing devices implanted in the right ventricle

MRI Technical Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Contents

1 Introduction

The Medtronic Micra AV2 and Micra VR2 transcatheter pacing devices are MR Conditional devices and, as such, are designed to allow patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. The MRI SureScan feature must be programmed using a Medtronic device manager and the Micra AV2 or Micra VR2 implantable device app.

It is important to read this MRI Technical Manual before conducting an MRI scan on a patient with an implanted Model Micra AV2 or Micra VR2 device. Contact a Medtronic representative if you have further questions.

Refer to the appropriate Medtronic device and reference manuals for non-MRI related instructions for use.

2 MRI conditions for use

The Micra AV2 and Micra VR2 transcatheter pacing devices are MR Conditional and, as such, allow the patient to undergo an MRI scan when used according to the instructions in this manual.

Warning: Do not scan a patient who has an active Micra AV2 or Micra VR2 device without first programming MRI SureScan to On. Scanning an active Micra AV2 or Micra VR2 device without programming MRI SureScan to On may result in patient harm.

Note: MRI SureScan cannot be programmed to On if the device reaches the Recommended Replacement Time (RRT).

Note: Micra AV2 and Micra VR2 devices can be safely scanned if the device is programmed to Device Off, or if the device has reached End of Service (EOS). For more information about EOS conditions, refer to the device manual Medtronic provided for this device.

2.1 Radiology requirements

The safety and reliability of the Micra AV2 and Micra VR2 devices has been evaluated using the following conditions for patients and MRI equipment:

MRI Safety Information

MR Conditional

Device identification	Micra AV2 or Micra VR2
Device manufacturer	Medtronic
Additional resources for MRI safety information	www.mrisurescan.com
Warning statement	A patient with a Micra AV2 or Micra VR2 may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient or device malfunction. For additional warnings and precautions, See *Chapter 3*
Static magnetic field strength (B_0) [T]	≤ 3 T
Type of nuclei	Hydrogen Proton
Static magnetic field (B_0) [T] orientation	Horizontal, Cylindrical Bore Perpendicular to Patient, AP Perpendicular to Patient, LR

MRI Safety Information

MR Conditional

Maximum spatial field gradient (SFG) [T/m] and [gauss/cm]	25 T/m (2500 gauss/cm)
Maximum gradient slew rate per axis [T/m/s]	200 T/m/s
RF polarization	No restrictions on RF Polarization
RF transmit coil type	Integrated whole body transmit RF coil Detachable head transmit/receive RF coil Detachable extremity transmit/receive RF coil
RF receive coil	Any receive-only RF coil may be used
RF operating mode or constraints	First Level Controlled Operating Mode or Normal Operating Mode
B_{1+RMS} [µT]	There is no B_{1+RMS} limit
Whole-body (averaged) specific absorption rate (SAR) [W/kg]	≤4 W/kg
Maximum head SAR [W/kg]	≤3.2 W/kg
Scan duration and wait time	There is no limit on scan duration for the labeled RF conditions
Anatomy at Isocenter	Any anatomic location at isocenter is acceptable.
Patient characteristics	• No abandoned leads are present • The active SureScan device is operating within the projected service life or the device is in a Device Off state if past the projected service life. • Pacing amplitude is ≤4.5 V at the programmed pulse width • No diaphragmatic stimulation is observed when MRI SureScan is programmed to Device On • If the patient has multiple MR Conditional devices, all MR Conditional requirements for each implanted device are satisfied
Patient position in scanner	Any patient position is acceptable
Device configuration	Micra AV2 or Micra VR2 implanted in the right ventricle
MR image artifact	Image artifact and distortion can result from the presence of a Micra AV2 or Micra VR2device within the field of view. Image artifact and distortion resulting from the presence of the device within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.
Required programming settings	MRI SureScan must be set to On for an active Micra AV2 or Micra VR2 device before MRI scan. Devices

	beyond their projected service life must in a Device Off state.
Instructions to be followed before, during, and after the MRI exam	**Preparation for patient rescue –** In the event that patient rescue is required, an external defibrillator must be available during the MRI scan. **Proper patient monitoring –** Proper patient monitoring must be provided during the MRI scan. This includes continuous monitoring of the patient's hemodynamic function and both of the following actions: • maintaining continuous visual and verbal contact with the patient • continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography **Note:** If the patient's hemodynamic function is compromised during the MRI scan, discontinue the scan, remove the patient from the magnet room, program MRI SureScan to Off, and take the proper measures to restore the patient's hemodynamic function. **Note:** Monitoring is required whether the device is active, or if the device is programmed to Device Off. **Completing an MRI scan –** MRI SureScan must be set to off for an active Micra AV2 or Micra VR2 device upon completion of the MRI For complete instructions for patient management see the following sections of this manual: • For preparing for a scan, See *Chapter 6* • For performing an MRI scan, See *Chapter 7* • For actions following a scan, See *Chapter 8*

2.2 Training requirements

- A health professional who has completed cardiology SureScan training must be present during the programming of the SureScan feature.
- A health professional who has completed radiology SureScan training must be present during the MRI scan.

3 MRI warnings and precautions

Warnings:

- Do not scan a patient who has an active Micra AV2 or Micra VR2 device without first programming MRI SureScan to On. Scanning an active Micra AV2 or Micra VR2 device without programming MRI SureScan to On may result in patient harm.
- Do not leave the device in MRI SureScan mode after the scan is complete. Be sure to program MRI SureScan to Off as soon as the scan is complete.

- Do not scan patients with abandoned leads. Patients with abandoned leads may be harmed if an MRI scan is performed.
- Do not scan patients with a Micra AV2 or Micra VR2 device implanted in a location other than the right ventricle.

Cautions:

- Do not scan patients with programmed outputs > 4.5 V.
- Do not scan patients who exhibit diaphragmatic stimulation when the device is pacing asynchronously during the MRI SureScan mode.
- Scanning patients who have multiple MR Conditional devices present is acceptable as long as the MR labeling conditions for all implanted devices can be satisfied.
- Do not bring the Medtronic device manager, patient connector, or base into the examination room (magnet room). They are MR Unsafe.

4 Potential adverse events

The Micra AV2 and Micra VR2 devices have been designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MR environment:

- potential for VT/VF induction when the patient is programmed to an asynchronous pacing mode during MRI SureScan
- damage to the device causing the device to fail to detect or treat irregular heartbeats, or causing the device to treat the patient's condition incorrectly

5 Cardiology-specific considerations

VT/VF induction – If an asynchronous MRI SureScan pacing mode is selected for a patient, be aware that the patient may be susceptible to cardiac arrhythmia induced by competitive pacing and other mechanisms. To avoid VT/VF induction, confirm that the patient needs asynchronous pacing, select a pacing rate that avoids competitive pacing, and minimize the period of time during which MRI SureScan is programmed to On.

Note: If the patient does not need pacing support, select a nonpacing mode (OVO).

Device information and records – All pertinent information about the implanted SureScan device such as model name, model number, and serial number should be recorded in the patient record in Patient Information on the implantable device app. This information will help with device identification in the future.

Patient ID card – Reference materials, such as an ID card, should be provided to all patients with an implanted SureScan device. These reference materials should indicate that the patient has a SureScan device.

Note: Be sure to advise patients to notify medical personnel that they have a pacemaker before entering the MR environment and to present their patient ID cards.

Multiple implanted devices – Scanning patients who have multiple MR Conditional devices present is acceptable when the MR labeling conditions for all implants are satisfied. Scanning patients who have multiple MR Conditional Micra devices is also acceptable when the MR labeling conditions for all Micra are satisfied.

6 Pre-MRI scan operations

The steps in the following sections are required before performing an MRI scan.

6.1 Identification of the SureScan device

You can verify that the patient has the SureScan device required for an MRI scan in the following ways:

1. **Patient records or patient ID cards (if applicable):** Use the patient records or patient ID cards, if applicable, to verify that the patient has a SureScan device. The patient records or patient ID cards must be

complete and accurate if they are to be used for the identification of the SureScan device. The patient may have implanted devices that are MRI contraindicated, but not noted on the Medtronic patient ID card.

2. **Patient information on the implantable device app:** The Patient Information feature is intended to be used by the implanting clinician to report the presence of any additional implanted medical devices. If the implanting clinician has entered the needed information completely and accurately, you can use the **PATIENT INFORMATION** screen to determine whether the patient has a SureScan system. The patient may have other implanted devices that are not approved for use in the MRI environment but are not noted in the **PATIENT INFORMATION** screen on the implantable device app.

   Tap the Menu button, then tap **PATIENT INFORMATION**. Review the fields for **Other Active Device** and **Notes**.

6.2 Required patient care

Before programming MRI SureScan to On, perform the following actions to help ensure patient safety:

Verify that the pacing amplitude is ≤ 4.5 V before programming MRI SureScan to On. – If the programmed output exceeds 4.5 V, do not scan the patient.

Evaluate the patient to determine whether or not pacing support is needed while MRI SureScan is programmed to On. – For patients who require pacing support, set the MRI SureScan pacing mode to VOO when programming MRI SureScan to On. For patients who do not require pacing support, set the MRI SureScan pacing mode to OVO when programming MRI SureScan to On. Asynchronous pacing may increase the risk of arrhythmia.

If the patient will require pacing support, ascertain an appropriate pacing rate. – An appropriate pacing rate is one that will help avoid competitive pacing while MRI SureScan is programmed to On.

7 Performing an MRI scan

Warning: Do not scan a patient who has an active Micra AV2 or Micra VR2 device without first programming MRI SureScan to On. Scanning an active Micra AV2 or Micra VR2 device without programming MRI SureScan to On may result in patient harm.

Note: Micra AV2 and Micra VR2 devices can be safely scanned if the device is programmed to Device Off, or if the device has reached EOS.

Warning: Do not leave the device in MRI SureScan mode after the scan is complete. Be sure to program MRI SureScan to Off as soon as possible after the scan is complete.

Note: The device automatically programs MRI SureScan to Off 24 hours after it is programmed to On. Before you program MRI SureScan to On, ensure that the MRI scan will be completed before this 24-hour timeout occurs. Refer to the MRI SureScan report for information about when MRI SureScan was programmed to On.

Caution: Do not bring the Medtronic device manager, patient connector, or base into the examination room (magnet room). They are MR Unsafe.

When programming MRI SureScan to On, you must select parameters that are appropriate for the patient. Pacing mode and rate (if applicable) are to be programmed per the physician's discretion. Based on whether or not the patient needs pacing support, an asynchronous pacing mode (VOO) or sensing only mode can be programmed. Sensed events will be ignored by the device when MRI SureScan is programmed to On, regardless of the programmed mode. The device maintains the selected parameters until MRI SureScan is programmed to Off after the MRI scan has been completed. After MRI SureScan is programmed to Off, the permanent device parameters are restored.

If using another Medtronic tool for enabling and disabling MRI SureScan mode, follow the instructions for use of that respective tool.

7.1 SureScan device integrity verification

The SureScan device provides automatic verification that no device issues that may compromise patient safety during an MRI scan are detected. Before allowing the user to initiate the SureScan feature, the SureScan device application software checks for the following issues:

Insufficient battery longevity – If the device is at Recommended Replacement Time (RRT), the device software prevents the SureScan feature from being initiated.

Note: Micra AV2 and Micra VR2 devices can be safely scanned if the device is programmed to Device Off, or if the device has reached EOS.

High pacing amplitude – If the patient's amplitude is greater than 4.5 V, the device software prevents the SureScan feature from being initiated.

7.2 Programming the MRI SureScan feature to On

Note: If using another Medtronic tool for enabling and disabling MRI SureScan mode, follow the instructions for use of that respective tool.

When programmed to On, the MRI SureScan feature allows patients to be safely scanned by an MRI machine.

To program the MRI SureScan feature to On, perform the following steps:

1. Tap the Menu button, then tap **PARAMETERS > MRI SureScan…**.
2. Review the checklist and select the checkbox if all items are satisfied for the patient.
   Note: To create a copy of the MRI SureScan checklist, tap the PDF button.
3. Tap **OK**.
4. On the **MRI SureScan** window, tap the **MRI SureScan** field, then tap **On**.
5. Tap the **Mode** field and select an appropriate MRI pacing mode as described in *Table 1*.
6. Tap the **Lower Rate** field and select an appropriate MRI pacing rate.
   Notes:
   - To avoid competitive pacing during the operation of asynchronous pacing, select an appropriate MRI SureScan pacing rate.
   - If the patient's device is programmed to the non-pacing (OVO) mode, the MRI pacing rate (Lower Rate) is not available for programming.

Table 1. MRI pacing modes

Situation	Mode
Patients that require pacing support	**Asynchronous mode:** VOO
Patients that do not require pacing support	**Non-pacing mode:** OVO

7. Tap **PROGRAM**.
   The implanted device is now ready for the MRI scan. The implanted device begins pacing at the selected MRI pacing mode and MRI pacing rate.
8. To create a copy of the programmed parameters, tap the PDF button.
9. To end the session, tap **End Session…**.
   Note: The status of the MRI SureScan mode and the programmed parameters may be confirmed by creating the MRI SureScan Parameters report.

7.3 Device considerations

Suspension of diagnostic data – When MRI SureScan is programmed to On, all device diagnostic measurements and collection are suspended.

Asynchronous bradyarrhythmia pacing therapy – Asynchronous bradyarrhythmia pacing therapy is provided when an asynchronous pacing mode is selected for MRI SureScan operation.

Automatic amplitude selection for MRI SureScan pacing mode – When MRI SureScan is programmed to On and the pacing mode is VOO, the device may automatically reset the amplitude values. If the permanently programmed RV Amplitude is ≤ 4.5 V, the amplitude is temporarily set to the current pacing amplitude plus 0.5 V.

Automatic canceling of MRI SureScan with Emergency programming – If you deliver any emergency therapy when MRI SureScan is programmed to On, MRI SureScan is automatically programmed to Off. After an Emergency feature is programmed, MRI SureScan must be programmed to On again before the patient can be scanned safely.

8 Following the MRI scan of an active device

Warning: Do not leave the device in SureScan mode after the scan is complete. Be sure to program MRI SureScan to Off as soon as possible after the scan is complete.

24-hour timeout period – The device automatically programs the MRI SureScan parameter to Off 24 hours after it was programmed to On.

Check the pacing capture threshold – Check the pacing capture threshold of the active device after the scan is complete, and be sure that the pacing parameters are programmed adequately for the patient based on the threshold.

8.1 Returning the active device to the pre-MRI configuration

After the MRI scan is complete, the MRI SureScan mode must be programmed to Off using the implantable device app. Programming the MRI SureScan mode to Off restores the device parameter values to the pre-MRI SureScan mode configuration.

The device maintains the parameters that were set while initiating MRI SureScan operation until the MRI SureScan mode is programmed to Off after the MRI scan or after the 24-hour timeout occurs.

To program the MRI SureScan mode to Off, perform the following steps:

1. On the **MRI SureScan** window, tap the **MRI SureScan** field to change the value to **Off**.
2. Tap **PROGRAM**.
3. Tap **CLOSE**.

   The **MRI SureScan** window closes and the implantable device app returns to the **PARAMETERS** screen. The device parameter values are now restored to the pre-MRI SureScan configuration.

Note: During each interrogation, the device is monitored for possible device reset conditions and disabled therapies. If a condition is detected that requires attention, the implantable device app displays a device status indicator warning in a separate window and on the **Quick Look** screen.

9 Medtronic warranty information

Please see the literature enclosed with the products for information regarding the product warranty or disclaimer of warranty as applicable.

10 Explanation of symbols

The following symbols are related to the magnetic resonance (MR) environment and are used to indicate the safety of devices and components in the MR environment.

SureScan symbol

MR Conditional symbol. The Medtronic SureScan pacing device is MR Conditional and, as such, is designed to allow implanted patients the ability to undergo an MRI scan under the specified MRI conditions for use.

MR Unsafe symbol. An item that is known to pose hazards in all MR environments. The Patient Assistant, Medtronic Device Manager, and the Medtronic Home Monitor are MR Unsafe.

11 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For more information, contact your local Medtronic representative or contact Medtronic at the appropriate telephone number or address listed on the back cover of this manual.

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

Medtronic USA, Inc.
Toll-free in the USA (24-hour technical consultation for physicians and medical professionals)
Bradycardia: +1 800 505 4636
Tachycardia: +1 800 723 4636

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