



AURORA EV-ICD™ MRI SURESCAN™ DVEA3E4



MRI procedural information for MRI SureScan cardioverter defibrillators with MRI SureScan leads

MRI Technical Manual

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

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Contents

1 Introduction	4
1.1 About the system	4
2 MR conditions for use	4
2.1 Cardiology requirements	4
2.2 Radiology requirements	4
2.3 Patient monitoring and rescue requirements	5
2.4 Training requirements	6
3 MRI warnings and precautions	6
4 Potential adverse events	6
5 Patient monitoring requirements	7
6 Cardiology-specific considerations	7
7 Radiology-specific considerations	7
7.1 MRI considerations	7
8 Pre-MRI scan operations	8
8.1 Identification of SureScan system components	8
8.2 Required patient care	8
9 Performing an MRI scan	8
9.1 SureScan system integrity verification	9
9.2 Programming the MRI SureScan feature to On	9
9.3 Device considerations	10
10 Following the MRI scan	10
10.1 Returning the device to the pre-MRI configuration	10
11 Medtronic warranty information	10
12 Explanation of MRI symbols	10
13 Service	11

1 Introduction

1.1 About the system

The Medtronic Aurora EV-ICD™ MRI SureScan™ system is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MR conditions for use. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned. The MRI SureScan feature must be programmed using the Medtronic Model SW041 software on a Medtronic CareLink 2090 Programmer or a Medtronic CareLink Encore 29901 Programmer.

It is important to read this MRI Technical Manual before conducting an MRI scan on a patient with an implanted SureScan system. Contact a Medtronic representative if you have further questions.

Note: The button labels and navigation instructions in this manual apply to the Medtronic Model SW041 software on a Medtronic CareLink 2090 Programmer or a Medtronic CareLink Encore 29901 Programmer. The details of the user interface are provided for reference only and may not match those of other applications.

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

2 MR conditions for use

A complete SureScan system is required for use in the MR environment. A complete SureScan system includes an extravascular SureScan VR ICD with an extravascular SureScan defibrillation lead. To verify that components are part of a SureScan system, visit <http://www.mrisurescan.com>. Any other combination may result in a hazard to the patient during an MRI scan.

Warning: Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan system.

Note: The MRI SureScan mode cannot be programmed to On if the device is recommended for replacement.

2.1 Cardiology requirements

Patients and their implanted systems must be screened to meet the following requirements:

- The patient has no implanted lead extenders, lead adaptors, or abandoned leads.
- The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history.
- The SureScan device is operating within the projected service life.

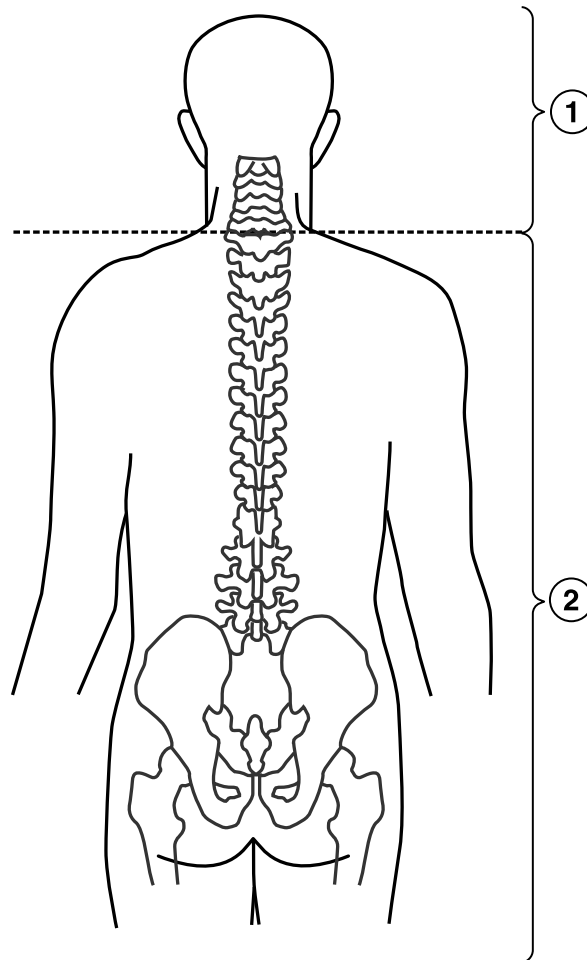
2.2 Radiology requirements

The safety and reliability of the SureScan system has been evaluated for scanning patients using MRI equipment that has the following operating characteristics:

Scanner type	Horizontal field, cylindrical bore, clinical system for hydrogen proton imaging
Scanner characteristics	<ul style="list-style-type: none">• Static magnetic field of one of the following strengths:<ul style="list-style-type: none">– 1.5 T– 3 T• Maximum spatial field gradient of ≤ 20 T/m (2000 gauss/cm)• Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 T/m/s

Scanner operation	1.5 T – MRI radio frequency (RF) power – Normal Operating Mode. <ul style="list-style-type: none"> • The whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg. • The head SAR must be ≤ 3.2 W/kg.
	3 T – MRI radio frequency (RF) power – First Level Controlled Operating Mode or Normal Operating Mode: <ul style="list-style-type: none"> • B_{1+RMS} must be ≤ 2.0 μT when the isocenter (center of the MRI bore) is inferior to the C7 vertebra. • Scans can be performed without B_{1+RMS} restriction when the isocenter is at or superior to the C7 vertebra (see <i>Figure 1</i>).

Figure 1. 3 T Scan location requirements



1 No B_{1+RMS} restrictions

2 B_{1+RMS} not to exceed 2.0 μ T

2.3 Patient monitoring and rescue requirements

Continuous patient monitoring is required during the MRI scan.

In the event that patient rescue is required, an external defibrillator must be immediately available.

2.4 Training requirements

- A health professional who has completed cardiology SureScan training must be present during the programming of the MRI 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 without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan system.
- Do not leave the device in MRI SureScan mode after the scan is complete. While MRI SureScan mode is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. Be sure to program MRI SureScan mode to Off as soon as the scan is complete.
- Do not scan patients who do not have a complete SureScan system, which includes an EV ICD MRI SureScan ICD with an EV ICD SureScan defibrillation lead. Any other combination may result in a hazard to the patient during an MRI scan.
- Do not scan patients with broken, abandoned, or intermittent leads. Lead fractures or other damage to the leads may cause changes in the electrical properties of the SureScan system that will make the system unsafe for an MRI scan. Patients with damaged leads may be harmed if an MRI scan is performed.

Cautions:

- Do not scan patients in a 1.5 T magnetic field with a whole body averaged SAR level > 2.0 W/kg. A scan above 2.0 W/kg may increase the risk of lead electrode heating resulting in patient discomfort.
- Do not scan patients in a 3 T magnetic field with a B_{1+RMS} value > 2.0 μ T when the isocenter (center of the MRI bore) is inferior to the C7 vertebra. A scan above 2.0 μ T may increase the risk of MRI-related hazards, including patient discomfort due to lead electrode heating.
- Do not scan patients with lead extenders or lead adaptors. Lead extenders and lead adaptors may increase the risk of MRI-related hazards, including patient discomfort due to lead electrode heating.
- It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks) because MRI scans during this period have not been prospectively studied by Medtronic.
- Scanning patients who have multiple MR Conditional devices present is acceptable as long as the MR labeling conditions for all implants can be satisfied.
- Do not bring the Medtronic programmer, Patient Assistant, or patient monitor into Zone 4 (MRI magnet room), as defined by the American College of Radiology. They are MR Unsafe.
- It is not recommended to perform an MR examination near the RF exposure limits for periods exceeding 60 min of active scan duration, as this may increase the risk for localized tissue damage from heating around the lead electrodes.

4 Potential adverse events

The SureScan system is designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MRI environment:

- lead electrode heating resulting in tissue damage near the lead electrodes or patient discomfort or both
- spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan mode is programmed to On
- device heating resulting in tissue damage in the implant pocket or patient discomfort or both
- MR-induced muscle stimulation resulting in patient discomfort

- damage to the device or leads causing the system to fail to detect or treat irregular heartbeats or causing the system to treat the patient's condition incorrectly
- damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer
- movement or vibration of the device or leads resulting in dislodgment

5 Patient monitoring requirements

While the MRI SureScan mode is programmed to On, tachyarrhythmia detection and therapy are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. Therefore, proper patient monitoring is required during the entire time when the MRI SureScan mode is programmed to On.

Proper patient monitoring must be provided during the MRI scan and includes all of the following actions:

- Continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography
- Continuous visual monitoring of the patient, maintaining verbal contact if the patient can communicate

Preparation for patient rescue – In the event that patient rescue is required, an external defibrillator must be immediately available.

Note: If the patient's hemodynamic function is compromised during the MRI scan, discontinue the scan, remove the patient from the magnet room, and take the proper measures to restore the patient's hemodynamic function.

6 Cardiology-specific considerations

Lead maturation – MRI scans during the lead maturation period (approximately 6 weeks) have not been prospectively studied by Medtronic and are not recommended.

Spontaneous tachyarrhythmia – Tachyarrhythmia detection and therapy are suspended while the MRI SureScan mode is programmed to On. Be sure to program the MRI SureScan mode to Off as soon as the MRI scan is complete.

System information and records – All pertinent information about the components of the implanted SureScan system such as model names, model numbers, and serial numbers should be recorded in the patient record and on the Patient Information screen on the programmer. This information will help with system identification in the future.

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

Note: Be sure to advise the patient to notify medical personnel that they have an ICD before entering the MR environment and to present their patient ID card.

7 Radiology-specific considerations

7.1 MRI considerations

3 T whole-body transmit coil RF excitations – 3 T MRI systems using 2 transmit channels (or fewer) may operate in the following RF excitations: 2 transmit channels (known as Multichannel-2 (MC-2)) or Circularly Polarized (CP). Systems that use more than 2 transmit channels have not been studied, but such systems could be operated in CP or MC-2, if available.

Use of transmit/receive and receive-only coils – There are no restrictions on the use of local transmit/receive coils for MRI scanning of the head or of the extremities, and there are no restrictions on the placement of receive-only coils.

Image artifact and distortion – SureScan leads have demonstrated minimal MRI scan distortion for areas surrounding the implanted leads when the device is out of the field of view. Significant MRI scan distortion will result from the presence of the device within the field of view. MRI scan artifacts and distortion resulting from the presence of the device and the leads within the field of view must be considered when selecting the field of view and the MRI scanning parameters. These factors must also be considered when interpreting the MRI scans.

Patient sensation during MRI – The device has been evaluated to ensure no risk of tissue damage. However, the patient may feel sensations of warmth or vibration in the implant site during the MRI scan. Tolerable levels of these sensations do not indicate that patient safety has been compromised.

8 Pre-MRI scan operations

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

8.1 Identification of SureScan system components

Use the following methods to verify that a patient has a SureScan system:

- **Patient records or patient ID card (if applicable):** Patient records and the patient ID card, if applicable, are the most reliable record of the medical devices that have been implanted in the patient. These records are available to clinicians other than the device clinician and can be accessed without the presence of the patient or the use of a programmer. These records must be complete and accurate if they are to be used to determine whether the patient has a SureScan system.
- **Patient information on the programmer:** The programmer Patient Information feature is intended to be used by the implanting clinician to document the components of the patient's SureScan system. If the implanting clinician has entered the needed information completely and accurately, you can use the Patient Information feature 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 not noted in the patient information on the programmer.
 1. Tap **Patient > Patient Information > MRI SureScan System/Other Hardware....**
The **MRI SureScan System/Other Hardware** window appears.
 2. View the **MRI SureScan System** fields for information about the patient's leads and whether or not they are MR Conditional.
 3. View the **Other Hardware** fields for information about other lead extenders, lead adaptors, and abandoned leads.

8.2 Required patient care

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

Prepare to provide proper patient monitoring while the MRI SureScan mode is programmed to On. –

Proper patient monitoring includes maintaining continuous visual and verbal contact with the patient, if the patient can communicate, and continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography.

Prepare for patient rescue. – In the event that patient rescue is required, an external defibrillator must be immediately available.

9 Performing an MRI scan

Warning: Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan system.

Warning: Do not leave the device in MRI SureScan mode after the scan is complete. While the MRI SureScan mode is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death

from untreated spontaneous tachyarrhythmia. Be sure to program the MRI SureScan mode to Off as soon as the scan is complete.

Note: The system automatically programs the MRI SureScan mode to Off 6 hours after it is programmed to On. Before you program the MRI SureScan mode to On, ensure that the MRI scan will be completed before this 6-hour timeout occurs. Refer to the MRI SureScan Parameters report or the Quick Look II report for information about when the MRI SureScan mode was programmed to On.

Caution: Do not bring the Medtronic programmer, the Patient Assistant, or the patient monitor into Zone 4 (MRI magnet room), as defined by the American College of Radiology. They are MR Unsafe.

Sensed events will be ignored by the device when the MRI SureScan mode is programmed to On, regardless of the programmed mode. The device maintains the selected parameters until the MRI SureScan mode is programmed to Off after the MRI scan has been completed. After the MRI SureScan mode is programmed to Off, the permanent device parameters are restored.

9.1 SureScan system integrity verification

The SureScan system provides for an acceptable impedance range of the lead vectors for patient safety during an MRI scan. The acceptable impedance ranges for the lead vectors are as follows:

- Ring 1 to Ring 2: 100 - 1500 Ω
- Ring 1 to Coil 2: 100 - 1500 Ω
- Coil 2 to Coil 1: 30 - 250 Ω
- Coil 2 to Can: 30 - 250 Ω

If any vector impedance falls outside these ranges, then MRI SureScan mode cannot be programmed On.

9.2 Programming the MRI SureScan feature to On

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

Perform the following steps to program the MRI SureScan feature to On.

1. Tap **Params > MRI SureScan....**

The **MRI SureScan Checklist** screen appears.

2. Review the MRI SureScan Checklist and select the check box if all items are satisfied for the patient.

Note: Tap **Print...** to print a copy of the MRI SureScan Checklist if desired.

3. Tap **OK**.

The **MRI SureScan** screen appears.

4. Tap the **MRI SureScan** field.

The MRI SureScan feature settings become available.

5. Set the **MRI SureScan** parameter to On.

6. Tap **PROGRAM**.

The implanted device is now ready for the MRI scan.

Notes:

- After the device is programmed for an MRI scan, available options are **Print...**, **End Session...**, and **Emergency**. The MRI SureScan parameter can also be programmed to Off.
- Selecting the **Emergency** button while in MRI SureScan mode programs the MRI SureScan parameter to Off.
- The status of the MRI SureScan mode and the programmed parameters may be confirmed by printing the MRI SureScan Parameters report. The MRI SureScan Parameters report may be printed by tapping **Print...**

9.3 Device considerations

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

Suspension of wireless telemetry and Medtronic CareAlert Monitoring – Wireless telemetry and the Medtronic CareAlert Monitoring feature are disabled when MRI SureScan mode is programmed to On.

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

Suspension of tachyarrhythmia detection – When MRI SureScan mode is programmed to On, the device does not detect ventricular tachyarrhythmias.

Note: When MRI SureScan mode is programmed to On, the message All Off appears on the Device Status Line to indicate that all detection and therapy features are suspended.

Suspension of tachyarrhythmia therapies – When MRI SureScan mode is programmed to On, tachyarrhythmia therapies are disabled.

10 Following the MRI scan

Program the MRI SureScan mode to Off – Program the MRI SureScan mode to Off as soon as the scan is complete to restore tachyarrhythmia therapies. If the device is inadvertently left in MRI SureScan mode after the scan, the device will remain in MRI SureScan mode until 6 hours have elapsed. After 6 hours, MRI SureScan mode will be changed to Off, and the device parameter values will be restored to the pre-MRI SureScan mode configuration.

10.1 Returning the device to the pre-MRI configuration

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

Perform the following steps to program the MRI SureScan mode to Off:

1. Tap the **MRI SureScan** field of the **MRI SureScan** screen, changing the value to **Off**.
2. Tap **PROGRAM**.
3. Tap **Close**.

The **MRI SureScan** screen closes and the programmer 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 electrical reset conditions and disabled therapies. If a condition is detected that requires attention, the programmer displays a Device Status Indicator warning in a pop-up window and on the Quick Look II screen.

11 Medtronic warranty information

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

12 Explanation of MRI 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.



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

13 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 call or write Medtronic at the appropriate telephone number or address listed on the back cover.

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