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ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems

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Technical Support

There are no user serviceable parts. If you have a specific question or issue, please contact your sales representative or call (833) DBS-INFO or (833) 327-4636.

Additional Information

Read this manual in its entirety before performing a MRI scan on patients who are implanted with any component of the Boston Scientific DBS System.

For detailed information about non-MRI aspects of implantation, features, programming, and use of the components of the DBS refer to the appropriate DFU for your DBS System as listed on your *DBS Reference Guide*.

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Introduction

About this Manual

This manual is intended for use by physicians, and other healthcare professionals (HCPs) responsible for managing patients with a Boston Scientific Deep Brain Stimulation (DBS) System, as well as radiologists and other HCPs involved in performing magnetic resonance imaging (MRI) scans on such patients.

The manual provides guidelines to determine whether and how to conduct a MRI scan on a patient implanted with any component of the Boston Scientific DBS System.

Caution: *Read this manual in its entirety before performing a MRI scan on a patient implanted with any component of the Boston Scientific DBS System.*

Caution: *MR conditional scan may be safely performed when implanted with only the Boston Scientific DBS components listed in this manual and when the patient is exposed to the MRI environment under specific conditions defined in this manual. Other configurations have not been evaluated.*

Obtain the Latest MRI Guidelines Labeling

Always obtain the latest MRI guidelines. Refer to the contact information at the back of this manual, or go to www.bostonscientific.com/manuals for the latest version of this manual.

MR Conditional System Description

A Full Body MR Conditional scan may be safely performed when implanted with the Boston Scientific DBS components described in Table 1 and exposed to the MRI environment under specific conditions defined in this manual.

Warning: *Scanning under different conditions may result in severe patient injury or device malfunction.*

DBS Implant System Conditions

The Full Body MR guidelines apply to the booted lead system that meets the following conditions:

- Patients implanted with a MR conditional system composed of the components listed in Table 1.
- Leads are capped with a lead boot on the proximal end and excess lead is coiled and fully-implanted under the scalp on the skull.
- No evidence of fractured leads.
- No lead extensions are present.
- No stimulator is present.

Caution: *The system has only been evaluated with a lead boot. Failure to boot the lead could increase the chance of the risks described in the Safety Information Section of this manual under Potential Interactions with MRI Environment.*

Table 1 lists the model numbers of the Boston Scientific DBS System components that are eligible for a Full Body MR Conditional scan.

Table 1. Boston Scientific DBS System components eligible for Full Body Conditional MR scan

Component	Model Number (s)
30 cm Lead	DB-2201-30-AC DB-2201-30-DC
45 cm Lead	DB-2201-45-BC DB-2201-45-DC
SureTek™ Burr Hole Cover	Provided in kits DB-4600-C and DB-4605-C
Lead Boot	Provided in the Vercise Physician Spares Kit DB-2500-C and with DBS leads (see above)
Silicone Suture Sleeves	Provided in Vercise Physician Spares Kit DB-2500-C and with DBS leads (see above)

Radiology Conditions

Boston Scientific Systems that are eligible for Full Body Conditional MR scans must be scanned under the following conditions:

1. MRI system conditions

    a. 1.5 Tesla (T) horizontal closed bore systems only. Do not use systems that are open-sided, vertical-field, or are operating at other static magnetic field strengths, the risks of using these MRI systems have not been determined and could be significant.

    b. Gradient systems with a maximum gradient slew rate per axis less than or equal to 200 T/m/s.

    c. Maximum spatial field gradient less than or equal to 40 T/m (4000 gauss/cm)

    d. Scan sequence throughout the scan must have
    B1+rms less than or equal to (≤) 2.0 µT

    If B1+rms is not available then scan sequence must have
    Whole body and head SAR less than or equal to (≤) 0.1 W/kg

    Note: *Using the SAR[1] value may result in a more restrictive MRI scan.*

    Warning: *Apply the required B1+rms (or SAR) limit in the Normal Operating Mode. Do not conduct MRI scans in the First Level and Second Level Controlled Operating Modes as it may increase the risk of unintended stimulation and excessive heating.*

    e. Cumulative active scan time (with RF On) should be limited to 30 minutes or less per imaging session. If 30 mins of active scan time is reached allow 60 mins of non-active time before proceeding.

2. MRI coil setup:

    a. Transmit coil: 1.5T Full Body transmit/receive or Head transmit/receive, RF quadrature[2] only.

    b. Receive-only coil: Any type.

    c. Hydrogen/proton imaging only.

3. Patient status and positioning:

    a. The patient is in supine or prone position only.

    b. The patient must have continuous audio/visual monitoring during the MRI.

1 Specific Absorption Rate (SAR)– radio frequency power absorbed per unit of mass (W/kg).

2 RF Quadrature coil– RF Quadrature Coils produce an RF field with circular polarization perpendicular to the static magnetic field.

Safety Information

Warnings

MRI System: Only use 1.5T Full Body transmit/receive or Head transmit/receive, RF quadrature only coils. Use hydrogen/proton imaging only. Do not use other transmit/receive coils (e.g., linear coils). Local receive-only coils may be used. Only 1.5T coils have been evaluated.

Active Scan Time: Do not exceed cumulative active scan time (with RF On) of 30 minutes per imaging session. If 30 mins of active scan time is reached allow 60 mins of non-active time before proceeding. Exceeding the active scan time increases the risk of tissue heating.

Potential Interactions with MRI Environment: During an MRI examination, there are potential interactions with the implanted DBS lead. Following the safety conditions designated in this manual will minimize the potential interactions described in this section.

- **Heating** – The MRI RF field induces voltages onto the lead system that can produce significant heating effects at the lead-electrode-tissue interface. This can cause tissue damage, edema, burns, discomfort, pain, nerve injury, device damage and/or the need for additional intervention.
- **Main Magnetic field interactions** – The MRI magnetic field may exert translation and torque effects on the implanted lead. Patients may feel a tugging sensation at the site of the lead implant. Patients with recent implant incisions may feel surgical wound discomfort.
- **Induced stimulation** – An MRI may induce energy into the implanted leads, potentially causing unintended or uncomfortable stimulation or unusual sensations.

If these interactions cause the patient discomfort, stop the MRI scan.

If an MRI scan is performed outside of the conditions advised in this manual, it may result in serious risks. These may include unintended stimulation, pain, tissue damage, burns, nerve injury, cerebrovascular accidents, coma, paralysis, or death.

Gradient Systems: Do not use gradient systems producing gradient slew rates greater than 200 T/m/s because they have not been evaluated and could cause increased risk of induced stimulation.

Body Temperature: The MRI conditional evaluation has been performed for patients with a typical body temperature of 37°C. Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which could cause tissue damage.

No Blankets: Do not cover the patient with blankets or heated blankets. Blankets raise the patient's body temperature and increase the risk of tissue heating, which could cause tissue damage.

Patient Positioning: Only place the patient in the prone or supine position. Do not position the patient in other positions, e.g., on his or her side (called the lateral decubitus position) within the MRI bore. Scanning patients in positions other than prone or supine has not been evaluated and could cause excessive tissue heating during an MRI scan.

External Devices: External components (i.e., External Trial Stimulator and OR Cables) are MR Unsafe. They must not be taken into any MR environment such as the MRI Scanner Room.

Supervision: A person with expert knowledge about MRI must ensure all procedures in this manual are followed and that the MRI scan parameters during both the prescan and the actual MRI examination are within the recommended settings listed in this manual.

Precautions

Explant of DBS lead extensions and Stimulator for MRI: The MR conditional system is comprised of a booted leads system consisting of the components listed in Table 1. The risk of explant to create an MR conditional configuration outlined in this manual should be evaluated by a health care professional.

Limitations

Other implanted Devices: An MRI can also be performed safely if, instead of the burr hole cover, a metal mini plate with screws[3] is used to secure the DBS leads to the skull. Boston Scientific has not evaluated the effect of other implanted devices in combination with or in proximity to the Boston Scientific System described in this manual. Boston Scientific does not recommend an MRI scan if other implanted devices are present.

Image Artifact

Artifacts and distortions may be produced in the MR image by any DBS system components. Users must be aware of these when selecting imaging parameters or interpreting MR images. Careful selection of pulse sequence parameters, and location of the imaging plane may minimize MR image artifacts. Although reduction of image distortion can be obtained by adjusting pulse sequence, this may compromise signal-to-noise ratio. The following guidelines will help minimize image artifacts and distortions:

- Use a local receive-only coil instead of a body receive coil whenever possible.
- Use imaging sequences with stronger gradients for both slice and read encoding directions.
- Use a higher bandwidth for radio-frequency pulse and data sampling.
- Select an orientation for the read-out axis that minimizes the in-plane distortion.
- Use a shorter echo time for gradient echo technique, whenever possible.

3 Similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws.

Patient Screening and Preparation

Table 2 summarizes the DBS Implant System and Patient-related Conditions of Use that must be met in order for an MR Conditional scan to be performed. For each condition or requirement, suggested methods to determine eligibility are listed. It is not required to use all suggested methods to determine eligibility. Any or a combination of the suggested methods to determine eligibility may be used. Appendix A has an MRI Full Body Patient Eligibility Form that may be used by the physician to confirm the patient meets the DBS Implant System Conditions for MRI Scans as described in this manual.

Table 2. DBS Implant System/Patient Screening and Preparation Conditions

#	Condition for Scanning	Suggested Methods to Determine Eligibility
1.	The patient is implanted with a booted lead system comprised of Vercise DBS leads listed in Table 1	• Check patient records and ensure that the model numbers of the implanted components match the model numbers listed in Table 1 of this manual. • Confirm with the physician responsible for implanting the patient's DBS system and ensure that the model numbers of the implanted components match the model numbers listed in Table 1 of this manual..
2.	Leads are capped with Lead Boots on the proximal ends and excess lead is coiled and implanted under the scalp on the skull.	• Confirm with the physician responsible for implanting the Patient's DBS system. • Verify by X-Ray
3.	No evidence can be found of fractured leads	• Confirm with the physician responsible for implanting the Patient's DBS system. • Review lead integrity records from Intraoperative testing performed during lead implantation.
4.	No lead extensions are present	• Check patient records and examine the patient by palpation to determine if extensions are present • Verify by X-Ray
5.	No Stimulator is present	• Check patient records and examine the patient by palpation to determine if a Stimulator is present. • Verify by X-Ray

MR System Preparation

Table 3 summarizes the MR Scanner-related Conditions of Use that must be met in order for an MR Conditional scan to be performed. For each condition or requirement, recommended actions to determine conformance are listed.

Table 3. MR System Conditions

#	Condition for Scanning	Actions
1.	MRI systems that meet the following criteria: • MRI magnet strength of 1.5T only, in a horizontal closed bore system (no vertical-field, standing, or extremity systems). • Gradient systems with a maximum gradient slew rate per axis less than or equal to 200 T/m/s. • Maximum spatial field gradient less than or equal to 40 T/m (4000 gauss/cm).	Check the technical specifications of the MRI Scanner.
2.	• Transmit coil: 1.5T Full Body transmit/receive or Head transmit/receive, RF quadrature only. • Receive-only coil: Any type. • Hydrogen/proton imaging only.	Check the technical specifications of the MRI Head Coil and/or Body Coil.
3.	Scan sequence throughout the scan must have B1+rms less than or equal to (≤) 2.0 µT If B1+rms is not available then scan sequence must have Whole body and head SAR less than or equal to (≤) 0.1 W/kg ***Note:*** *Using the SAR value may result in a more restrictive MRI scan.*	Ensure MRI Scanner is operated at or below B1+rms of 2.0 µT throughout the scan. If B1 + rms is not available then ensure MRI scanner is operated at or below Whole body and head SAR of 0.1 W/kg
4.	Patient must be positioned in supine or prone position during the scan.	Continuously monitor the patient to ensure the patient is in the correct position during scan.
5.	Cumulative active scan time (with RF On) should be limited to 30 minutes or less per imaging session. If 30 mins of active scan time is reached allow 60 mins of non-active time before proceeding.	Check the active scan time on the MRI scanner.

Supervision

Note: *The patient should be in a psychological condition and mental state in which the patient is able to provide immediate feedback of any problems during the examination. Maintain visual and audio monitoring of the patient throughout the MRI examination. Verify that the patient is feeling normal and is responsive during and between each individual scan sequence of the MRI examination. Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any adverse effects listed in the Safety Information Section of this manual under Potential Interactions with MRI Environment.*

Post-MRI Examination Review

Verify that the patient has not experienced any adverse effects as a result of the MRI. The potential adverse effects are listed in the Safety Information Section of this manual under Potential Interactions with MRI Environment. Contact Boston Scientific if the patient has experienced any adverse effects.

Appendix A

Boston Scientific DBS Systems MRI Full Body Patient Eligibility Form

This form provides information about the patient's implanted DBS System MRI scan eligibility. It may be provided to the radiologist to support the confirmation of the patient's MRI scan eligibility.

Patient Name		Date:
Physician Name		
Office Address		
Phone		

A. MR Conditional DBS System Information

	Model #	MRI Eligible	Not MRI Eligible
Leads and Accessories (check all that apply)			
30 cm Lead	DB-2201-30-AC	☐	
	DB-2201-30-DC	☐	
45 cm Lead	DB-2201-45-AC	☐	
	DB-2201-45-DC	☐	
Lead Boot	Provided in Lead kit	☐	
	Provided in DB-2500-C kit	☐	
Silicone Suture Sleeves	Provided in Lead kit	☐	
	Provided in DB-2500-C kit	☐	
Fixation (Check all that apply)			
Burr Hole Cover	DB-4600-C	☐	
	DB-4605-C	☐	
Other (List other implanted components) ***Note**: If the patient has medical implants from another manufacturer, consult the instructions from the manufacturer before making a decision about MRI eligibility.*			
		☐	☐
		☐	☐

B. Implant Configuration (All rows must be completed)

MRI Eligible		Not MRI Eligible	
☐	Stimulator NOT implanted	☐	Stimulator implanted
☐	Lead extensions NOT implanted	☐	Lead extensions implanted
☐	Leads capped with lead boot	☐	Leads NOT capped with lead boot
☐	Lead fully implanted under the scalp on the skull	☐	Lead NOT fully implanted under the scalp on the skull
☐	NO evidence of fractured leads	☐	Evidence of fractured leads

Note: *The patient is NOT MRI Eligible if any of the "Not MRI Eligible" boxes are checked.*

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