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ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems

Rx ONLY CAUTION: Federal law restricts this device to sale,
distribution and use by or on the order of a physician.

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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.

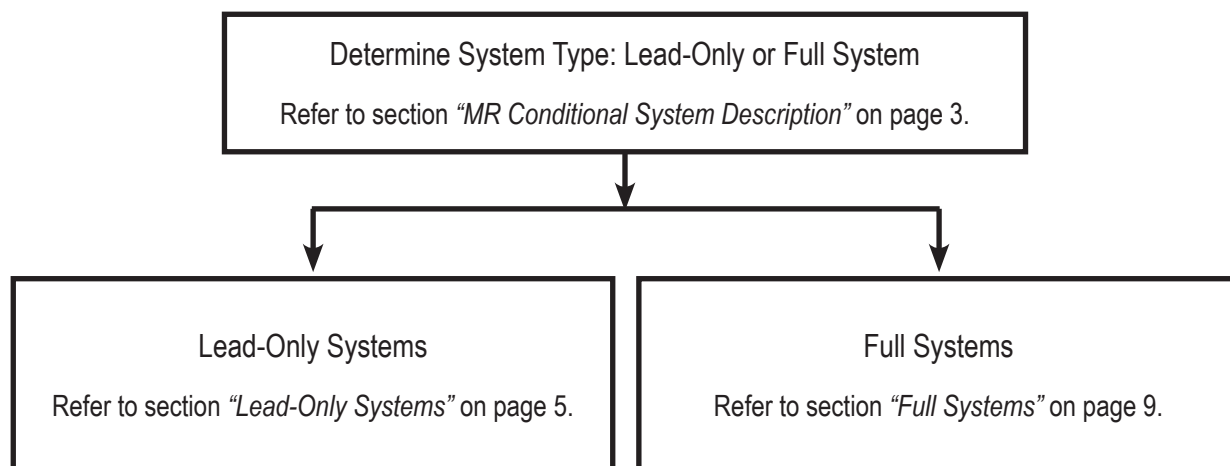
Caution: MR conditional scan may be safely performed when implanted with only the Boston Scientific DBS components listed in this manual and when the patient is exposed to the MRI environment under specific conditions defined in this manual. Other configurations have not been evaluated.

How to Use this Manual

The MRI Guidelines apply to two types of Boston Scientific DBS Systems:

- Lead-Only System
- Full System

Follow the steps in the chart below to identify the appropriate labeling for the system you intend to scan.



Note: A summary of all DBS Systems and their MR Radiology Conditions is provided in Appendix B.

Obtain the Latest MRI Guidelines Labeling

Always obtain the latest MRI guidelines. Refer to the “*Technical Support*” section of this manual, or go to www.bostonscientific.com/manuals for the latest version of this manual.

Patient ID Card

Advise the patient to bring the most up to date patient ID card to all MRI appointments. MRI personnel can use the patient ID card to identify Boston Scientific as the manufacturer of the patient’s DBS System and to confirm the model number of the implanted system components.

MR Conditional System Description

The MRI Guidelines apply to two types of Boston Scientific DBS Systems:

Lead-Only System

The patient is implanted with the following components:

- Lead
- Lead Boot
- Burr Hole Cover (Optional method of securing the Leads. It may or may not be used.)

Full System

The patient is implanted with the following components:

- Lead
- Extension
- Stimulator
- Burr Hole Cover (Optional method of securing the Leads. It may or may not be used.)

Table 1 lists the model numbers of the MR Conditional components for each of these two types of systems. An MR conditional scan may be safely performed when the patient is implanted with only the Boston Scientific DBS components listed in Table 1.

Table 1. Boston Scientific DBS System Components Eligible for Full Body MR Conditional Scan			
Component	Model Number (s)	Eligible for MR Conditional Scan	
		Leads-Only System	Full System
Leads: Standard Leads - DB-2201			
30 cm Lead	DB-2201-30-AC DB-2201-30-DC	Yes	Yes
45 cm Lead	DB-2201-45-BC DB-2201-45-DC	Yes	Yes
Leads: Directional Leads - DB-2202			
Vercise™ Cartesia™ 30 cm 8 Contact DBS Directional Lead	DB-2202-30	Yes	Yes
Vercise Cartesia 45 cm 8 Contact DBS Directional Lead	DB-2202-45	Yes	Yes
Extension			
55 cm 8 Contact Extension	NM-3138-55	No	Yes
Stimulator			
Vercise Gevia 16 Contact Implantable Pulse Generator	DB-1200-S	No	Yes
Fixation and Accessories			
SureTek™ Burr Hole Cover	Provided in kits DB-4600-C and DB-4605-C	Yes	Yes
Lead Boot	Provided in the Vercise Physician Spares Kit DB-2500-C and with DBS Leads (see above)	Yes	No
Silicone Suture Sleeves	Provided in Vercise Physician Spares Kit DB-2500-C and with DBS Leads (see above)	Yes	Yes

Lead-Only Systems

An MRI may be safely performed on a patient implanted with a Lead-Only System that meets the implant and radiology conditions listed in this section.

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.

Note: Refer to “Lead-Only System Implant Conditions” in Table 2 and “Lead-Only System Radiology Conditions” in Table 3 for detailed scan conditions.

MRI Safety Information for Lead-Only Systems

Testing has demonstrated that the Boston Scientific Lead-Only System (the DB-2201 or DB-2202 Leads, see Table 1) is MR Conditional. An MRI may be safely performed on a patient implanted with a Lead-Only System that meets the following scan conditions:

- Static magnetic field of 1.5 T
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum gradient slew rate per axis of less than or equal to 200 T/m/s
- Cumulative active scan time of less than or equal to 30 minutes
- Maximum B1+rms of less than or equal to 2.0 μ T
 - Applies with a Body or Head Transmit/Receive Coil
- If B1+rms is not available, the maximum MR system reported head or whole body averaged specific absorption rate (SAR) should be equal to or less than (\leq) 0.1 W/kg

Additional Information

- Patient must be positioned in supine or prone position during the scan.
- Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination.

Lead-Only System Implant Conditions

Table 2 summarizes the Lead-Only System Implant 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 suggested method or a combination of the suggested methods to determine eligibility may be used. Appendix A has an MRI Patient Eligibility Form that may be used by the physician to confirm the patient meets the DBS System Conditions for MRI Scans as described in this manual. All Conditions of Use must be met for an MRI scan to be performed.

#	Condition for Scanning	Suggested Methods to Determine Eligibility
1	The patient is implanted with a booted Lead system comprised of Leads, Lead Boots, and Burr Hole Cover listed in Table 1.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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 Extensions are present.	<ul style="list-style-type: none"> • Check patient records and examine the patient by palpation to determine if Extensions are present • Verify by X-Ray.
5	No Stimulator is present.	<ul style="list-style-type: none"> • Check patient records and examine the patient by palpation to determine if a Stimulator is present. • Verify by X-Ray.

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."*

Note: *An MRI can also be performed safely if, instead of the Burr Hole Cover, a metal mini plate with screws¹ 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 Systems described in this manual. Boston Scientific does not recommend an MRI scan if other implanted devices are present.*

¹ Similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws.

Lead-Only System Radiology Conditions

Table 3 summarizes the MRI Radiology 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. All Conditions of Use must be met for an MRI scan to be performed.

#	Condition for Scanning	Actions
1	<p>MRI systems that meet the following criteria:</p> <ul style="list-style-type: none"> MRI magnet strength of 1.5 Tesla (T) only, in a horizontal closed bore system (no open-sided, vertical-field, standing, or extremity systems). The risks of using these MRI systems have not been determined and could be significant. 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	<p>MRI coil setup:</p> <ul style="list-style-type: none"> Transmit coil: 1.5T Full Body transmit/receive or 1.5T Head transmit/receive, RF quadrature² only. Receive-only coil: Any type. Hydrogen/proton imaging only. 	Check the technical specifications of the MRI Head Coil and/or Full Body Coil.
3	<p>If using either Full Body or Head Transmit/Receive Coil and patient is implanted with either DB-2201 or DB-2202 Leads.</p> <p>Scan sequence throughout the scan must have B1+rms less than or equal to (\leq) 2.0 μT.</p>	<ul style="list-style-type: none"> Ensure MRI Scanner is operated at or below (\leq) B1+rms of 2.0 μT throughout the scan. If B1+rms is not available then ensure MRI scanner is operated at or below (\leq) Whole body and head SAR of 0.1 W/kg <p>Note: Using the SAR³ value may result in a more restrictive MRI scan.</p>
4	Cumulative active scan time (with RF On) should be limited to 30 minutes or less per imaging session. If 30 minutes of active scan time is reached allow 60 minutes of non-active time before proceeding.	Check the active scan time on the MRI scanner.
5	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.
6	Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination.	Maintain visual and audio monitoring of the patient throughout the MRI scan. Verify that the patient is feeling normal and is responsive during and between each MRI scan. Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any adverse effects listed under "Potential Interactions with MRI Environment" in the "Safety Information" section of this manual.

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

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

Post-MRI Examination Review for Lead-Only System

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 the patient’s physician and Boston Scientific if the patient has experienced any adverse effects.

Full Systems

An MRI may be safely performed on a patient implanted with a Full System that meets the implant and radiology conditions listed in this section.


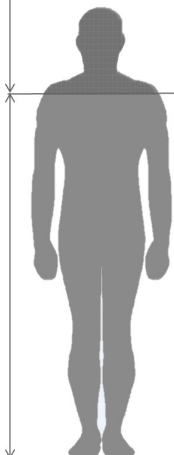
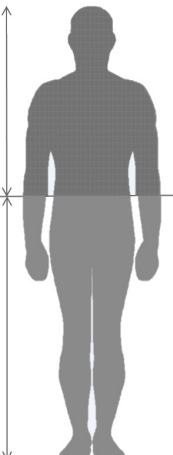
Caution: Read this manual in its entirety before performing a MRI scan on a patient implanted with any component of the Boston Scientific DBS System.

Note: Refer to “Full System Implant Conditions” in Table 5 and “Full System Radiology Conditions” in Table 6 for detailed scan conditions.

MRI Safety Information for Full Systems

Testing has demonstrated that the Vercise Gevia System (including the DB-2201 and the DB-2202 Leads, Lead Extension, and Stimulator, see Table 1) is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following scan conditions:

- Static magnetic field of 1.5 T
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum gradient slew rate per axis of less than or equal to 200 T/m/s
- Cumulative active scan time of less than or equal to 30 minutes
- Maximum B1+rms, see Table 4:

Table 4. B1+rms Limits for Full System Scans		
	Full System with DB-2201 Standard Lead	Full System with DB-2202 Cartesia Directional Lead
Head Transmit/Receive Coil	 <p>$B1+rms \leq 2.0 \mu T$</p>	
Full Body Transmit/Receive Coil	 <p>If Isocenter above T5 $B1+rms \leq 1.5 \mu T$</p> <p>If Isocenter at T5 or below T5 $B1+rms \leq 2.0 \mu T$</p>	 <p>If Isocenter above T12 $B1+rms \leq 1.2 \mu T$</p> <p>If Isocenter at T12 or below T12 $B1+rms \leq 2.0 \mu T$</p>

- If B1+rms is not available, the maximum MR system reported head or whole body averaged specific absorption rate (SAR) should be equal to or less than (\leq) 0.1 W/kg.

Additional Information

- Patient must be positioned in supine or prone position during the scan.
- Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination.
- MRI Mode must be enabled on the device prior to performing a scan.
- Stimulator must be fully charged prior to the MRI scan.

Full System Implant Conditions

Table 5 summarizes the Full System implant Conditions of Use that must be met in order for an MR Conditional scan to be performed and suggested methods to determine eligibility. 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 Patient Eligibility Form that may be used by the physician to confirm the patient meets the DBS System Conditions for MRI Scans as described in this manual. All Conditions of Use must be met for an MRI scan to be performed.




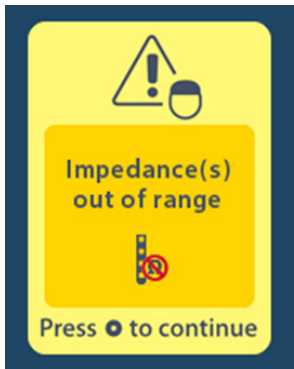
#	Condition for Scanning	Suggested Method to Determine Eligibility
1	The patient is implanted with the full DBS system comprised of Leads, Extensions, Stimulator, and Burr Hole Cover listed in Table 1.	<ul style="list-style-type: none"> Check patient ID card or patient records and ensure that the model 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	Stimulator must be implanted under the skin in a location near the clavicle (pectoral region) on the same side of the body as the implanted Lead-Extension. Note: In a bilateral implant where two Leads and Extensions are connected to a single Stimulator, the Dual-Lead Extensions must be routed on the same side of the body as the Stimulator.	<ul style="list-style-type: none"> Check patient records. Examine the patient by palpation to determine where the Stimulator is present. Verify by X-Ray.
3	Extensions must be connected directly to the Stimulator. Adapters should not be used.	<ul style="list-style-type: none"> Check patient records. Verify by X-Ray.
4	Stimulator is fully charged prior to the MRI scan. Note: The patient should bring the Charger and Remote Control to the MRI Center. The Charger and Remote Control are MR Unsafe and must not be brought into the MRI Scanner Room.	<ul style="list-style-type: none"> Ensure that three bars  are displayed for the Stimulator battery status on the Home Screen of the Patient Remote Control.
5	MRI Mode is enabled on the Stimulator. Note: Stimulation is automatically turned OFF when MRI Mode is enabled. Refer to the "MRI Mode for Full Systems" section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.	<p>Ensure that the Home screen of the Patient Remote Control displays the MR Conditional symbol  with the Stimulation turned OFF.</p> 


Table 5. Full System Conditions and Methods to Determine Eligibility		
#	Condition for Scanning	Suggested Method to Determine Eligibility
6	<p>No evidence can be found of fractured Leads or compromised Stimulator-Lead integrity.</p> <p>Note: An impedance check is automatically performed for Stimulator-Lead integrity when MRI Mode is enabled on the device. Refer to the “MRI Mode for Full Systems” section of this manual for more information on MRI Mode.</p>	<ul style="list-style-type: none"> • Confirm with the physician responsible for implanting and maintaining the patient’s DBS system • Stimulator-Lead integrity or impedance check is automatically performed when MRI Mode is enabled. If impedances are not within the acceptable range the Remote Control will display an error message before asking the user if they would like to continue with enabling MRI Mode.  <p>If this error is displayed, we recommend not proceeding with the MRI scan. Patients should contact their physician to arrange an evaluation of the system.</p>

Note: An MRI can also be performed safely if, instead of the Burr Hole Cover, a metal mini plate with screws⁴ 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 Systems described in this manual. Boston Scientific does not recommend an MRI scan if other implanted devices are present.

⁴ Similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws.

Full System Radiology Conditions

Table 6 summarizes the MRI Radiology 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. All Conditions of Use must be met for an MRI scan to be performed.

#	Condition for Scanning	Actions
1	<p>MRI systems that meet the following criteria:</p> <ul style="list-style-type: none"> • MRI magnet strength of 1.5 Tesla (T) only, in a horizontal closed bore system (no open-sided, vertical-field, standing, or extremity systems). The risks of using these MRI systems have not been determined and could be significant. • 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	<p>MRI coil setup:</p> <ul style="list-style-type: none"> • Transmit coil: 1.5T Full Body transmit/receive or Head transmit/receive, RF quadrature⁵ only. • Receive-only coil: Any type. • Hydrogen/proton imaging only. 	Check the technical specifications of the MRI Head Coil and/or Full Body Coil.
3a	<p>If Head Transmit/Receive Coil is used and patient is implanted with either DB-2201 or DB-2202 Leads:</p> <p>Scan sequence throughout the scan must have B1+rms less than or equal to (\leq) 2.0 μT.</p> <div style="display: flex; align-items: center;">  <ul style="list-style-type: none"> • Head Transmit/Receive Coil • DB-2201 or DB-2202 Leads • B1+rms \leq 2 μT </div>	<ul style="list-style-type: none"> • Check if Head Transmit/Receive Coil is being used. • Ensure MRI Scanner is operated at or below (\leq) B1+rms of 2.0 μT throughout the scan. • If B1+rms is not available then ensure MRI scanner is operated at or below (\leq) Whole body and head SAR of 0.1 W/kg. <p>Note: Using the SAR⁶ value may result in a more restrictive MRI scan.</p>

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

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

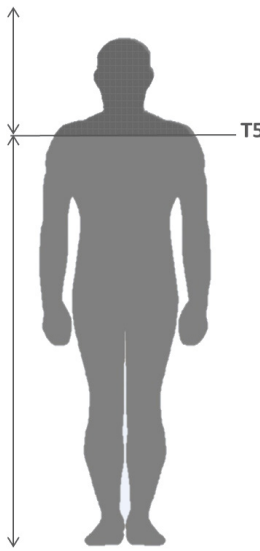
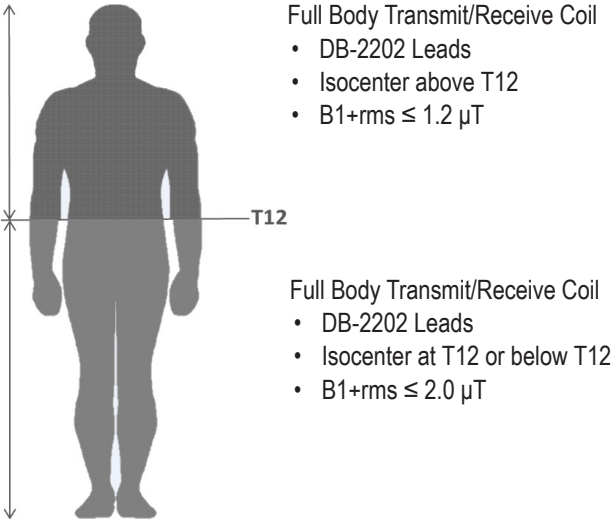
Table 6. Full System MRI Radiology Conditions and Recommended Actions		
#	Condition for Scanning	Actions
3b	<p>If Full Body Transmit/Receive Coil is used and patient is implanted with DB-2201 Leads:</p> <p>Scan sequences throughout the scan must have B1+rms values as follows:</p> <ul style="list-style-type: none"> When isocenter (center of the bore) is <u>above thoracic vertebra T5</u>: B1+rms less than or equal to (\leq) 1.5 μT When isocenter (center of the bore) is <u>at thoracic vertebra T5 or below thoracic vertebra T5</u>: B1+rms less than or equal to (\leq) 2.0 μT  <p>Full Body Transmit/Receive Coil</p> <ul style="list-style-type: none"> DB-2201 Leads Isocenter above T5 B1+rms \leq 1.5 μT <p>Full Body Transmit/Receive Coil</p> <ul style="list-style-type: none"> DB-2201 Leads Isocenter at T5 or below T5 B1+rms \leq 2.0 μT 	<ul style="list-style-type: none"> Check if Full Body Transmit/Receive Coil is being used. Check patient ID card or patient records and confirm Lead model number is DB-2201. Confirm anatomical location of the isocenter or where the landmark is placed on the body of the patient during set up. If landmark or isocenter is above T5, ensure MRI Scanner is operated at or below (\leq) B1+rms of 1.5 μT throughout the scan. If landmark or isocenter is at T5 or below T5, ensure MRI Scanner is operated at or below (\leq) B1+rms of 2.0 μT throughout the scan. If B1+rms is not available then ensure MRI scanner is operated at or below (\leq) Whole body and head SAR of 0.1 W/kg. <p>Note: Using the SAR value may result in a more restrictive MRI scan.</p>

Table 6. Full System MRI Radiology Conditions and Recommended Actions		
#	Condition for Scanning	Actions
3c	<p>If Full Body Transmit/Receive Coil is used and patient is implanted with DB-2202 Leads:</p> <p>Scan sequences throughout the scan must have B1+rms values as follows:</p> <ul style="list-style-type: none"> When isocenter (center of the bore) is <u>above thoracic vertebra T12</u>: B1+rms less than or equal to (\leq) 1.2 μT When isocenter (center of the bore) is <u>at thoracic vertebra T12 or below thoracic vertebra T12</u>: B1+rms less than or equal to (\leq) 2.0 μT  <p>Full Body Transmit/Receive Coil</p> <ul style="list-style-type: none"> DB-2202 Leads Isocenter above T12 B1+rms \leq 1.2 μT <p>Full Body Transmit/Receive Coil</p> <ul style="list-style-type: none"> DB-2202 Leads Isocenter at T12 or below T12 B1+rms \leq 2.0 μT 	<ul style="list-style-type: none"> Check patient ID card or patient records and confirm Lead model number is DB-2202. Check if Full Body Transmit/Receive Coil is being used. Confirm anatomical location of the isocenter or where the landmark is placed on the body of the patient during set up. If landmark or isocenter is above T12, ensure MRI Scanner is operated at or below (\leq) B1+rms of 1.2 μT throughout the scan. If landmark or isocenter is at T12 or below T12, 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 (\leq) Whole body and head SAR of 0.1 W/kg. <p>Note: Using the SAR value may result in a more restrictive MRI scan.</p>
4	Cumulative active scan time (with RF On) should be limited to 30 minutes or less per imaging session. If 30 minutes of active scan time is reached allow 60 minutes of non-active time before proceeding.	Check the active scan time on the MRI scanner.
5	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.
6	Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination.	Maintain visual and audio monitoring of the patient throughout the MRI scan. Verify that the patient is feeling normal and is responsive during and between each MRI scan. Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any adverse effects listed under “ <i>Potential Interactions with MRI Environment</i> ” in the “ <i>Safety Information</i> ” section of this manual.

Post-MRI Examination Review for Full System

1. 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 the patient’s physician and Boston Scientific if the patient has experienced any adverse effects.
2. After the MRI scan has been completed and the patient has exited the scanner room, the Remote Control must be used to disable MRI Mode on the Stimulator. Refer to the “*MRI Mode for Full Systems*” section of this manual for more information.

Note: *The Stimulator will retain the stimulation and program setting that was set prior to enabling MRI Mode. If the stimulation was ON before MRI Mode was enabled, then disabling MRI Mode turns the stimulation back ON. If stimulation was OFF before MRI Mode was enabled, then disabling MRI Mode keeps the stimulation OFF.*

3. Instruct the patient to contact their physician managing their DBS System or Boston Scientific if the Stimulation does not turn ON or displays any error messages.

MRI Mode for Full Systems


Prior to performing an MRI scan on a patient implanted with the Full System comprised of Leads, Extensions, Stimulator, and Burr Hole Cover listed in Table 1, MRI Mode must be enabled on the Stimulator using the Patient Remote Control.

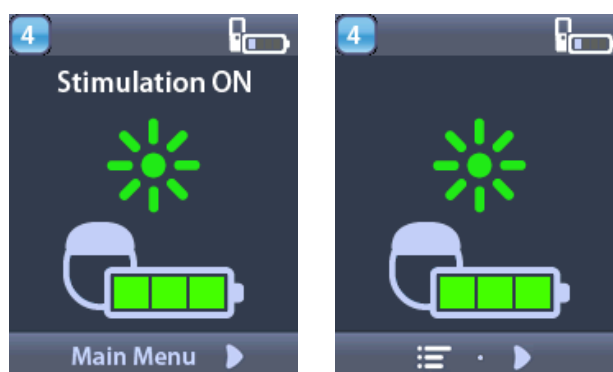
Enabling MRI Mode

When the Remote Control is linked to a Boston Scientific MR Conditional Stimulator, the Enter MRI Mode icon will appear on the System Settings screen. The Remote Control must be used to enable MRI Mode on the Stimulator before performing an MRI scan on a patient. The Stimulator is automatically turned OFF when MRI Mode is enabled.

Caution: Patients may become anxious or their symptoms may return once stimulation is turned OFF. Ensure that the patient has been given the appropriate medical care to manage the return of symptoms before performing an MRI scan.

To enable MRI Mode:

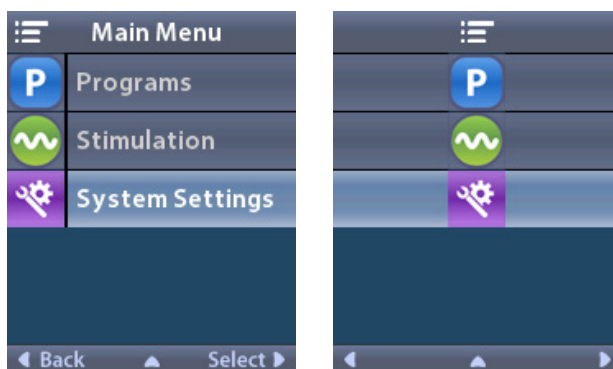
1. Unlock the Remote Control by pressing the **Lock/Unlock**  button on the right side of the Remote Control.
2. After unlocking the Remote Control, the Home screen will appear.



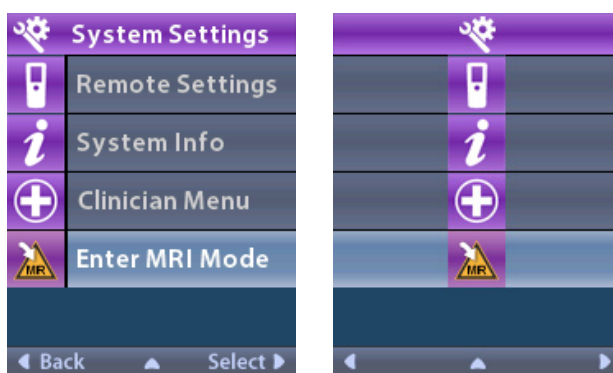
Note: The Remote Control may display either a text screen in one of the languages provided or an iconic screen.

3. Press the Right Arrow  button to navigate to the **Main Menu**.

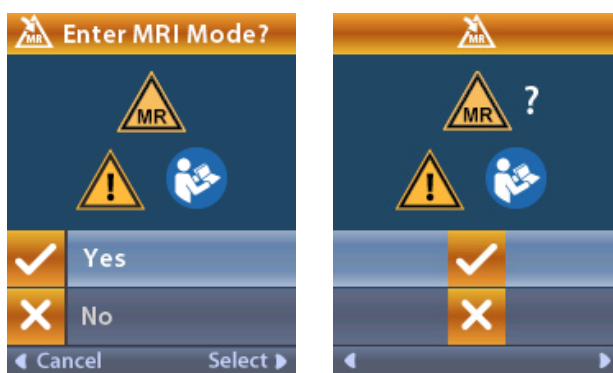
4. Select **System Settings** .



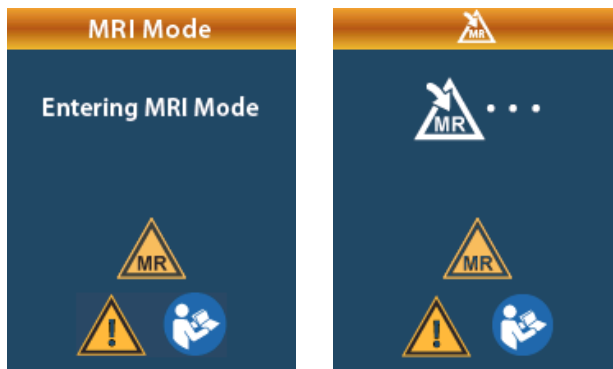
5. Select **Enter MRI Mode** .



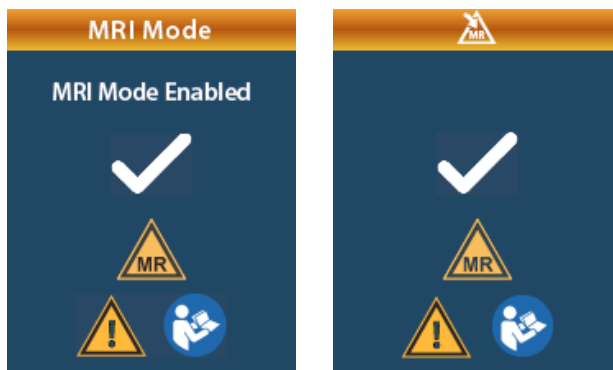
6. Select **Yes**  to enter MRI mode or **No**  to cancel the action.




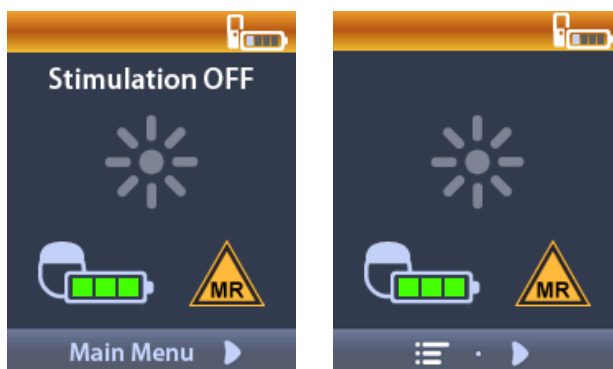
- The Stimulator performs a series of checks before MRI Mode is enabled.



- If MRI Mode is enabled, stimulation is turned OFF and the MRI Mode Enabled confirmation screen is displayed.




- The Home Screen on the Remote Control will display the MR Conditional Symbol  if MRI Mode is enabled. Always confirm that the home screen of the Remote Control displays the MRI Conditional Symbol before performing an MRI scan on the patient.

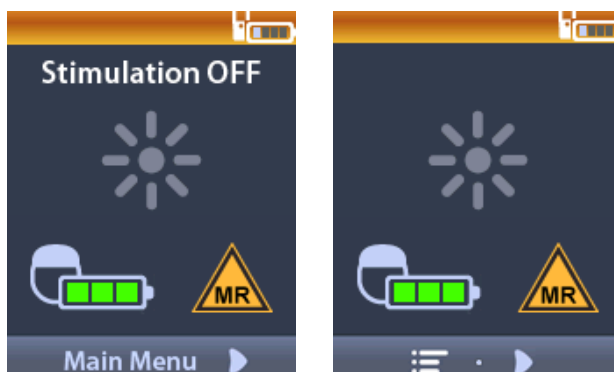




Disabling MRI Mode

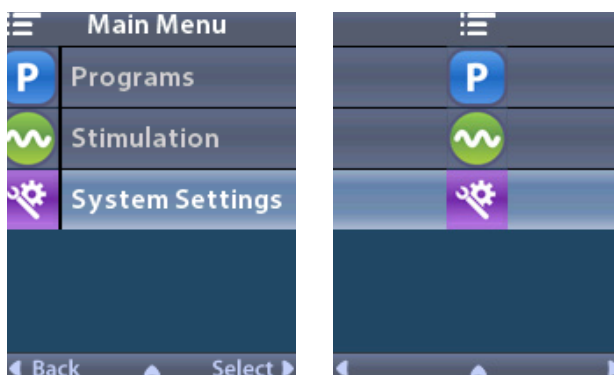
Upon completion of the MRI scan, the Remote Control must be used to disable the MRI Mode.

To disable MRI Mode:

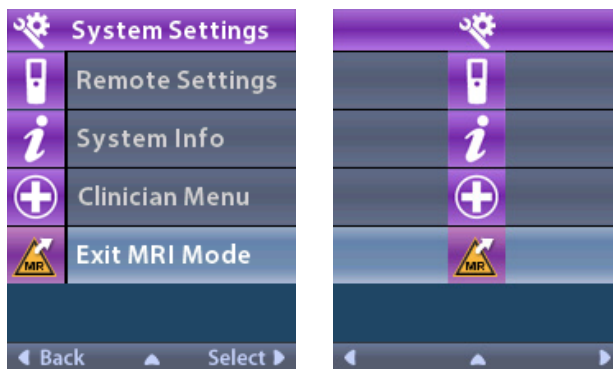
1. Unlock the Remote Control by pressing the **Lock/Unlock**  button on the right side of the Remote Control.
2. After unlocking the Remote Control, the Home screen appears.



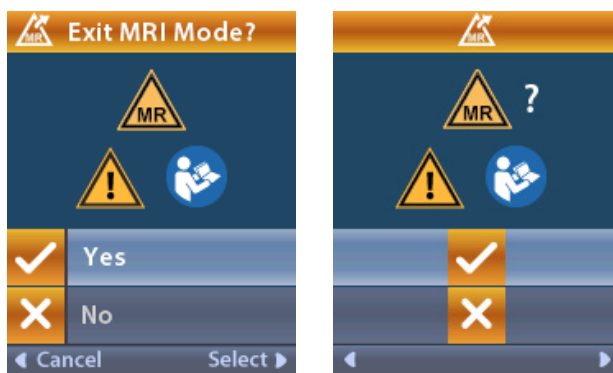
3. Press the Right Arrow  button to navigate to the **Main Menu**.
4. Select **System Settings** .



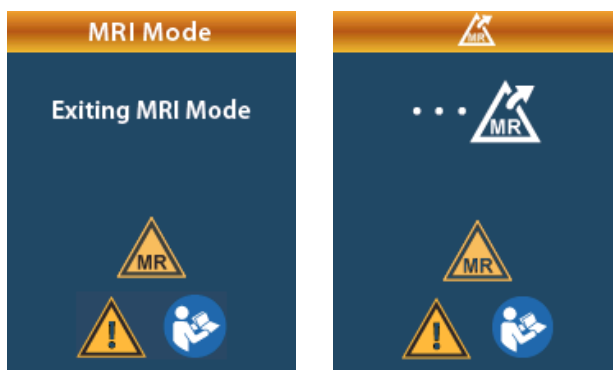
5. Select **Exit MRI Mode** .



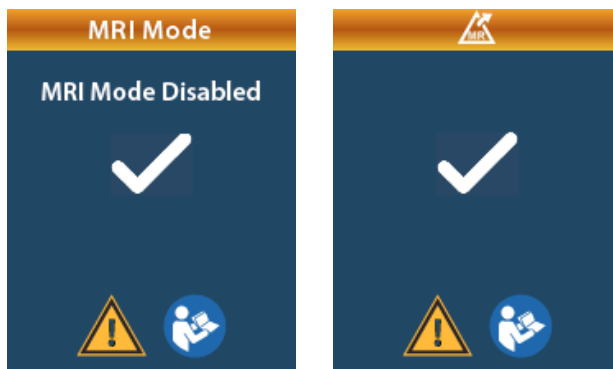
6. Select **Yes**  to Exit MRI Mode or **No**  to cancel the action.



7. The Stimulator performs a series of checks before disabling MRI Mode.

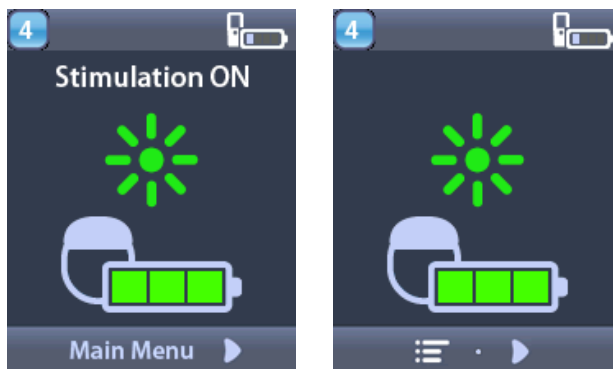


8. If MRI Mode is disabled, the MRI Mode Disabled confirmation screen is displayed.



Note: The Stimulator will retain the stimulation and program settings that were set before MRI Mode was enabled. If the stimulation was ON before MRI Mode was enabled, then disabling MRI Mode turns the stimulation back ON. If stimulation was OFF before MRI Mode was enabled, then disabling MRI Mode keeps the stimulation OFF.

9. The Home Screen on the Remote Control will not display the MR Conditional Symbol once MRI Mode is disabled.



MRI Mode Error Screens

The Remote Control performs system checks once “Enter MRI Mode” is selected from the Systems Settings. It will display Error Screens if:


- The Stimulator battery is not fully charged.
- The Impedance check detects an anomaly.
- There is an error in the Stimulator.

Charge Stimulator Now Screen

The Stimulator battery must be fully charged before the MRI Mode is enabled. If the Stimulator battery is not fully charged, the Remote Control will display one of the following messages instructing the patient to charge the Stimulator before enabling MRI Mode.

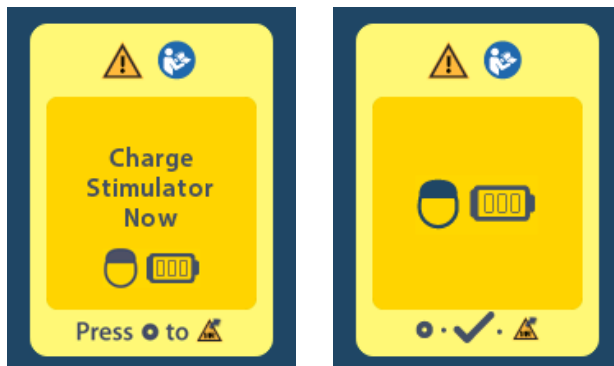


Warning: Always check the Stimulator battery to ensure that it is fully charged before performing a scan on the patient.




1. Press  to dismiss the error message and return to the Remote Control Home Screen.
2. Instruct the patient to charge the Stimulator.
3. Enable MRI Mode once the Stimulator is fully charged.

Charge Stimulator Now or Disable MRI Mode Screen


If MRI Mode has already been enabled and the Stimulator battery power falls below the recommended value, the Remote Control will display a message instructing the patient to charge the Stimulator.



To charge the Stimulator without disabling MRI Mode:

1. Do not press .
2. Instruct the patient to charge the Stimulator.
3. Check the Remote Control to confirm that the error message has cleared.
4. Navigate to the Home Screen on the Remote Control by pressing  button on the side panel of the Remote Control and confirm that the MR Conditional Symbol  is displayed on the Home Screen.

The patient can also disable the MRI Mode before charging the Stimulator:

1. Press  to disable the MRI Mode.
2. Instruct the patient to fully charge the Stimulator.
3. Check the Remote Control to confirm that the error message has cleared.
4. Enable MRI Mode by following instructions in the “Enabling MRI Mode” section of this manual.

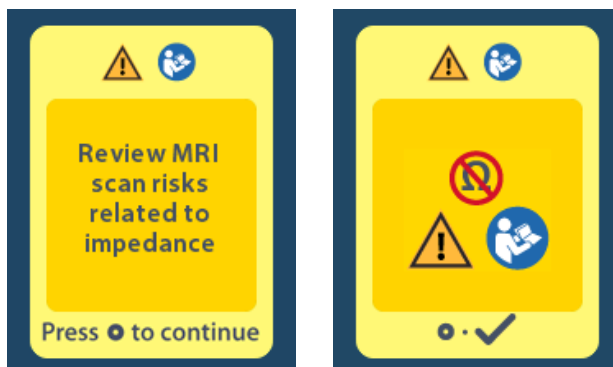
Caution: Charger and Remote Control are MR Unsafe and must not be brought into the MRI scanner room.

Impedances Out of Range Screen

The impedances must be within the acceptable range before MRI Mode is enabled. If the impedances are not within the acceptable range, the Remote Control will display an error message.



1. Press [button icon] to continue.
2. The Remote Control displays a new message instructing the user to review the MRI scan risks related to abnormal impedances. Review the “*Impedances Out of Range*” section under the “*Safety Information*” section of this manual before proceeding. Press [button icon] continue.



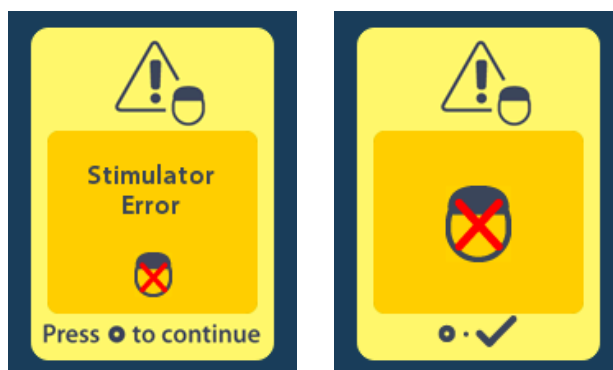
3. Select **Yes**  to proceed with enabling MRI Mode or **No**  to cancel the action.



Warning: An MRI scan is not recommended when the impedances are not within the acceptable range. Higher or lower than normal impedances could indicate compromised Stimulator-Lead integrity. Scanning under these conditions may increase the risk of potential adverse effects listed in the “Safety Information” section of this manual under “Potential Interactions with MRI Environment.”

Stimulator Error Screen

If the system check fails due to a Stimulator error, MRI Mode will not be enabled and the Remote Control will display the Stimulator Error Screen. Do not perform an MRI scan if this error is displayed. Instruct the patient to contact their physician managing their DBS System or Boston Scientific.



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.

MRI Scanner Operating Mode: 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 potential adverse effects listed below under *Potential Interactions with MRI Environment*.

MRI Mode (Applicable to Full System Only): MRI Mode must be enabled on the Stimulator before performing an MRI scan. Performing an MRI scan without MRI Mode enabled may lead to unintended stimulation and patient harm.

Impedances Out of Range: Higher or lower than normal impedances could indicate compromised Stimulator-Lead integrity. Scanning under these conditions may increase the risk of potential adverse effects listed under *Potential Interactions with MRI Environment*.

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

- **Heating** – The MRI RF field interacts with the implanted system and can produce significant heating effects at the Lead-electrode-tissue and/or Stimulator-tissue interface. This can cause tissue damage, edema, burns, discomfort, pain, nerve injury, inadequate stimulation, 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 and/or Stimulator. Patients may feel a tugging sensation, discomfort or pain at the site of the Lead or Stimulator 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 interactions occur and cause the patient discomfort, stop the MRI scan.

If an MRI scan is performed outside of the conditions advised in this manual, it may increase the risks of the potential interactions described above or result in more 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., Charger, Remote Control, External Trial Stimulator, ETS Adapter and OR Cables) are MR Unsafe. They must not be taken into any MRI 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 Non-MR Conditional Extensions and Stimulators for MRI: The Lead-Only MR conditional system is comprised of a booted Leads system comprised of Leads, Lead Boots, and Burr Hole Covers listed in Table 1. The risk of explant to create a Leads-Only MR conditional configuration outlined in this manual should be evaluated by a health care professional.

Return of Symptoms: Patients may become anxious or their symptoms may return once stimulation is turned OFF. Ensure that the patient has been given the appropriate medical care to manage the return of symptoms before performing an MRI scan.

Limitations

Other Implanted Devices: An MRI can also be performed safely if, instead of the Burr Hole Cover, a metal mini plate with screws⁷ is used to secure the DBS Leads to the skull in either the Leads-Only or Full System configurations. 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.

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

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.

Appendix A: MRI Patient Eligibility Form

Boston Scientific DBS Systems Full Body MRI 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. Type of MR Conditional DBS System

Lead-Only System	<input type="checkbox"/>
Full System	<input type="checkbox"/>

B. MR Conditional System Components

Component	Model Numbers	MRI Eligible	Not MRI Eligible
Leads: Standard Leads - DB-2201			
30 cm Lead	DB-2201-30-AC	<input type="checkbox"/>	
	DB-2201-30-DC	<input type="checkbox"/>	
45 cm Lead	DB-2201-45-BC	<input type="checkbox"/>	
	DB-2201-45-DC	<input type="checkbox"/>	
Leads: Directional Leads - DB-2202			
Vercise™ Cartesia™ 30 cm 8 Contact DBS Directional Lead	DB-2202-30	<input type="checkbox"/>	
Vercise Cartesia 45 cm 8 Contact DBS Directional Lead	DB-2202-45	<input type="checkbox"/>	
Extension			
55 cm 8 Contact Extension	NM-3138-55	<input type="checkbox"/>	
Stimulator			
Vercise Gevia 16 Contact Implantable Pulse Generator	DB-1200-S	<input type="checkbox"/>	

Component	Model Numbers	MRI Eligible	Not MRI Eligible
Fixation and Accessories			
SureTek™ Burr Hole Cover	Provided in kits DB-4600-C and DB-4605-C	<input type="checkbox"/>	
Lead Boot	Provided in the Vercise Physician Spares Kit DB-2500-C and with Leads (see above)	<input type="checkbox"/>	
Silicone Suture Sleeves	Provided in Vercise Physician Spares Kit DB-2500-C and with Leads (see above)	<input type="checkbox"/>	
Other (List other implanted components)			
<i>Note: If the patient has medical implants from another manufacturer, also consult the instructions from the manufacturer before making decision about MRI eligibility</i>			
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>

C. DBS Implant Configuration and System Integrity (Check all that apply for Lead-Only System or Full System)

Lead-Only System

MRI Eligible		Not MRI Eligible	
<input type="checkbox"/>	Stimulator NOT implanted.	<input type="checkbox"/>	Stimulator implanted.
<input type="checkbox"/>	Lead Extensions NOT implanted.	<input type="checkbox"/>	Lead Extensions implanted.
<input type="checkbox"/>	Leads capped with Lead Boot.	<input type="checkbox"/>	Leads NOT capped with Lead Boot.
<input type="checkbox"/>	Lead fully implanted under the scalp on the skull.	<input type="checkbox"/>	Lead NOT fully implanted under the scalp on the skull.
<input type="checkbox"/>	NO evidence of fractured Leads.	<input type="checkbox"/>	Evidence of fractured Leads.

Full System

MRI Eligible		Not MRI Eligible	
<input type="checkbox"/>	Stimulator must be implanted under the skin in a location near the clavicle (pectoral region) on the same side of the body as the implanted Lead-Extension.	<input type="checkbox"/>	Stimulator implanted in locations other than under the skin in a location near the clavicle (pectoral region) on the same side of the body as the implanted Lead-Extension.
<input type="checkbox"/>	Extensions directly connected to Stimulator. No adapters present.	<input type="checkbox"/>	Extension not directly connected to Stimulator. Adapter is present.
<input type="checkbox"/>	No Evidence of fractured Leads or compromised Stimulator-Lead system integrity.	<input type="checkbox"/>	Evidence of fractured Leads or compromised Stimulator-Lead system integrity.

D. Instructions for the patient or MRI Center prior to the MRI scan (Full System only)

1. Stimulator must be fully charged (Stimulator battery level on the Remote Control must be at three bars) before the MRI scan. Patient must bring their Charger to the MRI center in case additional charging is necessary.
2. MRI Mode must be enabled on the Stimulator using the patient Remote control before performing an MRI scan. Patient must bring their Remote Control to the MRI center.


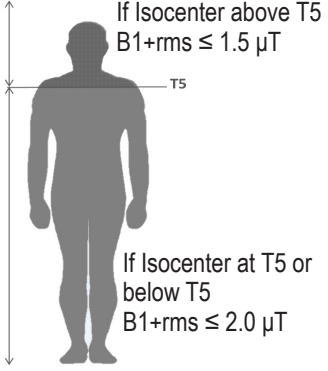
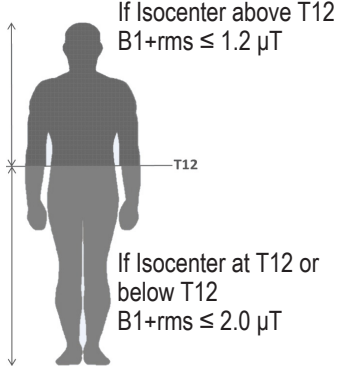
Note: *Charger and Remote Control are MR Unsafe and must not be brought into the MRI scanner room.*

Appendix B: Summary of Radiology Scan Conditions

Boston Scientific DBS Systems Summary of Radiology Scan Conditions

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. Ensure that the implanted system meets the implant conditions listed in this manual before performing a scan.

Testing has demonstrated the Boston Scientific Lead-Only System as well as the Vercise Gevia System are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following scan conditions:

MRI Safety Information			
<ul style="list-style-type: none"> • Static magnetic field of 1.5 T • Maximum spatial field gradient of 4,000 gauss/cm (40 T/m) • Maximum gradient slew rate per axis of less than or equal to 200 T/m/s • Cumulative active scan time of less than or equal to 30 minutes • If B1+rms is not available, the maximum MR system reported head or whole body averaged specific absorption rate (SAR) should be equal to or less than (\leq) 0.1 W/kg 			
Maximum B1+rms			
	Lead-Only System ⁸ (DB-2201 or DB-2202)	Full System ⁹ with Standard Lead (DB-2201)	Full System with Directional Lead (DB-2202)
Head Transmit/ Receive Coil			
Full Body Transmit/ Receive Coil	<p>B1+rms \leq 2.0 μT</p>		
Additional Information			
<ul style="list-style-type: none"> • Patient must be positioned in supine or prone position during the scan. • Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination. • MRI Mode must be enabled on Vercise Gevia prior to performing a scan. • Stimulator must be fully charged prior to the MRI scan. 			

⁸ A Lead-Only System is when the patient is implanted with DB-2201 or DB-2202, Lead Boot, and, optionally, Burr Hole Cover. Refer to Table 1 in this manual for eligible components.

⁹ A Full System is when the patient is implanted with DB-2201 or DB-2202, Extension NM-3138-55, Stimulator DB-1200-S, and, optionally, Burr Hole Cover. Refer to Table 1 in this manual for eligible components.

Boston Scientific

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