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ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems

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

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How to Use this Manual

The manual provides guidelines to determine whether and how to conduct an MRI scan on a patient implanted with any component of the Boston Scientific Deep Brain Stimulation (DBS) System as defined by this manual. Throughout this manual, the name “Boston Scientific DBS System” refers to the following: Vercise Genus™ and Vercise Gevia™ Deep Brain Stimulation Systems.

Read this manual in its entirety before performing an MRI scan on patients who are implanted with any component listed in this manual.

For detailed information about non-MRI aspects of implantation, features, programming, and use of the components of the DBS System refer to the appropriate Instructions for Use (IFU) for your DBS System as listed in your *DBS Reference Guide*.

Note: *Images of the Remote Control Home Screen within this manual are representative of those displayed for a rechargeable DBS System unless specified otherwise. The Home Screen for a non-rechargeable Stimulator does not include the battery level of the Stimulator.*

Note: *This manual is intended to be printed in color.*

Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Drawings are for illustration purposes only. Figures in this manual are not intended to be prescriptive, do not illustrate all possible configurations, and are intended to be used for reference only.

Trademarks

Vercise™, Vercise Gevia™, Vercise Genus™, Cartesia™, SureTek™, and ImageReady™ are trademarks of Boston Scientific Corporation or its affiliates.

All other trademarks are the property of their respective owners.

Warranty

For device warranty information, visit www.bostonscientific.com/warranty.

Technical Support

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

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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 an MRI scan on a patient implanted with any component of the Boston Scientific DBS System as defined by this manual.

Caution: *Read this manual in its entirety before performing an MRI scan on a patient implanted with any component listed in this manual.*

Caution: *MR Conditional scan may be safely performed when implanted with the 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.*

Note: *The term "Stimulator" in this manual refers to the Implantable Pulse Generator (IPG), unless specifically referred to as the External Trial Stimulator (ETS).*

Obtain the Latest MRI Guidelines

Always obtain the latest MRI guidelines. See the *"Technical Support"* section of this manual, or go to www.IFU-BSCI.com for the latest version of this manual.

Patient Materials for an MRI

Advise the patient to bring the following to all MRI appointments:

- Remote Control
- Charger (if implanted with a rechargeable IPG)
- Their most up-to-date Patient ID Card

The patient's Remote Control should be used to place the DBS System into MRI Mode prior to a scan; see the *"Enabling MRI Mode"* section of this manual for more information. In order to enter MRI Mode, rechargeable Stimulators must be fully charged. 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.

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

How to Use this Manual

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

- Fully Implanted Lead-Only System
  - A fully implanted Lead-Only DBS System is a booted Lead System comprised of Lead(s), Lead Boot(s), and Burr Hole Cover(s) or an alternative method of securing Leads (see Table 2 for scan eligible components).
- Externalized Lead-Only System
  - An externalized Lead-Only DBS System is comprised of Lead(s) and, optionally, Burr Hole Cover(s) or an alternative method of securing Leads (see Table 2 for scan eligible components).
- Vercise Genus DBS Full System
  - A Vercise Genus DBS Full System is comprised of Lead(s), Lead Extension(s), Vercise Genus DBS Stimulator(s), and Burr Hole Cover(s) or an alternative method of securing Leads (see Table 4 for scan eligible components). The Vercise Genus DBS Stimulators are an MR Conditional family of Stimulators.
- Vercise Genus DBS Mixed System
  - A Vercise Genus DBS Mixed System is comprised of Medtronic Lead(s), Medtronic Lead Extension(s), Boston Scientific Vercise M8 Adapter(s), any Boston Scientific Vercise Genus DBS Stimulator(s), and Medtronic Stimloc™ Burr Hole Cover(s) (see Table 5 for scan eligible components). The Vercise Genus DBS Stimulators are an MR Conditional family of Stimulators.
- Vercise Genus DBS Partially Mixed System
  - A Vercise Genus DBS Partially Mixed System is a bilateral system with a combination of Leads and Lead Extensions from different manufacturers connected to any two Boston Scientific Vercise Genus DBS Stimulators. This system is comprised of a Medtronic Lead, Medtronic Lead Extension, Medtronic Stimloc™ Burr Hole Cover, Boston Scientific Lead, Boston Scientific Vercise M8 Adapter, Boston Scientific Lead Extension, and a Boston Scientific Burr Hole Cover or alternative method of securing a Boston Scientific Lead (see Table 6 for scan eligible components). The Vercise Genus DBS Stimulators are an MR Conditional family of Stimulators.
- Vercise Gevia DBS Full System
  - A Vercise Gevia DBS Full System is comprised of Lead(s), Lead Extension(s), Vercise Gevia DBS Stimulator, and Burr Hole Cover(s) or an alternative method of securing Leads (see Table 7 for scan eligible components). The Vercise Gevia DBS Stimulator is an MR Conditional Stimulator.

See the *"MR Conditional System Description"* section of this manual for full definitions and eligible components of each system.

To use this manual:

1. Read this manual in its entirety before performing an MRI scan on a patient implanted with any component listed in this manual.
2. Determine the type of DBS System to be scanned.
3. Determine the isocenter of the scan.
4. Determine the transmit coil type.
5. Determine the scan conditions per Table 1 and then refer to the appropriate sections of this manual.

Note: *There are MR Conditional radio frequency (RF) limits in this manual that are below Normal Mode. In those instances, please be aware this could limit the availability of some MR procedures.*

MRI scan conditions differ based on the isocenter of the scan, the type of transmit coil being utilized for the scan (head transmit or body transmit), the type of system implanted (Lead-Only System, Full System, Mixed System, or Partially Mixed System), and the Stimulator (Vercise Genus DBS or Vercise Gevia DBS).

Table 1. MRI Safety Information Reference Table

System Components	System Type	Isocenter	Transmit Coil Type (Circular Polarized (CP) Only[1, 2, 3])	Implant Conditions Reference Section	Scan Conditions Reference Section
All Leads	Fully Implanted or Externalized Leads-Only	Any (Full Body)	Head or Body Coil	• See Table 2 on page 4 for scan eligible components. • See Table 3 on page 5 for system configuration.	• See Table 12 on page 15 for scan conditions.
Vercise Genus DBS System (Stimulator Model Numbers: DB-1408, DB-1416, DB-1432, DB-1216, and DB-1232)	Full System, Mixed System, or Partially Mixed System	Head	Head Coil	• See Table 4 on page 6 for Vercise Genus DBS Full System scan eligible components. • See Table 5 on page 7 for Vercise Genus DBS Mixed System scan eligible components. • See Table 6 on page 8 for Vercise Genus DBS Partially Mixed System scan eligible components. • See Table 8 on page 10 for Vercise Genus DBS Full System configuration. • See Table 9 on page 11 for Vercise Genus DBS Mixed System configuration. • See Table 10 on page 12 for Vercise Genus DBS Partially Mixed System configuration.	• See Table 13 on page 17 for scan conditions.
		At or Above C2	Body Coil		• See Table 14 on page 19 for scan conditions.
		C3 through T10			
		T11 through Femur			
		Lower Extremities (knee and below)			
		Lower Extremities (knee and below)	Lower Extremity Coil		• See Table 17 on page 23 for scan conditions.
Vercise Gevia DBS System (Stimulator Model Number: DB-1200-S)	Full System with DB-2201 or DB-2202 Lead(s)	Head	Head Coil	• See Table 7 on page 9 for scan eligible components. • See Table 11 on page 13 for system configuration.	• See Table 13 on page 17 for scan conditions.
	Full System with DB-2201 Lead(s)	Above T5	Body Coil	• See Table 7 on page 9 for scan eligible components. • See Table 11 on page 13 for system configuration.	• See Table 16 on page 21 for scan conditions.
		At or Below T5			
	Full System with DB-2202 Lead(s)	Above T12			
		At or Below T12			

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

1 MRI Transmit/Receive RF Quadrature Head Coil – a coil used to transmit and to receive RF energy that is constrained to the head region, and configured to use circular polarization (CP).

2 MRI Transmit/Receive RF Quadrature Body Coil – a coil used to transmit and to receive RF energy that encompasses the entire body region within the MR system bore, and configured to use circular polarization (CP).

3 MRI Transmit/Receive RF Quadrature Extremity Coil – a coil used to transmit and to receive RF energy that is constrained to an extremity, and configured to use circular polarization (CP).

MR Conditional System Description

Lead-Only System

Scan Eligible Components

Table 2. Lead-Only System Scan Eligible Components

Lead(s)	• DB-2201-30-AC, 30 cm 8 Contact Standard Lead • DB-2201-30-DC, 30 cm 8 Contact Standard Lead • DB-2201-45-BC, 45 cm 8 Contact Standard Lead • DB-2201-45-DC, 45 cm 8 Contact Standard Lead • DB-2202-30, Vercise™ Cartesia™ 30 cm 8 Contact DBS Directional Lead • DB-2202-45, Vercise™ Cartesia™ 45 cm 8 Contact DBS Directional Lead
Lead Extension(s)	None
Stimulator	None
Accessories	• Lead Boot(s) (not required if Leads are externalized) ○ Provided in the Vercise™ Physician's Spare Kit, DB-2500-C, and with DBS Leads • SureTek Burr Hole Cover(s) (optional if using alternative method of securing Leads[4]) ○ Provided in Burr Hole Cover, DB-4600-C, and Burr Hole Cover Spares Kit, DB-4605-C • Suture Sleeve(s) (optional) ○ Provided in the Vercise™ Physician's Spare Kit, DB-2500-C, and with DBS Leads

4 An MRI can also be performed safely if, instead of the Burr Hole Cover, a mini plate similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws is used to secure the Boston Scientific 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. Contact the appropriate device manufacturers with questions regarding other systems.

System Configuration

Table 3. Lead-Only System Configuration	
Lead(s)-Only, Fully Implanted Configuration	• A fully implanted Lead-Only DBS System is a booted Lead System comprised of Lead(s), Lead Boot(s), and Burr Hole Cover(s) or an alternative method of securing Leads[5] (see Table 2 for scan eligible components). • Fully implanted Lead(s) (not exposed). • Leads are capped with Lead Boots on proximal ends and excess Lead is coiled and implanted under the scalp on the skull.[6] • Patients with up to two Leads implanted are scan eligible. • No evidence can be found of fractured Leads. • No Lead Extensions or Stimulator present.
Lead(s)-Only, Externalized Configuration	• Partially implanted Lead(s) extending out of the patient must be straight with no loops. • The external portion of the partially implanted Lead cannot be in contact with either the patient or any part of the scanner (see Table 2 for scan eligible components). • Patients with up to two Leads implanted are scan eligible. • No evidence can be found of fractured Leads. • No Lead Extensions or Stimulator present.

5 An MRI can also be performed safely if, instead of the Burr Hole Cover, a mini plate similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws is used to secure the Boston Scientific 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. Contact the appropriate device manufacturers with questions regarding other systems.

6 The system has only been evaluated with a Lead Boot. Failure to use a Lead Boot could increase the chance of the risks described in the *"Safety Information"* section of this manual under *"Potential Interactions with MRI Environment."*

Full System, Mixed System, or Partially Mixed System

Vercise Genus DBS Full System Scan Eligible Components

Table 4. Vercise Genus DBS Full System Scan Eligible Components

Lead(s)	• DB-2201-30-AC, 30 cm 8 Contact Standard Lead • DB-2201-30-DC, 30 cm 8 Contact Standard Lead • DB-2201-45-BC, 45 cm 8 Contact Standard Lead • DB-2201-45-DC, 45 cm 8 Contact Standard Lead • DB-2202-30, Vercise™ Cartesia™ 30 cm 8 Contact DBS Directional Lead • DB-2202-45, Vercise™ Cartesia™ 45 cm 8 Contact DBS Directional Lead
Lead Extension(s)	• NM-3138-55, 55 cm 8 Contact Lead Extension • DB-3128-55B, 55 cm 2x8 Contact Lead Extension • DB-3128-95B, 95 cm 2x8 Contact Lead Extension
Stimulator(s)	• DB-1408, Vercise Genus™ P8 Implantable Pulse Generator • DB-1416, Vercise Genus™ P16 Implantable Pulse Generator • DB-1432, Vercise Genus™ P32 Implantable Pulse Generator • DB-1216, Vercise Genus™ R16 Implantable Pulse Generator • DB-1232, Vercise Genus™ R32 Implantable Pulse Generator
Accessories	• SureTek Burr Hole Cover(s) (optional if using alternative method of securing Leads[7]) ○ Provided in Burr Hole Cover, DB-4600-C, and Burr Hole Cover Spares Kit, DB-4605-C • Suture Sleeve(s) (optional) ○ Provided in the Vercise™ Physician's Spare Kit, DB-2500-C, and with DBS Leads • Port Plugs ○ Provided in the Port Plug Spares Kit, SC-4401, IPG Kits, DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, and Lead Extension Kits, DB-3128-55B, DB-3128-95B

7 An MRI can also be performed safely if, instead of the Burr Hole Cover, a mini plate similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws is used to secure the Boston Scientific 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. Contact the appropriate device manufacturers with questions regarding other systems.

Vercise Genus DBS Mixed System Scan Eligible Components

Table 5. Vercise Genus DBS Mixed System Scan Eligible Components	
Medtronic Lead(s)	• 3387-28, Medtronic 28cm 1.5mm Spaced 4 Contact Standard Lead • 3387S-28, Medtronic 28cm 1.5mm Spaced 4 Contact Standard Lead • 3387-40, Medtronic 40cm 1.5mm Spaced 4 Contact Standard Lead • 3387S-40, Medtronic 40cm 1.5mm Spaced 4 Contact Standard Lead • 3389-28, Medtronic 28cm 0.5mm Spaced 4 Contact Standard Lead • 3389S-28, Medtronic 28cm 0.5mm Spaced 4 Contact Standard Lead • 3389-40, Medtronic 40cm 0.5mm Spaced 4 Contact Standard Lead • 3389S-40, Medtronic 40cm 0.5mm Spaced 4 Contact Standard Lead
Medtronic Lead Extension(s)	• 37085-40, Medtronic 40cm Lead Extension • 37085-60, Medtronic 60cm Lead Extension • 37085-95, Medtronic 95cm Lead Extension • 37086-40, Medtronic 40cm Lead Extension • 37086-60, Medtronic 60cm Lead Extension • 37086-95, Medtronic 95cm Lead Extension
Adapter(s)	• DB-9218-15, Vercise™ M8 Adapter, 15cm • DB-9218-55, Vercise™ M8 Adapter, 55cm
Stimulator(s)	• DB-1408, Vercise Genus™ P8 Implantable Pulse Generator • DB-1416, Vercise Genus™ P16 Implantable Pulse Generator • DB-1432, Vercise Genus™ P32 Implantable Pulse Generator • DB-1216, Vercise Genus™ R16 Implantable Pulse Generator • DB-1232, Vercise Genus™ R32 Implantable Pulse Generator
Accessories	• Boston Scientific Port Plugs ○ Provided in the Port Plug Spares Kit, SC-4401, and IPG Kits, DB-1408, DB-1416, DB-1432, DB-1216, DB-1232 • Medtronic Stimloc Burr Hole Cover(s) ○ 924256

Vercise Genus DBS Partially Mixed System Scan Eligible Components

Table 6. Vercise Genus DBS Partially Mixed System Scan Eligible Components	
Boston Scientific Lead(s)	• DB-2201-30-AC, 30 cm 8 Contact Standard Lead • DB-2201-30-DC, 30 cm 8 Contact Standard Lead • DB-2201-45-BC, 45 cm 8 Contact Standard Lead • DB-2201-45-DC, 45 cm 8 Contact Standard Lead • DB-2202-30, Vercise™ Cartesia™ 30 cm 8 Contact DBS Directional Lead • DB-2202-45, Vercise™ Cartesia™ 45 cm 8 Contact DBS Directional Lead
Medtronic Lead(s)	• 3387-28, Medtronic 28cm 1.5mm Spaced 4 Contact Standard Lead • 3387S-28, Medtronic 28cm 1.5mm Spaced 4 Contact Standard Lead • 3387-40, Medtronic 40cm 1.5mm Spaced 4 Contact Standard Lead • 3387S-40, Medtronic 40cm 1.5mm Spaced 4 Contact Standard Lead • 3389-28, Medtronic 28cm 0.5mm Spaced 4 Contact Standard Lead • 3389S-28, Medtronic 28cm 0.5mm Spaced 4 Contact Standard Lead • 3389-40, Medtronic 40cm 0.5mm Spaced 4 Contact Standard Lead • 3389S-40, Medtronic 40cm 0.5mm Spaced 4 Contact Standard Lead
Boston Scientific Lead Extension(s)	• NM-3138-55, 55 cm 8 Contact Lead Extension • DB-3128-55B, 55 cm 2x8 Contact Lead Extension • DB-3128-95B, 95 cm 2x8 Contact Lead Extension
Medtronic Lead Extension(s)	• 37085-40, Medtronic 40cm Lead Extension • 37085-60, Medtronic 60cm Lead Extension • 37085-95, Medtronic 95cm Lead Extension • 37086-40, Medtronic 40cm Lead Extension • 37086-60, Medtronic 60cm Lead Extension • 37086-95, Medtronic 95cm Lead Extension
Adapter(s)	• DB-9218-15, Vercise™ M8 Adapter, 15cm • DB-9218-55, Vercise™ M8 Adapter, 55cm
Stimulator(s)	• DB-1408, Vercise Genus™ P8 Implantable Pulse Generator • DB-1416, Vercise Genus™ P16 Implantable Pulse Generator • DB-1432, Vercise Genus™ P32 Implantable Pulse Generator • DB-1216, Vercise Genus™ R16 Implantable Pulse Generator • DB-1232, Vercise Genus™ R32 Implantable Pulse Generator
Accessories	• SureTek Burr Hole Cover (optional if using alternative method of securing Boston Scientific Leads[8]) ○ Provided in Burr Hole Cover, DB-4600-C, and Burr Hole Cover Spares Kit, DB-4605-C • Medtronic Stimloc Burr Hole Cover ○ 924256 • Boston Scientific Suture Sleeve(s) (optional) ○ Provided in the Vercise™ Physician's Spare Kit, DB-2500-C, and with DBS Leads • Boston Scientific Port Plugs ○ Provided in the Port Plug Spares Kit, SC-4401, IPG Kits, DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, and Lead Extension Kits, DB-3128-55B, DB-3128-95B

8 An MRI can also be performed safely if, instead of the Burr Hole Cover, a mini plate similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws is used to secure the Boston Scientific 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. Contact the appropriate device manufacturers with questions regarding other systems.

Vercise Gevia DBS Full System Scan Eligible Components

Table 7. Vercise Gevia DBS Full System Scan Eligible Components	
Lead(s)	• DB-2201-30-AC, 30 cm 8 Contact Standard Lead • DB-2201-30-DC, 30 cm 8 Contact Standard Lead • DB-2201-45-BC, 45 cm 8 Contact Standard Lead • DB-2201-45-DC, 45 cm 8 Contact Standard Lead • DB-2202-30, Vercise™ Cartesia™ 30 cm 8 Contact DBS Directional Lead • DB-2202-45, Vercise™ Cartesia™ 45 cm 8 Contact DBS Directional Lead
Lead Extension(s)	• NM-3138-55, 55 cm 8 Contact Lead Extension
Stimulator	• DB-1200-S, Vercise Gevia™ 16 Contact Implantable Pulse Generator
Accessories	• SureTek Burr Hole Cover(s) (optional if using alternative method of securing Leads[9]) ○ Provided in Burr Hole Cover, DB-4600-C, and Burr Hole Cover Spares Kit, DB-4605-C • Suture Sleeve(s) (optional) ○ Provided in the Vercise™ Physician's Spare Kit, DB-2500-C, and with DBS Leads • Port Plugs ○ Provided in the Port Plug Spares Kit, SC-4401, and IPG Kit, DB-1200-S

9 An MRI can also be performed safely if, instead of the Burr Hole Cover, a mini plate similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws is used to secure the Boston Scientific 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. Contact the appropriate device manufacturers with questions regarding other systems.

Vercise Genus DBS Full System Configuration

Table 8. Vercise Genus DBS Full System Configuration

Vercise Genus DBS Full System Configuration(s)	• A fully implanted DBS Full System is comprised of Lead(s), Lead Extension(s), Stimulator(s), and Burr Hole Cover(s) or an alternative method of securing Leads[10] (see Table 4 for scan eligible components). • Stimulator(s) must be implanted under the skin in a location near the clavicle (pectoral region) or in the abdomen on the same side of the body as the implanted Lead Extension(s) to which the Stimulator is connected. • Up to two Stimulators may be implanted (one on each side of the body). When two Stimulators are implanted, each Lead and Lead Extension must be implanted on the same side of the body as the Stimulator to which it is connected. • Patients with up to two Leads implanted are scan eligible. • In a bilateral implant where two Leads and Lead Extensions are connected to a single Stimulator, both Lead Extensions must be routed on the same side of the body as the Stimulator. • Lead Extensions must be connected directly to the Stimulator without the use of an Adapter. • Unused Stimulator Ports require a Port Plug to be inserted in order to be scan eligible. • Any system with a single Lead and a single unused Lead Extension Port requires a Port Plug to be inserted into the unused Lead Extension Port in order to be scan eligible. ***Note:*** *To confirm the presence of a Port Plug in a Stimulator or Lead Extension, check the patient's record or confirm with the implanting physician.* ***Caution:*** *If more than two Stimulators are implanted, the patient is not scan eligible.* ***Caution:*** *When two Stimulators are implanted, a system containing DB-3128-55B or DB-3128-95B Lead Extension(s) is not scan eligible.* ***Caution:*** *There should be no evidence of fractured or abandoned Leads or compromised Stimulator-Lead integrity.*[11]
Vercise Genus DBS Full System Programming	• MRI Mode must be enabled on the Stimulator prior to performing scan.[12] • Rechargeable Stimulators must be fully charged prior to the scan.

10 An MRI can also be performed safely if, instead of the Burr Hole Cover, a mini plate similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws is used to secure the Boston Scientific 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. Contact the appropriate device manufacturers with questions regarding other systems.

11 An impedance check is automatically performed for Stimulator-Lead integrity when MRI Mode is enabled on the Stimulator. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode.

12 Stimulation is automatically turned OFF when MRI Mode is enabled. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Vercise Genus DBS Mixed System Configuration

Table 9. Vercise Genus DBS Mixed System Configuration

Vercise Genus DBS Mixed System Configuration(s)	• A fully implanted DBS Mixed System is comprised of Medtronic Lead(s), Medtronic Lead Extension(s), Boston Scientific Vercise M8 Adapter(s), any Boston Scientific Vercise Genus DBS Stimulator(s), and Medtronic Stimloc Burr Hole Cover(s) (see Table 5 for scan eligible components). • Stimulator(s) must be placed under the skin in a location near the clavicle (pectoral region) or in the abdomen on the same side of the body as the implanted Lead Extension(s) and Adapter(s) to which the Stimulator is connected. • Up to two Stimulators may be implanted (one on each side of the body). When two Stimulators are implanted, each Lead and Lead Extension must be implanted on the same side of the body as the Stimulator to which it is connected. • Patients with up to two Leads implanted are scan eligible. • In a bilateral implant where two Leads, Lead Extensions, and Adapters are connected to a single Stimulator, both Lead Extensions and Adapters must be routed on the same side of the body as the Stimulator. • Medtronic Lead Extensions must be connected directly to the M8 Adapter. • Unused Stimulator Ports require a Port Plug to be inserted in order to be scan eligible. ***Note:*** *To confirm the presence of a Port Plug in a Stimulator, check the patient's record or confirm with the implanting physician.* ***Caution:*** *All Lead, Lead Extension, and M8 Adapter length combinations are scan eligible except those that include both a 95cm Medtronic Lead Extension (37085-95 or 37086-95) and a 55cm M8 Adapter (DB-9218-55).* ***Caution:*** *Any system with an unused Lead Extension Port is not scan eligible.* ***Caution:*** *If more than two Stimulators are implanted, the patient is not scan eligible.* ***Caution:*** *When two Stimulators are implanted, a system containing DB-3128-55B or DB-3128-95B Lead Extension(s) is not scan eligible.* ***Caution:*** *There should be no evidence of fractured or abandoned Leads or compromised Stimulator-Lead integrity.*[13]
Vercise Genus DBS Mixed System Programming	• MRI Mode must be enabled on the Stimulator prior to performing scan.[14] • Rechargeable Stimulators must be fully charged prior to the scan.

13 An impedance check is automatically performed for Stimulator-Lead integrity when MRI Mode is enabled on the Stimulator. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode.

14 Stimulation is automatically turned OFF when MRI Mode is enabled. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Vercise Genus DBS Partially Mixed System Configuration

Table 10. Vercise Genus DBS Partially Mixed System Configuration	
Vercise Genus DBS Partially Mixed System Configuration(s)	• A Vercise Genus DBS Partially Mixed System is a bilateral system with a combination of Leads and Lead Extensions from different manufacturers connected to any two Boston Scientific Vercise Genus DBS Stimulators. A fully implanted Vercise Genus DBS Partially Mixed System is comprised of the following: ○ A Medtronic Lead, Medtronic Lead Extension, Medtronic Stimloc Burr Hole Cover, and a Boston Scientific Vercise M8 Adapter (see Table 6 for scan eligible components). ○ A Boston Scientific Lead, Boston Scientific Lead Extension, and a Boston Scientific Burr Hole Cover or alternative method of securing a Boston Scientific Lead[15] (see Table 6 for scan eligible components). • The Vercise Genus DBS Partially Mixed System is only MR Conditional when two Stimulators are implanted (one on each side of the body). When two Stimulators are implanted, each Lead, Lead Extension, and, if applicable, Adapter must be implanted on the same side of the body as the Stimulator to which it is connected. • Stimulators must be placed under the skin in a location near the clavicle (pectoral region) or in the abdomen. • Patients with two Leads implanted are scan eligible. • The Medtronic Lead Extension must be connected directly to the M8 Adapter. • Unused Stimulator Ports require a Port Plug to be inserted in order to be scan eligible. • Any unused Boston Scientific Lead Extension Port requires a Boston Scientific Port Plug to be inserted into the unused Boston Scientific Lead Extension Port in order to be scan eligible. ***Note:*** *To confirm the presence of a Port Plug in a Stimulator or Boston Scientific Lead Extension, check the patient's record or confirm with the implanting physician.* ***Caution:*** *All Lead, Lead Extension, and M8 Adapter length combinations are scan eligible except those that include both a 95cm Medtronic Lead Extension (37085-95 or 37086-95) and a 55cm M8 Adapter (DB-9218-55).* ***Caution:*** *Any system with an unused Medtronic Lead Extension Port is not scan eligible.* ***Caution:*** *If more than two Stimulators are implanted, the patient is not scan eligible.* ***Caution:*** *When two Stimulators are implanted, a system containing DB-3128-55B or DB-3128-95B Lead Extension(s) is not scan eligible.* ***Caution:*** *There should be no evidence of fractured or abandoned Leads or compromised Stimulator-Lead integrity.*[16]
Vercise Genus DBS Partially Mixed System Programming	• MRI Mode must be enabled on the Stimulators prior to performing scan.[17] • Rechargeable Stimulators must be fully charged prior to the scan.

15 An MRI can also be performed safely if, instead of the Burr Hole Cover, a mini plate similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws is used to secure the Boston Scientific 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. Contact the appropriate device manufacturers with questions regarding other systems.

16 An impedance check is automatically performed for Stimulator-Lead integrity when MRI Mode is enabled on the Stimulator. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode.

17 Stimulation is automatically turned OFF when MRI Mode is enabled. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Vercise Gevia DBS Full System Configuration

Table 11. Vercise Gevia DBS Full System Configuration	
Vercise Gevia DBS Full System Configuration(s)	• A fully implanted DBS Full System is comprised of Lead(s), Lead Extension(s), Stimulator, and Burr Hole Cover(s) or an alternative method of securing Leads[18] (see Table 7 for scan eligible components). • 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(s) to which the Stimulator is connected. • Patients with up to two Leads implanted are scan eligible. • In a bilateral implant where two Leads and Lead Extensions are connected to a single Stimulator, both Lead Extensions must be routed on the same side of the body as the Stimulator. • Lead Extensions must be connected directly to the Stimulator without the use of an Adapter. • Unused Stimulator Ports require a Port Plug to be inserted in order to be scan eligible. • Only system configurations using DB-2201 or DB-2202 Lead(s) with NM-3138-55 Lead Extension(s) are scan eligible. ***Note:*** *To confirm the presence of a Port Plug in a Stimulator, check the patient's record or confirm with the implanting physician.* ***Caution:*** *A Vercise Gevia DBS Stimulator is not scan eligible when implanted in the abdomen.* ***Caution:*** *Any system with an unused Lead Extension Port is not scan eligible.* ***Caution:*** *If multiple Stimulators are implanted, the patient is not scan eligible.* ***Caution:*** *There should be no evidence of fractured or abandoned Leads or compromised Stimulator-Lead integrity.*[19]
Vercise Gevia DBS Full System Programming	• MRI Mode must be enabled on the Stimulator prior to performing scan.[20] • Rechargeable Stimulators must be fully charged prior to the scan.

18 An MRI can also be performed safely if, instead of the Burr Hole Cover, a mini plate similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws is used to secure the Boston Scientific 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. Contact the appropriate device manufacturers with questions regarding other systems.

19 An impedance check is automatically performed for Stimulator-Lead integrity when MRI Mode is enabled on the Stimulator. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode.

20 Stimulation is automatically turned OFF when MRI Mode is enabled. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

MRI Safety Information

Lead-Only System Scan

Testing has demonstrated that the Boston Scientific Lead-Only System is MR Conditional. See the *"MR Conditional System Description"* section of this manual for the definition of a Lead-Only System.

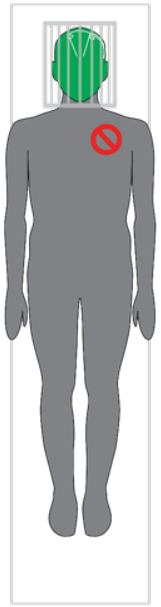
Appendix A has an MRI Patient Eligibility form that may be used by the physician to confirm the patient meets the DBS System Conditions for MRI Scans as described in this manual. A Pre-MRI Scan Condition Checklist to determine whether scan conditions have been met can be found in Appendix B. All Conditions of Use must be met for an MRI scan to be performed.

An MRI may be safely performed on a patient implanted with a Lead-Only System that meets the conditions outlined in Table 12.

Caution: *Read this manual in its entirety before performing a MRI scan on a patient implanted with any component listed in this manual.*

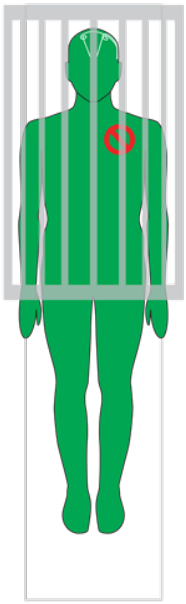
Table 12. Conditions for a Fully Implanted or Externalized Lead-Only System Scan

Head Coil



Or

Body Coil



MR Conditional	Yes
Static Magnet Strength	1.5T
Scanner Type	Horizontal field, cylindrical closed-bore 1.5T scanner
Operating Mode	Normal
Maximum Spatial Field Gradient	4000 gauss/cm (40 T/m)
Maximum Gradient Slew Rate	200 T/m/s per axis
MRI Coil Setup	• Head transmit/receive coil (Circular Polarized (CP) Only) or • Body transmit/receive coil (Circular Polarized (CP) Only) • Receive-only coil: Any type (in conjunction with using a body coil as a transmitter in Circular Polarized (CP) Mode) • Hydrogen/proton imaging only
Zone Indicated	Any (Full Body)
Maximum B1+rms	2.0 µT
Maximum SAR[21]	0.1 W/kg
System Programming	N/A
Scan Eligible System Components	See Table 2 on page 4.
System Configuration	See Table 3 on page 5.
Exposure Time	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.
Additional Information	• Patient must be positioned in supine or prone position during the scan. • If possible, patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination.

Note: *Green colored zones are indicative of scan eligible zones per the scan conditions of Table 12.*

Note: *The ⃠ icon indicates a Stimulator cannot be implanted when using the scan conditions listed in Table 12.*

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

Full System, Mixed System, or Partially Mixed System Scan

Testing has demonstrated that the Vercise Genus DBS Full System, Vercise Genus DBS Mixed System, Vercise Genus DBS Partially Mixed System, and Vercise Gevia DBS Full System are MR Conditional. See the *"MR Conditional System Description"* section of this manual for the definition of a Full System, Mixed System, or Partially Mixed System.

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. A Pre-MRI Scan Condition Checklist to determine whether scan conditions have been met can be found in Appendix B. All Conditions of Use must be met for an MRI scan to be performed.

A patient with this system can be safely scanned in an MR system meeting the conditions outlined in Table 13, Table 14, Table 16, or Table 17.

Full System, Mixed System, or Partially Mixed System Head Scan Using a Head Transmit Coil

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

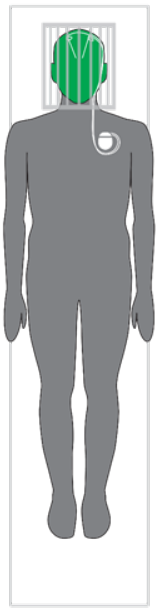
Caution: *Read this manual in its entirety before performing a MRI scan on a patient implanted with any component listed in this manual.*

A patient with this system can be safely scanned in an MR system meeting the conditions outlined in Table 13.

Vercise Genus DBS Full System, Vercise Genus DBS Mixed System, Vercise Genus DBS Partially Mixed System, Vercise Gevia DBS Full System

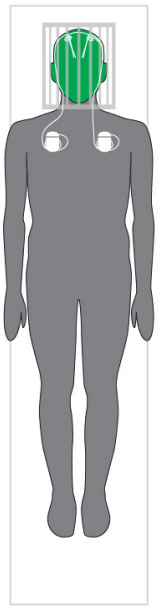
Table 13. Conditions for a Vercise Genus DBS Full System, Vercise Genus DBS Mixed System, Vercise Genus DBS Partially Mixed System, or Vercise Gevia DBS Full System Head Scan Using a Head Transmit Coil

Head Coil



Or

Dual IPG Head Coil



MR Conditional	Yes
Static Magnet Strength	1.5T
Scanner Type	Horizontal field, cylindrical closed-bore 1.5T scanner
Operating Mode	Normal
Maximum Spatial Field Gradient	4000 gauss/cm (40 T/m)
Maximum Gradient Slew Rate	200 T/m/s per axis
MRI Coil Setup	• Head transmit/receive coil (Circular Polarized (CP) Only) • Hydrogen/proton imaging only
Zone Indicated	Head
Maximum B1+rms	2.0 µT
Maximum SAR[22]	• 0.2 W/kg for Vercise Genus DBS Full System, Vercise Genus DBS Mixed System, or Vercise Genus DBS Partially Mixed System • 0.1 W/kg for Vercise Gevia DBS Full System
System Programming	• MRI Mode must be enabled on the Stimulator(s) prior to performing scan.[23] • Rechargeable Stimulators must be fully charged prior to the scan.
Scan Eligible System Components	• For Vercise Genus DBS Full System, see Table 4 on page 6. • For Vercise Genus DBS Mixed System, see Table 5 on page 7. • For Vercise Genus DBS Partially Mixed System, see Table 6 on page 8. • For Vercise Gevia DBS Full System, see Table 7 on page 9.
System Configuration	• For Vercise Genus DBS Full System, see Table 8 on page 10. • For Vercise Genus DBS Mixed System, see Table 9 on page 11. • For Vercise Genus DBS Partially Mixed System, see Table 10 on page 12. • For Vercise Gevia DBS Full System, see Table 11 on page 13.
Exposure Time	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.
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.

Note: *Green colored zones are indicative of scan eligible zones per the scan conditions of Table 13.*

Note: *A Vercise Gevia DBS Full System is not eligible for a configuration with more than one Stimulator implanted.*

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

23 Stimulation is automatically turned OFF when MRI Mode is enabled. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Full System, Mixed System, or Partially Mixed System Scan Using a Body Transmit Coil

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

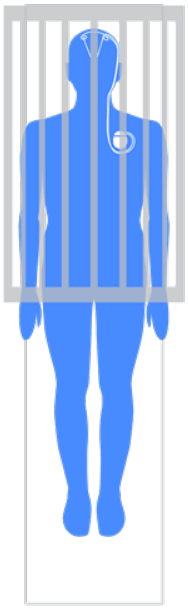
Caution: *Read this manual in its entirety before performing a MRI scan on a patient implanted with any component listed in this manual.*

A patient with this system can be safely scanned in an MR system meeting the conditions outlined in either Table 14 or Table 16.

Vercise Genus DBS Full System, Vercise Genus DBS Mixed System, Vercise Genus DBS Partially Mixed System

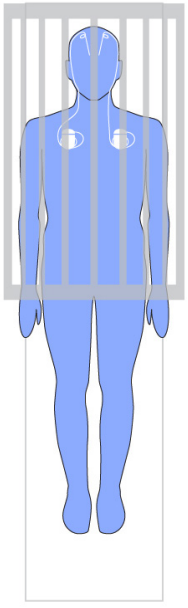
Table 14. Conditions for a Vercise Genus DBS Full System, Vercise Genus DBS Mixed System, or Vercise Genus DBS Partially Mixed System Scan Using a Body Transmit Coil

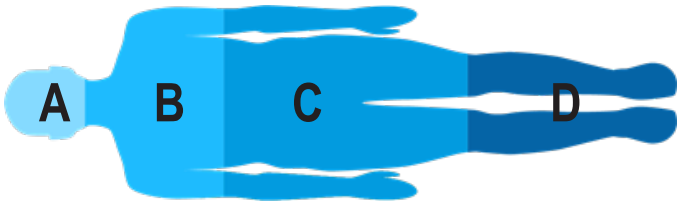
Body Coil



Or

Dual IPG Body Coil



MR Conditional	Yes
Static Magnet Strength	1.5T
Scanner Type	Horizontal field, cylindrical closed-bore 1.5T scanner
Operating Mode	Normal
Maximum Spatial Field Gradient	4000 gauss/cm (40 T/m)
Maximum Gradient Slew Rate	200 T/m/s per axis
MRI Coil Setup	• Body transmit/receive coil (Circular Polarized (CP) Only) • Receive-only coil: Any type (in conjunction with using a body coil as a transmitter in Circular Polarized (CP) Mode) • Hydrogen/proton imaging only
Zone Indicated	Any (Full Body)
Maximum B1+rms Per Zone	

Zone A	Zone B	Zone C	Zone D
Isocenter at or above C2	Isocenter C3 through T10	Isocenter T11 through Femur	**Isocenter Lower Extremities (Knee and Below)**
1.6 µT	2.0 µT	3.2 µT	**Normal Mode**

	Zone A	Zone B	Zone C	Zone D
Maximum SAR Per Zone[24]	0.2 W/kg	See Table 15	1.5 W/kg	**Normal Mode**

System Programming	• MRI Mode must be enabled on the Stimulator(s) prior to performing scan.[25] • Rechargeable Stimulators must be fully charged prior to the scan.
Scan Eligible System Components	• For Vercise Genus DBS Full System, see Table 4 on page 6. • For Vercise Genus DBS Mixed System, see Table 5 on page 7. • For Vercise Genus DBS Partially Mixed System, see Table 6 on page 8.
System Configuration	• For Vercise Genus DBS Full System, see Table 8 on page 10. • For Vercise Genus DBS Mixed System, see Table 9 on page 11. • For Vercise Genus DBS Partially Mixed System, see Table 10 on page 12.
Exposure Time	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.
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.

Note: *Blue colored zones are indicative of scan eligible zones per the scan conditions of Table 14.*

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

25 Stimulation is automatically turned OFF when MRI Mode is enabled. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Table 15. Maximum SAR for Zone B[26]		
Landmark Span	**Large Adult[27]**	**Adult**
Upper Chest	0.2 W/kg	0.2 W/kg
Heart	0.3 W/kg	0.4 W/kg
Lower Chest	0.5 W/kg	0.7 W/kg

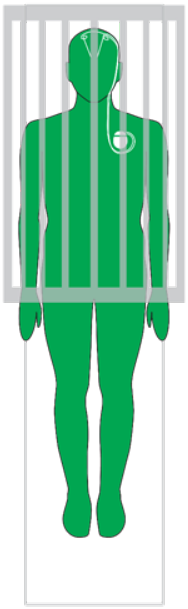
26 Specific Absorption Rate (SAR) – radio frequency power absorbed per unit of mass (W/kg).

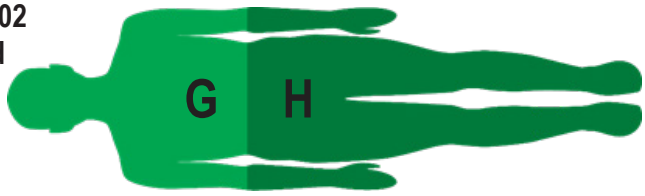
27 A large adult is defined as body mass greater than 119 kg (262 lb) or body mass index (BMI) greater than 36 kg/m^2 (lb/in^2 x 703).

Vercise Gevia DBS Full System

Table 16. Conditions for a Vercise Gevia DBS Full System Scan Using a Body Transmit Coil

Body Coil



MR Conditional	Yes
Static Magnet Strength	1.5T
Scanner Type	Horizontal field, cylindrical closed-bore 1.5T scanner
Operating Mode	Normal
Maximum Spatial Field Gradient	4000 gauss/cm (40 T/m)
Maximum Gradient Slew Rate	200 T/m/s per axis
MRI Coil Setup	• Body transmit/receive coil (Circular Polarized (CP) Only) • Receive-only coil: Any type (in conjunction with using a body coil as a transmitter in Circular Polarized (CP) Mode) • Hydrogen/proton imaging only
Zone Indicated	Any (Full Body)
Maximum B1+rms Per Zone and Lead	**DB-2201 Lead**  **DB-2202 Lead** 

Zone E	Zone F	Zone G	Zone H
Isocenter above T5	Isocenter at T5 or below T5	Isocenter above T12	**Isocenter at T12 or below T12**
1.5 µT	2.0 µT	1.2 µT	**2.0 µT**

Maximum SAR[28]	0.1 W/kg
System Programming	• MRI Mode must be enabled on the Stimulator prior to performing scan.[29] • Stimulator must be fully charged prior to the scan.
Scan Eligible System Components	See Table 7 on page 9.
System Configuration	See Table 11 on page 13.
Exposure Time	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.
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.

Note: *Green colored zones are indicative of scan eligible zones per the scan conditions of Table 16.*

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

29 Stimulation is automatically turned OFF when MRI Mode is enabled. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Full System, Mixed System, or Partially Mixed System Lower Extremity Scan Using a Lower Extremity Transmit Coil

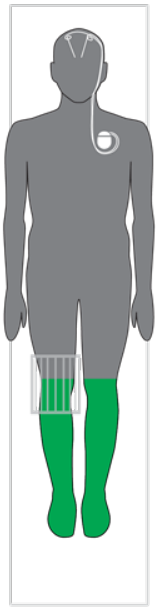
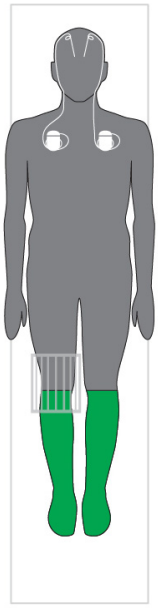
An MRI may be safely performed on a patient implanted with a Full System, Mixed System, or Partially Mixed System that meets the implant and radiology conditions listed in this section. Extremity transmit-only or extremity transmit/receive coils may not be placed directly over the implanted system.

Caution: *Read this manual in its entirety before performing a MRI scan on a patient implanted with any component listed in this manual.*

A patient with this system can be safely scanned in an MR system meeting the conditions outlined in Table 17.

Vercise Genus DBS Full System, Vercise Genus DBS Mixed System, Vercise Genus DBS Partially Mixed System

Table 17. Conditions for a Vercise Genus DBS Full System, Vercise Genus DBS Mixed System, or Vercise Genus DBS Partially Mixed System Lower Extremity Scan Using a Lower Extremity Transmit Coil

Lower Extremity Coil  **Or** **Dual IPG Lower Extremity Coil** 	**MR Conditional**	Yes
	Static Magnet Strength	1.5T
	Scanner Type	Horizontal field, cylindrical closed-bore 1.5T scanner
	Operating Mode	Normal
	Maximum Spatial Field Gradient	4000 gauss/cm (40 T/m)
	Maximum Gradient Slew Rate	200 T/m/s per axis
	MRI Coil Setup	• Lower extremity transmit/receive coil (Circular Polarized (CP) Only) • Hydrogen/proton imaging only
	Zone Indicated	Lower extremities (knee and below)
	Maximum B1+rms	Normal Mode
	Maximum SAR[30]	Normal Mode
	System Programming	• MRI Mode must be enabled on the Stimulator prior to performing scan.[31] • Rechargeable Stimulators must be fully charged prior to the scan.
	Scan Eligible System Components	• For Vercise Genus DBS Full System, see Table 4 on page 6. • For Vercise Genus DBS Mixed System, see Table 5 on page 7. • For Vercise Genus DBS Partially Mixed System, see Table 6 on page 8.
	System Configuration	• For Vercise Genus DBS Full System, see Table 8 on page 10. • For Vercise Genus DBS Mixed System, see Table 9 on page 11. • For Vercise Genus DBS Partially Mixed System, see Table 10 on page 12.
	Exposure Time	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.
	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.

Note: *Green colored zones are indicative of scan eligible zones per the scan conditions of Table 17.*

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

31 Stimulation is automatically turned OFF when MRI Mode is enabled. See the *"MRI Mode on the Remote Control"* section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Post-MRI Examination Review

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.

Post-MRI Examination Review for Full System, Mixed System, or Partially Mixed 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. See the *"MRI Mode on the Remote Control"* 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 stimulation was ON before MRI Mode was enabled, then disabling MRI Mode turns stimulation back ON. If stimulation was OFF before MRI Mode was enabled, then disabling MRI Mode keeps stimulation OFF.*

   Note: *Patients implanted with two Stimulators must disable MRI Mode on each Stimulator.*
3. Instruct the patient to contact the physician managing their DBS System or Boston Scientific if the Stimulator does not turn ON or the Remote Control displays any error messages.

MRI Mode on the Remote Control

MRI Mode must be enabled on the Stimulator using the Patient Remote Control prior to performing an MRI scan on a patient implanted with the Full System, Mixed System, or Partially Mixed System.

- See Table 4 for Vercise Genus DBS Full System scan eligible components.
- See Table 5 for Vercise Genus DBS Mixed System scan eligible components.
- See Table 6 for Vercise Genus DBS Partially Mixed System scan eligible components.
- See Table 7 for Vercise Gevia DBS Full System scan eligible components.

Once the MRI scan is complete, disable MRI Mode. Do not leave the Stimulator in MRI Mode for extended periods of time beyond what is necessary to perform the MRI scan. For patients with configurations that include two Stimulators, ensure MRI Mode is enabled and then disabled on both Stimulators.

The following Systems do not require MRI Mode to be enabled via the Patient Remote Control:

- A Fully Implanted Lead-Only System
- An Externalized Lead-Only System

Enabling MRI Mode

When the Remote Control is linked to an 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 stimulation is automatically turned OFF when MRI Mode is enabled.

Warning: *Do not perform an MRI scan if MRI Mode is not enabled. Scanning under different conditions may result in patient injury or Stimulator malfunction.*

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:

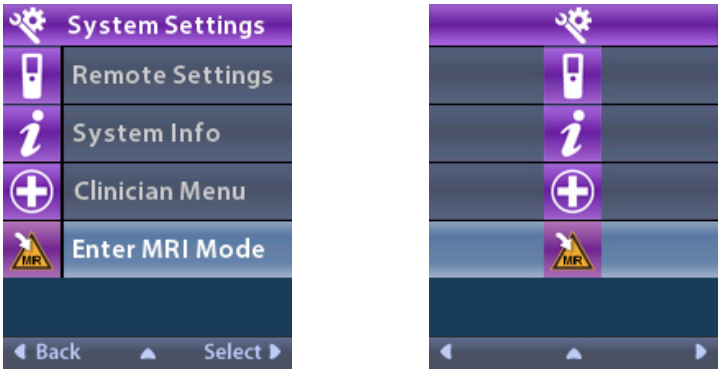
1. Unlock the Remote Control by pressing the **Lock/Unlock** button on the right side of the Remote Control.
2. After unlocking the Remote Control, the **Home** screen appears.

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

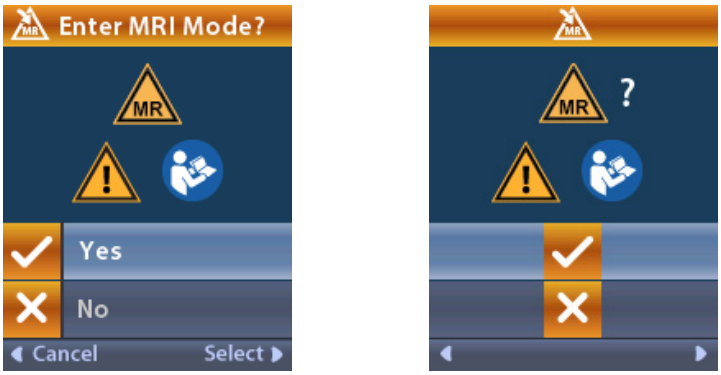
3. Press the **Right Arrow** button to navigate to the **Main Menu.**

4. Select **System Settings**.

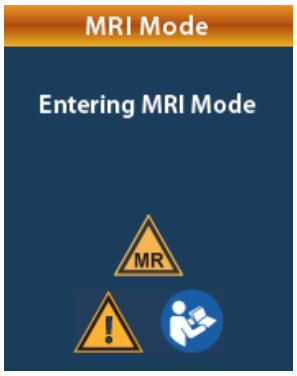
5. Select **Enter MRI Mode**.

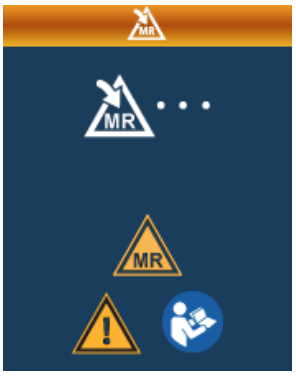


6. Select **Yes** to enter MRI Mode or **No** to cancel the action.

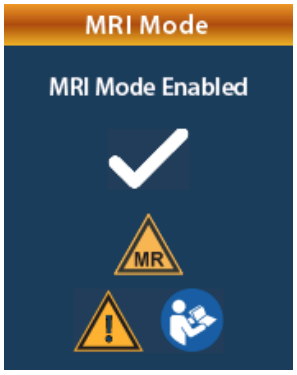


7. The System performs a series of checks before MRI Mode is enabled.

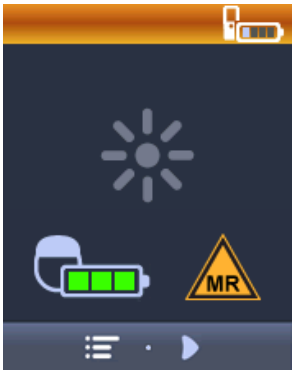




8. If MRI Mode is enabled, stimulation is turned OFF and the **MRI Mode Enabled** confirmation screen is displayed.



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

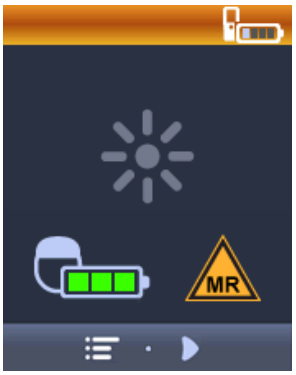


Disabling MRI Mode

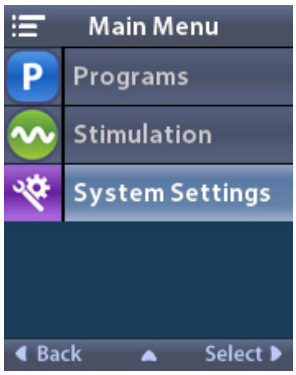
Upon completion of the MRI scan, the Remote Control must be used to disable MRI Mode.

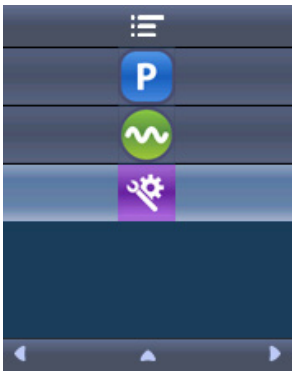
To disable MRI Mode:

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.

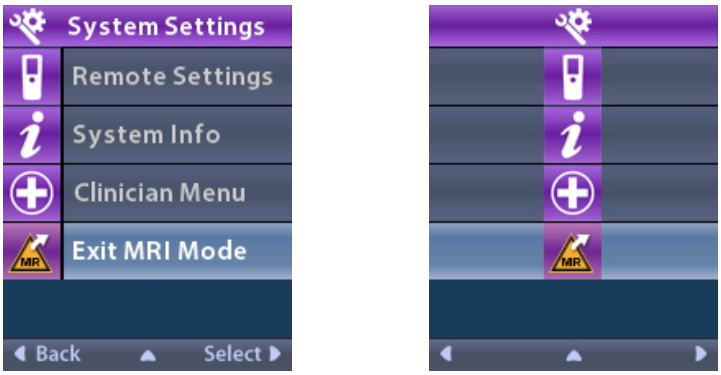


3. Press the **Right Arrow** button to navigate to the **Main Menu.**
4. Select **System Settings**.

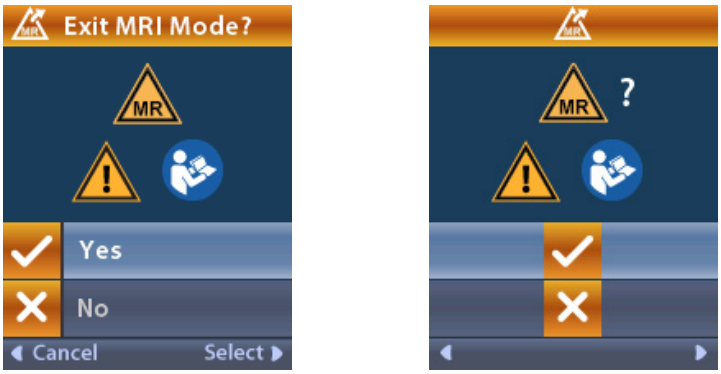




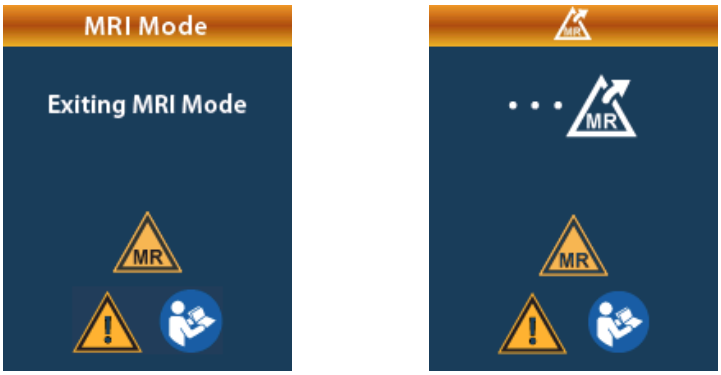
5. Select **Exit MRI Mode**.



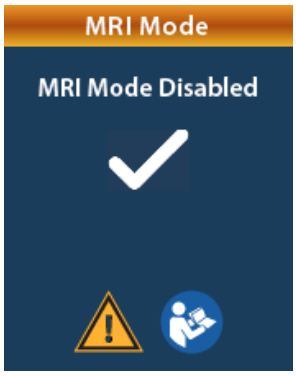
6. Select **Yes** to Exit MRI Mode or **No** to cancel the action.



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

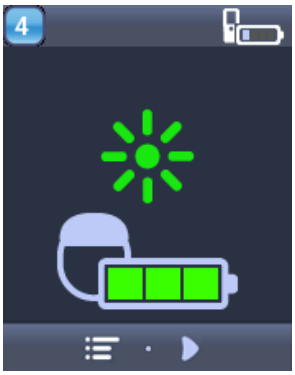


8. If MRI Mode is disabled, the **MRI Mode Disabled** confirmation screen is displayed.



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

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



MRI Mode Error Screens

The System performs a series of checks prior to entering MRI Mode. These checks are performed once  **Enter MRI Mode** is selected from the  **System Settings**. The Remote Control will display error screens if:

- The Stimulator battery is low.
- The Impedance check detects an anomaly.
- There is an error in the Stimulator.

Charge Stimulator Now Screen (Rechargeable Stimulators Only)

The Stimulator battery must be fully charged before 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 (Rechargeable Stimulators Only)

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 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 MRI Mode before charging the Stimulator:

1. Press to disable 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: *The Charger and Remote Control are MR Unsafe and must not be brought into the MRI scanner room.*

Stimulator Battery Low Screen Due to ERI or EOS (Non-Rechargeable Stimulators Only)

A Stimulator that has entered the Elective Replacement Indicator (ERI) or End of Service (EOS) period cannot be placed into MRI Mode. MRI Mode will not be enabled and the Remote Control will display “Cannot enter MRI Mode” and then “Stimulator Battery Low” messages.

Warning: *Do not perform an MRI scan if MRI Mode is not enabled. Scanning under different conditions may result in patient injury or Stimulator malfunction.*

ERI or EOS Screens During MRI Mode (Non-Rechargeable Stimulators Only)

If MRI Mode has already been enabled and the Stimulator battery power falls below the threshold, the Remote Control will display a message informing the patient that the Stimulator has entered the Elective Replacement Indicator (ERI) period or has reached End of Service (EOS) of the Stimulator.

The patient can disable MRI Mode:

1. Press to disable MRI Mode.

2. Check the Remote Control to confirm that the Stimulator battery error message still appears.

Caution: *The Remote Control is MR Unsafe and must not be brought into the MRI scanner room.*

Warning: *Do not perform an MRI scan if MRI Mode is not enabled. Scanning under different conditions may result in patient injury or Stimulator malfunction.*

Impedances Out Of Range Screen

The impedances should be within the acceptable range before MRI Mode is enabled. The system will automatically run an impedance check after MRI Mode is selected. If any impedances are not within the acceptable range, the Remote Control will display an error message.

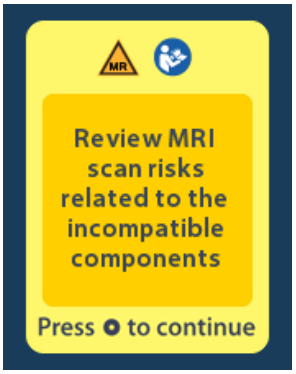
For a Mixed System or Partially Mixed System, the “Impedances out of range” warning is expected (see the note below) and the System is still scan eligible. For a System with a Port Plug in a Port, the “Impedances out of range” warning is expected (see the note below) and the System may be scan eligible. See Table 8, Table 9, Table 10, or Table 11 to confirm that the specific configuration is scan eligible. In these configurations you can run an impedance check on the Remote Control prior to entering MRI Mode to determine the impedances on each Lead Contact and confirm the configuration. See the *“Accessing the Clinician Menu”* section of this manual for instructions on how to check impedances using the Remote Control. You may move forward to place the System in MRI Mode, and the System will be scan eligible if all other scan conditions are met.

Note: *For a Vercise Genus DBS Mixed System or Vercise Genus DBS Partially Mixed System, impedance values for Contacts 5, 6, 7, and 8 of each Stimulator Port will be out of range (high) and the “Impedances out of range” warning will be displayed on the Remote Control. This is to be expected for this configuration because Medtronic Leads have only 4 Contacts.*

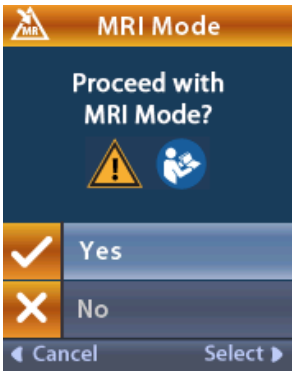
Note: *For a System with a Port Plug in either a Stimulator Port(s) or Lead Extension Port, impedances measured on Contacts within the Port with a Port Plug will be out of range (high). See Table 8, Table 9, Table 10, or Table 11 to confirm that the specific configuration is scan eligible.*

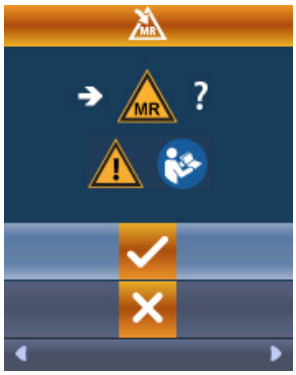
1. Press to continue.

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 to continue.



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

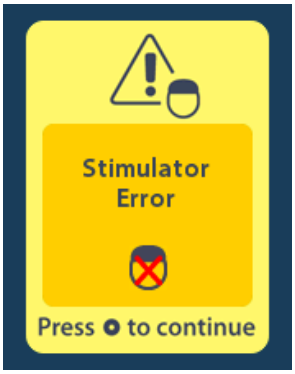




Warning: *An MRI scan is not recommended when the impedances are not within the acceptable range except when scanning a Vercise Genus DBS Mixed System or Vercise Genus DBS Partially Mixed System and Contacts 5, 6, 7, and 8 are out of range. Additionally, an MRI scan is not recommended when the impedances are not within the acceptable range except when scanning a System with a Port Plug in a Stimulator Port(s) or Lead Extension Port and all Contacts in the plugged Port are 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 that are 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. This screen may also be displayed when there is a communication error between the Remote Control and Stimulator. Press to acknowledge the message and retry entering MRI Mode. If this error screen immediately displays again, do not perform an MRI scan and instruct the patient to contact the healthcare provider managing their DBS System or Boston Scientific Technical Support.

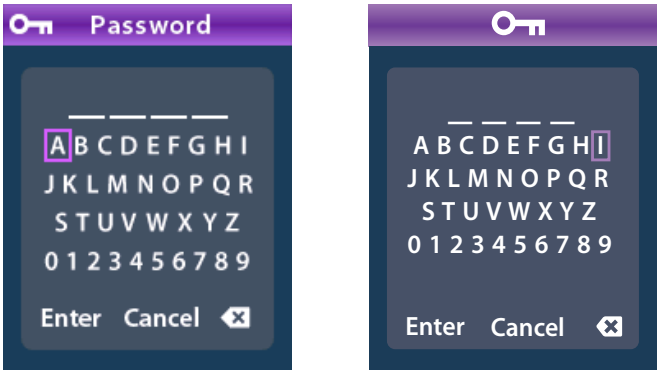


Accessing the Clinician Menu

The **Clinician Menu** allows you to check impedances. To enter the **Clinician Menu** you must enter a password. Contact Boston Scientific Technical Support for the Clinician Password.

From the **System Settings** menu:

1. Select the **Clinician Menu**. The **Password** screen displays.

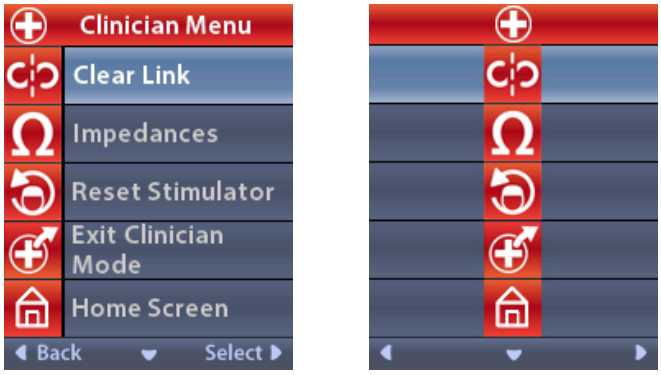


2. Use the **Navigation** buttons to enter your password.

   Or

   Use the **Navigation** buttons to cancel.

If the password is incorrect, the **Invalid Password** screen displays. If the password is correct, the **Clinician Menu** displays.



Note: *If the Remote Control is not linked to a Stimulator, the Stimulator Search option displays on the Clinician Menu instead of the Clear Link option.*

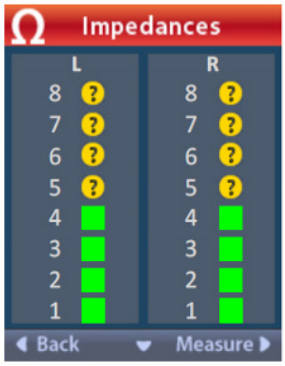
Impedances

You can use the Remote Control to check impedances.

From the **Clinician Menu**:

1. Select **Impedances**. An impedance measurement is taken and the **Impedances** screen is displayed.

   Note: *For a Vercise Genus DBS Mixed System or Vercise Genus DBS Partially Mixed System, Contacts 5 through 8 for each implanted Lead are expected to be out of range due to the fact that Medtronic Leads have 4 Contacts (see figure below).*



When an impedance measurement is taken, impedances are assessed between a Contact and the case (monopolar), and between pairs of Contacts (bipolar). A green square indicates that impedance is within the acceptable range. A yellow dot with a question mark indicates that impedance is outside of the acceptable range (200 Ohms to 8000 Ohms).

Safety Information

Warnings

MRI System: Only use 1.5T Full Body transmit/receive (Circular Polarized (CP) Only), Head transmit/receive (Circular Polarized (CP) Only), or lower extremity transmit/receive (Circular Polarized (CP) 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/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: 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, Stimulator malfunction, 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, discomfort, pain, inadequate stimulation, Stimulator malfunction, 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, edema, 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 MR Conditional evaluation has been performed for patients with a typical body temperature of 37 °C (98.6 °F). 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 (e.g., 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 fully implanted Lead-Only MR Conditional system is comprised of a booted Leads system comprised of Leads, Lead Boots, and Burr Hole Covers listed in Table 2. The risk of explant to create a Leads-Only MR Conditional configuration outlined in this manual should be evaluated by a healthcare 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 mini plate similar to a Stryker 12 mm titanium mini plate with Stryker titanium screws, is used to secure the Boston Scientific DBS Lead(s) 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. Contact the appropriate device manufacturers with questions regarding other systems.

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.

Adjusting for B1+rms/SAR Below Normal Mode[32]

Some pulse sequences may exceed the safety limits for the implanted Boston Scientific DBS System. The below guidelines will enable lower B1+rms/SAR levels to be achieved. If, at any point prior to completing the full workflow, an acceptable B1+rms/SAR level has been achieved, no further parameter adjustments are necessary.

Once a sequence has been optimized for reduced B1+rms, saving the parameters for the sequence locally may be helpful for use with other patients with similar implants.

Note: *Some scanners provide the user with an updated estimate of B1+rms/SAR while the user changes the sequence parameters. If a scanner does not provide this information in real time, one option is to initiate a scan each time after changing a parameter. At the time of a sequence initiation, the scanner should provide the new adjusted B1+rms/SAR level with the chosen parameters.*

Note: *Modifying RF limits below Normal Mode per the suggested adjustments below may limit the availability of some MR procedures.*

- If the scanner provides an 'implant option,' this option can be utilized to input scan conditions.
- If the scanner does not provide an 'implant option,' many pulse sequences under Normal Mode, especially in the gradient Echo family, have low B1+rms/SAR levels without any modifications.
- If the required pulse sequence exceeds the B1+rms/SAR limit for the implanted system, the RF pulse type may be set to 'Low SAR' if this option is available on the scanner. 'Low SAR' is available on most scanners and helps to reduce B1+rms/SAR without affecting image quality.
- If the 'Low SAR' option is unavailable or the B1+rms/SAR levels still exceed the manufacturer limits after setting the RF pulse type to 'Low SAR,' two additional options that can help reduce RF exposure are listed below. These two options are trade-offs and can be exercised together to achieve a good common trade-off.
    - Increasing TR. In some cases, 20%, e.g., from 2500 ms to 3000 ms could be sufficient, but this could be increased by 100% if need be e.g., from 550 ms to 1100 ms.
        - Choose this option when reducing the number of slices is not acceptable.
        - Avoid this option in T1-SE sequences as this impacts contrast.
        - Also avoid this option if longer scan time is not acceptable.
    - Reducing number of slices.
- If B1+rms/SAR levels still exceed the limit for the implanted system, reducing RF can still be achieved with:
    - Reducing flip-angle (alpha), reducing refocusing flip angle, or using fewer RF saturation bands.
    - Reducing number of echoes (echo train length/ turbo factor/ shot factor).

32 References

McRobbie, et al. "MRI from Picture to Proton." 2007. Cambridge university press.

Faulkner W.. "New MRI Safety Labels & Devices, B1+rms as a Condition of Use." SMRT Signals, Feb 2016 V5, Nol. https://www.ismrm.org/smrt/E-Signals/2016FEBRUARY/eSig_5_1_hot_2.htm

Franceschi A.M. et al. "Optimized, Minimal Specific Absorption Rate MRI for High-Resolution Imaging in Patients with Implanted Deep Brain Stimulation Electrodes." AJNR Am J Neuroradio1. 2016 Nov; 37(11): 1996-2000.

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

Fully Implanted Lead-Only System	☐
Externalized Lead-Only System	☐
Vercise Genus DBS Full System	☐
Vercise Genus DBS Mixed System	☐
Vercise Genus DBS Partially Mixed System	☐
Vercise Gevia DBS Full System	☐

B. MR Conditional System Components

Component	**Model Number(s)**	**Eligible for MR Conditional Scan**					
		Fully Implanted Lead-Only System	**Externalized Lead-Only System**	**Vercise Genus DBS Full System**	**Vercise Genus DBS Mixed System**	**Vercise Genus DBS Partially Mixed System**	**Vercise Gevia DBS Full System**
Leads: Standard Leads - DB-2201							
30 cm Lead	DB-2201-30-AC	☐	☐	☐	N/A	☐	☐
	DB-2201-30-DC	☐	☐	☐	N/A	☐	☐
45 cm Lead	DB-2201-45-BC	☐	☐	☐	N/A	☐	☐
	DB-2201-45-DC	☐	☐	☐	N/A	☐	☐
Leads: Directional Leads - DB-2202							
Vercise™ Cartesia™ 30 cm 8 Contact DBS Directional Lead	DB-2202-30	☐	☐	☐	N/A	☐	☐
Vercise™ Cartesia™ 45 cm 8 Contact DBS Directional Lead	DB-2202-45	☐	☐	☐	N/A	☐	☐

Component	Model Number(s)	Eligible for MR Conditional Scan					
		Fully Implanted Lead-Only System	Externalized Lead-Only System	Vercise Genus DBS Full System	Vercise Genus DBS Mixed System	Vercise Genus DBS Partially Mixed System	Vercise Gevia DBS Full System
Leads: Medtronic Leads							
Medtronic 28cm 1.5mm Spaced 4 Contact Standard Lead	3387-28	N/A	N/A	N/A	☐	☐	N/A
	3387S-28	N/A	N/A	N/A	☐	☐	N/A
Medtronic 40cm 1.5mm Spaced 4 Contact Standard Lead	3387-40	N/A	N/A	N/A	☐	☐	N/A
	3387S-40	N/A	N/A	N/A	☐	☐	N/A
Medtronic 28cm 0.5mm Spaced 4 Contact Standard Lead	3389-28	N/A	N/A	N/A	☐	☐	N/A
	3389S-28	N/A	N/A	N/A	☐	☐	N/A
Medtronic 40cm 0.5mm Spaced 4 Contact Standard Lead	3389-40	N/A	N/A	N/A	☐	☐	N/A
	3389S-40	N/A	N/A	N/A	☐	☐	N/A
Lead Extensions							
55 cm 8 Contact Lead Extension	NM-3138-55	N/A	N/A	☐	N/A	☐	☐
55 cm 2x8 Contact Lead Extension	DB-3128-55B	N/A	N/A	☐	N/A	☐	N/A
95 cm 2x8 Contact Lead Extension	DB-3128-95B	N/A	N/A	☐	N/A	☐	N/A
Medtronic Lead Extensions							
Medtronic 40cm Lead Extension	37085-40	N/A	N/A	N/A	☐	☐	N/A
Medtronic 60cm Lead Extension	37085-60	N/A	N/A	N/A	☐	☐	N/A
Medtronic 95cm Lead Extension	37085-95	N/A	N/A	N/A	☐	☐	N/A
Medtronic 40cm Lead Extension	37086-40	N/A	N/A	N/A	☐	☐	N/A
Medtronic 60cm Lead Extension	37086-60	N/A	N/A	N/A	☐	☐	N/A

Component	Model Number(s)	Eligible for MR Conditional Scan					
		Fully Implanted Lead-Only System	Externalized Lead-Only System	Vercise Genus DBS Full System	Vercise Genus DBS Mixed System	Vercise Genus DBS Partially Mixed System	Vercise Gevia DBS Full System
Medtronic 95cm Lead Extension	37086-95	N/A	N/A	N/A	☐	☐	N/A
Adapters							
Vercise™ M8 Adapter, 15cm	DB-9218-15	N/A	N/A	N/A	☐	☐	N/A
Vercise™ M8 Adapter, 55cm	DB-9218-55	N/A	N/A	N/A	☐	☐	N/A
Stimulators							
Vercise Gevia™ 16 Contact Implantable Pulse Generator	DB-1200-S	N/A	N/A	N/A	N/A	N/A	☐
Vercise Genus™ P8 Implantable Pulse Generator	DB-1408	N/A	N/A	☐	☐	☐	N/A
Vercise Genus™ P16 Implantable Pulse Generator	DB-1416	N/A	N/A	☐	☐	☐	N/A
Vercise Genus™ P32 Implantable Pulse Generator	DB-1432	N/A	N/A	☐	☐	☐	N/A
Vercise Genus™ R16 Implantable Pulse Generator	DB-1216	N/A	N/A	☐	☐	☐	N/A
Vercise Genus™ R32 Implantable Pulse Generator	DB-1232	N/A	N/A	☐	☐	☐	N/A
Fixation and Accessories							
SureTek™ Burr Hole Cover	Provided in Burr Hole Cover, DB-4600-C, and Burr Hole Cover Spares Kit, DB-4605-C.	☐	☐	☐	N/A	☐	☐
Medtronic Stimloc Burr Hole Cover	924256	N/A	N/A	N/A	☐	☐	N/A

Component	Model Number(s)	Eligible for MR Conditional Scan					
		Fully Implanted Lead-Only System	Externalized Lead-Only System	Vercise Genus DBS Full System	Vercise Genus DBS Mixed System	Vercise Genus DBS Partially Mixed System	Vercise Gevia DBS Full System
Lead Boot	Provided in Vercise™ Physician's Spare Kit, DB-2500-C, and with DBS Leads (see above).	☐	N/A	N/A	N/A	N/A	N/A
Silicone Suture Sleeves	Provided in Vercise™ Physician's Spare Kit, DB-2500-C, and with DBS Leads (see above).	☐	☐	☐	N/A	☐	☐
Port Plugs	Provided in Port Plug Spares Kit, SC-4401, and IPG Kit, DB-1200-S.	N/A	N/A	N/A	N/A	N/A	☐
Port Plugs	Provided in Port Plug Spares Kit, SC-4401, IPG Kits, DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, and Lead Extension Kits, DB-3128-55B, DB-3128-95B.	N/A	N/A	☐	☐	☐	N/A
Other (List other implanted components) ***Note:*** *If the patient has medical implants from another manufacturer, also consult the instructions from the manufacturer before making a decision about MRI eligibility*							
		☐	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐	☐

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

Fully Implanted Lead-Only System

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(s) fully implanted under the scalp on the skull.	☐	Lead(s) NOT fully implanted under the scalp on the skull.
☐	Patient has up to two Leads implanted.	☐	Patient has more than two Leads implanted.
☐	NO evidence of fractured Leads.	☐	Evidence of fractured Leads.

Externalized Lead-Only System

MRI Eligible		Not MRI Eligible	
☐	Stimulator NOT implanted.	☐	Stimulator implanted.
☐	Lead Extensions NOT implanted.	☐	Lead Extensions implanted.
☐	Partially implanted Lead(s) extending out of the patient are straight with no loops.	☐	Partially implanted Lead(s) extending out of the patient are NOT straight or HAVE loops.
☐	The external portion of the partially implanted Lead(s) is NOT in contact with either the patient or any part of the scanner.	☐	The external portion of the partially implanted Lead(s) is in contact with either the patient or any part of the scanner.
☐	Patient has up to two Leads implanted.	☐	Patient has more than two Leads implanted.
☐	NO evidence of fractured Leads.	☐	Evidence of fractured Leads.

Vercise Genus DBS Full System, Vercise Genus DBS Mixed System, or Vercise Genus DBS Partially Mixed System

MRI Eligible		Not MRI Eligible	
☐	The Stimulator(s) must be implanted under the skin in a location near the clavicle (pectoral region) or in the abdomen.	☐	The Stimulator(s) is NOT implanted near the clavicle (pectoral region) NOR implanted in the abdomen.
☐	Patient has up to two Leads implanted.	☐	Patient has more than two Leads implanted.
☐	The Stimulator(s) must be implanted on the same side of the body as the implanted Lead Extension(s) and, if applicable, Adapter(s) to which it is connected.	☐	The Stimulator(s) is NOT implanted on the same side of the body as the implanted Lead Extension(s) and, if applicable, Adapter(s) to which it is connected.
☐	For a Vercise Genus DBS Full System bilateral implant where two Leads and Lead Extensions are connected to a single Stimulator, both Lead Extensions are routed on the same side of the body as the Stimulator.	☐	For a Vercise Genus DBS Full System bilateral implant where two Leads and Lead Extensions are connected to a single Stimulator, both Lead Extensions are NOT routed on the same side of the body as the Stimulator.
☐	For a Vercise Genus DBS Mixed System bilateral implant where two Leads, Lead Extensions, and Adapters are connected to a single Stimulator, both Lead Extensions and Adapters are routed on the same side of the body as the Stimulator.	☐	For a Vercise Genus DBS Mixed System bilateral implant where two Leads, Lead Extensions, and Adapters are connected to a single Stimulator, both Lead Extensions and Adapters are NOT routed on the same side of the body as the Stimulator.
☐	For the Vercise Genus DBS Full System, Lead Extension(s) must be connected directly to the Stimulator. Adapters should not be used.	☐	For the Vercise Genus DBS Full System, Lead Extension is NOT connected directly to Stimulator. Adapter is present.
☐	For the Vercise Genus DBS Mixed System or the Vercise Genus DBS Partially Mixed System, M8 Adapter(s) must be connected directly to Medtronic Lead Extension(s).	☐	For the Vercise Genus DBS Mixed System or the Vercise Genus DBS Partially Mixed System, M8 Adapter(s) is NOT connected directly to Medtronic Lead Extension(s).
☐	Unused Stimulator Ports have a Port Plug inserted.	☐	Unused Stimulator Ports do NOT have a Port Plug inserted.
☐	A Vercise Genus DBS Full System with a single Lead and a single unused Lead Extension Port HAS a Port Plug inserted into the unused Lead Extension Port.	☐	A Vercise Genus DBS Full System with a single Lead and a single unused Lead Extension Port does NOT have a Port Plug inserted into the unused Lead Extension Port.
☐	For the Vercise Genus DBS Mixed System or the Vercise Genus DBS Partially Mixed System, Medtronic Lead Extension(s) has a Lead inserted (does NOT have a Port Plug inserted).	☐	For the Vercise Genus DBS Mixed System or the Vercise Genus DBS Partially Mixed System, Medtronic Lead Extension(s) does NOT have a Lead inserted (is unused or has a Port Plug inserted).
☐	A Vercise Genus DBS Partially Mixed System with an unused Boston Scientific Lead Extension Port HAS a Boston Scientific Port Plug inserted into the unused Boston Scientific Lead Extension Port.	☐	A Vercise Genus DBS Partially Mixed System with an unused Boston Scientific Lead Extension Port does NOT have a Boston Scientific Port Plug inserted into the unused Boston Scientific Lead Extension Port.
☐	For the Vercise Genus DBS Mixed System or the Vercise Genus DBS Partially Mixed System, the Lead Extension and M8 Adapter length combinations do NOT include both a 95cm Medtronic Lead Extension (37085-95 or 37086-95) and a 55cm M8 Adapter (DB-9218-55).	☐	For the Vercise Genus DBS Mixed System or the Vercise Genus DBS Partially Mixed System, the Lead Extension and M8 Adapter length combinations include both a 95cm Medtronic Lead Extension (37085-95 or 37086-95) and a 55cm M8 Adapter (DB-9218-55).
☐	No Evidence of fractured or abandoned Leads or compromised Stimulator-Lead system integrity.	☐	Evidence of fractured or abandoned Leads or compromised Stimulator-Lead system integrity.

MRI Eligible		Not MRI Eligible	
☐	For the Vercise Genus DBS Full System or the Vercise Genus DBS Mixed System, up to two Stimulators are implanted.	☐	For the Vercise Genus DBS Full System or the Vercise Genus DBS Mixed System, more than two Stimulators are implanted.
☐	For the Vercise Genus DBS Partially Mixed System, two Stimulators are implanted (one on each side of the body).	☐	For the Vercise Genus DBS Partially Mixed System, two Stimulators are NOT implanted (one on each side of the body).
☐	If two Stimulators are implanted, a single Stimulator, Lead, Lead Extension, and, if applicable, Adapter is implanted on each side of the body.	☐	If two Stimulators are implanted, more than one Stimulator, Lead, Lead Extension, or Adapter is implanted on each side of the body.
☐	If two Stimulators are implanted, Lead Extension(s) DB-3128-55B or DB-3128-95B is NOT implanted.	☐	If two Stimulators are implanted, Lead Extension(s) DB-3128-55B or DB-3128-95B is implanted.

Vercise Gevia DBS Full System

MRI Eligible		Not MRI Eligible	
☐	The Stimulator must be implanted under the skin in a location near the clavicle (pectoral region).	☐	The Stimulator is NOT implanted near the clavicle (pectoral region).
☐	The Stimulator must be implanted on the same side of the body as the implanted Lead Extension(s).	☐	The Stimulator is NOT implanted on the same side of the body as the implanted Lead Extension(s).
☐	Patient has up to two Leads implanted.	☐	Patient has more than two Leads implanted.
☐	For a bilateral implant where two Leads and Lead Extensions are connected to a single Stimulator, both Lead Extensions are routed on the same side of the body as the Stimulator.	☐	For a bilateral implant where two Leads and Lead Extensions are connected to a single Stimulator, both Lead Extensions are NOT routed on the same side of the body as the Stimulator.
☐	Lead Extensions directly connected to Stimulator. No adapters present.	☐	Lead Extension NOT directly connected to Stimulator. Adapter is present.
☐	Unused Stimulator Ports have a Port Plug inserted.	☐	Unused Stimulator Ports do NOT have a Port Plug inserted.
☐	The 8 Contact Lead Extension, NM-3138-55, has a Lead inserted (does NOT have a Port Plug inserted).	☐	The 8 Contact Lead Extension, NM-3138-55, does NOT have a Lead inserted (HAS a Port Plug inserted).
☐	No Evidence of fractured or abandoned Leads or compromised Stimulator-Lead system integrity.	☐	Evidence of fractured or abandoned Leads or compromised Stimulator-Lead system integrity.
☐	Single Stimulator is implanted.	☐	More than one Stimulator is implanted.
☐	When Vercise Gevia DBS System is implanted, DB-2201 or DB-2202 Leads with NM-3138-55 Lead Extensions are implanted.	☐	When Vercise Gevia DBS System is implanted with a Lead Extension other than NM-3138-55 Lead Extension.

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

Advise the patient to bring the following to all MRI appointments:

- Remote Control
- Charger (if implanted with a rechargeable IPG)
- Their most up to date Patient ID Card

In addition, the following are required:

- The rechargeable Stimulator must be fully charged (Stimulator battery level on the Remote Control must be at three bars) before the MRI scan.
- MRI Mode must be enabled on the Stimulator using the patient's Remote Control before performing an MRI scan.

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

Appendix B: Pre-MRI Scan Condition Checklist

Lead-Only System Eligibility

Table 18. Lead-Only Conditions and Methods to Determine Eligibility

Condition for Scanning	Suggested Methods to Determine Eligibility
The patient is implanted with a fully implanted or externalized Leads-Only configuration whose components are listed in Table 2. ***Note:*** *This step does not need to be completed if the MRI Patient Eligibility Form (Appendix A) is already complete.*	☐ Check patient records and ensure that the model numbers of the implanted components match the model numbers listed in Table 2 of this manual. OR ☐ 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 2 of this manual.
The patient's DBS System meets the Lead-Only System configuration requirements listed in Table 3. ***Note:*** *This step does not need to be completed if the MRI Patient Eligibility Form (Appendix A) is already complete.*	☐ Check patient records and ensure that the system configuration meets the requirements listed Table 3 of this manual. OR ☐ Confirm with the physician responsible for implanting the patient's DBS System and ensure the system configuration meets the requirements listed in Table 3 of this manual.
MRI systems that meet the following criteria: • MRI magnet strength of 1.5 Tesla (T) only, in a horizontal closed bore system (no open-sided, vertical-field, standing). 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.
MRI coil setup: • 1.5T Transmit coil: ○ Full body transmit/receive (Circular Polarized (CP) Only). ○ Head transmit/receive (Circular Polarized (CP) Only). • Receive-only coil: Any type (in conjunction with using a body coil as a transmitter in Circular Polarized (CP) Mode). • Hydrogen/proton imaging only.	☐ Check the technical specifications of the MRI head coil and/or body coil.
If using either full body or head transmit/receive coil (Circular Polarized (CP) Only) and patient is implanted with either DB-2201 or DB-2202 Leads, scan sequence throughout the scan must have B1+rms less than or equal to (≤) 2.0 µT. The SAR[33] value must be less than or equal to (≤) 0.1 W/kg.	☐ Ensure the MRI Scanner is operated at or below (≤) B1+rms of 2.0 µT throughout the scan. ☐ Ensure the MRI scanner is operated at or below (≤) whole body and head SAR of 0.1 W/kg.
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.
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.

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

Table 18. Lead-Only Conditions and Methods to Determine Eligibility	
Condition for Scanning	**Suggested Methods to Determine Eligibility**
If possible, 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. If possible, verify that the patient is feeling normal and is responsive during and between each MRI scan. Discontinue the MRI immediately if the patient experiences any adverse events listed under *"Potential Interactions with MRI Environment"* in the *"Safety Information"* section of this manual, or if an awake patient becomes unresponsive to questions.

Full System, Mixed System, or Partially Mixed System Eligibility

Table 19. Full System, Mixed System, or Partially Mixed System Conditions and Methods to Determine Eligibility

Condition for Scanning	Suggested Methods to Determine Eligibility
The patient is implanted with the DBS System comprised of components listed in: • Table 4 for Vercise Genus DBS Full System • Table 5 for Vercise Genus DBS Mixed System • Table 6 for Vercise Genus DBS Partially Mixed System or • Table 7 for Vercise Gevia DBS Full System. ***Note:*** *This step does not need to be completed if the MRI Patient Eligibility Form (Appendix A) is already complete.*	☐ Check Patient ID Card or patient records and ensure that the model numbers of the implanted components match the model numbers listed in Table 4 for Vercise Genus DBS Full System, Table 5 for Vercise Genus DBS Mixed System, Table 6 for Vercise Genus DBS Partially Mixed System, or Table 7 for Vercise Gevia DBS Full System. OR ☐ 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 4 for Vercise Genus DBS Full System, Table 5 for Vercise Genus DBS Mixed System, Table 6 for Vercise Genus DBS Partially Mixed System, or Table 7 for Vercise Gevia DBS Full System.
The patient's DBS System meets the System configuration requirements listed in: • Table 8 for Vercise Genus DBS Full System • Table 9 for Vercise Genus DBS Mixed System • Table 10 for Vercise Genus DBS Partially Mixed System or • Table 11 for Vercise Gevia DBS Full System. ***Note:*** *This step does not need to be completed if the MRI Patient Eligibility Form (Appendix A) is already complete.*	☐ Check Patient ID Card or patient records and ensure that the system configuration meets the requirements listed in Table 8 for Vercise Genus DBS Full System, Table 9 for Vercise Genus DBS Mixed System, Table 10 for Vercise Genus DBS Partially Mixed System, or Table 11 for Vercise Gevia DBS Full System. OR ☐ Confirm with the physician responsible for implanting the patient's DBS System and ensure the system configuration meets the requirements listed in Table 8 for Vercise Genus DBS Full System, Table 9 for Vercise Genus DBS Mixed System, Table 10 for Vercise Genus DBS Partially Mixed System, or Table 11 for Vercise Gevia DBS Full System.
Rechargeable 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.*	☐ Ensure that three bars  are displayed for the Stimulator battery status on the **Home** screen of the patient's Remote Control.
MRI Mode is enabled on the Stimulator. ***Note:*** *Stimulation is automatically turned OFF when MRI Mode is enabled. See the "MRI Mode on the Remote Control" section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.*	☐ Ensure that the Home screen of the Patient Remote Control displays the MR Conditional symbol  with the Stimulation turned OFF. 

Table 19. Full System, Mixed System, or Partially Mixed System Conditions and Methods to Determine Eligibility

Condition for Scanning	Suggested Methods to Determine Eligibility
MRI systems that meet the following criteria: • MRI magnet strength of 1.5 Tesla (T) only, in a horizontal closed bore system (no open-sided, vertical-field, standing). 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.
MRI coil setup: • 1.5T Transmit coil: ○ Full body transmit/receive (Circular Polarized (CP) Only). ○ Head transmit/receive (Circular Polarized (CP) Only). ○ Lower extremity transmit/receive (Circular Polarized (CP) Only). • Receive-only coil: Any type (in conjunction with using a body coil as a transmitter in Circular Polarized (CP) Mode). • Hydrogen/proton imaging only.	☐ Check the technical specifications of the MRI head coil, body coil, and/or lower extremity coil.
Scan sequences must not exceed RF exposure limits (B1+rms/SAR).	☐ Check anatomical location of the isocenter. ☐ Determine implanted components by checking Patient ID Card or patient record. ***Note:*** *RF exposure limits and compatible components differ for Full System scans when patients are implanted with the Vercise Gevia Stimulator. When the Vercise Gevia Stimulator is implanted, only configurations using DB-2201 or DB-2202 Lead(s) with NM-3138-55 Lead Extension are scan-eligible.* ☐ Determine the coil type: ☐ Head transmit/receive (Circular Polarized (CP) Only) OR ☐ Body transmit/receive coil (Circular Polarized (CP) Only) OR ☐ Lower extremity transmit/receive coil (Circular Polarized (CP) Only) ☐ Ensure MRI Scanner is operated at or below (≤) appropriate RF exposure limits (B1+rms/SAR) based on isocenter, implanted components, and coil type (see Table 13, Table 14, Table 16, and Table 17).
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.
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.
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 or experiences any adverse events listed under *"Potential Interactions with MRI Environment"* in the *"Safety Information"* section of this manual.

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

MRI Safety Information

- Static magnetic field of 1.5T
- 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 (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.

RF Exposure Limits

System Components	System Type	Isocenter	Transmit Coil Type	B1+rms	SAR[34]
All Leads	Fully Implanted or Externalized Leads-Only	Head	Head or Body Coil	≤ 2.0 µT	≤ 0.1 W/kg
Vercise Genus DBS System (Stimulator Model Numbers: DB-1408, DB-1416, DB-1432, DB-1216, and DB-1232)	Full System, Mixed System, or Partially Mixed System	Head	Head Coil	≤ 2.0 µT	≤ 0.2 W/kg
		At or Above C2	Body Coil	≤ 1.6 µT	≤ 0.2 W/kg
		C3 through T10		≤ 2.0 µT	See Table 20
		T11 through Femur		≤ 3.2 µT	≤ 1.5 W/kg
		Lower Extremities (knee and below)		Normal Mode	Normal Mode
		Lower Extremities (knee and below)	Lower Extremity Coil	Normal Mode	Normal Mode
Vercise Gevia DBS System (Stimulator Model Number: DB-1200-S)	Full System with DB-2201 or DB-2202 Lead(s)	Head	Head Coil	≤ 2.0 µT	≤ 0.1 W/kg
	Full System with DB-2201 Lead(s)	Above T5	Body Coil	≤ 1.5 µT	
		At or Below T5		≤ 2.0 µT	
	Full System with DB-2202 Lead(s)	Above T12		≤ 1.2 µT	
		At or Below T12		≤ 2.0 µT	

Additional Information

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

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

Table 20. Maximum SAR for Zone B[35]		
Landmark Span	**Large Adult[36]**	**Adult**
Upper Chest	0.2 W/kg	0.2 W/kg
Heart	0.3 W/kg	0.4 W/kg
Lower Chest	0.5 W/kg	0.7 W/kg

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

36 A large adult is defined as body mass greater than 119 kg (262 lb) or body mass index (BMI) greater than 36 kg/m^2 (lb/in^2 x 703).

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