



ImageReady™
MRI Guidelines
for Boston Scientific
Deep Brain Stimulation
Systems

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*. Advise the patient that additional information may be available to them on the Boston Scientific website www.bostonscientific.com/patientlabeling.

Note: *Throughout this manual, the Vercise™ DBS Controller may be referred to as the Controller App.*

Note: *Users of the Remote Control are instructed to “enable” or “disable” MRI Mode. Users of the mobile device with the Controller App are instructed to “enter” or “exit” MRI Mode. When applied throughout this manual, these terms are considered equivalent.*

Note: *Images of the Remote Control or Controller App 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.

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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. To contact Boston Scientific for any other reason, use the contact information provided for your locality via www.bostonscientific.com, 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 or mobile device with the Controller App
- Charger (if implanted with a rechargeable IPG)
- Their most up-to-date Patient Implant Card

The Remote Control or Controller App should be used to place the DBS System into MRI Mode prior to a scan; see the “*Enable MRI Mode on the Remote Control*” or the “*Enter MRI Mode on the Controller App*” 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 Implant 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.

Warning: *The Charger, Remote Control, and mobile device used with the Controller App 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 M8 System¹
 - A Vercise Genus DBS Mixed M8 System is comprised of at least one Medtronic Lead, Medtronic Lead Extension, Boston Scientific Vercise Adapter M8, any Boston Scientific Vercise Genus DBS Stimulator(s), and at least one Medtronic Stimloc™ Burr Hole Cover(s), (see Table 5 for scan eligible components and Table 9 for full configuration details). The Vercise Genus DBS Stimulators are an MR Conditional family of Stimulators.
- Vercise Genus DBS Mixed S8 System¹
 - A Vercise Genus DBS Mixed S8 System is comprised of at least one Abbott Lead, Abbott Lead Extension, Boston Scientific Vercise Adapter S8, any Boston Scientific Vercise Genus DBS Stimulator(s), and at least one Abbott Guardian™ Burr Hole Cover(s) (see Table 6 for scan eligible components and Table 10 for full configuration details). 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.*

¹ A patient with Vercise Adapter M8 and Vercise Adapter S8 implanted is considered to have a Vercise Genus DBS Mixed S8 System. For patients with Vercise Adapter M8 and Vercise Adapter S8 implanted, see information pertaining to the Vercise Genus DBS Mixed S8 System.

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 M8 System, or Mixed S8 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^{2, 3, 4})	Implant Conditions Reference Section	Scan Conditions Reference Section
All Leads	Fully Implanted or Externalized Leads-Only	Any (Full Body)	Head or Body Coil	<ul style="list-style-type: none"> See Table 2 on page 4 for scan eligible components. See Table 3 on page 5 for system configuration. 	<ul style="list-style-type: none"> See Table 12 on page 17 for scan conditions.
Vercise Genus DBS System (Stimulator Model Numbers: DB-1408, DB-1416, DB-1432, DB-1216, and DB-1232)	Full System, Mixed M8 System, or Mixed S8 System	Head	Head Coil	<ul style="list-style-type: none"> 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 M8 System scan eligible components. See Table 6 on page 8 for Vercise Genus DBS Mixed S8 System scan eligible components. See Table 8 on page 11 for Vercise Genus DBS Full System configuration. See Table 9 on page 12 for Vercise Genus DBS Mixed M8 System configuration. See Table 10 on page 13 for Vercise Genus DBS Mixed S8 System configuration. 	<ul style="list-style-type: none"> See Table 13 on page 19 for scan conditions.
		At or Above C2	Body Coil		<ul style="list-style-type: none"> See Table 14 on page 21 for Full System or Mixed M8 System scan conditions. See Table 16 on page 23 for Mixed S8 System scan conditions.
		C3 through T10			
		T11 through Femur			
		Lower Extremities (knee and below)	Lower Extremity Coil		<ul style="list-style-type: none"> See Table 19 on page 27 for scan conditions.
Lower Extremities (knee and below)					
Vercise Gevia DBS System (Stimulator Model Number: DB-1200-S)	Full System with DB-2201 or DB-2202 Lead(s)	Head	Head Coil	<ul style="list-style-type: none"> See Table 7 on page 10 for scan eligible components. See Table 11 on page 15 for system configuration. 	<ul style="list-style-type: none"> See Table 13 on page 19 for scan conditions.
		Above T5	Body Coil		
	At or Below T5				
	Above T12				
Full System with DB-2202 Lead(s)	At or Below T12				

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

- 2 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).
- 3 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).
- 4 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)	<ul style="list-style-type: none"> • DB-2201-30AC, Lead, 8 Contact, 30cm • DB-2201-30DC, Lead, 8 Contact, 30cm • DB-2201-45BC, Lead, 8 Contact, 45cm • DB-2201-45DC, Lead, 8 Contact, 45cm • DB-2202-30, Vercise™ Cartesia™ Directional Lead, 8 Contact, 30cm • DB-2202-45, Vercise™ Cartesia™ Directional Lead, 8 Contact, 45cm • DB-2203-30, Vercise™ Cartesia™ X Directional Lead, 16 Contact (5x3+1), 30cm • DB-2203-45, Vercise™ Cartesia™ X Directional Lead, 16 Contact (5x3+1), 45cm • DB-2204-30, Vercise™ Cartesia™ HX Directional Lead, 16 Contact (4x3+4), 30cm • DB-2204-45, Vercise™ Cartesia™ HX Directional Lead, 16 Contact (4x3+4), 45cm
Lead Extension(s)	None
Stimulator	None
Accessories	<ul style="list-style-type: none"> • Lead Boot(s) (not required if Leads are externalized) <ul style="list-style-type: none"> ○ Provided in the Vercise™ Physician's Spare Kit 8 Contact Lead, DB-2500-C, Vercise™ Physician's Spare Kit 16 Contact Lead, DB-2501, and with DBS Leads • SureTek Burr Hole Cover(s) (optional if using alternative method of securing Leads⁵) <ul style="list-style-type: none"> ○ Provided in SureTek™ Burr Hole Cover Kit, DB-4600-C, and SureTek™ Burr Hole Cover Spares Kit, DB-4605-C • Suture Sleeve(s) (optional) <ul style="list-style-type: none"> ○ Provided in the Vercise™ Physician's Spare Kit 8 Contact Lead, DB-2500-C, Vercise™ Physician's Spare Kit 16 Contact Lead, DB-2501, and with DBS Leads

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.

System Configuration

Table 3. Lead-Only System Configuration

Lead(s)-Only, Fully Implanted Configuration	<ul style="list-style-type: none"> • 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 Leads⁶ (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.⁷ • 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	<ul style="list-style-type: none"> • 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.

⁶ 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.

⁷ 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 M8 System, or Mixed S8 System

Vercise Genus DBS Full System Scan Eligible Components

Table 4. Vercise Genus DBS Full System Scan Eligible Components

Lead(s)	<ul style="list-style-type: none"> • DB-2201-30AC, Lead, 8 Contact, 30cm • DB-2201-30DC, Lead, 8 Contact, 30cm • DB-2201-45BC, Lead, 8 Contact, 45cm • DB-2201-45DC, Lead, 8 Contact, 45cm • DB-2202-30, Vercise™ Cartesia™ Directional Lead, 8 Contact, 30cm • DB-2202-45, Vercise™ Cartesia™ Directional Lead, 8 Contact, 45cm • DB-2203-30, Vercise™ Cartesia™ X Directional Lead, 16 Contact (5x3+1), 30cm • DB-2203-45, Vercise™ Cartesia™ X Directional Lead, 16 Contact (5x3+1), 45cm • DB-2204-30, Vercise™ Cartesia™ HX Directional Lead, 16 Contact (4x3+4), 30cm • DB-2204-45, Vercise™ Cartesia™ HX Directional Lead, 16 Contact (4x3+4), 45cm
Lead Extension(s)	<ul style="list-style-type: none"> • NM-3138-55, Lead Extension, 8 Contact, 55cm • DB-3128-55, Lead Extension, 2x8 Contact, 55cm • DB-3128-95, Lead Extension, 2x8 Contact, 95cm • DB-3128-55B, Lead Extension, 2x8 Contact, 55cm • DB-3128-95B, Lead Extension, 2x8 Contact, 95cm • DB-3216-55, Lead Extension, 16 Contact, 55cm • DB-3216-95, Lead Extension, 16 Contact, 95cm
Stimulator(s)	<ul style="list-style-type: none"> • DB-1408, Vercise Genus™ P8 Implantable Pulse Generator, 8 Contact • DB-1416, Vercise Genus™ P16 Implantable Pulse Generator, 16 Contact • DB-1432, Vercise Genus™ P32 Implantable Pulse Generator, 32 Contact • DB-1216, Vercise Genus™ R16 Implantable Pulse Generator, 16 Contact • DB-1232, Vercise Genus™ R32 Implantable Pulse Generator, 32 Contact
Accessories	<ul style="list-style-type: none"> • SureTek Burr Hole Cover(s) (optional if using alternative method of securing Leads⁸) <ul style="list-style-type: none"> ○ Provided in SureTek™ Burr Hole Cover Kit, DB-4600-C, and SureTek™ Burr Hole Cover Spares Kit, DB-4605-C • Suture Sleeve(s) (optional) <ul style="list-style-type: none"> ○ Provided in the Vercise™ Physician's Spare Kit 8 Contact Lead, DB-2500-C, Vercise™ Physician's Spare Kit 16 Contact Lead, DB-2501, and with DBS Leads • Port Plugs <ul style="list-style-type: none"> ○ Provided in the Precision Spectra™ IPG Port Plug, SC-4401, IPG Kits, DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, and Lead Extension Kits, DB-3128-55, DB-3128-55B, DB-3128-95, DB-3128-95B, DB-3216-55, DB-3216-95

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 Genus DBS Mixed M8 System Scan Eligible Components

Table 5. Vercise Genus DBS Mixed M8 System Scan Eligible Components	
Boston Scientific Lead(s)	<ul style="list-style-type: none"> • DB-2201-30AC, Lead, 8 Contact, 30cm • DB-2201-30DC, Lead, 8 Contact, 30cm • DB-2201-45BC, Lead, 8 Contact, 45cm • DB-2201-45DC, Lead, 8 Contact, 45cm • DB-2202-30, Vercise™ Cartesia™ Directional Lead, 8 Contact, 30cm • DB-2202-45, Vercise™ Cartesia™ Directional Lead, 8 Contact, 45cm
Medtronic Lead(s)	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • NM-3138-55, Lead Extension, 8 Contact, 55cm • DB-3128-55B, Lead Extension, 2x8 Contact, 55cm • DB-3128-95B, Lead Extension, 2x8 Contact, 95cm
Medtronic Lead Extension(s)	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • DB-9218-15, Vercise™ Adapter M8, 8 Contact, 15cm • DB-9218-55, Vercise™ Adapter M8, 8 Contact, 55cm
Stimulator(s)	<ul style="list-style-type: none"> • DB-1408, Vercise Genus™ P8 Implantable Pulse Generator, 8 Contact • DB-1416, Vercise Genus™ P16 Implantable Pulse Generator, 16 Contact • DB-1432, Vercise Genus™ P32 Implantable Pulse Generator, 32 Contact • DB-1216, Vercise Genus™ R16 Implantable Pulse Generator, 16 Contact • DB-1232, Vercise Genus™ R32 Implantable Pulse Generator, 32 Contact
Accessories	<ul style="list-style-type: none"> • SureTek Burr Hole Cover (optional if using alternative method of securing Boston Scientific Leads⁹) <ul style="list-style-type: none"> ○ Provided in SureTek™ Burr Hole Cover Kit, DB-4600-C, and SureTek™ Burr Hole Cover Spares Kit, DB-4605-C • Medtronic Stimloc Burr Hole Cover <ul style="list-style-type: none"> ○ 924256 • Boston Scientific Suture Sleeve(s) (optional) <ul style="list-style-type: none"> ○ Provided in the Vercise™ Physician's Spare Kit 8 Contact Lead, DB-2500-C, and with DBS Leads • Boston Scientific Port Plugs <ul style="list-style-type: none"> ○ Provided in the Precision Spectra™ IPG Port Plug, SC-4401, IPG Kits, DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, and Lead Extension Kits, DB-3128-55B, DB-3128-95B

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 Mixed S8 System Scan Eligible Components

Table 6. Vercise Genus DBS Mixed S8 System Scan Eligible Components	
Boston Scientific Lead(s)	<ul style="list-style-type: none"> • DB-2201-30AC, Lead, 8 Contact, 30cm • DB-2201-30DC, Lead, 8 Contact, 30cm • DB-2201-45BC, Lead, 8 Contact, 45cm • DB-2201-45DC, Lead, 8 Contact, 45cm • DB-2202-30, Vercise™ Cartesia™ Directional Lead, 8 Contact, 30cm • DB-2202-45, Vercise™ Cartesia™ Directional Lead, 8 Contact, 45cm
Medtronic Lead(s)¹⁰	<ul style="list-style-type: none"> • 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
Abbott Lead(s)¹⁰	<ul style="list-style-type: none"> • 6170, Abbott Directional Lead, 30cm, 0.5mm Spacing • 6171, Abbott Directional Lead, 30cm, 1.5mm Spacing • 6172, Abbott Directional Lead, 40cm, 0.5mm Spacing • 6173, Abbott Directional Lead, 40cm, 1.5mm Spacing
Boston Scientific Lead Extension(s)	<ul style="list-style-type: none"> • NM-3138-55, Lead Extension, 8 Contact, 55cm • DB-3128-55B, Lead Extension, 2x8 Contact, 55cm • DB-3128-95B, Lead Extension, 2x8 Contact, 95cm
Medtronic Lead Extension(s)	<ul style="list-style-type: none"> • 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
Abbott Lead Extension(s)	<ul style="list-style-type: none"> • 6371, Abbott Flexible Extension, 50cm • 6372, Abbott Flexible Extension, 60cm
Adapter(s)	<ul style="list-style-type: none"> • DB-9218-15, Vercise™ Adapter M8, 8 Contact, 15cm • DB-9218-55, Vercise™ Adapter M8, 8 Contact, 55cm • DB-9208-15, Vercise™ Adapter S8, 8 Contact, 15cm¹¹ • DB-9208-55, Vercise™ Adapter S8, 8 Contact, 55cm¹²
Stimulator(s)	<ul style="list-style-type: none"> • DB-1408, Vercise Genus™ P8 Implantable Pulse Generator, 8 Contact • DB-1416, Vercise Genus™ P16 Implantable Pulse Generator, 16 Contact • DB-1432, Vercise Genus™ P32 Implantable Pulse Generator, 32 Contact • DB-1216, Vercise Genus™ R16 Implantable Pulse Generator, 16 Contact • DB-1232, Vercise Genus™ R32 Implantable Pulse Generator, 32 Contact

(Table 6 continues on next page)

10 A patient with Vercise Adapter M8 and Vercise Adapter S8 implanted is considered to have a Vercise Genus DBS Mixed S8 System. For patients with Vercise Adapter M8 and Vercise Adapter S8 implanted, see information pertaining to the Vercise Genus DBS Mixed S8 System.

11 SC-9208-15 is the same Adapter as DB-9208-15 and is interchangeable for MR Conditionality.

12 SC-9208-55 is the same Adapter as DB-9208-55 and is interchangeable for MR Conditionality.

Table 6. Vercise Genus DBS Mixed S8 System Scan Eligible Components

Accessories	<ul style="list-style-type: none"> • SureTek Burr Hole Cover (optional if using alternative method of securing Boston Scientific Leads¹³) <ul style="list-style-type: none"> ○ Provided in SureTek™ Burr Hole Cover Kit, DB-4600-C, and SureTek™ Burr Hole Cover Spares Kit, DB-4605-C • Medtronic Stimloc Burr Hole Cover <ul style="list-style-type: none"> ○ 924256 • Abbott Burr Hole Cover <ul style="list-style-type: none"> ○ Provided in the Guardian™ Cranial Burr Hole Cover System, 6010 • Boston Scientific Suture Sleeve(s) (optional) <ul style="list-style-type: none"> ○ Provided in the Vercise™ Physician's Spare Kit 8 Contact Lead, DB-2500-C, and with DBS Leads • Boston Scientific Port Plugs <ul style="list-style-type: none"> ○ Provided in the Precision Spectra™ IPG Port Plug, SC-4401, IPG Kits, DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, and Lead Extension Kits, DB-3128-55B, DB-3128-95B
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13 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

Lead(s)	<ul style="list-style-type: none"> • DB-2201-30AC, Lead, 8 Contact, 30cm • DB-2201-30DC, Lead, 8 Contact, 30cm • DB-2201-45BC, Lead, 8 Contact, 45cm • DB-2201-45DC, Lead, 8 Contact, 45cm • DB-2202-30, Vercise™ Cartesia™ Directional Lead, 8 Contact, 30cm • DB-2202-45, Vercise™ Cartesia™ Directional Lead, 8 Contact, 45cm
Lead Extension(s)	<ul style="list-style-type: none"> • NM-3138-55, Lead Extension, 8 Contact, 55cm
Stimulator	<ul style="list-style-type: none"> • DB-1200-S, Vercise Gevia™ 16 Contact Implantable Pulse Generator
Accessories	<ul style="list-style-type: none"> • SureTek Burr Hole Cover(s) (optional if using alternative method of securing Leads¹⁴) <ul style="list-style-type: none"> ○ Provided in SureTek™ Burr Hole Cover Kit, DB-4600-C, and SureTek™ Burr Hole Cover Spares Kit, DB-4605-C • Suture Sleeve(s) (optional) <ul style="list-style-type: none"> ○ Provided in the Vercise™ Physician's Spare Kit 8 Contact Lead, DB-2500-C, and with DBS Leads • Port Plugs <ul style="list-style-type: none"> ○ Provided in the Precision Spectra™ IPG Port Plug, SC-4401, and IPG Kit, DB-1200-S

¹⁴ 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)	<ul style="list-style-type: none"> • 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 Leads¹⁵ (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 Extension(s) must be connected directly to the Stimulator without the use of an Adapter. • The proximal end of each Boston Scientific Lead Extension(s) must terminate in a Stimulator Port. • 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. <p>Note: <i>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.</i></p> <p>Caution: <i>If more than two Stimulators are implanted, the patient is not scan eligible.</i></p> <p>Caution: <i>When two Stimulators are implanted, a system containing DB-3128-55, DB-3128-55B, DB-3128-95, DB-3128-95B, DB-3216-55, or DB-3216-95 Lead Extension(s) is not scan eligible.</i></p> <p>Caution: <i>When two Stimulators are implanted, a system containing DB-2203-30, DB-2203-45, DB-2204-30, or DB-2204-45 Lead(s) is not scan eligible.</i></p> <p>Caution: <i>There should be no evidence of fractured or abandoned Leads or compromised Stimulator-Lead integrity.¹⁶</i></p>
Vercise Genus DBS Full System Programming	<ul style="list-style-type: none"> • MRI Mode must be enabled on the Stimulator 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" or the "MRI Mode on the Controller App" 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" or the "MRI Mode on the Controller App" section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Vercise Genus DBS Mixed M8 System Configuration

Table 9. Vercise Genus DBS Mixed M8 System Configuration

<p>Vercise Genus DBS Mixed M8 System Configuration(s)</p>	<ul style="list-style-type: none"> • A fully implanted Vercise Genus DBS Mixed M8 System may be comprised of one of the two configurations identified below. A configuration may include a combination of Lead(s) and Lead Extension(s) from Medtronic and/or Boston Scientific connected to any Boston Scientific Vercise Genus DBS Stimulator(s) using an Adapter where applicable. <ul style="list-style-type: none"> ○ A Vercise Genus DBS Mixed M8 System may be comprised of up to two Medtronic Lead(s), Medtronic Lead Extension(s), Boston Scientific Vercise Adapter(s) M8, and Medtronic Stimloc Burr Hole Cover(s) (see Table 5 for scan eligible components). ○ A Vercise Genus DBS Mixed M8 System may be comprised of one Medtronic Lead, Medtronic Lead Extension, Medtronic Stimloc Burr Hole Cover, Boston Scientific Vercise Adapter M8, Boston Scientific Lead, Boston Scientific Lead Extension, and Boston Scientific Burr Hole Cover or an alternative method of securing a Boston Scientific Lead¹⁸ (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, if applicable, 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, Lead Extension, and, if applicable, Adapter 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 Adapter(s) are connected to a single Stimulator, both Lead Extensions and, if applicable, Adapter(s) must be routed on the same side of the body as the Stimulator. • Medtronic Lead Extension(s) must be connected directly to the Adapter(s) M8. • The proximal end of each Boston Scientific Lead Extension(s) and Adapter(s) must terminate in a Stimulator Port. • 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. <p>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.</p> <p>Caution: All Lead, Lead Extension, and Adapter M8 length combinations are scan eligible except those that include both a 95cm Medtronic Lead Extension (37085-95 or 37086-95) and a 55cm Adapter M8 (DB-9218-55).</p> <p>Caution: Any system with an open Lead Extension Port is not scan eligible. Any system with an unused Medtronic Lead Extension Port is not scan eligible.</p> <p>Caution: If more than two Stimulators are implanted, the patient is not scan eligible.</p> <p>Caution: When two Stimulators are implanted, a system containing DB-3128-55B or DB-3128-95B Lead Extension(s) is not scan eligible.</p> <p>Caution: There should be no evidence of fractured or abandoned Leads or compromised Stimulator-Lead integrity.¹⁹</p>
<p>Vercise Genus DBS Mixed M8 System Programming</p>	<ul style="list-style-type: none"> • 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" or the "MRI Mode on the Controller App" 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" or the "MRI Mode on the Controller App" section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Vercise Genus DBS Mixed S8 System Configuration

Table 10. Vercise Genus DBS Mixed S8 System Configuration

Vercise Genus DBS Mixed S8 System Configuration(s)

- A fully implanted Vercise Genus DBS Mixed S8 System may be comprised of one of the three configurations identified below. A configuration may include a combination of Lead(s) and Lead Extension(s) from Medtronic, Abbott, and/or Boston Scientific connected to any Boston Scientific Vercise Genus DBS Stimulator(s) using an Adapter where applicable.
 - A Vercise Genus DBS Mixed S8 System may be comprised of up to two Abbott Lead(s), Abbott Lead Extension(s), Boston Scientific Vercise Adapter(s) S8, and Abbott Guardian Burr Hole Cover(s) (see Table 6 for scan eligible components).
 - A Vercise Genus DBS Mixed S8 System may be comprised of one Abbott Lead, Abbott Lead Extension, Abbott Guardian Burr Hole Cover, Boston Scientific Vercise Adapter S8, Boston Scientific Lead, Boston Scientific Lead Extension, and Boston Scientific Burr Hole Cover or an alternative method of securing a Boston Scientific Lead²¹ (see Table 6 for scan eligible components).
 - A Vercise Genus DBS Mixed S8 System may be comprised of one Abbott Lead, Abbott Lead Extension, Abbott Guardian Burr Hole Cover, Boston Scientific Vercise Adapter S8, Medtronic Lead, Medtronic Lead Extension, Medtronic Stimloc Burr Hole Cover, and Boston Scientific Vercise Adapter M8 (see Table 6 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, if applicable, 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, Lead Extension, and, if applicable, Adapter 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, if applicable, Adapter(s) are connected to a single Stimulator, both Lead Extensions and Adapter(s) must be routed on the same side of the body as the Stimulator.
- Medtronic Lead Extension(s) must be connected directly to the Adapter(s) M8.
- Abbott Lead Extension(s) must be connected directly to the Adapter(s) S8.
- The proximal end of each Boston Scientific Lead Extension(s) and Adapter(s) must terminate in a Stimulator Port.
- 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.

(Table 10 continues on next page)

²¹ 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.

Table 10. Vercise Genus DBS Mixed S8 System Configuration

Vercise Genus DBS Mixed S8 System Configuration(s)	<p>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.</p> <p>Caution: All Lead, Lead Extension, and Adapter M8 length combinations are scan eligible except those that include both a 95cm Medtronic Lead Extension (37085-95 or 37086-95) and a 55cm Adapter M8 (DB-9218-55).</p> <p>Caution: Abbott Extensions connected to a 55cm Adapter S8 (DB-9208-55) are MR Conditional only when the Stimulator is implanted in the abdomen. A 50cm Abbott Extension (6371) connected to a 15cm Adapter S8 (DB-9208-15) is MR Conditional only when the Stimulator is implanted near the clavicle (pectoral region).</p> <p>Caution: Any system with an open Lead Extension Port is not scan eligible. Any system with an unused Abbott and/or Medtronic Lead Extension Port is not scan eligible.</p> <p>Caution: If more than two Stimulators are implanted, the patient is not scan eligible.</p> <p>Caution: When two Stimulators are implanted, a system containing DB-3128-55B or DB-3128-95B Lead Extension(s) is not scan eligible.</p> <p>Caution: There should be no evidence of fractured or abandoned Leads or compromised Stimulator-Lead integrity.²²</p>
Vercise Genus DBS Mixed S8 System Programming	<ul style="list-style-type: none"> • MRI Mode must be enabled on the Stimulator prior to performing scan.²³ • Rechargeable Stimulators must be fully charged prior to the scan.

²² 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" or the "MRI Mode on the Controller App" section of this manual for more information on MRI Mode.

²³ Stimulation is automatically turned OFF when MRI Mode is enabled. See the "MRI Mode on the Remote Control" or the "MRI Mode on the Controller App" 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)	<ul style="list-style-type: none"> • 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 Leads²⁴ (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. <p>Note: <i>To confirm the presence of a Port Plug in a Stimulator, check the patient's record or confirm with the implanting physician.</i></p> <p>Caution: <i>A Vercise Gevia DBS Stimulator is not scan eligible when implanted in the abdomen.</i></p> <p>Caution: <i>Any system with an unused Lead Extension Port is not scan eligible.</i></p> <p>Caution: <i>If multiple Stimulators are implanted, the patient is not scan eligible.</i></p> <p>Caution: <i>There should be no evidence of fractured or abandoned Leads or compromised Stimulator-Lead integrity.²⁵</i></p>
Vercise Gevia DBS Full System Programming	<ul style="list-style-type: none"> • MRI Mode must be enabled on the Stimulator prior to performing scan.²⁶ • Rechargeable Stimulators must be fully charged prior to the scan.

24 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.

25 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.

26 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


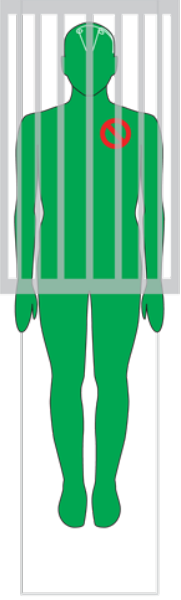
Testing has demonstrated that the Boston Scientific Lead-Only System is MR Conditional. See the “*MR Conditional System Description*” section of this manual for the definition of a Lead-Only System.

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		
	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	<ul style="list-style-type: none"> • 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)
Or Body Coil		
	Maximum B1+rms	2.0 μ T
	Maximum SAR ²⁷	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	<ul style="list-style-type: none"> • 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.

²⁷ Specific Absorption Rate (SAR) – radio frequency power absorbed per unit of mass (W/kg).

Full System, Mixed M8 System, or Mixed S8 System Scan

Testing has demonstrated that the Vercise Genus DBS Full System, Vercise Genus DBS Mixed M8 System, Vercise Genus DBS Mixed S8 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 M8 System, or Mixed S8 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, Table 18, or Table 19.



Full System, Mixed M8 System, or Mixed S8 System Head Scan Using a Head Transmit Coil

An MRI may be safely performed on a patient implanted with a Full System, Mixed M8 System, or Mixed S8 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 M8 System, Vercise Genus DBS Mixed S8 System, Vercise Gevia DBS Full System
Table 13. Conditions for a Vercise Genus DBS Full System, Vercise Genus DBS Mixed M8 System, Vercise Genus DBS Mixed S8 System, or Vercise Gevia DBS Full System Head Scan Using a Head Transmit Coil

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	<ul style="list-style-type: none"> Head transmit/receive coil (Circular Polarized (CP) Only) Hydrogen/proton imaging only
	Zone Indicated	Head
	Maximum B1+rms	2.0 μ T
	Maximum SAR²⁸	<ul style="list-style-type: none"> 0.2 W/kg for Vercise Genus DBS Full System, Vercise Genus DBS Mixed M8 System, or Vercise Genus DBS Mixed S8 System 0.1 W/kg for Vercise Gevia DBS Full System
Or Dual IPG Head Coil 	System Programming	<ul style="list-style-type: none"> MRI Mode must be enabled on the Stimulator(s) prior to performing scan.²⁹ Rechargeable Stimulators must be fully charged prior to the scan.
	Scan Eligible System Components	<ul style="list-style-type: none"> For Vercise Genus DBS Full System, see Table 4 on page 6. For Vercise Genus DBS Mixed M8 System, see Table 5 on page 7. For Vercise Genus DBS Mixed S8 System, see Table 6 on page 8. For Vercise Gevia DBS Full System, see Table 7 on page 10.
	System Configuration	<ul style="list-style-type: none"> For Vercise Genus DBS Full System, see Table 8 on page 11. For Vercise Genus DBS Mixed M8 System, see Table 9 on page 12. For Vercise Genus DBS Mixed S8 System, see Table 10 on page 13. For Vercise Gevia DBS Full System, see Table 11 on page 15.
	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	<ul style="list-style-type: none"> Patient must be positioned in supine or prone position during the scan. Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination.

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.

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” or the “MRI Mode on the Controller App” section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Full System, Mixed M8 System, or Mixed S8 System Scan Using a Body Transmit Coil

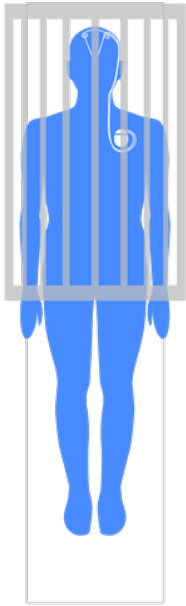
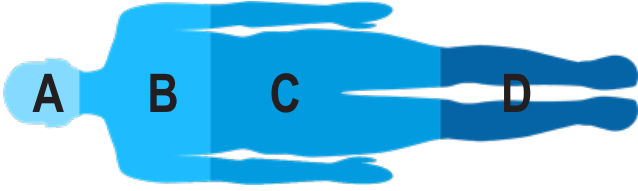
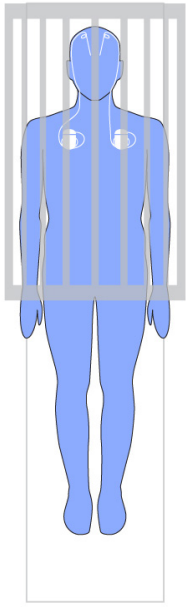
An MRI may be safely performed on a patient implanted with a Full System, Mixed M8 System, or Mixed S8 System that meets the implant and radiology conditions listed in this section.

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 14, Table 16, or Table 18.

Vercise Genus DBS Full System or Vercise Genus DBS Mixed M8 System

Table 14. Conditions for a Vercise Genus DBS Full System or Vercise Genus DBS Mixed M8 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	<ul style="list-style-type: none"> 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)															
																		
	<p>Or Dual IPG Body Coil</p> 		Maximum B1+rms Per Zone	<table border="1"> <thead> <tr> <th>Zone A</th> <th>Zone B</th> <th>Zone C</th> <th>Zone D</th> </tr> </thead> <tbody> <tr> <td>Isocenter at or above C2</td> <td>Isocenter C3 through T10</td> <td>Isocenter T11 through Femur</td> <td>Isocenter Lower Extremities (Knee and Below)</td> </tr> <tr> <td>1.6 μT</td> <td>2.0 μT</td> <td>3.2 μT</td> <td>Normal Mode</td> </tr> </tbody> </table>				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 μ T	2.0 μ T	3.2 μ T
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 μ T		2.0 μ T	3.2 μ T	Normal Mode														
		Maximum SAR Per Zone ³⁰	<table border="1"> <thead> <tr> <th>Zone A</th> <th>Zone B</th> <th>Zone C</th> <th>Zone D</th> </tr> </thead> <tbody> <tr> <td>0.2 W/kg</td> <td>See Table 15</td> <td>1.5 W/kg</td> <td>Normal Mode</td> </tr> </tbody> </table>				Zone A	Zone B	Zone C	Zone D	0.2 W/kg	See Table 15	1.5 W/kg	Normal Mode				
Zone A		Zone B	Zone C	Zone D														
0.2 W/kg		See Table 15	1.5 W/kg	Normal Mode														
		System Programming	<ul style="list-style-type: none"> MRI Mode must be enabled on the Stimulator(s) prior to performing scan.³¹ Rechargeable Stimulators must be fully charged prior to the scan. 															
		Scan Eligible System Components	<ul style="list-style-type: none"> For Vercise Genus DBS Full System, see Table 4 on page 6. For Vercise Genus DBS Mixed M8 System, see Table 5 on page 7. 															
		System Configuration	<ul style="list-style-type: none"> For Vercise Genus DBS Full System, see Table 8 on page 11. For Vercise Genus DBS Mixed M8 System, see Table 9 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	<ul style="list-style-type: none"> Patient must be positioned in supine or prone position during the scan. Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination. 																

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

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” or the “MRI Mode on the Controller App” section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

Table 15. Maximum SAR for Zone B³²
(Vercise Genus DBS Full System or Vercise Genus DBS Mixed M8 System Scan Using a Body Transmit Coil)

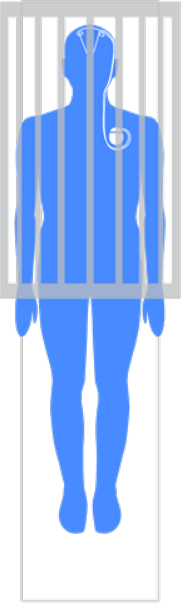
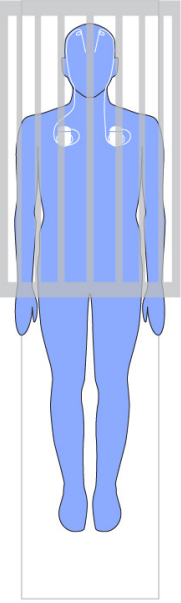
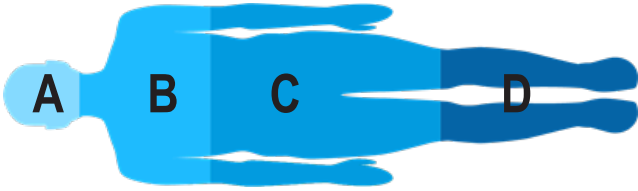
Landmark Span	Large Adult ³³	Adult
Upper Chest	0.2 W/kg	0.2 W/kg
Heart	0.3 W/kg	0.4 W/kg
Lower Chest	0.5 W/kg	0.7 W/kg

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

33 A large adult is defined as body mass greater than 119 kg (262 lb) or body mass index (BMI) greater than 36 kg/m² (lb/in² x 703).

Vercise Genus DBS Mixed S8 System

Table 16. Conditions for a Vercise Genus Mixed S8 System Scan Using a Body Transmit Coil

	Body Coil	MR Conditional	Yes				
		<p>Or Dual IPG Body Coil</p>	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	<ul style="list-style-type: none"> 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					
Maximum SAR Per Zone³⁴	System Programming						
Scan Eligible System Components	System Configuration						
Exposure Time	Additional Information						

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

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

³⁵ Stimulation is automatically turned OFF when MRI Mode is enabled. See the “MRI Mode on the Remote Control” or the “MRI Mode on the Controller App” section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.

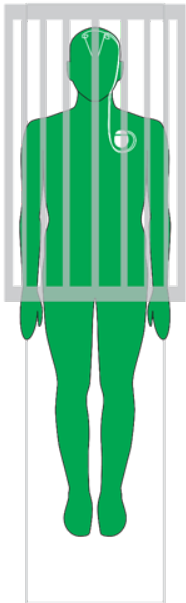


Table 17. Maximum SAR for Zone B³⁶ (Vercise Genus DBS Mixed S8 System Scan Using a Body Transmit Coil)		
Landmark Span	Large Adult³⁷	Adult
Upper Chest	0.1 W/kg	0.1 W/kg
Heart	0.2 W/kg	0.2 W/kg
Lower Chest	0.5 W/kg	0.4 W/kg

³⁶ Specific Absorption Rate (SAR) – radio frequency power absorbed per unit of mass (W/kg).

³⁷ A large adult is defined as body mass greater than 119 kg (262 lb) or body mass index (BMI) greater than 36 kg/m² (lb/in² x 703).

Vercise Gevia DBS Full System

Table 18. Conditions for a Vercise Gevia DBS Full System Scan Using a Body Transmit 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	<ul style="list-style-type: none"> 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	<p>DB-2201 Lead</p>  <p>DB-2202 Lead</p>  <table border="1"> <thead> <tr> <th>Zone E</th> <th>Zone F</th> <th>Zone G</th> <th>Zone H</th> </tr> </thead> <tbody> <tr> <td>Isocenter above T5</td> <td>Isocenter at T5 or below T5</td> <td>Isocenter above T12</td> <td>Isocenter at T12 or below T12</td> </tr> <tr> <td>1.5 μT</td> <td>2.0 μT</td> <td>1.2 μT</td> <td>2.0 μT</td> </tr> </tbody> </table>	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 μ T	2.0 μ T	1.2 μ T	2.0 μ T
	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 μ T	2.0 μ T	1.2 μ T	2.0 μ T											
Maximum SAR³⁸	0.1 W/kg													
System Programming	<ul style="list-style-type: none"> MRI Mode must be enabled on the Stimulator prior to performing scan.³⁹ Stimulator must be fully charged prior to the scan. 													
Scan Eligible System Components	See Table 7 on page 10.													
System Configuration	See Table 11 on page 15.													
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	<ul style="list-style-type: none"> Patient must be positioned in supine or prone position during the scan. Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination. 													

Note: Green colored zones are indicative of scan eligible zones per the scan conditions of Table 18.

³⁸ Specific Absorption Rate (SAR) – radio frequency power absorbed per unit of mass (W/kg).

³⁹ 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 M8 System, or Mixed S8 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 M8 System, or Mixed S8 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 19.

Vercise Genus DBS Full System, Vercise Genus DBS Mixed M8 System, Vercise Genus DBS Mixed S8 System

Table 19. Conditions for a Vercise Genus DBS Full System, Vercise Genus DBS Mixed M8 System, or Vercise Genus DBS Mixed S8 System Lower Extremity Scan Using a Lower Extremity Transmit Coil

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	<ul style="list-style-type: none"> 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 SAR⁴⁰	Normal Mode
	System Programming	<ul style="list-style-type: none"> MRI Mode must be enabled on the Stimulator prior to performing scan.⁴¹ Rechargeable Stimulators must be fully charged prior to the scan.
Or Dual IPG Lower Extremity Coil 	Scan Eligible System Components	<ul style="list-style-type: none"> For Vercise Genus DBS Full System, see Table 4 on page 6. For Vercise Genus DBS Mixed M8 System, see Table 5 on page 7. For Vercise Genus DBS Mixed S8 System, see Table 6 on page 8.
	System Configuration	<ul style="list-style-type: none"> For Vercise Genus DBS Full System, see Table 8 on page 11. For Vercise Genus DBS Mixed M8 System, see Table 9 on page 12. For Vercise Genus DBS Mixed S8 System, see Table 10 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	<ul style="list-style-type: none"> Patient must be positioned in supine or prone position during the scan. Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination.

Note: Green colored zones are indicative of scan eligible zones per the scan conditions of Table 19.

⁴⁰ Specific Absorption Rate (SAR) – radio frequency power absorbed per unit of mass (W/kg).

⁴¹ Stimulation is automatically turned OFF when MRI Mode is enabled. See the “MRI Mode on the Remote Control” or the “MRI Mode on the Controller App” 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 M8 System, or Mixed S8 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 or Controller App must be used to disable MRI Mode on the Stimulator. See the “*MRI Mode on the Remote Control*” or the “*MRI Mode on the Controller App*” 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 or Controller App displays any error messages.

MRI Mode on the Remote Control

For patients that utilize the Remote Control, MRI Mode must be enabled on the Stimulator using the Remote Control prior to performing an MRI scan on a patient implanted with the Full System, Mixed M8 System, or Mixed S8 System.


- See Table 4 for Vercise Genus DBS Full System scan eligible components.
- See Table 5 for Vercise Genus DBS Mixed M8 System scan eligible components.
- See Table 6 for Vercise Genus DBS Mixed S8 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 Remote Control:

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


Enable MRI Mode on the Remote Control

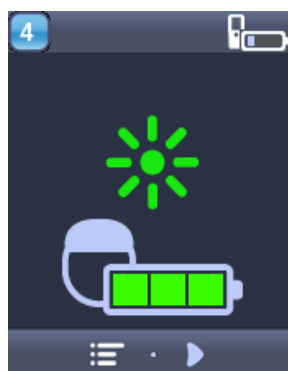
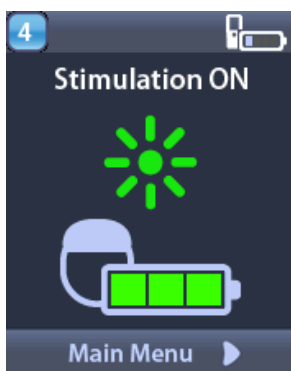
When the Remote Control is linked to an MR Conditional Stimulator, the **Enter MRI Mode** icon  will appear on the **System Settings** screen. The Remote Control must be used to enable MRI Mode on the Stimulator before performing an MRI scan on a patient. The stimulation is automatically turned OFF when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

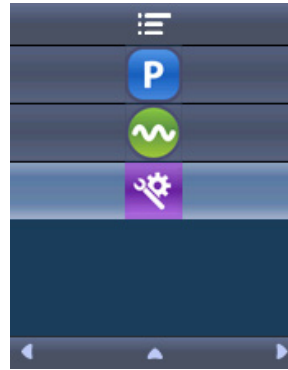
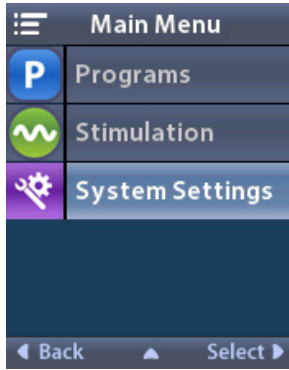
1. Unlock the Remote Control by pressing the **Lock/Unlock**  button on the right side of the Remote Control.
2. After unlocking the Remote Control, the **Home** screen appears.



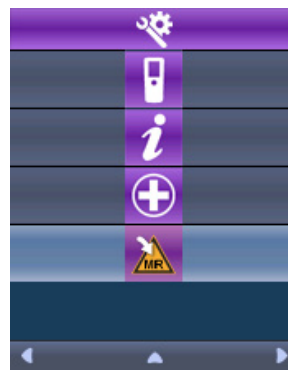
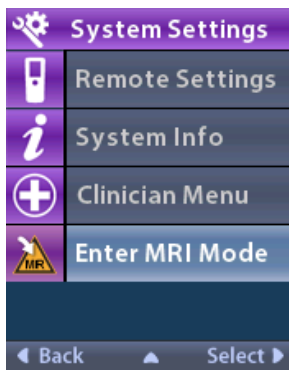
Note: *The Remote Control may display either a text screen in one of the languages provided or an iconic screen.*

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

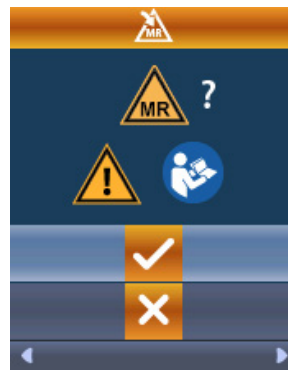
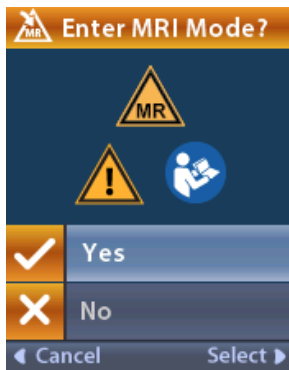
4. Select  **System Settings**.



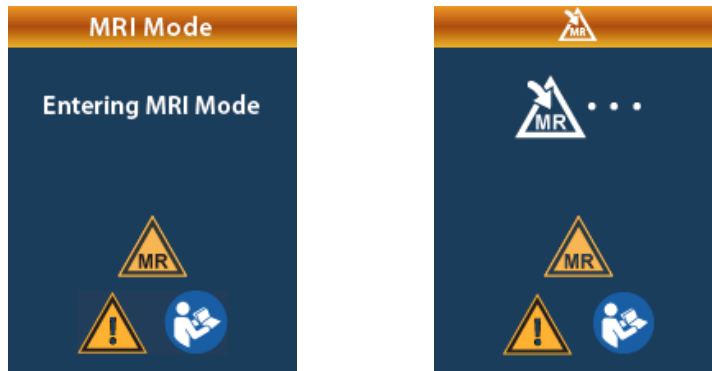
5. Select  **Enter MRI Mode**.



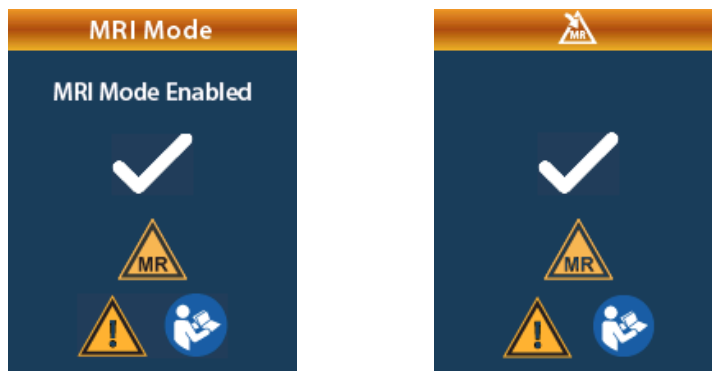
6. Select  **Yes** to enter MRI Mode or  **No** to cancel the action.



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






Disable MRI Mode on the Remote Control

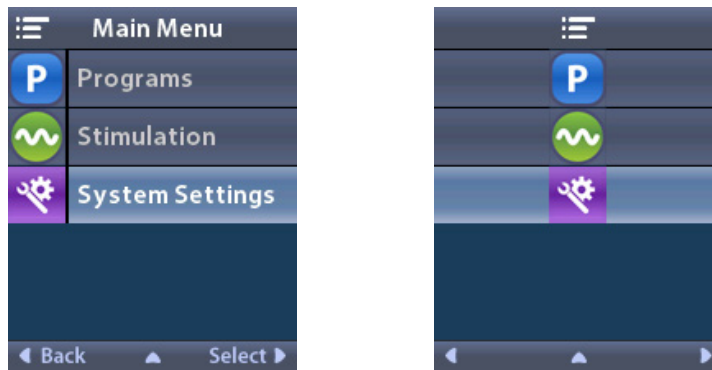
Upon completion of the MRI scan, the Remote Control must be used to disable MRI Mode.

To disable MRI Mode:

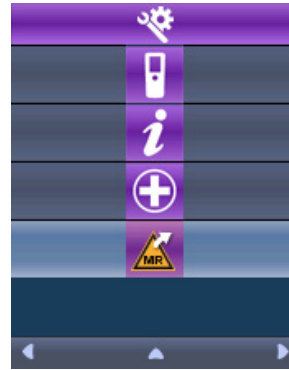
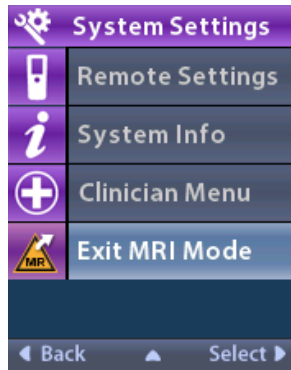
1. Unlock the Remote Control by pressing the **Lock/Unlock**  button on the right side of the Remote Control.
2. After unlocking the Remote Control, the **Home** screen appears.



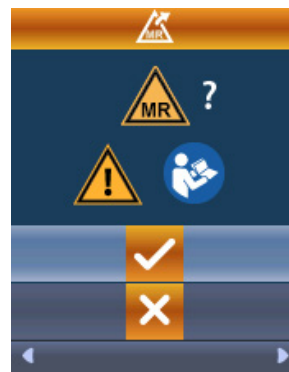
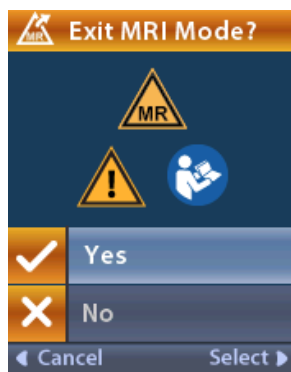
3. Press the **Right Arrow**  button to navigate to the  **Main Menu**.
4. Select  **System Settings**.



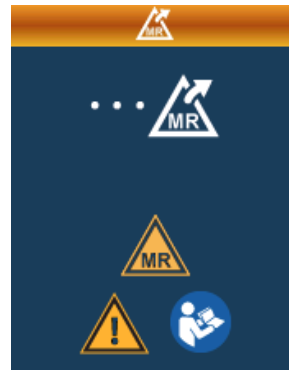
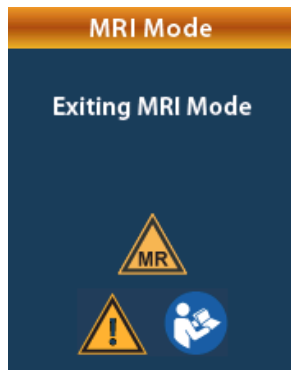
5. Select  **Exit MRI Mode**.



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**  once MRI Mode is disabled.



MRI Mode Error Screens on the Remote Control

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.

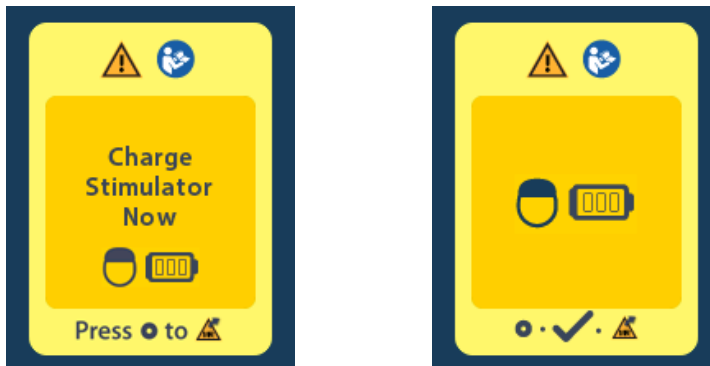


Warning: Always check the Stimulator battery to ensure that it is fully charged before performing an MRI scan on the patient.




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 “*Enable MRI Mode on the Remote Control*” section of this manual.

Warning: *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.

Warning: *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.*

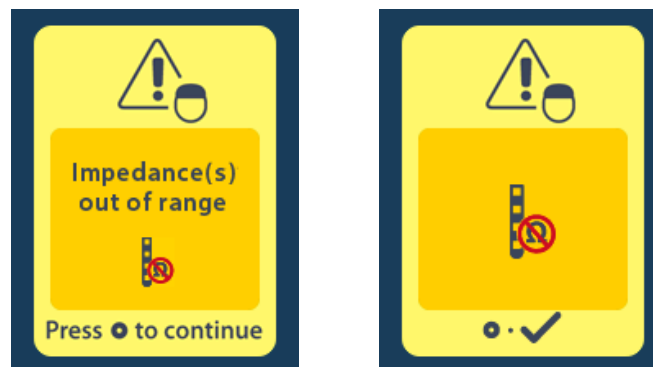
Impedances Out Of Range Screen



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.

When scan eligible Medtronic Leads are used in a Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 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 “Access the Clinician Menu on the Remote Control” and “Check Impedances on the Remote Control” sections 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: When scan eligible Medtronic Leads are used in a Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 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.

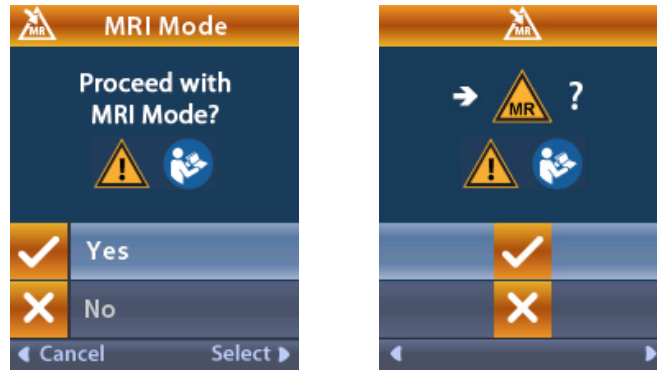
Note: For a System with a Port Plug in either a Stimulator Port(s) or Lead Extension Port, impedances measured on Contacts within the Port with a Port Plug will be out of range (high). See Table 8, Table 9, Table 10, or Table 11 to confirm that the specific configuration is scan eligible.



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.




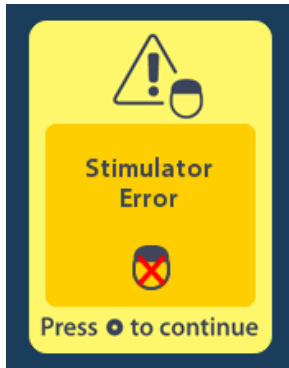
3. Select  **Yes** to proceed with enabling MRI Mode or  **No** to cancel the action.



Warning: *An MRI scan is not recommended when the impedances are not within the acceptable range except when scanning a Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 System and Contacts 5, 6, 7, and 8 are out of range for the scan eligible Medtronic Leads. 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.

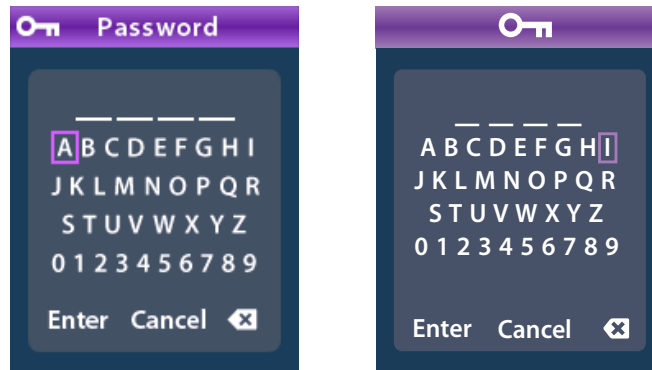


Access the Clinician Menu on the Remote Control

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.

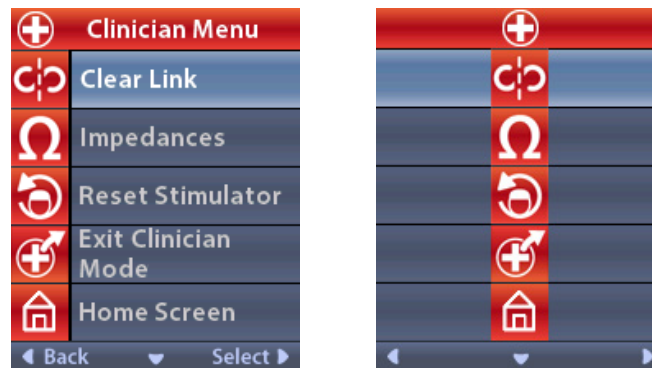


2. Use the **Navigation**  buttons to enter your password.

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.

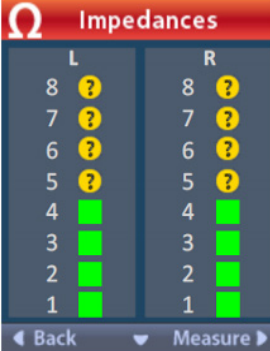
Check Impedances on the Remote Control

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 M8 System or Vercise Genus DBS Mixed S8 System, Contacts 5 through 8 for each implanted scan eligible Medtronic Lead are expected to be out of range due to the fact that Medtronic Leads have 4 Contacts (see figure below).



Impedances	
L	R
8 ?	8 ?
7 ?	7 ?
6 ?	6 ?
5 ?	5 ?
4 ■	4 ■
3 ■	3 ■
2 ■	2 ■
1 ■	1 ■

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).

MRI Mode on the Controller App

For patients that utilize the Controller App, MRI Mode must be entered on the Stimulator using the Controller App prior to performing an MRI scan on a patient implanted with the Full System, Mixed M8 System, or Mixed S8 System.

- See Table 4 for Vercise Genus DBS Full System scan eligible components.
- See Table 5 for Vercise Genus DBS Mixed M8 System scan eligible components.
- See Table 6 for Vercise Genus DBS Mixed S8 System scan eligible components.

Once the MRI scan is complete, exit 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 entered and then exited on both Stimulators.

The following Systems are not compatible with the Controller App:

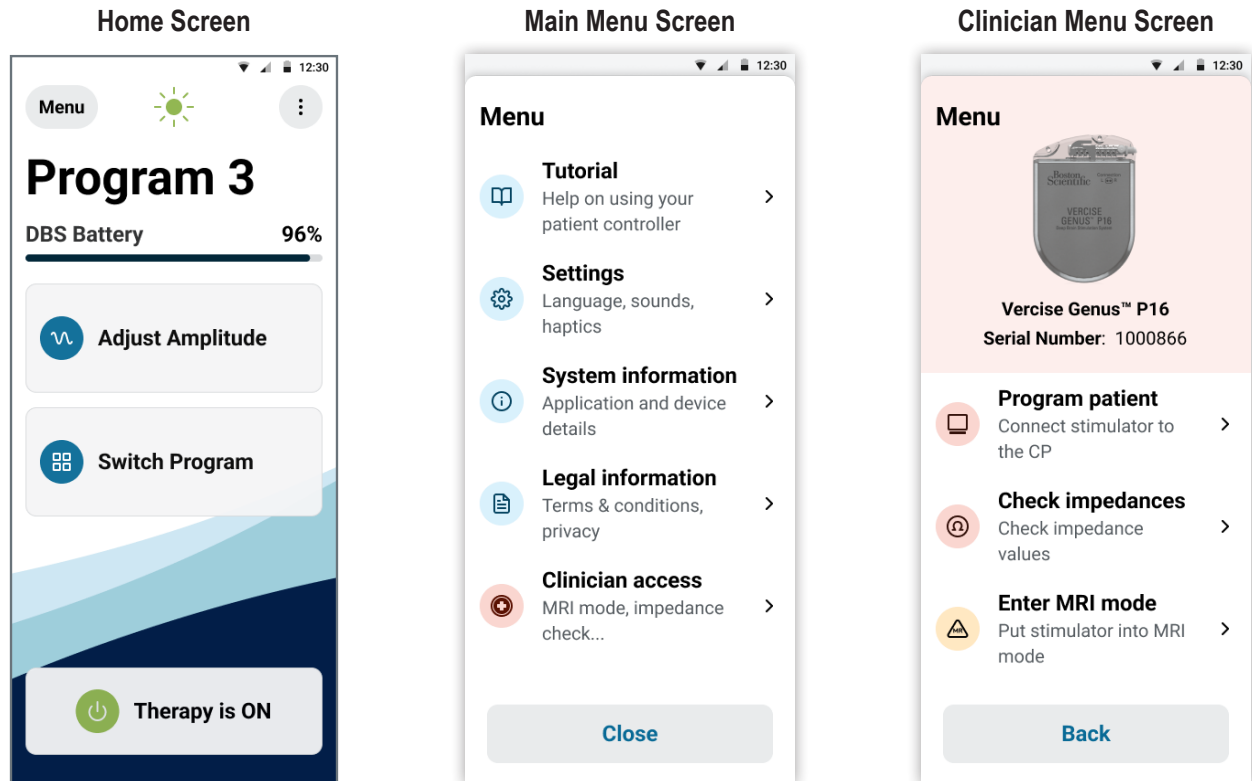
- A Fully Implanted Lead-Only System
- An Externalized Lead-Only System
- A Vercise Gevia DBS Full System

Enter MRI Mode on the Controller App




The Controller App must be used to enter MRI Mode on the Stimulator before performing an MRI scan on a patient. Therapy is automatically turned OFF when MRI Mode is entered.


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

Caution: Patients may become anxious, or their symptoms may return, once therapy 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.

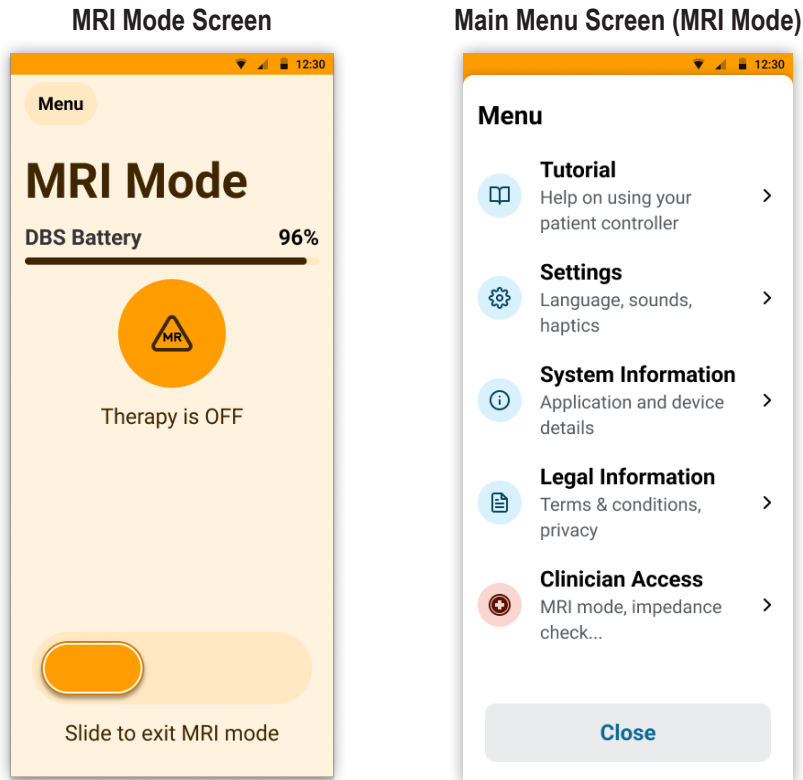


To enter MRI Mode:

1. From the Home screen, tap the **Menu** icon .
2. Tap **Clinician access** .
3. Tap **Enter MRI mode** .
4. A prompt will appear, tap **Continue**.

5. The System performs a series of checks before MRI Mode is entered.
6. The MRI Mode screen displays the MR Conditional Symbol  and states "Therapy is OFF." Always confirm that the MRI Mode screen displays the MR Conditional Symbol and states "Therapy is OFF" before performing an MRI scan on the patient.

Note: To access the Main Menu while in MRI Mode, tap the **Menu** icon .



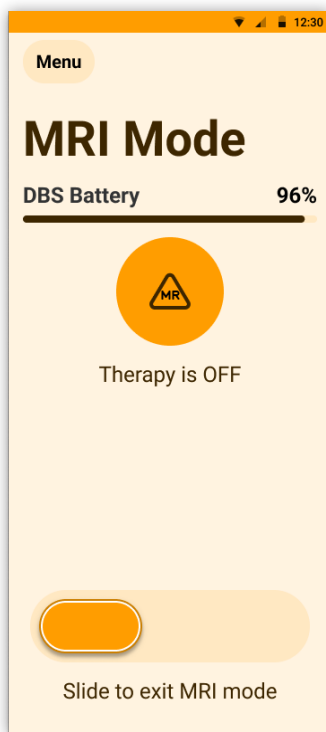
Exit MRI Mode on the Controller App

Upon completion of the MRI scan, the Controller App must be used to exit MRI Mode.




Upon exiting MRI Mode, the Stimulator keeps the settings that were active prior to entering MRI Mode. If therapy was ON before entering MRI Mode, then exiting MRI Mode turns therapy back ON. If therapy was OFF before entering MRI Mode, then exiting MRI Mode keeps therapy OFF.

To exit MRI Mode:

1. From the MRI Mode screen, slide the toggle to the right to exit MRI Mode.
2. Tap **Exit** to confirm the action.
3. The System performs a series of checks before MRI Mode is exited.



MRI Mode Error Messages on the Controller App

Message	Meaning
 <p>Stimulator Battery Low</p>	<p>The Stimulator battery is low and cannot enter MRI Mode.</p> <p>For Rechargeable Stimulators: Advise the patient to fully charge their Stimulator in order to enter MRI Mode. Advise the patient to refer to their <i>Charging Handbook</i> for charging instructions. Advise the patient that the Controller App does not communicate with the Stimulator while the Stimulator is charging.</p> <p>Warning: <i>Always check the rechargeable Stimulator battery to ensure it is fully charged before performing an MRI scan on the patient. Depending on the Stimulator battery level, it may take a few hours to fully charge the Stimulator.</i></p> <p>Warning: <i>The Charger and the mobile device used with the Controller App are MR Unsafe and must not be brought into the MRI scanner room.</i></p> <p>For Non-Rechargeable Stimulators: Do not perform an MRI scan if MRI Mode cannot be entered. Advise the patient to contact the healthcare provider managing their DBS System or Boston Scientific.</p> <p>Warning: <i>Do not perform an MRI scan if MRI Mode is not entered. Scanning under different conditions may result in patient injury or Stimulator malfunction.</i></p>
 <p>Charging Reminder</p>	<p>Rechargeable Stimulators Only: The Stimulator battery is low and needs to charge in order to return to MRI Mode. This error message appears if the Stimulator battery level falls below the threshold value after entering MRI Mode.</p> <p>Advise the patient to fully charge their Stimulator in order to return to MRI Mode. The patient may exit MRI Mode and charge their Stimulator or charge their Stimulator without exiting MRI Mode. Advise the patient to refer to their <i>Charging Handbook</i> for charging instructions. Advise the patient that the Controller App does not communicate with the Stimulator while the Stimulator is charging.</p> <p>Warning: <i>The Charger and the mobile device used with the Controller App are MR Unsafe and must not be brought into the MRI scanner room.</i></p>
 <p>Battery Low</p>	<p>Non-Rechargeable Stimulators Only: The Stimulator battery is too low to remain in MRI Mode and needs replacement. This error message appears if the Stimulator battery level falls below the threshold value after entering MRI Mode.</p> <p>Do not perform an MRI scan. Select Exit MRI Mode. Advise the patient to contact the healthcare provider managing their DBS System or Boston Scientific.</p> <p>Warning: <i>The mobile device used with the Controller App is MR Unsafe and must not be brought into the MRI scanner room.</i></p> <p>Warning: <i>Do not perform an MRI scan if MRI Mode is not entered. Scanning under different conditions may result in patient injury or Stimulator malfunction.</i></p>



Impedances Out of Range

Upon entering MRI Mode, the system performs a check of Lead impedances. This error message appears if the impedances are not within the acceptable range.

When scan eligible Medtronic Leads are used in a Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 System, the “Impedances Out of Range” error message may display (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” error message is expected (see the note below) and the System may be scan eligible. See Table 8, Table 9, or Table 10 to confirm that the specific configuration is scan eligible. In these configurations you can run an impedance check on the Controller App prior to entering MRI Mode to determine the impedances on each Lead Contact and confirm the configuration. See the “*Check Impedances on the Controller App*” section of this manual for instructions on how to check impedances using the Controller App. 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: *When scan eligible Medtronic Leads are used in a Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 System, impedance values for Contacts 5, 6, 7, and 8 of each Stimulator Port may be out of range (high). The “Impedances Out of Range” error message may display on the Controller App or Contacts 5, 6, 7, and 8 may display as not configured. 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, or Table 10 to confirm that the specific configuration is scan eligible.*

Review the “*Impedances Out of Range*” section under the “*Safety Information*” section of this manual before proceeding.

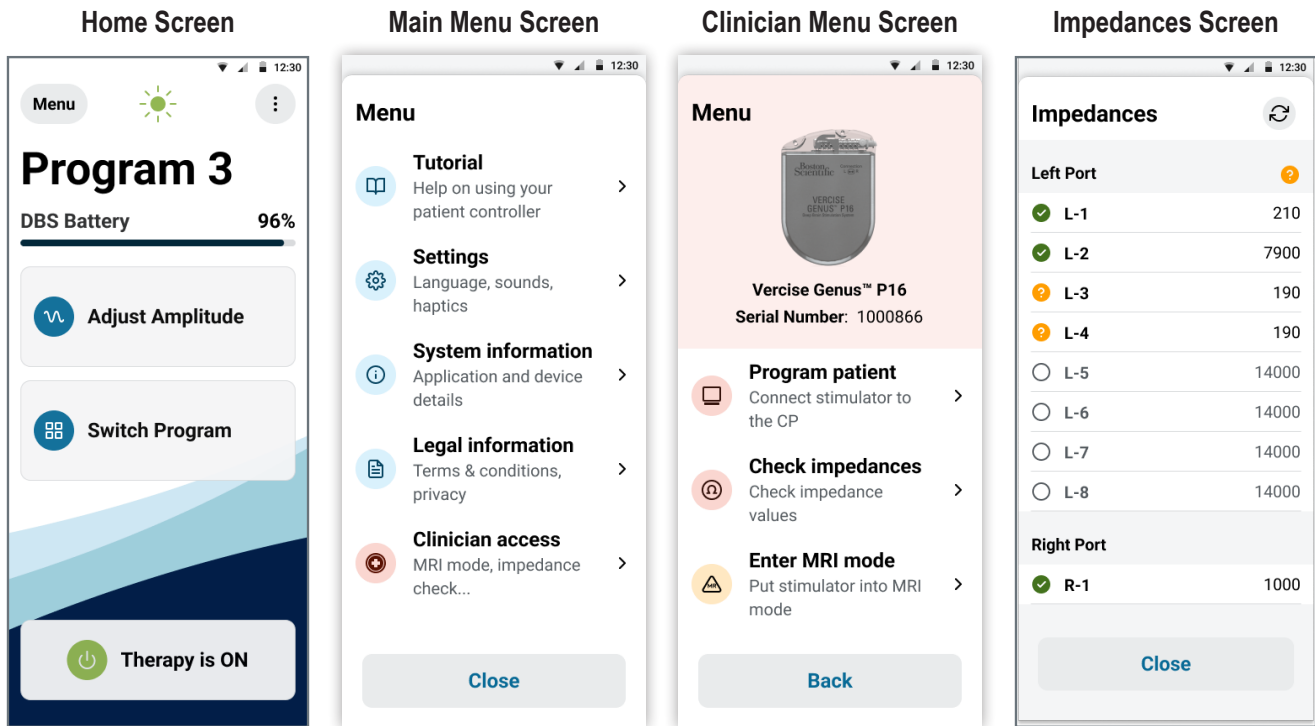
After your review, either select **Exit** to cancel the action or **Continue** to proceed with entering MRI Mode.

Warning: *An MRI scan is not recommended when the impedances are not within the acceptable range except when scanning a Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 System and Contacts 5, 6, 7, and 8 are out of range for the scan eligible Medtronic Leads. 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.*”*




 <p>Stimulator Error</p>	<p>If the system check fails due to a Stimulator error, MRI Mode cannot be entered. This error message may display when there is a communication error between the Controller App and the Stimulator.</p> <p>Select Exit to acknowledge the message and retry entering MRI Mode. If this error message immediately displays again, do not perform an MRI scan since MRI Mode cannot be entered. Advise the patient to contact the healthcare provider managing their DBS System or Boston Scientific. Contact your Boston Scientific representative or Boston Scientific Technical Support for assistance.</p> <p>Warning: <i>Do not perform an MRI scan if MRI Mode is not entered. Scanning under different conditions may result in patient injury or Stimulator malfunction.</i></p>
 <p>Communication Error</p>	<p>The Controller App cannot communicate with the Stimulator. Do not perform an MRI scan until the error is resolved.</p> <p>Move the mobile device used with the Controller App closer to the Stimulator. Advise the patient to refer to their <i>Information for Patients</i> manual for more information about the quality of wireless service and troubleshooting wireless coexistence issues.</p> <p>Additionally, you may refer to the <i>DBS Information for Prescribers IFU</i> for more information about the quality of wireless service and troubleshooting wireless coexistence issues. If the error persists, contact your Boston Scientific representative or Boston Scientific Technical Support for assistance.</p> <p>Warning: <i>Do not perform an MRI scan if MRI Mode is not entered. Scanning under different conditions may result in patient injury or Stimulator malfunction.</i></p>

Check Impedances on the Controller App

When an impedance measurement is taken, impedances are assessed between a Contact and the case (monopolar), and between pairs of Contacts (bipolar). Use the Controller App to check impedances.






To check impedances:

1. From the Home screen, tap the **Menu** icon .
2. Tap **Clinician access** .
3. Tap **Check impedances** . An impedance measurement is taken and the Impedances screen displays.

Note: When scan eligible Medtronic Leads are used in a Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 System, impedance values for Contacts 5, 6, 7, and 8 of each Stimulator Port may be out of range (high). The "Impedances Out of Range" error message may display on the Controller App or Contacts 5, 6, 7, and 8 may display as not configured (see figure above). This is to be expected for this configuration because Medtronic Leads have only 4 Contacts.

4. If needed, from the Impedances screen, tap  to remeasure impedances.

A green check mark icon  means that the system is measuring impedances that are within range (200 Ohms to 8000 Ohms). A yellow question mark icon  means that the system is measuring impedances that are out of range. If an electrode is not configured by the CP, a white circle icon  appears in front of the electrode.

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, mobile device with Controller App, External Trial Stimulator, ETS Adapter, O.R. Cables, Clinician Programmer, Pairing Magnet, Programming Wand, and accessories) 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 Mode⁴²

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).

42 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/smr/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 Neuroradiol. 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	<input type="checkbox"/>
Externalized Lead-Only System	<input type="checkbox"/>
Vercise Genus DBS Full System	<input type="checkbox"/>
Vercise Genus DBS Mixed M8 System	<input type="checkbox"/>
Vercise Genus DBS Mixed S8 System	<input type="checkbox"/>
Vercise Gevia DBS Full System	<input type="checkbox"/>

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 M8 System	Vercise Genus DBS Mixed S8 System	Vercise Gevia DBS Full System
Leads: Standard Leads - DB-2201							
Lead, 8 Contact, 30cm	DB-2201-30AC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	DB-2201-30DC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lead, 8 Contact, 45cm	DB-2201-45BC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	DB-2201-45DC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Leads: Directional Leads - DB-2202, DB-2203, DB-2204							
Vercise™ Cartesia™ Directional Lead, 8 Contact, 30cm	DB-2202-30	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vercise™ Cartesia™ Directional Lead, 8 Contact, 45cm	DB-2202-45	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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 M8 System	Vercise Genus DBS Mixed S8 System	Vercise Gevia DBS Full System
Vercise™ Cartesia™ X Directional Lead, 16 Contact (5x3+1), 30cm	DB-2203-30	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A	N/A	N/A
Vercise™ Cartesia™ X Directional Lead, 16 Contact (5x3+1), 45cm	DB-2203-45	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A	N/A	N/A
Vercise™ Cartesia™ HX Directional Lead, 16 Contact (4x3+4), 30cm	DB-2204-30	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A	N/A	N/A
Vercise™ Cartesia™ HX Directional Lead, 16 Contact (4x3+4), 45cm	DB-2204-45	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A	N/A	N/A
Leads: Medtronic Leads							
Medtronic 28cm 1.5mm Spaced 4 Contact Standard Lead	3387-28	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
	3387S-28	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Medtronic 40cm 1.5mm Spaced 4 Contact Standard Lead	3387-40	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
	3387S-40	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Medtronic 28cm 0.5mm Spaced 4 Contact Standard Lead	3389-28	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
	3389S-28	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Medtronic 40cm 0.5mm Spaced 4 Contact Standard Lead	3389-40	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
	3389S-40	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Leads: Abbott Leads							
Abbott Directional Lead, 30cm, 0.5mm Spacing	6170	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Abbott Directional Lead, 30cm, 1.5mm Spacing	6171	N/A	N/A	N/A	N/A	<input type="checkbox"/>	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 M8 System	Vercise Genus DBS Mixed S8 System	Vercise Gevia DBS Full System
Abbott Directional Lead, 40cm, 0.5mm Spacing	6172	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Abbott Directional Lead, 40cm, 1.5mm Spacing	6173	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Lead Extensions							
Lead Extension, 8 Contact, 55cm	NM-3138-55	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lead Extension, 2x8 Contact, 55cm	DB-3128-55B	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Lead Extension, 2x8 Contact, 95cm	DB-3128-95B	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Lead Extension, 2x8 Contact, 55cm	DB-3128-55	N/A	N/A	<input type="checkbox"/>	N/A	N/A	N/A
Lead Extension, 2x8 Contact, 95cm	DB-3128-95	N/A	N/A	<input type="checkbox"/>	N/A	N/A	N/A
Lead Extension, 16 Contact, 55cm	DB-3216-55	N/A	N/A	<input type="checkbox"/>	N/A	N/A	N/A
Lead Extension, 16 Contact, 95cm	DB-3216-95	N/A	N/A	<input type="checkbox"/>	N/A	N/A	N/A
Medtronic Lead Extensions							
Medtronic 40cm Lead Extension	37085-40	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Medtronic 60cm Lead Extension	37085-60	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Medtronic 95cm Lead Extension	37085-95	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Medtronic 40cm Lead Extension	37086-40	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Medtronic 60cm Lead Extension	37086-60	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	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 M8 System	Vercise Genus DBS Mixed S8 System	Vercise Gevia DBS Full System
Medtronic 95cm Lead Extension	37086-95	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Abbott Lead Extensions							
Abbott Flexible Extension, 50cm	6371	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Abbott Flexible Extension, 60cm	6372	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Adapters							
Vercise™ Adapter M8, 8 Contact, 15cm	DB-9218-15	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Vercise™ Adapter M8, 8 Contact, 55cm	DB-9218-55	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Vercise™ Adapter S8, 8 Contact, 15cm	DB-9208-15	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Vercise™ Adapter S8, 8 Contact, 55cm	DB-9208-55	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Precision™ Adapter S8, 8 Contact, 15cm	SC-9208-15	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Precision™ Adapter S8, 8 Contact, 55cm	SC-9208-55	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Stimulators							
Vercise Gevia™ 16 Contact Implantable Pulse Generator	DB-1200-S	N/A	N/A	N/A	N/A	N/A	<input type="checkbox"/>
Vercise Genus™ P8 Implantable Pulse Generator, 8 Contact	DB-1408	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Vercise Genus™ P16 Implantable Pulse Generator, 16 Contact	DB-1416	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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 M8 System	Vercise Genus DBS Mixed S8 System	Vercise Gevia DBS Full System
Vercise Genus™ P32 Implantable Pulse Generator, 32 Contact	DB-1432	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Vercise Genus™ R16 Implantable Pulse Generator, 16 Contact	DB-1216	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Vercise Genus™ R32 Implantable Pulse Generator, 32 Contact	DB-1232	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Fixation and Accessories							
SureTek Burr Hole Cover	Provided in SureTek™ Burr Hole Cover Kit, DB-4600-C, and SureTek™ Burr Hole Cover Spares Kit, DB-4605-C.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medtronic Stimloc Burr Hole Cover	924256	N/A	N/A	N/A	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Abbott Guardian Cranial Burr Hole Cover	Provided in Guardian™ Cranial Burr Hole Cover System, 6010	N/A	N/A	N/A	N/A	<input type="checkbox"/>	N/A
Lead Boot	Provided in Vercise™ Physician's Spare Kit 8 Contact Lead, DB-2500-C, Vercise™ Physician's Spare Kit 16 Contact Lead, DB-2501, and with DBS Leads (see above).	<input type="checkbox"/>	N/A	N/A	N/A	N/A	N/A
Silicone Suture Sleeves	Provided in Vercise™ Physician's Spare Kit 8 Contact Lead, DB-2500-C, and with DBS Leads (see above).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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 M8 System	Vercise Genus DBS Mixed S8 System	Vercise Gevia DBS Full System
Silicone Suture Sleeves	Provided in Vercise™ Physician's Spare Kit 16 Contact Lead, DB-2501, and with DBS Leads (see above).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A	N/A	N/A
Port Plugs	Provided in Precision Spectra™ IPG Port Plug, SC-4401, and IPG Kit, DB-1200-S.	N/A	N/A	N/A	N/A	N/A	<input type="checkbox"/>
Port Plugs	Provided in Precision Spectra™ IPG Port Plug, 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Port Plugs	Provided in Precision Spectra™ IPG Port Plug, SC-4401, IPG Kits, DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, and Lead Extension Kits, DB-3128-55, DB-3128-95, DB-3216-55, DB-3216-95.	N/A	N/A	<input type="checkbox"/>	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							
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C. DBS Implant Configuration and System Integrity (Check all that apply for Lead-Only System, Full System, Mixed M8 System, or Mixed S8 System)

Fully Implanted Lead-Only System

MRI Eligible		Not MRI Eligible	
<input type="checkbox"/>	Stimulator NOT implanted.	<input type="checkbox"/>	Stimulator implanted.
<input type="checkbox"/>	Lead Extensions NOT implanted.	<input type="checkbox"/>	Lead Extensions implanted.
<input type="checkbox"/>	Leads capped with Lead Boot.	<input type="checkbox"/>	Leads NOT capped with Lead Boot.
<input type="checkbox"/>	Lead(s) fully implanted under the scalp on the skull.	<input type="checkbox"/>	Lead(s) NOT fully implanted under the scalp on the skull.
<input type="checkbox"/>	Patient has up to two Leads implanted.	<input type="checkbox"/>	Patient has more than two Leads implanted.
<input type="checkbox"/>	NO evidence of fractured Leads.	<input type="checkbox"/>	Evidence of fractured Leads.

Externalized Lead-Only System

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

Vercise Genus DBS Full System, Vercise Genus DBS Mixed M8 System, or Vercise Genus DBS Mixed S8 System

MRI Eligible		Not MRI Eligible	
<input type="checkbox"/>	The Stimulator(s) must be implanted under the skin in a location near the clavicle (pectoral region) or in the abdomen.	<input type="checkbox"/>	The Stimulator(s) is NOT implanted near the clavicle (pectoral region) NOR implanted in the abdomen.
<input type="checkbox"/>	Patient has up to two Leads implanted.	<input type="checkbox"/>	Patient has more than two Leads implanted.
<input type="checkbox"/>	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.	<input type="checkbox"/>	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.
<input type="checkbox"/>	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.	<input type="checkbox"/>	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.
<input type="checkbox"/>	For a Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 System bilateral implant where two Leads, Lead Extensions, and Adapter(s) are connected to a single Stimulator, both Lead Extensions and, if applicable, Adapter(s) are routed on the same side of the body as the Stimulator.	<input type="checkbox"/>	For a Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 System bilateral implant where two Leads, Lead Extensions, and Adapter(s) are connected to a single Stimulator, both Lead Extensions and, if applicable, Adapter(s) are NOT routed on the same side of the body as the Stimulator.
<input type="checkbox"/>	For the Vercise Genus DBS Full System, Lead Extension(s) must be connected directly to the Stimulator. Adapters should not be used.	<input type="checkbox"/>	For the Vercise Genus DBS Full System, Lead Extension is NOT connected directly to Stimulator. Adapter is present.
<input type="checkbox"/>	For the Vercise Genus DBS Mixed M8 System or the Vercise Genus DBS Mixed S8 System, Adapter(s) M8 must be connected directly to Medtronic Lead Extension(s) and/or Adapter(s) S8 must be connected directly to Abbott Lead Extension(s).	<input type="checkbox"/>	For the Vercise Genus DBS Mixed M8 System or the Vercise Genus DBS Mixed S8 System, Adapter(s) M8 is NOT connected directly to Medtronic Lead Extension(s) and Adapter(s) S8 is NOT connected directly to Abbott Lead Extension(s).
<input type="checkbox"/>	The proximal end of each Boston Scientific Lead Extension(s) and/or Adapter(s) is terminated in a Stimulator Port.	<input type="checkbox"/>	The proximal end of each Boston Scientific Lead Extension(s) and/or Adapter(s) is NOT terminated in a Stimulator Port.
<input type="checkbox"/>	Unused Stimulator Ports have a Port Plug inserted.	<input type="checkbox"/>	Unused Stimulator Ports do NOT have a Port Plug inserted.
<input type="checkbox"/>	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.	<input type="checkbox"/>	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.
<input type="checkbox"/>	For the Vercise Genus DBS Mixed M8 System or the Vercise Genus DBS Mixed S8 System, Medtronic Lead Extension(s) has a Lead inserted and/or Abbott Lead Extension(s) has a Lead inserted (does NOT have a Port Plug inserted).	<input type="checkbox"/>	For the Vercise Genus DBS Mixed M8 System or the Vercise Genus DBS Mixed S8 System, Medtronic Lead Extension(s) does NOT have a Lead inserted and/or Abbott Lead Extension(s) does NOT have a Lead inserted (is unused or has a Port Plug inserted).
<input type="checkbox"/>	A Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 System with an unused Boston Scientific Lead Extension Port HAS a Boston Scientific Port Plug inserted into the unused Boston Scientific Lead Extension Port.	<input type="checkbox"/>	A Vercise Genus DBS Mixed M8 System or Vercise Genus DBS Mixed S8 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.

MRI Eligible		Not MRI Eligible	
<input type="checkbox"/>	For the Vercise Genus DBS Mixed M8 System or the Vercise Genus DBS Mixed S8 System, the Medtronic Lead Extension and Adapter M8 length combinations do NOT include both a 95cm Medtronic Lead Extension (37085-95 or 37086-95) and a 55cm Adapter M8 (DB-9218-55).	<input type="checkbox"/>	For the Vercise Genus DBS Mixed M8 System or the Vercise Genus DBS Mixed S8 System, the Medtronic Lead Extension and Adapter M8 length combinations include both a 95cm Medtronic Lead Extension (37085-95 or 37086-95) and a 55cm Adapter M8 (DB-9218-55).
<input type="checkbox"/>	For the Vercise Genus DBS Mixed S8 System, Abbott Lead Extensions are connected to a 55cm Adapter S8 (DB-9208-55) when the Stimulator is implanted in the abdomen.	<input type="checkbox"/>	For the Vercise Genus DBS Mixed S8 System, Abbott Lead Extensions are NOT connected to a 55cm Adapter S8 (DB-9208-55) when the Stimulator is implanted in the abdomen.
<input type="checkbox"/>	For the Vercise Genus DBS Mixed S8 System, 50cm Abbott Lead Extensions (6371) are connected to a 15cm Adapter S8 (DB-9208-15) when the Stimulator is implanted near the clavicle (pectoral region).	<input type="checkbox"/>	For the Vercise Genus DBS Mixed S8 System, 50cm Abbott Lead Extensions (6371) are NOT connected to a 15cm Adapter S8 (DB-9208-15) when the Stimulator is implanted near the clavicle (pectoral region).
<input type="checkbox"/>	For the Vercise Genus DBS Mixed M8 System, Vercise Adapter S8 is NOT implanted. ⁴³	<input type="checkbox"/>	For the Vercise Genus DBS Mixed M8 System, Vercise Adapter S8 is implanted. ⁴³
<input type="checkbox"/>	No evidence of fractured or abandoned Leads or compromised Stimulator-Lead system integrity.	<input type="checkbox"/>	Evidence of fractured or abandoned Leads or compromised Stimulator-Lead system integrity.
<input type="checkbox"/>	For the Vercise Genus DBS Full System, the Vercise Genus DBS Mixed M8 System, or the Vercise Genus DBS Mixed S8 System, up to two Stimulators are implanted.	<input type="checkbox"/>	For the Vercise Genus DBS Full System, the Vercise Genus DBS Mixed M8 System, or the Vercise Genus DBS Mixed S8 System, more than two Stimulators are implanted.
<input type="checkbox"/>	If two Stimulators are implanted, a single Stimulator, Lead, Lead Extension, and, if applicable, Adapter is implanted on each side of the body.	<input type="checkbox"/>	If two Stimulators are implanted, more than one Stimulator, Lead, Lead Extension, or Adapter is implanted on each side of the body.
<input type="checkbox"/>	If two Stimulators are implanted, each Lead must be implanted on the same side of the body as the Lead Extension, Adapter, if applicable, and Stimulator to which it is connected.	<input type="checkbox"/>	If two Stimulators are implanted, each Lead is NOT implanted on the same side of the body as the Lead Extension, Adapter, if applicable, and Stimulator to which it is connected.
<input type="checkbox"/>	If two Stimulators are implanted, Lead Extension(s) DB-3128-55, DB-3128-55B, DB-3128-95, DB-3128-95B, DB-3216-55, or DB-3216-95 is NOT implanted.	<input type="checkbox"/>	If two Stimulators are implanted, Lead Extension(s) DB-3128-55, DB-3128-55B, DB-3128-95, DB-3128-95B, DB-3216-55, or DB-3216-95 is implanted.
<input type="checkbox"/>	If two Stimulators are implanted, Lead(s) DB-2203-30, DB-2203-45, DB-2204-30, or DB-2204-45 is NOT implanted.	<input type="checkbox"/>	If two Stimulators are implanted, Lead(s) DB-2203-30, DB-2203-45, DB-2204-30, or DB-2204-45 is implanted.

⁴³ A patient with Vercise Adapter M8 and Vercise Adapter S8 implanted is considered to have a Vercise Genus DBS Mixed S8 System. For patients with Vercise Adapter M8 and Vercise Adapter S8 implanted, see information pertaining to the Vercise Genus DBS Mixed S8 System.

Vercise Gevia DBS Full System

MRI Eligible		Not MRI Eligible	
<input type="checkbox"/>	The Stimulator must be implanted under the skin in a location near the clavicle (pectoral region).	<input type="checkbox"/>	The Stimulator is NOT implanted near the clavicle (pectoral region).
<input type="checkbox"/>	The Stimulator must be implanted on the same side of the body as the implanted Lead Extension(s).	<input type="checkbox"/>	The Stimulator is NOT implanted on the same side of the body as the implanted Lead Extension(s).
<input type="checkbox"/>	Patient has up to two Leads implanted.	<input type="checkbox"/>	Patient has more than two Leads implanted.
<input type="checkbox"/>	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.	<input type="checkbox"/>	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.
<input type="checkbox"/>	Lead Extensions directly connected to Stimulator. No Adapters present.	<input type="checkbox"/>	Lead Extension NOT directly connected to Stimulator. Adapter is present.
<input type="checkbox"/>	Unused Stimulator Ports have a Port Plug inserted.	<input type="checkbox"/>	Unused Stimulator Ports do NOT have a Port Plug inserted.
<input type="checkbox"/>	The 8 Contact Lead Extension, NM-3138-55, has a Lead inserted (does NOT have a Port Plug inserted).	<input type="checkbox"/>	The 8 Contact Lead Extension, NM-3138-55, does NOT have a Lead inserted (HAS a Port Plug inserted).
<input type="checkbox"/>	No evidence of fractured or abandoned Leads or compromised Stimulator-Lead system integrity.	<input type="checkbox"/>	Evidence of fractured or abandoned Leads or compromised Stimulator-Lead system integrity.
<input type="checkbox"/>	Single Stimulator is implanted.	<input type="checkbox"/>	More than one Stimulator is implanted.
<input type="checkbox"/>	When Vercise Gevia DBS System is implanted, DB-2201 or DB-2202 Leads with NM-3138-55 Lead Extensions are implanted.	<input type="checkbox"/>	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 M8 System, or Mixed S8 System only):

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

- Remote Control or mobile device with Controller App
- Charger (if implanted with a rechargeable IPG)
- Their most up to date Patient Implant Card

In addition, the following are required:

- The rechargeable Stimulator must be fully charged before the MRI scan.
 - Stimulator battery level on the Remote Control must be at three bars.
 - Stimulator battery level on the Controller App must be blue.
- MRI Mode must be enabled on the Stimulator using the Remote Control or Controller App before performing an MRI scan.

Warning: *The Charger, Remote Control, and mobile device used with the Controller App 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 20. Lead-Only Conditions and Methods to Determine Eligibility	
Condition for Scanning	Suggested Methods to Determine Eligibility
<p>The patient is implanted with a fully implanted or externalized Leads-Only configuration whose components are listed in Table 2.</p> <p>Note: This step does not need to be completed if the MRI Patient Eligibility Form (Appendix A) is already complete.</p>	<p><input type="checkbox"/> Check patient records and ensure that the model numbers of the implanted components match the model numbers listed in Table 2 of this manual.</p> <p>OR</p> <p><input type="checkbox"/> 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.</p>
<p>The patient's DBS System meets the Lead-Only System configuration requirements listed in Table 3.</p> <p>Note: This step does not need to be completed if the MRI Patient Eligibility Form (Appendix A) is already complete.</p>	<p><input type="checkbox"/> Check patient records and ensure that the system configuration meets the requirements listed Table 3 of this manual.</p> <p>OR</p> <p><input type="checkbox"/> 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.</p>
<p>MRI systems that meet the following criteria:</p> <ul style="list-style-type: none"> • MRI magnet strength of 1.5 Tesla (T) only, in a horizontal closed bore system (no open-sided, vertical-field, standing). 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). 	<p><input type="checkbox"/> Check the technical specifications of the MRI scanner.</p>
<p>MRI coil setup:</p> <ul style="list-style-type: none"> • 1.5T Transmit coil: <ul style="list-style-type: none"> ○ 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. 	<p><input type="checkbox"/> Check the technical specifications of the MRI head coil and/or body coil.</p>
<p>If using either full body or head transmit/receive coil (Circular Polarized (CP) Only) and patient is implanted with either DB-2201, DB-2202, DB-2203, or DB-2204 Leads, scan sequence throughout the scan must have B1+rms less than or equal to (\leq) 2.0 μT. The SAR⁴⁴ value must be less than or equal to (\leq) 0.1 W/kg.</p>	<p><input type="checkbox"/> Ensure the MRI scanner is operated at or below (\leq) B1+rms of 2.0 μT throughout the scan.</p> <p><input type="checkbox"/> Ensure the MRI scanner is operated at or below (\leq) whole body and head SAR of 0.1 W/kg.</p>
<p>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.</p>	<p><input type="checkbox"/> Check the active scan time on the MRI scanner.</p>
<p>Patient must be positioned in supine or prone position during the scan.</p>	<p><input type="checkbox"/> Continuously monitor the patient to ensure the patient is in the correct position during scan.</p>

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

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.	<input type="checkbox"/> 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 “ <i>Potential Interactions with MRI Environment</i> ” in the “ <i>Safety Information</i> ” section of this manual, or if an awake patient becomes unresponsive to questions.

Full System, Mixed M8 System, or Mixed S8 System Eligibility



Table 21. Full System, Mixed M8 System, or Mixed S8 System Conditions and Methods to Determine Eligibility	
Condition for Scanning	Suggested Methods to Determine Eligibility
<p>The patient is implanted with the DBS System comprised of components listed in:</p> <ul style="list-style-type: none"> • Table 4 for Vercise Genus DBS Full System • Table 5 for Vercise Genus DBS Mixed M8 System • Table 6 for Vercise Genus DBS Mixed S8 System <p>or</p> <ul style="list-style-type: none"> • Table 7 for Vercise Gevia DBS Full System. <p>Note: This step does not need to be completed if the MRI Patient Eligibility Form (Appendix A) is already complete.</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Check Patient Implant 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 M8 System, Table 6 for Vercise Genus DBS Mixed S8 System, or Table 7 for Vercise Gevia DBS Full System. <p>OR</p> <ul style="list-style-type: none"> <input type="checkbox"/> 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 M8 System, Table 6 for Vercise Genus DBS Mixed S8 System, or Table 7 for Vercise Gevia DBS Full System.
<p>The patient's DBS System meets the System configuration requirements listed in:</p> <ul style="list-style-type: none"> • Table 8 for Vercise Genus DBS Full System • Table 9 for Vercise Genus DBS Mixed M8 System • Table 10 for Vercise Genus DBS Mixed S8 System <p>or</p> <ul style="list-style-type: none"> • Table 11 for Vercise Gevia DBS Full System. <p>Note: This step does not need to be completed if the MRI Patient Eligibility Form (Appendix A) is already complete.</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Check Patient Implant 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 M8 System, Table 10 for Vercise Genus DBS Mixed S8 System, or Table 11 for Vercise Gevia DBS Full System. <p>OR</p> <ul style="list-style-type: none"> <input type="checkbox"/> 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 M8 System, Table 10 for Vercise Genus DBS Mixed S8 System, or Table 11 for Vercise Gevia DBS Full System.
<p>Rechargeable Stimulator is fully charged prior to the MRI scan.</p> <p>Note: The patient should bring the Charger and Remote Control or mobile device with Controller App to the MRI Center.</p> <p>Warning: The Charger, Remote Control, and mobile device used with the Controller App are MR Unsafe and must not be brought into the MRI scanner room.</p>	<ul style="list-style-type: none"> <input type="checkbox"/> For users of the Remote Control, ensure the Stimulator battery status on the Home screen displays three bars . <p>OR</p> <ul style="list-style-type: none"> <input type="checkbox"/> For users of the Controller App, ensure the DBS Battery status on the Home screen is blue .

Table 21. Full System, Mixed M8 System, or Mixed S8 System Conditions and Methods to Determine Eligibility




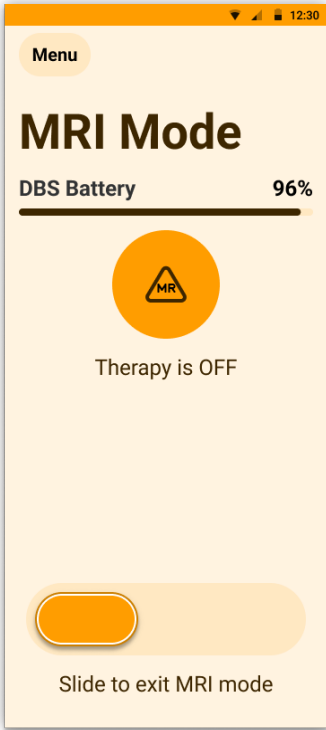
Condition for Scanning	Suggested Methods to Determine Eligibility
<p>MRI Mode is enabled on the Stimulator.</p> <p>Note: Stimulation is automatically turned OFF when MRI Mode is enabled. See the “MRI Mode on the Remote Control” or the “MRI Mode on the Controller App” section of this manual for more information on MRI Mode including instructions for enabling MRI Mode.</p>	<p><input type="checkbox"/> For users of the Remote Control, ensure the Home screen displays the MR Conditional Symbol  with the Stimulation turned OFF.</p>  <p>OR</p> <p><input type="checkbox"/> For users of the Controller App, ensure the MRI Mode screen displays the MR Conditional Symbol  and states “Therapy is OFF.”</p> 
<p>MRI systems that meet the following criteria:</p> <ul style="list-style-type: none"> • MRI magnet strength of 1.5 Tesla (T) only, in a horizontal closed bore system (no open-sided, vertical-field, standing). 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). 	<p><input type="checkbox"/> Check the technical specifications of the MRI scanner.</p>

Table 21. Full System, Mixed M8 System, or Mixed S8 System Conditions and Methods to Determine Eligibility	
Condition for Scanning	Suggested Methods to Determine Eligibility
<p>MRI coil setup:</p> <ul style="list-style-type: none"> • 1.5T Transmit coil: <ul style="list-style-type: none"> ○ 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. 	<input type="checkbox"/> Check the technical specifications of the MRI head coil, body coil, and/or lower extremity coil.
<p>Scan sequences must not exceed RF exposure limits (B1+rms/SAR).</p>	<input type="checkbox"/> Check anatomical location of the isocenter. <input type="checkbox"/> Determine implanted components by checking Patient Implant Card or patient record. <p>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.</p> <input type="checkbox"/> Determine the coil type: <ul style="list-style-type: none"> <input type="checkbox"/> Head transmit/receive (Circular Polarized (CP) Only) OR <input type="checkbox"/> Body transmit/receive coil (Circular Polarized (CP) Only) OR <input type="checkbox"/> Lower extremity transmit/receive coil (Circular Polarized (CP) Only) <input type="checkbox"/> Ensure the MRI scanner is operated at or below (\leq) appropriate RF exposure limits (B1+rms/SAR) based on isocenter, implanted components, and coil type (see Table 13, Table 14, Table 16, Table 18, and Table 19).
<p>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.</p>	<input type="checkbox"/> Check the active scan time on the MRI scanner.
<p>Patient must be positioned in supine or prone position during the scan.</p>	<input type="checkbox"/> Continuously monitor the patient to ensure the patient is in the correct position during scan.
<p>Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problems during the examination.</p>	<input type="checkbox"/> 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 an MRI scan.

MRI Safety Information					
<ul style="list-style-type: none"> • 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 ⁴⁵
All Leads	Fully Implanted or Externalized Leads-Only	Any (Full Body)	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 or Mixed M8 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 22
		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 Genus DBS System (Stimulator Model Numbers: DB-1408, DB-1416, DB-1432, DB-1216, and DB-1232)	Mixed S8 System	Head	Head Coil	≤ 2.0 μT	≤ 0.2 W/kg
		At or Above C2	Body Coil	≤ 1.4 μT	≤ 0.1 W/kg
		C3 through T10		≤ 1.6 μT	See Table 23
		T11 through Femur		≤ 3.2 μT	≤ 0.2 W/kg
		Lower Extremities (knee and below)		Normal Mode	Normal Mode
		Lower Extremities (knee and below)	Lower Extremity Coil	Normal Mode	Normal Mode
(Summary continues on next page)					

⁴⁵ Specific Absorption Rate (SAR) – radio frequency power absorbed per unit of mass (W/kg).

Vercise Gevia DBS System (Stimulator Model Number: DB-1200-S)	Full System with DB-2201 or DB-2202 Lead(s)	Head	Head Coil	$\leq 2.0 \mu\text{T}$	$\leq 0.1 \text{ W/kg}$
	Full System with DB-2201 Lead(s)	Above T5	Body Coil	$\leq 1.5 \mu\text{T}$	
		At or Below T5		$\leq 2.0 \mu\text{T}$	
	Full System with DB-2202 Lead(s)	Above T12		$\leq 1.2 \mu\text{T}$	
		At or Below T12		$\leq 2.0 \mu\text{T}$	
Additional Information					
<ul style="list-style-type: none"> MRI Mode must be enabled on the Stimulator prior to performing an MRI 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. 					

**Table 22. Maximum SAR for Zone B⁴⁶
(Vercise Genus DBS Full System or Vercise Genus DBS Mixed M8 System Scan Using a Body Transmit Coil)**

Landmark Span	Large Adult ⁴⁷	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

**Table 23. Maximum SAR for Zone B⁴⁶
(Vercise Genus DBS Mixed S8 System Scan Using a Body Transmit Coil)**

Landmark Span	Large Adult ⁴⁷	Adult
Upper Chest	0.1 W/kg	0.1 W/kg
Heart	0.2 W/kg	0.2 W/kg
Lower Chest	0.5 W/kg	0.4 W/kg

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

47 A large adult is defined as body mass greater than 119 kg (262 lb) or body mass index (BMI) greater than 36 kg/m² (lb/in² x 703).

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92438760-12 2024-12

