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ImageReady™ MRI Full Body Guidelines for WaveWriter Alpha™ and WaveWriter Alpha™ Prime Spinal Cord Stimulator Systems with Adapters

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

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Read this manual in its entirety before performing a full body scan on patients who are implanted with the WaveWriter Alpha and WaveWriter Alpha Prime Systems with ImageReady MRI Full Body Technology. Refer to the WaveWriter Alpha and WaveWriter Alpha Prime System product manuals for detailed information about non-MRI aspects of implantation, features, programming, and use of the components of the WaveWriter Alpha and WaveWriter Alpha Prime systems.

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.

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Additional Information

The products covered in this manual are components of a Boston Scientific System. For System information (such as indications and contraindications) and other device-specific information not included in this manual, refer to the appropriate Instructions for Use (IFU) for your System, as listed in your *Reference Guide*.

Boston Scientific recommends that implanting physicians read all product labeling prior to using our devices.

Labeling Symbols

For an explanation of labeling symbols, refer to the Labeling Symbols document

Warranty

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

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Introduction

About this Manual

This manual is intended for use by physicians and other healthcare professionals (HCPs) involved in managing patients with a WaveWriter Alpha™ and WaveWriter Alpha™ Prime Spinal Cord Stimulator Systems with ImageReady™ MRI Full Body Technology, as well as radiologists and other HCPs involved in performing magnetic resonance imaging (MRI) scans on such patients.

For more information on scanning MRI conditional Boston Scientific Leads, refer to the *ImageReady MRI Full Body Guidelines for WaveWriter Alpha and WaveWriter Alpha Prime Spinal Cord Stimulator Systems*.

References to WaveWriter Alpha Spinal Cord Stimulator (SCS) System include the following implantable pulse generators (IPG):

- WaveWriter Alpha IPG
- WaveWriter Alpha 16 IPG
- WaveWriter Alpha Prime IPG
- WaveWriter Alpha Prime 16 IPG

WaveWriter Alpha and WaveWriter Alpha 16 are rechargeable IPGs. References to the Charging System or charging process are applicable only when using a rechargeable SCS Stimulator.

WaveWriter Alpha Prime and WaveWriter Alpha Prime 16 are non-rechargeable IPGs.

Boston Scientific's ImageReady MRI Full Body Technology makes safe MRI scans possible. The WaveWriter Alpha SCS System with ImageReady MRI Full Body Technology is "MR Conditional" only when exposed to the MRI environment under the specific conditions defined in this manual.

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

Caution: *The instructions in this manual apply* ***only*** *to the following:*

- *On-label indications (epidural placement) of the* WaveWriter Alpha *Spinal Cord Stimulator Systems. Other configurations have not been evaluated.*
- *A complete and functional* WaveWriter Alpha *System composed only of components listed in "Table 1. Components that are eligible for WaveWriter Alpha Systems with ImageReady MRI Full Body Technology with Adapters" on page 4, including IPG, Leads, Adapters, and surgical accessories.*

This manual is a supplement to the WaveWriter Alpha System product manuals and focuses specifically on the use of 1.5T horizontal closed bore MRI systems for patients implanted with the WaveWriter Alpha System.

> **MRI** *procedures should be performed using ONLY a 1.5T horizontal closed bore MRI system. Do not use MRI systems that are open-sided, vertical-field, or are operating at other static magnetic field strengths. The risks of using these MRI systems have not been determined and could be significant.*

Obtain the latest MRI Guidelines

This manual may be updated periodically. Always obtain the latest version of this manual. Refer to the contact information at the back of this manual or go to www.bostonscientific.com/imageready.

Patient ID card

Advise the patient to bring the most up-to-date patient ID card to all MRI appointments. MRI personnel can then use the patient ID card to identify Boston Scientific as the manufacturer of the patient's Spinal Cord Stimulator System and to confirm the model number of the implanted components.

MR Conditional System Description

The following table lists model numbers of components that may comprise a Full Body MR Conditional WaveWriter Alpha Systems with Adapters.

Warning: *The WaveWriter Alpha SCS System with Adapters can be "Full Body MR Conditional" only when exposed to the MRI environment under the specific conditions defined in this manual.*

Note: *The system must be fully implanted and must include both an IPG, a Lead(s), and an Adapter(s), at a minimum, to be MR Conditional. The Lead(s) should be connected to the Adapter(s). No Lead Extensions and Splitters are allowed. Leads implanted without the IPG are not MR Conditional. Medtronic MRI Conditional Leads connected to Precision™ Adapters M8 and St. Jude (Abbott) MRI Conditional Leads connected to Precision™ Adapters S8 are Full Body MR conditional.*

Table 1. Components that are eligible for WaveWriter Alpha Systems with ImageReady MRI Full Body Technology with Adapters

Component	Description	Model Number(s)	MRI System Settings
IPG	WaveWriter Alpha IPG WaveWriter Alpha 16 IPG WaveWriter Alpha Prime IPG WaveWriter Alpha Prime 16 IPG	SC-1232 SC-1216 SC-1432 SC-1416	Follow the MRI System Settings used with the implanted Lead(s).
Adapters	Precision™ Adapter M8, 15 cm	SC-9218-15	Normal Operating Mode with B1+rms limits (See "Radiology" on page 6, MRI System Settings)
	Precision™ Adapter M8, 55 cm	SC-9218-55	
	Precision™ Adapter S8, 15 cm	SC-9208-15	
	Precision™ Adapter S8, 55 cm	SC-9208-55	
Medtronic Lead connected to Precision™ Adapter M8	Vectris™ SureScan™ MRI 1x8 subcompact Lead, 60 cm	977A160	
	Vectris SureScan MRI 1x8 subcompact Lead, 75 cm	977A175	
	Vectris SureScan MRI 1x8 subcompact Lead, 90 cm	977A190	
	Vectris SureScan MRI 1x8 compact Lead, 60 cm	977A260	
	Vectris SureScan MRI 1x8 compact Lead, 75 cm	977A275	
	Vectris SureScan MRI 1x8 compact Lead, 90 cm	977A290	
St. Jude (Abbott) Lead connected to Precision™ Adapter S8	Octrode™, 60 cm	3186	
	Penta™, 60 cm	3228	
Surgical Accessories	IPG Port Plugs	SC-4401	Surgical Accessories should follow the MRI System Settings used with the associated implanted Lead(s).
	Clik Anchor	SC-4316	
	Clik X Anchor	SC-4318	
	Clik™ X MRI Anchor	SC-4319	
	Silicone Suture Sleeves	N/A, included in kit	
	Med-A	SC-4320	

MR Conditions of Use

The WaveWriter Alpha System with ImageReady MRI Full Body Technology is MR Conditional. A patient with this system may be scanned only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction. The following Conditions of Use must be met in order for a patient with a WaveWriter Alpha System with ImageReady MRI Full Body Technology to undergo an MRI scan. Adherence to the Conditions of Use must be verified prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MRI scan.

SCS Implant System Conditions

Appendix A, "ImageReady MRI Full Body Patient Eligibility," contains a form that may be used by the physician managing the patient's SCS system to confirm the patient meets the SCS Implant System Conditions for MRI Scans as described in this manual.

1. The patient is implanted with a WaveWriter Alpha SCS System composed only of components listed in "Table 1. Components that are eligible for WaveWriter Alpha Systems with ImageReady MRI Full Body Technology with Adapters" on page 4 of this manual.

   Note: *Patient should not be implanted with Lead Extensions or Splitters.*

   The Precision Adapter M8, 55 cm (SC-9218-55) with 75cm or 90cm Medtronic Leads (977A175, 977A275, 977A190, and 977A290) was not tested for MRI conditionality for the WaveWriter Alpha System.

   When connecting to Adapter M8 or Adapter S8, use one 16 Contact Lead, one 8 Contact Lead, or two 8 Contact Leads. All Leads must be from the same manufacturer. Do not add Boston Scientific Leads. Having a combination of Leads from different manufacturers was not tested for MRI conditionality for the WaveWriter Alpha System.

   Do not use Adapters of different lengths (for example, one 15 cm and one 55 cm) when connecting two of the Adapter M8 or Adapter S8 to the WaveWriter Alpha System. Connecting Adapters of different lengths was not tested for MRI conditionality for this system.

2. The Lead implant location is epidural.
3. The patient has no abandoned Leads or IPGs (i.e. Leads or IPGs that are not connected to the functioning WaveWriter Alpha System).
4. The IPG is implanted in the upper buttock or the lower flank.
5. No evidence of fractured Leads or compromised IPG-Lead system integrity.

6. The patient has been informed of what to do or expect in preparation for their MRI scan:

    a. If the patient has a rechargeable IPG: Prior to arrival at the MRI Center, the patient should ensure that the IPG is fully charged (IPG charge shown as three (3) bars on the Remote Control or Therapy Controller App) for the MRI scan. The patient should bring the Charger (in case charging is necessary) to the MRI center. The Charger is MR Unsafe and must not be brought into the MRI Scanner Room.

    b. At the MRI Center, prior to entering the scanner room, the patient should enable MRI Mode using the Remote Control or Therapy Controller App. The Remote Control and mobile device with Therapy Controller App are MR Unsafe and must not be brought into the MRI Scanner Room.

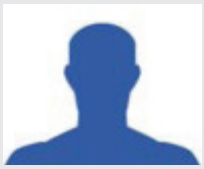
    c. The patient should be aware of the potential perceptible effects of undergoing MRI with an SCS System, which are as follows: vibration or tugging (moving) sensation in the IPG pocket, warming of the implanted system, and sensation of stimulation. The patient should be directed to immediately notify the MRI personnel if any of these effects become uncomfortable or intolerable. Refer to the “Potential Interactions with MRI Environment” in the Safety Information section of this manual for additional information.

Radiology

1. MRI systems must meet the following criteria:
    - MRI magnet strength of 1.5T only, in a horizontal closed bore system (no vertical-field, standing, or extremity systems).
    - Gradient systems with a maximum gradient slew rate per axis less than or equal to 200 T/m/s.
    - Maximum spatial field gradient less than or equal to 40 T/m (4000 gauss/cm).
2. MRI coil setup must meet the following specifications:
    - Transmit coil: 1.5T Full Body transmit/receive, Head transmit/receive, or Extremity transmit/receive. Circular Polarized (CP)[1] only.
    - Receive-only coil: Any type.
    - Hydrogen/proton imaging only.
3. Patient status and positioning:
    - The patient is in supine or prone position only.
    - The Lead implant location is epidural.
    - The IPG is implanted in the upper buttock or the lower flank.
    - The patient has enabled MRI Mode.

1 RF Quadrature Coils produce an RF field with circular polarization perpendicular to the static magnetic field.

4. MRI system settings:

	Full System with All Leads listed in Table 1
Head Transmit/ Receive Coil 	Normal Operating Mode limits for RF and Gradient Exposure: Head SAR must be (≤) 3.2 W/kg **Note:** *Whole Body SAR is not applicable for Head Transmit/Receive scanning.*
Full Body Transmit/ Receive Coil or Extremity Transmit/ Receive Coil or Receive-only Coil: Any type 	B1+rms ≤ 3.2 uT Whole body and Head SAR less than or equal to (≤) 0.4 W/kg

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

5. Monitoring:
   - The patient must be under continuous audio/visual monitoring during the MRI.
6. 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.

Safety Information

Warnings

The WaveWriter Alpha Systems with ImageReady MRI Full Body Technology have been shown through non-clinical testing to minimize the potential interactions with MRI when the appropriate conditions described in this manual are followed.

If an MRI scan is performed in a condition other than advised in the MR Conditions of Use section it may result in serious risks, such as tissue damage or severe patient injury.

Only use 1.5T Full Body transmit/receive, Head transmit/receive, or Extremity transmit/receive coils. Circular Polarized (CP) only. 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.

Gradient Systems: Do not use gradient systems producing gradient slew rates per axis greater than 200 T/m/s, because they have not been tested and could cause increased risk of induced stimulation (resulting in shocking or jolting sensations, discomfort, or pain for the patient) or warming of the neurostimulator.

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.

Impedance 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 system that may result in heating, magnetic field effects, induced stimulation, or damage to the device, requiring its replacement. Following the safety conditions designated in this manual will minimize potential interactions described in this section.

- **Heating** – The MRI fields may interact with the Spinal Cord Stimulator System causing warming of the IPG and Leads. This may cause discomfort, pain, or burns.
- **Mechanical effects:** The MRI magnetic field may exert force or torque on the Spinal Cord Stimulator System. Patients may feel a tugging or vibration sensation. Patients with recent implant incisions may feel surgical wound discomfort.
- **Induced stimulation:** An MRI may induce energy onto the implanted Leads, potentially causing unintended or uncomfortable sensations (e.g., tingling, shocking, or jolting).

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

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

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

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

External Devices: External components (i.e., External Trial Stimulator and OR Cables, Remote Control and accessories, mobile device with Therapy Controller App, and Battery Charger) are **MR Unsafe**. They must not be taken into any MR environment such as the MRI Scanner Room.

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

Limitations

- 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.
- Physicians should not prescribe MRI for patients undergoing trial neurostimulation and/or having systems that are not fully implanted.

Image Artifacts and Distortion

The WaveWriter Alpha Systems has minimal image distortion when the device is out of the field of view. Significant image distortion can result from the presence of the device within the field of view. Image artifacts and distortion resulting from the presence of the device and the Leads within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.

Careful choice of pulse sequence parameters and location of the imaging plane may minimize MR image artifacts. However, the reduction in image distortion obtained by adjustment of pulse sequence parameters will usually compromise signal-to-noise ratio.

The following general principles should be followed:

- Avoid using the body receive coil if possible. Use a local receive-only coil instead.
- Use imaging sequences with stronger gradients for both slice and read encoding directions. Use higher bandwidth for both radio-frequency pulse and data sampling.
- Choose an orientation for the read-out axis that minimizes the appearance of in- plane distortion.

- Use a shorter echo time for gradient echo technique, whenever possible.
- Be aware that the actual imaging slice shape can be curved in space due to the presence of the field disturbance of the neurostimulator.
- Identify the location of the implant in the patient, and when possible, orient all imaging slices away from the implanted neurostimulator.

Warnings

- If the MRI targeted image area is near the neurostimulator, it may be necessary to move the neurostimulator to obtain an image, or use alternate imaging techniques. MRI images may be severely distorted or image target areas can be completely blocked from view near the implanted neurostimulation system components, especially near the neurostimulator.
- If the neurostimulator is removed, remove the entire neurostimulation system. Do not remove the neurostimulator and leave the Lead system implanted as this can result in higher than expected Lead heating under MRI exposure. Testing has not been completed to demonstrate safety of this configuration under MRI exposure. Excessive heating can result in tissue damage or serious patient injury.

Adjusting for RF Level (B1+rms or SAR) Below Normal Mode[2]

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

Once a sequence has been optimized for reduced RF level, 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 or 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 or SAR level with the chosen parameters.*

- 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 or SAR levels without any modifications.

2 References

McRobbie, et al. “MRI from Picture to Proton.” 2007. Cambridge university press.
Faulkner W.. “New MRI Safety Labels & Devices, B1+rms as a Condition of Use.” SMRT Signals, Feb 2016 V5, Nol.
https://www.ismrm.org/smrt/E-Signals/2016FEBRUARY/eSig_5_1_hot_2.htm
Franceschi A.M. et al. “Optimized, Minimal Specific Absorption Rate MRI for High-Resolution Imaging in Patients with Implanted Deep Brain Stimulation Electrodes.”
AJNR Am J Neuroradio1. 2016 Nov; 37(11): 1996-2000.

- If the required pulse sequence exceeds the implant B1+rms or SAR limit, 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 or SAR without affecting image quality.
- If the ‘Low SAR’ option is unavailable or the B1+rms or SAR levels still exceed the manufacturer limits after setting the RF pulse type to ‘Low SAR,’ two additional options that can help reduce
    - 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 or SAR levels still exceed the implant limit, 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).

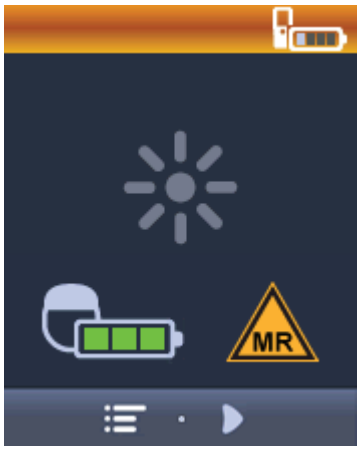
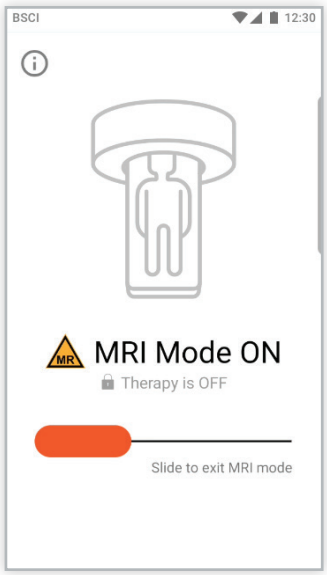
Patient Screening and Preparation

The following table summarizes the WaveWriter Alpha Systems/Patient-related Conditions of Use that must be met in order for an MR Conditional scan to be performed. For each condition or requirement, suggested methods to determine eligibility are listed. It is not required to use all suggested methods. Any or a combination of the suggested methods may be used.

Appendix A, "ImageReady MRI Full Body Patient Eligibility," contains a form that may be used by the physician managing the patient's SCS system to confirm the patient meets the SCS Implant System Conditions for MRI Scans as described in this manual.

Table 2. WaveWriter Alpha Systems/Patient Screening and Preparation Conditions

#	Condition for Scanning	Suggested Methods to Determine Eligibility
1.	The patient is implanted with a WaveWriter Alpha SCS System composed only of components listed in "Table 1. Components that are eligible for WaveWriter Alpha Systems with ImageReady MRI Full Body Technology with Adapters" on page 4 of this manual. **Note:** *Leads should be connected via Adapter into the IPG. Patient should not be implanted with Lead Extensions or Splitters.*	• Check patient records • Check the Patient ID card • Check model numbers in Table 1 of this manual or by contacting Boston Scientific Neuromodulation Technical Services. • Confirm with the physician responsible for managing the Patient's SCS System.
2.	The Lead implant location is epidural.	• Check patient records • Verify by X-Ray
3.	The patient has no abandoned Leads or IPGs (i.e. Leads or IPGs that are not connected to the functioning WaveWriter Alpha System).	• Check patient records • Verify by X-Ray
4.	The IPG is implanted in the upper buttock or the lower flank	• Check patient records • Examine the patient by palpation to determine the location of the IPG • Verify by X-Ray
5.	For rechargeable systems, IPG is fully charged prior to the MRI scan.	Make sure three bars are displayed at the top right of the Home screen on the Remote Control or Therapy Controller App. Remote Control:  Therapy Controller App: 

#	Condition for Scanning	Suggested Methods to Determine Eligibility
6.	MRI Mode is enabled on the Stimulator. **Note:** *Stimulation is automatically turned OFF when MRI Mode is enabled. Refer to MRI Mode Section for more information on MRI Mode including instructions for enabling MRI Mode.*	• Ensure that the Home screen of the Patient Remote Control or Therapy Controller App displays the MR Conditional symbol  with the Stimulation turned OFF. Remote Control:  Therapy Controller App: 

#	Condition for Scanning	Suggested Methods to Determine Eligibility
7.	No evidence can be found of fractured Leads or compromised IPG-Lead system integrity. **Note:** *An Impedance check is automatically performed for Stimulator-Lead integrity when MRI Mode is enabled on the device. Refer to MRI Mode Section for more information on MRI Mode.*	• Check patient records • Verify by X-Ray • Stimulator-Lead integrity or impedance check is automatically performed when MRI Mode is enabled. If impedances are not within the acceptable range the Remote Control or Therapy Controller App display an error message, stating "Impedance(s) out of range", before asking the user if they would like to continue with enabling MRI Mode. An MRI scan is not recommended when the impedances are not within the acceptable range. Patients should contact their physician to arrange an evaluation of the system **Note: Therapy Controller App.** *A gray electrode icon signifies unused ports on the IPG. A gray electrode icon on an unused port does not constitute fractured leads or compromised IPG-Lead system integrity.* **Remote Control**. *A red "X" signifies an unused port on the IPG. A red "X" on an unused port does not constitute fractured leads or compromised IPG-Lead system integrity.*
8.	The patient should be aware of the potential perceptible effects of undergoing MRI with an SCS System, which are as follows: vibration or tugging (moving) sensation in the IPG pocket, warming of the implanted system, and sensation of stimulation. Refer to the "Potential Interactions with MRI Environment" in the Safety Information section of this manual for additional information. Direct the patient to immediately notify the MRI personnel if any of these effects become uncomfortable or intolerable.	N/A.

MR System Preparation

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

Table 3. MR System Conditions

#	Condition for Scanning	Actions
1.	MRI systems that meet the following criteria: • MRI magnet strength of 1.5T only, in a horizontal closed bore system (no vertical-field, standing, or extremity systems). • Gradient systems with a maximum gradient slew rate per axis less than or equal to 200 T/m/s. • Maximum spatial field gradient less than or equal to 40 T/m (4000 gauss/cm).	Check the technical specifications of the MRI Scanner.
2.	MRI coil setup: • 1.5T Full Body transmit/receive coil, head transmit/receive coil, or Extremity transmit/receive coil • Receive only coil: Any type • Hydrogen/proton imaging only	Check the technical specifications of the MRI Coil.
3.	MRI System Settings **For Patients Implanted with WaveWriter Alpha System and Leads listed in Table 1:** If Head Transmit/Receive Coil is used, scanner operation at or below Normal Operating Mode limits for RF and Gradient Exposure: Head SAR must be ≤ 3.2 W/kg. If Full Body Transmit/Receive Coil or Extremity Transmit/Receive Coil is used, then the scan sequence throughout the scan must have B1+rms less than or equal to (≤) 3.2 µT., whole body and head SAR less than or equal to (≤) 0.4 W/kg.	Ensure MRI Scanner is operated at or below Normal Operating Mode. For Head Transmit/Receive Coil, ensure MRI Scanner is operated at or below Normal Operating Mode. For Full Body or Extremity Transmit/Receive Coil, ensure MI Scanner is operated at or below B1+rms of 3.2 µT., whole body and head SAR less than or equal to (≤) 0.4 W/kg.
4.	Patient must be positioned in supine or prone position during the scan.	Continuously monitor the patient to ensure the patient is in the correct position during scan.

Supervision

Note: *The patient should be in a psychological condition and mental state in which the patient is able to provide immediate feedback of any problems during the examination.*

Maintain visual and audio monitoring of the patient throughout the MRI examination. Verify that the patient is feeling normal and is responsive during and between each individual scan sequence of the MRI examination. Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any adverse effects listed in the Safety Information Section of this manual.

Post-MRI Examination Review

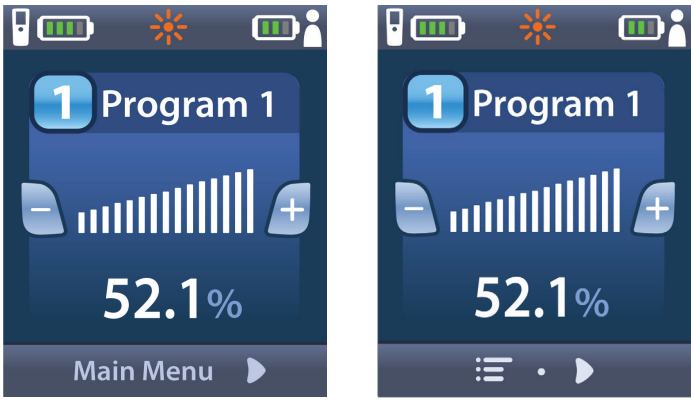
1. Verify that the patient has not experienced any adverse effects as a result of the MRI. The potential adverse effects are listed in the Safety Information Section of this manual. Contact Boston Scientific if the patient has experienced any adverse effects.
2. Instruct the patient to use the Remote Control or Therapy Controller App (outside of the scanner room) to turn on the neurostimulator. Verify that the neurostimulator is functional. If the patient cannot turn stimulation back on, or an error message displays on their device, instruct the patient to contact the clinician managing the patient's neurostimulator system.

MRI Mode Using the Remote Control

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

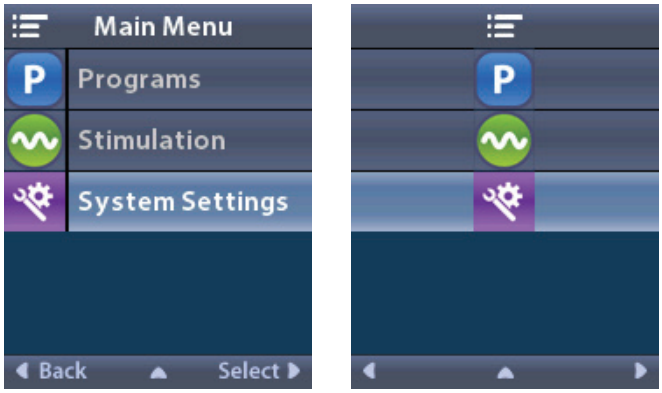
Entering MRI Mode

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

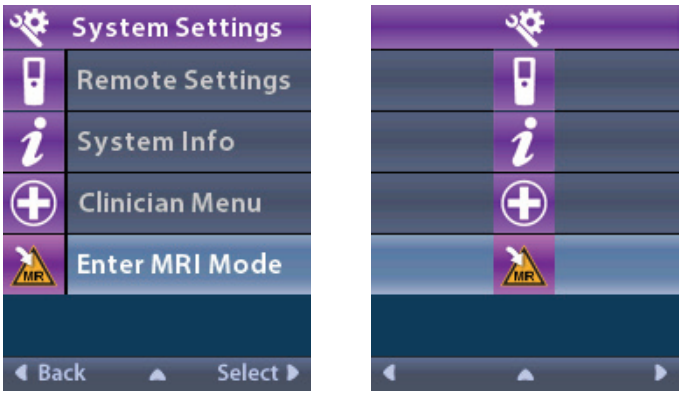


Note: *The Remote Control may display either a text screen in one of the languages provided or an iconic screen.*

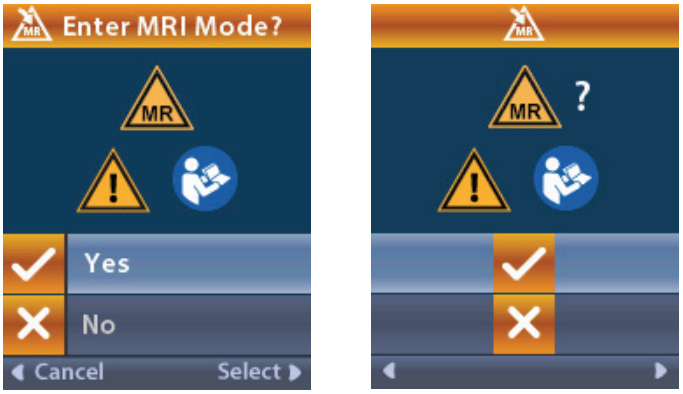
3. Press the Right Arrow button to navigate to the **Main Menu**.
4. Select **System Settings** .



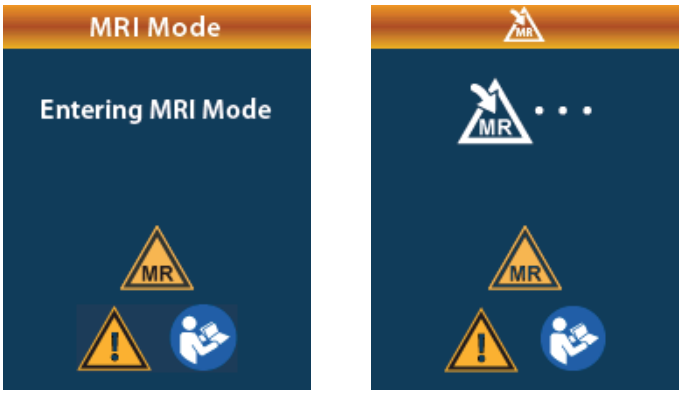
5. Select **Enter MRI Mode** .



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

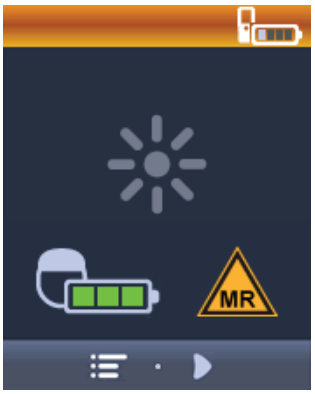


7. The System performs a series of checks before MRI Mode is enabled.



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.

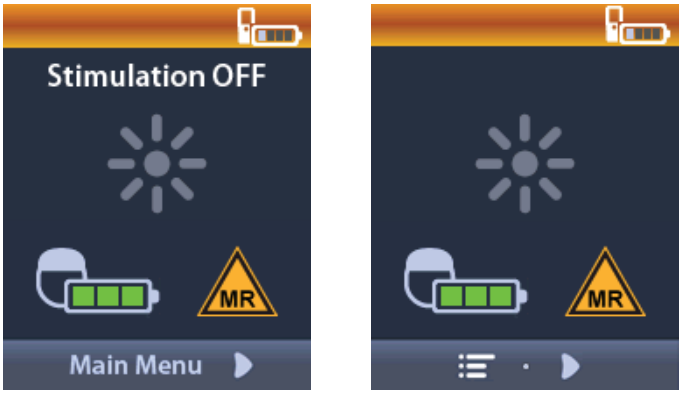


Exiting MRI Mode

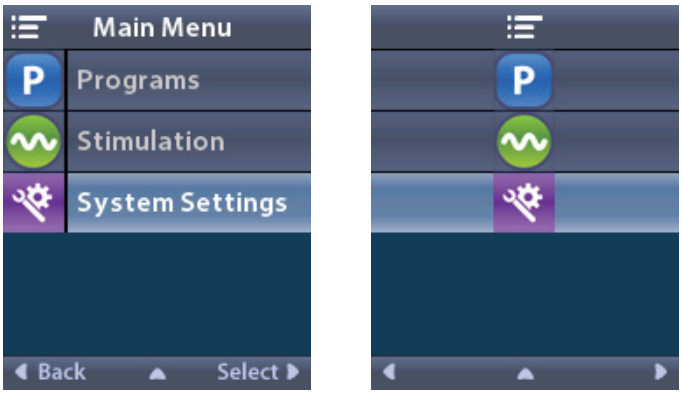
Upon completion of the MRI scan, the Remote Control must be used to disable the MRI Mode.

1. Unlock the Remote Control by pressing the **Lock/Unlock** button on the right side of the Remote Control.

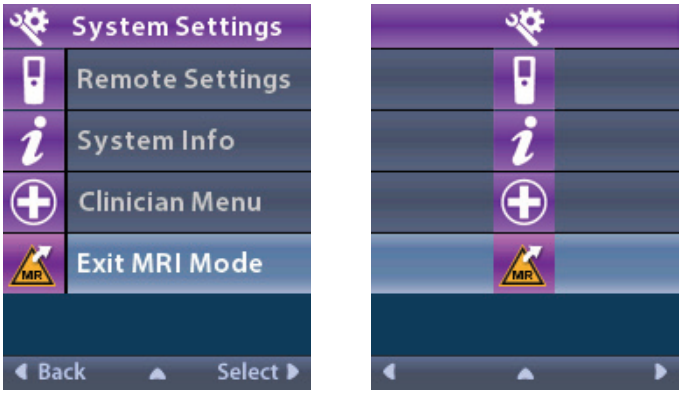
2. After unlocking the Remote Control, the Home screen appears.



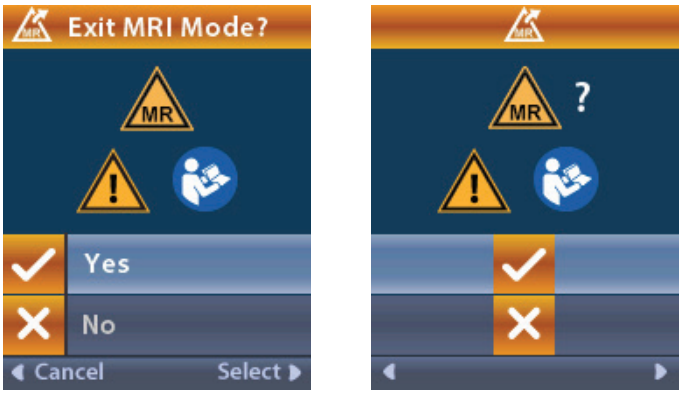
3. Press the Right Arrow button to navigate to the Main Menu.
4. Select **System Settings** .



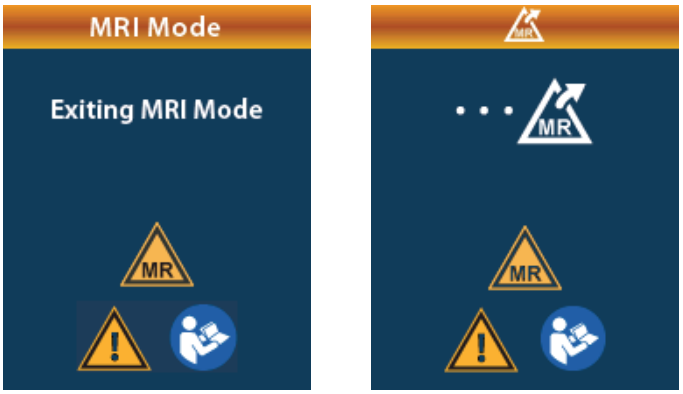
5. Select **Exit MRI Mode** .



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



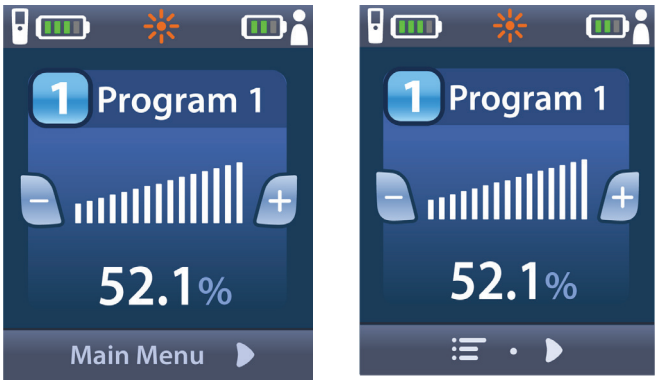
7. The Stimulator performs a series of checks before disabling MRI Mode.



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

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

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



MRI Mode Error Screens

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

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

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.

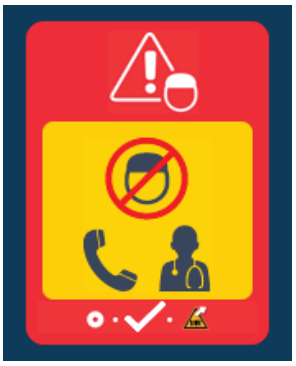
Warning: *Do not perform an MRI scan if MRI Mode is not enabled. Scanning under different conditions may result in patient injury or device malfunction.*

ERI or EOS Screens During MRI Mode

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 device.

The patient can disable MRI Mode:

1. Press to disable the MRI Mode.



2. Check the Remote Control to confirm that the Stimulator battery error message still appears. See “Stimulator Battery Low Screen Due to ERI or EOS (Non-Rechargeable Stimulators Only)” on page 22.

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

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

Charge Stimulator Now Screen (Rechargeable Stimulators only)

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

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

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

Charge Stimulator Now 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 button on the side panel of the Remote Control and confirm that the MR Conditional Symbol is displayed on the home screen.

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

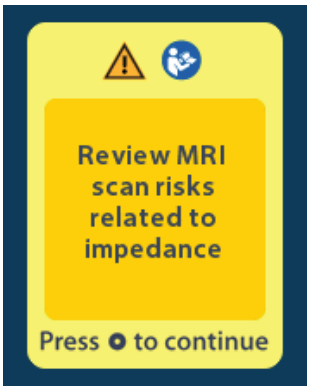
1. Press to disable the MRI Mode.
2. Instruct the patient to fully charge the Stimulator.
3. Check the Remote Control to confirm that the error message has cleared.
4. Enable MRI Mode by following instructions in the Enabling MRI Mode section of this manual.

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

Impedances Out of Range Screen

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

1. Press 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 *Impedance Out of Range* section under *Safety Information* before proceeding. Press continue.



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

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

Stimulator Error Screen

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

MRI Mode Using the Therapy Controller App

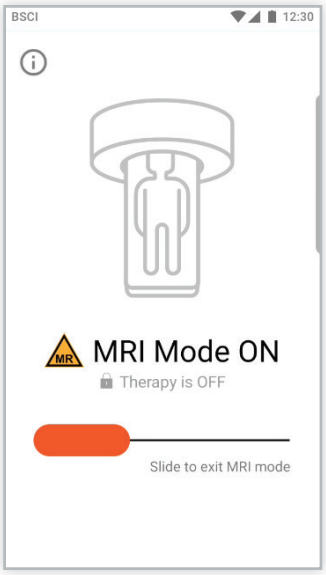
The mobile device with the mySCS™ GO Therapy Controller App must be used to enable MRI Mode on the Stimulator before performing an MRI scan on a patient.

Entering MRI Mode

Note: *Stimulation automatically turns OFF when MRI Mode is enabled.*

From the Home screen:

1. Tap ☰
2. Tap ⓘ
3. Find and tap to update MRI Mode to ON
4. Confirm the screen displays the **MRI Mode ON** message



5. Note: The Therapy Controller App performs a series of checks before entering MRI Mode. MRI Mode is not on until the screen displays **MRI Mode ON**. If the screen displays an error message instead, see “MRI Mode Error Messages” on page 30 for guidance.

Exiting MRI Mode

The Stimulator keeps the settings that were active before 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.

Follow the instructions on the screen to exit MRI Mode.

MRI Mode Error Messages

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

Message	Meaning
Impedances out of Range	Impedances are not within the acceptable range. Do not continue with the MRI scan. Review the MRI scan risks related to impedances out of range, see “Safety Information” on page 8. **Warning:** *An MRI scan is not recommended when the impedances are not within the acceptable range. Higher or lower than normal impedances could indicate compromised Stimulator-Lead integrity. Scanning under these conditions may increase the risk of potential adverse effects that are listed in “Safety Information” on page 8.*
Stimulator Error	A Stimulator error caused MRI Mode entry to fail. Do not proceed with the MRI scan. Instruct the patient to contact the healthcare provider managing their System or Boston Scientific Technical Support.
ERI or EOS During MRI Mode	The Stimulator has entered the Elective Replacement Indicator (ERI) or End of Service (EOS) period and cannot enter MRI Mode. Do not proceed with the MRI scan. Instruct the patient to contact the healthcare provider managing their System or Boston Scientific Technical Support.
Stimulator Battery Low	For Rechargeable Stimulators: The Stimulator battery is not fully charged. Fully charge the Stimulator battery before entering MRI Mode. **Warning:** *Always check the 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.* For Non-Rechargeable Stimulators: The Stimulator has entered the Elective Replacement Indicator (ERI) or End of Service (EOS) period and cannot enter MRI Mode. **Warning:** *Do not perform an MRI scan if MRI Mode is not enabled. Scanning under different conditions may result in patient injury or device malfunction.*
Charge Stimulator Now	For Rechargeable Stimulators: If this message appears after entering MRI Mode, either exit MRI Mode before charging the Stimulator or charge the Stimulator without exiting MRI Mode.

MRI Basic Concepts

MRI is a diagnostic tool that uses three types of magnetic and electromagnetic fields to image soft tissue in the body:

- A static magnetic field generated by a superconducting electromagnet coil, typically 1.5 Tesla (T) in strength.
- Gradient magnetic fields of much lower intensity, but with high rates of change over time. Three sets of gradient coils are used to create the gradient fields.
- A pulsed radio frequency (RF) field produced by transmission RF coils (approximately 64 MHz for 1.5 T Hydrogen/proton).

These fields may create physical forces or electrical currents that can affect the functioning of active implantable medical devices (AIMDs) such as implantable pulse generators and Leads. Therefore, only patients implanted with specific configurations of the WaveWriter Alpha Systems are eligible for MRI scans. Patients with a WaveWriter Alpha Sytem can undergo MRI scans *only* by complying with all of the MRI Conditions of Use outlined in this manual.

Glossary

Hertz (Hz) – a unit of frequency in Hertz or cycles per second. One Megahertz (MHz) is one million cycles per second.

MR Conditional[3] – an item with demonstrated safety in the MR environment within defined conditions. At a minimum, these address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.

MRI – Magnetic Resonance Imaging.

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).

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).

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).

Radio Frequency (RF) – high frequency electrical fields whose frequencies are in the range of 10,000 Hz and above. The RF used in the 1.5T MRI Scanner is ~64MHz.

Specific Absorption Rate (SAR)[3] – radiofrequency power absorbed per unit of mass (W/kg).
IEC 60601-2-33

Tesla (T) – the unit of measure of magnetic field strength. One T is equal to 10,000 Gauss.

W/kg – Watts per kilogram, a measure of the power that is absorbed per kilogram of tissue.

[3] ASTM F 2503-13, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment”

Appendix A

WaveWriter Alpha Systems ImageReady MRI Full Body Patient Eligibility with Adapters

This form provides information about the patient's implanted WaveWriter Alpha Spinal Cord Stimulator System and MRI scan eligibility. It may be provided to the radiologist to support the confirmation of the patient's scan.

- Prior to performing an MRI Scan, confirm that MRI mode is enabled using the Remote Control or Therapy Controller App
- Refer to www.IFU-BSCI.com for labeling and safety conditions

Patient Name:		Date:
Physician Name:		
Office Address:		
Phone:		

A. **MR Conditional WaveWriter Alpha Systems Information**	**Model #**	**MRI Full Body Eligible**	**Not MRI Eligible**
1. Implantable Pulse Generator (IPG)			
• WaveWriter Alpha 16 Contact IPG	SC-1216	☐	
• WaveWriter Alpha 32 Contact IPG	SC-1232	☐	
• WaveWriter Alpha Prime 16 Contact IPG	SC-1416	☐	
• WaveWriter Alpha Prime 32 Contact IPG	SC-1432	☐	
NOTE: *If you have another model number IPG, please refer to the labeling specific to your IPG model number.*			
2. Adapters			
• Precision™ Adapter M8, 15 cm	SC-9218-15	☐	
• Precision™ Adapter M8, 55 cm	SC-9218-55	☐	
• Precision™ Adapter S8, 15 cm	SC-9208-15	☐	
• Precision™ Adapter S8, 55 cm	SC-9208-55	☐	
• Precision™ M8 Trial Adapter, 15 cm	SC-9218-15E		☐
• Precision™ M8 Trial Adapter, 55 cm	SC-9218-55E		☐
• Precision™ S8 Trial Adapter, 15 cm	SC-9208-15E		☐
• Precision™ S8 Trial Adapter, 55 cm	SC-9208-55E		☐
3. Medtronic Lead connected to Precision™ Adapter M8			
• Vectris™ SureScan™ MRI 1x8 subcompact Lead, 60 cm	977A160	☐	
• Vectris SureScan MRI 1x8 subcompact Lead, 75 cm	977A175	☐	

- Vectris SureScan MRI 1x8 subcompact Lead, 90 cm 977A190 ☐
- Vectris SureScan MRI 1x8 compact Lead, 60 cm 977A260 ☐
- Vectris SureScan MRI 1x8 compact Lead, 75 cm 977A275 ☐
- Vectris SureScan MRI 1x8 compact Lead, 90 cm 977A290 ☐

4. St. Jude (Abbott) Lead connected to Precision™ Adapter S8

- Octrode™, 60 cm 3186 ☐
- Penta™, 60 cm 3228 ☐

5. Surgical Accessories (check all that apply)

- IPG Port Plugs SC-4401 ☐
- Clik X MRI Anchor SC-4319 ☐
- Clik X Anchor SC-4318 ☐
- Clik Anchor SC-4316 ☐
- Med-A SC-4320 ☐
- Silicone Suture Sleeves ☐
- Lead Extensions or Splitters: ☐
- Other:_____

Note: *Patient should not be implanted with Lead Extensions or Splitters.*

The Precision Adapter M8, 55 cm (SC-9218-55) with 75cm or 90cm Medtronic Leads (977A175, 977A275, 977A190, and 977A290) was not tested for MRI conditionality for the WaveWriter Alpha System.

When connecting to Adapter M8 or Adapter S8, use one 16 Contact Lead, one 8 Contact Lead, or two 8 Contact Leads. All Leads must be from the same manufacturer. Do not add Boston Scientific Leads. Having a combination of Leads from different manufacturers was not tested for MRI conditionality for the WaveWriter Alpha System.

Do not use Adapters of different lengths (for example, one 15 cm and one 55 cm) when connecting two of the Adapter M8 or Adapter S8 to the WaveWriter Alpha System. Connecting Adapters of different lengths was not tested for MRI conditionality for this system.

B. Patient Implant Configuration Information (ALL QUESTIONS MUST BE ANSWERED)

		MRI Full Body Eligible	**Not MRI Eligible**
1.	The Lead implant location is epidural.	Yes	No
2.	The IPG is implanted in the upper buttock or lower flank.	Yes	No
3.	Patient has no abandoned Leads or IPGs (Leads or IPGs that are not connected to the functioning WaveWriter Alpha System).	Yes	No
4.	No evidence can be found of fractured Leads or compromised IPG-Lead system integrity.	Yes	No

C.	**Instructions for the patient prior to the MRI Exam**	**MRI Full Body Eligible**	**Not MRI Eligible**
1.	MRI Mode must be enabled using the Therapy Controller App or Remote Control before performing an MRI scan. Patient must bring their mobile device with Therapy Controller App or Remote Control to the MRI Center .		
2.	For rechargeable IPGs, instruct the patient to fully charge their IPG (IPG charge shown as 3 bars on the Therapy Controller App or Remote Control) and bring the Charger to the MRI Center (in case charging is necessary) .		

Note: *The mobile device with Therapy Controller App, Remote Control, and Charger are MR Unsafe and must not be brought into the MRI Scanner Room.*

Boston Scientific

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