MRI Procedure Information

MR Conditional Eterna™ Spinal Cord Stimulation System

Clinician's Manual

Abbott

Contents

Introduction

Read the information in this manual before conducting an MRI scan on a patient with an implanted Abbott Medical MR Conditional Eterna™ spinal cord stimulation (SCS) system. This manual contains information about the components that comprise the MR Conditional system, applicable warnings and precautions related to the MR Conditional system, and the requirements that you must follow for the implanted neurostimulation system to be conditionally safe for MRI scans.

Refer to the appropriate clinician's manual or user's guide for non-MRI related information and a complete listing of device-specific indications, contraindications, warnings, precautions, potential adverse events, and directions for use. If you have any questions, contact Technical Support (page 10).

NOTE: Before conducting an MRI scan, always ensure that you are using the most recent version of the MRI procedures manual. Contact Technical Support or get the most recent version online at medical.abbott/manuals. For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 1. Symbols and definitions

Symbol	Definition
	Caution
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, 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.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Follow instructions for use on this website

Terms Used in This Document

This section contains definitions of some terms used in this document.

B1+rms. The root-mean-squared value of the MRI effective component of the RF magnetic (B1) field, measured in micro-Tesla (µT).

Circularly Polarized. Also known as quadrature mode. A type of RF coil operation mode.

Integrated Body Coil. The coil built-in to the MRI system that functions as both a transmit and receive coil, but can be used as a transmit-only coil in conjunction with receive-only coils.

IPG. Implantable pulse generator. Battery-powered device, implanted in the body, which delivers electrical pulses through the leads.

Clinician programmer. The clinician programmer is a handheld device that allows the clinician to prescribe and adjust therapies for the patient and place the system in MRI Mode.

Patient controller. The patient controller is a handheld device used to place the system into MRI Mode. The patient controller can also turn the stimulation on and off and adjust therapy.

Transmit/Receive extremity coil. A coil used to transmit and receive RF energy that is limited to an extremity only, for example, knee coil.

Transmit/Receive head coil. A coil used to transmit and receive RF energy that is limited to the head only.

Trial system. A portable and external device that allows the patient to test the therapy prior to an IPG being implanted.

SAR. Specific Absorption Rate. Radiofrequency power absorbed per unit of mass (W/kg).

Start Here - Eligibility Forms for Safe MRI Scans

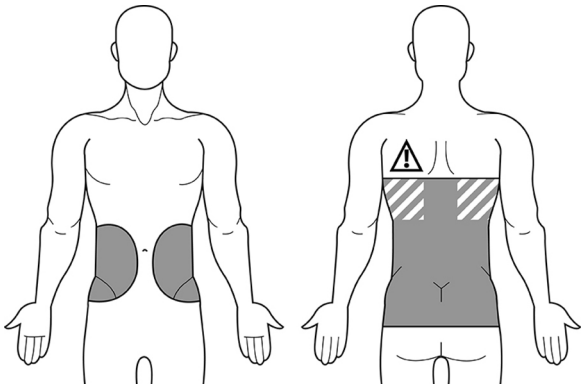
Complete all three eligibility checklists for safe MRI scans. The MR Conditional Eterna™ SCS system consists of an implantable pulse generator (IPG) and lead(s) implanted in eligible locations.

Step 1: Patient Eligibility Checklist

WARNING: If any response is "No," do not perform the MRI.

1. Is the patient implanted with the following implantable pulse generator (IPG) model? □ Yes □ No
   □ 32400
   WARNING: If the patient does not have an IPG, do not perform the MRI.

2. Is the IPG implanted in the gray region shown below? If unknown, ask the patient where the IPG or battery is located. □ Yes □ No



Approved IPG locations (shown in gray)

⚠ With lead model 3186, the hatched areas are **not** allowed IPG locations. With lead models 3228, 3219, 3292, 3189, the hatched areas are allowed IPG locations.

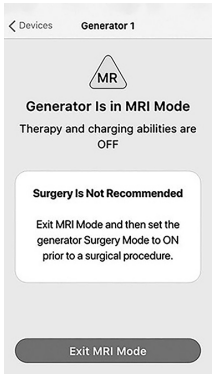
3. Is the patient implanted with only the following lead models? □ Yes □ No
   □ 3219 □ 3228 □ 3189 □ 3186 □ 3292

4. Are all lead tips located in the spinal epidural space between C1 and S2? □ Yes □ No

5. Have you confirmed that no implanted components have broken through the skin? □ Yes □ No

6. On the day of the scan, is the patient's temperature normal or below normal? □ Yes □ No

7. On the day of the scan, has the IPG been placed into MRI Mode? A phone or tablet connected to the patient's system must display the following screen. For instructions, see Using the Patient Controller to Confirm MRI Mode (page 6) and troubleshooting (page 10). □ Yes □ No
   WARNING: If an error persists and the following screen does not display, do not perform the MRI.



WARNING: All responses must be "Yes" to proceed to Step 2: MRI System Eligibility Checklist (page 3). If any response is "No," do not perform the MRI.

Step 2: MRI System Eligibility Checklist

1. Is the MRI scanner a 1.5T magnet?	□ Yes □ No
2. Is the scanner a cylindrical-bore, horizontal field magnet?	□ Yes □ No
3. Is the patient positioned supine, with hands by the sides?	□ Yes □ No
4. Will the scan time be limited to 30 minutes or less, with a wait time of 30 minutes if the limit is reached?	□ Yes □ No

WARNING: All responses must be "Yes" to proceed to Step 3: Operating Condition Checklist (page 4). You must complete the operating condition checklist before proceeding with the scan. If any response is "No," do not perform the MRI.

Step 3: Operating Condition Checklist

Answer the questions in this checklist. The lead model, scan location, and choice of RF coil may require limiting the RF power through monitoring the SAR or B1+rms. Personnel knowledgeable in MR safety should be involved to optimally plan the scan and monitor RF power levels during the scan. SAR or B1+rms must be displayed prior to starting the scan.

1. Are you scanning the head, leg (knee and below), or arm (elbow and below)?

   □ Yes — Proceed to question 2.

   □ No — Proceed to question 3.

2. Are you scanning the head, leg, or arm using a local transmit **AND** receive (T/R) coil?
   NOTE: If unsure, check "No" or contact the manufacturer to confirm the coil is a T/R coil.

   □ Yes — Scan in Normal Operating Mode with no additional RF power restrictions. **Checklist complete.**

   □ No — Proceed to question 3.

3. Are you scanning any body part with an integrated whole-body transmit and any receive coil?

   □ Yes — Proceed to question 4.

   □ No — This is not a supported MR coil type. Please use an integrated whole-body transmit with any receive coil, or start over from question 1.

4. Check the lead model(s) implanted in the patient. Use the most restrictive condition checked.

   □ 3228 — **Limit B1+rms ≤2.1 µT**. If B1+rms is not available, **Limit Whole Body SAR ≤0.5 W/kg**.

   □ 3189 — **Limit B1+rms ≤3.2 µT**. If B1+rms is not available, **Limit Whole Body SAR ≤0.6 W/kg**.

   □ 3186 — Scan in Normal Operating Mode with no additional RF power restrictions.

   □ 3219 — Scan in Normal Operating Mode with no additional RF power restrictions.

   □ 3292 — Scan in Normal Operating Mode with no additional RF power restrictions.

Checklist complete. If all patient eligibility criteria, MR system criteria, and operating conditions are met, proceed to Performing the Scan and Monitoring the Patient (page 9).

Warnings and Precautions

Read this section for warnings and precautions related to an MR Conditional neurostimulation system.

Warnings

Unapproved components. Do not perform an MRI scan on patients who have any components of a neurostimulation system that are unapproved for use in an MR environment. Serious patient injury could occur.

Abandoned devices. Do not perform an MRI scan on patients who have an incomplete neurostimulation system, where a lead is present without the IPG or disconnected from the system. Serious patient injury could occur.

Nonfunctional leads. Do not perform an MRI scan on patients when the “MRI is Not Advised. There may be a problem with the implanted lead(s).” message displays when attempting to enter MRI Mode on the patient controller. MRI scans of nonfunctional leads may result in excessive heating occurring at the location of the implanted lead electrodes and serious patient injury.

Location of implanted system. To meet the MR Conditional requirements, components must be implanted according to the approved locations specified by the MRI labeling. The MR Conditional leads must be implanted in the epidural space and routed subcutaneously to the IPG pocket. Two leads should travel in close proximity to one another from the IPG to the spine. Lead tips can be located at different spinal epidural levels. MRI scans of implants that are not located in approved locations can possibly result in increased unintended stimulation, excessive heating at the lead electrodes, and serious patient injury.

Skin erosion. Do not perform an MRI scan on patients who have any portion of their implanted system exposed due to skin erosion. The MRI scan may result in excessive heating of the system and serious patient injury.

Neurostimulation trial systems. Do not perform an MRI scan on patients who have an external neurostimulation trial system or any components that are not fully implanted. Serious patient injury could occur.

Multiple neurostimulation systems. Do not perform an MRI scan on patients who have multiple MR Conditional neurostimulation systems for pain (multiple IPGs for pain). MRI scans may result in excessive heating of the lead electrodes and serious patient injury.

Other implanted medical devices. Prior to an MRI examination, determine whether the patient has multiple medical device implants, either active medical device implants (such as deep brain stimulation systems, implantable cardiac defibrillators, pacemakers) or passive medical device implants (such as spinal hardware, stents). Of all medical device implants, the most restrictive MRI exposure requirements must be used. Do not conduct an MRI scan if any conditions or implants prohibit it, as serious patient injury could occur. If you are unclear what implants are present, perform an X-ray to determine the implant type and location.

Imaging with atoms other than hydrogen. Do not conduct MRI scans with nonproton scanning frequencies (such as 13C, 23Na, or 31P). Frequencies other than 64 MHz could cause device damage, excessive heating, and serious patient injury.

MRI system type. Only use 1.5T cylindrical-bore magnet, horizontal field orientation MRI systems. Do not scan with other MRI systems, such as 1.0T and 3.0T machines or vertical field orientation machines, as device damage, excessive heating of implanted components, and serious patient injury could occur.

Patient position. Do not scan with the patient in any prone positions or “superman” positions (where the patient's arm is raised above his or her head). Use of these positions could cause device damage and excessive heating of implanted components, which could result in serious patient injury.

Operating mode. Do not conduct MRI scans in first-level controlled or second-level controlled operating mode. These modes allow higher levels of RF energy and may cause excessive heating of implanted components, which could result in serious patient injury.

SAR or B1+rms limits. For scans requiring maximum SAR <2 W/kg or specific maximum B1+rms value, personnel knowledgeable in MR safety should be involved to optimally plan the scan and actively monitor SAR or B1+rms levels during the scan. Ensure the scanner displays the SAR or B1+rms value prior to starting the scan. Exceeding the SAR or B1+rms limits may cause excessive heating of implanted components, which could result in serious patient injury.

Transmit coils. Only use circularly polarized transmit coil designs. Do not scan with other transmit coil designs (for example, linear, phased-array, or saddle) as serious patient injury could occur.

Active scan time. The total active scan time must be limited to 30 minutes per session with a wait time of 30 minutes between sessions. Exceeding the active scan time limit increases the risk of excessive heating and serious patient injury.

Fever. Before an MRI scan, determine the patient's body temperature. If the patient has a fever, do not perform an MRI scan. 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 the MRI scan could result in excessive heating of implanted components and serious patient injury.

Precautions

External devices. Do not allow external control devices into the scanner magnet room, such as a programmer, controller, or charging system. Because these devices contain ferromagnetic material, they can be affected by the MRI magnet, may present a projectile hazard, and are considered MR Unsafe.

Electromagnetic interference (EMI). Some electrical equipment, such as an MRI machine, may generate enough EMI to interfere with the operation of the internal or external electronic components of a neurostimulation system if the equipment is too close to the system component. To mitigate the effects of possible EMI, increase the distance between the electrical equipment and the system component that is affected, and try performing the operation again.

Potential Adverse Events

The Eterna™ SCS system has been designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MRI environment:

- Lead electrode heating resulting in patient discomfort, tissue damage, or serious patient injury
- IPG heating resulting in tissue damage in the implant pocket or patient discomfort or both
- Induced currents on leads resulting in overstimulation or shocking sensations
- Damage to the IPG or leads causing the system to fail to deliver stimulation or causing the system to deliver overstimulation
- Damage to the functionality or mechanical integrity of the IPG resulting in the inability to communicate with the IPG
- Movement or vibration of the IPG or leads

Preparing for an MRI Scan

Before the MRI procedure, inform the patient to:

- Set the IPG to MRI Mode within a day of the scheduled procedure.
- Bring patient ID card (also referred to as patient implant card), patient controller, and charger.
- Recharge the IPG, patient controller, and charger.
- Consult with the clinician who manages the neurostimulation system.

Before conducting an MRI scan, you must perform the following steps:

1. Fill out the Patient Eligibility Checklist (page 2) for safe MRI scans. All answers must be “Yes.” If any answer is “No,” do not perform the scan.

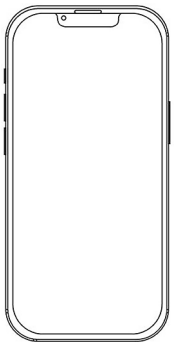
   NOTE: When used with the approved MR Conditional Eterna™ SCS system, Abbott Medical lead anchors and port plug are MR Conditional components. Multiple MR Conditional anchors may be implanted.

2. Fill out the MRI System Eligibility Checklist (page 3) for safe MRI scans. All answers must be “Yes.” If any answer is “No,” do not perform the scan.
3. Fill out the Operating Condition Checklist (page 4) for safe MRI scans and determine whether any RF power restrictions apply.

Ensure the Neurostimulation System is in MRI Mode

MRI Mode is a special configuration of the implanted neurostimulation system that allows a patient to safely receive an MRI scan according to the conditions and requirements in this document. Before conducting an MRI scan, ensure that the patient’s neurostimulation system is in MRI Mode using the patient's handheld device: a patient controller.

Figure 1. Patient controller



CAUTION: Do not bring any external control devices, such as a programmer, controller, or charger (if applicable) into the scanner magnet room (Zone IV). Because these devices contain ferromagnetic material, they can be affected by the MRI magnet, may present a projectile hazard, and are considered MR Unsafe.

NOTE: If the patient did not bring the patient controller on the day of the MRI procedure, a clinician programmer can also be used by an authorized representative. After connecting to the IPG using the clinician programmer, an authorized representative can place the IPG in MRI Mode.

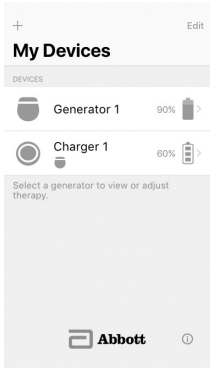
Using the Patient Controller to Confirm MRI Mode

To ensure that the patient’s Eterna™ SCS system is in MRI Mode using the patient controller:

1. Turn on the patient controller.
2. Tap the patient controller app icon on the Home screen to start the app. While the app starts up, you will see the Start-up screen, followed by the My Devices screen.

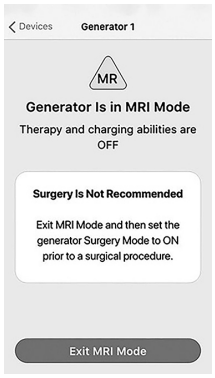
3. On the My Devices screen, tap the generator you want to connect with.
   NOTE:
   - In some cases, use of Bluetooth® wireless media devices (such as headphones or speakers) may prevent the patient controller from connecting to the IPG. Abbott Medical recommends disconnecting these accessories before you attempt to set the IPG mode using the patient controller.
   - The patient controller app times out after 3 minutes of inactivity.

Figure 2. My Devices screen



4. After the app connects with the IPG, the following screen appears if the IPG is in MRI Mode. If you do not see this screen, you must set the IPG to MRI Mode (page 7).

Figure 3. MRI Mode screen

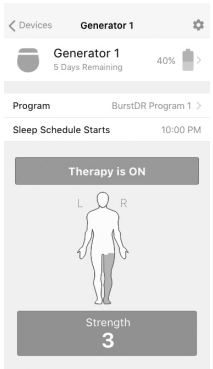


Setting the IPG to MRI Mode Using a Patient Controller

To set the IPG to MRI Mode:

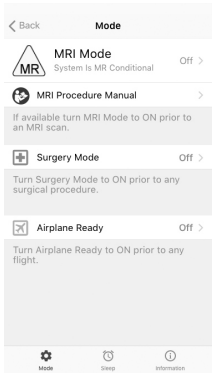
1. Ensure the patient controller is connected with the IPG. If MRI Mode is not enabled, the Therapy screen displays.

Figure 4. Therapy screen



2. Tap ⚙ on the Therapy screen to display the Mode screen.

Figure 5. Mode screen

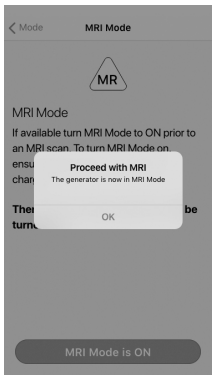


3. Tap **MRI Mode** to view the MRI Mode screen.
4. Tap the **Turn MRI Mode On** button.
5. When a “Set Generator to MRI Mode” message appears, tap **Continue**. Stimulation turns off, and the patient controller app checks the system for any issues.

   NOTE: If a warning message appears instead of a “Proceed with MRI” message, you cannot set the generator to MRI Mode and the patient cannot receive an MRI scan. See Troubleshooting (page 10) for more information. After troubleshooting, if you continue to receive a warning message, do not perform the MRI scan.

6. If the checks are successful, a “Proceed with MRI” message appears and the MRI Mode is on. Tap **OK**.

Figure 6. Proceed with MRI message

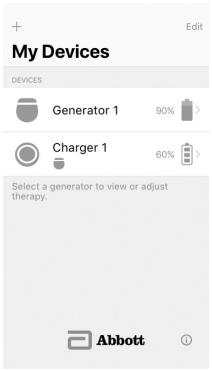


Using the Patient Controller to Confirm the System Components

To confirm that the patient's Eterna™ SCS system contains only MR Conditional components using the patient controller:

1. Turn on the patient controller.
2. Tap the patient controller app icon on the Home screen to start the app. While the app starts up, you will see the Start-up screen, followed by the My Devices screen.

Figure 7. Patient controller start-up screen (left) and My Devices screen (right)

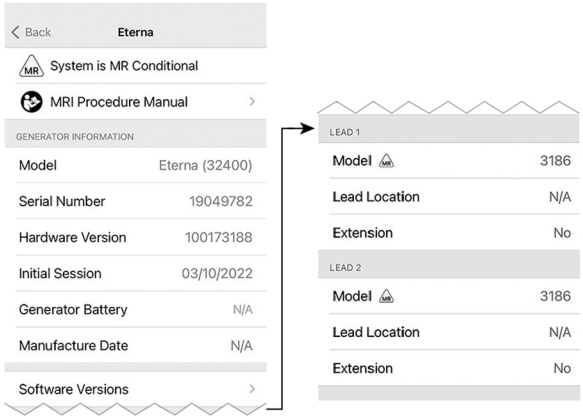


3. Tap ⓘ on the My Devices screen, and then tap the name of the generator you want to view to display the system information.

- If the patient is implanted with only MR Conditional components, the top of the screen displays “System is MR Conditional.”

- If the system contains components other than approved MR Conditional models, the screen displays “MRI is Not Permitted.”

Figure 8. System screen showing MR Conditional components



Scroll down to see bottom part of screen.

Performing the Scan and Monitoring the Patient

Before performing the scan, ensure that you have completed the three eligibility forms for safe MRI scans (patient eligibility checklist, the MR system checklist, and the operating condition checklist) and that all conditions are met.

While performing the scan, follow these guidelines:

- Leave any external control devices, such as a controller or charger, out of the scanner magnet room (Zone IV).
- If RF power must be limited based on the operating condition checklist, involve personnel knowledgeable in MR safety to actively monitor the SAR levels during the scan. SAR or B1+rms level must be displayed before starting the scan.
- Keep the duration of the total active scanning time to 30 minutes or less per session. Wait at least 30 minutes between scanning sessions.
- Instruct the patient to notify MR personnel immediately if any discomfort, pain, heating, stimulation, or vibration is experienced.
- During the MRI scan, visually and audibly monitor the patient, including verbal communication.
- When selecting the field of view and imaging parameters, consider that image distortion may occur around an implanted lead or IPG. Also consider these factors when interpreting the MRI images.

Disabling MRI Mode

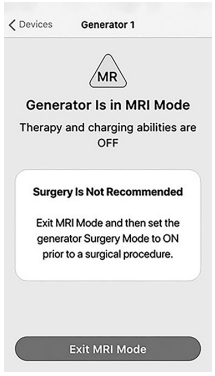
After you have finished scanning the patient and the patient is outside of the MRI environment, you can disable the MRI Mode using the patient controller.

NOTE: If the patient did not bring the patient controller the day of the MRI procedure, a clinician programmer that has been paired with the IPG can also be used. After connecting to the IPG using the clinician programmer, an authorized representative can disable MRI Mode by following steps similar to those for the patient controller.

To disable MRI Mode using the patient controller:

1. Start the patient controller app and connect with the IPG. You should see the following screen, showing that the generator is in MRI Mode.

Figure 9. MRI Mode screen



2. Tap **Exit MRI Mode**. The patient controller app disables MRI Mode. The Therapy screen appears, showing that stimulation therapy is off.
3. To start stimulation, tap **Therapy is OFF**.

Troubleshooting

The following tables show issues you may encounter using the patient controller. The first table identifies possible issues that you may encounter on the System screen while trying to access the MRI Mode screen. The second table shows patient controller messages or screens that you may see while setting MRI Mode before a scan. Follow the guidelines to help troubleshoot the issue.

NOTE:

- If you experience a situation other than one listed in the following table, contact the patient's physician or Technical Support (page 10).
- The clinician programmer displays messages similar to the patient controller. If an authorized representative is using the clinician programmer to help confirm or enable MRI Mode, the information in the following tables provides possible solutions to these issues.

Table 2. Possible causes and solutions for potential issues with accessing the MRI Mode screen

Problem	Possible Cause	Solution
MRI is Not Permitted is displayed instead of the **MRI Mode** option on the Mode screen.	Patient has a system component that is not MR Conditional.	Do not perform the MRI scan. Check the patient's identification card to identify implanted models.
Cannot access the **Mode** screen.	The IPG is not connected to the patient controller.	Try connecting to the IPG again.

Table 3. Troubleshooting messages for MRI Mode using a patient controller

Message	Solution
Turn On Bluetooth® Wireless Technology to Access Generator	Turn on Bluetooth® wireless technology on the patient controller if communication is disabled. 1. Return to the patient controller Home screen and tap **Settings**. 2. Tap **Bluetooth**, then tap the Bluetooth toggle button.
System Problem The system encountered a problem. Contact Abbott if this problem persists.	Try the action again. If you continue to encounter this problem, contact Technical Support.
Generator Unavailable Make sure the generator is in range and has enough battery power.	Make sure the generator is in range and has enough battery power; then try connecting to the IPG again.
Generator Not Connected Connect to the generator to adjust your therapy.	The connection has timed out. Reconnect to the IPG.
Connection Problem with the Generator	Try connecting to the IPG again. If you continue to encounter this problem, contact Technical Support.
Connection Lost A magnet was used to place the generator in the Bluetooth® wireless technology pairing mode.	Try connecting to the IPG again. If you continue to encounter this problem, contact Technical Support.
Connection Not Ready This device was not ready to find the generator.	Try connecting to the IPG again. If you continue to encounter this problem, contact Technical Support.
MRI is Not Advised There may be a problem with the implanted lead(s).	Do not perform the MRI scan. The IPG is not in MRI Mode.
MRI is Not Advised The generator battery voltage is too low.	Recharge the generator battery and retry. If problem persists, do not perform the MRI scan as the IPG is not in MRI Mode.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Reference Table for Safe MRI Scans

A patient implanted with an Eterna™ SCS system may be safely scanned at 1.5T under the following conditions.

WARNING: Failure to follow these conditions may result in serious injury to the patient.

MRI Scan Conditions

Parameter	Condition
MR Conditional	Yes
Eligible Abbott Devices	The MR Conditional Eterna™ SCS system consists of an implantable pulse generator (IPG) and lead(s) implanted in eligible locations. **WARNING: Do not scan if no IPG is implanted.** ▪ IPG (model **32400**) ▪ Lead(s) (models **3186**, **3189**, **3228**, **3219**, **3292**)
Eligible Implant Location	**WARNING: Lead tip and IPG must be located in the locations listed below.** ▪ Lead tip in the **spinal epidural space C1-S2** ▪ IPG in **upper buttock**, **flank**, **abdomen**, or **low back** NOTE: For mid-back IPG location, do not scan until IPG location is compared with the figure in the Patient Eligibility Checklist (page 2).
Device Configuration	Device must be placed in **MRI Mode** (page 6)**.**
MRI System	1.5T Cylindrical-bore magnet, horizontal field orientation
Maximum Spatial Field Gradient	3000 G/cm (30 T/m)
Maximum Slew Rate	200 T/m/s per axis
RF Coil Type	Transmit: Integrated Whole-Body Receive: Any
	Local Transmit/Receive Coils
Operating Mode/ RF Conditions	For lead **3228**: **B1+rms ≤2.1 µT**. If B1+rms is not reported, **limit Whole Body SAR ≤0.5 W/kg**. NOTE: If using local transmit/receive coil AND scanning head, knee and below, or elbow and below, then Normal Operating Mode with no additional restrictions can be used.
	For lead **3189**: **B1+rms ≤3.2 µT**. If B1+rms is not reported, **limit Whole Body SAR ≤0.6 W/kg**. NOTE: If using local transmit/receive coil AND scanning head, knee and below, or elbow and below, then Normal Operating Mode with no additional restrictions can be used.
	For leads **3186**, **3219**, **3292**: Normal Operating Mode with no additional restrictions
Scan Region	With Body Transmit and Any Receive Coil: Any body part or landmark is allowed
	With Local Transmit/Receive Coil: Head, arm (elbow and below), or leg (knee and below)
Patient Position	Supine, patient's arms must be at his or her sides.
Scan Duration and Wait Time	Maximum 30 minutes of active scan time, followed by 30-minute wait time if this limit is reached
Image Artifact	Image distortion may occur around the implanted lead or IPG.

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