MRI Procedure Information

MR Conditional Proclaim™ DRG Neurostimulation 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 Proclaim™ DRG (dorsal root ganglion) neurostimulation 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 11).

> 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 (triangle)	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 (circle, crossed)	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.
📖i medical.abbott/manuals	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 Proclaim™ DRG neurostimulation 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 only one neurostimulation system for the treatment of pain?	□ Yes □ No

2. Is the patient implanted with the following implantable pulse generator (IPG) model?
    □ 3664
    WARNING: If the patient does not have an IPG, do not perform the MRI.
	□ Yes □ No

3. Is the IPG implanted in the upper buttock, flank, abdomen, or low back? If unknown, ask the patient where the IPG or battery is located.	□ Yes □ No

4. Is the patient implanted with only the following lead models?
    □ MN10450-50 □ MN10450-50A
    NOTE: Up to four leads may be implanted. Extensions are considered MR Unsafe.
	□ Yes □ No

5. Are all lead tips located in the epidural space between T10 and S2?	□ Yes □ No
6. Have you confirmed that no implanted components have broken through the skin?	□ Yes □ No
7. On the day of the scan, is the patient's temperature normal or below normal?	□ Yes □ No
8. 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). **WARNING: If an error persists and the following screen does not display, do not perform the MRI.**	□ Yes □ No

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

Step 2: MRI System Eligibility Checklist

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

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

5. Are you using one of the following types of RF coils?
    □ Integrated whole-body transmit coil with any receive coil
    □ Local head or extremity transmit-receive coil
	□ Yes □ No

WARNING: All responses must be "Yes" to proceed to Step 3: Operating Condition Checklist (page 3). 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.
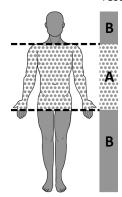
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1. Does the scan region lie within the dotted region below?

☐ Yes   When scanning in the dotted region (Region A), **Limit B1+rms ≤2.9 μT**. If B1+rms is not available, **Limit Whole Body SAR ≤0.7 W/kg**.*

☐ No   When scanning in the gray region (Region B), scan in Normal Operating Mode with no additional RF power restrictions.

Scan regions

- Dotted (Region A*)
  - **Limit B1+rms ≤2.9** μT
  - **OR limit Whole Body SAR ≤0.7 W/kg**

- Gray (Region B)
  - Normal Operating Mode with no additional RF power restrictions

* NOTE: When scanning the arm (elbow and below) with a local transmit-receive (T/R) coil, the scan can be performed 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. Implant location can be confirmed with X-ray imaging or by referring to the patient records. The MR Conditional leads must be implanted in the epidural space and routed subcutaneously to the IPG pocket. 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 are implanted with more than one MR Conditional neurostimulation system for the treatment of pain (from any manufacturer). 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.

MRI Mode patient instructions. A paired patient controller or clinician programmer is required to disable MRI Mode. The inability to disable MRI Mode would require device replacement surgery to restore therapy. Provide the following instructions to patients.

Prior to enabling MRI Mode:

- Upgrade their patient controller to the latest version of the patient controller app from the App Store.
- Disable automatic updates for the patient controller app and the device operating system software (such as Apple‡ iOS‡).
- Do not enable MRI Mode more than 24 hours prior to the MRI scan.

While in MRI Mode:

- Do not alter, damage, update, or lose their patient controller while in MRI Mode.
- Do not update, install, or delete the patient controller app while in MRI Mode.
- Do not delete the pairing between the IPG and the patient controller or delete the IPG from the Generators list while in MRI Mode.
- Do not update the device operating system while in MRI Mode.

Disabling MRI Mode. An inability to disable MRI Mode will occur if the patient controller is no longer paired to the IPG and there is no previously paired clinician programmer available or if the clinician programmer lost its pairing to the IPG. The inability to disable MRI Mode would require device replacement surgery to restore therapy.

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 Proclaim™ DRG neurostimulation 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, instruct the patient to:

- Contact the clinician managing their neurostimulation system.
- Set the IPG to MRI Mode within a day prior to the scheduled procedure.

    WARNING: Before attempting to place the device into MRI Mode, instruct the patient to:
    - **Upgrade their patient controller to the latest version of the patient controller app from the App Store.**
    - **Disable automatic updates for the patient controller app and the device operating system software (such as Apple‡ iOS‡).**
    - **Do not enable MRI Mode more than 24 hours prior to the MRI scan.**

- Bring the patient ID card (also referred to as patient implant card) and patient controller.
- Recharge the patient controller.

    WARNING: A paired patient controller or clinician programmer is required to disable MRI Mode. The inability to disable MRI Mode would require device replacement surgery to restore therapy. Provide the following instructions to patients:
    - **Do not alter, damage, update, or lose their patient controller while in MRI Mode.**
    - **Do not update, install, or delete the patient controller app while in MRI Mode.**
    - **Do not delete the pairing between the IPG and the patient controller or delete the IPG from the Generators list while in MRI Mode.**
    - **Do not update the device operating system while in MRI Mode.**

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 Proclaim™ DRG neurostimulation system, Abbott Medical lead anchors and port plugs are MR Conditional components. Multiple MR Conditional anchors and port plugs may be implanted.

2. Fill out the MRI System Eligibility Checklist (page 2) 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 3) 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 that has been paired with the IPG can also be used. After connecting to the IPG using the clinician programmer, an authorized representative can place the IPG in MRI Mode. For instructions to set an IPG in and out of MRI Mode using the clinician programmer, refer to the clinician programmer manual.

Using the Patient Controller to Confirm MRI Mode

To ensure that the patient's Proclaim™ DRG neurostimulation 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. The patient controller app automatically connects to the IPG. While the app starts up, you will see the Start-up screen.
   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 to MRI Mode using the patient controller.
   - The patient controller app times out after 3 minutes of inactivity.

Figure 2. Start-up screen

3. 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 the 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

1. Mode

2. Tap **Mode** to display the Mode screen.

Figure 5. Mode screen

3. Tap **MRI Mode** to view the MRI Mode screen.

Figure 6. MRI Mode screen

4. Tap the **MRI Mode** toggle 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 7. Proceed with MRI message

Using the Patient Controller to Confirm the System Components

To confirm that the patient's Proclaim™ DRG neurostimulation 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. The patient controller app automatically connects to the IPG. While the app starts up, you will see the Start-up screen.
   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 to MRI Mode using the patient controller.
   ▪ The patient controller app times out after 3 minutes of inactivity.

Figure 8. Start-up screen

3. After the app connects with the IPG, the Therapy screen displays.

Figure 9. Therapy screen

4. Tap ⓘ on the Therapy screen. A system screen opens showing information about the generator, including the model number.
▪ 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 10. System screen showing MR Conditional components

5. To view information about the implanted leads, such as model numbers, tap the Leads/Extensions icon at the bottom of the screen.

6. When you finish reviewing the system information, tap **Done**.

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, immediately use the patient controller to disable MRI Mode and restore therapy, with the help of the Abbott Medical representative or managing clinician, if needed.

> NOTE: If the patient did not bring the patient controller on 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. For instructions to set an IPG in and out of MRI Mode using the clinician programmer, refer to the clinician programmer manual.

> **WARNING: An inability to disable MRI Mode will occur if the patient controller is no longer paired to the IPG and there is no previously paired clinician programmer available or if the clinician programmer lost its pairing to the IPG. The inability to disable MRI Mode would require device replacement surgery to restore therapy.**

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 11. 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.

Figure 12. Therapy screen showing stimulation off

3. To start stimulation, tap **Therapy is OFF**.
4. If you are unable to use your patient controller to disable MRI Mode, contact the Abbott Medical representative or Technical Support immediately.

   NOTE: MRI Mode should be disabled as soon as possible following the MRI procedure.

5. Re-enable automatic updates for the app and install iOS software updates as they are made available by Apple, after verifying iOS software version compatibility with the patient controller app via www.NMmobiledevicesync.com/cp.

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 11).
- 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.
Cannot disable MRI Mode using the patient controller.	- Patient controller is lost, damaged, or altered while the generator is in MRI Mode. - Patient controller is locked (for example, forgotten Apple password) while the generator is in MRI Mode. - Patient controller app or device operating system software (such as iOS‡) is updated or deleted while the generator is in MRI Mode. - The pairing between the IPG and the patient controller is deleted. - The IPG is deleted from the Generators list on the patient controller app while in MRI Mode.	- Attempt to disable MRI Mode using a paired clinician programmer app. - Contact Abbott Medical representative or Technical Support immediately, as there may be additional troubleshooting steps to restore communication with the generator and disable MRI Mode.

Table 3. Troubleshooting messages for MRI Mode using the 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.	Do not perform the MRI scan. 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.

Reference Table for Safe MRI Scans

The following information serves as a reference table for safe MRI scans. For a step-through guide for determining eligibility, see the Eligibility Forms for Safe MRI Scans (page 2).

A patient implanted with a Proclaim™ DRG neurostimulation 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 Proclaim™ DRG neurostimulation system consists of an implantable pulse generator (IPG) and lead(s) implanted in eligible locations. **WARNING: Do not scan if no IPG is implanted. Do not scan when more than one neurostimulation system for the treatment of pain is implanted.** ▪ IPG (model **3664**) ▪ Lead(s) (models **MN10450-50**, **MN10450-50A**) 　NOTE: Up to four leads may be implanted. Extensions are considered MR Unsafe.
Eligible Implant Location	**WARNING: Lead tip and IPG must be located in the locations listed below.** ▪ Lead tip in the **epidural space T10–S2** ▪ IPG in **upper buttock**, **flank**, **abdomen**, or **low back**
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/ Scan Region	If the scan region lies between the shoulder and groin, **limit B1+rms ≤2.9 µT**. If B1+rms is not available, **limit Whole Body SAR ≤0.7 W/kg**.* * If scanning the arm (elbow and below) with a local transmit/receive (T/R) coil, the scan can be performed in Normal Operating Mode with no additional RF power restrictions. 　NOTE: Refer to the "Scan regions" figure in the Operating Condition Checklist (page 3).
	If the scan region lies above the shoulder or below the groin, then Normal Operating Mode with no additional restrictions can be used. 　NOTE: Refer to the "Scan regions" figure in the Operating Condition Checklist (page 3).
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.

6 0 0 2 4 8 0 1 8

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