MRI Procedure Information

For Abbott Medical MR Conditional Deep Brain Stimulation Systems

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 deep brain stimulation (DBS) 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 in order for the implanted DBS system to be conditionally safe for MRI scans.

Refer to the appropriate clinician's manual or user's guide for non-MRI related information. If you have any questions, contact Technical Support. See "Technical Support" (page 13).

> NOTE: Before conducting an MRI scan, always ensure that you are using the most recent version of these MRI procedures. 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 following symbols may be used in this document and on some of the products and packaging:

Table 1. Symbols and definitions

Symbol	Definition
	Caution, consult accompanying documents
	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.
	Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment

Warnings and Precautions

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

Abandoned devices. Do not perform an MRI scan on patients who have any abandoned neurostimulation devices, such as an implantable pulse generator (IPG), lead, extension, or adapter.

Nonfunctional leads or extensions. Do not perform an MRI scan on patients with broken or intermittent MR Conditional leads or extensions, or impedance measurements not within the impedance limits. MRI scans of patients with nonfunctional leads may result in higher than normal heating occurring at the location of the implanted lead electrodes.

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 and extensions must be fully implanted under the skin and routed on the same side of the body as the IPG pocket.

Routing multiple leads and extensions to the same IPG. If multiple MR Conditional leads and extensions are routed to the same IPG, they should be routed in close proximity on the same side of the body as the IPG. Nonadjacent leads and extensions can result in increased unintended stimulation or heating at the lead electrodes.

Partially implanted or exposed components. Do not perform an MRI scan on patients who have any portion of their system exposed due to partial implantation or skin erosion. The MRI scan may cause heating of the system, which could result in serious patient injury.

Multiple neurostimulation systems. If a patient is implanted with two DBS IPGs, ensure that both IPGs are set to MRI mode before scanning. If a patient is implanted with one lead-only system and one full system, follow the more restrictive MRI scanning requirements of the systems, and ensure that the IPG is set to MRI mode before scanning.

Other implanted medical devices. Scanning patients who have other MR Conditional devices is acceptable as long all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it. 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. Imaging with atoms other than hydrogen has not been tested and could result in serious patient injury.

Patient body temperature. Before an MRI scan, determine the patient's body temperature. If the patient has a fever, you should not perform an MRI scan.

Precautions

External devices. Do not allow external control devices, such as a patient controller or clinician programmer, into the scanner magnet room. 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.

Turning off stimulation before a scan. When you set a full system into MRI mode, stimulation turns off. Carefully consider a patient's underlying medical condition and disease symptoms before turning off a neurostimulation system when performing an MRI scan. Consult with the appropriate medical professional, such as a patient's DBS managing clinician, to determine if it is safe to turn off stimulation to conduct an MRI scan. Do not conduct an MRI scan if stimulation needs to stay on.

Potential Adverse Events

The Abbott Medical MR Conditional 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 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 unpleasant sensations or motor disturbances
- Damage to the IPGs, leads, or extensions 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 IPGs, leads, or extensions

Models and Implant Locations for MR Conditional DBS Systems

This manual contains different requirements for two types of fully implanted DBS systems:

- **Lead-only systems**, which consist of at least one implanted lead connected to a lead protection boot, as well as an optional cranial burr hole cover.
- **Full systems**, which consist of at least one implantable pulse generator (IPG), lead, and extension, as well as an optional cranial burr hole cover.

  WARNING: For an MR Conditional system, all implanted components must be approved MR Conditional models. If the implanted system contains any other components or models than what appears in the following tables, then the system is considered untested for an MRI environment.

Lead-Only System Components

All components listed must be implanted unless noted as "optional". Up to two leads, lead protection boots, and burr hole covers may be implanted. See "Full System Components" (page 3) if the patient has an IPG and extensions implanted.

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Table 2. Approved models and implant locations for an MR Conditional lead-only system for DBS

Component	Model	Location of Implanted Component
Lead	6170 directional lead, 30 cm, 0.5-mm spacing, black 6171 directional lead, 30 cm, 1.5-mm spacing, black 6172 directional lead, 40 cm, 0.5-mm spacing, black 6173 directional lead, 40 cm, 1.5-mm spacing, black	• Fully implanted in brain, routed under the scalp • Must be connected to a lead protection boot
Lead protection boot	Included in lead kit	• Fully implanted under the skin • Must be connected to a lead
Burr hole cover (optional)	6010 Guardian™ cranial burr hole cover system	Head

Full System Components

All components listed must be implanted unless noted as "optional." Up to two IPGs, leads, extensions, and burr hole covers may be implanted. See "Lead-Only System Components" (page 2) if the patient has a lead-only system implanted.

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Table 3. Approved models and implant locations for an MR Conditional full system for DBS

Component	Model	Location of Implanted Component
IPG*	6660 Infinity™ 5 IPG 6662 Medical Infinity™ 7 IPG	Pectoral, abdomen
Lead	6170 directional lead, 30 cm, 0.5-mm spacing, black 6171 directional lead, 30 cm, 1.5-mm spacing, black 6172 directional lead, 40 cm, 0.5-mm spacing, black 6173 directional lead, 40 cm, 1.5-mm spacing, black	• Fully implanted in brain, routed under the scalp and connected to an extension • May cross the head's midline
Extension	6371 flexible extension, 50 cm 6372 flexible extension, 60 cm	Head and neck, routed to the IPG on the same side of the body as the IPG
Burr hole cover (optional)	6010 Guardian™ cranial burr hole cover system	Head

* The IPG port plug associated with these models is also an MR Conditional component.

Confirming the MR Conditional Components

The following subsections provide information for confirming that a patient's DBS system contains MR Conditional components.

NOTE: Before the day of the MRI procedure, inform patients to bring their patient identification card or patient controller with them. If a patient does not have his or her system identification card or patient controller, consider other means of confirming the full system, such as referencing the patient's medical history or contacting Technical Support. See "Technical Support" (page 13).

Confirming the Lead-Only System

To confirm the lead-only system contains only MR Conditional components, follow these steps:

1. Identify the implanted components by referencing the patient's medical history or contact the patient's implanting physician or neurologist to provide the model numbers of the implanted leads.
2. Confirm that the model numbers of the implanted leads match what is shown in the table for lead-only systems in "Lead-Only System Components" (page 2).

Confirming the Full System Using a Patient Identification Card

To confirm that the patient's full system contains only MR Conditional components using the patient identification card, follow these steps:

1. Request the identification card from the patient.
2. Cross-reference the model numbers on the card with the model numbers of the MR Conditional components shown in the table for full systems in "Full System Components" (page 3).

Confirming the Full System Using a Patient Controller

To confirm that the patient's full system contains only MR Conditional components using the patient controller, follow these steps:

1. Turn on the patient controller by pressing the power button.
2. Tap the patient controller app icon on the Home screen to launch the app.
3. Do either of the following:
   - For patients with only one IPG, wait for the patient controller app to automatically connect to the IPG.
   - For patients with more than one IPG, tap the IPG with which you want to connect.

   NOTE: In some cases, use of Bluetooth® wireless technology 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.

   NOTE: The patient controller app times out after 3 minutes of inactivity.

4. After you connect to the IPG, you should see a screen similar to the following Therapy screen.

Figure 1. Therapy screen

5. Tap the information icon in the upper-right corner of the 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 the message "System is MR Conditional" (see the following figure).
   - If the system contains components other than approved MR Conditional models, the screen displays "MRI is Not Permitted."

Figure 2. System screen showing MR Conditional components

6. To view information about the implanted leads and extensions, such as model numbers, tap the Leads/Extensions icon at the bottom of the screen.
7. Cross-reference the model numbers on the controller screens with the model numbers of the MR Conditional components shown in the table for full systems in "Full System Components" (page 3).
8. When you are finished reviewing the system information, tap **Done**.
9. If the patient has more than one IPG, tap **< Generators** in the upper-left corner of the screen, tap the other IPG to select it, and then repeat the previous three steps to confirm that the components for the other implanted system are also MR Conditional.

Step 1: Complete the MRI Procedure Eligibility Checklist

Use this checklist to determine the eligibility of a patient with an implanted deep brain stimulation (DBS) system for an MRI scan. Do not perform an MRI scan if you answer "No" to any question. When you finish answering the questions, go to "Step 3: Set Up the MRI Equipment Based on the Scanning Requirements" (page 9).

1. **Is the patient's body temperature normal or below normal on the day of the scan?**

☐ Yes.	☐ No, patient has a fever. **STOP! DO NOT PERFORM MRI.**

2. **Does the patient have an MR Conditional lead or leads implanted?**

To identify system components, see "Confirming the MR Conditional Components" (page 3).

☐ Yes (check model or models that apply). ☐ 6170 ☐ 6171 ☐ 6172 ☐ 6173	☐ No. **STOP! DO NOT PERFORM MRI.**

3. **Is each lead connected to a lead protection boot *and* fully implanted under the skin?**

☐ N/A, patient has a full system. **-OR-** ☐ Yes.	☐ No. **STOP! DO NOT PERFORM MRI.**

4. **Does the patient have an MR Conditional IPG or IPGs implanted?**

To identify system components, see "Confirming the MR Conditional Components" (page 3).

☐ N/A, patient has a lead-only system. **-OR-** ☐ Yes (check model or models that apply). ☐ 6660 Infinity™ 5 IPG ☐ 6662 Infinity™ 7 IPG	☐ No. **STOP! DO NOT PERFORM MRI.**

5. **Does the patient have an MR Conditional extension or extensions implanted?**

To identify system components, see "Confirming the MR Conditional Components" (page 3).

☐ N/A, patient has a lead-only system. -OR- ☐ Yes (check model or models that apply). ☐ 6371 ☐ 6372	☐ No. **STOP! DO NOT PERFORM MRI.**

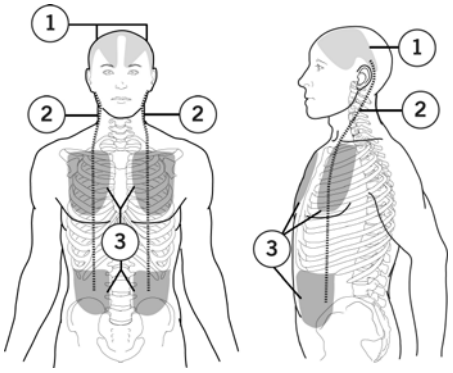
6. **Does the patient have only fully implanted, functional MR Conditional components?**

For more information, see "Warnings and Precautions" (page 1).

☐ Yes.	☐ No, one or more of the following conditions exist (check all that apply). ☐ Unapproved components ☐ Abandoned devices ☐ Nonfunctional leads or extensions ☐ Partially implanted or exposed components **STOP! DO NOT PERFORM MRI.**

7. **Are the components implanted only in the following approved zones?**
   - Zone 1, lead location: fully implanted in brain, routed under the scalp
   - Zones 2 and 3, extension location (full systems only): head and neck, routed along the same side of the body as the IPG
   - Zone 3, IPG location (full systems only): pectoral or abdomen

☐ Yes.



☐ No.

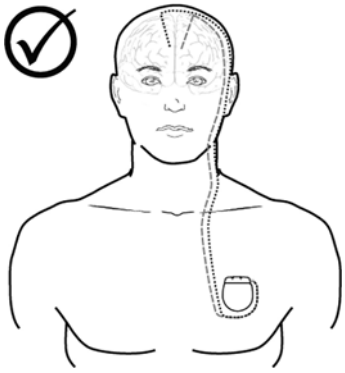
STOP! DO NOT PERFORM MRI.

8. **Are the leads and extensions routed correctly?**
   - **Correct (left image).** Leads connect to extensions that are both routed on the same side as the IPG or each lead connects to an extension that is routed on the same side as the IPG.
   - **Incorrect (right image).** Leads connect to extensions that are routed to an IPG on the opposite side of the body. In general, the routing pathway is incorrect if at least one extension is routed to an IPG on the opposite side of the body or each lead connects to an extension that is routed to an IPG on the opposite side of the body.

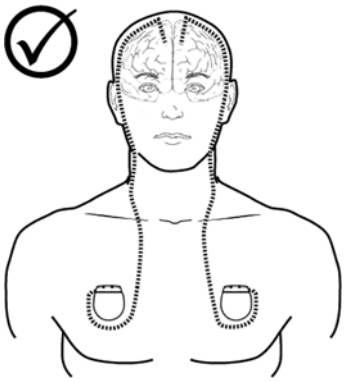
☐ N/A, patient has a lead-only system.

-OR-

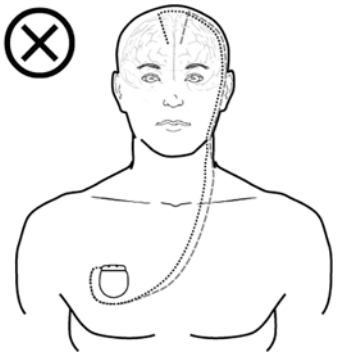
☐ Yes.



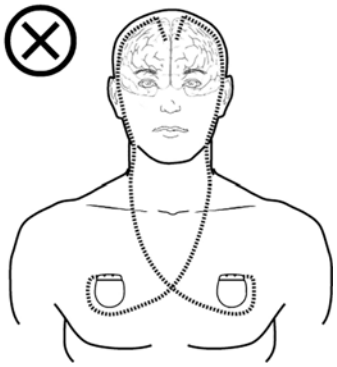
-OR-



☐ No.



-OR-



STOP! DO NOT PERFORM MRI.

9. **Is it safe to turn off stimulation to conduct an MRI scan?**

For more information, see "Warnings and Precautions" (page 1).

☐ N/A, patient has a lead-only system. **-OR-** ☐ Yes.	☐ No. **STOP! DO NOT PERFORM MRI.**

10. **Is each IPG set to MRI mode?**

For more information, see "Step 2: Set the IPG to MRI Mode (Full Systems Only)" (page 7).

☐ N/A, patient has a lead-only system. **-OR-** ☐ Yes.	☐ No. **STOP! DO NOT PERFORM MRI.**

NOTE: If you answered "Yes" or "N/A" to all the questions, go to "Step 3: Set Up the MRI Equipment Based on the Scanning Requirements" (page 9).

Step 2: Set the IPG to MRI Mode (Full Systems Only)

MRI mode is a special configuration of the IPG that allows a patient to safely receive an MRI scan according to the conditions and requirements in this document. Before conducting an MRI scan on patients implanted with full systems, ensure that the patient's neurostimulation system is in MRI mode according to these guidelines.

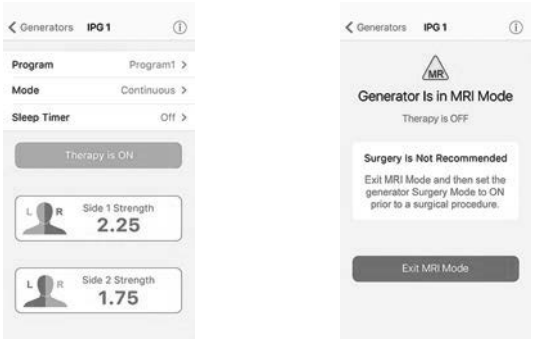
WARNING: If a patient has more than one DBS IPG implanted, ensure that both IPGs are set to MRI mode before scanning.

NOTE: Before the MRI procedure, inform patients to recharge their patient controller and bring it with them to be able to confirm that the IPG is set to MRI mode.

NOTE: If the patient did not bring the patient controller the day of the MRI procedure, a clinician programmer can also be used by an authorized clinician or representative.

1. Turn on the patient controller by pressing the power button.
2. Tap the patient controller app icon on the Home screen to launch the app.
3. Do either of the following:
   - For patients with only one IPG, wait for the patient controller app to automatically connect to the IPG.
   - For patients with more than one IPG, tap the IPG with which you want to connect.
4. After the app connects with the IPG, you will see one of the following screens:
   - If MRI mode is not enabled, you will see the Therapy screen (see the following figure, left). Go to the next step.
   - If MRI mode is enabled, you will see the Generator is in MRI Mode screen (see the following figure, right). Go to step 10.

Figure 3. Therapy screen (left) versus Generator is in MRI Mode screen (right)



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

Figure 4. Mode screen

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

Figure 5. MRI Mode screen

7. Tap the **MRI Mode** switch.
8. When the "Set Generator to MRI Mode" message appears, tap **Continue**. Stimulation stops, and the patient controller app checks the system for any issues. If the checks are successful, the "Proceed with MRI" message appears and the MRI mode is on (see the following figure).

   NOTE: If a warning screen appears instead of the "Proceed with MRI" message, you cannot set the IPG to MRI mode and cannot perform an MRI scan. Refer to "Troubleshooting (Full Systems Only)" (page 12) for more information. After troubleshooting, if you continue to receive a warning screen, do not perform the MRI scan.
9. Tap **OK**.

Figure 6. Proceed with MRI message

10. If the patient has more than one IPG, tap **< Generators** in the upper-left corner of the screen, and then repeat the steps in this section to set the other IPG to MRI mode.
11. When all IPGs are set to MRI mode, proceed with the MRI scan.

Step 3: Set Up the MRI Equipment Based on the Scanning Requirements

This section provides MRI equipment and scanning requirements for the MR Conditional components of a fully implanted lead-only system or full system.

CAUTION: Before reviewing the following requirements, use the information in "Step 1: Complete the MRI Procedure Eligibility Checklist" (page 5) to confirm the presence of only MR Conditional neurostimulation components at approved implant locations. Then review the following requirements carefully because different RF coil types have different scanning restrictions.

NOTE: For information about the MRI equipment that will be used to scan the patient, including important safety information, equipment features, and instructions for use, refer to the manual for the MRI equipment.

General Scanning Requirements for Lead-Only and Full Systems

For lead-only and full systems, set up the MRI equipment according to the general requirements in the following table:

Table 4. General scanning requirements; see "RF Field Requirements for Lead-Only Systems" (page **9**) or "RF Field Requirements for Full Systems" (page **10**) for component-specific scanning requirements

MRI system type	1.5-T cylindrical-bore magnet, horizontal field orientation	**WARNING:** Only use 1.5-T cylindrical-bore magnet, horizontal field orientation MRI systems. Other MRI systems, such as 1.0-T and 3.0-T machines or vertical field orientation machines, have not been tested and could cause device damage and excessive heating of implanted components, which could result in serious patient injury.
Gradient slew rate	Maximum gradient slew rate of ≤ 200 T/m/s per axis	**WARNING:** Do not use gradient slew rates greater than 200 T/m/s because they have not been tested and could increase the risk of induced stimulation or heating of the neurostimulator.
Spatial field gradient	Maximum spatial field gradient of 30 T/m (3000 G/cm)	
Total active scan time (RF on-time)	• 30 minutes total of active scan time per session • 30-minute wait between sessions	**WARNING:** Exceeding the active scan time limit increases the risk of excessive heating, which could result in serious patient injury.

RF Field Requirements for Lead-Only Systems

The following table shows the RF field requirements for scanning patients with lead-only systems according to the scan region. See "RF Field Requirements for Full Systems" (page 10) if the patient also has an IPG and extension implanted.

Table 5. RF field requirements for lead-only systems; see "General Scanning Requirements for Lead-Only and Full Systems" (page **9**) for additional scanning requirements.

RF Field Requirements for Lead-Only Systems			
Scan Region	**RF Coil Type**	**RF Power**	**Notes and Warnings**
Head	RF transmit-receive head coil (quadrature only)	B_{1+rms} ≤ 2.9 µT -or- Head SAR ≤ 0.8 W/kg	See **1**, **2**, and **4**.
Head	Body RF transmit coil (quadrature only) with body receive coil or head receive coil	B_{1+rms} ≤ 2.3 µT -or- Whole body SAR ≤ 0.1 W/kg	See **1** and **4**.
Isocenter inferior to C1 vertebra, including hips and shoulders	Body RF transmit coil (quadrature only) with any receive coil	B_{1+rms} ≤ 1.3 µT -or- Whole body SAR ≤ 0.1 W/kg	See **1** and **4**.
Upper and lower extremities, excluding hips and shoulders	RF transmit-receive extremity coil (quadrature only)	Normal Operating Mode	See **2** and **3**.

Table 5. RF field requirements for lead-only systems; see "General Scanning Requirements for Lead-Only and Full Systems" (page 9) for additional scanning requirements.

RF Field Requirements for Lead-Only Systems			
Scan Region	**RF Coil Type**	**RF Power**	**Notes and Warnings**

1. **WARNING: Personnel knowledgeable in MR safety should be involved to optimally plan the scan and actively monitor the RF power level during the scan. Some scanners may not update the displayed RF power when manual adjustments are made after the prescan. In this case, do not manually adjust the scan parameters after the prescan because the implanted system may be exposed to higher-than-expected RF power. Exceeding the safe RF power limit could increase the risk of excessive heating of implanted components.**
2. **WARNING: Only quadrature, birdcage RF transmit-receive coil designs have been tested. Do not use other transmit coil designs (e.g., linear, phased-array, or saddle) because these have not been tested and could result in serious patient injury.**
3. **WARNING: Scans of the hips and shoulders have not been tested using RF transmit-receive extremity coils. For hip and shoulder scans, use a body RF transmit coil with any receive coil according to the requirements for the isocenter inferior to the C1 vertebra.**
4. NOTE: If the B_{1+rms} display is unavailable on your scanner, then you must maintain the specific absorption rate (SAR) limit. Ensure the scanner displays the SAR parameters prospectively (whole body SAR, head SAR, or both as applicable). To allow the MRI scanner to estimate the SAR, ensure that you enter the patient's body weight accurately into the scanner.

RF Field Requirements for Full Systems

The following table shows the RF field requirements for scanning patients with full systems according to the scan region. See "RF Field Requirements for Lead-Only Systems" (page 9) if the patient has only leads implanted.

Table 6. RF field requirements for full systems; see "General Scanning Requirements for Lead-Only and Full Systems" (page 9) for additional scanning requirements.

RF Field Requirements for Full Systems			
Scan Region	**RF Coil Type**	**RF Power**	**Notes and Warnings**
Head	RF transmit-receive head coil (quadrature only)	$B_{1+rms} \leq 1.8$ µT -or- Head SAR ≤ 0.3 W/kg	See **1**, **2**, and **4**.
Head	Body RF transmit coil (quadrature only) with body receive coil or head receive coil	$B_{1+rms} \leq 1.1$ µT	See **1**.
Isocenter inferior to C1 vertebra, including hips and shoulders	Body RF transmit coil (quadrature only) with any receive coil	$B_{1+rms} \leq 1.1$ µT -or- Whole body SAR ≤ 0.1 W/kg	See **1** and **4**.
Upper and lower extremities, excluding hips and shoulders	RF transmit-receive extremity coil (quadrature only)	Normal Operating Mode	See **2** and **3**.

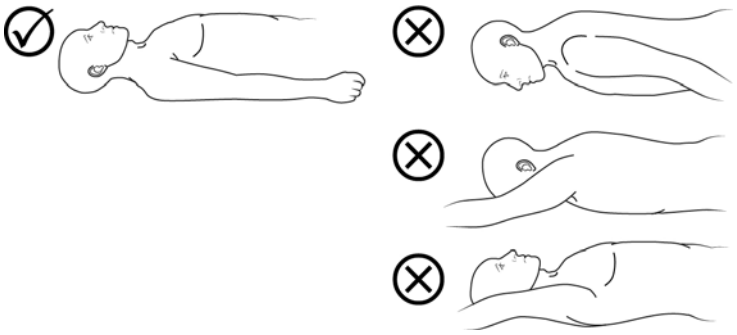
1. **WARNING: Personnel knowledgeable in MR safety should be involved to optimally plan the scan and actively monitor the RF power level during the scan. Some scanners may not update the displayed RF power when manual adjustments are made after the prescan. In this case, do not manually adjust the scan parameters after the prescan because the implanted system may be exposed to higher-than-expected RF power. Exceeding the safe RF power limit could increase the risk of excessive heating of implanted components.**
2. **WARNING: Only quadrature, birdcage RF transmit-receive coil designs have been tested. Do not use other transmit coil designs (e.g., linear, phased-array, or saddle) because these have not been tested and could result in serious patient injury.**
3. **WARNING: Scans of the hips and shoulders have not been tested using RF transmit-receive extremity coils. For hip and shoulder scans, use a body RF transmit coil with any receive coil according to the requirements for the isocenter inferior to the C1 vertebra.**
4. NOTE: If the B_{1+rms} display is unavailable on your scanner, then you must maintain the specific absorption rate (SAR) limit. Ensure the scanner displays the SAR parameters prospectively (whole body SAR, head SAR, or both as applicable). To allow the MRI scanner to estimate the SAR, ensure that you enter the patient's body weight accurately into the scanner.

Step 4: Place the Patient in the Correct Position for the Scan

Place the patient supine with the patient's arms at his or her sides (see the following figure).

WARNING: Any prone patient positions or "superman" positions (where the patient's arm is raised above his or her head) are excluded and have not been tested.

Figure 7. Correct patient position (left) versus incorrect positions (right)



Step 5: Perform the Scan and Monitor the Patient

While performing the scan, follow these guidelines:

- Leave any external control devices, such as a patient controller, out of the scanner magnet room (Zone IV).
- Involve personnel knowledgeable in MR safety to actively monitor the RF power levels during 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.
- 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 IPG, lead, or extension. Refer to the following section for more information.

Considerations for Image Artifacts and Distortion

The implanted components can cause artifacts or distortion in an image. Anatomical regions near the implanted components may appear severely distorted or may be blocked completely from the view. Consider image artifacts and distortion from IPGs, leads, or extensions when selecting the field of view and imaging parameters. Also consider these factors when interpreting the MRI images.

By carefully choosing pulse sequence, slice orientation, and location of the imaging plane, you may minimize MR image artifacts related to the DBS system. To help reduce image artifacts and distortion, consider the following general guidelines:

- Use a shorter echo time, when possible, to reduce susceptibility effects.
- Use spin echo sequences instead of gradient echo sequences to lower the severity and extent of image artifacts.
- Identify the location of the implanted components, and orient all imaging slices away from the implanted components when possible.
- Avoid using the body receive coil if possible. Use a local receive-only coil instead.
- Use stronger slice selection and readout gradients to reduce in-plane distortion. Use higher readout bandwidth/data-sampling bandwidth to reduce in-plane distortion. However, this approach may reduce the image signal-to-noise ratio (SNR).
- Choose an orientation for the read-out direction that minimizes the appearance of in-plane distortion.

Step 6: Disable the MRI Mode (Full Systems Only)

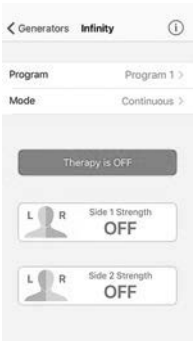
For patients with full systems, you should disable the MRI mode after you have finished scanning the patient and the patient is outside of the MRI environment. To disable the MRI mode using a patient controller, follow these steps:

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 clinician or representative can disable MRI mode by following steps similar to those for the patient controller.

1. Turn on the patient controller.
2. On the Home screen, tap the patient controller app icon to launch the app.
3. Do either of the following:
   - For patients with only one IPG, wait for the patient controller app to automatically connect to the IPG.
   - For patients with more than one IPG, tap the IPG with which you want to connect.
4. After the app connects with the IPG, you should see a screen indicating that the IPG is in MRI mode.

5. Tap **Exit MRI Mode**. The patient controller app disables MRI mode, and a screen similar to the following Therapy screen appears, showing that stimulation therapy is off.

Figure 8. Therapy screen showing stimulation off



6. To start stimulation, tap **Therapy is OFF**.
7. If the patient has more than one IPG, tap **< Generators** in the upper-left corner of the screen, tap the other IPG to select it, and then repeat the previous two steps to disable MRI mode for the other IPG.

Troubleshooting (Full Systems Only)

The following tables show issues you may encounter using the patient controller. The first table identifies possible issues that you may encounter on the Mode 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. See "Technical Support" (page 13).

NOTE: 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 7. Possible causes and solutions for potential issues with accessing the MRI Mode screen from the 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 8. Troubleshooting messages for MRI mode using a patient controller

Message	Solution
Turn On Bluetooth 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.

Table 8. Troubleshooting messages for MRI mode using a patient controller

Message	Solution
Connection Lost A magnet was used to place the generator in the Bluetooth 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). Contact your clinician.	Do not perform the MRI scan. The IPG is not in MRI mode.
MRI is Not Advised There may be a problem with the implanted lead(s). Contact your clinician. Your clinician can perform an additional check to see if MRI Mode can be set.	Do not perform the MRI scan. The IPG is not in MRI mode. Contact your clinician for additional assistance.
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.

Appendix A: Patient Eligibility Form for MRI Scans

Use this form along with the checklist in "Step 1: Complete the MRI Procedure Eligibility Checklist" (page 5) in these MRI procedures to help you determine the eligibility of a patient with an implanted deep brain stimulation (DBS) system for an MRI scan.

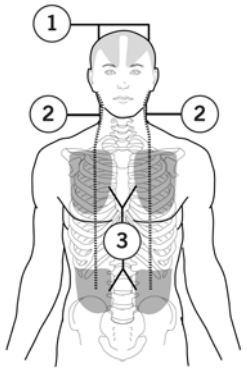
If the answers to all of the following questions are “Yes” or "N/A," consider performing an MRI scan after confirming that all the requirements in these MRI procedures are met. If the answer to any of the questions is “No,” do not perform the scan. If you are unsure, contact the patient’s DBS managing clinician or Technical Support for help.

WARNING: Scanning patients who have other MR Conditional devices is acceptable as long all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it. If you are unclear what implants are present, perform an X ray to determine the implant type and location.

NOTE: Before conducting an MRI scan, always ensure that you are using the most recent version of these MRI procedures. 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.

Patient's name	
Physician’s name and contact information (office name, address, phone number)	
Date of eligibility assessment	
IPG model/models	**IPG location/locations**
Lead model/models	**Lead location/locations**
Extension model/models	**Extension location/locations**

Eligibility Factor		Yes	N/A	No
1.	Is the patient's body temperature normal or below normal on the day of the scan?			
2.	Does the patient have implanted components that are MR Conditional, and are the MR Conditional components the only neurostimulation components implanted?			
3.	**Lead-only systems.** Identify the location of the implanted components and mark them on the diagram to the right. Are the leads within zone 1 and connected to the lead protection boot?			
4.	**Full systems.** Identify the location of the implanted components and mark them on the diagram to the right. Are the leads within zone 1, extensions within zones 2 and 3, and IPGs within zone 3?			
5.	Are all components fully implanted (not exposed due to partial implantation or skin erosion)?			
6.	Is the patient free of broken or abandoned neurostimulation devices?			
7.	**Full systems.** Are the lead and extension routed on the same side of the body as their associated IPG?			
8.	Is it safe to turn off stimulation to conduct an MRI scan?			
9.	**Full systems.** Is each IPG set to MRI mode?			
10.	Does the intended scan region meet the conditions of use for the RF coil that will be used?			

Approved Implant Locations
Zone 1, lead location: Brain, routed subcutaneously along scalp
Zones 2 and 3, extension location (full systems only): Head and neck
Zone 3, IPG location (full systems only): Pectoral or abdomen


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