MRI Procedure Information

MR Conditional
Proclaim™ Spinal Cord Stimulation System
Prodigy MRI™ Spinal Cord Stimulation System
Protégé MRI™ 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 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 18).

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.

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.

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 lead adapter.

Nonfunctional leads. Do not perform an MRI scan on patients with broken or intermittent MR Conditional leads, or lead impedance measurements not within the lead 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 must be implanted in the epidural space and routed subcutaneously to the IPG pocket. Multiple MR Conditional leads should be routed in close proximity. Nonadjacent leads can possibly result in increased unintended stimulation or heating at the lead electrodes.

Location of RF transmit-receive coils. Head or extremity MRI scans can be conducted safely using a Detachable Head or Extremity RF transmit-receive coil when no parts of the implanted neurostimulation system are within the transmit-receive coil according to the conditions specified for each system in the MRI labeling. This can be confirmed with X-ray imaging of the neck, head, and extremity regions or by referring to the patient records. This warning is not applicable to IPG model 3660, 3662, 3670, or 3672 with lead model 3186.

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 cause heating of the system, which could result in serious patient injury.

Neurostimulation trial systems. Do not perform an MRI scan on patients who have a neurostimulation trial system or any components that are not fully implanted because these devices have not been tested in an MR environment.

Multiple neurostimulation systems. MRI has not been tested with multiple MR Conditional neurostimulation systems (multiple IPGs) and may cause heating of the lead electrodes, which could result in serious patient injury.

Other implanted medical devices. Scanning patients who have other MR Conditional devices is acceptable as long as 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.

MRI Mode patient instructions. For Proclaim™ spinal cord stimulation (SCS) systems, 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 for generators with the following software versions: 1.1.0.1, 1.1.1.1, 1.1.2.1. See Using the Patient Controller to Confirm the System Components (page 3) to determine the generator software version.

To keep the ability to disable MRI Mode, provide the following instructions to patients with a Proclaim SCS system.

Before enabling MRI Mode:

- Upgrade their patient controller to the latest version of the patient controller app from the mobile device app store.
- Disable automatic updates for the patient controller app and the mobile device operating system software.
- Do not enable MRI Mode more than 24 hours before 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 mobile device operating system while in MRI Mode.

Disabling MRI Mode. For Proclaim™ spinal cord stimulation (SCS) systems, 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 for generators with the following software versions: 1.1.0.1, 1.1.1.1, 1.1.2.1. See Using the Patient Controller to Confirm the System Components (page 3) to determine the generator software version.

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 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 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 before the scheduled procedure.

  WARNING: For Proclaim™ spinal cord stimulation (SCS) systems, before attempting to place the IPG into MRI Mode, instruct the patient to:

  - **Upgrade their patient controller to the latest version of the patient controller app from the mobile device app store.**
  - **Disable automatic updates for the patient controller app and the mobile device operating system software.**
  - **Do not enable MRI Mode more than 24 hours before the MRI scan.**
- Bring the patient ID card (also referred to as patient implant card), their patient controller or programmer, and their charger (if applicable).
- Recharge the patient controller (if applicable).

  WARNING: For Proclaim™ spinal cord stimulation (SCS) systems, 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 for generators with the following software versions: 1.1.0.1, 1.1.1.1, 1.1.2.1. See Using the Patient Controller to Confirm the System Components (page 3) to determine the generator software version.

  To keep the ability to disable MRI Mode, provide the following instructions to patients with a Proclaim SCS system:

  - **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 mobile device operating system while in MRI Mode.**

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

1. Confirm the MR Conditional components and location of the system.
2. Confirm that no adverse conditions to MR scanning are present.
3. Ensure the patient's neurostimulation system is in MRI Mode.
4. Review the general scan requirements.
5. Confirm implant locations and scan requirements for the patient's system.

The following sections provide more information about each of these steps. You can also use the form in the appendix of this manual as a quick-reference checklist to help you determine a patient's eligibility for an MRI scan.

Step 1: Confirm the MR Conditional Components and Location of the System

Before performing a scan, confirm the patient's neurostimulation system components are MR Conditional and implanted in approved locations. When a neurostimulation system is implanted, a patient receives an identification card (also referred to as patient implant card) and patient controller (if applicable) that identifies the model numbers of the implanted components to help you identify them as MR Conditional. To confirm that the patient's implanted system contains only MR Conditional components, review the patient's identification card or use the patient controller for his or her system. Use the following table to determine if the components are implanted in approved locations.

NOTE: If a patient does not have his or her identification card or patient controller, consider other means of confirming the MR Conditional system, such as referencing the patient's medical history or contacting Technical Support (page 18).

Using a Patient Identification Card to Confirm the Implanted System Components

To confirm that the patient's system contains only MR Conditional components and that those components are implanted in approved locations:

1. Request the identification card from the patient.
2. Using the following table, check the IPG and lead model numbers on the card are MR Conditional components.
3. Using the following table, check the IPG and lead model numbers on the card are implanted in approved locations.

WARNING: For a neurostimulation system to be MR Conditional, all implanted components must be approved MR Conditional models and implanted in approved locations according to the following table. If the implanted system contains components or models not listed in the following table, then the system is considered MR Unsafe. In addition, a component must be implanted in its approved location as listed in the following table or the entire implanted system is considered MR Unsafe.

Table 1. Approved models and implant locations for an MR Conditional neurostimulation system

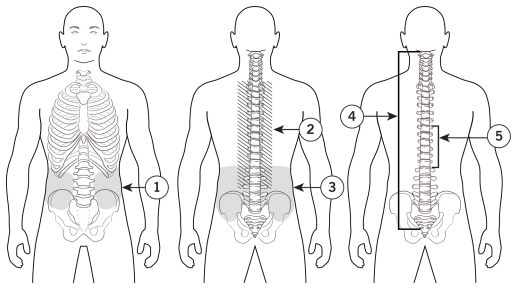
MR Conditional System Components		**Approved Implant Locations (as shown in the figure below)**
IPG*	**Lead****	
3660 Proclaim™ XR 5 3662 Proclaim™ XR 7 3670 Proclaim™ Plus 5 3672 Proclaim™ Plus 7	3186 Octrode™, 60 cm	▪ IPG in upper buttock, low back, flank, abdomen, or midline ▪ Lead tip in the epidural space between the C1 and S2 vertebrae
	3228 Penta™, 60 cm	▪ IPG in upper buttock, low back, flank, abdomen, or midline ▪ Lead tip in the epidural space between the T7 and T12 vertebrae
3771 Protégé MRI™ 3772 Prodigy MRI™	3186 Octrode™, 60 cm 3228 Penta™, 60 cm	▪ IPG in upper buttock, low back, flank, abdomen, or midline ▪ Lead tip in the epidural space between the T7 and T12 vertebrae

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

** The anchors associated with these models are MR Conditional components. Multiple MR Conditional leads and anchors may be implanted.

NOTE: Extensions are untested and are therefore considered MR Unsafe.

Figure 1. Anatomical locations for implanted components of MR Conditional neurostimulation systems



IPG Implant Locations*

1. Abdomen
2. Midline
3. Upper buttock, low back, flank

Lead Tip Locations*

4. C1–S2
5. T7–T12

* Refer to the table above for approved locations for each IPG and lead configuration.

Using the Patient Controller to Confirm the System Components

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

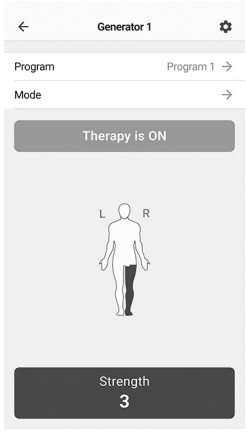
1. Turn on the patient controller.

2. Ensure that the patient controller is connected to the IPG. This may require navigating through the Home screen by tapping **My Therapy Controller** to access the My Devices screen, or by directly accessing the My Devices screen or the Generator screen. After the My Devices screen or Generator screen is accessed, tap the generator name.

   NOTE:

   - In some cases, using 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.
3. After you connect to the IPG, you should see a screen similar to the following Therapy screen.

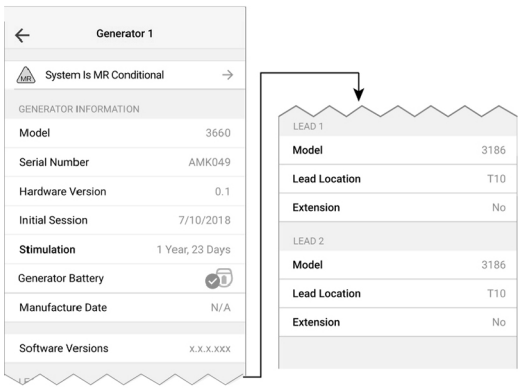
Figure 2. Therapy screen



4. Tap ⚙ or tap ⓘ in the upper-right corner of the screen.
   - For ⚙, the Mode screen appears. Tap ⓘ in the lower-right corner of the Mode screen. Then tap the generator name to view the system screen.
   - For ⓘ, a system screen automatically opens. Tap **Leads/Extensions** as necessary to view the Leads/Extensions screen.

   A system screen opens showing information about the generator, including the model number and the generator software version.
   - 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 3. System screen showing MR Conditional components



* This screen is a representation; information varies depending on the generator model and components.

** Scroll down to see bottom part of screen.

5. Confirm the IPG and lead model numbers on the controller screens are MR Conditional components listed in the table of approved models and implant locations for an MR Conditional neurostimulation system. See Using a Patient Identification Card to Confirm the Implanted System Components (page 3).

Step 2: Confirm No Adverse Conditions to Scanning Are Present

If any conditions exist that could make an MRI scan unsafe, do not perform the MRI scan. Such conditions include any of the following:

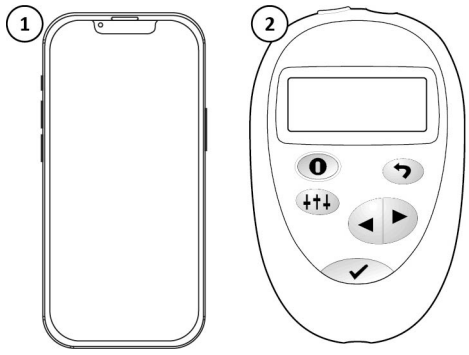
- The presence of implanted neurostimulation components that are not listed as MR Conditional. See Using a Patient Identification Card to Confirm the Implanted System Components (page 3).
- The location of MR Conditional components in an area other than what is listed in the previous table. See Using a Patient Identification Card to Confirm the Implanted System Components (page 3).
- The presence of abandoned neurostimulation devices, such as an IPG, lead, extension, or lead adapter
- The presence of broken or intermittently functioning MR Conditional leads

- The presence of more than one IPG
- Any exposed portions of MR Conditional neurostimulation system components due to skin erosion
- The presence of any other implanted devices (active or passive implanted devices) that prohibit safe scanning
- The presence of a fever in the patient on the day of the scan (only applicable to IPG models 3660, 3662, 3670, 3672)

Step 3: 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. Before you begin, you need to identify the type of handheld device the patient has: a patient controller or a patient programmer. The following figure shows the differences between a patient controller and a patient programmer.

Figure 4. Patient controller versus patient programmer



1. Patient controller
2. Patient programmer

- To ensure the system is set to MRI Mode using a patient controller, refer to the instructions in Using the Patient Controller to Confirm MRI Mode (page 5).
- To ensure the system is set to MRI Mode using a patient programmer, refer to the instructions in Using the Patient Programmer to Confirm MRI Mode (page 7).

  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

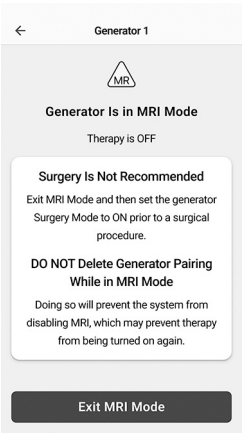
To ensure that the patient's neurostimulation system is in MRI Mode using the patient controller:

1. Ensure that the patient controller is connected to the IPG. This may require navigating through the Home screen by tapping **My Therapy Controller** to access the My Devices screen, or by directly accessing the My Devices screen or the Generator screen. After the My Devices screen or Generator screen is accessed, tap the generator name.

   NOTE:

   - In some cases, using 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.
2. 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 6).

Figure 5. MRI Mode screen

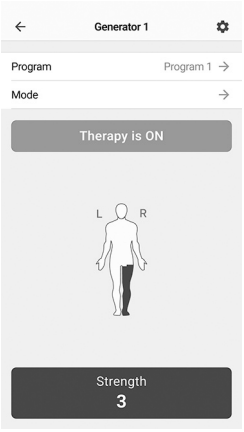


Setting the IPG to MRI Mode Using the Patient Controller

To set the IPG to MRI Mode:

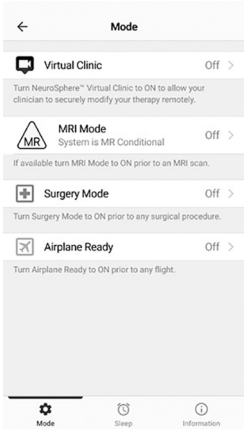
1. Ensure that the patient controller is connected to the IPG. If MRI Mode is not enabled, a screen similar to the following Therapy screen appears.

Figure 6. Therapy screen



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

Figure 7. Mode screen



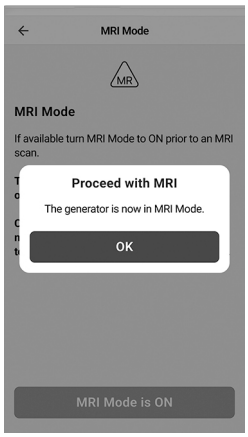
This screen is a representation. Information may vary depending on the generator model and software version.

3. Tap **MRI Mode** to view the MRI Mode screen.
4. Tap **Turn MRI Mode ON** or tap the **MRI Mode** toggle button.
5. When the “Set Generator to MRI Mode?” message appears, tap **Continue**. Stimulation stops, and the patient controller app checks the system for any issues.

   NOTE: If a warning message appears instead of the “Proceed with MRI” message, you cannot set the IPG to MRI Mode and cannot perform an MRI scan. See Troubleshooting (page 16) 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, the “Proceed with MRI” message appears and MRI Mode is on. Tap **OK**.

Figure 8. Proceed with MRI message

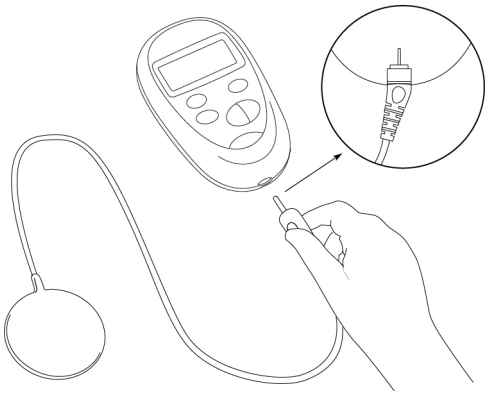


Using the Patient Programmer to Confirm MRI Mode

To ensure that the patient's neurostimulation system is in MRI Mode using a patient programmer:

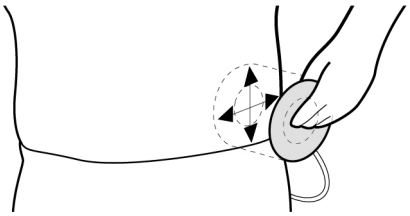
1. Ensure that the programmer is off. (It turns itself off after one minute of non-use.)
2. Plug the communication wand into the wand port on the bottom of the programmer.

Figure 9. Plug the wand into the programmer



3. Press the Power key to turn on the programmer. The Diagnostic Test screen appears.
4. Place the flat, circular end of the wand over the IPG site.

Figure 10. Place the wand over the IPG site



5. Wait for the LOCATING IPG screen to appear, and hold the wand in place. The programmer beeps while it is trying to locate the IPG.

Figure 11. LOCATING IPG screen

NOTE:

- The programmer will try to locate the IPG for about 5 seconds before a screen appears to retry communication. If the programmer does not establish communication, move the wand slowly over the IPG site in small circular movements until you achieve communication.
- After you have established communication with the IPG, keep the wand in place. If you move the wand from over the IPG site, you may lose communication with the IPG.

6. Check the programmer's screen to verify that the programmer has established communication with the IPG. When the programmer finds the IPG, the beeping stops and the following screen appears.

Figure 12. IPG FOUND screen

7. Next, an IPG information screen appears. If the IPG is part of an MR Conditional system, the patient programmer will show an MR icon in the upper right corner of the screen.

Figure 13. MR icon on the IPG information screen

8. If the IPG is set to MRI Mode, the following screen appears. If you do not see this screen, the IPG will need to be set to MRI Mode. See the following section.

Figure 14. MRI Mode screen

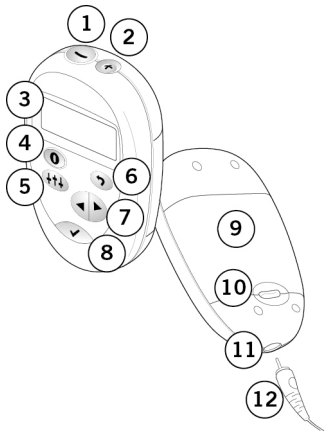
Setting the IPG to MRI Mode Using the Patient Programmer

To set the IPG to MRI Mode:

NOTE: Before patients arrive for the MRI procedure, consider reminding them to fully recharge their IPG to be able to set the IPG to MRI Mode. Also advise patients to set their IPG to MRI Mode within a day of their procedure.

The following image shows the different parts of the patient programmer.

Figure 15. Parts of the patient programmer



1. Amplitude Decrease key
2. Amplitude Increase key
3. Display screen
4. Power key
5. Balance key
6. Previous Screen key
7. Scroll keys (left and right)
8. Select key
9. Battery pack
10. Battery release latch
11. Wand port
12. Communication wand connector

1. Ensure that you have established communication with the patient programmer by following the steps in Using the Patient Programmer to Confirm MRI Mode (page 7). The following screen appears.

Figure 16. Operational Display screen

2. Press either one of the Scroll keys on the programmer until the MRI Mode icon (MR) appears in the user option window on the bottom left corner of the screen.

Figure 17. Scroll to the MRI Mode icon

3. Press the Select key on the programmer. The following screen appears.

Figure 18. Enter MRI Mode screen

4. Press the Select key. The programmer stops stimulation, checks the impedance on the lead electrodes, and checks the remaining battery capacity of the IPG. If the checks are successful, the following screen appears indicating that the IPG is in MRI Mode.

   NOTE: If you see a warning screen instead of the following MRI Mode screen, refer to Troubleshooting (page 16) for guidelines on how to proceed. After troubleshooting, if you continue to receive a warning screen, do not perform the MRI scan. Contact Technical Support to resolve the issue.

Figure 19. MRI Mode screen

Step 4: Review the General Scan Requirements

After you have confirmed that the patient's IPG is set to MRI Mode, set up the MRI equipment. Refer to the following tables for MRI equipment and scanning requirements.

Patients implanted with MR Conditional components of an Abbott Medical neurostimulation system must be scanned using a 1.5-T system according to the following requirements.

CAUTION: Before reviewing the following requirements, use the information in Using a Patient Identification Card to Confirm the Implanted System Components (page 3) to confirm the implanted neurostimulation system components are MR Conditional and are within the indicated implant locations. Use the following information to review the scanning requirements and restrictions for the various IPG and lead configurations.

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.

Table 2. General scan 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)	
Patient position	Supine, patient's arms must be at his or her sides	**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.**
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.** NOTE: During the MRI scan, visually and audibly monitor the patient, including verbal communication. Instruct the patient to notify MR personnel immediately if any discomfort, pain, heating, stimulation, or vibration is experienced.

Step 5: Confirm Implant Locations and Scan Requirements for the Patient's System

Find the patient’s IPG and lead configuration in the list below. The list directs you to the information for implant locations and scan requirements for that system. Click the link or go to the page listed for the appropriate system.

- Proclaim™ XR or Proclaim™ Plus IPG with Octrode™ Lead (page 12)
- Proclaim™ XR or Proclaim™ Plus IPG with Penta™ Lead (page 13)
- Protégé MRI™ or Prodigy MRI™ IPG with Octrode™ or Penta™ Lead (page 14)

Proclaim™ XR or Proclaim™ Plus IPG with Octrode™ Lead

Table 3. Implant Locations for Proclaim™ XR or Proclaim™ Plus IPG with Octrode™ Lead

IPG*	Lead**	Approved Implant Locations
3660 Proclaim XR 5 3662 Proclaim XR 7 3670 Proclaim Plus 5 3672 Proclaim Plus 7	3186 Octrode, 60 cm	▪ IPG in upper buttock, low back, flank, abdomen, or midline ▪ Lead tip in the epidural space between the C1 and S2 vertebrae

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

** The anchors associated with these models are MR Conditional components. Multiple MR Conditional leads and anchors may be implanted.

NOTE: Extensions are untested and are therefore considered MR Unsafe.

CAUTION: Confirm the lead and IPG locations are approved per the table above.

Table 4. RF Field Requirements for Proclaim™ XR or Proclaim™ Plus IPG with Octrode™ Lead

IPG Model	Lead Model	Scan Region	RF Coil	RF Power	Notes and Warnings
Proclaim XR 3660 3662 Proclaim Plus 3670 3672	Octrode 3186	Any body part	Integrated Whole body transmit coil (Circularly Polarized only) with any receive coil	Normal operating mode	1, 2, 3, 6
		Head scans	Integrated Whole body transmit coil (Circularly Polarized only) with any receive coil	Normal operating mode	1, 2, 3, 6
			-OR-		
			Detachable Head transmit-receive coil (Circularly Polarized only)	Normal operating mode	1, 2, 3, 4, 6
		Extremity scans			
		▪ All **including** hip and shoulder	Integrated Whole body transmit coil (Circularly Polarized only) with any receive coil	Normal operating mode	1, 2, 3, 6
		▪ All **except** hip and shoulder	Detachable Extremity transmit-receive coil (Circularly Polarized only)	Normal operating mode	1, 2, 3, 4, 5, 6

1. NOTE: The SAR requirements will be met if the scanner is in normal operating mode.
2. NOTE: To allow the MRI scanner to estimate the SAR, ensure that you enter the patient's body weight accurately into the scanner.
3. **WARNING: 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.**
4. **WARNING: Only Circularly Polarized, birdcage designs of Detachable Head and Extremity RF transmit-receive coils have been tested. Do not use other transmit coil designs (for example, linear, phased-array, or saddle) because these have not been tested and could result in serious patient injury.**
5. **WARNING: Scans of the hips and shoulders have not been tested using Detachable Extremity RF transmit-receive coils. For hip and shoulder scans, use an Integrated Whole body RF transmit coil (Circularly Polarized only) with any receive coil according to RF power requirements listed above.**
6. **WARNING: Before an MRI scan, determine the patient's body temperature. If the patient has a fever, you should not perform an MRI scan.**

Proclaim™ XR or Proclaim™ Plus IPG with Penta™ Lead

Table 5. Implant Locations for Proclaim™ XR or Proclaim™ Plus IPG with Penta™ Lead

IPG*	Lead**	Approved Implant Locations
3660 Proclaim XR 5 3662 Proclaim XR 7 3670 Proclaim Plus 5 3672 Proclaim Plus 7	3228 Penta, 60 cm	▪ IPG in upper buttock, low back, flank, abdomen, or midline ▪ Lead tip in the epidural space between the T7 and T12 vertebrae

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

** The anchors associated with these models are MR Conditional components. Multiple MR Conditional leads and anchors may be implanted.

NOTE: Extensions are untested and are therefore considered MR Unsafe.

CAUTION: Confirm the lead and IPG locations are approved per the table above.

Table 6. RF Field Requirements for Proclaim™ XR or Proclaim™ Plus IPG with Penta™ Lead

IPG Model	Lead Model	Scan Region	RF Coil	RF Power	Notes and Warnings
Proclaim XR 3660 3662 Proclaim Plus 3670 3672	Penta 3228	Any body part	Integrated Whole body transmit coil (Circularly Polarized only) with any receive coil	Whole body SAR ≤0.1 W/kg	2, 3, 4, 8
		Head scans	Integrated Whole body transmit coil (Circularly Polarized only) with any receive coil	Whole body SAR ≤0.1 W/kg	2, 3, 4, 8
			-OR-		
			Detachable Head transmit-receive coil (Circularly Polarized only)	Normal operating mode	1, 2, 3, 4, 5, 7
		Extremity scans			
		▪ All **including** hip and shoulder	Integrated Whole body transmit coil (Circularly Polarized only) with any receive coil	Whole body SAR ≤0.1 W/kg	2, 3, 4, 8
		▪ All **except** hip and shoulder	Detachable Extremity transmit-receive coil (Circularly Polarized only)	Normal operating mode	1, 2, 3, 4, 5, 6

1. NOTE: The SAR requirements will be met if the scanner is in normal operating mode.
2. NOTE: To allow the MRI scanner to estimate the SAR, ensure that you enter the patient's body weight accurately into the scanner.
3. **WARNING: 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.**
4. **WARNING: Before an MRI scan, determine the patient's body temperature. If the patient has a fever, you should not perform an MRI scan.**
5. **WARNING: Only Circularly Polarized, birdcage designs of Detachable Head and Extremity RF transmit-receive coils have been tested. Do not use other transmit coil designs (for example, linear, phased-array, or saddle) because these have not been tested and could result in serious patient injury.**
6. **WARNING: Scans of the hips and shoulders have not been tested using Detachable Extremity RF transmit-receive coils. For hip and shoulder scans, use an Integrated Whole body RF transmit coil (Circularly Polarized only) with any receive coil according to RF power requirements listed above.**
7. **WARNING: To avoid excessive heating that could cause serious patient injury, do not place any part of the Detachable Head RF transmit-receive coil over any implanted neurostimulation system component.**
8. **WARNING: Personnel knowledgeable in MR safety should be involved to optimally plan the scan and actively monitor specific absorption rate (SAR) levels during the scan. Ensure the scanner displays SAR prospectively. Exceeding these SAR limits could increase the risk of excessive heating of implanted components.**

Protégé MRI™ or Prodigy MRI™ IPG with Octrode™ or Penta™ Lead

Table 7. Implant Locations for Protégé MRI™ or Prodigy MRI™ IPG with Octrode™ or Penta™ Lead

IPG*	Lead**	Approved Implant Locations
3771 Protégé MRI 3772 Prodigy MRI	3186 Octrode, 60 cm 3228 Penta, 60 cm	▪ IPG in upper buttock, low back, flank, abdomen, or midline ▪ Lead tip in the epidural space between the T7 and T12 vertebrae

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

** The anchors associated with these models are MR Conditional components. Multiple MR Conditional leads and anchors may be implanted.

NOTE: Extensions are untested and are therefore considered MR Unsafe.

CAUTION: Confirm the lead and IPG locations are approved per the table above.

Table 8. RF Field Requirements for Protégé MRI™ or Prodigy MRI™ IPG with Octrode™ or Penta™ Lead

IPG Model	Lead Model	Scan Region	RF Coil	RF Power	Notes and Warnings
Protégé MRI 3771 -or- Prodigy MRI 3772	Octrode 3186 -or- Penta 3228	Head scans	Detachable Head transmit-receive coil (Circularly Polarized only)	Normal operating mode	1, 2, 3, 4, 6, 7
		Extremity scans ▪ All **except** hip and shoulder	Detachable Extremity transmit-receive coil (Circularly Polarized only)	Normal operating mode	1, 2, 3, 4, 5, 7

1. NOTE: The SAR requirements will be met if the scanner is in normal operating mode.
2. NOTE: To allow the MRI scanner to estimate the SAR, ensure that you enter the patient's body weight accurately into the scanner.
3. **WARNING: 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.**
4. **WARNING: Only Circularly Polarized, birdcage designs of Detachable Head and Extremity RF transmit-receive coils have been tested. Do not use other transmit coil designs (for example, linear, phased-array, or saddle) because these have not been tested and could result in serious patient injury.**
5. **WARNING: Scans of the hips and shoulders have not been tested using Detachable Extremity RF transmit-receive coils.**
6. **WARNING: To avoid excessive heating that could cause serious patient injury, do not place any part of the Detachable Head RF transmit-receive coil over any implanted neurostimulation system component.**
7. **WARNING: To avoid excessive heating that could cause serious patient injury, do not use the Integrated Whole body RF transmit coil.**

Performing the Scan and Monitoring the Patient

Before performing the scan, ensure that you have consulted the general and specific requirements for IPG and lead configurations.

While performing the scan, follow these guidelines:

- Leave any external control devices, such as a programmer or charger, out of the scanner magnet room (Zone IV).
- For head or extremity scans using the Detachable Head or Extremity RF transmit-receive coil, ensure that the transmit-receive coil does not cover any part of the implanted MR Conditional system (not applicable to IPG model 3660, 3662, 3670, or 3672 with lead model 3186).
- For scans using the Whole body RF transmit coil, involve personnel knowledgeable in MR safety to actively monitor the SAR levels during the scan (not applicable to IPG model 3660, 3662, 3670, or 3672 with lead model 3186).
- 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 finish scanning the patient and the patient is outside of the MRI environment, immediately disable MRI Mode and restore therapy, with the help of the Abbott Medical representative or managing clinician, if needed.

- To disable MRI Mode using a patient controller, refer to the instructions in Using the Patient Controller to Disable MRI Mode (page 15).
- To disable MRI Mode using a patient programmer, refer to the instructions in Using the Patient Programmer to Disable MRI Mode (page 16).

  NOTE: To identify which handheld device you are using, see the figure in Step 3: Ensure the Neurostimulation System Is in MRI Mode (page 5).

Using the Patient Controller to Disable MRI Mode

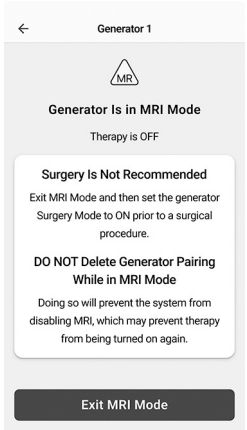
NOTE: If the patient did not bring the patient controller on the day of the MRI procedure, a clinician programmer that has been paired with the IPG can also be used. After connecting to the IPG using the clinician programmer, an authorized representative can disable MRI Mode by following steps similar 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: For Proclaim™ spinal cord stimulation (SCS) systems, 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 for generators with the following software versions: 1.1.0.1, 1.1.1.1, 1.1.2.1. See Using the Patient Controller to Confirm the System Components (page 3) to determine the generator software version.

To disable MRI Mode using the patient controller:

1. Start the patient controller app and connect to the IPG. You will see a screen showing that the generator is in MRI Mode.

Figure 20. 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**.

4. If you are unable to use the 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.
6. Install operating system software updates as they are made available, after verifying software version compatibility with the patient controller app via www.NMmobiledevicesync.com.

Using the Patient Programmer to Disable MRI Mode

To disable MRI Mode using the patient programmer:

1. Establish communication with the patient's IPG. See the steps in Setting the IPG to MRI Mode Using the Patient Programmer (page 8). You should see the following screen indicating that the IPG is in MRI Mode.

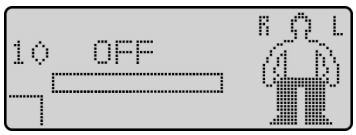
Figure 21. MRI Mode screen

2. Press the Select key. The following screen appears.

Figure 22. Exit MRI Mode screen

3. Press the Select key. The programmer disables MRI Mode, and a screen appears similar to the following Operational Display screen showing that stimulation is off.

Figure 23. Operational Display screen showing stimulation off



4. To start stimulation, press the Amplitude Increase key on the top of the programmer.

Figure 24. Operational Display screen showing stimulation on

Troubleshooting

This section provides information about troubleshooting issues you may encounter with the patient's handheld device.

NOTE: To identify which handheld device you are using, see the figure in Step 3: Ensure the Neurostimulation System Is in MRI Mode (page 5).

Troubleshooting Using the Patient Controller

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 18).
- 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 9. 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 password) while the generator is in MRI Mode. ▪ Patient controller app or mobile device operating system software 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 10. Troubleshooting messages for MRI Mode using the patient controller

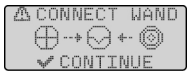
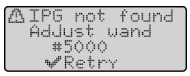
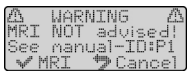
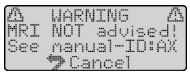
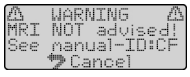
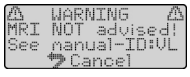
Message	Solution
Turn On Bluetooth® Wireless Technology to Access Generator	Turn on Bluetooth® wireless connection if connectivity is disabled. Refer to the manufacturer's information provided with the mobile device.
System Problem The system encountered a problem. Contact Abbott if this problem persists.	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.

Troubleshooting Using the Patient Programmer

The following table shows patient programmer screens that you may see while setting MRI Mode before a scan. If you see any of these screens, 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 18).

Table 11. Troubleshooting screens for MRI Mode

Screen	Description	Guideline
	The communication wand is not properly connected to the programmer.	Disconnect the communication wand from the programmer and reinsert it fully. Then press the Select key.
	The programmer did not locate the IPG when trying to establish communication with it.	Reposition the communication wand over the IPG site, and press the Select key to try to establish communication with the IPG again.
	The programmer encountered a problem communicating with the IPG (when entering or exiting MRI Mode).	Ensure the communication wand is positioned over the IPG site, and press the Select key to try to communicate with the IPG again.
	The battery capacity of the IPG is too low.	▪ Press the Previous Screen key on the programmer. ▪ Instruct the patient to fully recharge the IPG battery.
	The check of the lead impedance failed, likely because no lead is inserted in port 1 of the IPG header.	▪ Check the patient's identification card. ▪ If the patient only has one MR Conditional lead implanted, then consider pressing the Select key to proceed to MRI Mode. ▪ If the patient has two leads, do not perform the MRI scan. Press the Previous Screen key on the programmer, and contact Technical Support.
	The check of the lead impedance failed, likely because no lead is inserted in port 2 of the IPG header.	▪ Check the patient's identification card. ▪ If the patient only has one MR Conditional lead implanted, then consider pressing the Select key to proceed to MRI Mode. ▪ If the patient has two leads, do not perform the MRI scan. Press the Previous Screen key on the programmer, and contact Technical Support.
	The check of the lead impedance failed, likely because one or both ports of the IPG header contain a 4-electrode lead, which is not MR Conditional. (The actual screen shows a number in place of the "X," ranging from 1 to 5.)	Do not perform the MRI scan.
	The check of the lead impedance failed for another reason unrelated to the lead configuration.	▪ Do not perform the MRI scan. ▪ Contact Technical Support.
	The check of the lead impedance did not complete.	Press the Previous Screen key on the programmer, and try entering MRI Mode again.
	The system check failed because of a problem with the IPG.	▪ Do not perform the MRI scan. ▪ Contact Technical Support.

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 an MRI Scan

Complete this form to help you determine the eligibility of a patient with an implanted neurostimulation system for an MRI scan.

If the answers to all of the following questions are "Yes," consult the MRI procedures manual for complete information on conducting an MRI scan. If the answer to any of the questions is "No," do not perform the scan. If "Unsure," contact the patient's physician or Technical Support for help.

WARNING: Scanning patients who have other MR Conditional devices is acceptable as long as 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 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.

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

Eligibility Factors for an MRI Scan	**Yes**	**No**	**Unsure**
1. Does the patient have IPG and lead models that are MR Conditional? (See the patient's ID card for IPG and lead models.)	□	□	□
2. Are the MR Conditional components the only neurostimulation components implanted?	□	□	□
3. Does the location of the implanted components (including lead tips) meet the approved conditions of use? See Step 1: Confirm the MR Conditional Components and Location of the System (page 3).	□	□	□
4. Is only one IPG implanted?	□	□	□
5. Is the patient free of broken or abandoned neurostimulation devices?	□	□	□
6. Does the intended scan region meet the conditions of use for the RF coil that will be used? See Step 5: Confirm Implant Locations and Scan Requirements for the Patient's System (page 11).	□	□	□
7. Did you confirm the patient does not have a fever? (only applicable to IPG models 3660, 3662, 3670, 3672)	□	□	□
8. Is the IPG set to MRI Mode?	□	□	□

Appendix B: 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 12. 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

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