

MRI Procedure Information

For St. Jude Medical MR Conditional Neurostimulation Systems

CLINICIAN'S MANUAL

Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL and the nine-squares symbol are trademarks and service marks of St. Jude Medical, Inc. and its related companies. © 2015 St. Jude Medical, Inc. All Rights Reserved.

For a listing of patents for St. Jude Medical neuromodulation products, visit <http://patent.sjmneuro.com>.

Contents

Introduction	1
Symbols and Definitions	1
Models and Implant Locations for MR Conditional Neurostimulation Systems	2
MRI Equipment and Scanning Requirements	3
Warnings and Precautions.....	4
Warnings	4
Precautions	4
Potential Adverse Events	4
Preparing a Patient for an MRI Scan.....	4
Step 1: Confirm the Implanted System Contains Only MR Conditional Components	5
Step 2: Confirm No Adverse Conditions to Scanning Are Present	5
Step 3: Ensure the Neurostimulation System Is in MRI Mode.....	5
Step 4: Select the MRI Parameters According to the Scanning Requirements.....	8
Performing the Scan and Monitoring the Patient	8
Disabling the MRI Mode.....	9
Troubleshooting	10
Technical Support.....	10
Appendix A: Patient Eligibility Form for MRI Head or Extremity Scans.....	11

Introduction

Read the information in this manual before conducting an MRI scan on a patient with an implanted St. Jude 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 in order 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. If you have any questions, contact Technical Support. See "Technical Support" (page 10).

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 sjmprofessional.com/MRI.

Symbols and Definitions

The following symbols may be used in this manual and on the products and packaging:

Symbol	Description
	Caution, Consult Accompanying Documents
	Magnetic resonance (MR) conditional, device with demonstrated safety in an MRI environment within the defined conditions
	Magnetic resonance (MR) unsafe, device poses unacceptable risks to the patient, medical staff, or other people in an MRI environment

Models and Implant Locations for MR Conditional Neurostimulation Systems

The following table lists the approved model numbers and implant locations of the components that can comprise an implanted MR conditional neurostimulation system. The following figure shows the approved locations of an MR conditional IPG and lead (or leads).

WARNING:

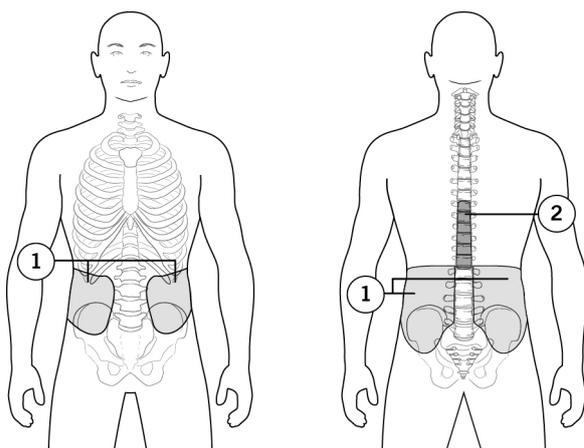
For an MR conditional system, all implanted components must be approved MR conditional models and implanted in approved locations according to the following table. If the implanted system contains any other components or models, then the system is considered untested for an MRI environment. In addition, a component must be implanted according to its approved location or the entire implanted system is considered untested.

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

Component	Model	Location of Implanted Component
IPG	3772 Prodigy MRI IPG	Upper buttock, low back, midline, flank, or abdomen
Lead*	3186 Octrode 60-cm lead 3228 Penta 60-cm lead	Lead tip in the epidural space between the T7 and T12 vertebrae
Lead anchor	All St. Jude Medical models	All locations

* Multiple MR conditional lead models may be implanted.

Figure 1. Approved locations for implanted components



1. Implant locations for the MR conditional IPG are the upper buttock, low back, midline, flank, and abdomen.
2. Implant locations for the tips of the MR conditional leads are in the epidural space between the T7 and T12 vertebrae.

MRI Equipment and Scanning Requirements

Patients implanted with MR conditional components of a St. Jude Medical™ neurostimulation system must be scanned according to the following requirements:

Table 2. MRI equipment and scanning requirements

	Scan Region		Notes and Warnings
	Head scans	Extremity scans	
Scan region (isocenter)	Head only Use head coil only.	<ul style="list-style-type: none"> Lower extremities: all except hip Upper extremities: wrist only Use extremity coil only.	WARNING: Do not place any part of the RF transmit-receive coil over any implanted neurostimulation system component. WARNING: Scans of the hips, shoulders, and hands are excluded and have not been tested.
Patient position	Supine, patient's arms must be at his or her sides for head scans	Supine, patient's arm must be at his or her side for upper extremity scans	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.
MRI system type	1.5-T closed-bore, horizontal field orientation	1.5-T closed-bore, horizontal field orientation	WARNING: Only use 1.5-T closed-bore horizontal field orientation MRI systems. Other MRI systems, such as 1.0-T and 3.0-T machines or open-bore machines, have not been tested and could cause device damage and excessive heating, which could result in serious patient injury.
Gradient slew rate	Maximum gradient slew rate of ≤ 200 T/m/s per axis	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 gradient	Maximum spatial gradient of 30 T/m (3000 G/cm)	Maximum spatial gradient of 30 T/m (3000 G/cm)	
RF coil	RF transmit-receive head coil (quadrature only)	RF transmit-receive extremity coil (quadrature only)	WARNING: To avoid excessive heating that could cause serious patient injury, do not use the body RF transmit coil. WARNING: Only quadrature, birdcage coil designs have been tested. Do not use other transmit coils designs (e.g., linear, phased-array, or saddle) because these have not been tested and could result in serious patient injury.
RF power (SAR)	Normal operating mode	Normal operating mode	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, which could result in serious patient injury. WARNING: Imaging with atoms other than hydrogen has not been tested and could result in serious patient injury. NOTE: The specific absorption rate (SAR) requirements will be met if the scanner is in normal operating mode.
Total active scan time (RF on-time)	<ul style="list-style-type: none"> 30 minutes total of active scan time per session 30-minute wait between sessions 	<ul style="list-style-type: none"> 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.

Warnings and Precautions

Read this section for warning 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 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. An MRI scan can be conducted safely using an RF transmit-receive coil when no parts of the implanted neurostimulation system component are within the coil. This can be confirmed with X-ray imaging of the neck, head, and extremity regions or 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.

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 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.

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 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 correct 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 St. Jude 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 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 a Patient for an MRI Scan

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

1. Confirm that the implanted neurostimulation system contains only MR conditional components.
2. Confirm that no adverse conditions to MR scanning are present.
3. Ensure the patient's neurostimulation system is in MRI mode.
4. Select the MRI parameters according to the scanning requirements.

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.

NOTE:

Before the day of the MRI procedure, inform patients to bring their patient ID card, their patient programmer, and their charger with them.

Step 1: Confirm the Implanted System Contains Only MR Conditional Components

To confirm that the patient's implanted neurostimulation system contains only MR conditional components, review the patient's identification card for his or her system. When a neurostimulation system is implanted, a patient receives an identification card that identifies the model numbers of the implanted components to help you identify them as MR conditional.

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 identified in the table in "Models and Implant Locations for MR Conditional Neurostimulation Systems" (page 2).

NOTE:

If a patient does not have his or her system identification card, consider other means of confirming the MR conditional system, such as referencing the patient's medical history or contacting Technical Support.

Step 2: Confirm No Adverse Conditions to Scanning Are Present

If any conditions exist that could make an MRI scan unsafe, do not scan the patient. Such conditions include

- The presence of implanted neurostimulation components that are not listed as MR conditional as outlined in the table in "Models and Implant Locations for MR Conditional Neurostimulation Systems" (page 2)
- The location of MR conditional components in an area other than what is noted in the table in "Models and Implant Locations for MR Conditional Neurostimulation Systems" (page 2)
- 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

Step 3: Ensure the Neurostimulation System Is in MRI Mode

Ensure that the patient's neurostimulation system is in MRI mode according to these guidelines:

CAUTION:

Do not bring any external control devices, such as the programmer or charger, into the scanner magnet room (Zone IV). Because these devices contain ferromagnetic material, they can be affected by the MRI magnet and are considered MR unsafe.

1. Turn on the patient's programmer and communicate with the IPG.
2. Confirm that the IPG is set to MRI mode using the patient's programmer (see the following image).

Figure 2. MRI mode screen



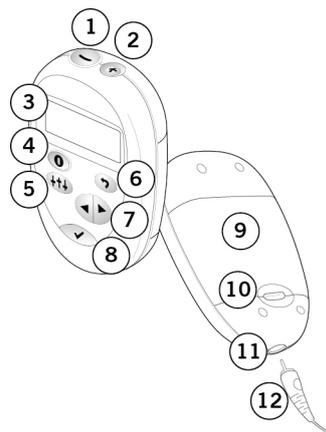
3. If needed, set the IPG to MRI mode.

Each of the following subsections provide information for completing each of these guidelines.

Parts of the Patient Programmer

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

Figure 3. Parts of the patient programmer



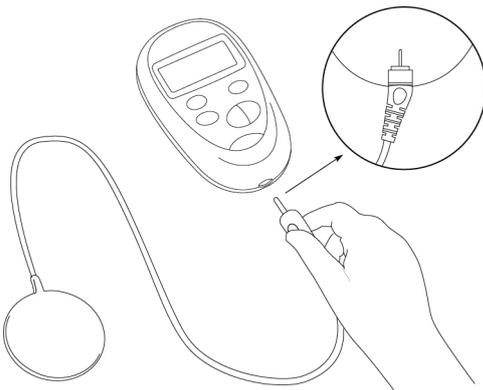
1. Amplitude Decrease key
2. Amplitude Increase key
3. Display screen
4. Power key
5. Balance key
6. Previous Screen key
7. Scroll keys (left and right)
8. Select key
9. Battery pack
10. Battery release latch
11. Wand port
12. Communication wand connector

Communicating With the IPG and Confirming MRI Mode

To establish communication with the IPG, follow these steps:

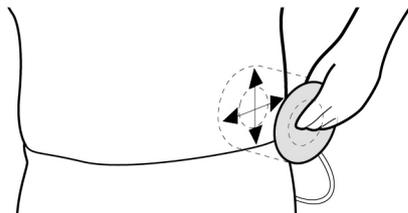
1. Ensure that the programmer is off. (It turns itself off after one minute of non-use.)
2. Plug the communication wand into the wand port on the bottom of the programmer.

Figure 4. 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 5. 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 6. 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.

NOTE:

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 7. IPG FOUND screen



Next, an IPG information screen appears that is similar to the following figure. 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 8. MR icon on the IPG information screen



If the IPG is set to MRI mode, the following screen will be displayed. If you do not see this screen, you will need to enable MRI mode. See the following section, "Setting the IPG to MRI Mode" (page 7), for information on how to do this.

Figure 9. MRI mode screen



Setting the IPG to MRI Mode

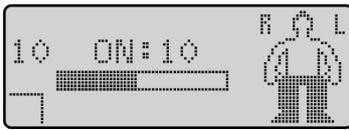
If you do not see the MRI mode screen after communicating with the IPG, follow these steps to place the device into MRI mode:

NOTE:

Before patients arrive for the MRI procedure, consider reminding them to fully recharge their IPG in order 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.

1. Ensure that you have established communication with the patient's programmer by following the steps in "Communicating With the IPG and Confirming MRI Mode" (page 6). If MRI mode is not enabled, you should see a screen similar to the following Operational Display screen.

Figure 10. 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 11. Scroll to the MRI mode icon



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

Figure 12. 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 10) for guidelines on how to proceed.

Figure 13. MRI mode screen



Step 4: Select the MRI Parameters According to the Scanning Requirements

After you have confirmed that the patient’s IPG is set to MRI mode, set up the MRI equipment. Refer to the table in “MRI Equipment and Scanning Requirements” (page 3).

Performing the Scan and Monitoring the Patient

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).
- Ensure that the transmit-receive coil does not cover any part of the implanted MR conditional system.
- Keep the duration of the total active scanning time to 30 minutes or less per session using the head coil or the extremity coil. 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 minimal image distortion may occur around an implanted lead or IPG. Consider these factors also when interpreting the MRI images.

Disabling the MRI Mode

After you have finished scanning the patient, you can use the patient’s programmer to disable the MRI mode. To disable the MRI mode, follow these steps:

1. Establish communication with the patient’s IPG. See the steps in “Communicating With the IPG and Confirming MRI Mode” (page 6). You should see the following screen indicating that the IPG is in MRI mode.

Figure 14. MRI mode screen



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

Figure 15. 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 16. Operational Display screen showing stimulation off



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

Figure 17. Operational Display screen showing stimulation on



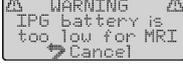
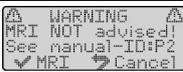
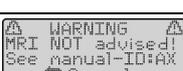
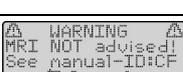
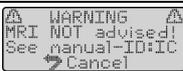
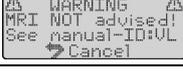
Troubleshooting

The following table shows 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.

Table 3. 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> Do not perform the MRI scan. Contact Technical Support.

Technical Support

For technical questions and support for your St. Jude Medical™ neuromodulation product, use the following information:

- +1 972 309 8000
- +1 800 727 7846 (toll-free within North America)

For additional assistance, call your local St. Jude Medical representative.

Appendix A: Patient Eligibility Form for MRI Head or Extremity Scans

Complete this form to help you determine the eligibility of a patient with an implanted neurostimulation system for an MRI head or extremity scan using the RF transmit-receive coil only.

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 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 retrieve the most recent version online at sjmprofessional.com/MRI.

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

Eligibility Factor	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. Identify the location of the implanted components (including lead tips) and mark them on the diagram to the right. Is the IPG within zone 1, and are the leads within zone 2?			
4. Is only one IPG implanted?			
5. Is the patient free of broken or abandoned neurostimulation devices?			
6. Is the MRI for an approved scan region?			
7. Is the IPG set to MRI mode?			

<p>Approved Implant Locations</p> <p>Zone 1, IPG location: Upper buttock, low back, midline, flank, or abdomen</p> <p>Zone 2, lead tip location: T7–T12</p>

Manufacturer:
St. Jude Medical
6901 Preston Road
Plano, Texas 75024
USA
+1 972 309 8000

Manufacturing Site:
St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5
Santana Industrial Park
Arecibo, PR 00612
USA

sjm.com

European Authorized Representative:
St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

Manufacturing Site:
St. Jude Medical Operations (M) Sdn. Bhd.
Plot 102, Lebuhraya Kampung Jawa,
Bayan Lepas Industrial Zone
11900 Penang
Malaysia

Australian Sponsor:
St. Jude Medical Australia Pty. Limited
17 Orion Road
Lane Cove NSW 2066
Australia



ST. JUDE MEDICAL™



2015-07
ARTEN100125922 A

CE
0123