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examinations

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If you have an MRI appointment

Warning: MRI should not be prescribed for patients undergoing trial (test) stimulation or who have any neurostimulation system components that are not fully implanted. If an MRI scan is required, the clinician must explant all trial (test) stimulation components. MRI has not been tested on trial (test) stimulation components and may cause heating of the lead electrodes, resulting in tissue damage or serious patient injury.

Depending on what kind of neurostimulation system components that you have implanted, you may be eligible for one of the following types of magnetic resonance imaging (MRI) scans:

- MRI scans of the head only (this is referred to as head-only eligible).
- MRI scans of any part of your body (this is referred to as full-body eligible).

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Responsibilities of the patient in preparing for the MRI appointment

 If you have a patient identification (ID) card given to you by Medtronic for your implanted neurostimulation system, be sure to bring your most current card to every MRI appointment.

The patient ID card shows the MRI clinician that Medtronic is the manufacturer of your implanted neurostimulation system. The patient ID card also identifies your neurostimulator model number.

The MRI clinician can use this information to obtain instructions to determine the eligibility of your implanted neurostimulation system for the MRI scan and the MRI scan safety conditions required by your neurostimulation system.

 Bring the MRI scan eligibility sheet to the MRI appointment if you were given one

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from your clinician managing your neurostimulation system.

Note: The MRI scan eligibility sheet information should match what is displayed on the **In MRI Mode** screen of your controller.

 Bring your controller to every MRI appointment. However, do **not** take the controller into the MRI scanner (magnet) room.

At the MRI appointment

- If you have a patient identification (ID) card given to you by Medtronic for your implanted neurostimulation system, present your most current card to the MRI clinician.
- Be sure to inform the MRI clinician that you have an implanted neurostimulation system for chronic pain.
- If you no longer have an implanted neurostimulator, be sure to inform the MRI

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clinician of any leads or other components that still remain implanted.

- To obtain the MRI guidelines, the MRI clinician can refer to the contact information at the back of this manual, or the MRI clinician can go to www.medtronic.com/mri.
- Warning: Inform the MRI clinician before you enter the MRI scanner (magnet) room that you have an implanted neurostimulation system. If you do not provide this important information, you may be given an inappropriate MRI scan, which could cause you injury or could cause damage to your implanted medical device. The MRI clinician conducting your MRI scan needs to be aware of all medical implants in order to assess the conditions for safely performing your MRI scan.

Determining if you are in MRI mode

Be sure your stimulation is turned off and your neurostimulator is in MRI mode. Refer to the

following instructions to determine if you are in MRI mode.

- If necessary, unlock your controller by pressing and holding the Lock () button on the Unlock screen.
 - You should see the In MRI Mode screen. Refer to Figure 6.2 on page 136 for examples of these screens. If you see the In MRI Mode screen, you are in MRI mode.
 - If you see the Home screen, you are not in MRI mode. Refer to "Using your controller to activate MRI mode" on page 134.

Notes:

- If you bring your controller to the MRI appointment, the information displayed on the In MRI Mode screen accurately displays the MRI eligibility for your neurostimulation system.
- If you also have an MRI eligibility sheet from your clinician, the In MRI Mode screen

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should match the information on the MRI eligibility sheet.

Placing your neurostimulation system in MRI mode for the MRI scan

Your implanted neurostimulation system must be placed in MRI mode before your MRI scan. MRI mode turns stimulation off.

MRI mode can be activated with your controller or with a clinician programmer. Table 6.1 shows where to go in this chapter for more information.

Table 6.1 Activating MRI mode

| With a controller | See "Using your controller to activate MRI mode" on page 134. |
|-----------------------------|---|
| With a clinician programmer | See "Visiting your clinician to activate MRI mode" on page 141. |
| | |

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Using your controller to activate MRI mode

If you brought your controller to the MRI appointment, you can place your neurostimulation system in MRI mode before your MRI scan and outside of the MRI scanner (magnet) room. MRI mode turns stimulation off.

When you activate MRI mode with your controller, stimulation is turned off and the **In MRI Mode** screen will appear (Figure 6.2 on page 136). Show this screen to the MRI clinician.

During the MRI scan, keep your neurostimulation system in MRI mode (stimulation must remain off).

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After the MRI scan and outside of the MRI scanner (magnet) room, you can turn stimulation back on using your controller or you can return to the clinician managing your neurostimulation system to have stimulation turned back on.

Activating MRI mode

Complete the following steps to activate MRI mode.

- 1. If necessary, unlock your controller by pressing and holding the Lock () button on the Unlock screen.
- 2. Press the Menu () button on the Home screen.
- 3. Select the MRI Mode button. The Enter MRI Mode screen appears (Figure 6.1).



Figure 6.1 Enter MRI Mode screen.

4. Press the **Continue** button to continue.

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When MRI mode is activated, your implanted neurostimulation system has been placed in MRI mode and stimulation is turned off.

In addition, one of three **In MRI Mode** screens will appear showing the MRI scan eligibility for your implanted neurostimulation system (Figure 6.2). The display of the **In MRI Mode** screen confirms that your neurostimulation system has been placed in MRI mode and stimulation has been turned off.



Figure 6.2 The In MRI Mode screen displays your MRI scan eligibility.

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Table 6.2 MRI scan eligibility icons

| con combination | Explanation |
|-------------------------|---|
| <u>A</u> (=) (<u>i</u> | Full-body scan eligible |
| | The implanted neurostimulation system allows the patient to be eligible to have MRI scans of any part of the body under specific conditions. The MRI clinician must consult the MRI guidelines for those conditions. |
| 🛕 (@) 🕕 | Head scan eligible with transmit/ receive head coil |
| | The implanted neurostimulation system allows the patient to be eligible for MRI scans of the head only using an RF transmit/receive head coil and under other specific conditions. The MRI clinician must consult the MRI guidelines for those conditions. |
| <u>A</u> []i | The neurostimulation system MRI scan eligibility cannot be determined. |
| | The MRI clinician must consult the MRI guidelines to determine how to proceed or contact Medtronic Technical Support. |

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5. Do not press any other keys or buttons.

Note: The **In MRI Mode** screen on the controller will display for 10 minutes. The keys on the controller are disabled when in MRI mode.

6. Give your controller to the MRI clinician with the **In MRI Mode** screen displayed.

Note: Do **not** take your controller into the MRI scanner (magnet) room. If you brought the recharger with you to the MRI appointment, do **not** take the recharger into the MRI scanner (magnet) room either.

Caution: Do not turn stimulation back on before your MRI scan. Leaving stimulation on during the scan could increase the potential for uncomfortable, unintended stimulation.

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Turning stimulation back on after the MRI scan

Turn stimulation back on when the MRI scan is complete and you are **outside** of the MRI scanner (magnet) room.

Turning stimulation back on deactivates MRI mode. Stimulation can be turned on with the controller or the clinician programmer:

- If you do not have your controller with you, go to the clinician managing your neurostimulation system to turn stimulation on using the clinician programmer.
- If you brought your controller to the MRI appointment, turn stimulation back on using the controller (see the steps that follow).

Complete the following steps to turn on stimulation using the controller.

 If necessary, unlock your controller by pressing and holding the Lock () button on the Unlock screen.

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2. Press the Exit MRI Mode button on the In MRI Mode screen (Figure 6.3).



Figure 6.3 Example In MRI Mode screen.

The **Stimulation is off** screen appears (Figure 6.4).



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Figure 6.4 Stimulation is off screen.

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- **3.** Press one of the available buttons from the **Stimulation is off** screen (Figure 6.4):
 - Press the **OK** button to keep stimulation off and to return to the **Home** screen.
 - Press the Turn On button to turn on stimulation and return to the Home screen. Your stimulation settings will return to how they had been programmed before you entered MRI Mode.

If the **Home** screen is not shown after exiting **MRI Mode**, refer to "Troubleshooting" on page 163.

Visiting your clinician to activate MRI mode

Note: The model number for your implanted neurostimulator is on your patient ID card.

If you have a neurostimulator with SureScan MRI Technology, the clinician managing your neurostimulation system can place your neurostimulation system in MRI mode for your

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MRI examination using the clinician programmer.

You may need to inform your clinician managing your neurostimulation system that an MRI examination has been prescribed for you and that you need MRI mode activated.

MRI mode turns stimulation off. Do not turn stimulation back on before your MRI scan.

Caution: Do not turn stimulation back on before your MRI scan. Leaving stimulation on during the scan could increase the potential for uncomfortable, unintended stimulation.

The clinician may give you an MRI scan eligibility sheet to bring to your MRI appointment. Give the eligibility sheet to the MRI clinician.

During the MRI scan, keep your neurostimulation system in MRI mode (stimulation must remain off).

After the MRI scan and outside of the MRI scanner (magnet) room, you can turn

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stimulation back on using your controller or you can return to the clinician managing your neurostimulation system to have stimulation turned back on.

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7 Using the recharging system with the implanted neurostimulator

This section of the manual provides instructions on how to recharge your implanted neurostimulator.

The recharging system is packaged separately from the controller. Refer to the manual packaged with the recharging system for more information about the recharging system components.

△ Caution: Check battery status and charge the battery regularly. Battery capacity will continue to slowly drain, even when the neurostimulator is off. If the battery becomes completely discharged, therapy will be lost.

Recharging the implanted neurostimulator battery

Recharging the neurostimulator battery

The controller battery pack should be charged before starting to recharge the neurostimulator

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battery. Refer to "Recharging the controller battery pack" on page 158.

Only use the controller and recharger with the implanted neurostimulator listed in this manual.

Charge the controller battery pack and implanted neurostimulator even if you are not using them for an extended period of time. You cannot charge the controller and neurostimulator at the same time.

Your ability to locate your neurostimulator and the depth of the neurostimulator determine the efficiency of the recharging session. With practice, you will find the best location on your skin for placing your recharger.

Note: Recharging quality is affected by factors such as implant depth and location. Recharging quality will vary between patients. Discuss your recharging quality with your clinician.

▲ Warning: DO NOT use the recharger on an unhealed wound. The recharging system is

not sterile, and contact with the wound can cause an infection.

1. If desired, place the recharger head into the opening on the belt.

Note: The belt is packaged with the recharging system. For more information about using the belt, refer to the manual packaged with the recharging system.

2. Plug the recharger into the controller charging port (Figure 7.1).



Figure 7.1 Plugging the recharger into the controller charging port.

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3. If necessary, press and hold the Lock () button on the Unlock screen. The Position screen will be displayed (Figure 7.2).



Figure 7.2 Position screen.

- 4. Press your skin where your neurostimulator is located to determine the best place to position the recharger.
- 5. Position the recharger over your neurostimulator and press the **Continue** button.

A series of screens will appear on the controller screen describing the recharging activity.

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Note: Your recharger may make clicking noises while it searches for the neurostimulator. This is considered normal.

6. If the recharger is able to successfully locate the neurostimulator, the **Batteries** screen (Figure 7.3) will display with the recharging quality.



Figure 7.3 Batteries screen with the neurostimulator recharging quality.

Notes:

 The recharging light will flash green while your neurostimulator is recharging.

- Refer to Table 7.1 on page 153 for more information about recharging status indicators.
- Press the Exit (X) button to view the Home screen. If you intend to make adjustments to your stimulation while recharging, refer to "Changing parameter and stimulation settings" on page 101.
- 8. Press the Lock () button to lock the controller while recharging.

Note: When the controller is locked during the recharging process, it will still continue to recharge your neurostimulator.

The recharger should remain over your neurostimulator until the recharging light is steady green and no longer flashing. When recharging is complete, the **Batteries** screen displays **Finished** (Figure 7.4).