USING YOUR INTELLIS™ IMPLANTABLE SPINAL CORD STIMULATION SYSTEM
This guide provides basic resources and information to help you use your Medtronic Intellis™ Spinal Cord Stimulation system.

Note that the words **Controller and Programmer** are used interchangeably. The Controller/Programmer controls the recharger and allows you to adjust your therapy. The word **Programmer** is used primarily in this booklet.

Refer to the **Controller (Programmer) User Manual** for more information.

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Your Medtronic Patient Identification Card

Keep your ID card with you at all times, and ensure the information on it is accurate.

**Your ID card:**
- Identifies you as having an implanted device in an emergency
- Includes a toll-free number to contact Medtronic
- Helps Medtronic maintain current and accurate information for your records
- Allows you to notify security personnel and health professionals that you have an implanted medical device

Present your ID card when you have any medical or dental procedures, or when you must pass through a security screening system (such as airport security) where your device may set off an alarm.

GETTING AN IDENTIFICATION CARD

You should have received a temporary ID card at the time of your implant procedure. You will automatically receive a permanent ID card from Medtronic three to four weeks after the procedure. There is no fee for the card.

Contact Patient Registration at the number below if you do not receive a permanent ID card in four to six weeks.

If you move or change physicians, or change any of the other information on your card, contact Patient Registration. You may also update your card online at medtronic.com by selecting the Patients and Caregivers tab, then clicking on Contact Patient Services under the Support heading. Look for Neuromodulation Patient Service title and click on Device registration (ID Card).

If your ID card is lost or stolen, Patient Registration can issue a replacement card. Patient Registration can also issue an extra card for a spouse.

**Patient Registration Contact Information**

Call (800) 551-5544 Monday–Friday, 7 a.m. to 6 p.m. CT.

**Programmer Basics**

**PROGRAMMER KEYS**

1. **Stimulator On/Off**
   - Turns stimulation on or off
2. **Recharging Light**
   - Indicates battery charging status (used with rechargeable neurostimulators)
3. **Touchscreen**
   - Screen reacts to your touch and allows you to press buttons and functions that are displayed on the screen
4. **Increase/Decrease Key**
   - Wakes up the programmer
   - Adjusts stimulation
   - Selects and navigates settings displayed on the screen
5. **Charging Port**
   - (used with rechargeable neurostimulators)
     - Connects to the recharger cord
     - Used to recharge the programmer
     - Used to recharge the neurostimulator

**Note:** To perform most functions on the programmer, you must first press the Increase/Decrease key to wake up the programmer.
THERAPY SCREEN OVERVIEW

1. Battery status button
   - Press to check battery status
   - Left icon on this button displays the programmer battery status
   - Right icon displays the neurostimulator battery status

2. Lock Button
   - Press to lock programmer

3. Menu Button
   - Press to access Menu screen

4. Group Button
   - Press to show group name (indicated by A, B, or C)
   - Green highlighting indicates the group is active
   - Note: The Group button will be gray when stimulation is off. An orange message will appear, alerting you that stimulation is off.

5. Program Buttons
   - Press to show up to four programs, indicated by numbered boxes (1-4)
   - After pressing the Program button on the Home screen, available settings for that program will appear:
     - Intensity — Controls the strength of the stimulation
     - Stimulation — Turns stimulation on or off
     - Rate — Sets the speed of the stimulation pulses
     - AdaptiveStim™ — Turns AdaptiveStim™ on or off (this feature is only available with the Intellis™ with AdaptiveStim™ technology implanted neurostimulator)
     - Pulse width — Sets the length of the stimulation pulse (pulse width affects the strength and coverage area of the stimulation)
     - Cycling — Turns stimulation on and off at regular intervals, as programmed by your clinician
     - Up/Down buttons — Press to view additional parameter and stimulation settings for a program (these buttons may not appear, depending on how your clinician has programmed your neurostimulator)

BASIC PROGRAMMER FUNCTIONS

Unlocking your programmer

1. When the Increase/Decrease key is pressed to wake up the programmer, the Unlock screen appears.
   - When the programmer is locked, you can press the Stimulation On/Off key to bypass the Unlock screen and to turn stimulation on or off.

2. Press and hold the Lock ( ) button on the Unlock screen.
   - As the Lock button is held, bars appear on the screen and move toward the Lock button.
   - Stop pressing the Lock button when the screen changes to a circle of dots. This indicates that the programmer is searching for your neurostimulator.

Turning stimulation On or Off for all programs within a group

1. Press the Stimulation On or Off button, which is located on the top of your programmer, to turn the stimulation on or off.
   - Press the Go To Unlock button, if you wish to access the Home screen instead.

2. The Home screen will appear to confirm whether stimulation is on.
   - Note: When stimulation is on, the active Group will be highlighted in green.

Adjusting stimulation

1. Press a Program button on the Home screen. The available setting for that program will display.

2. Use the Increase/Decrease keys to adjust desired program settings.
   - Note: Some settings may not be available, depending on what your clinician has programmed for your neurostimulator.
Changing a group
1. From the Home screen, select the current group on the left side of the screen to access the other groups available, then select the circle next to the desired group. Only one group can be selected at a time.
2. Up to three groups may be available. Groups are viewed by letters A, B, and C.
3. Press the OK button. The Home screen will display, showing the selected group.

Checking programmer battery level
4. From the Home screen, press the Battery status button. Two battery figures appear.
5. Press the Exit (X) button at the top right corner of the touchscreen to exit.

WARNING, ALERT, AND NOTIFICATION SCREENS
Warning screens indicate a problem with the programmer, recharger, or neurostimulator. See pages 163–171 of the controller (programmer) manual for more explanation of each warning screen.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
<th>Screen Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Red triangle with an exclamation point</td>
<td>Warning screen</td>
</tr>
<tr>
<td>!</td>
<td>Orange triangle with an exclamation point</td>
<td>Alert screen</td>
</tr>
<tr>
<td>i</td>
<td>Blue circle with the letter “i”</td>
<td>Notification screen</td>
</tr>
</tbody>
</table>

Alert screens indicate a pairing or other connection problem between the programmer, recharger, or neurostimulator. See pages 171–181 of the controller (programmer) manual for more explanation of each Alert screen.

Notification screens provide information about stimulation settings, error conditions, and battery levels. See pages 181–186 of the controller (programmer) manual for more explanation of each Notification screen.

AdaptiveStim™ Technology
This feature is only available with the Intellis™ with AdaptiveStim™ technology model 97715 implanted neurostimulator.

When AdaptiveStim™ is turned on, the implanted neurostimulator can automatically sense your body position and adjust the stimulation based on your body position.

Note: AdaptiveStim™ must be turned on to view or change AdaptiveStim™ settings.

Turning AdaptiveStim™ on or off
1. Press a Program button on the Home screen for the program you want to adjust.
2. Press the AdaptiveStim™ (On/Off) button. The AdaptiveStim™ screen is shown at right.
3. Press the On or Off button to turn AdaptiveStim™ on or off.

Note: When you turn AdaptiveStim™ on or off for one program, it affects all programs the same way.

4. Press the Exit (X) button at the top right corner of the touchscreen to exit.

Making adjustments to AdaptiveStim™
1. To change AdaptiveStim™ intensity settings for a specific position, place your body in the desired position before making the adjustments.
2. Use the Check Position feature to confirm that the neurostimulator recognizes your body position.
3. Make the appropriate adjustments to your intensity settings.
4. You may need to stay in your current position for up to five minutes before the new intensity settings are recorded. Your clinician can adjust this length of time. Confirm the length of time with your clinician.
5. The next time you return to this position, the intensity settings automatically change to the recorded settings.
Recharging System

If you have a rechargeable neurostimulator, this section explains how to recharge both your neurostimulator and the recharger.

The Recharging System includes the following components:

1. The Recharger (attached to the programmer) charges your implanted neurostimulator.
2. The Belt can be used to keep the antenna positioned directly over the implanted neurostimulator during a charging session.
3. The Programmer Battery Pack is the rechargeable power source for the patient programmer.
4. The AC Power Supply charges the programmer using AC power. Plug one end into a wall outlet and the other end into the programmer.

RECHARGING YOUR IMPLANTED NEUROSTIMULATOR

If the Low Battery screen appears, you need to recharge your implanted neurostimulator:

1. If desired, place the recharger head into the opening on the belt.
2. Plug the recharger into the programmer charging port.
3. If necessary, press and hold the Lock button on the Unlock screen. The Position screen will be displayed.
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 programmer screen describing the recharging activity.

Note: The recharging light above the touchscreen will flash green while your neurostimulator is recharging.

Tips

- Recharging can only be performed with the rechargeable battery pack installed in the programmer.
- The programmer battery pack should be charged before starting to recharge the neurostimulator battery.
- Charge the programmer battery pack and implanted neurostimulator even if you are not using them for an extended period of time.
- You cannot charge the programmer and neurostimulator at the same time.
- Your ability to locate your implanted 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.

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.

- You can turn stimulation on and off during a charging session, and also adjust stimulation during this time.
- If the recharger has a poor connection to your neurostimulator, the Reposition Antenna screen will appear.

Note: Your recharger may make clicking noises while it searches for the neurostimulator.
Changing the recharging temperature and speed:

The recharging temperature and speed can only be adjusted while the neurostimulator is being actively recharged. The higher the number, the quicker and warmer recharging will be. The default recharging temperature and speed is 4.

1. If necessary, press and hold the Lock (-Qaeda) button on the Unlock screen.
2. Press the Exit (X) button on the Batteries screen.
3. Press the Menu (D) button on the Home screen.
4. Drag the slider bar, or use the Increase/Decrease key to view additional preferences on the Menu screen.
5. Select the Recharging button. The Recharging screen is shown to the right.
6. Using the touchscreen or the Increase/Decrease key, select the circle next to the desired recharging temperature and speed.
   - The more bars you select, and the higher the number, the faster the recharging speed and the warmer the recharger will feel while you are recharging.
   - It is normal to feel some heat under the recharger while recharging. If it is uncomfortable, reduce the recharging speed.
   - The recharging temperature and speed that you select will stay the same until you change the setting again.
7. Press the OK button to exit.
8. Press the Exit (X) button to return to the Home screen.
9. Press the Battery status (D) button to view the Batteries screen.

Or, press the Lock ( Niagara) button to lock the programmer.

RECHARGING THE PROGRAMMER BATTERY PACK

The power supply cannot be used to recharge AA batteries.

1. Plug the power supply into an electrical outlet.
2. Plug the connector end of the power supply into the charging port of the programmer.
3. Press and hold the Lock (Y) button on the Unlock screen. If recharging is successful, the word “Recharging” will begin to flash on the Batteries screen.

Note: The recharging light above the touchscreen will flash green while your programmer battery pack is recharging. When the programmer battery pack is completely charged, the recharging light above the touchscreen will be steady green and no longer flashing. The Batteries screen will display Finished.

4. Press the Exit (X) button to view the Home screen.
5. Press the Lock (Y) button to lock the programmer while recharging.
6. To complete recharging the programmer battery pack, unplug the power supply from the programmer charging port.
Before Your MRI

You may be eligible for an MRI scan anywhere on your body or on just your head. This will depend on the type of neurostimulation system you have.

1. **Tell the doctor who prescribed your MRI scan that you have an implanted Medtronic neurostimulation system.**

2. **Contact your pain specialist to discuss your upcoming MRI scan.** Your pain specialist may also provide you or your radiologist with a copy of the MRI Patient Eligibility Form. The information on this form can help the radiologist confirm your eligibility for the prescribed MRI scan.

3. **Schedule your MRI appointment.** When your MRI appointment is scheduled, provide them with the model number of your implanted neurostimulation system and the contact information for your pain specialist. This information is located on your Medtronic Patient ID Card and on the MRI Patient Eligibility Form (which may have been provided by your pain specialist).

**Note:** Ensure your neurostimulator has been recharged prior to your MRI appointment, to avoid any unnecessary delays.

If you have questions about your MRI Scan eligibility or how to prepare your neurostimulation system for an MRI scan, contact your pain specialist or Medtronic Patient Services at (800) 510-6735.

An MRI scan may be safely performed under certain specific conditions.* Not following the specific conditions can cause tissue damage and can result in serious patient injury.

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**USING YOUR PROGRAMMER TO ACTIVATE MRI MODE**

Place your neurostimulation system in MRI mode before your MRI scan and **outside** of the MRI scanner (magnet) room.

When you activate MRI mode with your programmer, stimulation is turned off and the In MRI Mode screen will appear. Show this screen to the MRI clinician.

**Activating MRI mode:**

Complete the following steps to activate MRI mode.

1. Press the Menu (●) button on the Home screen.
2. Select the MRI Mode button. The Enter MRI Mode screen appears.
3. Press the Continue button to continue.

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.

MRI Mode Screen displays your MRI scan eligibility.

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*Please have your healthcare professional contact Medtronic for the latest MRI guidelines for your neurostimulation system for chronic pain.

Contact information is found at the back of this manual, or the healthcare professional can go to www.medtronic.com/mri.
MRI scan eligibility icons

<table>
<thead>
<tr>
<th>Icon combination</th>
<th>Explanation</th>
</tr>
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<tbody>
<tr>
<td>![MR]</td>
<td>Full-body scan eligible&lt;br&gt;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.</td>
</tr>
<tr>
<td>![MR] + ![Head coil]</td>
<td>Head scan eligible with transmit/receive head coil&lt;br&gt;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.</td>
</tr>
<tr>
<td>![MR] + ![D]</td>
<td>The neurostimulation system MRI scan eligibility cannot be determined&lt;br&gt;The MRI clinician must consult the MRI guidelines to determine how to proceed or contact Medtronic Technical Support.</td>
</tr>
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</table>

**Note:** The In MRI Mode screen on the programmer will display for 10 minutes.

**Do not press any other keys or buttons.**

**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.

**WARNING:** You may be given an inappropriate MRI scan, which could cause you injury or could cause damage to your implanted medical device if you do not inform the MRI clinician before you enter the MRI scanner (magnet) room that you have an implanted neurostimulation system. 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.

**TURNING STIMULATION BACK ON AFTER THE MRI SCAN**

Complete the following steps to turn on your stimulation using the programmer:

1. If necessary, unlock your programmer by pressing and holding the Lock (เฉพาะ) button on the Unlock screen.
2. Press the Exit MRI Mode button on the In MRI Mode screen. The Stimulation is off screen appears.
3. Press one of the available buttons from the Stimulation is off screen:
   - Press the OK button to keep stimulation off and to return to the Home screen.
   - Or, 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.
4. If the Home screen is not shown after exiting MRI Mode, refer to the “Troubleshooting” section on page 161 of the controller (programmer) manual.

**Note:** Do not take your programmer into the MRI scanner (magnet) room.
More Resources

Call Patient Services at (800) 510-6735 Monday–Friday, 8 a.m. to 5 p.m. CT for assistance with:

- Programmer or recharger troubleshooting
- Finding a new physician if you are traveling or moving
- Your Medtronic Patient ID card

Follow up with your doctor for assistance with:

- Medical concerns
- Managing your therapy, including what stimulation level you should use and adjustments to the stimulation level, if needed
NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

Brief Summary: Product manuals must be reviewed prior to use for detailed disclosure.

Indications

Implantable neurostimulation systems - A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) system as an aid in the management of chronic, intractable pain of the trunk and/or limbs—including unilateral or bilateral pain associated with the following conditions:

- Failed Back Syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia

Contraindications

Diathermy - Do not use shortwave diathermy, microwave or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the locations of the implanted electrodes, resulting in severe injury or death.

Warnings

Sources of strong electromagnetic interference (e.g., defibrillation, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device.

Precautions

The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 18), pregnancy, unborn fetus, or delivery. To properly assess test stimulation, patients should be detoxified from narcotics prior to lead placement. Clinicians and patients should follow programming guidelines and precautions provided in product manuals. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components. Patients should not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA). Electromagnetic interference, postural changes, and other activities may cause shocking or jolting. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging.

Adverse Events

Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, gastrointestinal symptoms (diarrhea, constipation, and leakage of stool), bladder symptoms (urinary retention and frequency and leakage of urine) and surgical risks.

For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic’s website at www.medtronic.com.

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