USING YOUR INTELLIS IMPLANTABLE SPINAL CORD STIMULATION SYSTEM

Intellis™ Platform

Medtronic
Further, Together
Thank you for making the decision to receive a Medtronic Intellis™ Neurostimulator to help relieve your chronic pain. We are grateful to have the opportunity to support your needs throughout your pain journey. This guide will provide basic information to help you use your Medtronic Intellis™ Spinal Cord Stimulation system. If you have questions or concerns, please see below the list of resources we have available for you to connect with us.

Resources

TALK TO A PAIN AMBASSADOR
An ambassador is a current patient who has a spinal cord stimulator for relief of chronic pain and has volunteered to share his or her experience.
medtronic.com/painambassador

ASK A NURSE
A registered nurse who is experienced in Medtronic chronic pain therapies. They can help answer questions you may have after the surgery about your therapy or your Intellis™ neurostimulator.
medtronic.com/nurse
Or, call 888-430-PAIN (7246) to schedule an appointment.

HELPFUL EMAIL REMINDERS
Living Well Program
Medtronic wants to help you make the most of your Medtronic pain therapies experience. The Living Well campaign will provide helpful tips and reminders to help you live successfully with a spinal cord stimulator.
medtronic.com/livingwell

PATIENT SERVICES
The Medtronic Patient Services team is able to help you with:
- Programmer or recharger troubleshooting
- Finding a new physician if you are traveling or moving
- Your Medtronic Patient ID Card
Call 800-510-6735 Monday–Friday, 8 a.m. to 5 p.m. Central time.

“My hope was for the therapy to just take the edge off the pain. Just enough so I could get to the back of the grocery store without resting. The trial lasted one week. For the first time in four years, pain was not the focus of my thoughts! I knew I wanted SCS.”

Nicole A.
Post-Operative Tips

- After your spinal cord stimulator implant procedure, follow your physician’s recovery and care instructions. It is important to keep all follow-up appointments as scheduled.
- Immediately following surgery, you will likely feel some discomfort at the incision sites. Neurostimulation will not relieve new incisional pain (post-op pain). To allow time for healing, your doctor may recommend that you restrict your daily activity.
- Activities you may need to avoid immediately following surgery:
  - Avoid sudden bending or twisting.
  - Avoid lifting more than 5 pounds (a gallon of milk).
  - Avoid reaching over your head (no reaching up, over, across, down).
- Talk with your doctor about which activities you can do. Follow up with your doctor for assistance if you:
  - Have medical concerns
  - Experience additional or unusual pain
  - Notice changes in the effect your therapy is having on your pain
  - Need to discuss managing your therapy, including what stimulation level you should use and adjustments to the stimulation level, if needed
- Positions will affect intensity of the stimulation.
- There are many stimulation settings available, so what you walk out of the procedure with is not the only option. Follow up with your doctor to ensure that your spinal cord stimulation is working correctly and relieving your pain.
- If you are having a problem with your neurostimulator, turn off the system and contact your doctor’s office.
- Do not drive while the neurostimulator is on.
- Do not get the programmer wet.

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.

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 by going online to medtronic.com/IDRegistration.

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. Central time.

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.

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.

My device systems implanted medical device
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 may appear. (Please note, your clinician determines what you have access to, so you may not see all the icons listed.):
     - **Intensity** — Controls the strength of the stimulation
     - **Stimulation** — Turns stimulation on or off for the selected program
     - **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.

   The Home screen will appear to confirm whether stimulation is on.

Note: When stimulation is on, the active Group will be highlighted in green. When stimulation is off, programs will be gray and will display the words stimulation is off.

Adjusting stimulation

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

1. From the Home screen, press the Battery status button. Two battery figures appear.
2. Press the Exit ( ) 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>ℹ️</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 icon on the Home screen for the program you want to adjust.
2. Press the AdaptiveStim™ (ihanna) icon. The AdaptiveStim™ screen is shown at right.
3. Press the On or Off icon to turn AdaptiveStim™ on or off.
4. Press the Exit (X) icon at the top right corner of the touchscreen to exit.

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

Making adjustments to AdaptiveStim™

5. To change AdaptiveStim™ intensity settings for a specific position, place your body in the desired position before making the adjustments.
6. Use the Check Position feature to confirm that the neurostimulator recognizes your body position.
7. Make the appropriate adjustments to your intensity settings.
8. 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.
9. The next time you return to this position, the intensity settings will automatically change to the recorded settings.

Recharging System

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.
- After getting a good/excellent recharge quality it is suggested to allow the screen to “go to sleep” and monitor the blinking green light.
- The screen will display “Finished” if the charging session is stopped. (Note: This does not mean your stimulator battery level is at 100%)
- If the stimulator battery depletes to the red warning level, the therapy/stimulation will turn off and will require to be turned back on manually once the INS has a minimum of 15% (yellow).

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. If repositioning the recharger does not complete the connection, select “Try Again.”

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 (🔒) button on the Unlock screen.
2. Press the Exit (❌) button on the Batteries screen.
3. Press the Menu (🔧) 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 (❌) button to return to the Home screen.
9. Press the Battery status (🔋) button to view the Batteries screen. Or, press the Lock (🔒) 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 (🔒) 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 (❌) button to view the Home screen.
5. Press the Lock (🔒) 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.

*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 medtronic.com/mri.

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

MRI scan eligibility icons

<table>
<thead>
<tr>
<th>Icon combination</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR ( )</td>
<td>Full-body scan eligible</td>
</tr>
<tr>
<td>MR ( )</td>
<td>Head scan eligible with transmit/receive head coil</td>
</tr>
<tr>
<td>!</td>
<td>The neurostimulation system MRI scan eligibility cannot be determined</td>
</tr>
</tbody>
</table>

An MRI scan eligibility icon combination is shown for each of the following:

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.

The MRI clinician must consult the MRI guidelines to determine how to proceed or contact Medtronic Technical Support.

Do not press any other keys or buttons.

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

Give your programmer to the MRI clinician with the In MRI Mode screen displayed.

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

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 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 (🔒) 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.

"Having the neurostimulator has changed my life tremendously ... And the time that I'm able to spend with my grandchildren doing activities. I'm very grateful to have that back in my life."

Tammy B.
Intellis™ patient
INDICATIONS  Spinal cord stimulation (SCS) is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs—including unilateral or bilateral pain.

CONTRAINDICATIONS  Diathermy - Energy from diathermy can be transferred through the implanted system and cause tissue damage resulting in severe injury or death.

WARNINGS  Sources of electromagnetic interference (e.g., defibrillation, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the system, resulting in unexpected changes in stimulation, serious patient injury or death. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and electrical pulses from the neurostimulator may cause inappropriate response of the cardiac device.

PRECAUTIONS  Safety and effectiveness has not been established for pediatric use, pregnancy, unborn fetus, or delivery. Avoid activities that put stress on the implanted neurostimulation system components. Recharging a rechargeable neurostimulator may result in skin irritation or redness near the implant site.

ADVERSE EVENTS  May include: undesirable change in stimulation (uncomfortable, jolting or shocking); hematoma, epidural hemorrhage, paralysis, seroma, infection, erosion, device malfunction or migration, pain at implant site, loss of pain relief, and other surgical risks.

Refer to www.medtronic.com for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events. Rx only. Rev 0119