Medtronic
Engineering the extraordinary

Designed for life in motion

Inceptiv™ spinal cord stimulation (SCS) implant guide

Contents

Welcome to a new day in technology!

This guide offers information to help you use your Medtronic Inceptiv™ SCS system.

If you have questions or concerns, please see the list of resources below to connect with us.

Inceptiv™ neurostimulator

Patient programmer

Resources

Talk with your doctor first

Your physician should be your first resource in case of medical concerns. If you have questions or experience any pain or discomfort with your device, contact your physician.

Patient services

The Medtronic Patient Services team is able to help you with:

- Programmer troubleshooting
- Recharger troubleshooting

Visit medtronic.com/scshelp
Or, call 800-510-6735 Monday–Friday, 8 a.m. to 5 p.m. Central time.

For additional SCS resources and support, visit medtronic.com/info

Find a new physician if you are traveling or moving, visit medtronic.com/scshelp

Postoperative tips

What to expect

- Follow your physician's post-surgery recovery instructions, and keep all follow-up appointments.
- If you feel some discomfort at the incision site after surgery, your doctor may recommend restricting daily activity.

  (Neurostimulation will not relieve new incisional pain.)
- Body positions may affect intensity of the stimulation.
- Several stimulation settings are available. Follow up with your doctor if you are not getting the relief expected.

Do

- Talk with your doctor about which activities you can do.
- Follow up with your doctor if you:
  1. Have medical concerns
  2. Experience additional or unusual pain
  3. Notice changes in the effect your treatment is having on your pain
  4. Need to discuss managing your treatment
- If you're having a problem with your neurostimulator, turn off the system and contact your doctor's office.

Don't

- Activities to avoid immediately following surgery:
  1. Sudden bending or twisting
  2. Lifting more than 5 pounds *(a gallon of milk)*
  3. Reaching over your head *(no reaching up, over, across, down)*
- Do not drive while the neurostimulator is on.
- Do not get the programmer wet.

The Inceptiv™ SCS system: an advancement in chronic pain management

Pain is personal. With the Medtronic Inceptiv™ SCS system, relief can be personalized. That's because this innovative spinal cord stimulator with **closed-loop feature** senses† and responds to your body signals to adjust your treatment as needed.

Nothing to slow you down. No reason to hold back.

The Inceptiv™ system was designed for comfort, making it the smallest fully implantable SCS device available. It was engineered for convenience, with full-body MRI access‡ and a battery longevity of at least 9 years. And it's introduced with confidence, backed by a reputation built on 50 years of SCS treatment innovation.

9 out of 10

patients preferred using closed-loop stimulation over open-loop stimulation[1]

Go to medtronic.com/painrelief for more information

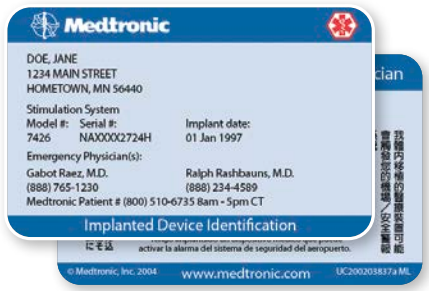
†Sensing signals may not be measurable in all cases.
‡Under specific conditions. Refer to product labeling for full list of conditions.

1. ECHO MAC Final Clinical Study Report V1.0 2021-08-18.

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 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 about two weeks after the procedure. There is no fee for the card.

If you move or change physicians, or edit other information on your card, contact Patient Registration at the number below.

You may also update your card by going to medtronic.com/idregistration.

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

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

Scan QR code to request an ID Card
medtronic.com/idcardrequest

Patient Registration contact information

Call 800-551-5544 Monday–Friday, 7 a.m. to 6 p.m. Central time.

Your pain treatment system

MyStim™ RC smart patient programmer

To view and adjust your treatment, you need to use these products together:

- Smart patient programmer with the MyStim™ RC treatment application preloaded
- Communicator

MyStim™ RC app

The app allows you to adjust your treatment and obtain system information from your implantable neurostimulator. The app comes installed on the patient programmer.

Patient programmer

The patient programmer includes the applications used to communicate with your implantable neurostimulator. It has a screen like a smartphone but does not function as a phone.

Communicator

The communicator connects your patient programmer to your implantable neurostimulator.

WiFi is not enabled on the patient programmer.

Important: Make sure to keep your patient programmer, communicator, and charging cables with you at all times in case you need to adjust your treatment or turn your treatment on or off.

Programmer basics

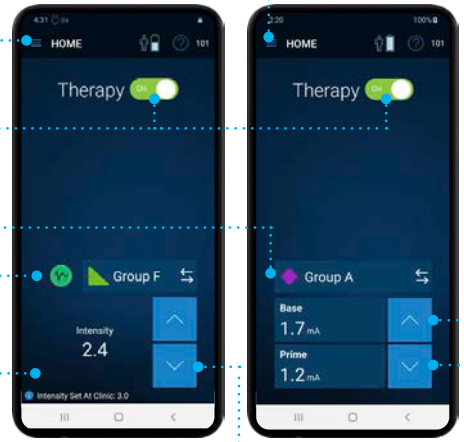
Menu button

Therapy toggle
Tap to turn treatment on or off

Change group button
Tap to select a different treatment group

Program buttons
Tap to view program status and adjust treatment settings

Adjust buttons
Tap to adjust intensity for all programs in active group



Closed-loop (Neuro Sense) group

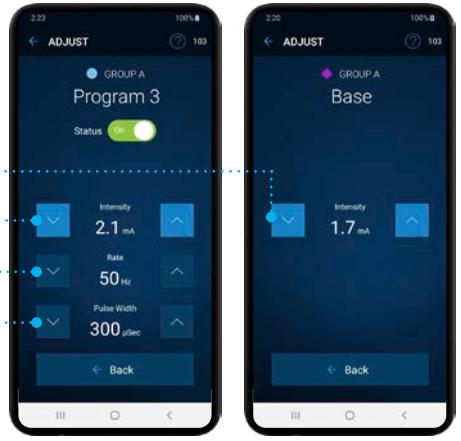
DTM™ group

Adjusting treatment settings
Depending on the patient controls defined by your clinician, you may be able to adjust one or more treatment settings. There are three settings that control stimulation:

Intensity
Controls the strength of the stimulation

Rate
Affects the number of electrical pulses delivered each second

Pulse width
Affects the length or duration of an electrical pulse



Closed-loop (Neuro Sense) group

DTM™ group

To view and adjust your treatment, you must connect to your neurostimulator using two devices:

- **Patient programmer** – with the MyStim™ RC app
- **Communicator** – Smaller white device

1. Turn on the communicator by pressing the power button.
2. Check that the battery indicator light is green.
3. Turn on the patient programmer and check that it is charged. If needed, refer to the patient programmer quick start guide.
4. Tap the **MyStim™ RC** app icon on the patient programmer.
5. Ensure that the communicator is within 1 meter (or 3 feet) of your neurostimulator.
6. Tap the Connect button on the patient programmer.

After the app connects to your neurostimulator, you will see the home screen.

Get to know your MyStim™ patient programmer

Scan QR code with your phone's camera or visit **medtronic.com/painrelief** to watch a brief video.

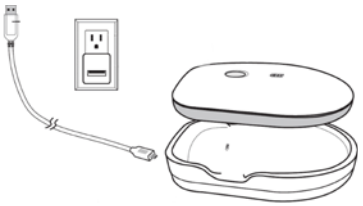
Patient programmer

Communicator

Inceptiv™ neurostimulator

Recharging system

Charge your recharger



Charging | Fully Charged

1. Connect the USB cable to the dock.
2. Plug the USB cable into the power adapter and plug the adapter into a wall outlet. The dock must rest on a flat surface while plugged in.
3. Place the recharger, button-side up, into the dock.
4. When your recharger is fully charged the battery icon will display as shown in the figure.

NOTE: Battery charging level should be at least 2 bars to be able to recharge neurostimulator.

NOTE: Leave your recharger on the dock between recharging sessions to maintain full charge.

Charging your implant

1. While on dock, ensure recharger has at least 2 bars.
2. Open recharger application.

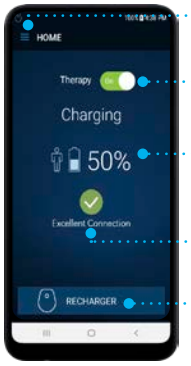
3. Remove recharger from dock and place recharger into belt, aligning circles on recharger with circles on belt. Start recharger with a short press of the power button.

4. Place belt so that two circles are over neurostimulator, facing your body. Wear a thin undergarment or piece of fabric between skin and the recharger.
   Recharger continuously beeps while looking for the neurostimulator. Move recharger slowly over implant site until you hear 2 tones rising in pitch and beeping stops. Once connected, charging automatically begins.
   A series of tones rising in pitch indicates a full charge. It's recommended to keep your neurostimulator charged to maintain therapy.

5. Use recharger application to aid in placement of the recharger, which may reduce recharge time.
   While moving recharger, pause to allow app to indicate connection strength.

NOTE: An "excellent" connection strength will help charge the neurostimulator faster than a "good" connection strength.

Using the recharger app



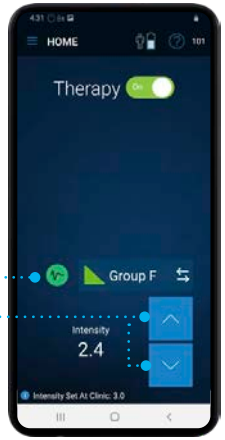
1. **Menu** button (≡) – Tap to access charging speed settings and app information. The recharger defaults to fastest speed.
2. **Therapy on/off** toggle – You can turn the therapy on or off while recharging.
3. **Neurostimulator Battery** icon – Your neurostimulator battery status. The number next to this image indicates how full the neurostimulator battery is.
4. **Connection** icon – Your connection status between your recharger and your neurostimulator.
5. **Recharger** button – Tap to view the recharger battery status and change the volume of your recharger.

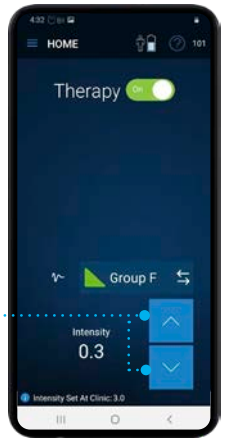
Closed-loop technology

Closed-loop technology personalizes treatment based on your body signals.

If your active programmed group is a closed-loop (Neuro Sense) group *(with green triangle icon)*, the neurostimulator can adjust your stimulation by sensing signals from your body.

You can also adjust the settings with the **up and down arrows** if needed.





If you want to **increase or decrease** the intensity back to the original clinic setting displayed on the patient programmer, use the arrows on the bottom of the screen.

AdaptiveStim™ technology

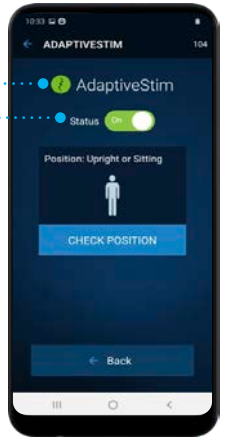
AdaptiveStim™ technology is another option that might be programmed for you.

It would be programmed in a different group than closed-loop technology and is based on body positions.

If AdaptiveStim™ is enabled in your therapy group, you'll see a **spine icon.**

Tap that icon if you want to turn AdaptiveStim™ on or off.

AdaptiveStim™ can recognize **seven different body positions.**



If you want to change your pain therapy intensity for one of the seven positions with AdaptiveStim™, get in that position and adjust the therapy to your comfort.

The next time you return to this position, the AdaptiveStim™ feature will remember and **automatically adjust.**

Warnings, alerts, and notifications

Warning screens indicate a problem with the programmer or neurostimulator.

See the Patient Therapy Guide for more about warnings.

Alert screens indicate a pairing or other connection problem between the programmer or neurostimulator.

See the Patient User Guide for more about alerts.

Notification screens provide information about stimulation settings, error conditions, and battery levels.

See the Patient User Guide for more about notifications.

Icon	Description	Screen type
	Red triangle with an exclamation point	Warning screen
	Orange triangle with an exclamation point	Alert screen
	Blue circle with the letter "i"	Notification screen

Troubleshooting

Alerts and actions

Alert	Action
Communicator Not Found	Turn on your communicator, hold it near your patient programmer, and then try to connect the devices again.
No Device Response	Hold your communicator directly over your neurostimulator and try to connect the devices again. Metal surfaces can interfere with the communication between the communicator and the neurostimulator. If the communicator is on a metal table or metal tray, move the communicator to a nonmetal surface.
Update Settings	Your neurostimulator settings need to be updated. Contact your clinician.
Therapy Off	Your treatment turned off because your current treatment settings are too high. Contact your clinician. You can try to reduce intensity or select another group, if those features are available to you.
No Therapy	Your neurostimulator is not providing treatment. There is either a firmware issue or the neurostimulator has not been programmed yet. Contact your clinician.
Replacement Recommended (ERI)	Your neurostimulator is working, but it is nearing the end of its service life. Contact your clinician.
Neurostimulator Battery Empty	Therapy unavailable as the alert and your neurostimulator battery is too low to provide therapy and needs to be recharged.
Low Output Detected	There is no issue with the programmer. This message displays when the neurostimulator is unable to deliver the energy required for the current treatment settings. No action is needed.

Electromagnetic interference

Electromagnetic interference (EMI) is a field of energy made by equipment found in the home, work, medical, or public environments. It can disrupt communication between your patient control device and neurostimulator.

If EMI disrupts communication during programming, move away from the likely source of EMI and try again.

Getting an MRI scan

Before your MRI

The Inceptiv™ SCS system allows MRI scans to be conducted anywhere on the body depending on certain conditions.

Before an MRI scan, review the following information to confirm your system is eligible for an MRI.

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).

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 specific conditions.†,‡,§ Not following the specific conditions can cause tissue damage and can result in serious patient injury.

Scan QR code to learn more about getting an MRI

medtronic.com/scsmri

†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.***

‡Patients with non-Medtronic leads and an EMBSNV20 adaptor extension are not eligible for an MRI.

§Under specific conditions. Refer to product labeling for full list of conditions.

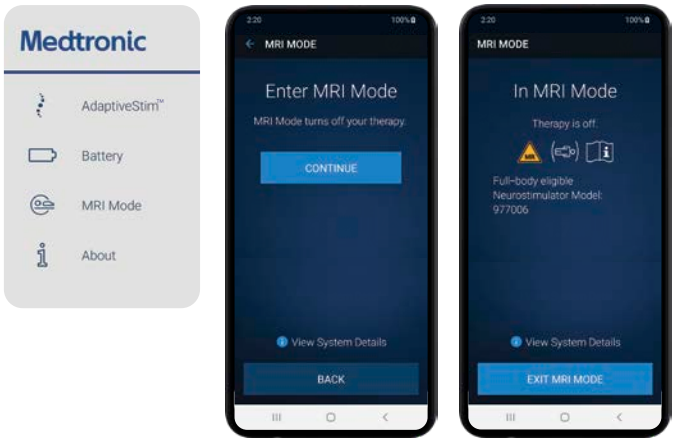
Using your patient programmer to activate MRI mode

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 communicator, 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.

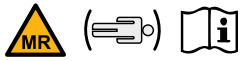
1. Press the Menu (≡) button on the home screen.
2. Select the MRI Mode (MRI) button. The Enter MRI Mode screen appears.
3. Press the Continue button to continue. When MRI mode is activated, your implanted neurostimulation system has been placed in MRI mode and stimulation is turned off. In addition, one of three In MRI Mode screens will appear, showing the MRI scan eligibility.



4. Do not press any other keys or buttons.
5. 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.

Icon combination	Explanation
	**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 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.
	**MR unsafe** You cannot have an MRI scan if your neurostimulation system contains any non-Medtronic component because safety in the MR environment is unknown.

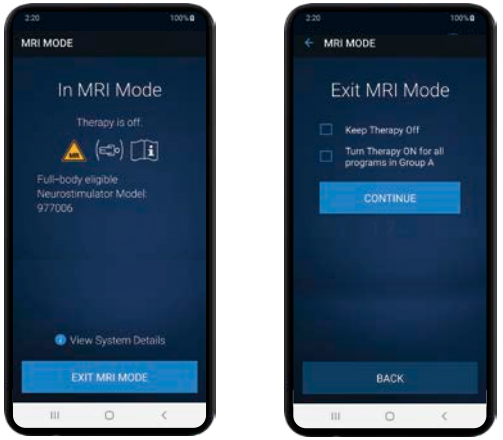
WARNING: You may be given an inappropriate MRI scan, which could cause you injury or could cause damage to your implanted medical device if you do not inform the MRI clinician before you enter the MRI scanner (magnet) room that you have an implanted neurostimulation system. The MRI clinician conducting 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. Press the **Exit MRI Mode** button on the In MRI Mode screen.
2. Select the appropriate option on the Exit MRI Mode screen:
   - Select "**Keep Therapy Off**" if you want treatment to remain off.
   - Or, select "**Turn Therapy ON for all programs**" to turn treatment on.
3. Tap **Continue**

Note: *Your stimulation settings will return to how they had been programmed before you entered MRI Mode.*



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.

If you're experiencing any pain or discomfort with your device, contact your physician.

Patient services

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Neurostimulation systems for pain therapy brief summary

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. Patients with diabetes may have more frequent and severe complications with surgery. A preoperative assessment is advised for some patients with diabetes to confirm they are appropriate candidates for surgery.

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. Adverse events may result in fluctuations in blood glucose in patients with diabetes.

Refer to www.medtronic.com for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events. Rx only. Rev 0422

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