

For More Moments That Matter

Vanta[™] Spinal Cord Stimulation Guide

Medtronic

Welcome to a new day in pain relief and thanks for making the decision to receive a Medtronic Vanta™ spinal cord stimulation (SCS) system. We're grateful to have the opportunity to support your chronic pain needs.

This guide offers information to help you use your Medtronic Vanta.™ If you have questions or concerns, please see the list of resources we have available for you to connect with us.



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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
- Finding a new physician if you are traveling or moving

Visit medtronic.com/SCSHelp

Or, call 800-510-6735 Monday-Friday, 8 a.m. to 5 p.m. Central time.

Ask a Nurse

Speak with a registered nurse who is experienced in Medtronic chronic pain therapies. They can help answer your questions about ongoing SCS therapy. This Nurse is a paid consultant of Medtronic.

Visit medtronic.com/nurse

Or, call 888-430-PAIN (7246) to schedule an appointment.

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



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 sites after surgery, your doctor may recommend restricting daily activity.

(Neurostimulation will not relieve new incisional pain.)

- Positions may affect intensity of the stimulation.
- Several stimulation settings are available. Follow up with your doctor to ensure your SCS system is working correctly and relieving your pain.



Dos

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



Don'ts

- Activities you may need to avoid immediately following surgery:
- 1. Sudden bending or twisting.
- 2. Lifting more than five 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.

Your **Vanta**™ **Advantage**



Recharge-free Convenience:

With the Vanta $^{\rm m}$ SCS, you are ready to have more days of hassle-free pain relief.



Full Body MRI Access†:

Medtronic offers full-body MRI access. Vanta™ SCS will never hold you back from getting a scan anywhere on your body if you need it.



Tailored Pain Relief:

Your therapy will be customized to help you manage your pain. One therapy setting your clinician may choose to use is called AdaptiveStim™ technology. This unique feature personalizes pain relief by sensing changes in your body position and automatically tailors stimulation. Only available on Medtronic devices.



Sleek and Small Device:

Vanta™ SCS is designed with your comfort in mind. Its thin size may give you enhanced comfort and may remain undetected under clothing.



MR

¹Under specific conditions. Refer to product labeling for full list of conditions. Patients with non-Medtronic leads and an EMBSNV2O adaptor extension are not eliable for an MRI.

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

Patient Registration Contact Information

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

Your Therapy System

MyStim[™] PC Smart Patient Programmer

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

 Smart Handset with the MyStim[™] PC Therapy Application pre-loaded

Communicator

Smart Handset

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

The MyStim[™] PC App

The app allows you to adjust your therapy and obtain system information from your implantable neurostimulator.
The app comes installed on the handset.

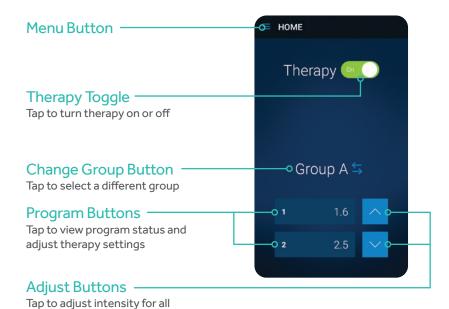
Communicator

The communicator connects your handset to your implantable neurostimulator.

Important: Make sure to keep your handset, communicator and charging cable with you at all times in case you need to adjust your therapy or turn your therapy on or off.

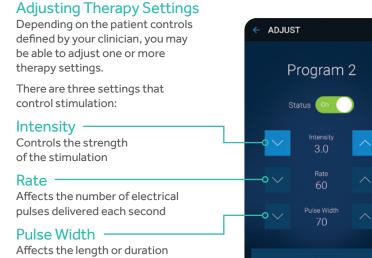


Therapy Screen Overview



programs in active group

of an electrical pulse



Basic Programmer Functions

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

- Handset with the MyStim[™] PC 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 handset and check that it is charged. If needed, refer to the handset quick start quide.
- 4. Tap the **MyStim PC** app icon on the handset.



- 5. Ensure that the communicator is within 1 meter of your neurostimulator.
- Tap the Connect button on the handset.



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





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Scan QR code to watch a brief video.

Warnings, Alerts & Notifications

Warning screens indicate a problem with the programmer, or neurostimulator. See the Patient Therapy Guide for more on warnings.

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

See the Patient User Guide for more on alerts.

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

See the Patient User Guide for more explanation on notifications.

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

AdaptiveStim[™] Technology

When AdaptiveStim™ technology 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™ Technology On or Off

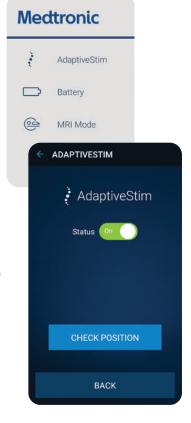
To turn the AdaptiveStim feature on or off, follow these steps:

- On the HOME screen, tap the Menu button
 (≡) and then select AdaptiveStim.
- 2. Tap the Status toggle on the AdaptiveStim screen to turn on and off.

Making Adjustments to AdaptiveStim™ Technology Settings

To change the intensity setting for a specific body position, follow these steps:

- 1. Make sure the AdaptiveStim feature is on.
- 2. Place your body in a desired position. (Example: lying down, sitting, on your side, etc.)
- 3. Adjust the intensity setting as needed. Refer to "Adjusting Therapy Settings" in your Patient User Guide.



Troubleshooting

Alerts and Actions

Alert	Action
Not Found Communicator	Turn on your communicator, hold it near your handset 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 therapy turned off because your current therapy 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 therapy. 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	Your neurostimulator has reached the end of its service life and is not providing therapy. Contact your clinician.
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 therapy 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

Before Your MRI

Your Vanta™SCS system allows you to have an MRI scan anywhere on your body. This will depend on the type of neurostimulation system you have.

- 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 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.



Scan QR code to learn more about getting an MRI

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

Using Your Handset 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 () 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.
- 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 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.

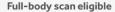
Icon combination

Explanation









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.

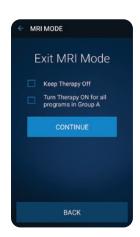
Turning Stimulation Back on After the MRI Scan

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 therapy to remain off.
 - Or, select "Turn Therapy ON for all programs" to turn therapy 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.

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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. Diabetic patients may have more frequent and severe complications with surgery. A preoperative assessment is advised for some diabetic patients 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 diabetic patients. Refer to www.medtronic.com for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events. Rx only. Rev 0222

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