Medtronic

Symptom control starts here.

The InterStim X[™] system patient therapy handbook



Welcome to Medtronic and your InterStim X[™] system.

For 25 years, we've helped hundreds of thousands of people like you get more control over their symptoms. We are here to help you along every step of this journey.

You can use this handbook to learn how to:

- Use your smart programmer and communicator
- Manage your therapy for more sustainable control
- Prepare for an MRI if you need one

We've also included more patient resources and commonly asked questions in the back.



Use your cellphone camera to scan this QR code to access more information online.

What you'll find inside

Get started

What to expect at home2
Your support team
Get to know your InterStim $X^{\mbox{\tiny M}}$ system
Your smart programmer6
InterStim $X^{\scriptscriptstyle\rm TM}$ My Therapy app7
Your communicator

How to operate your system and manage your therapy

Using your InterStim X [™] system	10
Manage your stimulation	12
Change programs	13
App notifications	14

Additional resources

Commonly asked questions1	6
Helpful resources	0
More life ahead2	2
MRI	5

What to expect at home

Take it easy

Follow your healthcare provider's instructions on activities to avoid and when to resume your normal routine.

Check your incision

Call your healthcare provider if you:

- Have issues with pain or bleeding as you heal
- Notice signs of infection, such as a fever or increased pain or redness around the incision

Understand your stimulation

When your therapy is initially turned on, you may feel a sensation that most people describe as a tingling, flutter, or vibration in the pelvic area. It should not be painful.

That sensation may dissipate over time, and you may eventually feel nothing. This is normal and does not mean adjustments need to be made.

As long as you're having 50% or greater improvement over your baseline symptoms, the therapy is working.

Your support team

Once your device has been implanted, a member of your Care Team will contact you within 48-72 hours . Check your caller ID for a call from Medtronic (or 855-894-6514).

Contact your healthcare provider if:

You have general questions about your therapy, stimulation settings, changes in symptoms, or anything related to medical care

Medtronic Patient Services

800-510-6735, Monday-Friday, 8 a.m.-5 p.m. CT

Contact Medtronic Patient Services if:

- You have technical questions about your programmer or communicator
- You have a notification on your programmer that you are unable to resolve



Your InterStim X[™] system



Implanted neurostimulator and lead

Your implant generates and delivers stimulation for your therapy.



Communicator

Your communicator connects the programmer with your neurostimulator.

Use the dual power port and white micro USB cord to charge your communicator.*



Smart programmer

Your programmer allows you and your healthcare provider to manage your therapy as needed.

Use the dual power port and black USB-C cord to charge your programmer.*



Carrying case

For convenience and device protection, you can keep your programmer and communicator in your carrying case.

^{*}Please note that the included charging blocks and cables may vary in style and color.

A closer look

Your smart programmer



The physical buttons on the programmer will not change your stimulation. This can only be done through the app.

InterStim X[™] My Therapy app

Metronic InterStim X My Therapy The app is similar to the one you used during your test.

Use the app to:

- Check your neurostimulator battery level
- Adjust your stimulation
- Turn stimulation on or off
- Change the therapy program (as directed by your healthcare provider)
- Activate MRI mode and check MRI eligibility

 \checkmark

Your communicator



Use your communicator to connect to your programmer and access programming features on your neurostimulator. Always store your communicator with your programmer. Keep both your programmer and communicator charged.

Keep in mind:

- The battery levels of your communicator and smart programmer do not reflect the battery level of your neurostimulator.
- The communicator can't be used while it is charging. If the communicator battery level is at 0%, you'll need to charge it for at least 5 minutes before it's ready to communicate with your neurostimulator.



Using your InterStim X[™] system



Power on your programmer

Press and hold the power button. To unlock the screen, swipe the blue Medtronic screen in any direction.



Power on your communicator

Quickly press the power button on the white side of the communicator until the blue indicator light starts flashing. The blue light won't stop flashing until the app is open and the communicator has connected with the programmer.





Connect your communicator and neurostimulator together

Once the blue light on the communicator is solid, place the communicator over your neurostimulator implant with the blue side toward the body (your neurostimulator is located below your incision on your left or right upper buttock). You may also find it easier to tuck the communicator into your pants to hold it in place and free up your hands.

• Tap FIND DEVICE

Your programmer will begin searching for your neurostimulator.

If the communicator fails to connect, readjust its location over the neurostimulator and **tap RETRY**.



Tap the InterStim X[™] My

Therapy app on your programmer to open it.

Manage your therapy

Once your programmer and communicator are connected to your neurostimulator, see pages 12 and 13 to learn how to increase or decrease stimulation or change the program (as directed by your healthcare provider).

Be sure to keep your communicator over your neurostimulator while making any therapy adjustments.

Adjusting your stimulation settings



Change programs



Depending on your level of symptom relief, your healthcare provider may ask you to change programs to optimize your therapy. If so, tap the **program button** to select a different program.

 The screen responds best to quick, light taps. Do not hold the buttons down, as this could change your stimulation too quickly.



To exit the screen and end your session, tap the **back arrow** in the bottom righthand corner of your screen and select **END SESSION** when prompted.

App notifications

You may see these common pop-up notifications on the smart programmer while using the InterStim X[™] My Therapy app.



Your communicator needs to be charged. Plug it into the charger. Remember, you can't use the communicator while it's recharging.



Your programmer has lost connection with your communicator due to low communicator battery or a failed connection. Ensure that your communicator is charged, unplugged, powered on, and close to your programmer, then tap **RETRY**.

When you are finished using your InterStim X[™] accessories:



Tap the back arrow in the bottom righthand corner of your programmer screen and select **END SESSION.**



Power off the programmer (press and hold the power button; then touch **POWER OFF** on the screen)



Power off the communicator

(push and hold the power button until the blue light goes off)



Watch video tutorials to learn how to use your InterStim X[™] system Scan this QR code with your phone camera. Click the link that pops up on your screen.

medtronic.com/rechargefree



Your programmer has lost connection with your neurostimulator. Reposition the communicator over your neurostimulator, ...• then tap **RETRY**. (Your neurostimulator is located below your incision on your left or right upper buttock.)



Need help? For any technical questions about your smart programmer, **call 800-510-6735**, Monday-Friday, 8 a.m.-5 p.m. CT

Questions? We've got you covered!

Medical tests and procedures

Can I have an MRI?

People with an InterStim X[™] system can have a full-body MRI scan under certain conditions.[†] Your healthcare provider will determine whether you meet those conditions when you're implanted. You can also check your MRI eligibility on your smart programmer. Please see page 25 for more information.

Will medical tests affect my therapy?

Most routine medical tests, such as X-rays, CT scans, and diagnostic ultrasounds, should not affect your therapy. Contact your healthcare provider or Medtronic Patient Services at 800-510-6735 for safety information.

Using and maintaining your system

1 What if the InterStim X[™] My Therapy app or programmer isn't responding?

First, make sure both the programmer and communicator are charged. If they are charged and the app or programmer is still unresponsive, restart the programmer by holding down the power button on the side of the programmer and tap RESTART to re-boot it.

2 Can I leave them plugged into the wall?

To help preserve the batteries in your programmer and communicator, it's best to unplug accessories once they have reached a full charge. Just like your cell phone, regular recharging of your programmer and communicator are recommended to ensure they're available for use.

3 What if I lose one of my therapy accessories?

Contact Medtronic Patient Services at 800-510-6735 as soon as possible.

[†]See approved labeling for details. Patients with InterStim[™] SureScan[™] MRI Leads only.

My therapy experience

Do I need to feel the stimulation in order for the therapy to work?

No. When your therapy is initially turned on, you may feel a sensation that most people describe as a tingling, flutter, or vibration in the pelvic area. It should not be painful. That sensation may dissipate over time, and you may eventually feel nothing. This is normal and does not mean adjustments need to be made. As long as you're having 50% or greater symptom improvement, the therapy is working.

What makes one program different from another?

The wire that is stimulating your nerve is comprised of four contact points or electrodes. Each of these electrodes stimulate your nerve at different locations, which can impact your symptom relief. Your healthcare provider and Medtronic representative will select the optimal program for you.

What should I do if I am no longer getting relief?

Use your programmer to make sure your stimulation is ON (see page 12 for instructions). If so, adjust your stimulation or switch programs as directed by your healthcare provider. If this issue persists, follow up with your healthcare provider.

Travel

Should I take my programmer and communicator with me when I travel?

Yes. For convenience and device protection, you can store your programmer and communicator in your carrying case during travel.

2 What do I do at the airport?

Show your patient ID card and ask to bypass the security system or undergo a manual search. If you must walk through the system, first turn off your therapy. Turn your therapy back on after your security scan.

Can I use my programmer during air travel?

Yes. While in flight, turn your programmer off or use airplane mode to disable cellular function (as required by the airline). You can still make adjustments in airplane mode. Make sure to turn airplane mode off after your flight.

Helpful resources



Your patient ID card

You should have received a temporary patient ID card at your implant. A permanent one will be mailed to you within a few weeks. Carry this ID card with you at all times.

If you lose your patient ID card, request a new one by calling device registration at 800-551-5544 or visiting Medtronic.com/idcard.

There is an additional card with a user ID on it for your smart programmer. This is not a card for your implanted device. Keep this card somewhere safe in case your programmer is lost.

Your symptom diary

Download a diary at Medtronic.com/diary and complete it before appointments with your healthcare provider, especially if you feel like your symptom improvement has changed.

Medtronic Patient Services

800-510-6735, Monday-Friday, 8 a.m.-5 p.m. CT

Contact Medtronic Patient Services if:

- You have technical questions about your programmer or communicator
- You have a notification on your programmer that you are unable to resolve

MyJourney[™] app

Your digital diary and resource

Paper diaries do not work well for everyone.

The MyJourney[™] app:

- Offers a convenient, easy, and discreet way for you to track your symptoms for your doctor to review
- Shares timely and personalized information with you before, during, and after your implant procedure
- Saves key information from your doctor's visits for you to access it whenever you need it





Use your cellphone camera to scan this QR code to download the MyJourney[™] app.

More life ahead

Your InterStim X[™] system **helps achieve bladder or bowel control.** Continue any lifestyle changes – like avoiding dietary triggers – that you and your healthcare provider have discussed. These habits will still be helpful!

You've chosen **a recharge-free neurostimulator** – and that comes with more freedom and convenience. Most people just visit their healthcare provider annually to discuss their progress and maintain symptom control. Talk with your provider to set up a schedule that works for you.

You can expect **more than 10 years** with your InterStim X[™] system.* When it's time to replace your neurostimulator, your healthcare provider will discuss your options.

Thank you for choosing Medtronic and joining the **more than** 400,000 people who've trusted our InterStim[™] system for bladder or bowel control. Expect more from us as we continue to put patients like you at the center of our innovation.



*Under expected therapy settings and telemetry use



Medtronic Bladder Control Therapy delivered by the InterStim[™] system treats urinary retention (inability to completely empty the bladder) and the symptoms of overactive bladder, including urinary urge incontinence (leakage) and significant symptoms of urgency-frequency. It should be used after you have tried other treatments such as medications and behavioral therapy and they have not worked, or you could not tolerate them. This therapy is not intended for patients with urinary blockage.

Safety and effectiveness have not been established for pregnancy and delivery; patients under the age of 16; or for patients with neurological disease origins.

Medtronic Bowel Control Therapy delivered by InterStim[™] system treats chronic fecal incontinence (an accident or leaking involving stool). It should be used after you have tried other treatments such as medications and dietary modifications and they have not worked, or if you are not a candidate for them.

Safety and effectiveness have not been established for pregnancy and delivery; patients under the age of 18; or for patients with progressive, systemic neurological diseases.

Medtronic Bladder Control Therapy and Medtronic Bowel Control Therapy: You must demonstrate an appropriate response to the evaluation to be a candidate. You cannot have diathermy (deep heat treatment from electromagnetic energy) if you have an InterStim[™] device.

In addition to risks related to surgery, complications can include pain at the implant sites, new pain, infection, lead (thin wire) movement/migration, device problems, interactions with certain other devices or diagnostic equipment such as MRI, undesirable changes in urinary or bowel function, and uncomfortable stimulation (sometimes described as a ioltina or shockina feelina).

This therapy is not for everyone. This treatment is prescribed by your doctor.

Please talk to your doctor to decide whether this therapy is right for you. Your doctor should discuss all potential benefits and risks with you. Although many patients may benefit from the use of this treatment, results may vary. For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com.

USA Rx Only. Rev 0517

Before your MRI

MRI Instructions

DOES NO⁷

 $\stackrel{\square}{=}$ Follow these simple steps to prepare for your scan:

Charge your programmer and communicator and bring them to your MRI appointment.



• Turn your communicator on.



on your programmer.



4 Place the communicator over your implanted neurostimulator with the blue side toward your body.





Your healthcare professional can access MRI guidelines for your InterStim[™] system at medtronic.com/MRI







• Select **MRI** from the menu list.



Your MRI eligibility



ACTIVATE MRI MODE

ating MRI mode will resu therapy turning off

related to your InterStim[™] device will appear on the screen. Your therapy will be 🛕 (=>) 🖬 turned off while MRI mode is activated. If you are not undergoing an MRI

and only checking your eligibility, tap **DEACTIVATE**. Then tap YES to turn your therapy back on.

Medtronic Patient Services: Need help with MRI mode or guidelines? Call 800-510-6735

Having an MRI

People with an InterStim X[™] system can have a full-body MRI scan under certain conditions.[†] Your healthcare provider will determine whether you meet those conditions when you're implanted.

Scheduling your MRI

When making your appointment, the radiology department may request information about your InterStim X[™] system, including:

Lead:

Neurostimulator:

Patient name:

Your implant date:

†See approved labeling for details. Patients with InterStim[™] SureScan[™] MRI Leads only.



After your MRI

To deactivate MRI mode and turn your therapy back on, repeat steps 2-7. Tap **DEACTIVATE**. Then tap **YES** and your therapy will resume under your previous settings.



Medtronic

710 Medtronic Parkway Minneapolis, MN 55432-5604, USA

medtronic.com/rechargefree

©2024 Medtronic. Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic. All other brands are trademarks of a Medtronic company. UC202500601 EN - [WF#13153965]