

# GETTING STARTED

Evaluation of Medtronic Bladder or Bowel  
Control delivered by the InterStim™ systems

# YOUR LIFE IS WAITING

Congratulations on taking the first step to discovering life without limits with Medtronic Bladder or Bowel Control Therapy delivered by the InterStim™ systems.

Use this guide to understand how to use your programmer and make the most of your evaluation.



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## Doctor Discussions

Call your doctor if you have general questions about your therapy, stimulation settings, changes in symptoms, or anything related to medical care. Record your doctor's contact information and your evaluation type below for easy access.

My Doctor: \_\_\_\_\_

Phone: \_\_\_\_\_

- Basic Evaluation
- Advanced Evaluation

# JUST THE BEGINNING

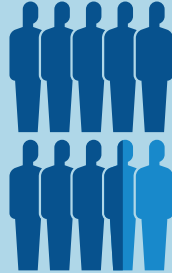
A successful evaluation can lead to long-term results, something many people have found with the InterStim™ system.

## 82%

of people with overactive bladder (OAB) using Medtronic Bladder Control Therapy continued to experience success at 5 years.<sup>1\*</sup>

## 89%

of people using Medtronic Bowel Control Therapy continued to experience success at 5 years.<sup>2\*\*</sup>



# DELIVERING LIFE-CHANGING RELIEF

Fewer accidents.

Less worry.

More confidence to resume the relationships and activities you love.



Implanting an InterStim™ system has risks similar to any surgical procedure, including swelling, bruising, bleeding, and infection. Talk to your doctor about ways to minimize these risks.

\* Success defined as  $\geq 50\%$  reduction of episodes/day. This patient group had data at both baseline and the 5-year visit. Another analysis reported 67% of people achieved success. For this patient group, missing data at 5 years because of a device-related reason was counted as failure.

\*\* Success defined as  $\geq 50\%$  reduction of episodes/week. This patient group had data at both baseline and the 5-year visit. Another analysis reported 69% of people achieved success with Medtronic Bowel Control Therapy. For this patient group, missing data at 5 years because of a device-related reason was counted as failure, or if it was missing for non-device related reasons, the most recent data was carried forward.

1. Siegel S, Noblett K, Mangel J, et al. Five-Year Follow-up Results of a Prospective, Multicenter Study in Overactive Bladder Subjects Treated with Sacral Neuromodulation. *J Urol*. 2018;199(1):229–236.

2. Hull T, Giese C, Wexner SD, et al. Long-term Durability of Sacral Nerve Stimulation Therapy for Chronic Fecal Incontinence. *Dis Colon Rectum*. 2013;56(2):234–45.

# YOUR EVALUATION SYSTEM

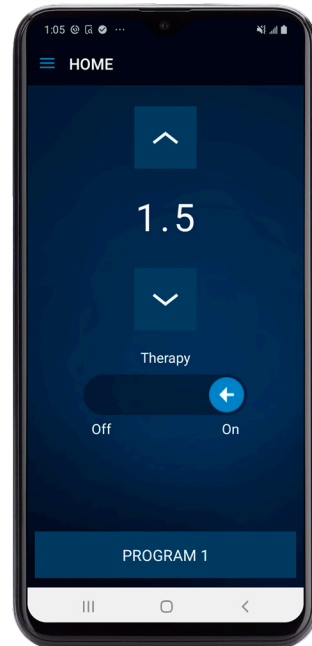
## External Neurostimulator (ENS)

Your ENS is the device, worn externally with a belt, that generates the stimulation.



## Programmer

The handheld programmer is how you can adjust and manage your stimulation.



## Charging Cable

The black cord is for charging your programmer. Remember to keep your programmer charged.



Please return all Medtronic issued equipment on the final day of your evaluation, including:

- Your Samsung programmer
- Charging block
- Power cord
- Medtronic case.

You will not need this equipment after your evaluation.

# YOUR PROGRAMMER

The programmer functions below will not alter your therapy.



# POWER ON

Press and hold the **Power button** to turn your programmer on.

Once the blue Medtronic screen appears, swipe the screen in any direction to unlock the device.

# CHARGE YOUR PROGRAMMER

Keep your programmer charged by plugging it in using the cord that came in your box. The battery indicator at the top of the programmer screen will show you how much battery is left.

## TIP

The programmer is not set up to make phone calls or access the Internet. It's designed only to manage your evaluation.

# APPS



## My Therapy

This app allows you to manage your stimulation.



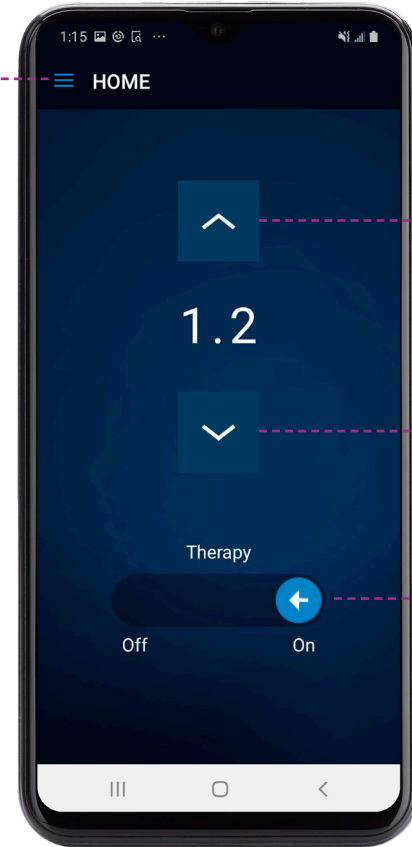
## Clinician

You should not use this app; it is intended only for clinicians.



# MY THERAPY APP

- Menu
  - Home
  - About
  - Battery
  - Tutorial

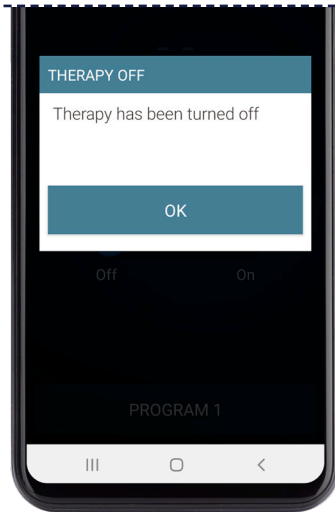
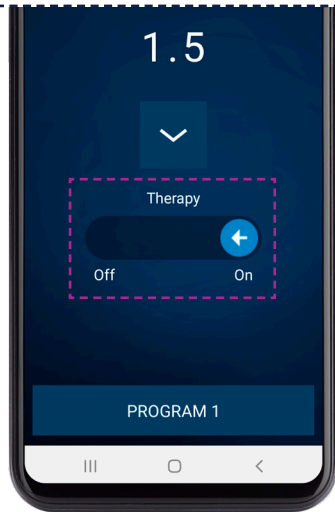


■ Increase Stimulation

■ Decrease Stimulation

■ Turn your Stimulation On or Off

# TURN STIMULATION ON OR OFF

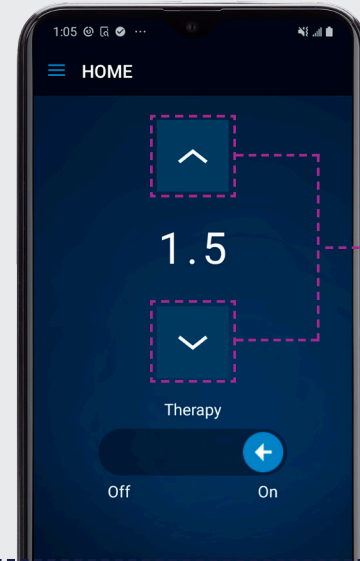


To turn stimulation on, use your finger to swipe the **On/Off indicator** to the right.

To turn stimulation off, use your finger to swipe the **On/Off indicator** to the left.

Tap **OK** to acknowledge that you have turned your therapy off.

# ADJUST YOUR STIMULATION



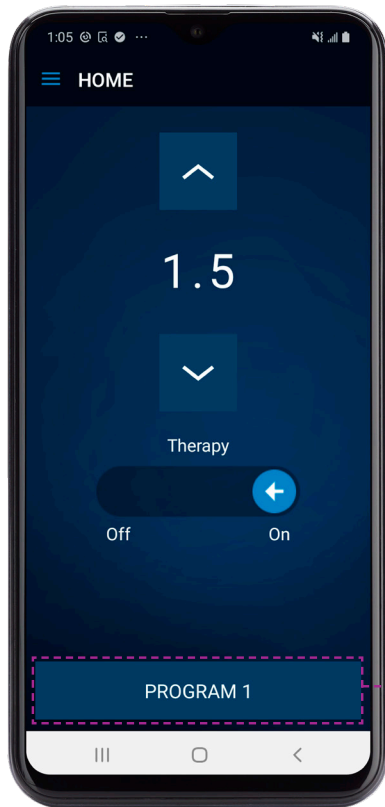
Tap the **Arrows Up or Down** to increase or decrease stimulation.

## TIP

Use quick, light taps to make sure you only hit buttons one time. Do not hold the button down.

# CHANGE PROGRAMS

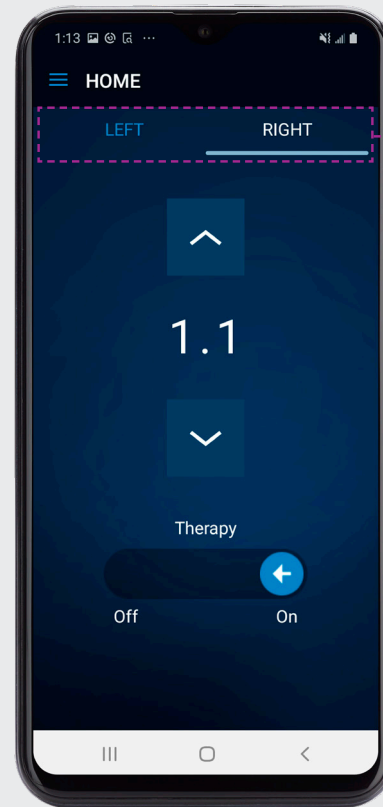
Only available for individuals undergoing an Advanced Evaluation



If you are undergoing an **Advanced Evaluation**, your clinician may ask you to change programs. If so, tap the **Program Button** to select a new program.

# SWITCH SIDES

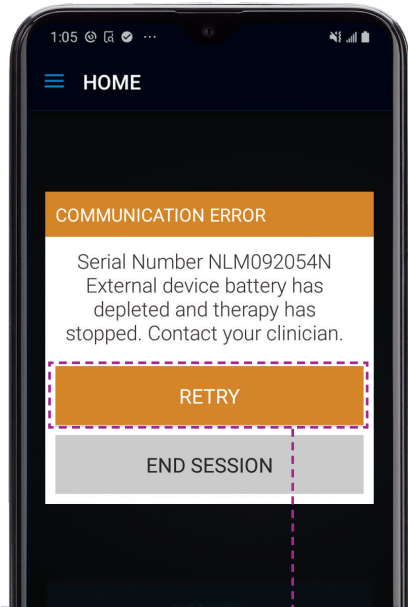
Only available for individuals undergoing a Basic Evaluation



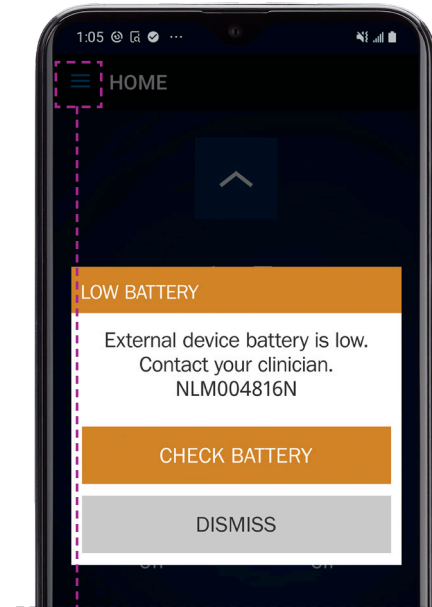
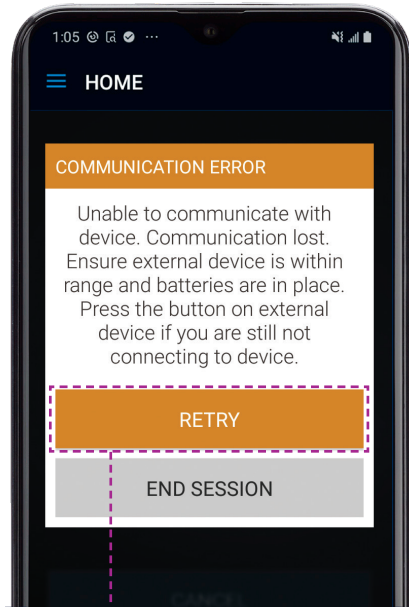
If you are undergoing a **Basic Evaluation**, your clinician may ask you to switch sides of stimulation. If so, tap the appropriate **LEFT** or **RIGHT** button. The underline indicates the side delivering therapy.

# APP NOTIFICATIONS

You may receive alerts from your My Therapy App. If you have questions about an alert not listed here, contact your physician.



Your programmer has lost connection with your ENS due to low battery or a failed signal. Tap **Retry** to reconnect the programmer. If the issue continues, contact your clinician to reestablish the connection.



Your ENS device has a low battery. If your ENS battery is low, contact your clinician.

# IMPORTANT REMINDERS

## TRACKING YOUR SYMPTOMS

- Be sure to complete the diary as directed by your doctor, and bring it to your next appointment.

## FEELING THE STIMULATION

- If you don't feel the stimulation but you're getting symptom relief, there's no need to adjust your stimulation.
- Changes in body position may affect intensity or location of the stimulation, requiring you to adjust your stimulation. Discuss this with your doctor.

## MANAGING YOUR ACTIVITY LEVEL

- Keep your activity level low to moderate; avoid bending, stretching, twisting, sexual activity, or lifting heavy objects.
- Follow your doctor's instructions regarding returning to work.
- Avoid baths and showers. Take sponge baths, but be careful to keep the area around the lead (thin wire) and external neurostimulator (ENS) dry.

## USING YOUR PROGRAMMER

- If your programmer or the My Therapy App is unresponsive, make sure your programmer is charged. If it's charged and still unresponsive, turn the programmer off and back on again.
- Your ENS will have new batteries when you go home. The batteries should last for the entire therapy evaluation period. If you receive a low battery alert, contact your doctor.
- Turn stimulation off while driving or using power tools.
- You can use your programmer during air travel, but you'll need to put it in Airplane Mode. Your programmer will still function and you can adjust your therapy in Airplane Mode.
- If you lose your programmer, contact your clinician or Medtronic Patient Services right away. Your programmer can only be used for evaluations and can be disabled remotely if lost or stolen.
- Remember to return the programmer to your doctor's office when your evaluation is complete.

## UNDERGOING OTHER MEDICAL TREATMENTS

- If you see other doctors during the evaluation, inform them that you are using an external neurostimulator evaluating sacral neuromodulation.
- Contact your doctor before any other medical treatments during your evaluation period. Do not have diathermy or an MRI examination during your evaluation.
- Talk with your doctor about any questions you may have regarding your specific situation.
- Call your doctor if you notice any redness or swelling at the site.





**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 a 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 jolting or shocking feeling).

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](http://www.medtronic.com).

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# Medtronic

Medtronic  
710 Medtronic Parkway  
Minneapolis, MN 55432-5604  
USA  
Tel: 763-505-5000

[medtronic.com](http://medtronic.com)

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