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MY THERAPY APP FOR SACRAL NEUROMODULATION THERAPY

Patient User Guide for the Verify™
Evaluation System



! USA Rx only

CE0123
2017

Medtronic

SYMBOLS

Explanation of symbols on product and packaging



Manufacturer

CE0123

Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive AIMD 90/385/EEC.



Authorized representative in the European community



For USA audiences only

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Refer to the indications sheet for indications and related information.

Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

Refer to the MRI Guidelines for the InterStim™ system for the MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan.

Refer to System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications.

! USA Refer to the clinical summary booklet for information on the clinical study results of the neurostimulation system and individualization of treatment.

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HOW TO USE THIS GUIDE

Please read this entire guide before using the My Therapy app on the evaluation handset. This guide will help you to understand the therapy evaluation process using the Verify™ evaluation system. This guide also contains instructions for using the My Therapy app to adjust your therapy. Ask your clinician to explain anything that is unclear to you.

- Information about how to contact Medtronic, and other questions concerning your therapy begins on page 6.
- A glossary is provided in this guide to describe terms relating to your therapy that may be unfamiliar to you. Terms that are **bold** throughout this guide are defined in the glossary. Glossary terms and definitions begin on page 9.
- “PART ONE: Using the My Therapy App For Therapy Evaluation” provides instructions on how to use the My Therapy app during your therapy evaluation. Part one of this guide includes information on turning your therapy on and off, adjusting your therapy settings, checking battery status, switching therapy sides (if applicable), and changing programs

(if applicable). For more information, Refer to page 15.

- The “Troubleshooting” section provides explanations and solutions for various troubleshooting scenarios you may encounter while using the evaluation handset. This includes common questions you may have about sacral neuromodulation therapy, explanations on important My Therapy app notifications, and who to contact if the evaluation handset is lost or broken.
- “PART TWO: About Your Therapy” describes the therapy evaluation procedure, keeping a diary, what to expect during therapy evaluation, and important safety information. Part two of this guide begins on page 39.

How to Contact Medtronic

The Patient Services group is available to answer any questions or concerns you may have about your Verify™ evaluation system during your therapy evaluation period. Have the name and telephone number of your clinician at hand if you have any questions or problems. Refer to the Medtronic contacts at the end of this manual.

! USA For assistance in the US, call 1-800-510-6735. They are available Monday through Friday from 8:00AM to 5:00PM (central time).

Who should I contact if I have a question or concern about my health or Verify™ evaluation system?

Always discuss any questions or concerns you have about your health or Verify™ evaluation system settings with your clinician. Your clinician is the appropriate person to contact about your health or therapy management. He or she has your medical records and knows your medical history. As a medical device manufacturer, Medtronic is not able to comment on your medical condition.

Special Notes

The following includes some things to keep in mind during your therapy evaluation:

- Bring this guide to all of your health care provider appointments and share this information with clinicians, dentists, MRI operators, and other health professionals who may not be familiar with the Verify™ evaluation system.

- Always carry your handset. The My Therapy app on the evaluation handset is the only way to adjust or turn therapy on and off. Also, it is very important that you bring your handset to all follow-up appointments, including appointments with other health care providers. During certain procedures, you may need to turn your external neurostimulator off. When necessary, you should also bring this user guide. It contains important information about sacral neuromodulation therapy that your health care providers should be aware of.
- Refer to “WARNINGS AND PRECAUTIONS” on page 40 for information on what you should and should not do during your therapy evaluation period.

GLOSSARY

The following is a list of glossary terms that may be unfamiliar to you. The words that appear in **bold** in this guide are defined here for your convenience.

(Therapy) Amplitude	The strength or intensity of stimulation measured in volts.
Caution	See Precaution.
Clinician	The term clinician is used in this guide to refer to a specialized medical professional such as a doctor, nurse, medical technician, or specialist.
Defibrillator	A small implantable device which is used to treat heart beats that are too fast.

Diathermy	A type of medical treatment that delivers energy to treat specific areas of the body. The treatments are typically used to relieve pain, stiffness, muscle spasms, reduce joint pain and swelling after surgery, and promote wound healing.
Evaluation handset	A hand-held electronic device used by the patient to control therapy settings and to turn the external neurostimulator on and off.
External neurostimulator (ENS)	A battery-powered device, worn externally, that sends mild electrical pulses to the sacral nerve.
InterStim™ system	An implanted system that sends mild electrical pulses to sacral nerves or muscles in order to treat your symptoms.

Lead	A thin wire with protective coating that has metal electrodes on one end and a connector on the other.
Long-term lead	A type of implanted lead used for long-term sacral neuromodulation therapy.
Magnetic Resonance Imaging (MRI)	A diagnostic method that produces computerized images of internal body tissues.
Neurostimulator	The power source of a neurostimulation system. It contains the battery and electronics that control the stimulation.
Precaution	A statement describing actions that could result in damage to or improper functioning of a device.

Program	A specific combination of stimulation settings assigned to deliver therapy to a specific site.
Sacral nerves	Nerves located near the base of the tailbone just above the cleft of the buttocks. Sacral nerves control the bladder, bowel, and pelvic organs.
Stimulation	The delivery of electrical pulses to a specific site.
Temporary-lead	A type of lead used for short-term sacral neuromodulation therapy evaluation.
Therapy	Treatment of a disease or condition. When neuromodulation therapy is prescribed, a neurostimulation system is used to deliver therapy to a specific site.

Therapy evaluation	A multi-day evaluation of a patient's response to therapy using an external neurostimulator and implanted leads.
Therapy settings	Refers to the features that define the therapy you feel. The clinician programs all therapy settings. You can adjust some of your therapy settings within clinician-defined limits.
Ultrasound	High-frequency sound waves used to diagnose certain conditions.
Warning	An alert about possible injury or a problem that may happen as you use or misuse a device.



PART ONE: Using the My Therapy App For Therapy Evaluation

ABOUT THE MY THERAPY APP

The My Therapy app is a patient software application (app) for sacral neuromodulation therapy, to be used as part of the Verify™ evaluation system. The My Therapy app is intended to be used for controlling and monitoring your therapy during therapy evaluation. The app is installed on and used with a patient control device called an **evaluation handset**.

Note: For more information about what therapy evaluation is, refer to “What Is Therapy Evaluation?” on page 44.

How Does It Work?

The My Therapy app communicates wirelessly with an **external neurostimulator** (ENS) by sending signals to and receiving signals from the external neurostimulator. Your **clinician** will initially set up the handset according to your specific needs for therapy evaluation.

Note: Make sure to keep your evaluation handset with you at all times in the event that you need to adjust or turn your therapy off.

How Do I Use the My Therapy App?

Use the My Therapy app on the evaluation handset to modify your therapy as directed by your clinician. The evaluation handset has a touchscreen display that reacts to touch and allows you to tap or select icons that are displayed on the screen. Use one finger when tapping icons. You can use the touchscreen in the following ways depending on the function or task:

- Short, light taps for icon selection
- Swipe left/right to access additional options or turn your therapy on or off.

Note: None of the physical buttons or keys on the handset itself will alter your therapy.

The Verify™ Evaluation System

The Verify™ evaluation system is an evaluation system that uses an external neurostimulator to deliver mild electrical pulses to stimulate the **sacral nerves** and muscles located near the tail bone. The Verify evaluation system includes:

- A small external neurostimulator device which generates mild electrical **stimulation**, similar to a pacemaker.

- A **lead(s)** or insulated wire that is implanted. One end of the lead is connected to the **neurostimulator** and the other end delivers mild electrical pulses to your sacral nerve area.
- A patient control device, called an evaluation handset. Use the My Therapy app on the handset to adjust your **therapy** or turn your therapy on or off as directed by your clinician during therapy evaluation.

Accessing the My Therapy App

You can access the My Therapy app (Figure 1) by locating the following icon on the main screen of the handset. Tap the icon to open and begin using the My Therapy app.



Figure 1. My Therapy Patient app icon

Main features

The My Therapy app has a few basic features that allow you to manage certain aspects of your therapy. On the Home screen, you can do the following tasks:

- Adjust **therapy amplitude** (stimulation)
- Turn your therapy On or Off
- Switch between **programs** (if available)
- Switch therapy sides (if applicable)
- Access the My Therapy app tutorial
- Access system and neurostimulator battery status information.

My Therapy app tutorial

The My Therapy app includes a brief tutorial that will help you understand its basic functions. When you open the My Therapy app for the first time you will be presented with this tutorial.

In the event that you would like to view the tutorial again in the future, you can do so at any time.

To view the tutorial:

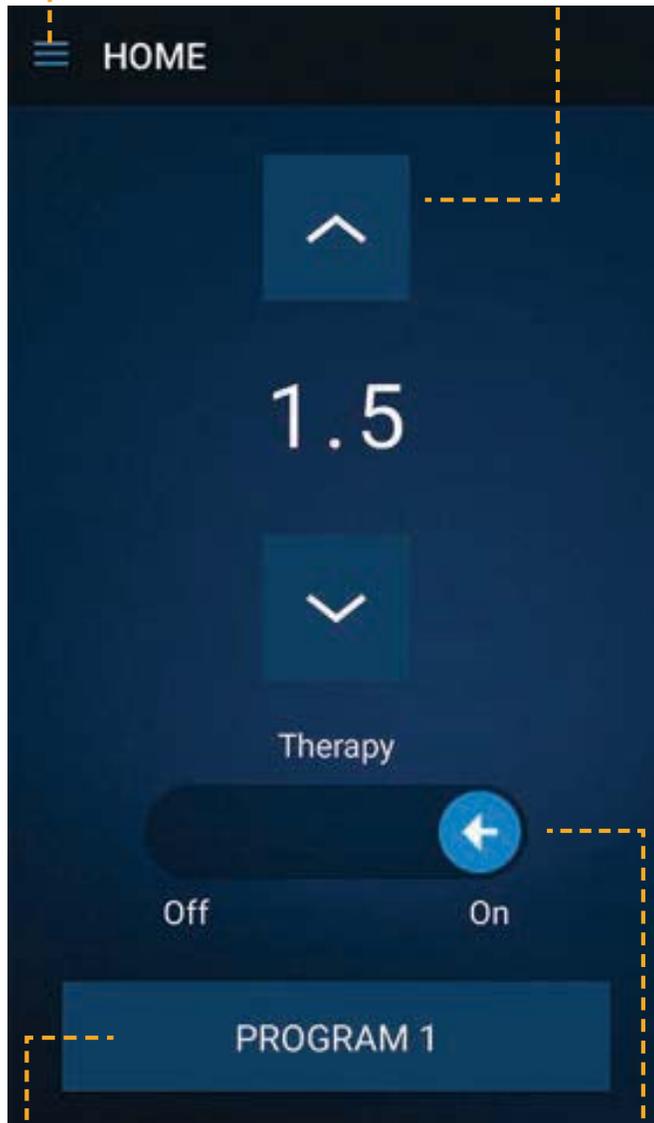
Tap  to open the menu, and select **Tutorial** from the list of options.

Home screen

The Home screen is the main screen where you will adjust your **therapy settings**. Figure 2 provides an overview of the Home screen.

Note: The Home screen may look slightly different than the image shown depending on how your clinician set up the handset.

Tap to access menu options. Tap the arrows to increase or decrease therapy amplitude.



Tap the **PROGRAM** button to switch between programs.

Slide the arrow to turn therapy on or off.

Figure 2. Home screen

Accessing system information and checking battery status

You can access the My Therapy app system information as well as check the battery status of the external neurostimulator (Figure 3).

To view system information:

Tap  in the corner of the screen and select **About**.

To check external neurostimulator battery status:

Tap  in the corner of the screen and select **Battery**.



Figure 3. Accessing system info and checking battery status

ADJUSTING YOUR THERAPY

The following sections provide instructions for using the My Therapy app to modify your therapy.

Turning Therapy On or Off

You have the ability to turn your therapy on or off at any time.

To turn therapy on:

1. On the Home screen, use your finger to swipe the On/Off switch from **Off** to **On**.

Note: You can also turn therapy on by tapping  on the Home screen.

To turn therapy off:

1. On the Home screen, use your finger to swipe the On/Off switch from **On** to **Off**.

Note: You can also turn therapy off by tapping  on the Home screen until the therapy amplitude is set to zero.

2. Tap **OK** to confirm that you would like to turn off the therapy.

Note: If the therapy becomes uncomfortable and you need to turn therapy off immediately, but the My Therapy app is unavailable or not

responding, firmly press the **ENS** button on the external neurostimulator until you feel the button click, then hold the button for a count to ten (Figure 4).

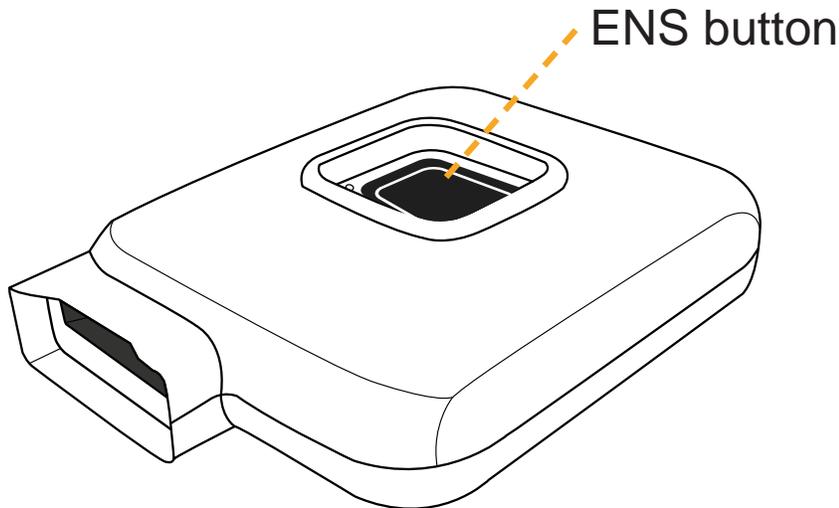


Figure 4. ENS button on the external neurostimulator

Adjusting Therapy Amplitude

You have the ability to adjust your therapy amplitude to your comfort level. If your clinician set up your therapy with different programs, only the programs that are made available to you can be adjusted. For more information on adjusting therapy amplitude for different programs (if available), see “Switching Programs” on page 28.

To adjust your therapy amplitude:

On the Home screen, tap the **arrows** to increase or decrease therapy amplitude as directed by your clinician.

Switching Therapy Sides (if two leads were placed)

If your clinician placed two leads during your evaluation procedure, you have the ability to switch the side where you receive therapy.

- Instructions on when to switch therapy sides are provided by your clinician.
- If your clinician placed only one lead, the option to switch therapy sides will not be available.

Tap **LEFT** or **RIGHT** to switch the side your receive therapy

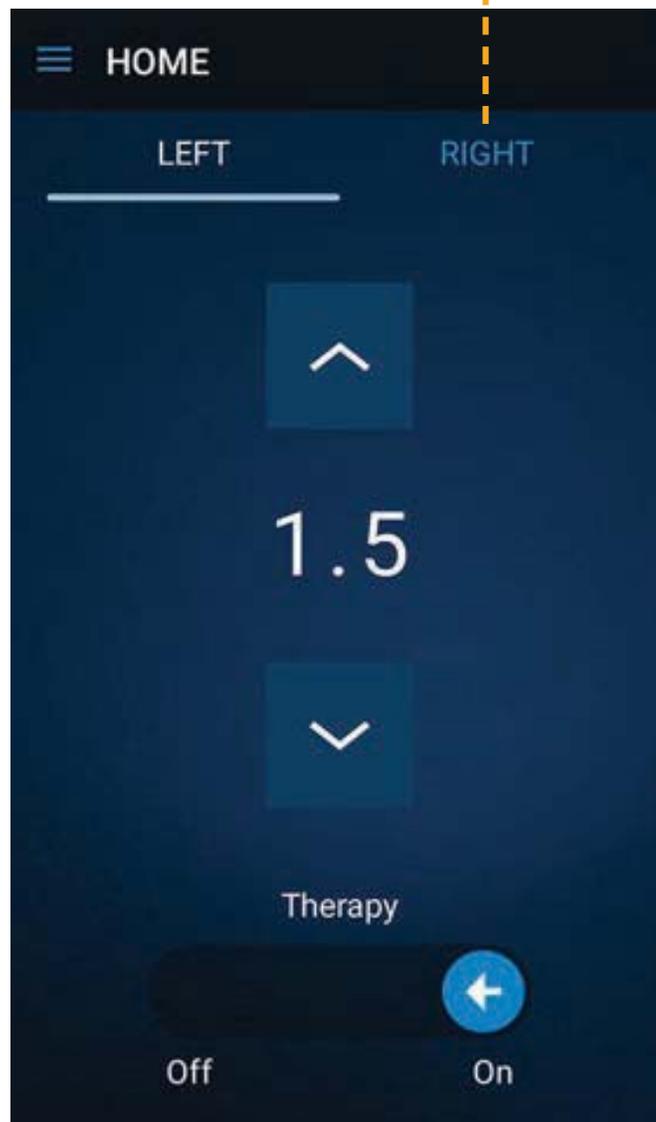


Figure 5. Switching therapy sides if you have two leads placed

To switch therapy sides:

1. On the Home screen, tap the inactive side (**left** or **right**) that you would like to switch to.
2. Tap **SWITCH THERAPY**.
3. Tap the **arrows** to adjust the therapy amplitude. Refer to “Adjusting Therapy Amplitude” on page 25 for more information.

Switching Programs

Programs are created by your clinician to provide you with the best therapy results. Each program has a different therapy setup. If multiple programs are made available to you, you have the ability to switch between the available programs as directed by your clinician.

Note: If your clinician set up your handset so that only one program is available to you, switching programs is not possible.

To switch between programs:

1. Tap the **PROGRAM** button at the bottom of the Home screen (Figure 5).
2. Select the desired program from the list, and tap **DONE**.

3. Tap the **arrows** to increase the therapy amplitude to the desired setting. Refer to “Adjusting Therapy Amplitude” on page 25 for more information.

TROUBLESHOOTING

The following sections contain information you may use to troubleshoot the My Therapy app, and answers to potential questions you might have while using it.

Therapy (stimulation) Problems

Table 1 provides troubleshooting scenarios you may encounter, as well as explanations and solutions to resolve problems if you are experiencing issues with your therapy.

Table 1. Possible scenarios and solutions for therapy problems

Scenario	Explanations and Solutions
Therapy area changes	<p>You notice an unexpected change in where you feel the therapy (stimulation).</p> <p>Call your clinician.</p>
Therapy is too strong	<ol style="list-style-type: none"> 1. Turn the therapy (stimulation) down or off. <p>See “Adjusting Therapy Amplitude” on page 25 for instructions on how to adjust your therapy.</p> <ol style="list-style-type: none"> 2. If this does not solve the problem, call your clinician.

Scenario	Explanations and Solutions
<p>Not receiving symptom relief</p>	<p>Therapy may be turned off, or the therapy (stimulation) might not be strong enough.</p> <ol style="list-style-type: none"> 1. Check that your therapy is on, then increase the therapy amplitude as directed by your clinician. 2. If this does not solve the problem, call your clinician.
<p>Uncomfortable or intolerable therapy</p>	<p>You are experiencing side effects from the therapy (stimulation).</p> <ol style="list-style-type: none"> 1. Turn the therapy (stimulation) down or off. See “Adjusting Therapy Amplitude” on page 25 for instructions. See “Turning Therapy On or Off” on page 24 for instructions. 2. If the My Therapy app is unresponsive, firmly press the ENS button on the external neurostimulator until you feel the button click, then hold the button for a count to ten. 3. If you are still experiencing side effects, call your clinician.

Scenario	Explanations and Solutions
<p>Uncomfortable tapping sensation</p>	<p>You feel a tapping sensation that is too slow or too fast.</p> <ol style="list-style-type: none"> 1. Turn the therapy (stimulation) down or off. See “Adjusting Therapy Amplitude” on page 25 for instructions. See “Turning Therapy On or Off” on page 24 for instructions. 2. If this does not solve the problem, call your clinician.
<p>The evaluation handset, or the My Therapy app is unresponsive.</p>	<p>Therapy may have stopped:</p> <ol style="list-style-type: none"> 1. Turn off the power for the evaluation handset, then turn the power back on. 2. If the issue persists, contact Medtronic support.

App Notifications

App notifications can pop up while using the My Therapy app to notify you of any problems or issues with the Verify™ evaluation system. Table 2 provides important notifications you may come across along with explanations and solutions.

Table 2. Important app notifications

App notification	Explanations and solutions
Maximum Settings	<p>Your system is operating at maximum settings. The therapy (stimulation) cannot be increased.</p> <ol style="list-style-type: none"> 1. If you are receiving symptom relief, tap OK to continue with the evaluation. 2. If you are not receiving symptom relief, call your clinician.
System Error	<p>Therapy may have stopped. The external neurostimulator may need to be replaced.</p> <p>Call your clinician.</p>
Button jammed	<p>The ENS button is stuck in the pressed position and therapy cannot be provided.</p> <p>If your finger is still pressing the ENS button, lift your finger to release the button. If the problem persists, call your clinician. The external neurostimulator may need to be replaced to continue therapy.</p>

App notification	Explanations and solutions
<p>Low battery</p>	<p>The external neurostimulator batteries are low and therapy may soon become unavailable. You can check the battery status of your external neurostimulator at any time during therapy evaluation. It is recommended that you check the batteries of the handset and the external neurostimulator every day.</p> <p>To check battery status of the external neurostimulator:</p> <ol style="list-style-type: none"> 1. On the Home screen, tap  and select Battery from the list of options. 2. If the external neurostimulator batteries are low and need to be replaced, call your clinician.
<p>Improper Device Setup</p>	<p>The device was not set up properly.</p> <p>Call your clinician.</p>
<p>Device Communication Lost</p>	<p>Communication is lost or has been interrupted.</p> <ol style="list-style-type: none"> 1. Tap RETRY to reconnect to the external neurostimulator. 2. If the issue persists, call your clinician.
<p>Not Installed Properly</p>	<p>The My Therapy app was not installed properly.</p> <p>Call your clinician.</p>

App notification	Explanations and solutions
Communication Error	<p>The My Therapy app is unable to communicate with the external neurostimulator.</p> <ol style="list-style-type: none"> 1. Tap RETRY to reconnect to the external neurostimulator. 2. If the issue persists, call your clinician.
Cable Not Attached	<p>The cable is not attached.</p> <ol style="list-style-type: none"> 1. Tap RETRY. 2. If the issue persists, call your clinician.

Other Troubleshooting Scenarios

Table 3 provides additional troubleshooting scenarios and solutions.

Table 3. Other troubleshooting scenarios and solutions

Scenario	Explanations and Solutions
<p>The evaluation handset has no power or has lost power.</p>	<ol style="list-style-type: none"> 1. The handset battery is depleted. Recharge the handset using the charger. 2. The handset is damaged or malfunctioning. Call your clinician.
<p>The evaluation handset will not charge.</p>	<ol style="list-style-type: none"> 1. The charger is disconnected from the handset. Connect the charger to the handset. 2. The wrong charger is connected to the handset. Connect an appropriate charger to the handset. 3. The charger is defective. Call your clinician. 4. The handset is damaged or malfunctioning. Call your clinician.
<p>The evaluation handset is lost or broken.</p>	<p>Call your clinician.</p> <p>Note: If you need to turn therapy off, firmly press the ENS button on the external neurostimulator until you feel the button click, then hold the button for a count to ten.</p>

Scenario	Explanations and Solutions
<p>You will be passing through a theft detector or security device.</p> <p>You will be using potentially dangerous equipment.</p> <p>You will be having a medical or dental procedure.</p>	<p>Before engaging in any of these activities, refer to “PART TWO: About Your Therapy” on page 39 for details.</p> <p>WARNING: Failure to follow the recommendations in “PART TWO: About Your Therapy” may injure you or damage the Verify™ evaluation system.</p>
<p>External Defibrillation</p>	<p>You received external defibrillation.</p> <p>Turn the therapy off and call your clinician.</p>



PART TWO: About Your Therapy

WARNINGS AND PRECAUTIONS

Warnings

Due to the temporary nature of therapy evaluation, you need to be aware of certain **warnings** and **precautions** that apply to you during the therapy evaluation period.

⚠ **WARNING:** DO NOT have **diathermy**. Refer to “Diathermy” on page 10 for more information.

⚠ **WARNING:** DO NOT have an MRI examination during the therapy evaluation period. If an MRI scan is required, contact your clinician for more information. Full MRI safety information is also available at www.medtronic.com/mri.

⚠ **WARNING:** Turn the external neurostimulator off when you drive a car or use power tools. Brief increases in stimulation due to lead movement could startle you and cause you to lose control of these devices and hurt yourself or others.

⚠ **WARNING:** (Urinary control therapy only)
This therapy is not intended for you if you have a mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

Precautions

The following precautions should be observed during the therapy evaluation period.

- Using any of the following medical equipment and treatments may adversely affect you and your Verify™ evaluation system:
 - **Defibrillators**
 - Lithotripsy and electrocautery
 - Radiation therapy over the neurostimulator
 - Radio-frequency (RF)/microwave ablation
 - Diagnostic **ultrasound** or scanning equipment
- Do not use the device in the proximity of equipment that generates electromagnetic interference (EMI). EMI may cause a disruption in device function. Examples of common medical sources of EMI are magnetic resonance imaging (**MRI**) and lithotripsy.
- Call your clinician if you see any redness or swelling at the lead site. This could be a sign of infection.

- During the therapy evaluation period, avoid sexual activity to ensure the therapy evaluation lead stays in place.
- Limit your physical activity to low or moderate levels. Turn your external neurostimulator off when you operate a vehicle.
- Take it easy during your therapy evaluation. Avoid bending, stretching, or lifting heavy objects. Be aware that the lead can move, which may cause therapy (stimulation) to increase or decrease suddenly. Quick movements or straining could increase the therapy (stimulation) and cause temporary minor discomfort.
- Avoid baths and showers. Take sponge baths, but be careful to keep the area around the lead and external neurostimulator dry and undisturbed.
- If you see any of your health care providers during your therapy evaluation period, inform them that you have a temporary lead.
- Ask your clinician what to do if you feel a change in your therapy when you stand up, walk, or change positions. You may need to

adjust the therapy settings. Remember, the goal is to feel comfortable stimulation.

- Adjust the therapy settings if the therapy becomes uncomfortable. Using the My Therapy app on the evaluation handset, turn the therapy off, turn it back on, and then slowly turn it up again until you feel comfortable stimulation.
- Call your clinician if you feel any sensation near the ground pad (if a ground pad was used). It may need to be checked to see whether it has been moved.

CONDUCTING A THERAPY EVALUATION

If your clinician feels you are a candidate for an implanted **InterStim™ system**, you will be scheduled for a therapy evaluation using the Verify™ evaluation system. A therapy evaluation allows you to experience the effects of sacral neuromodulation therapy at home for a period of time. Based on the results of the therapy evaluation, your clinician can determine if the implanted InterStim system may be beneficial for you.

Before conducting a therapy evaluation, your clinician will review your medical history with you, and will ask you to record your symptoms in a diary. This information will be used to decide if you are a good candidate for a fully implanted InterStim system.

What Is Therapy Evaluation?

Your clinician will discuss the therapy evaluation procedure with you and the options for using either a **temporary lead** or **long-term lead** for therapy evaluation. One end of the lead is implanted near your sacral nerves and the other end is connected to a small external

neurostimulator. The neurostimulator generates mild electrical pulses that are carried to the sacral nerve by the lead.

Note: The option to use two temporary leads is also possible. Only one lead will be actively stimulating at a time.

While you wear the external neurostimulator, you will need to complete a diary to record how the therapy affects your symptoms. At the end of the therapy evaluation period, you and your clinician will decide if a fully implanted InterStim™ system is right for you.

The therapy evaluation procedure

You may want to bring a spouse, relative, or friend to provide support during the procedure.

The procedure may be done in an operating room while you are under general anesthesia or your clinician may give you a mild anesthetic along with local sedation so that you can provide feedback during the procedure.

During the procedure, your clinician will insert a needle just above your tailbone to locate the appropriate sacral nerves. When the needle is in place, the external neurostimulator will be turned on, and your clinician will ask you to describe what

you feel. Some people feel a “pulling” or “tingling” sensation in their pelvic muscles or big toe.

Women may feel a sensation in the vaginal area, men in the scrotum.

If you do not feel the sensation, your clinician will slowly increase the therapy (stimulation) until you do. The sensation should not be painful. Some people have trouble feeling the stimulation or feel no stimulation at all. However, regardless of whether you feel the stimulation or not, your clinician will make sure that the lead is in the correct position by looking for a muscle response in your buttocks and big toe (the same nerve causes a muscle response in both places).

Once the correct position and responses have been confirmed, the lead is placed at that site. If the long-term lead is used, it is fully implanted under the skin. If the temporary lead is used, just one end of the temporary lead is implanted under the skin.

The long-term lead or the temporary lead is connected to the external neurostimulator. When the system is in place, an x-ray may be taken to confirm the position of the lead. The clinical staff will work with you to find the most comfortable way to wear the external neurostimulator.

Operating the External Neurostimulator

After confirming that the temporary lead is in the correct position, your clinician will show you how to operate the external neurostimulator, and will also inform you of precautions related to the external neurostimulator and of activity restrictions.

The sensation of stimulation should not be painful. Most people describe it as a slight pulling or tingling in the pelvic area. If you experience pain, decrease your therapy amplitude. If the painful sensation caused by the stimulation persists, turn your therapy off and contact your clinician.

KEEPING A DIARY

During the therapy evaluation period, you will be asked to complete a diary. You will use it to track your symptoms. This history will help your clinician evaluate whether an InterStim system is right for you. This record of your symptoms will provide your clinician with valuable information.

Your clinician will ask you to take the following actions:

- Before your therapy evaluation, record information, such as how often and how much you experience symptoms.
- During your therapy evaluation, record how the therapy affects your symptoms.
- After your therapy evaluation, monitor any return of symptoms.

You may need to complete several diaries before, during, and after your therapy evaluation. It is important to complete the diary accurately in order to give your clinician a detailed picture of how sacral neuromodulation therapy works for you. Each time you experience symptoms, record any information relating to your evaluation as directed by your clinician. It takes just a moment to do this, but the information is very important. It will help

you and your clinician determine whether a fully implanted InterStim™ system can help you.

Your clinician will show you how to complete the diary. If you have questions later, contact your clinician. Be sure to bring the diary with you when you visit the clinician's office again.

Therapy Evaluation Results

Generally, if your symptoms improved and you did not experience any problems during your therapy evaluation, then you and your clinician will discuss whether to proceed with a long-term implanted InterStim™ system. If your therapy evaluation results using the temporary lead are inconclusive, your clinician may recommend a second therapy evaluation using a long-term lead or recommend a different treatment option.

Common Questions

I'm not sure if the therapy is working. What should I do?

Check that the external neurostimulator is working. If the external neurostimulator is working, turn therapy off and back on, and then gradually increase the therapy amplitude to a

comfortable setting. Call your clinician if you have any questions or are still unsure that the external neurostimulator is working.

What does receiving therapy (stimulation) feel like?

Stimulation varies from person to person, but most people describe it as a slight “pulling” or a “tingling” sensation in the pelvic area. It should not be painful. If you feel any pain, turn off the external neurostimulator, and call your clinician.

Will therapy evaluation cure my condition?

No. Therapy evaluation is temporary. It is a tool that helps determine whether a long-term InterStim™ system is appropriate for you. Once the lead is removed, your original symptoms will return.

If you have had positive results with the evaluation, then you and your clinician may decide to use a long-term InterStim system to treat your symptoms.

Will the therapy (stimulation) change at all?

You may feel slight changes in stimulation when you move from a sitting to a standing position or

from a standing to a walking position. Check with your clinician; you may need to adjust the therapy when that happens.

Will stimulation hurt my nerves?

No. Research has shown that the nerves are not harmed by the stimulation when used properly.

How long will the external neurostimulator battery last?

Your external neurostimulator will have new batteries when you go home. The batteries should last for the entire therapy evaluation period. If your batteries are low, contact your clinician.

Can I have sex during the therapy evaluation period?

No, you should avoid sexual activity during the therapy evaluation period because it could cause the lead to move. This restriction only applies to the therapy evaluation period, there are no restrictions on sexual activity during long-term sacral neuromodulation therapy.

Contacts:

Asia: Medtronic International Ltd.

Tel. 02919-1300

Fax 02891-6830

Medtronic Asia Ltd.

Tel. (02)-548-1148

Fax (02)-518-4786

Australia: Medtronic Australasia Pty. Ltd.

97 Waterloo Road

North Ryde, NSW 2113

Australia

Tel. +61-2-9857-9000

Fax +61-2-9878-5100

Toll-free 1-800-668-670

Austria: Medtronic Österreich GmbH

Tel. 01-240440

Fax 01-24044-100

Belgium: Medtronic Belgium S.A.

Tel. 02-456-0900

Fax 02-460-2667

Canada: Medtronic of Canada Ltd.

Tel. (1-905)-460-3800

Fax (1905)-826-6620

Czech Republic: Medtronic Czechia s.r.o.

Tel. 2-965-795-80

Fax 2-965-795-89

Denmark: Medtronic Danmark A/S

Tel. 45-32-48-18-00

Fax 45-32-48-18-01

Finland: Medtronic Finland Oy/LTD

Tel. (09)-755-2500

Fax (09)-755-25018

France: Medtronic France S.A.S.

Tel. 01-5538-1700

Fax 01-5538-1800

Germany: Medtronic GmbH

Tel. (02159)-81490

Fax (02159)-8149100

Greece: Medtronic Hellas S.A.

Tel. 210-67-79-099

Fax 210-67-79-399

Hungary: Medtronic Hungária Kft.

Tel. 1-889-06-00

Fax 1-889-06-99

Ireland: Medtronic Ireland Ltd.

Tel. (01)-890-6522

Fax (01)-890-7220

Italy: Medtronic Italia SpA

Tel. 02-241371

Fax 02-241381

Tel. 06-328141

Fax 06-3215812

Japan: Medtronic Japan

Tel. 03-6776-0017

Fax 03-6774-4645

Latin America: Medtronic, Inc.

Tel. (1305)-500-9328

Fax (1786)-709-4244

Norway: Medtronic Norge AS

Tel. 67-10-32-00

Fax 67-10-32-10

Poland: Medtronic Poland Sp. z.o.o.

Tel. (022)-465-69-00

Fax (022)-465-69-17

Portugal: Medtronic Portugal, Lda.

Tel. 21-724-510

Fax 21-724-5199

Russia: Medtronic Russia

Tel. (8495) 580-7377

Fax (8495) 580-7378

Slovakia: Medtronic Slovakia, o.z.
Tel. 0268 206 911
Fax 0268 206 999

Spain: Medtronic Ibérica, S.A.
Tel. 91-625-0400
Fax 91-650-7410

Sweden: Medtronic AB
Tel. 08-568-585-00
Fax 08-568-585-01

Switzerland: Medtronic (Schweiz) AG
Tel. 031-868-0100
Fax 031-868-0199

The Netherlands: Medtronic B.V.
Tel. (045)-566-8000
Fax (045)-566-8668

Turkey: Medtronic Turkey
Tel. +90 216 636 1000
Fax +90 216 636 1008

U.K.: Medtronic U.K. Ltd.
Tel. 01923-212213
Fax 01923-241004

USA: Medtronic, Inc.
Tel. (1-763)-505-5000
Fax (1-763)-505-1000
Toll-free: (1-800)-328-0810

Medtronic

Manufacturer



Medtronic, Inc.
710 Medtronic Parkway,
Minneapolis, MN 55432-5604,
USA
www.medtronic.com
Tel. +1-763-505-5000
Fax +1-763-505-1000

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Authorized Representative in the European Community

Medtronic B.V.
Earl Bakkenstraat 10,
6422 PJ Heerlen,
The Netherlands
Tel. +31-45-566-8000
Fax +31-45-566-8668

Europe/Africa/Middle East Headquarters

Medtronic International Trading Sàrl
Route du Molliau 31,
Case Postale 84
CH - 1131 Tolochenaz,
Switzerland
www.medtronic.eu
Tel. +41-21-802-7000
Fax +41-21-802-7900

Asia-Pacific

Medtronic International Ltd.
Suite 1106-11, 11/F, Tower 1, The Gateway,
25 Canton Road, Tsimshatsui,
Kowloon,
Hong Kong
Tel. +852-2919-1300
Fax +852-2891-6830

Contacts for specific countries are listed inside
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