

A52300

PATIENT THERAPY APP
FOR SACRAL
NEUROMODULATION THERAPY

Patient User Guide for InterStim™
systems

with Model 97800 InterStim X
neurostimulator



Application version 1.0

! USA Rx only

Medtronic

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The handset, as configured, does not support voice communication and therefore cannot be used to make any calls (including emergency calls).

SYMBOLS

Explanation of symbols



Manufacturer



Authorized representative in the European community



Importer



For USA audiences only



Magnetic Resonance (MR) Conditional



Magnetic Resonance (MR) Unsafe

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HOW TO USE THIS GUIDE

Welcome to your guide to the patient therapy app for Medtronic Bladder or Bowel Control Therapy delivered by the InterStim™ system (also called sacral neuromodulation therapy). We created this guide to help you understand how the patient therapy application (app) on your handset works. Please read the entire guide before using the app to adjust your therapy. Ask your clinician to explain anything that is unclear.

- Information about how to contact Medtronic is on page 8 and the back cover.
- 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 10.
- Important safety information regarding your therapy begins on page 14.
- The “USING THE PATIENT THERAPY APP” section provides instructions on how to use the app to adjust your therapy after your InterStim device has been implanted. This section of the guide includes information on turning your therapy on and off, adjusting your therapy settings, checking battery level, and changing programs (if applicable). See page 22.

- The “MRI EXAMINATIONS” section includes instructions for using the app to prepare for an MRI scan. See page 29.
- The “TROUBLESHOOTING” section provides explanations and solutions for various troubleshooting scenarios you may encounter while using your handset. This includes explanations on important patient therapy app notifications, and who to contact if your handset is lost or broken. “TROUBLESHOOTING” starts on page 39.

Contact Information

Be sure to write down important contact information in the following fields, so it's easy to find in the future:

| | |
|-----------------------------|---|
| Clinician Name <hr/> | Clinician Telephone Number <hr/> |
| Hospital Name <hr/> | Hospital Telephone Number <hr/> |

How to Contact Medtronic

Medtronic is available to answer any technical or troubleshooting device related questions or concerns you may have about your InterStim system components. Have the name and telephone number of your **clinician** at hand if you have any questions or problems. See the Medtronic contacts on the back cover of this manual.

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

If you lose your identification card, contact:

USA

Medtronic Inc., Patient Registration Services
Mail Stop SLK35
800 53rd Avenue NE
Minneapolis, MN 55421-1200
(1-800-551-5544)

Europe, Africa, Middle East, and Asia-Pacific Countries

Refer to the Medtronic contacts on the back cover of this manual.

Important Tips

The following includes some things to keep in mind while using sacral neuromodulation therapy:

- Always carry your handset and **communicator**. The patient therapy app on the handset is the only way to adjust or turn therapy on and off. Also, it is very important that you bring your handset and communicator to all follow-up appointments, including appointments with other clinicians. During certain procedures, you may need to turn your therapy off.
- Bring this guide to all your appointments and share this information with clinicians, dentists, MRI operators, and other professionals who may not be familiar with the InterStim system patient therapy app. When necessary, you should also bring your Patient Therapy Guide for InterStim systems; it contains important information about sacral neuromodulation therapy that your clinicians should be aware of.
- Refer to “GENERAL WARNINGS & PRECAUTIONS” on page 14 and throughout the manual for information on what you should and should not do while using the InterStim system.

Notes:

For more information about the communicator, see the TM90 Communicator Instructions for Use.

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.

| | |
|--------------|---|
| Caution | A statement that describes an action or situation which could harm the patient or damage the device. |
| 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. |
| Communicator | A communication device that includes a radio-frequency technology that allows the neurostimulator and the handset to communicate with each other. |

| | |
|------------------------------|--|
| Electromagnetic interference | A strong field of energy near electrical or magnetic devices that could prevent the neurostimulator from functioning properly, damage the neurostimulator, or even injure you. |
| Handset | A hand-held electronic device used by the patient to control therapy settings and to turn the neurostimulator on and off. |
| InterStim system | An implanted system that sends mild electrical pulses to sacral nerves 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. |
| Patient therapy app | An app used to modify sacral neuromodulation therapy. |

| | |
|---------------------------------------|---|
| Neurostimulator | The power source of a neurostimulation system. It contains the battery and electronics that control the stimulation. |
| Pair (concerning a device or devices) | The process of wirelessly connecting in order to send and receive information between the patient therapy app, the communicator, and the implanted neurostimulator. |
| Precaution | See Caution. |
| 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. |

| | |
|-------------------|--|
| Therapy | Treatment of a disease or condition. When neuromodulation therapy is prescribed, a neurostimulation system is used to deliver therapy (stimulation) to a specific site. |
| Therapy amplitude | The strength or intensity of stimulation measured in milliamps. |
| Therapy settings | Refers to the features that define the therapy. The clinician programs all therapy settings. You can adjust some of your therapy settings within clinician-defined limits. |
| Warning | A statement that describes an action or situation which could seriously harm the patient. |

GENERAL WARNINGS & PRECAUTIONS

Warnings

⚠ WARNING: Wound contact — Do not use the communicator on an unhealed wound. The communicator is not sterile and contact with the wound may cause an infection. Keep a sterile bandage or barrier between the wound and the device.

Precautions

⚠ CAUTION: Communication interference from EMI sources – When using your handset and communicator to communicate with your **neurostimulator**, move away from equipment that may generate **electromagnetic interference (EMI)** or turn off the likely source of EMI. EMI may disrupt communication between the handset, communicator, and neurostimulator. Examples of EMI sources are computer monitors, and motorized wheelchairs. For more information about EMI, refer to the Patient Therapy Guide for InterStim systems.

⚠ CAUTION: Contact your clinician if you experience unintended changes in therapy.

Other **warnings** and **precautions** are found throughout the manual.

For warnings, precautions, and adverse events related to sacral neuromodulation

therapy, refer to the Patient Therapy Guide for InterStim systems. If you did not receive the Patient Therapy Guide, contact your clinician.

ABOUT THE PATIENT THERAPY APP

The **patient therapy app** is a software application (app) for Medtronic Bladder or Bowel Control Therapy delivered by the InterStim system with the Model 97800 InterStim X neurostimulator. The app is intended to be used for controlling and monitoring your therapy. It is installed on and used with the **handset** to adjust your therapy.

Intended Use

The patient therapy application provides the user interface for patients to adjust therapy and obtain system information from an implantable neurostimulator as part of a neurostimulation system for sacral neuromodulation therapy.

How Does the App Work?

Your clinician used the clinician app on your handset to program your **therapy settings**. Your therapy is provided through the implanted neurostimulator (INS). Your clinician uses programs to control the delivery of your therapy. If needed, your clinician will use the clinician app to change your therapy settings. You will use the patient therapy app to:

- Turn your therapy on and off, page 25
- Adjust therapy amplitude within the limits set by your clinician, page 25

- Change **programs** (if available), page 26
- Activate MRI mode, page 31

The patient therapy app on the handset uses a communicator to communicate wirelessly with the implanted neurostimulator (INS) by sending signals to and receiving signals from the neurostimulator. To send and receive the signals, the communicator must be connected or **paired** to the handset as well as the neurostimulator.

Your neurostimulator only accepts programming from the clinician app or the patient therapy app. Other devices are not able to program your neurostimulator.

Your clinician will initially set up the handset according to your specific needs, after the implant procedure. However, if for any reason the communicator and/or handset has been disconnected or unpaired from the neurostimulator, or you received a replacement device(s), you will need to reconnect.

For more information about connecting the communicator to the handset and implanted device, see “TROUBLESHOOTING” on page 39.

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

How do I use the patient therapy app on the handset?

Use the patient therapy app on the handset to adjust your therapy as directed by your clinician. The handset has a touchscreen display that 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 turn your therapy on or off.

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

Instructions for using the app to adjust your therapy settings begin on page 25.

Accessing the Patient Therapy App

You can access your patient therapy app (Figure 1) by locating the appropriate icon on the main screen of the handset. Tap the icon to open the app and begin using it.

The first time you or your clinician opens the app, it will request permission for data storage. Tap **OK** to continue. Then tap **ALLOW** for the next messages.

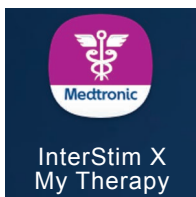


Figure 1. InterStim X My Therapy app icon

Patient Therapy App Tutorial

The app includes a brief tutorial that will help you understand its basic functions. When you open the app for the first time you will be presented with this tutorial. If 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 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 from the image shown depending on how your clinician set up the handset.

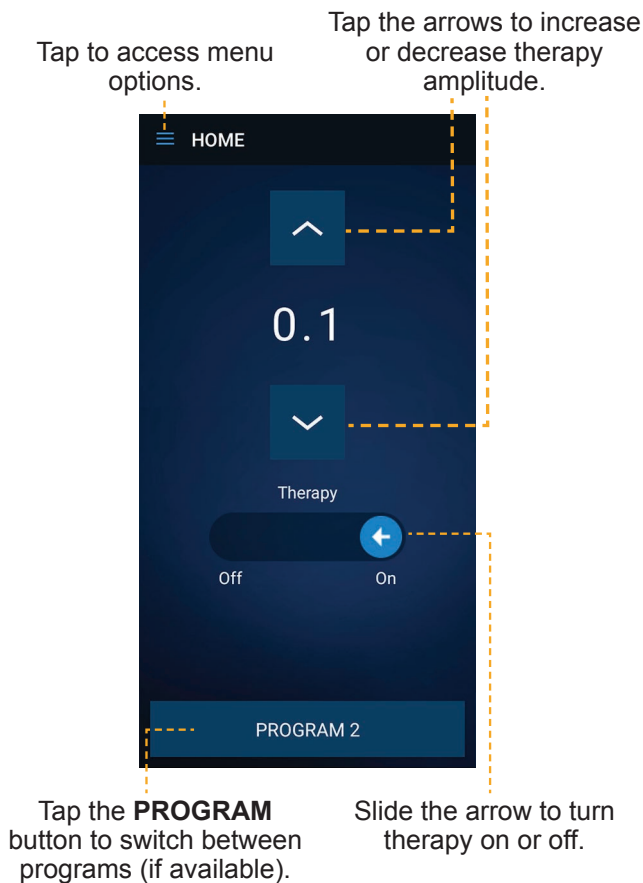


Figure 2. Home screen

Accessing system information

Use the patient therapy app to access neurostimulator system information as well as

check the battery level of the neurostimulator, and prepare for MRI. (Figure 3).

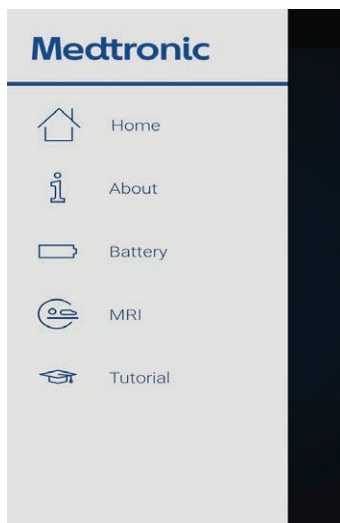



Figure 3. Accessing system information

To view system information:

Tap  in the corner of the screen and select from the following:

- **About** to see general information about your system
- **Battery** for battery level (See “Checking Battery Level” on page 27 for details.)
- **MRI** to prepare for MRI (See “MRI EXAMINATIONS” on page 29 for important information.)
- **Tutorial** to review basic functions

USING THE PATIENT THERAPY APP

Your clinician will provide complete guidelines about when you may want to adjust your therapy. The following sections provide instructions for using the app to modify your therapy.

Main Features

The patient therapy app has a few basic features that allow you to manage certain aspects of your therapy. Using the app, you can perform the following tasks:


- Adjust **therapy amplitude** (stimulation), page 25
- Turn your therapy On or Off, page 25
- Switch between **programs** (if available), page 26
- Access the app tutorial, page 19
- Access system status and neurostimulator battery level information, page 27
- Activate MRI mode, page 31

Using the Communicator to Connect your Handset and Neurostimulator

The patient therapy app will need to communicate with your implanted neurostimulator. Use the following procedure to use the communicator to connect your

handset and implanted neurostimulator before adjusting your therapy.

To connect your handset and neurostimulator using the communicator:

1. Press  on the communicator to turn the communicator on. The communicator will attempt to connect to the handset (Figure 4). The blue LED indicator on the communicator will continuously blink to indicate it is on and in discovery mode.

Note: For details about button and functions of the communicator, see the TM90 Communicator Instructions for Use.

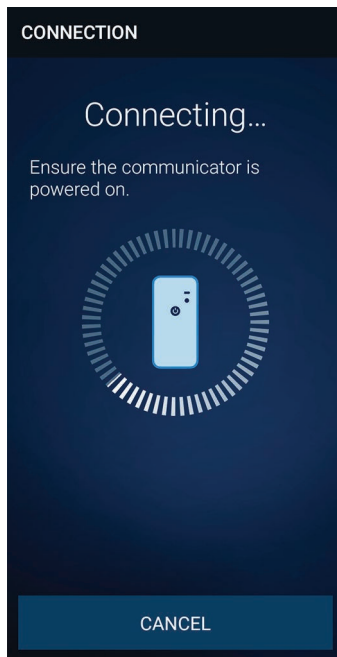


Figure 4. Connection screen

2. Open the patient therapy app on the handset.
3. Once the communicator has successfully connected to the handset, the blue LED indicator on the communicator will be solid and no longer blinking. Place the communicator over the neurostimulator site (Figure 5), and tap **FIND DEVICE** on the handset.

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



Figure 5. Connecting the communicator to the implanted neurostimulator

4. Once the communicator has successfully connected to the implanted neurostimulator, you will see the tutorial (if enabled) or the Home screen where you can adjust your therapy as directed by your clinician.

Adjusting Therapy Amplitude

The patient therapy app allows you to adjust your therapy amplitude to your comfort level as your needs change.

To adjust your therapy amplitude:

1. Place the communicator over the neurostimulator site.
2. On the Home screen, tap the **arrows** to increase or decrease therapy amplitude as directed by your clinician.

Turning Therapy On or Off

In the patient therapy app you have the ability to turn therapy on or off.

To turn therapy on:

1. Place the communicator over the neurostimulator site.
2. On the Home screen, swipe the **On/Off** switch from Off to **On**.

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

To turn therapy off:

1. Place the communicator over the neurostimulator site.
2. On the Home screen, swipe the **On/Off** switch from On to **Off**.
3. A pop-up will appear confirming that therapy has been turned off. Tap **OK** to acknowledge therapy has been turned off.

Note: You can also turn therapy off by tapping \vee on the Home screen until the therapy amplitude is set to -- (off).

Switching Programs

Programs are created by your clinician to provide you with the best therapy results. Each program has different therapy settings. 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 an option.


To switch between programs:

1. Place the communicator over the neurostimulator site.
2. Tap the **PROGRAM** button at the bottom of the Home screen.
3. Select the desired program from the list, and tap **DONE**.

4. Tap the **arrows** to adjust the therapy amplitude to the desired setting. See “Adjusting Therapy Amplitude” on page 25 for more information.

Checking Battery Level

To check neurostimulator battery level:

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

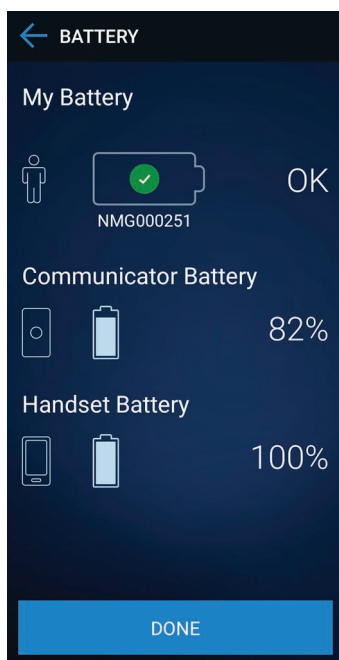




Figure 6. Battery screen

Table 1. Neurostimulator battery level descriptions

| My Battery | Neurostimulator battery level |
|---|--|
|  | OK |
|  | <p>LOW</p> <p>Consult your clinician if a low battery icon appears, or if you receive a low battery message.</p> |

Notes:

For information about communicator battery level and charging your communicator, see the TM90 Communicator Instructions for Use.

For information about handset battery level and charging the handset, follow the directions provided with your handset.

MRI EXAMINATIONS



Magnetic Resonance (MR) Conditional:

Depending on what kind of neurostimulation system components that you have implanted, you may be eligible for one of the following types of magnetic resonance imaging (MRI) scans:

- MRI scans of the head only (this is referred to as head-scan only eligible).
- MRI scans of any part of your body (this is referred to as full-body scan eligible).

Note: Always consult the clinician managing your InterStim system before having an MRI scan.



Magnetic Resonance (MR) Unsafe:

External devices such as your handset or communicator are unsafe in the MR environment. Do not take any external devices into the MRI scanner (magnet) room.

Preparing for Your MRI Appointment

⚠ WARNING: Do not undergo an MRI scan without first determining if you are eligible and consulting with your clinician. Inform the MRI clinician that you have an implanted device, and activate MRI mode before your MRI scan, while you are still outside the scanner (magnet)room. Failure to do so may result in serious or permanent harm to you or damage to your implanted system.

⚠ CAUTION: Deactivate MRI mode when the MRI scan is complete and you are outside

the MRI scanner (magnet) room. Failure to deactivate MRI mode and return therapy amplitude to the previous level may result in a return of symptoms.

Before Your MRI Scan:

1. Consult the clinician managing your InterStim system before having an MRI scan.
2. Bring your handset, communicator, and Medtronic patient ID card to every MRI appointment, and inform the MRI clinician that you have an implanted device.
3. If the clinician managing your InterStim system gave you an MRI scan eligibility sheet, bring it to the MRI appointment along with your handset and communicator.
4. Activate MRI mode before your MRI scan, while you are still outside the scanner (magnet) room, using the following instructions. MRI mode turns therapy off and prepares your InterStim system for scanning.

Notes:

Inform the MRI clinician if you think you have a fever. Having a fever may affect your ability to have an MRI scan.

Remember to charge the handset and communicator prior to the MRI appointment.


To obtain the MRI guidelines, the MRI clinician can refer to the contact information on the

back cover of this manual, or the MRI clinician can go to www.medtronic.com/mri.

Activating MRI Mode Using Your Handset

The handset must be used to place the InterStim system in MRI mode before an MRI scan. Ensure you are outside of the MRI scanner (magnet) room before proceeding with the following steps. When you use the handset to place your InterStim system in MRI mode, scan eligibility icons will appear on the screen (See “Table 2. MRI mode eligibility displays” on page 33). Show that screen to the MRI clinician.

Note: During the MRI scan, leave the handset outside the scanner (magnet) room with the InterStim system in MRI mode. Do not tap **DEACTIVATE**. Therapy must remain off.

1. Press  on the communicator to turn the communicator on. The communicator will attempt to connect to your handset, but cannot do so until the patient therapy app is launched. The blue LED light on the communicator will continuously blink to indicate it is on and in discovery mode.
2. Open the patient therapy app on the handset to initiate the connection process.
3. Once the communicator has successfully connected to the handset, the blue LED light on the communicator will

be solid and no longer blinking. Place the communicator over the implanted neurostimulator and tap **FIND DEVICE** on the handset.

Note: If the communicator fails to connect to the neurostimulator, readjust the location of the communicator over the neurostimulator, and tap **RETRY** on the handset.




4. Once the communicator has successfully connected to the implanted neurostimulator, you will be taken to the Home screen.
5. Tap **≡** in the corner of the Home screen and select **MRI**.
6. Tap **ACTIVATE** to activate MRI mode.
7. One of the following messages will appear:
 - MR Conditional Full Body Scan Eligible
 - MR Conditional Head Scan Eligible with Transmit/Receive Head Coil
 - MRI eligibility cannot be determined

Note: If the handset screen says **MRI eligibility cannot be determined**, further assessment by the clinician who manages your InterStim system is necessary before scanning. Contact your clinician.

8. After activating MRI mode, show your handset to the MRI clinician with the screen displayed. Do not tap **DEACTIVATE** or turn therapy back **ON** until your MRI scan is complete and you are outside the scanner (magnet)

room. See “Table 2. MRI mode eligibility displays” for descriptions.

Table 2. MRI mode eligibility displays

| Screen image, text and description |
|---|
|  <p>MR Conditional Full Body Scan Eligible</p> |
|  <p>MR Conditional Head Scan Eligible with Transmit/ Receive Head Coil</p> |
|  <p>MRI eligibility cannot be determined</p> |

Notes:

Your scan eligibility depends on several factors. Show your handset to the MRI clinician with the screen displayed. If the handset screen says **MRI eligibility cannot be determined** or any other unexpected message, do not proceed with an MRI scan. Contact the clinician who manages your InterStim system.


Do not take your handset, communicator, or any other patient control device into the MRI scanner (magnet) room.

Do not deactivate MRI mode until after the MRI scan is complete and you are outside the scanner (magnet) room.

Turning Therapy On After Your Scan

Deactivate MRI mode when the MRI scan is complete and you are outside the MRI scanner (magnet) room. You can deactivate MRI mode and turn therapy on using your handset, or you can return to the clinician managing your neurostimulation system to have therapy turned back on for you.

Complete the following steps to turn therapy on using your handset.

1. Connect to your neurostimulator as usual.
2. On the Home screen, tap  then select **MRI**.
3. Tap **DEACTIVATE** at the bottom of the screen.
4. Tap **DEACTIVATE** a second time when prompted.
5. Tap **YES** when prompted to return to previous therapy settings, if desired.

Note: Contact your clinician if you are unable to turn therapy on.

Visiting Your Clinician to Activate MRI Mode

Inform the clinician managing your InterStim system that an MRI examination has been

prescribed for you and that you need MRI mode activated. Remember to bring your handset and communicator to every appointment, including the MRI appointment. Your clinician may place your system in MRI mode for you.

Keep your neurostimulation system in MRI mode during the MRI scan. The clinician may also give you an MRI scan eligibility sheet to bring to your MRI appointment. Give the MRI scan eligibility sheet to the MRI clinician.

ADDITIONAL INFORMATION

The following sections provide additional information about your device, including information on data security and network connectivity, cleaning and care, and disposal information.

Data Security and Network Connectivity

The patient therapy app uses and stores data about your health and medical device. This information is protected by the app and handset. Personal files or data you choose to store or access elsewhere on the handset are not protected.

You are ultimately responsible for protecting the data that is stored on the handset. To help protect your data, Medtronic recommends the following:

- Secure your handset by disabling the Wi-Fi network connection when using the app.
- Use a trusted, secure Wi-Fi network when Internet access is needed.

Note: Connecting to a Wi-Fi network is not required to use your therapy, however network connectivity is needed for Medtronic app updates and communicator firmware updates.

- If your handset is lost or stolen, contact Medtronic right away using the contact information at the end of this guide.

- If you no longer need the handset to manage your therapy, see “Disposal” on page 38.

If you suspect the security of your handset has been compromised, stop using the app (if possible) and contact Medtronic to document and respond to the suspected incident.

Software Updates

You might be notified that you should update your software. Connect to Wi-Fi to receive the update. When the update is complete, you can turn Wi-Fi off again.

Safety and Technical Checks

Periodic safety and technical checks or periodic maintenance of the handset are not required. If the handset requires repair or is nonfunctional, contact Medtronic. Refer to the contact information at the end of this guide.

Cleaning and Care

Follow these guidelines to ensure that the handset and accessories function properly:

- Keep the handset and communicator out of the reach of children and pets.
- Use the handset and communicator only as explained to you by your clinician or as discussed in this manual and others provided to you by Medtronic.
- Follow all warnings and cautions in this guide, and the Patient Therapy Guide

for InterStim systems provided by your clinician.

- Handle the handset and communicator with care. Do not drop, strike, or step on the device.
- Do not dismantle or tamper with the handset or communicator. Do not attempt to service them yourself.
- Clean the outside of the handset and communicator with a damp cloth when necessary.
- The handset and communicator are not waterproof. Do not allow moisture to get inside.

Disposal

Contact Medtronic if you no longer need your handset. Medtronic can help you delete your personal and health data, and dispose of the handset. Contact information for Medtronic can be found at the end of this manual.

TROUBLESHOOTING

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

Therapy (stimulation) Problems

Table 3 provides troubleshooting scenarios you may encounter, as well as explanations and solutions to resolve problems if you are experiencing issues with your therapy.

Table 3. Possible scenarios and solutions for therapy problems

| Scenario | Explanations and/or Solutions |
|---------------------------------------|--|
| <p>Delayed therapy changes</p> | <p>You do not feel therapy right away after turning on the neurostimulator or you feel therapy after turning off the neurostimulator.</p> <p>Your clinician may have enabled SoftStart/ Stop™ so that therapy starts and stops gradually. If SoftStart/ Stop is enabled, it may take a few seconds for your neurostimulator to turn on and off. You may feel a residual effect after the neurostimulator is turned off.</p> |

| Scenario | Explanations and/or Solutions |
|--|--|
| <p>Intermittent therapy</p> | <p>You feel your therapy only some of the time.</p> <p>Your clinician may have programmed your neurostimulator to turn on and off at regular intervals. If therapy is uncomfortable or symptoms return, call your clinician.</p> |
| <p>Therapy area changes</p> | <p>You notice an unexpected change in where you feel the therapy (stimulation).</p> <p>Call your clinician.</p> |
| <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 these steps do not solve the problem, call your clinician. |

| Scenario | Explanations and/or Solutions |
|---|---|
| Uncomfortable or intolerable therapy (stimulation) | <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 or “Turning Therapy On or Off” on page 25 for instructions. 2. If you are still experiencing uncomfortable therapy (stimulation), call your clinician. |
| Uncomfortable tapping sensation | <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 or “Turning Therapy On or Off” on page 25 for instructions. 2. If you are still experiencing an uncomfortable tapping sensation, call your clinician. |

| Scenario | Explanations and/or Solutions |
|---|--|
| <p>Therapy does not relieve your symptoms</p> | <ol style="list-style-type: none"> 1. Adjust therapy amplitude OR switch programs (if available). 2. If the issue persists, call your clinician. |
| <p>You have unexpected changes in therapy</p> | <ol style="list-style-type: none"> 1. Turn your therapy off. 2. Turn your therapy on by pushing the up arrow once and slowly increasing therapy amplitude to the desired level OR switch programs (if available). 3. If the issue persists, call your clinician. |
| <p>The handset, or the patient therapy app is unresponsive</p> | <p>Therapy may have stopped:</p> <ol style="list-style-type: none"> 1. Turn off the power on the handset, then turn the power back on and reopen the patient therapy app. 2. If the issue persists, call your clinician. |

| Scenario | Explanations and/or 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, see the Patient Therapy Guide for InterStim systems for details.</p> |
| <p>You received external defibrillation</p> | <p>Turn the therapy off and call your clinician.</p> |
| <p>The handset is unable to connect to the communicator</p> | <ol style="list-style-type: none"> 1. The communicator is not powered on. You will need to turn on the communicator to communicate with your implanted neurostimulator. <p>Once the communicator is powered on, follow the connection steps (A) provided at the end of this section to reconnect your existing communicator.</p> |

| Scenario | Explanations and/or Solutions |
|----------|--|
| | <p>2. The communicator is not charged or is in the process of charging. You will need to charge the communicator using the charger provided in your product package.</p> <p>Once charged, follow the connection steps (A) provided at the end of this section to reconnect your existing communicator.</p> <p>Note: The communicator cannot be used while charging.</p> <p>3. The communicator is out of range. Make sure the communicator is near the handset.</p> <p>Once in range, follow the connection steps (A) provided at the end of this section to reconnect to your existing communicator.</p> |

| Scenario | Explanations and/or Solutions |
|----------|--|
| | <p data-bbox="464 203 888 455">4. You received a replacement communicator. You will need to connect the new communicator to the handset and the implanted device.</p> <p data-bbox="505 472 871 690">Follow the connection steps (B) provided at the end of this section to connect to a new/replacement communicator device.</p> <p data-bbox="464 707 850 774">5. Your communicator needs to be updated.</p> <p data-bbox="505 791 878 976">Follow the connection steps (C) provided at the end of this section to update your communicator.</p> <p data-bbox="464 992 905 1060">6. If the issue persists, call your clinician.</p> |

| Scenario | Explanations and/or Solutions |
|--|--|
| <p>A. To reconnect with your neurostimulator using an existing communicator you have used before:</p> | <ol style="list-style-type: none">1. Make sure the communicator is turned on. Note: For details about button and functions of the communicator, see the TM90 Communicator Instructions For Use.2. Open the patient therapy app on the handset.3. When the communicator has successfully connected to the handset, place the communicator over the neurostimulator site, and tap FIND DEVICE on the handset. Once connected, you will be taken to the Home screen where you can adjust your therapy.4. If the communicator you would like to connect to is not shown, tap RETRY.5. If you are having trouble, call your clinician. |

| Scenario | Explanations and/or Solutions |
|----------|---|
| | <p data-bbox="184 203 871 270">B. To connect using a new or replacement communicator for the first time:</p> <ol data-bbox="213 290 897 1004" style="list-style-type: none"><li data-bbox="213 290 897 450">1. Make sure the communicator is turned on. Note: For details about button and functions of the communicator, see the TM90 Communicator Instructions For Use.<li data-bbox="213 467 897 534">2. Open the patient therapy app on the handset.<li data-bbox="213 551 897 769">3. After the app searches for and fails to find a communicator that has been paired previously, a screen will be displayed showing that the communicator is not found. Tap SWITCH COMMUNICATOR on the handset to connect.<li data-bbox="213 786 897 1004">4. Select the communicator serial number found on the back of the communicator that you would like to pair to and tap CONTINUE. The serial number of the communicator should match the serial number shown on the screen. Note: If the communicator you would like to connect to is not shown, tap RETRY. <ol data-bbox="213 1021 897 1140" style="list-style-type: none"><li data-bbox="213 1021 897 1140">5. If you are having trouble, call your clinician. |

| Scenario | Explanations and/or Solutions |
|----------|--|
| | <p>C. To update your communicator:</p> <ol style="list-style-type: none"> 1. Connect the handset to a Wi-Fi network. 2. Make sure the communicator is turned on. 3. Open the patient therapy app on the handset. 4. A screen will be displayed showing that an update is needed for the communicator. Tap UPDATE on the handset to update. <p>Note: The update will take a few minutes to complete.</p> <ol style="list-style-type: none"> 5. If you are having trouble, contact your clinician. |

App Notifications

Notifications can pop up on the handset while using the patient therapy app to notify you of problems or issues with the InterStim system. Table 4 provides important notifications along with explanations and solutions.

Table 4. Important app notifications

| App notification | Explanations and/or Solutions |
|---|---|
| Communicator connection lost | <ol style="list-style-type: none"> 1. Ensure the Bluetooth® on the handset is turned on. 2. Make sure the communicator is fully charged. 3. Reposition the communicator over the neurostimulator, and tap RETRY on the handset. 4. If the issue persists, call your clinician. |
| Device not responding | <ol style="list-style-type: none"> 1. Reposition the communicator over the neurostimulator, and tap RETRY. |
| Internal device data lost or Data lost | Call your clinician. |
| Implanted neurostimulator (INS) low battery | <p>Your neurostimulator will need to be replaced soon</p> <p>Call your clinician.</p> |

| App notification | Explanations and/or Solutions |
|---|---|
| <p>Maximum Settings Reached</p> <p>Note: In addition to the notification, an orange icon will appear.</p> | <p>Your neurostimulator has reached the limit of its therapy (stimulation) range.</p> <ol style="list-style-type: none"> 1. Turn therapy amplitude down. 2. Swipe the On/Off switch to Off, then to On. 3. Slowly increase therapy amplitude. 4. If the notification is shown again, switch programs (if available) and adjust amplitude to the settings specified by your clinician. 5. If the issue persists, call your clinician. |
| <p>Neurostimulator End of Service</p> | <p>Your neurostimulator battery is depleted. Therapy can no longer be provided.</p> <p>Call your clinician to discuss replacement options.</p> |
| <p>System Error</p> | <p>The system has encountered an unexpected error.</p> <p>Call your clinician.</p> |

| App notification | Explanations and/or Solutions |
|----------------------------------|---|
| Device Communication Lost | Communication is lost or has been interrupted. <ol style="list-style-type: none"> 1. Close the app and try to reconnect. 2. If the issue persists, call your clinician. |
| Not Installed Properly | The patient therapy app was not installed properly Contact Medtronic support. |
| Communicator Low Battery | The communicator battery is low, and may be unable to communicate with the handset and/or the neurostimulator soon. Charge the communicator. Note: If the communicator battery level is below 10%, the battery will need to be charged to above 10% before use. |
| No Implant Date | Implant date not recorded in handset. Call your clinician. |
| Update required | Device must be updated to continue. Call your clinician. |

| App notification | Explanations and/or Solutions |
|--------------------------------|--|
| Power on Reset detected | <p>POR has occurred.</p> <ol style="list-style-type: none"> 1. Check neurostimulator battery level 2. From the Home screen, swipe the On/Off switch from Off to On. 3. If the issue persists, call your clinician. |

Other Troubleshooting Scenarios

Table 5 provides additional troubleshooting scenarios and solutions.

Table 5. Other troubleshooting scenarios and solutions

| Scenario | Explanations and/or Solutions |
|---|---|
| <p>The handset has no power or has lost power</p> | <ol style="list-style-type: none"> <li data-bbox="425 258 840 416">1. The handset battery is depleted. Recharge the handset using the charger. <li data-bbox="425 433 840 702">2. The handset cannot be charged with the charger, or the handset may be damaged or malfunctioning. Contact Medtronic support. |
| <p>The handset will not charge</p> | <ol style="list-style-type: none"> <li data-bbox="425 767 909 959">1. The charger is disconnected from the handset. Connect the charger to the handset. <li data-bbox="425 976 909 1167">2. The charging cable or wall plug are not fully inserted. Ensure the charging cable and wall plug are fully inserted. |

| Scenario | Explanations and/or Solutions |
|---|---|
| | <p>3. An incompatible charger is connected to the handset. Connect an appropriate charger to the handset.</p> <p>4. The charger is defective. Call your clinician.</p> <p>5. The handset is damaged or malfunctioning. Contact Medtronic support.</p> |
| <p>The handset is lost or broken</p> | <p>Contact Medtronic to order a replacement. Medtronic can also attempt to remotely delete your personal and health data from a missing handset. Contact information for Medtronic can be found on the back cover of this manual. You should also call your clinician to say that you have ordered a replacement.</p> |

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