Medtronic

Clinician Therapy and Programming Guide for the InterStim T™ System

Tibial Neuromodulation Therapy

Model P7850N InterStim T Neurostimulator
Model P720R1 Recharger
Model CD9000A Recharger dock
Model P742A1 Ankle band
Model P7A2C11 InterStim T Clinician application version 1.0

! USA Rx only

Not For Human USE
Spectrum Authority Only.

Not For Human USE
Spectrum Authority Only.

Symbols

Explanation of symbols on product or package labeling

Rx only — **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.


Class II equipment


ISO 15223-1 [5.4.3]
Consult instructions for use

ISO 15223-1 [5.4.3]
Consult electronic instructions for use at this website


ISO 15223-1 [5.1.3]
Date of manufacture


Direct current


2012/19/EU
Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.

See http://recycling.medtronic.com for instructions on proper disposal of product.

ISO 15223-1 [5.2.6]
Do not resterilize


ISO 15223-1 [5.4.2]
Do not reuse


ISO 15223-1 [5.2.8]
Do not use if package is damaged and consult instructions for use


ISO 15223-1 [5.2.12]
Double sterile barrier system


Follow instructions for use

For USA audiences only


IEC 60601-1/EN60601-1, Type BF Equipment (IEC 60417-5333)


Implantable neurostimulator


Keep dry

ISO 15223-1 [5.1.5]
Lot number


ISO 15223-1 [5.1.1]
Manufacturer

ASTM F2503 [7.4.6]
Magnetic Resonance (MR) Conditional

ISO 15223-1 [5.7.7]
Medical device

Model number

ASTM F2503 [7.4.10]

Magnetic Resonance (MR) Unsafe

Open here

Package contents

Product documentation

ISO 15223-1 [5.1.6]

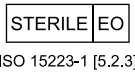
Reorder number

ISO 15223-1 [5.1.7]

Serial number

ISO 15223-1 [5.2.11]

Single sterile barrier system



ISO 15223-1 [5.2.3]

Sterilized using ethylene oxide

IP21

This product meets the basic safety and essential performance requirements indicated in the IP21 conditioning test.

IP22

This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test.

ISO 15223-1 [5.7.10]

Unique device identifier

ISO 15223-1 [5.1.4]

Use by

Information available for the system:

The clinician therapy and programming guide provides therapy information about indications, contraindications, warnings, precautions, adverse events, patient selection, individualization of treatment, and component disposal.

The clinician therapy and programming guide also provides product information about the system and its components including device description, package contents, device specifications, product-specific warnings and precautions, and instructions for use, maintenance information, information about battery longevity calculations, and battery characteristics.

MRI guidelines provide information about any MRI conditions and MRI-specific contraindications, warnings, and precautions for MRI scans with the neuromodulation system. For the MRI Guidelines for the InterStim T Neurostimulator, search by neurostimulator model number at www.medtronic.com/mri.

The implant manual and pocket dissector manual provide device descriptions, package contents, device specifications, product specific warnings and precautions, instructions for use, and component disposal.

! USA The clinical summary provides information about the clinical study results for the neurostimulation system.

Refer to the literature provided by the clinician tablet manufacturer for information regarding wireless use.

Table of contents

Introduction

The Medtronic Model P7A2C11 InterStim T Clinician application (app) is intended for use with the Model CT900F Clinician tablet and Model P720R1 Recharger to program, adjust, and troubleshoot the Medtronic Model P7850N InterStim T neurostimulator for tibial neuromodulation therapy.

About this guide

This guide is intended to be used by clinicians to learn about the indications for use associated with the InterStim T system, the therapy risks, and programming the neurostimulator. This guide also includes product specifications and neurostimulator lifetime information.

Please note:

- Before using the system for the first time, refer to the information provided in this guide for initial setup.
- In this guide, figures of the clinician app screens are representative. What is displayed on the actual screens may differ.
- All patient-related instructions on using the recharger and the patient app on the patient programmer (handset) are included in the Patient Guide for the InterStim T System. The patient guide is available at www.medtronic.com/patientmanuals.

Contact Medtronic for issues with product documentation.

About InterStim T therapy

Indications

The Medtronic InterStim T system is indicated for the treatment of overactive bladder (OAB) and associated symptoms including urinary urgency, urinary frequency (UF), and/or urinary urge incontinence (UUI).

Contraindications

The InterStim T system is contraindicated for patients who are not able to operate or receive assistance in operating the system.

Therapy-level warnings and precautions

Warnings:

Use as indicated and instructed – Read all information in this guide before using this system. Only use products for the indicated therapy and indicated populations. The consequences of using products for uses other than indicated and instructed are unknown. No claims of safety or efficacy are made with regard to the use of products for non-indicated or non-instructed uses.

Diathermy – Diathermy is 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 healing. Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulator. Energy from diathermy can be transferred through the implanted device and can cause tissue

damage. Diathermy can also damage the neurostimulator, requiring removal.

Effects on other implanted systems – The neurostimulation system may affect the operation of other implanted systems. Clinicians involved with both systems should evaluate potential interactions before implant based on intended locations.

Precautions:

Electromagnetic interference (EMI) – EMI is a field of energy generated by some medical equipment, which may be strong enough to interfere with the function of the neurostimulation system or cause unexpected changes in stimulation. For any of the following, do not direct at or place over the neurostimulator, because doing so may cause heating that could result in tissue damage:

- Radio frequency/microwave ablation
- Electrolysis
- Transcutaneous electrical nerve stimulation (TENS)
- Procedures involving laser beams
- High radiation sources
- Electrocautery

Patients should inform health care providers that they have an implanted neurostimulator.

EMI may also be present in the home, office, or public environment, but is not likely to affect the InterStim T system.

Other medical procedures – EMI from the following medical procedures is unlikely to affect this neurostimulation system. Images may be distorted if scanning near the neurostimulator. Avoid exerting excess force on the neurostimulator during medical procedures such as the following:

- Computerized axial tomography (CT or CAT) scans
- Diagnostic ultrasound (such as carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans

Notes:

- For MRI information see "MRI information", page 14, and the **MRI Guidelines for the InterStim T Neurostimulator.**
- Additional warnings and cautions are found throughout this guide.

Clinician experience

- **Prescribing clinicians** should be experienced in the diagnosis and treatment of overactive bladder and associated symptoms including urinary urgency, UF, and UUI, and should be familiar with using the InterStim T system.
- **Implanting clinicians** should be experienced in general surgical procedures, including perioperative infection control, and should review the procedures described in the InterStim T implant manual before surgery.

Individualization of treatment

Best results are achieved when the patient is fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities.

Patient selection

Select patients carefully to ensure that they are appropriate candidates for surgery.

⚠ **Warning:** This therapy is not intended for patients considered poor surgical candidates or who are at risk for poor wound healing. This may include, but is not limited to, patients who have:

- Skin lesions, compromised skin integrity, or open sores at the implant site
- Severe, uncontrolled diabetes
- Clinically significant edema in the lower leg
- Clinically significant peripheral neuropathy in the lower leg
- Venous insufficiency in the lower leg
- Previous surgeries at the implant site, which precludes use of device

⚠ **Caution: Implanted metal objects (chronic) –** Before beginning the implant procedure, determine whether the patient has any chronically implanted metal objects, such as metal pins or plates, within 10 cm of the planned implant location (for example, in the ankle). If the patient has chronically implanted metal objects within 10 cm of the implant location in one leg, the other leg should be selected for implant. If the patient has chronically implanted metal objects within 10 cm of the implant location in both legs, the patient will not be an appropriate candidate for implant due to the potential for heating when recharging the implanted neurostimulator. Failure to confirm the appropriateness of this system before implant could result in recharge heating leading to tissue damage, and surgery to explant the device.

Use in specific populations

The safety and effectiveness of this therapy has not been established for:

- Pregnant women
- Patients under the age of 18
- Patients with progressive, systemic neurological disease
- Bilateral stimulation

Possible adverse events

In addition to the risks normally associated with surgery, the following adverse events may occur with the use of an implantable neurostimulation system for tibial neuromodulation. Possible complications for an implanted InterStim T system will vary from person to person. Some of these possible complications may require surgical intervention.

Risks (potential adverse events) related to the InterStim T implant or explant procedure:

- Implant site pain
- Infection
- Reaction to local anesthetic (such as redness, irritation at the injection site)
- Wound complications (such as swelling, hematoma, bruising, bleeding, seroma)

Risks (potential adverse events) after implantation of the InterStim T neurostimulator:

- Allergic or immune system response to the implanted materials
- Implant site pain
- Infection
- Neurostimulator movement or skin erosion at implant site
- Uncomfortable stimulation sensations
- Adverse change in bowel or urinary function

If a serious incident related to a patient's therapy occurs, immediately report the incident to Medtronic and the applicable competent authority.

Patient counseling information post-implant

Provide patients with the following:

- Information about the indications, contraindications, warnings, precautions, and adverse events for this system
- Information about the components of the system
- Instructions for using the system
- Information about their therapy schedules
- Completed patient identification card before they are discharged
- Guidance on postoperative analgesia, per clinician discretion
- Normal signs and symptoms of healing

For the initial healing period (minimum of 72 hours post procedure), advise patients to:

- Keep the implant site dry and covered.
- Wear a compression sock to minimize swelling and aid in healing. If repositioning occurred or the pocket was enlarged, consider longer periods based on clinician discretion.

For 4 weeks after the procedure, advise patients to:

- Avoid soaking the incision site (for example, swimming, hot tub, or taking a bath).
- Avoid strenuous, long duration activities or exercise.
- Avoid footwear that is constrictive around the implant.

△ **Cautions:**

Patient activities 4 weeks post-implant – Patients should avoid strenuous, long duration activities or exercise and placing pressure on the neurostimulator site for 4 weeks post-implant. These activities may result in swelling or affect the wound healing process. Undue pressure to the site may cause discomfort or pain at the neurostimulator site, complications at the surgical site including wound dehiscence, or delayed healing.

Unexpected stimulation – Ensure that the patient understands their stimulation schedule(s), and when they will receive stimulation in order to avoid stimulation at an unexpected time. Patients should also consider limiting activities during a therapy session, when stimulation could be distracting or dangerous.

Check and correct the time setting on the clinician tablet before connecting to a patient INS. Connecting to an INS with a tablet that does not have the correct time setting could cause the INS to adopt that incorrect time setting resulting in unexpected stimulation.

Note: Space is provided at the end of the patient's **Quick Reference Guide for the InterStim T™ System** to record schedule information, if desired.

Also instruct patients to:

- Avoid physically manipulating the neurostimulator after implant.
- Always inform health care professionals that they have an implanted neurostimulator before any procedure.
- Bring all InterStim T system components to follow-up appointments, and make sure all system components are charged.

- Contact their clinician if they notice any unusual signs or symptoms while the implant site is healing such as redness, drainage, swelling, opening of the incision, or fever.
- Contact their clinician if they are in an accident impacting the neurostimulator. In the event the neurostimulator is damaged, the patient may be exposed to battery chemicals leading to burns, or the INS may fail to operate properly over the service life.
- Be aware that if they require a temporary metal implant within 10 cm of the implanted neurostimulator, they should not use the recharger in recharging mode until the temporary metal implant has been removed. They can continue to use the recharger in communication-only mode. Instruct the patient to see the patient guide for the system for more information on recharger modes.

Scuba diving or hyperbaric chambers

The InterStim T neurostimulator has been tested to 4.0 atmospheres absolute (ATA). Pressures above 4.0 ATA have not been tested and could damage the neurostimulator. In the event the neurostimulator is damaged, the patient may be exposed to battery chemicals leading to burns, or the INS may fail to operate properly over the service life. Advise patients to contact their clinician about the effects of high pressure before diving or using a hyperbaric chamber.

High-altitude activities

High altitudes should not affect the InterStim T neurostimulator.

Patient counseling post explant

For the initial healing period (minimum of 72 hours post procedure), advise patients to:

- Keep the explant site dry and covered.
- Wear a compression sock to minimize swelling and aid in healing (may be used longer at clinicians discretion).

For 2 weeks after the explant procedure, advise patients to:

- Avoid soaking incision site (for example, swimming, hot tub, or taking a bath).
- Avoid strenuous, long duration activities or exercise.
- Avoid footwear that may rub or is constrictive around the incision and explant site.

MRI information

Magnetic Resonance (MR) Conditional – Non-clinical testing has demonstrated that the Model P7850N InterStim T Neurostimulator is MR Conditional and is Full Body Scan Eligible. Magnetic resonance imaging (MRI) examinations on any part of the anatomy may be safely performed under specific conditions, following all instructions and conditions in the **MRI Guidelines for the InterStim T Neurostimulator** found at www.medtronic.com/MRI. Scanning under different conditions may result in serious patient injury or device damage.

If a patient is prescribed an MRI, instruct them to do the following:

- Bring their patient ID card to the MRI examination. The patient ID card provides information that will be used to confirm MRI eligibility.
- Inform the MRI-prescribing clinician and MRI technician that they have an implanted device before the MRI examination appointment.
- Inform the MRI technician if they have a fever. Having a fever may affect their ability to have an MRI scan.

- Inform the MRI technician if they experience heating of the device, shocking sensations, uncomfortable stimulation, or unusual sensations during the MRI scan.

Note: There are no restrictions on programming settings for MRI. A neurostimulator configured to ON or ACTIVE, OFF, a non-responsive device, an unknown status device, or a device that has reached the end of its service life can be scanned under specific conditions.

X-ray identification

Radiopaque identification shows the manufacturer and neurostimulator model number (Figure 1) using standard x-ray procedures. The Medtronic symbol identifies Medtronic as the manufacturer. For the InterStim T neurostimulator, the designated characters are NTI.

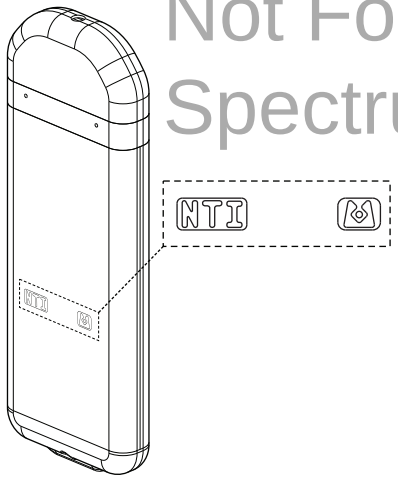


Figure 1. The Model P7850N InterStim T Neurostimulator with radiopaque code block (visible with x-ray)

About the InterStim T system

System description

The InterStim T system is a programmable neuromodulation system that delivers electrical stimulation to the tibial nerve. The InterStim T system includes a leadless neurostimulator, recharger, clinician and patient control devices (clinician tablet and patient programmer, respectively), and ankle band.

The key features include a system based on a rechargeable, implantable neurostimulator (INS) that is intended to treat symptoms associated with OAB and associated symptoms including urinary urgency, urinary frequency (UF), and/or urinary urge incontinence (UUI) by sending electrical pulses to the tibial nerve. The INS is intended to be programmed by the health care provider, offers programming functionality to the patient, and has the flexibility to be recharged by the user inside or outside of a health care office setting (for example, at home).

System components and compatibility

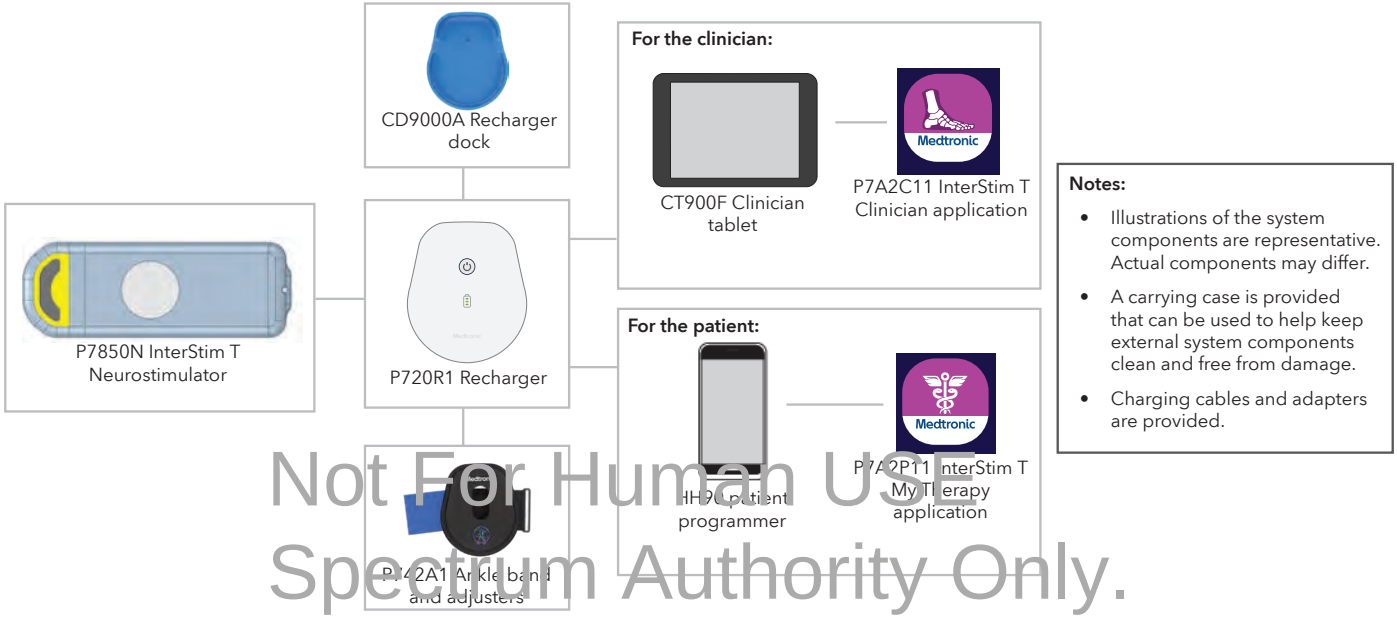


Figure 2. The InterStim T system

Follow these guidelines when selecting system components:

- **Medtronic components –** For proper therapy, use only components that are compatible with the InterStim T system. Compatible Medtronic components are listed in Figure 2.

  Note: There are other Medtronic rechargers and docks that resemble the Model P720R1 and Model CD9000A components used for the InterStim T system. If you have more than one recharger and dock, check the model number on the back of the components to ensure you are using the correct model for this system.

- **Non-Medtronic components –** The use of non-Medtronic components with the InterStim T system may result in damage of Medtronic components, loss of stimulation, or patient injury.

  ! USA Use of non-Medtronic components may void Medtronic warranty coverage.

Model P7850N InterStim T Neurostimulator

The Model P7850N InterStim T Neurostimulator is a rechargeable, implantable neurostimulator (INS) also referred to as "the implant" in this guide. The leadless INS generates electrical pulses and delivers stimulation to the tibial nerve for InterStim T therapy. The INS is intended for single use and should not be re-sterilized.

Model P720R1 Recharger

The Model P720R1 Recharger is used to recharge the INS and provide a communication bridge between the clinician and patient applications and the INS.

- To operate normally as a recharger, it should be positioned directly over the INS. The power button on the recharger must be pressed to start recharging.
- To operate normally as a communication bridge, it should be directly over the INS. The power button on the recharger does not need to be pressed to communicate with and program the INS.

Model CD9000A Recharger dock

The Model CD9000A Recharger dock (referred to in the rest of this guide as "the dock") is used to charge the recharger. A Universal Serial Bus (USB) charging cable and alternating current (AC) power adapter are also included in the kit.

Model P742A1 Ankle band

The Model P742A1 Ankle band is provided as an optional accessory that can be used to hold the recharger while recharging or communicating with the INS. The ankle band also comes with adjusters that can be used to lengthen or shorten the ankle band.

Model CT900F Clinician tablet and Model P7A2C11 InterStim T Clinician application

The Model CT900F Clinician tablet, with Android-based operating system, is used in conjunction with the Model P7A2C11 InterStim T Clinician application (app) to program the INS and collect system information about InterStim T therapy. Throughout this guide, "the app" refers to the clinician app, unless stated otherwise.

A tablet quick start guide is also provided in the clinician kit and contains instructions for the initial configuration of the tablet.

How the system components interact

Figure 3. How the InterStim T system components interact

The clinician and patient apps interact with the INS through the recharger (Figure 3).

1. The clinician app on the clinician tablet and the patient app on the patient programmer connect to the recharger using Bluetooth® wireless communication.
2. The recharger connects to the neurostimulator using telemetry through near-field magnetic induction communication

How the recharger functions within the InterStim T system

The recharger is used both to recharge the neurostimulator battery and to serve as a communication bridge between the clinician programmer or patient programmer and the neurostimulator.

Recharger modes

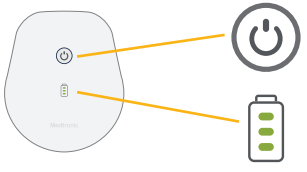
The recharger has 2 operating modes:

- **Recharging mode** in which the recharger can both communicate with and recharge the implant battery
- **Communication-only mode** in which the recharger communicates with the implant without recharging it

Changing recharger modes

- **Taking the recharger off the plugged-in dock:** Removing the recharger from the dock places the recharger in **communication-only mode**.
- **Switching modes:** A short press on the power button switches the recharger between modes.
- **Turning off the recharger:** To turn off the recharger, press and hold the power button until the power and battery lights turn off.

Table 1. Recharger modes

Recharging mode	Communication-only mode
	
In recharging mode, the recharger searches for an implant (spinning green power light with tones). When it connects to the implant, it starts recharging (solid green power light). **In recharging mode, you can use the recharger both to recharge and communicate with the implant at the same time.**	In communication-only mode (power light off, battery light on), you can use the recharger to communicate with the implant **without recharging** the implant (safe mode for use near temporary metal implants).

System warnings and cautions

Warnings:

Recharger may affect other medical devices – Do not place the recharger over a medical device with which it is incompatible (such as other neurostimulators, pacemakers, defibrillators, and insulin pumps). The recharger may change the operation of the other medical device.

Wound contact – Do not use the recharger or ankle band in direct contact with an unhealed wound. The recharger and ankle band are not sterile and contact with the wound may cause an infection. Keep a sterile bandage or barrier between the wound and the recharger or ankle band until the wound is healed.

Cautions:

Component disposal – Dispose of the recharger and its accessories according to local regulations, or consult http://recycling.medtronic.com. Failure to dispose of the device correctly may lead to environmental damage.

Electric shock – Do not handle the recharger, dock, or other electrical accessories near liquids. Allowing the device or accessories to be submerged in liquid could damage the device or accessories, resulting in electric shock.

Metal objects and recharging – Do not use the recharger to recharge the neurostimulator battery within 10 cm of metal objects, including implanted metal other than the implanted neurostimulator. Using the recharger to recharge the neurostimulator near a metal object could cause heating of the metal object, resulting in heating sensation or tissue damage. If the patient has a temporary metal object implanted near the implanted neurostimulator, they will not be able to recharge the neurostimulator battery until the metal object is removed. Ensure the neurostimulator battery is recharged before any temporary metal object is implanted to maximize the INS battery charge life until the metal object is removed. Patients can still use the recharger in communication-only mode.

Neurostimulator battery charge level – Inform the patient to check the battery level and recharge the neurostimulator battery when needed. The neurostimulator battery will continue to slowly drain, even when stimulation is off. If the neurostimulator battery level falls too low, the patient will not receive therapy sessions until the neurostimulator has been recharged. If the implant battery is not recharged, it can eventually become drained to the point that therapy will be disabled even after the battery is recharged. In this case, you will need to connect to the patient's implant and update the implant clock to resume therapy.

Recharger damage – Check the recharger for damage before use. If you notice damage to the recharger, do not use the recharger. A damaged recharger may not be able to charge or communicate with the neurostimulator and may result in exposure to chemicals or sharp edges.

Telemetry signal disruption from EMI – Do not attempt telemetry near equipment that may generate electromagnetic interference (EMI). EMI may cause a disruption in programmer function. If EMI disrupts programming, move the programmer and the neurostimulator away from the likely source of EMI.

Getting started with the clinician app

Before using the Model P7A2C11 InterStim T Clinician app (to program the neurostimulator), see the following sections for basic information about the app related to:

Icons

The following is a list of the key icons found in the clinician app along with their associated descriptions. Note that if an icon appears gray within the clinician app, that option is not currently available.

Table 2. Icons and descriptions

Icon	Description
	**Settings:** Tap for additional screen options.
	**Menu:** Tap to access the Menu side bar.
	**Back:** Tap to exit the current screen and go back to the previous screen.
	**Home:** Tap to return to the Home screen.
	**Exit session:** Tap to exit the current programming session and return to the startup screen.

Accessing the clinician app

You can access the clinician app by locating the appropriate icon on the main screen of the tablet (Figure 4). To open the clinician app, tap the icon.

Figure 4. Clinician app icon

Note: The first time you open the app, it will request permissions. Accept all permissions. Tap **OK** to continue. Then tap **ALLOW** on the next message.

Navigating the startup screen

Figure 5. Startup screen

On the startup screen you can:

① Access Demo mode

Demo mode allows you to explore the clinician app without being connected to a neurostimulator.

- To access Demo mode, tap **DEMO** on the startup screen.
- The **DEMO** indicator is displayed next to the screen title when the app is operating in Demo mode.

② Connect the clinician tablet to the recharger and neurostimulator.

- If this is your first time using the system, see "Initial system setup", page 23, for more information about first-time connection.
- If you have already completed the initial device connection, see the table below for workflow options:

Workflow	Description
Express Setup (page 26)	A basic setup process that allows you to program a new INS with default settings
Custom Setup (page 29)	A step-by-step process that allows you to program a new INS with custom settings
Follow-up (page 35)	Use for follow-up appointments after the INS has been set up to view therapy details, usage insights, recharge information, and make therapy adjustments as needed

③ Access reports

See "Reports", page 42, for more information.

Initial system setup

This section provides instructions for the initial setup of the InterStim T system. If this is your first time using this system, use the instructions provided in this section to:

- Set up a new or replacement recharger (page 23)
- Charge the clinician tablet (page 23)
- Check the clinician tablet clock (page 23)
- Pair the clinician tablet to the recharger (page 23)
- Set up the patient kit (page 24)

First-time setup of a new recharger - turning off shipping mode

Before pairing and using a new or replacement recharger for the first time, the recharger must be taken out of shipping mode.

1. Plug in the dock to a power outlet using the USB charging cable and power adapter provided by Medtronic.
2. Place the recharger, blue side down, on the dock. Do not remove for at least 30 seconds to ensure that the recharger establishes a proper connection to the dock.
3. When the recharger is successfully out of shipping mode, it will emit a “power up” sound and the battery light will slowly flash green, indicating that the recharger is now charging
4. When the recharger is fully charged, you will see 3 solid green bars on the battery light ( ).

The clinician tablet or the patient programmer should be paired to the recharger after the recharger is removed from shipping mode. The new recharger is now setup for operation.

Charging the clinician tablet

Charge the tablet with the USB charging cables and power adapters provided by Medtronic.

Checking the clinician tablet clock

Check and correct the time setting on the clinician tablet before connecting to a patient INS. Connecting to an INS with a tablet that does not have the correct time setting could cause the INS to adopt that incorrect time setting resulting in unexpected stimulation.

Pairing the clinician tablet to the recharger

Before using the clinician tablet, you need to pair the tablet to the recharger and then connect the recharger to the neurostimulator.

Note: This only needs to be done once for a new or replacement recharger.

1. Remove recharger from the plugged-in dock.
2. Turn on the tablet.
3. Open the InterStim T clinician app.
4. Tap **CONNECT** on the startup screen.
5. Turn the recharger over to view the back side. Scan the code or enter the serial number manually (Figure 6).

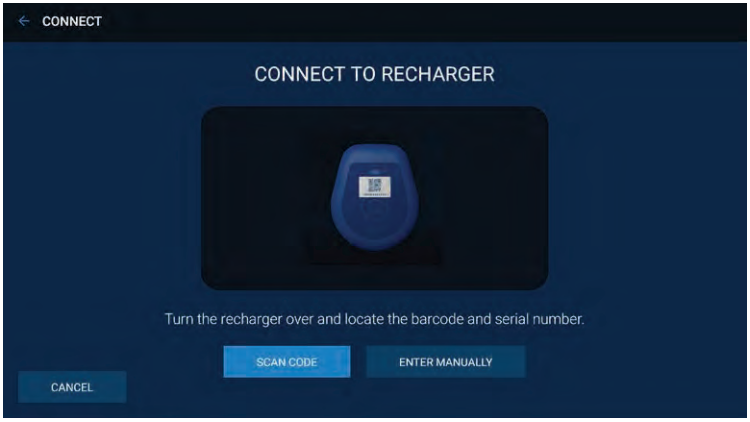


Figure 6. Connect to Recharger screen

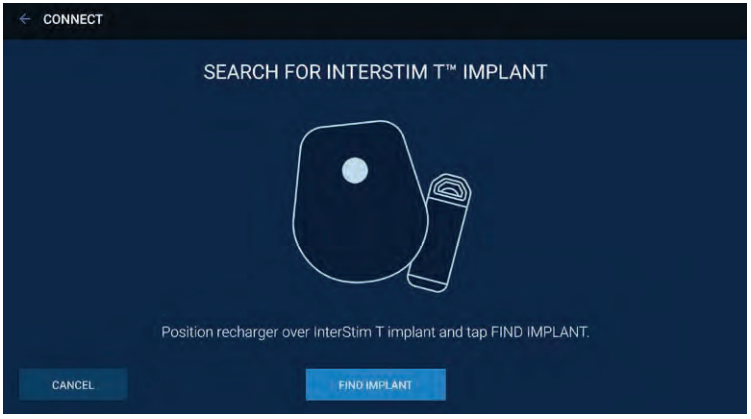


Figure 7. Search for InterStim T implant screen

6. After the barcode has been scanned or serial number has been entered, the app will attempt to connect to the recharger.
7. Once the recharger connects to the tablet, you will see the Search for InterStim T Implant screen (Figure 7), or a list of INSs for you to select from.
8. Continue to "Connect to the neurostimulator and begin programming", page 26, to finish the connection process.

Setting up the patient kit

Before sending the patient home with the InterStim T system, complete the initial setup of all patient kit components for the patient.

Use the same steps described in this manual to do the following:

- Take the patient's new recharger out of shipping mode.
- Charge the patient programmer.
- Pair the patient programmer to the recharger.
- Pair the patient programmer to the implant.

For more detailed instructions or for information about the patient application, refer to the **Patient Guide for the InterStim T System**.

Programming a new neurostimulator

Before each programming session, check the battery level of the tablet and recharger. If charging is needed, see “Charging the clinician tablet”, page 23, or “Charging the recharger battery”, page 46, for instructions. You will also need to have the tablet and recharger paired. If you have not already done this initial pairing, see “Pairing the clinician tablet to the recharger”, page 23.

Therapy can be programmed and started on the day of the procedure. When setting up a new INS, you can choose to use the “Express Setup” or “Custom Setup” workflow.

The **Express Setup** is a quick start workflow to program a new INS using default settings. You will only need to set the amplitude and review setup.

The **Custom Setup** is a step-by-step workflow to program a new INS using custom settings. The custom workflow goes through:

- Configuring stimulation parameters and patient limits
- Configuring therapy schedule
- Entering patient and device information
- Reviewing setup

Table 3 lists the available stimulation parameter settings along with their descriptions.

Table 3. Stimulation parameter descriptions

Stimulation parameter setting	Definition
Amplitude	Amplitude is the intensity or strength of the stimulation, measured in milliamps (mA). By increasing amplitude, you are increasing the intensity of the stimulation. By decreasing amplitude, you are reducing the intensity. A typical setting for amplitude is based on patient comfort, which is determined during a programming session.
Pulse Width	Pulse width is the time or duration of the stimulation pulse measured in microseconds (us).
Rate	Rate is the number of times per second a pulse is delivered, measured in Hertz (Hz).
SoftStart/Stop™	SoftStart/Stop, measured in seconds (sec), is intended to provide a gentle or “soft” start as stimulation begins.
Patient Limits	Patient Limits sets the boundary for how high or low the amplitude value can be raised above or below the programmed therapy amplitude value by the patient. After a programming session, patients can use the patient app to adjust the therapy amplitude, within the programmed Patient Limits set by the clinician.

Connect to the neurostimulator and begin programming

1. Remove the recharger from the plugged-in dock and position the recharger over the INS.
2. Open the InterStim T clinician app.
3. Tap **CONNECT** on the startup screen.
4. Tap **FIND IMPLANT** (Figure 8).

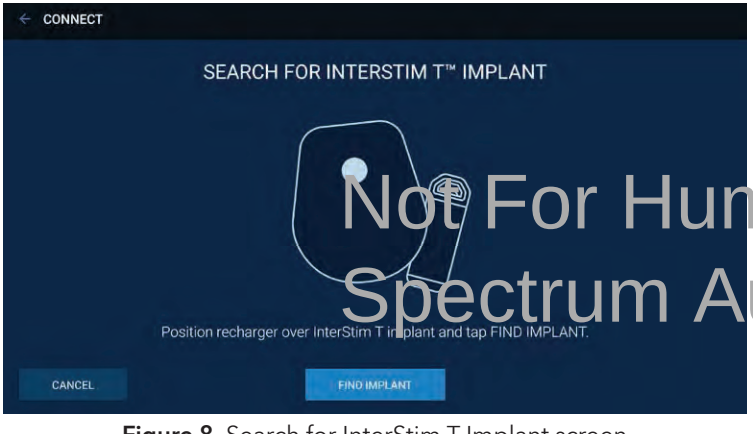


Figure 8. Search for InterStim T Implant screen

5. Select the appropriate INS according to the serial number (found on the patient ID card or patient records) and tap **CONTINUE**. If the neurostimulator serial number is not listed, tap **REFRESH LIST** (↻).
6. Once the recharger connects to the INS, the Home screen will be displayed (Figure 9).

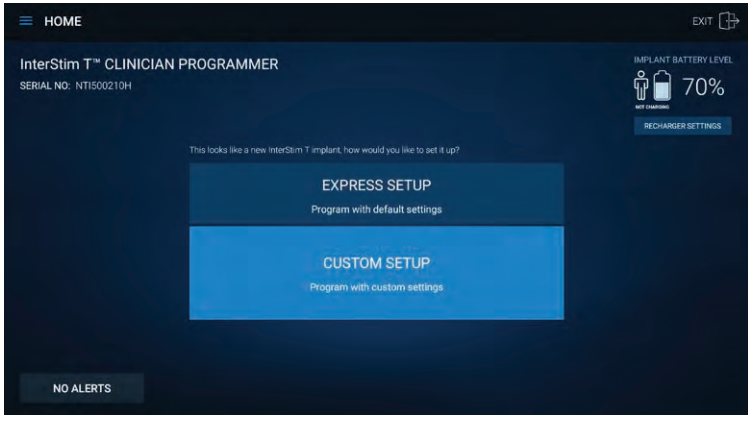


Figure 9. Home screen

7. Select the setup workflow you want to use by tapping either **EXPRESS SETUP** or **CUSTOM SETUP**.
   - For **Express Setup**, proceed to page 26.
   - For **Custom Setup**, proceed to page 29.

Express setup

In the Express Setup, you will only need to set the amplitude and review the settings. The pulse width, rate, and SoftStart/Stop parameters are already preset. The patient's therapy schedule is also set to the default schedule of Monday, Wednesday, Friday (three 30-minute therapy sessions per week) starting at 9:00 PM local time. Note that patients can change the schedule therapy start time using their patient app.

Table 4. Default settings

Stimulation parameter	Setting
Amplitude	0.1 mA
Pulse Width	200 µs
Rate	20 Hz
SoftStart/Stop	On, with a 4 sec duration
Patient Limits	Minimum Amplitude: 0.1 mA Maximum Amplitude: 150% of the prescribed amplitude

If you would like to customize these settings, you can do one of the following:

- Make adjustments to the presets from the Review and Finish Setup screen at the end of the Express Setup.
- Use the Custom Setup workflow. Refer to "Custom setup", page 29, for instructions.

Configure amplitude

1. Adjusting amplitude requires stimulation to be on. From the Basic Stimulation screen, tap the Stimulation toggle ( ) (Figure 10) to turn stimulation on ( ).

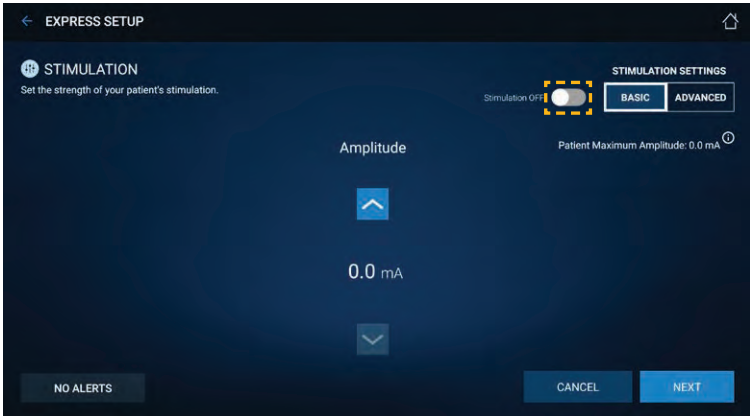


Figure 10. Express Setup: Basic Stimulation screen

2. When stimulation is turned on for the first time for a neurostimulator, you will see a notification asking you to confirm that the correct time is set on the clinician tablet and informing you that turning on stimulation will start the implant's service life (Figure 11). It is important for the clinician tablet clock to be correct at this point as it will set the implant service life which cannot be changed once it is set.
3. Check the time setting on the clinician tablet. If it is incorrect, tap **CANCEL** and correct the tablet's time setting.
4. Tap the acknowledge checkbox. Then tap **ACTIVATE IMPLANT** to continue.

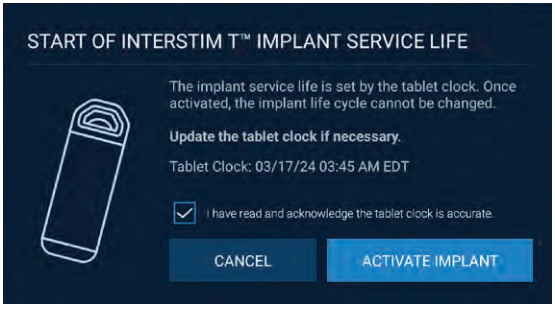


Figure 11. Start of InterStim T Implant Service Life notification

5. Use the arrow buttons to set the amplitude (Figure 12). Tap the arrow buttons to adjust the amplitude by 0.1 mA; press and hold the arrow buttons to adjust the amplitude by 1.0 mA.

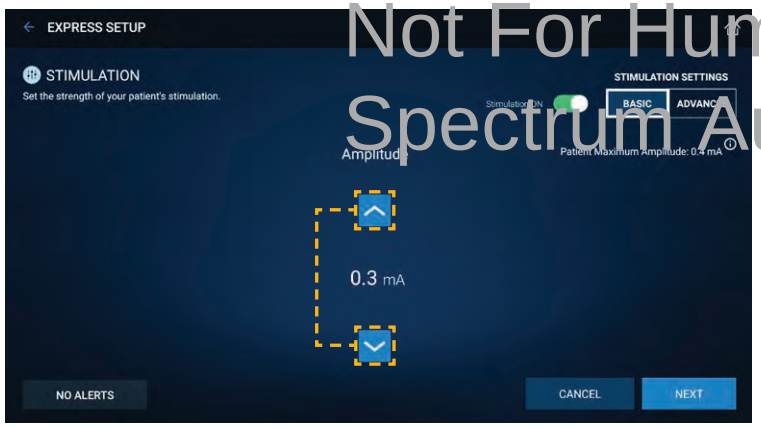


Figure 12. Express Setup: Basic Stimulation screen

6. Adjust the stimulation amplitude to a comfortable level for the patient.
   - If desired, a motor or sensory response can be used to help set stimulation level (see Table 5).

     However, note that not all patients will experience motor or sensory responses to stimulation.
   - If the tibial nerve was anesthetized during the implant procedure, the patient's motor or sensory responses to stimulation may be temporarily inhibited.

Table 5. Common motor and sensory responses to tibial neurostimulation

Nerve	Motor response	Sensory response
Tibial	Flexion of the big toe, fanning or flexion of the toes, or extension of the whole foot	A radiating, tapping, or tingling sensation in the sole, heel, or toes

7. When you are done setting the amplitude, tap **NEXT**.

   Note: The amplitude is automatically saved to the neurostimulator.
8. A Stimulation Will Be Turned Off notification will appear. Tap **OK** to continue to the Review and Finish Setup screen. Stimulation will be turned off until the next scheduled stimulation session.

Review and finish setup

The Review and Finish Setup screen (Figure 13) allows you to review the default settings and amplitude entered.

Figure 13. Express Setup: Review and Finish Setup screen

1. If adjustments are needed, tap **EDIT** (Figure 13-①) found in the upper right-hand corner of each panel. You will then be taken out of the Express Setup and placed in the Custom Setup workflow.
2. Make the adjustments needed on the appropriate screen(s) and navigate back to the Review and Finish Setup screen using the **NEXT** buttons.
3. To complete the programming session, tap **FINISH SETUP** Figure 13-②).
4. A confirmation notification will appear. Tap **OK**.
5. After the setup process is complete, you will return to the Home screen which will now display a dashboard.
6. Tap **EXIT** to end the session.

Note: If you exit the workflow session or the app before tapping **FINISH SETUP**, the schedule and patient information will not be saved to the INS.

Custom setup

In the Custom Setup, you are able to configure multiple program parameters using a step-by-step workflow.

Configure stimulation parameters

1. Adjusting amplitude requires stimulation to be on. From the Basic Stimulation screen, tap the Stimulation toggle ( ) (Figure 14) to turn stimulation on ( ).

Figure 14. Custom Setup: Basic Stimulation screen

2. When stimulation is turned on for the first time for a neurostimulator, you will see a notification asking you to confirm that the correct time is set on the clinician tablet and informing you that turning on stimulation will start the implant's service life (Figure 15). It is important for the clinician tablet clock to be correct at this point as it will set the implant service life which cannot be changed once it is set.
3. Check the time setting on the clinician tablet. If it is incorrect, tap **CANCEL** and correct the tablet's time setting.

4. Tap the acknowledge checkbox. Then tap **ACTIVATE IMPLANT** to continue (Figure 15).

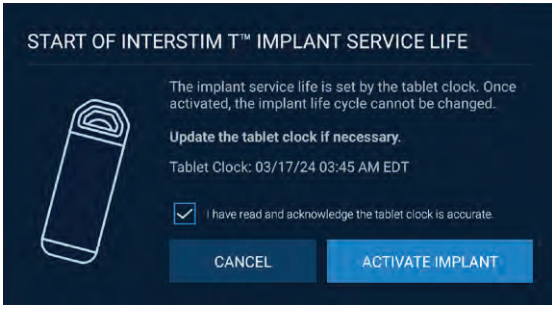


Figure 15. Start of InterStim T Implant Service Life notification

5. Use the arrow buttons to set the amplitude (Figure 16). Tap the arrow buttons to adjust the amplitude by 0.1 mA; press and hold the arrow buttons to adjust the amplitude by 1.0 mA.

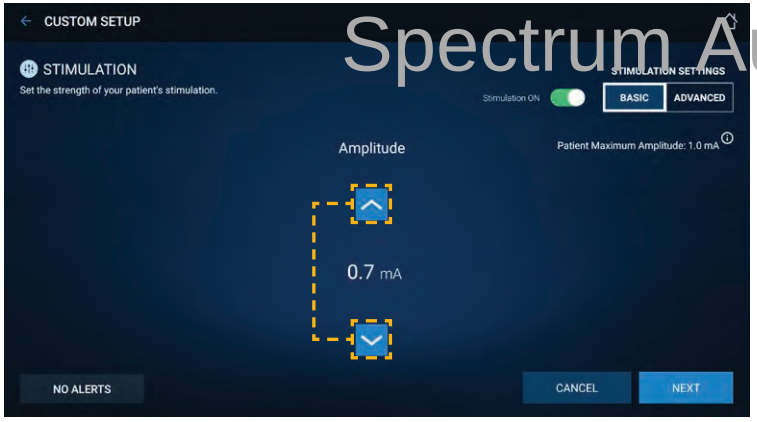


Figure 16. Custom Setup: Basic Stimulation screen

6. Adjust the stimulation amplitude to a comfortable level for the patient.
   - If desired, a motor or sensory response can be used to help set stimulation level (see Table 6). However, note that not all patients will experience motor or sensory responses to stimulation.
   - If the tibial nerve was anesthetized during the implant procedure, the patient's motor or sensory responses to stimulation may be temporarily inhibited.

Table 6. Common motor and sensory responses to tibial neurostimulation

Nerve	Motor response	Sensory response
Tibial	Flexion of the big toe, fanning or flexion of the toes, or extension of the whole foot	A radiating, tapping, or tingling sensation in the sole, heel, or toes

7. For more settings, tap **ADVANCED** (Figure 17).

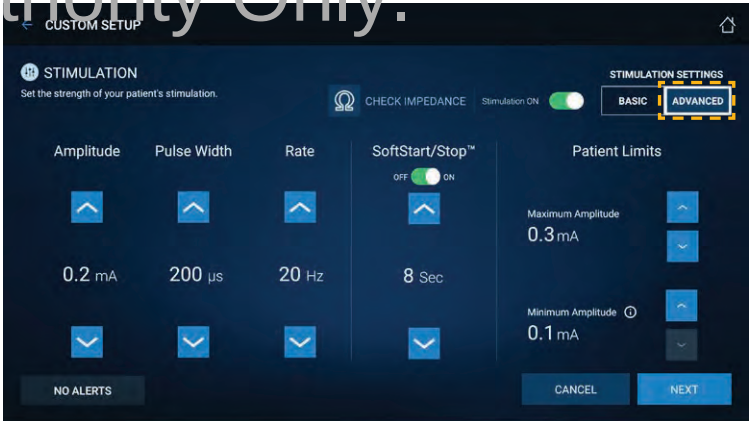


Figure 17. Custom Setup: Advanced Stimulation screen

8. Use the arrow buttons to set pulse width, rate, SoftStart/Stop time, and the maximum and minimum amplitude for patient limits, if desired.

   Notes:

   - Because this is a leadless system, impedance checks are not required to verify system integrity. Any impedance value received should not impact clinical workflow. Impedance measurements may help troubleshoot issues that occur after implant. Contact Medtronic for more information.
   - SoftStart/Stop is enabled by default and can be turned OFF or ON as needed.
   - If you do not specify the Patient Limits, by default, the patient will only be able to increase stimulation up to 150% of the prescribed amplitude.
   - If you do not want the patient to be able to adjust their stimulation level, set the minimum and maximum amplitudes to the prescribed amplitude.

9. When you are done configuring the stimulation parameters, tap **NEXT**.

   Note: The stimulation parameters are automatically saved to the neurostimulator.

10. A Stimulation Will Be Turned Off notification will appear. Tap **OK** to continue to the Schedule screen. Stimulation will be turned off until the next scheduled therapy session.

Configure therapy schedule

On the Schedule screen, the therapy schedule type is preset to "Default". To customize your patient's therapy schedule, select "Default", "Custom", or "Continuous" from the dropdown menu.

Note that patients with a "Default" or "Custom" schedule can change the scheduled therapy start time using their patient app.

Default schedule

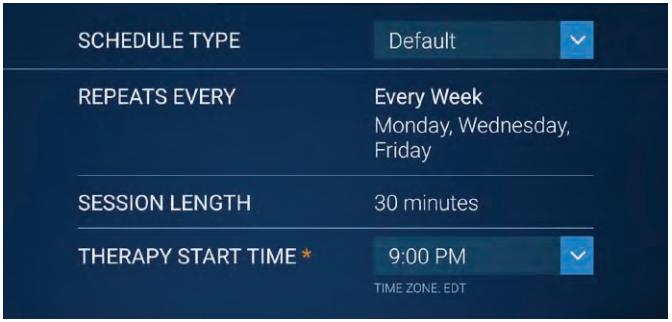


Figure 18. "Default" Schedule screen

By default, three 30 minute therapy sessions are scheduled to occur weekly on Monday, Wednesday, Friday.

When the schedule type is set to "Default", you can only change the therapy start time. Select the therapy start time and tap **NEXT** to continue.

Custom schedule

When the schedule type is set to "Custom", you can configure 1 or 2 custom schedules for the patient (Figure 19). The first schedule that you create is referred to as the **CURRENT SCHEDULE**. The second (optional) schedule is the **MAINTENANCE SCHEDULE**.

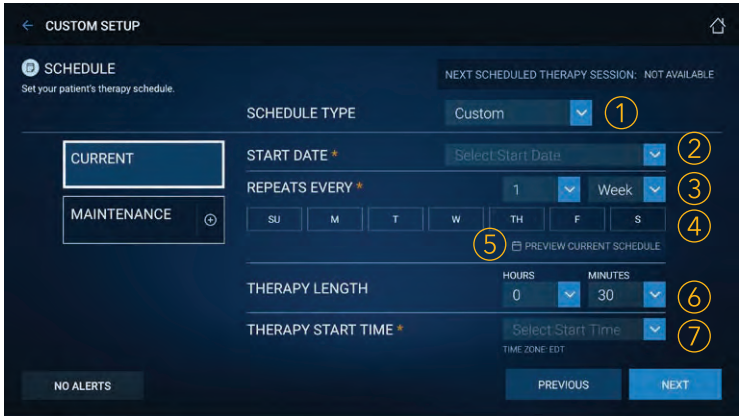


Figure 19. "Custom" Schedule screen

The ability to create two schedules allows you to set a CURRENT schedule wherein the patient receives a set of stimulation sessions for a defined period (for example, after implant or as a follow up schedule).

This can then be followed by a MAINTENANCE schedule that will continue indefinitely, unless it is updated. This allows for a second set of stimulation paradigms to be introduced later (for example, reduced stimulation session frequency).

Note that only the CURRENT schedule is required. For patients who only have 1 schedule, stimulation based on that schedule will be delivered indefinitely, unless that schedule is updated.

With "Custom" selected as the schedule type (Figure 19-①), you can fully customize and configure the following parameters:

- Start Date, Figure 19-②
- Repetition, Figure 19-③. For example, you could set stimulation sessions to repeat every 1 day (Figure 20) or every 2 weeks (Figure 21)
- Days of the Week, Figure 19-④
- Therapy Length, Figure 19-⑥
- Therapy Start Time, Figure 19-⑦

After making your selections, you can preview the schedule by tapping **PREVIEW CURRENT SCHEDULE** (Figure 19-⑤). If you do not want to add a maintenance schedule, tap **NEXT** to continue.

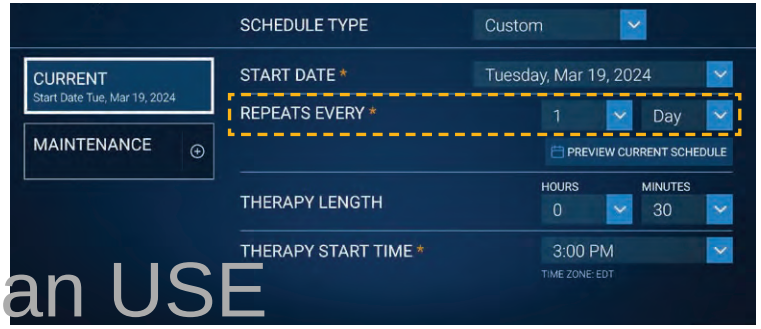


Figure 20. Sample Custom Schedule – Daily

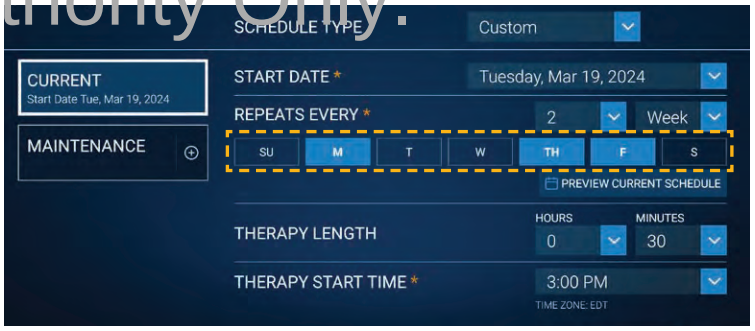


Figure 21. Sample Custom Schedule – Weekly

(Optional) Maintenance schedule

To add a maintenance schedule:

1. From the Schedule screen, tap ⊕ **MAINTENANCE** to open a new schedule form.
2. Set the schedule parameters as desired. When programming two schedules, the start date of the MAINTENANCE schedule must be after the start date of the CURRENT schedule.
3. Tap **PREVIEW MAINTENANCE SCHEDULE** to preview the schedule.
4. Once you are done, tap **SAVE** to continue.

Notes:

- Once the CURRENT schedule period is complete, the schedule will automatically transition to the MAINTENANCE schedule. At that time, the MAINTENANCE schedule becomes the new CURRENT schedule and will be displayed as such.
- Modifying the start date of the CURRENT schedule will delete the MAINTENANCE schedule.

To delete a maintenance schedule:

1. From the Schedule screen, tap 🗑.
2. A confirmation notification will appear. Tap **DELETE**.

To view CURRENT and MAINTENANCE schedule details:

1. When the patient is still in the CURRENT schedule period, the CURRENT and MAINTENANCE schedules will be displayed on the Review and Finish Setup screen or the **follow-up dashboard**.
2. Tap **CURRENT** or **MAINTENANCE** in the Schedule panel to view the schedule details (Figure 22).

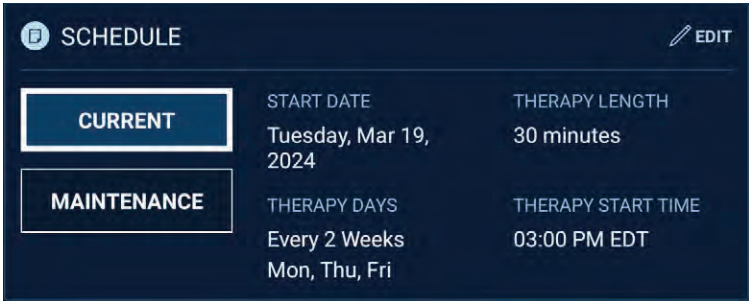


Figure 22. View CURRENT and MAINTENANCE schedule details

Continuous schedule

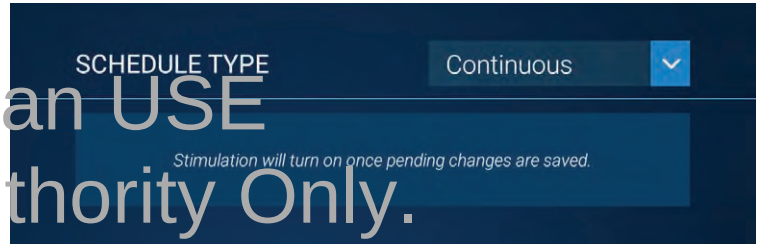


Figure 23. "Continuous" Schedule screen

Setting a patient's therapy schedule to continuous means that stimulation will be delivered continuously. To set a continuous schedule, select "Continuous" from the Schedule Type dropdown menu and then tap **SAVE**.

Note: With a continuous schedule, stimulation will be turned on when you tap **FINISH SETUP** on the Review and Finish Setup screen.

Configure patient and device information

The Patient and Device Information screen (Figure 24) allows you to enter information about the patient and implant. After finishing the

setup, you can view and update this information as needed from the follow-up dashboard.

- Patient information includes first name, last name, date of birth, and clinic-assigned patient ID.
- Device information includes implant date and implant location.
- The "Clinician Notes" field allows you to enter any relevant notes.

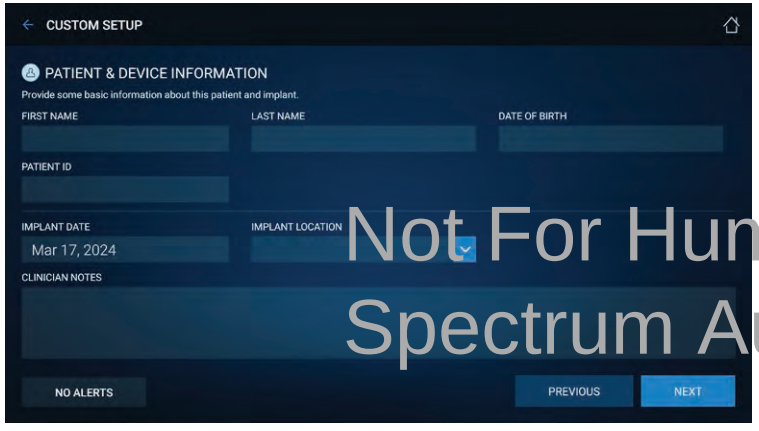


Figure 24. Custom Setup: Patient and Device Information screen

Review and finish setup

The Review and Finish Setup screen (Figure 25) allows you to review the information and therapy settings entered during a programming session.

Figure 25. Custom Setup: Review and Finish Setup screen

1. If adjustments are needed, tap **EDIT** found in the upper right-hand corner of each panel (Figure 25-①).
2. To complete the programming session, tap **FINISH SETUP** (Figure 25-②).
3. A confirmation notification will appear. Tap **OK**.
4. After the setup process is complete, you will return to the Home screen which will now display a dashboard.
5. Tap **EXIT** to end the session.

Note: If you exit the workflow session or the app before tapping **FINISH SETUP**, the schedule and patient information will not be saved to the INS.

Follow-up status check and programming

The follow-up dashboard, also referred to as "the dashboard" in this guide, is used in follow-up appointments with the patient after the INS has been set up. If you have not programmed the INS, see page 25 for instructions.

Connect to the neurostimulator and begin follow-up programming

1. Remove the recharger from the plugged-in dock and position the recharger over the INS.
2. Open the InterStim T clinician app.
3. Tap **CONNECT** on the start up screen.
4. Tap **FIND IMPLANT** (Figure 26).

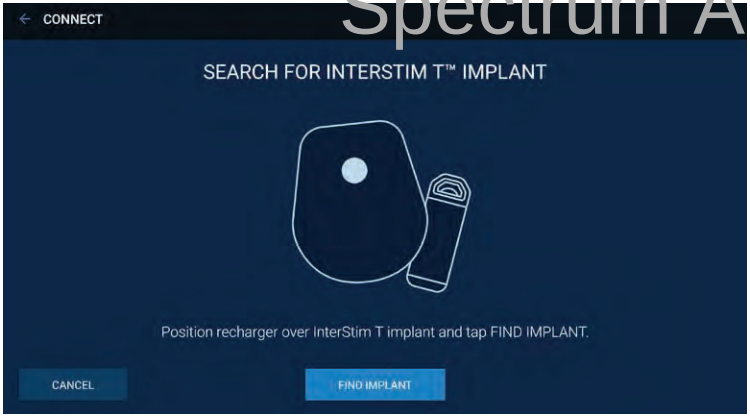


Figure 26. Search for InterStim T implant screen

5. Select the appropriate INS according to the serial number (on the patient ID card or in patient records) and tap **CONTINUE**. If the neurostimulator serial number is not listed, tap **REFRESH LIST** (↻).
6. Once the recharger connects to the INS, the dashboard will be displayed.

Notes:

- Check and, if necessary, correct the time setting on the clinician tablet before connecting to a patient INS. Connecting a tablet with an incorrect time setting to an INS could cause the INS to adopt that incorrect time setting. This could result in unexpected stimulation.
- During connection, if there is a time difference of **less than 5 minutes** between the clinician tablet and the INS, the INS time will be updated to match the clinician tablet.
- If there is a time difference of **5 minutes or more** between the clinician tablet and the INS, a notification will appear alerting you to the discrepancy (Figure 27).

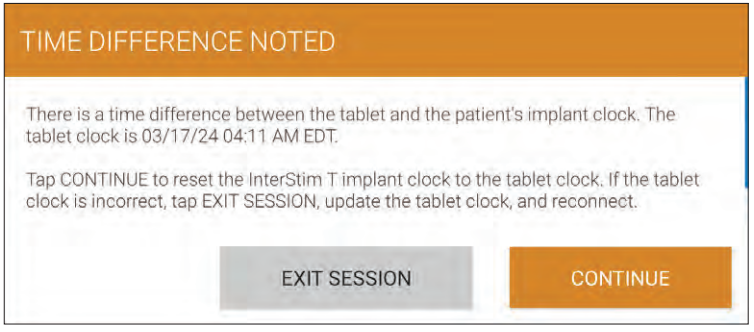


Figure 27. Time difference noted

Navigating the dashboard

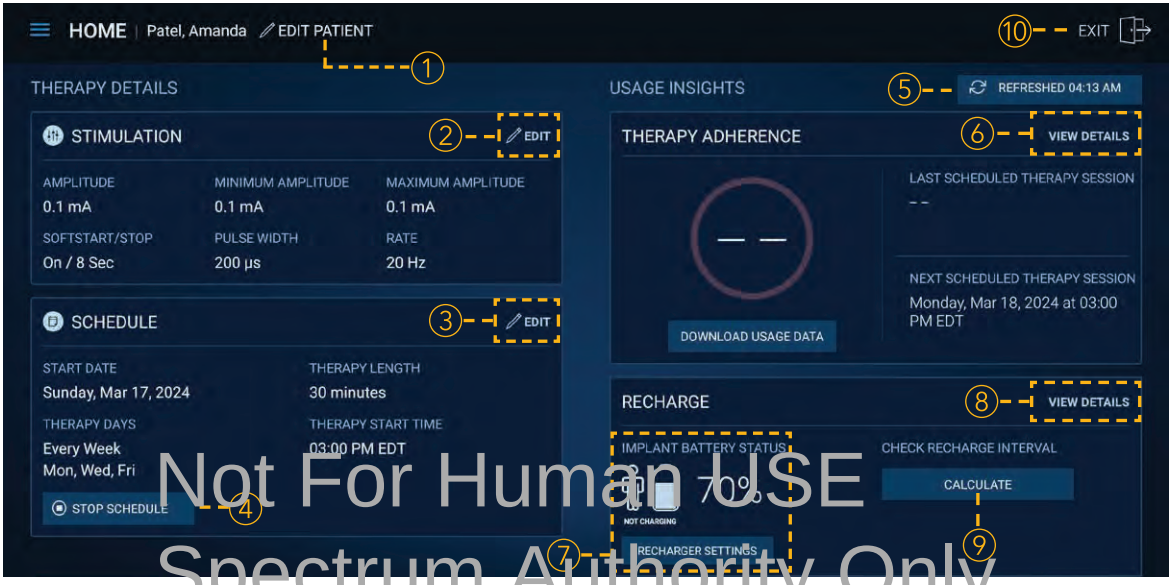


Figure 28. Follow-up dashboard

After connecting to the INS, you can view the therapy details and usage insights for an individual patient on the dashboard.

From the dashboard, you can:

① Edit patient and device information (page 33)

② Adjust programmed stimulation parameters (page 37)

③ Adjust programmed therapy schedule (page 37)

④ Stop or resume a patient's therapy schedule (page 40)

⑤ Refresh therapy schedule status

⑥ View therapy adherence details (page 37)

⑦ View and adjust recharger settings (page 50)

⑧ View recharge details (page 38)

⑨ Check recharge interval (page 39)

⑩ Exit session and return to startup screen