Adjust therapy details

On the dashboard, information about the stimulation and schedule settings can be found under the **Therapy Details** section.

STIMULATION		/ EDI
AMPLITUDE	MINIMUM AMPLITUDE	MAXIMUM AMPLITUDE
5.1 mA	0.1 mA	7.6 mA
SOFTSTART/STOP	PULSE WIDTH	RATE
On / 4 Sec	200 µs	20 Hz
SCHEDULE		/ EDI
SCHEDULE		/ EDI
SCHEDULE START DATE Sunday Mar 17, 2024	THERAPY 30 minu	/ EDI
SCHEDULE START DATE Sunday, Mar 17, 2024 TUTATON DATA	THERAPY 30 minu	/ EDI
SCHEDULE START DATE Sunday, Mar 17, 2024 THERAPY DAYS Event Work	THERAPY 30 minu THERAPY	✓ EDI LENGTH tes START TIME
SCHEDULE START DATE Sunday, Mar 17, 2024 THERAPY DAYS Every Week Mon, Wed, Fri	THERAPY 30 minu THERAPY N 09:00 P	LENGTH tes START TIME COFOR H

- 2. Adjust settings as needed.
- 3. Tap **SAVE** to save the changes and return to the dashboard.

View therapy adherence



Figure 30. Usage Insights: Therapy Adherence panel

 Mon, Wed, Fri
 Image: Store schedule
 Image: Store schedule</th

To adjust programmed stimulation settings:

1. Tap **EDIT** found in the upper right-hand corner of the Stimulation panel.

Note: Adjusting stimulation parameters requires that stimulation be turned on.

- 2. Adjust settings as needed.
- 3. Tap **DONE** to save the changes and return to the dashboard.

To adjust therapy schedule settings:

1. Tap **EDIT** found in the upper right-hand corner of the Schedule panel.

A therapy session is considered completed if the INS is on for the full therapy length. A therapy session that is partially completed is considered a skipped session in the therapy adherence calculation.

The date and time of the last and next therapy sessions is also shown in this panel.

Note: Therapy adherence information is not available for patients that receive constant stimulation.

To display therapy adherence information on the dashboard:

- Tap DOWNLOAD USAGE DATA (Figure 28-5)).
- Tap **VIEW DETAILS** to open the Therapy History screen to see more detailed information.

The Therapy History screen (Figure 31) provides the status of each patient session, grouped monthly, and provides details based on therapy type, including:

- Date of session
- Time session started
- Amplitude adjustment events
- Session length
- Delivery amount (length of delivered therapy ÷ length of scheduled therapy)

	HERENCE	Patel, Amanda			
THERAPY HIST	ORY				
Date	Time	Amplitude Adjustment	Session Length	Delivery Amount	DATE RANGE
April 2023					Start Date
Wed Apr 05, 2023	06:26 AM		9 hr 28 mins	40%	Mar 05, 2023 🛛 🖌
Mon Apr 03, 2023	06:26 AM	— 0.7 mA	23 hr 3 m 3	M t	
Sat Apr 01, 2023	05:43 PM		12 hr 13 mins	52.	
Sat Apr 01, 2023	05:39 PM	— 0.7 mA	4 mins		METRICS
Sat Apr 01. 2023			5 mins	na	
Sat Apr 01, 2023	06:26 AM	— 0.1 mA	6 hr 16	PC	
March 2023				•	Sessions completed/Sessions prescribed
Fri Mar 31, 2023	06:26 AM		23 hr 30 mins	100%	O% Of sessions with amplitude adjustment
ALERTS: 1					DONE

Figure 31. Therapy History screen

The data are formatted into a vertically scrollable table with each row representing an individual scheduled therapy session. Data can be filtered by using the Date Range selection.

Note: If the INS has a low battery event or an INS power-on reset occurs, collection of therapy adherence data could be interrupted. See "Clinician app, tablet, and recharger scenarios", page 53, for more information.

View recharge details



Figure 32. Usage Insights: Recharge panel

On the dashboard, the Recharge panel displays the current neurostimulator battery level and charging status. To see more details about recharge tap **VIEW DETAILS** to open the Recharge Details screen (Figure 33).

The Recharge Details graph displays the following information for the act 11 recharging sessions:

- Neurostimulator battery percentage before and after each
 recharcing session
- Quality of recharge coupling to the INS
- Recharge time



Figure 33. Recharge Details screen

1. Tap **CALCULATE** found in the Recharge panel on the dashboard screen (Figure 34) to open the Recharge Interval screen.



Figure 34. Recharge CALCULATE button

2. Tap **CALCULATE** on the Recharge Interval screen (Figure 35).



From the dashboard, you can check how the current programmed settings will affect the recharge interval. The recharge interval is the time it takes a fully charged INS to reach a critically low battery level.

To guide your patient on how frequently to recharge their INS and help avoid therapy disruptions, use the "suggested recharge frequency" on the recharge interval results (Figure 36).

While a patient could wait until the "fully charged implant battery cycle" time period to recharge the INS, recharging based on the "suggested recharge frequency" will help avoid therapy disruptions.

To check recharge interval:



3. Stimulation will be turned on during the recharge interval calculation. Once the calculation is complete, the results will be displayed to the screen (Figure 36).



1 schedule

2 schedules

Figure 36. Recharge interval results for 1 or 2 schedules (examples)

4. Tap **DONE** to close the Recharge Interval screen and return to the dashboard.

Notes:

- The measured data are not saved or displayed on the . dashboard. Tapping **DONE** will clear the results after every check.
- The displayed recharge interval is an estimate, based on • the current stimulation settings and therapy schedule parameters. See "Estimating recharge interval", page 71.
- Actual battery longevity will depend on any changes made • to the programmed settings and patient use throughout the service life of the INS.
- During recharge interval measurement, the recharger short • button press will be temporarily disabled. Wait until the measurement has completed before starting or stopping recharging.

Recharge interval calculation

Recharge interval calculations are based on how long it takes a fully charged implant battery to cycle. Table 7 shows some suggested recharge intervals for a set of sample battery cycle times.

Table 7. Recharge interval suggestions

Cycle time (fully charged battery)	Suggested recharge frequency
2 weeks	1 week
3 weeks to 5 weeks	2 weeks
6 weeks to 4 months	1 month
5 months to 8 months	3 months
9 months to 14 months	6 months
15 or more nomin	12 months

Stop and resume schedule

If e Stor, Schedule button allows you to stop the therapy schedule for a patient until it is re-enabled by you or your patient.

To stop your patient's schedule:

1. On the dashboard, tap **STOP SCHEDULE** (Figure 37).

5 SCHEDULE	// EDIT
START DATE	THERAPY LENGTH
Sunday, Mar 17, 2024	30 minutes
THERAPY DAYS	THERAPY START TIME
Every Week	03:00 PM EDT
Mon, Wed, Fri	
STOP SCHEDULE	
Element 27 STOR SCHER	ULE house of a set of an algorithm and

Figure 37. STOP SCHEDULE button located on dashboard

- 2. Follow the instructions provided on the screen.
- 3. The dashboard will be updated to indicate that the schedule is stopped (Figure 38).

3. The dashboard will be updated to indicate the next scheduled therapy session.

Stop and resume continuous stimulation

To stop your patient's continuous stimulation:

- 1. On the dashboard, tap **EDIT** to open the Stimulation screen.
- 2. Toggle Stimulation OFF.
- 3. Tap **DONE**.

To resume your patient's continuous stimulation:

1. On the dashboard, tap **EDIT** to open the Stimulation screen.



Figure 38. Schedule status when schedule is stopped

To resume your patient's schedule:

- 1. In the SCHEDULE panel on the dashboard, tap RESUME SCHEDULE.
- 2. Follow the instructions provided on the screen.

Implant diagnostic data

To download data from the INS to the clinician app:

- 1. Tap the Menu button (==) in the upper left-hand corner of the Home screen.
- Select Implant Diagnostic Data from the Menu. 2.
- 3. Tap DOWNLOAD DATA.

Note: This process may take some time. The session will automatically exit once the download is complete.

4. A file will be generated that can be accessed from the Reports screen.

See "Reports", page 42, for more information about how to view and access the reports.

Note: While downloading data from the NS, the recharger sho button press will be temporarily disabled. Wait until the download has completed before starting or stopping recharging

Reports

From the Reports screen (Figure 39), you can access therapy reports, which contain:

- **Error** conditions
- Battery state transitions
- Impedance measurement (if taken).
- Therapy schedule and stimulation: status, parameters, . changes made (tap **DOWNLOAD DATA** to access)
- Therapy adherence and recharge compliance (tap **DOWNLOAD DATA** to access)

A therapy report is automatically generated each time you finish a programming session.



Figure 39. Reports screen

View and download reports

1. From the startup screen, tap **REPORTS** (Figure 40).

INTERSTIM T [*] ©* CLINICIAN PROGRAMMING APPLICATION	 Find and tap the desired report from the scrollable list. The most recent report appears at the top. Tap one of the buttons shown in Table 8.
	Table 8. Report icons and descriptions
	Icon Description
	View – to view the report.
Medtronic	This action takes you out of the clinician app. The app runs in the background and your session data remains intact.
	Share – to send the report to another destination.
Figure 40. Reports button 2. (Optional) Filter reports using patient name/ID or a date	This action takes you out of the clinician app. The app runs in the background and your session data remains intact.
range (Figure 41-①). NOT FOT HUM	the clinician tablet.
123-456 Spectrum AU	This action saves the report file in the default ports order on the clinician tablet.
Session Report (PDF) 2	Delete – to delete the report.
Figure 41. Options to filter located on the Reports screen	

- a. Enter the patient name/ID or start and end dates using the calendar control.
- b. To dismiss the calendar control, tap **CANCEL** or **DONE**.
- c. Tap **FILTER**.
- 3. (Optional) Use the dropdown menu to select by file format as needed (Figure 41-(2)).

Viewing system information

The About screen is accessed by tapping the Menu button () in the upper left-hand corner of the Home screen and selecting **About** from the menu.

This screen provides the following information:

- Neurostimulator information such as model number, serial number, and elective replacement date.
- Clinician tablet and app information such as model numbers, identification (ID) number, and version numbers.
- Recharger information such as model number, firmware version number, and serial number.
- General licensing information such as copyrights and trademarks.

Software and firmware information

Data security

The clinician programming system uses and stores data about the patient's health and implanted medical device. This data is protected by application-level controls and encryption provided by the clinician tablet. The clinician programming system does not provide data protection for data exported to another destination. Exported data should be handled in accordance with your facility's security policy for data handling and storage. Medtronic recommends that you always save exported data to the default reports location on the clinician tablet.

Not For Humanworksonectivity

Spectrum Au professional theory of Methodic arp updates and firmware updates. Network connectivity is not required for neurostimulator programming. To protect your clinician programming system, Medtronic recommends you implement the following security measures:

- Secure your clinician tablet by disabling network connectivity during any programming session.
- Use a managed, trusted Wi-Fi connection when network connectivity is needed.
- Connect the clinician tablet to the network periodically to check for notifications on available updates.

Note: Connecting the clinician tablet to a network that includes other equipment could result in unforeseen risks to patients, operators, or third-parties. Changes to your network (such as

adding, disconnecting, and upgrading equipment; upgrading or installing software; or changing network configurations) could also introduce additional risks. Analyze, evaluate, and control any identified risks.

If you suspect a cybersecurity event has occurred, stop using the app (if possible) and contact Medtronic using the contact information listed at the end of this guide. Medtronic will document the cybersecurity event, analyze the event, and recommend actionable items appropriate for the event in a timely manner.

If your clinician tablet is lost or stolen, contact Medtronic using the contact information listed at the end of this guide.

Model A902 Patient Data Service Application

The Model A902 Patient Data Service app works with the Model

P7A2C11 InterStim T Clinician app to store patient and therapy.

Installing INS firmware updates

If the clinician app connects to an INS that needs a firmware update, a notification will appear informing you that a firmware update is required. Follow the instructions provided on the screen and keep the recharger over the INS for the entirety of the firmware update process. Removal of the recharger could cause a failure of the firmware update.

The clinician app will indicate that the update was completed successfully. The user can reconnect to the INS and proceed with normal workflow.

Note: During a firmware update, the recharger short button press will be temporarily disabled. Wait until the update has completed before starting or stopping recharging.

If the patient experiences uncomfortable stimulation due to the start of a scheduled stimulation session during the firmware update, take the following sceps:

device records that are used when generating a report. You do not need to open or use this app. **Spectrum Author** in the firm wave update **D**

Installing software updates

Medtronic periodically updates to the InterStim T Clinician application, and will not install updates without notifying you. Network connectivity is required to update the app. When notified that an app update is available, follow the instructions provided by Medtronic to install the update.

Note: Before installing a clinician app update, download the most recent report following instructions in the "Reports" section, page 42. Make a record of the patient's active program and therapy settings. The stimulation schedule will need to be re-enabled after installing the application update. For instructions on how to re-enable the stimulation schedule refer to "Stop and resume schedule", page 40.

- 2. Tap **EXIT SESSION**.
- 3. Reconnect to the InterStim T implant.
- 4. Tap BYPASS UPDATE.
- 5. End the current session or turn stimulation off (if in continuous stimulation) or adjust the stimulation amplitude.
- 6. Tap Exit Session.
- 7. Reconnect to the InterStim T implant.
- 8. Retry firmware update.

Installing recharger firmware updates

When the clinician app is paired to a recharger that needs a firmware update, the app will push firmware updates to the recharger. While the recharger is downloading the firmware update, the recharger should be positioned on the plugged-in dock. Do not attempt to use the recharger during the firmware update process. Once the recharger has downloaded the firmware update, the recharger will reset.

The clinician app will indicate that the update was completed successfully. The user can exit the session, reconnect to the recharger, and proceed with normal workflow.

Return and replacement

If you need to return or replace any component of the system, contact Medtronic using the contact information listed at the end of this guide. Instructions will be provided, ncluding its tructions to **man** preparing the clinician tablet for return.

Removing identifying patient health Authority Only information from the INS

At explant and before disposal, ensure identifying patient health information is removed from the neurostimulator.

- 1. Navigate to the Patient and Device Information screen.
- 2. Delete patient first name and last name, change the date of birth to a different value, delete clinic-assigned patient ID and any patient identifying clinician notes from the Patient and Device Information screen
- 3. Tap **SAVE** to save deletions to the INS.

Refer to the InterStim T[™] Model P7850N Neurostimulator Implant manual for instructions on explant.

Charging the recharger battery

If you have not set up the recharger for the first time, see "First-time setup of a new recharger - turning off shipping mode", page 23.



- Battery light
 USB cable (micro-USB end)
 Power button
 Comparison
 Recharger
 Dock
 Wall outlet (example)
- Plug in the dock to a power outlet using the USB charging cable and power adapter provided by Medtronic.

Note: There is a green light (not pictured) on the dock near the USB cable when power is running to the dock.

- 2. Place the recharger, blue side down, on the plugged-in dock. Do not remove for at least 30 seconds to ensure that the recharger establishes the proper connection to the dock.
- 3. While the recharger is charging, the battery light will slowly flash green.
- 4. When the recharger is fully charged, you will see 3 solid green bars on the battery light (a).

Between sessions, keep the recharger on the dock and keep the dock plugged into a wall outlet. While the recharger does not need to be fully charged for use, keeping it fully charged is recommended.

To disconnect from the main power source, unplug the dock from the wall outlet.

Recharging the neurostimulator

This section provides instructions for:

- Checking neurostimulator and recharger battery levels (page 47)
- Recharging the neurostimulator before implant (page 48) and after implant (page 49)
- Viewing and adjusting recharger settings (page 50)

Notes:

• Before you can recharge the neurostimulator, the tablet must be paired to the recharger. See "Pairing the clinician tablet to the recharger", page 23.

Not For Human One baired you do not need the clinician tablet to recharge any InterStim T neurostimulator. You can use the recharger on

Spectrum Authörity Only. Checking neurostimulator battery and recharger battery levels

- Tap the Menu button () in the upper left-hand corner of the Home screen and tap **RECHARGER SETTINGS** to open the Recharger Settings screen.
- On the dashboard, INS battery status is on the Recharge panel. Tap **RECHARGER SETTINGS** to check recharger level.

Table 9 shows the neurostimulator battery icons and their associated meaning.

	Table 9.	Neurostimulat	or battery l	level des	scriptions
--	----------	---------------	--------------	-----------	------------

Status	Implant Battery Level	before implant
Status: 30-100%	Implant Battery Level: OK	The battery level of the INS can be determined using the clinician app without starting the service life of the INS. See upper right-hand corner of the Home screen for INS battery level.
\mathbb{C}		The target graphic (\oplus) on the neurostimulator package indicates that the neurostimulator can be recharged and interrogated through the packaging.
Status: 20%	Implant Battery Level: LOW	To recharge the neurostimulator before implant:
	Recharge the InterStim T implant.	 Place the recharger over the target graphic (⊕) found on the package. Ensure that the 2 circles (⊚) on the back of the recharger are aligned directly over the target graphic (⊕).
	Not For Hur	2. To start resharge, give the power button (③) on the recharger
Status: 0%	Implant Battery Level: CRITICAL Recharge the other Star Tip plant	3. As the recharger attempts to connect to the neurostimulator, you will hear a repeating tone and the green lights on the power button will spin (@).
ŢĨ	A programming session may be interrupted due to critically low battery level.	 When the recharger has connected to the neurostimulator and starts recharging, you will hear 2 tones rising in pitch and the green lights on the power button will pulsate (
	Note: Therapy may stop due to critically low battery level. You may need to reset the implant clock and restart therapy for the patient.	If the recharger is unable to connect to the neurostimulator through the outer package, remove the inner, sterile package from the outer package and recharge through the sterile package.

- When recharging is complete, a series of tones rising in pitch will sound and the power button light will change to solid green (⁽⁶⁾).
- 6. Turn off the recharger with a long press (3 to 5 seconds).

Recharging the neurostimulator

Recharging the neurostimulator after implant

To recharge the neurostimulator after implant:

1. Remove the recharger from the plugged-in dock and press the power button ((()) on the recharger.

As the recharger attempts to connect to the INS, you will hear a repeating beeping tone and the green lights on the power button will spin (@).

2. Position the recharger over the INS.

An ankle band can be used to help hold the recharger in position, if desired. See "(Optional) Using the ankle band", page 49, for instructions.

- When recharging is complete, a series of tones rising in pitch will sound and the power button light will change to solid green (⁽⁶⁾).
- 5. Remove the recharger from the ankle band (if using) and return it to the plugged-in dock.

Notes:

- The recharger must be kept over the INS for the duration of the recharging session.
- If the recharger power button is displaying an orange light, indicating an error, refer to "Clinician app notifications", page 58, for more information.

(Optional) Using the ankle band

When using the recharge in a clinic, place it outsice a layer of patient clothing or a barrier to avoid cross containing ich Note: If the implant battery has dropped to CRITICAL battery level, you may need to recharger to complete thesigning the clinician tablet.



Front view

Back view

Figure 43. Inserting the recharger into the ankle band pouch

See "Recharge speed", page 52, for instructions.

3. When the recharger has connected to the INS it begins charging automatically. You will hear 2 tones rising in pitch

indicating that the INS is recharging.

and the green lights on the power button will pulsate (0),

Caution: Discomfort during recharge – Turn down the charging speed if the patient experiences discomfort or changes in stimulation during a recharging session. The recharger may induce heat or stimulation on the implanted

neurostimulator, leading to heating sensations or excessive

stimulation.

2. When using the ankle band in the clinic, place it outside a layer of patient clothing or a barrier to avoid cross contamination.



Figure 44. Using a barrier in the clinic

Position the recharger so that the 2 circles ((()) on the back of 3. the ankle band are directly over the INS (Figure 45). Hold the recharger in this position as you continue



Figure 46. Securing the ankle band

(Optional) Using the ankle band adjusters

The ankle band comes with adjusters that can be used to lengthen or shorten the ankle band, if needed.

In length en hean le band:

Secure one or more adjusters to the end of the ankle band.

hread the ankle band through the eyelet.



Figure 45. Positioning the recharger over the INS

4. Secure the ankle band. The ankle band should be snug, but comfortable (Figure 46).

To shorten the ankle band:

- 1. Cut the ankle band down to the desired length.
- Secure an adjuster to the end of the ankle band. 2.
- Thread the ankle band through the eyelet. 3.

View and adjust recharger settings

To view and adjust recharger settings use the clinician app and connect to the neurostimulator.

1. From the Recharge panel on the dashboard, tap **RECHARGER SETTINGS** to open the Recharger Settings screen (Figure 47).

RECHARGE	VIEW DETAILS
IMPLANT BATTERY STATUS	CHECK RECHARGE INTERVAL
₩ € 70%	CALCULATE
RECHARGER SETTINGS	

Figure 47. Recharger panel on dashboard

2. On the Recharger Settings screen (Figure 48), you can:

Check recharger and neurostimulator battery levels (page 47)

- (2) Check recharge coupling status (page 51)
- 3 Adjust recharge speed to a ge 52
- (4) Adjust recharger volume (page 52)



Figure 48. Recharger Settings screen

Recharge coupling status

The Recharger Settings screen provides information about the recharger position and allows you to check the coupling status, an indication of the strength of the connection between the recharger and the neurostimulator. Table 10 displays the coupling status indicators and their associated meaning.

Table 10. Recharger coupling status indicators and definitions

Indicator	Meaning
	OK or Good coupling status.
	Acceptable recharger position for recharging and communication.
	veeds attention.
	Decharger requires repositioning.
hority	Only
f an orange in dir.a	itor is di player:

1. Reposition the recharger and hold it in place until the position strength updates and the coupling status has improved.

Note: If you continue to see the orange indicator and "Needs attention", palpate the INS and try to center the 2 circles ((()) on the back of the recharger over the INS.

2. Once an "OK" or "Good" coupling status is reached, maintain that position for the duration of the recharging session.

Recharge speed

The recharge speed is set to the fast/warm mode automatically. It is normal to feel warmth during a recharging session. If the implant site feels too warm for the patient's comfort during a recharging session, use the following steps to change the recharge speed.

- 1. On the Recharger Settings screen (Figure 48-(3)), select the speed (fast or slow) that is most comfortable.
- 2. Tap **DONE** to set your selection.

Notes:

- Reducing the recharge speed will make the recharging • session longer.
- The new recharge speed will save to the INS and take effect • on the next recharging session and for all future sessions with this INS unless it is changed again For Human USE

Recharger volume

Adjustments to recharger volume Space Ceach Udividual Authority Only. recharger.

In the clinician app, the volume settings for the recharger can be accessed from the Recharger Settings screen (Figure 48-(4)).

- 1. Use the arrows to adjust the volume. As you change the volume, the recharger will emit a tone to indicate the current volume setting.
- 2. Tap **DONE** to set your selection.

Notes:

Both the clinician and patient apps can be used to adjust ۰ recharger volume. For instructions on adjusting recharger volume using the patient app, refer to the Patient Guide for the InterStim T System.

- Make sure that you use the recharger you want to adjust the volume settings for.
- If you turn the volume completely off, you will not be able to hear the feedback tones described in this guide.

Troubleshooting

Clinician app, tablet, and recharger scenarios

Table 11. Clinician app, tablet, and recharger scenarios and solutions

Scenario	Explanations and possible solutions
l am unable to connect to the recharger	The recharger is not turned on.
	Turn on the recharger to connect with the tablet. Once the recharger is turned on, follow the connection steps to reconnect to an existing recharger.
	The recharger is not charged.
	Charge the recharger using the dock provided with the recharger. Once charged, follow the connection steps to reconnect to an existing recharger.
	The tablet is not paired to the recharger. See "Pirity the clinic an tablet to the recharger", page 23
	The recharger is still in shipping mode.
	Take the recharger cut or shipping mode prior owns, the instructions in "first-time setup of a new recharger - turning off shipping mode , page 23.
	The recharger may be connected to another tablet.
	Turn off the recharger and then turn it back on.
	The recharger and tablet failed to establish a Bluetooth connection.
	1. Turn off the recharger with a 3-5 second button press, then turn it back on and follow the connection steps to attempt to reconnect.
	Note: If the recharger is unresponsive and does not turn off after a 3-5 second button press, hold down the power button for at least 20 seconds to reset the recharger.
	2. If Step 1 was unsuccessful, turn off the tablet, turn it back on, and try to connect again.
	3. If the steps outlined above do not result in successful communication between the tablet and the recharger, contact Medtronic.

Scenario	Explanations and possible solutions
The recharger is unable	The recharger is out of range.
to connect to and	Reposition the recharger over the neurostimulator and tap RETRY .
neurostimulator	The rechargeable neurostimulator battery is depleted.
	Recharge the neurostimulator. See "Recharging the neurostimulator after implant", page 49.
	The implant battery is drained to the point that it cannot communicate with the recharger.
	If while trying to connect the recharger to the INS you see an Unable to Connect screen, follow the on-screen instructions:
	1. Position the recharger over the implant and recharge for up to 10 minutes.
	 Once the implant is sufficiently recharged, the screen will update to show the Low InterStim T Implant Battery screen. Buttery screen. Difference age result of the plant you will be the Select InterStim T Implant screen. Tap to select the implant and then tap the CONTINUE button. If unsuccessful, follow instructions for "Clinician Reset and Recharge workflow", page 57.
The tablet has no power or has lost power	The tablet battery is depleted.
	Charge the tablet using the charger.
	The tablet is damaged or malfunctioning.
	Contact Medtronic.

Table 11. Clinician app, tablet, and recharger scenarios and solutions

Table 11. Clinician app, tablet, and recharger scenarios and solutions

Scenario	Explanations and possible solutions	
The tablet will not charge	The charger is disconnected from the tablet or power source.	
	Connect the charger to the tablet.	
	An incompatible charger is connected to the tablet.	
	Connect the appropriate charger to the tablet.	
	Charger or tablet is defective, damaged, or malfunctioning.	
	Contact Medtronic.	
I cannot find the clinician	The clinician app may not have downloaded properly or may have been deleted from the tablet.	
app on the tablet	Contract Medtronic.	
The tablet or clinician app	1. Turn the tablet off, then turn the power back on and make sure that the tablet is charged.	
is unresponsive	2. I that loe: not as rive the issue are another tablet is available.	
	3. If you are near possible sources of electromagnetic interference (EMI), move away from the source of EMI.	
	If me issue persists, contact Medtronic.	
l cannot find my downloaded report	Downloaded reports can be found in the Reports folder on the tablet.	
	You can access a downloaded report by navigating to the Reports folder on the tablet or by connecting the tablet to a computer and navigating to the Reports folder through the computer.	
	If you use more than one tablet, you may have downloaded the report on another tablet.	
	Check other tablets you may be using or download the report again.	
l want to connect to a different recharger	1. After tapping CONNECT on the startup screen, a Connecting to Recharger screen will appear as the app attempts to connect to the paired recharger.	
	2. Tap $\operatorname{\mathfrak{C}}$ to connect to a different recharger.	

Scenario	Explanations and possible solutions
The patient has remarked that their stimulation sessions are starting earlier or later than expected	It is normal for an implant clock to lose or gain a few minutes over time. If needed, you can correct the time set on an implant clock:
	1. Ensure that the clinician tablet is set to the correct time. (Correct tablet time setting if necessary.)
	2. Connect the implant to the clinician app.
	3. If the app detects a time difference between the tablet and the implant of less than 5 minutes, it will automatically correct the implant clock.
	4. If the app detects a time difference between the tablet and the implant that is 5 minutes or more, the app will prompt you to correct the implant clock.
Therapy adherence history appears to be interrupted or incomplete	If the INS has had a low battery event or an INS power-on reset occurs, the collection of therapy adherence data could have been interrupted. If that happens, review the therapy history and download the therapy adherence report (see "View and download reports", page 42) to understand the system event that in errupted the data collection. Discuss behaviors that will lead to better therapy adherence with your patient.

Table 11. Clinician app, tablet, and recharger scenarios and solutions

Spectrum Authority Only.

Therapy Settings Out of Range alert

The system cannot use certain combinations of amplitude, pulse width, and rate, because the neurostimulator has reached the limit of its therapy range. Typically, this alert is caused by temporary stimulation limitations that occur after the neurostimulator is implanted - the limits usually resolve as healing progresses.

To resolve this alert, perform one of the following actions:

- Navigate to the Stimulation panel on the dashboard and • decrease the stimulation amplitude.
- Check the battery level. If the battery level is low, consider • recharging the neurostimulator.

If you are still experiencing issues, contact Medtronic.

Clinician Reset and Recharge workflow

3. With the recharger on the dock, enter Clinician Reset and Recharge by using the button press sequence: short, short, long. You will see the battery indicator fill up and hear a tone with each button press.

Note: A short button press is 1-2 seconds. A long button press is 4-6 seconds. The recharger will beep at the end of a correct duration button press.

- 4. The light on the power button indicator will show a spinning orange light and the recharger will beep.
- Remove the recharger from the plugged-in dock and hold 5. it over the patient's INS. Within 2 minutes, the power button indicator will show a flashing orange light (0) and beeping will get faster. This means that the recharger is preparing to reset the neurostimulator.

Keep the sector ger over the INS after the beeping stops. The Perform the Clinician Reset and Recharge workflow if the reset will start after the beeping ends and will take up to 1 minute to complete. The recharger indicator light will change clinician app or the recharger is unable to communicate with the to an plange pulse and ther a green pulse when the reset neurostimulator or if troubleshooting in contest that a clinic an has completed. reset is needed. This workflow will use the recharger to reset the neurostimulator.

Note: If the volume on the recharger is turned off, you will be unable to hear the audio feedback in the following steps. See "Recharger volume", page 52 for instructions to change the recharger volume.

To perform the Clinician Reset and Recharge workflow:

- 1. Connect the dock to a power supply. Place the recharger on the dock as if to charge the recharger.
- 2. Palpate the patient's skin to determine the approximate location of the neurostimulator.

7. After the reset, the recharger transitions to a special recharging session that may take up to 30 minutes if the neurostimulator battery needs to be recovered. Keep the recharger over the INS until it enters a recharging session.

Note: The recharger indicator light will turn green when the INS enters a normal recharging session.

8. Check the therapy status after performing Clinician Reset and Recharge and turn therapy on if needed.

Note: If the clinician app or the recharger is still unable to communicate with the INS after the Clinician Reset and Recharge workflow, contact Medtronic for assistance.

Clinician app notifications

The clinician app displays notifications that you may encounter while using the app. When a notification appears in the app, follow the onscreen instructions carefully. If a notification says to contact Medtronic, provide the service code shown on the notification screen.

Table 12 lists some important notifications and what to do if you see them.

App notification	Explanations and possible solutions
Recharger Docked	The recharger is on the dock.
	Remove the recharger from the dock and place it over the InterStim T implant.
Time Difference Noted	There is a time difference between the tablet and the patient's implant clock.
	Tap CONTINUE to reset the InterStim T implant clock to match the tablet clock.
	If the tablet clock is incorrect, tap EXIT SESSION , update the tablet clock, and reconnect.
Recharger Logs	Recharge ogs are available for incubies noting USE
	To download the recharger logs, tap CONFIRM . Otherwise, tap CANCEL .
Recharger Logs Download Complete	The period is a cost of the period successfully down concerning ONY. Tap OK.
Communication to the	The connection between the tablet and the recharger has been lost.
Recharger Has Been Lost	Tap EXIT SESSION and reconnect. If this issue persists, contact Medtronic.
Communication to the InterStim T Implant Has Been Lost	Communication to the InterStim T implant was interrupted and the therapy schedule was disabled.
	Tap EXIT SESSION and reconnect to re-enable the therapy schedule. If this issue persists, contact Medtronic.

App notification	Explanations and possible solutions
Unsuccessful Scan	The recharger code cannot be read.
	Position the camera over the code on the back of the recharger and tap RETRY .
	You have scanned an incompatible recharger.
	Locate the model number on the back of the recharger. Check that you are using the InterStim T recharger (Model P720R1). Code can also be entered manually if scanning is unsuccessful.
InterStim T Implant Reset	A neurostimulator reset workflow has been initiated.
	Follow the instructions for Clinician Reset and Recharge workflow, page 57.
Firmware Update	The neurostimulator or recharger requires a firmware update.
Required	Follow the instructions in the notification.
	Yes will receive a Firmware Inclate Complete notification of the clinician app when the update is done.
Firmware Update Complete	The firmware update has completed.
	Tapexin SESSION and reconnect to continge program may the interstim Trimplant.
Firmware Update Unsuccessful	An error has occurred during the neurostimulator or recharger firmware update.
	1. Tap EXIT SESSION and reconnect the recharger to the tablet.
	2. If the update continues to fail, contact Medtronic.
Place Recharger On Dock	The recharger was removed from the dock during the firmware update.
	Place the recharger on the dock. Tap EXIT SESSION and reconnect to restart the update.

App notification	Explanations and possible solutions
No InterStim T Implant Found	The recharger is out of range.
	Reposition the recharger over the neurostimulator and tap RETRY .
	The rechargeable neurostimulator battery is depleted.
	Recharge the neurostimulator. See "Recharging the neurostimulator", page 47. If unsuccessful, follow instructions for Clinician Reset and Recharge workflow, page 57.
	The neurostimulator is not responding to the recharger.
	Follow the instructions for Clinician Reset and Recharge workflow, page 57.
Recharger Low Battery	Recharger battery is low.
	Place the recharger on the dock to charge.
	Note The recharger should be left on the dock in between sessions when not in use so it remains charged.
Incompatible Recharger	The tablet does not recognize the recharger.
	Ensure that you are using the correct recharger (Model P720R1) for the InterStim T implant. If the problem persists, contact Me Ittoric.
Low Battery: InterStim T	The InterStim T implant battery is low.
Implant	Recharge the neurostimulator to avoid losing therapy.
Charge Density Threshold	The stimulation parameters are set too high.
Exceeded	From the Stimulation screen, lower the stimulation parameters to remain within safe limits. See "Configure stimulation parameters", page 29.
Recharger Temperature	The recharger is either too hot or too cold to recharge.
Problem	Return the recharger to room temperature before recharging again.
	Note: Always store the recharger at room temperature. See Table 17, page 68, for more information about temperature.

App notification	Explanations and possible solutions
System Error	The system has encountered an unexpected problem.
	1. Restart the clinician app.
	2. If the problem persists, contact Medtronic.
Replacement	The InterStim T implant has reached the end of its service life.
Recommended	Schedule a replacement procedure.
Permission Needed	The clinician application will ask for permissions that it needs.
	Tap OK and allow all permissions.
Permission Denied	The clinician application cannot run without permissions.
	1. Tap GO TO SETTINGS. 2. Alocation for Human USE
Stimulation Required	Stimulation must be on before entering advanced settings. Turner simulation to continue programming. Only Only

Problems during a recharging session

This section provides solutions to problems that you may encounter using the recharging system. Table 13 lists some problems and alerts encountered while recharging the neurostimulator and what to do if you encounter them. If you cannot solve a problem, or it is not described here, contact Medtronic.

Table 13. Recharger scenarios and solutions

Scenario / Alert	Cause and Action
	The recharger is attempting to connect to the implant, or is in a poor position for recharging. If the tones continue, the recharger's position over the implant needs to be adjusted.
Lights: Spinning green Tones: Repeating tones of the same pitch	Hold the recharger in place for at least 10 seconds before adjusting the position. If the searching tones continue for longer than 10 seconds, adjust the positioning of the recharger to align it with the implant. See "Recharge coupling status", page 51
	The recharger initializating that you need to connect to the op.

Lights: Spinning orange and green

Tones: 2 tones falling in pitch

Open the clinic an loo and tap CONNICTAN USE

Spectrum Authority Only.



Lights: Flashing orange Tones: 2 tones, falling in pitch and repeating The recharger or neurostimulator is not functioning properly.

- 1. Use the clinician app to resolve any error messages by following the directions provided on the app.
- 2. Turn off the recharger with a 3-5 second button press, then turn it back on.
- 3. Reposition the recharger over the neurostimulator and try again.

If the alert or error persists:

- 1. Check the clinician app for any system errors or alerts and address as needed.
- 2. Reset the recharger by holding the power button down for at least 20 seconds or until the battery lights begin to flash.
- 3. If alert or error persists, contact Medtronic.

Table 13. Recharger scenarios and solutions

Scenario / Alert	Cause and Action		
	The tablet has not been paired to the recharger.		
	Pair the tablet to the recharger and try again. See "Pairing the clinician tablet to the recharger", page 23.		
Lights: Solid orange briefly, then off			
Tones: 2 tones, falling in pitch (not repeating)			
	The recharger battery is low.		
	Charge the recharger by placing it on the plugged-in dock before attempting further use. See "Charging the recharger battery", page 46.		
Lights: Flashing orange			
pitch and repeating	Not For Human USE		
The recharger feels too warm during a recharging session.	You may need to adjust the charging speed. See Record of Physics Authority Only.		
The patient experiences	You may need to adjust the charging speed.		
heating sensation, discomfort, or redness near the implanted neurostimulator during recharging.	See "Recharge speed", page 52.		
	The patient's surgical wound may not be fully healed.		
	Have the patient take the following steps:		
	1. Take a break from recharging.		
	2. Move to a comfortable position while recharging.		
	3. Loosen the ankle band so that it is comfortable and only tight enough to secure the recharger in place.		
	4. If an ankle band is not being used, place a thin piece of fabric between the patient's skin and the recharger.		
	5. If symptoms are severe, stop recharging.		

Table 13. Recharger	scenarios and	solutions
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Scenario / Alert	Cause and Action
The tones from the recharger are too loud or too quiet.	The recharger volume may need to be adjusted.
	See "Recharger volume", page 52.
The lights on the recharger are on, but it is not recharging the neurostimulator.	You may be using the recharger for programming and the recharger may be in communication-only mode.
	If recharging is desired, give the power button on the recharger a short press (less than 2 seconds) to switch to recharging mode.
	If the short press appears to do nothing, check that any connected app is not currently using the recharger to communicate with the neurostimulator. Wait until the connected app is finished, and then a short press will start a recharge session.
	Note: It is not recommended to start recharge if extensive programming is needed.

Recharger recovery model For Human USE

The recharger will automatically enter recovery mode if it has difficulty connecting to the neurostimulator. If this occurs, an "Unable to connect" alert will appear on the screen eleventer directions provided in the alert ity Only.

Other troubleshooting scenarios

Table 14 addresses therapy (stimulation) issues and other issues.

Table 14. Other troubleshooting scenarios and solutions

Scenario	Explanations and possible solutions
Uncomfortable or intolerable stimulation	The patient is experiencing side effects or discomfort from the therapy (stimulation).
	Turn the therapy (stimulation) down or off. See "Adjust therapy details", page 37; "Stop and resume schedule", page 40; or "Stop and resume continuous stimulation", page 41 for instructions.

Scenario	Explanations and possible solutions
The patient is not receiving stimulation	The therapy schedule might be stopped.
	Check the schedule status on the dashboard. Re-enable the therapy schedule if it has been stopped. See "Stop and resume schedule" page 40 or "Stop and resume continuous stimulation", page 41 for instructions.
	The neurostimulator battery may be depleted.
	The neurostimulator will need to be recharged.
	The recharger may need to connect to the clinician app.
	If the recharger power button displays spinning orange and green lights and two tones falling in pitch are sounded after recharging is complete, connect to the clinician app for instructions.
The patient's scheduled	Therapy may be scheduled at a different time or the schedule was stopped by the patient or clinician.
therapy sessions are not occurring, or are occurring at an unexpected time	Check the status and therapy start time on the deshibbard. SE The neurostimulator battery was faily depicted.
	Connect neurostimulator to the clinician app. The patient traveled to a new time zone and the therapy sciedule time has yot yet been updated with the local time.
	Connect neurostimulator to the clinician app.
	A system error occurred.
	Connect to the clinician app for additional information.

Table 14. Other troubleshooting scenarios and solutions

Table 14. Other troubleshooting scenarios and solutions	
Scenario	Explanations and possible solutions
l want to unpair the neurostimulator from the patient app	To unpair the neurostimulator:
	1. Turn on the patient programmer, and open the patient app.
	2. Tap the Settings button (③) in the upper right corner, and select About .
	3. Tap the Implant tab to navigate to information about the neurostimulator.
	4. Tap the UNPAIR NEUROSTIMULATOR button.
	5. Tap the CONFIRM button on the notification that appears.

Not For Human USE Spectrum Authority Only.

Product specifications

Neurostimulator



Figure 49. InterStim T neurostimulator

The neurostimulator serial number (SN) can be found on the packaging, on the neurostimulator before implant (Figure 49), on the patient ID card, or in patient records after implant.

 Table 15. Operating values for the Model P7850N

 InterStim T Nou ostimulato

Table 16. Physical characteristics of the Model P7850NInterStim T Neurostimulatora

Description	Specification	
Length	43.66 mm	
Thickness	4.53 mm	
Mass	7.43 g	
Volume	2.57 cm ³	
Power source ^b	Medtronic lithium-io battery with Overdri	n rechargeable ve battery technology
Expected lifetime	15 years before reco replacement notifica	ommended ation
Se ia number pret x-	NTI	
Radiopaque identification code	Dnlv.	
Materials and substances to which the patient can be exposed ^d	Titanium alloy, platir liquid silicone rubbe adhesive, Parylene C	num-iridium alloy, er, silicone medical
Transmitter and	Carrier frequency	175 kHz
receiver	Output power	<30 dBµA/m at 10 meters
Wireless technology type	Near-field magnetic communication	inductive
^a All measurements are	approximate.	

^b The power source is hermetically sealed within the case.

Parameter Operating values and ranges

Amplitude0.1 mA to 252 μ2 GULIUITPulse width40 μs to 450 μsRate3 Hz to 130 HzSoftStart/StopOff, On: 1 sec to 30 sec (with options of 1, 2, 4, 8, 15, 30 sec ramp duration)

Table 16. Physical characteristics of the Model P7850N InterStim T Neurostimulator^a

Description	Specification
Height	15.66 mm

^c The serial number is the serial number prefix followed by a number. The clinician app displays the entire number beginning with the serial number prefix.

^d The materials listed are ordered from the most to least amount.

Recharger

Table 17. Electrical, physical, and operating characteristicsfor the Model P720R1 Recharger

	Description	Specification
Not For Hum Spectrum Au	Power source	Internal rechargeable lithium-ion battery with a minimum capacity of 2.2 Ah and a voltage range of 3.2 Volts (V) to 4.1 V
	Operating temperature	5°C to 40°C (41°F to 104°F) ^{a, b}
	Short-term storage temperature	-35°C to 70°C (-31°F to 158°F) ^c
	Long-term storage temperature	Approximately room temperature
	Size (L x W x H,	14.2 cm x 11.7 cm x 2.5 cm
	approximate) Weight, including batteries (approximate)	(5 6 in x 4.6 in x 0.98 in) ^c 363 g (0.80 lb) ^d
	Battery life, normal use	3 years ^e
	Case material	Polycarbonate/ABS blend plastic resin
	^a At the upper range c reach 43°C (109°F).	of operating temperature, the recharger may
	^b A relative humidity ra requiring a water vapo atmospheric pressure	ange of 15% to 90%, non-condensing, but not or partial pressure greater than 50 hPa, and an range of 700 hPa to 1060 hPa.

^c 5°C to 35°C at a relative humidity up to 90%, non-condensing; and greater than 35°C to 70°C at a water vapor pressure up to 50 hPa.

^d Maximum

^e Minimum

Notes:

- Allow 75 minutes for the recharger to warm up before • use if it has been stored at or near the minimum storage temperature.
- Allow 90 minutes for the recharger to cool down before • use if it has been stored at or near the maximum storage temperature.

Recharger dock

Table 18. Electrical, physical, and operating characteristics for the Model CD9000A Recharger dock

	Parameter	Operating values and ranges
e recharger to warm up before at or near the minimum storage e recharger to cool down before at or near the maximum storage	Power source	USB 2.0 cable with external power supply
	Operating temperature	5°C to 40°C (41°F to 104°F) ^a
	Short-term storage temperature	-35°C to 70°C (-31°F to 158°F) ^ь
	Long-term storage temperature	Approximately room temperature
Not For Hum		16 cm x 16 cm x 3 cm (6.3 in x 6.3 in x 1.18 in) ^c
Spectrum Au		2503 0.55 lb)°
	Input	5.0 V to 5.6 V 1.5 A
	Output	4.5 to 5.6V
	Case materials	Polycarbonate/ABS blend plastic resin

^a A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa and an atmospheric pressure range of 700 hPa to 1060 hPa.

^b 5°C to 35°C at a relative humidity up to 90%, non-condensing; and greater than 35°C to 70°C at a water vapor pressure up to 50 hPa.

^c Maximum

Table 19. Dock power adapter^a and USB cable^a

Parameter	Operating values and ranges
Power source	AC mains (Wall outlet)
Operating temperature	5°C to 40°C (41°F to 104°F)
Input	100 V to 240 V ~ 50 to 60 Hz
Output	5.0 V to 5.6 V 1.5 A
USB cable	USB-A to USB Micro

^aThe use of other power adapters or equipment not provided by Medtronic has not been tested for safety and could lead to serious injury or damage to parts of your system.

Ankle band and adjusters

Table 20. Physical characteristics of the Model P742A1Ankle band and adjuster^a

Description	Specification
Adjuster width	2 mm
Materials and substances to which the patient can be exposed ^b	Nylon, spandex, polypropylene, styrene- butadiene rubber, silicone, acetal

^a All measurements are approximate.

^b The materials listed are ordered from the most to least amount.

Ankle band and adjusters

Table 20. Physical characteristics of the Model 747A1 Authority Only.

Description	Specification
Ankle Band length	300 mm
Ankle Band height	76.2 mm
Ankle Band width	3 to 5mm
Adjuster length	152.4 mm
Adjuster height	50.8 mm

Estimating recharge interval

The amount of time before the Model P7850N InterStim T neurostimulator battery requires charging is affected by the following factors:

- Programmed parameters (amplitude, rate, pulse width, duration and frequency of stimulation sessions)
- System impedance
- The degree of patient control over programmable stimulation parameters

Higher stimulation settings will require more frequent recharging sessions. Patients should define a recharge schedule that meets their individual needs while maintaining a charge level that can sustain programmed stimulation settings.

See "Check recharge interval", r age 89 for instructions or UMAN estimating recharge intervals using the clinician app.

Cleaning and care

- Use the system components only as instructed in this guide.
- Handle the recharger with care. Do not drop, strike, or step on the components.
- Do not dismantle or tamper with the recharger and dock.
- Clean the recharger with a damp cloth or sponge. Mild household cleaners or medical cleaners will not damage the device.
 - Clinicians should clean the recharger as needed between uses on different patients. When using the recharger in a clinic, place it outside a barrier or a layer of patient clothing to avoid cross contamination.

The recharger, dock, USB cable, and AC power acceptor are not waterproof. Do not allow moisture to get inside the components.

Spectrum Auth to clean the ankle band remove the recharger. Hand wash

- Avoid machine-washing or cleaning with harsh chemicals, as this can compromise the integrity of the ankle band.
- Additional ankle bands can be ordered from Medtronic. When using the ankle band in a clinic, place it outside a barrier or a layer of patient clothing to avoid cross contamination.

How to contact Medtronic

Medtronic is available to answer any technical or troubleshooting questions you may have about the system components. Contact Medtronic using the phone number below or the information at the end of the manual.

! USA For assistance in US, call Medtronic Technical Services at 1-800-707-0933. Support is available Monday through Friday from 8:00 AM to 5:00 PM (Central Time).

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