

Medtronic

Tibial Neuromodulation Therapy

P7850N

Altaviva™ Neurostimulator Implant Manual

Implant manual

 USA Rx only

Medtronic and Medtronic logo are trademarks of Medtronic. TM* Third-party brands are trademarks of their respective owners.
All other brands are trademarks of a Medtronic company.
For U.S. Patents, see: www.medtronic.com/patents.

Table of contents

Introduction	5
Description	5
Indications	5
Contraindications	5
Patient selection	5
Use in specific populations	5
Lower leg anatomy	6
Package contents	7
Sterilization, packaging, and single use	7
Patient identification card and implant registration form	7
Preparing for the implant procedure	8
Checking battery level of the neurostimulator	8
Procedure supplies	8
Instructions for use	8
Model P7850N Altaviva neurostimulator implant procedure overview	8
Implanting the neurostimulator using the Medtronic Model P71001 pocket dissector	9
Locating the nerve and creating the incision using the pocket dissector	9
Creating a pocket for the neurostimulator using the pocket dissector	13
(Optional) Repositioning the neurostimulator	15
(Optional) Fixating the neurostimulator	15
Closing the incision	15
Post-implant care	15
Model P7850N Altaviva neurostimulator explant, replacement, or disposal	15
Explanting or replacing the neurostimulator	15
Disposing of the neurostimulator	15

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 description, product specifications, product-specific warnings, precautions, and instructions for use, and information about battery longevity and recharge interval.

[USA] The clinical summary in the clinician therapy and programming guide provides information about the clinical study results for the neurostimulation system.

MRI guidelines provide information about any MRI conditions and MRI-specific contraindications, warnings, and precautions for MRI scans with the neurostimulation system. MRI Guidelines for the Altaviva Neurostimulator can be found by searching by neurostimulator model number at www.medtronic.com/mri.

The implant manual provides device description, package contents, product-specific warnings and precautions, instructions for use, and component disposal.

The pocket dissector manual provides device description, package contents, product specifications, product-specific warnings and precautions, instructions for use, and component disposal.

The EMC declaration outlines electromagnetic compatibility, disturbance, and wireless communication details for the recharger system and its interaction with an implanted neurostimulator and programming components.

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

Introduction

This manual provides instruction for clinicians on implanting the Medtronic Model P7850N Altaviva™ neurostimulator using the recommended Model P71001 pocket dissector. Explanting and disposal instruction is also provided.

Read all information in this manual before implanting an Altaviva neurostimulator.

For programming information, imaging techniques, device specifications, and changing recharge speed, refer to the Clinician Therapy and Programming Guide for the Altaviva System at <https://manuals.medtronic.com/>.

For additional instructions for use for the recommended Medtronic Model P71001 pocket dissector, including warnings, cautions, and device specifications, refer to the associated manual found at <https://manuals.medtronic.com/>.

Description

The Medtronic Model P7850N Altaviva neurostimulator is a rechargeable, leadless implantable neurostimulator (INS) that generates electrical pulses and delivers stimulation to the tibial nerve for tibial neuromodulation therapy.

Indications

The Medtronic Altaviva system is indicated for treatment of urge urinary incontinence (UUI) in patients who failed or could not tolerate more conservative treatments.

Contraindications

The Altaviva system is contraindicated for the following patients:

- Poor surgical candidates, including:
 - Patients with skin lesions or compromised skin integrity
 - Patients with a current or recent history of venous insufficiency and/or venous stasis ulcers in the lower leg
 - Patients with anatomical defects or previous surgeries at the implant site which preclude use of the device
- Patients who are not able to operate or receive assistance in operating the system

Patient selection

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



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

- Severe, uncontrolled diabetes
- Clinically significant edema in the lower leg
- Clinically significant peripheral neuropathy, nerve damage, or a neurological condition affecting the lower leg.



Warning: Metal implants: Do not implant the neurostimulator within 5 cm of another metal implant - If the patient has a metal implant within 5 cm proximally or distally from the edge of the neurostimulator in the planned implant location, choose the other leg for implant. If the patient has metal implants within 5 cm of the implant location in both legs, do not implant the neurostimulator. Implanting the neurostimulator within 5 cm of another metal implant may cause recharge heating leading to tissue damage and possible surgical intervention.



Warning: Mechanical obstruction - This therapy is not intended for patients with current and unresolved mechanical obstruction such as caused by benign prostatic hypertrophy, cancer, or urethral stricture.



Warning: Allergic reaction - This therapy is not intended for patients with known allergies to any of the materials in the neurostimulator.

Use in specific populations

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

- Pregnant women
- Patients under the age of 18
- Patients with progressive, systemic neurological disease
- Patients with history of urinary retention

Lower leg anatomy

Warning: Metal implants: Do not implant the neurostimulator within 5 cm of another metal implant - If the patient has a metal implant within 5 cm proximally or distally from the edge of the neurostimulator in the planned implant location, choose the other leg for implant. If the patient has metal implants within 5 cm of the implant location in both legs, do not implant the neurostimulator. Implanting the neurostimulator within 5 cm of another metal implant may cause recharge heating leading to tissue damage and possible surgical intervention.

The tibial nerve runs deep to the gastrocnemius and soleus muscle in the lower leg before exiting below the soleus muscle on the posteromedial aspect of the lower leg with the posterior tibial artery and vein.

In the distal third of the leg, the nerve courses superficially covered by the skin, subcutaneous fat, and deep fascia before passing under the flexor retinaculum and entering the tarsal tunnel posterior to the medial malleolus. Anteriorly it borders the flexor digitorum longus muscle and posterior tibial vasculature, and posteriorly it borders the flexor hallucis longus muscle and the Achilles tendon (Figure 1).

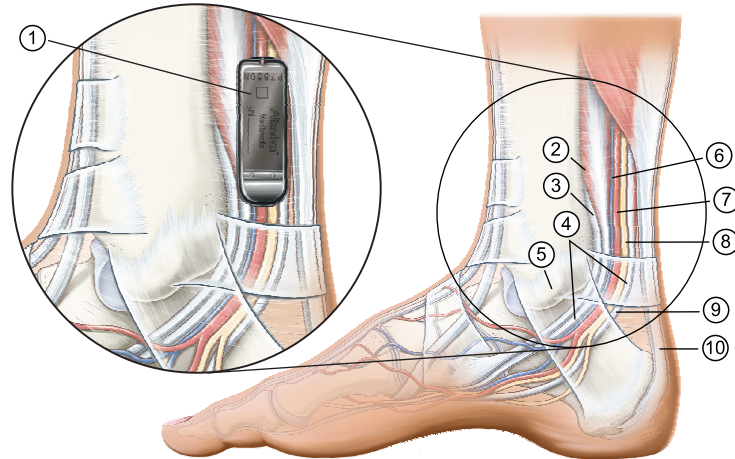


Figure 1. Schematic view of the lower leg anatomy and view of the lower leg with the neurostimulator in place on the deep fascia (not to scale)

- | | |
|---|-----------------------------|
| ① Neurostimulator in place on the deep fascia | ⑥ Posterior tibial vein |
| ② Flexor digitorum longus m. | ⑦ Posterior tibial artery |
| ③ Tibialis posterior m. | ⑧ Tibial nerve |
| ④ Flexor retinaculum | ⑨ Flexor hallucis longus m. |
| ⑤ Medial malleolus | ⑩ Achilles tendon |

The neurostimulator is placed in a pocket created on the deep fascia superior to the medial malleolus and flexor retinaculum and just anterior to the Achilles tendon to avoid contact with the Achilles tendon and medial malleolus (Figure 2).

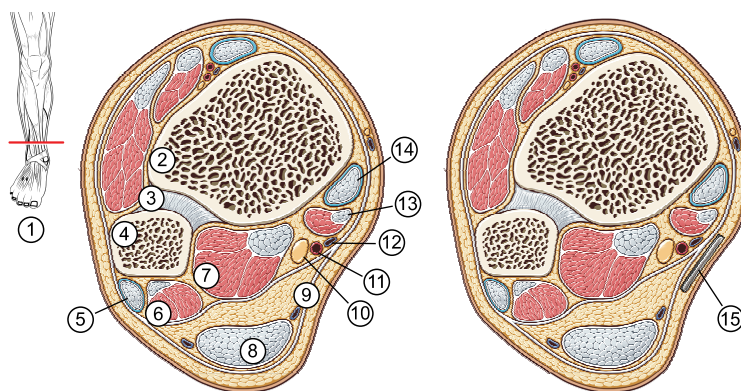


Figure 2. Cross section of the lower leg at the level of the neurostimulator location without and with the neurostimulator (not to scale)

- | | |
|-----------------------------|------------------------------|
| ① Orientation | ⑨ Deep fascia |
| ② Tibia | ⑩ Tibial nerve |
| ③ Interosseous membrane | ⑪ Posterior tibial artery |
| ④ Fibula | ⑫ Posterior tibial vein |
| ⑤ Fibularis longus m. | ⑬ Flexor digitorum longus m. |
| ⑥ Fibularis brevis m. | ⑭ Tibialis posterior m. |
| ⑦ Flexor hallucis longus m. | ⑮ Neurostimulator |
| ⑧ Achilles tendon | |

Package contents

- Neurostimulator
- Product literature, including eManual web reference card and patient identification card
- Registration form

Sterilization, packaging, and single use

Sterilization: Medtronic has sterilized the package contents according to the process indicated on the package label before shipment.

Warning: Component packaging - Visually inspect the sterile packaging for damage that may invalidate device sterility before opening, and inspect the components before use. Do not implant a component if any of the following have occurred:

- The storage package or sterile pack has been pierced or altered because component sterility cannot be guaranteed and infection may occur.
- The component shows signs of damage because the component may not function properly.
- The use-by date has expired because component sterility cannot be guaranteed and infection may occur; also, neurostimulator battery longevity may be reduced and may require early replacement.

Warning: Single use - Do not reuse, reprocess, or resterilize single use products. Reusing, reprocessing, or resterilizing may compromise the functional integrity of the products and may create a risk of contamination, which could result in patient injury, illness, or infection.

Patient identification card and implant registration form

A patient identification card is packaged with this device. Ensure that the completed patient identification card is given to the patient, and advise the patient to carry the card at all times.

USA The patient identification card packaged with the device is temporary; a permanent card will be mailed to the patient when Medtronic receives the registration form.

USA The implant registration form registers the neurostimulator warranty and creates a record of the device in the Medtronic implant data system.

Complete the device tracking and patient registration paperwork and return the documents to Medtronic.

Preparing for the implant procedure

Warning: Do not implant a damaged device, including a neurostimulator that was dropped onto a hard surface from a height of 30 cm (12 in) or more. Burns could result from exposure to battery chemicals. Additionally, a damaged device may fail to operate properly over the service life of the device.

Checking battery level of the neurostimulator

Before opening the sterile package, the battery level of the neurostimulator can be checked and the neurostimulator can be recharged if needed.

For instructions about device connection, checking battery level, and recharging, refer to the "Initial system setup" and "Recharging the neurostimulator" sections of the Clinician Therapy and Programming Guide for the Altaviva System, which can be found at <https://manuals.medtronic.com/>.

Checking battery level or programming require the following items:

- Model P720R1 recharger
- Model CT900F clinician tablet with installed Model P7A2C11 Altaviva clinician application

Procedure supplies

In addition to standard surgical instruments and supplies selected by the clinician, the following items are required:

- Surgical instrument for creating the pocket: Medtronic Model P71001 pocket dissector – sterile, single use – is recommended (Figure 3)
- Sterile marking pen
- 2-0 nonabsorbable suture
- Compression sock of appropriate size

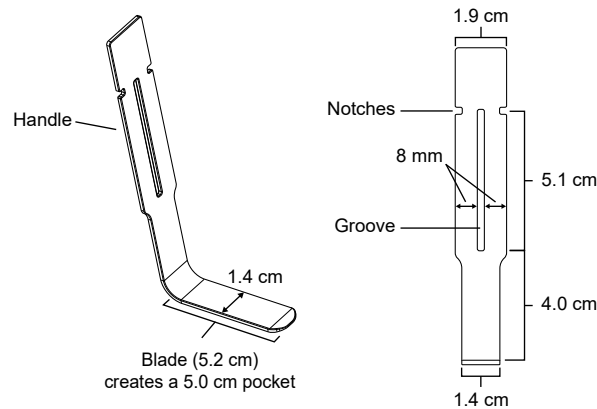


Figure 3. Model P71001 pocket dissector specifications for the implant procedure. (Dimensions are approximate.)

Instructions for use

Model P7850N Altaviva neurostimulator implant procedure overview

Warning: Do not allow the neurostimulator to come into contact with any nonsterile surface. Do not place on skin. If an infection occurs, it may require medical treatment or surgery to remove the implanted device.

1. Position the patient and aseptically prep the leg and foot.
2. Locate medial malleolus and anterior border of the Achilles tendon (Figure 4).
3. Identify the location for the pocket over the tibial nerve and skin incision (Figure 4).
4. Anesthetize the skin and pocket with local anesthetic.
5. Create the incision.
6. Create the pocket for the neurostimulator.
7. Implant the neurostimulator.
8. Close the incision.

Note: Perioperative antibiotic use should be based on the standard of prevailing care for infection prevention and control.

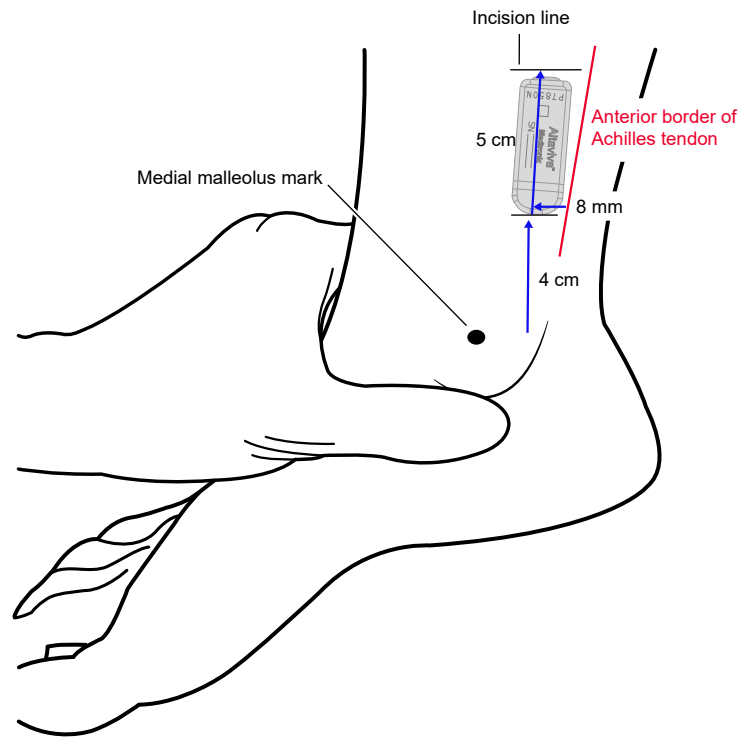


Figure 4. Overview of the implant location

Implanting the neurostimulator using the Medtronic Model P71001 pocket dissector

Locating the nerve and creating the incision using the pocket dissector

Warning: Ensure landmarks and markings are correct. Incorrect landmarking or marking could result in implanting the device in an unintended location or damage to unintended anatomy, such as the Achilles tendon.

1. Position the patient and foot to allow access to the medial aspect of the lower leg.
2. Aseptically prepare and drape the leg and foot.
3. Palpate the medial malleolus on the inside of the ankle. Use a sterile marking pen to mark the midpoint of the medial malleolus (Figure 5).

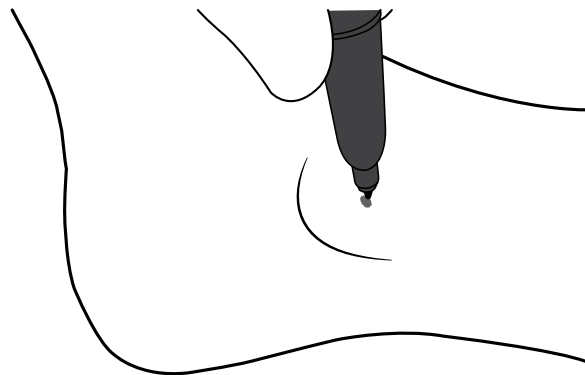


Figure 5. Marking the medial malleolus

4. Locate the Achilles tendon. Mark a line along the length of the anterior border of the Achilles tendon (Figure 6).
Note: Flexing the foot may aid in palpating the anterior border of the Achilles tendon.

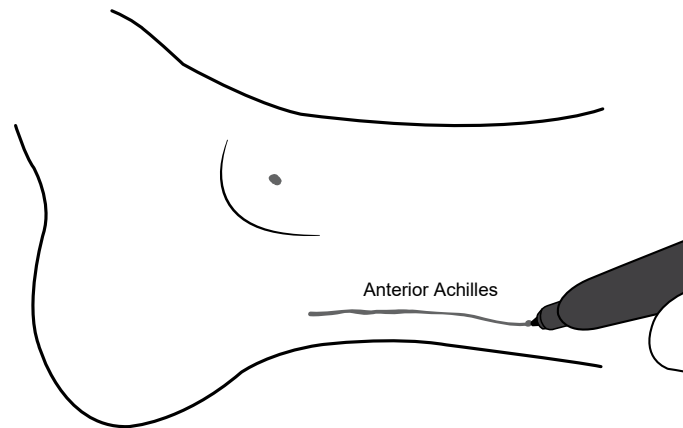


Figure 6. *Marking the anterior border of the Achilles tendon*

5. Place the handle of the pocket dissector flat against the skin and align the edge of the handle along the line of the anterior Achilles tendon (Figure 7).
Note: A dotted line may be drawn between the medial malleolus and the Achilles tendon to aid in lining up the base of the pocket dissector blade (Figure 7).
6. Keeping the handle of the pocket dissector flat against the skin, align the base of the blade level with the mark of the medial malleolus (Figure 7).

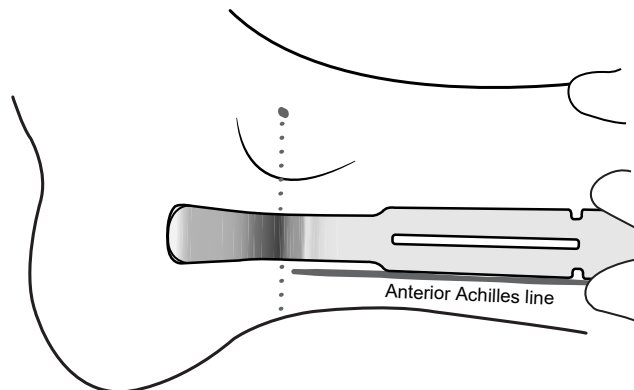


Figure 7. *Aligning the pocket dissector flat against the skin for marking*

Note: Avoid improper placement of the pocket dissector. See examples of improper placement (Figure 8), page 11.

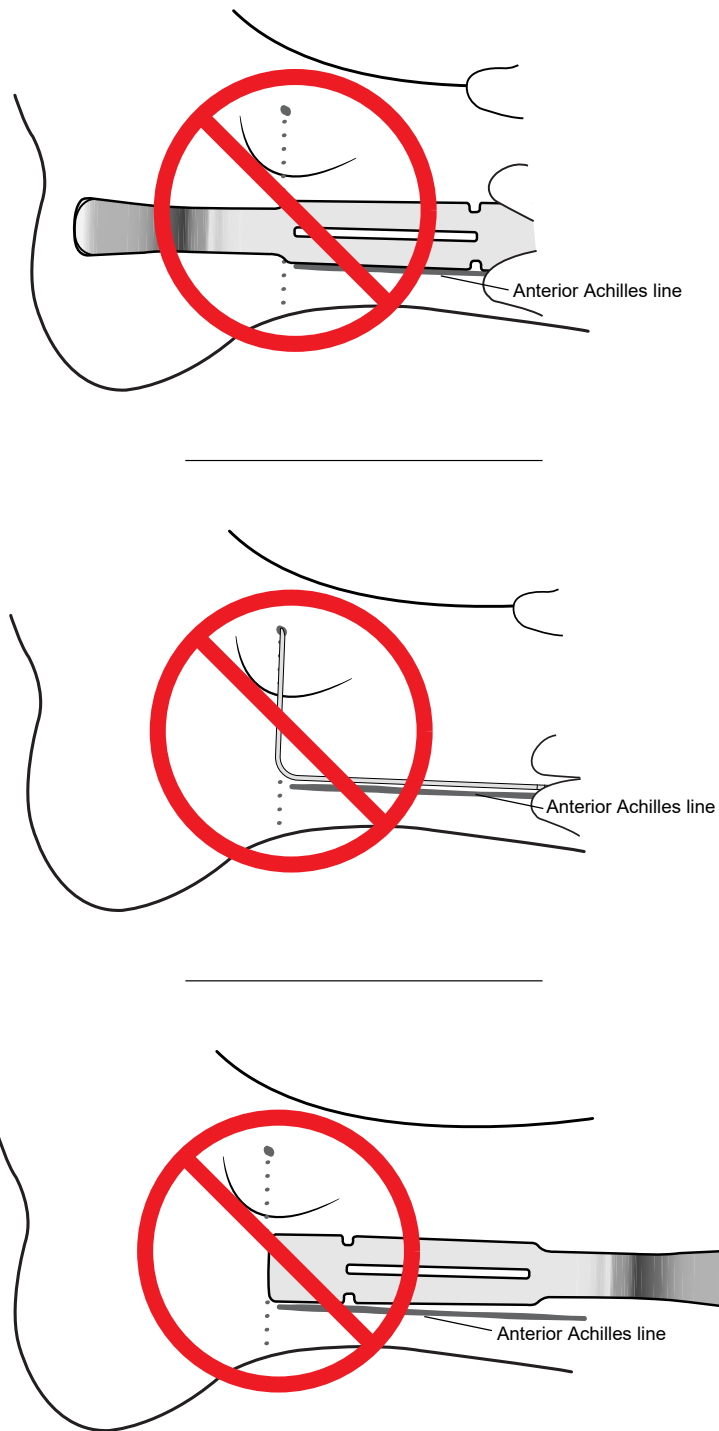


Figure 8. Examples of improper placement of the pocket dissector, leading to incorrect implant location of INS

7. With a sterile marker placed in the groove in the pocket dissector handle, draw a line the length of the groove (Figure 9).
Note: This will be the approximate location of the tibial nerve. The tibial nerve runs anterior and parallel to the Achilles tendon.

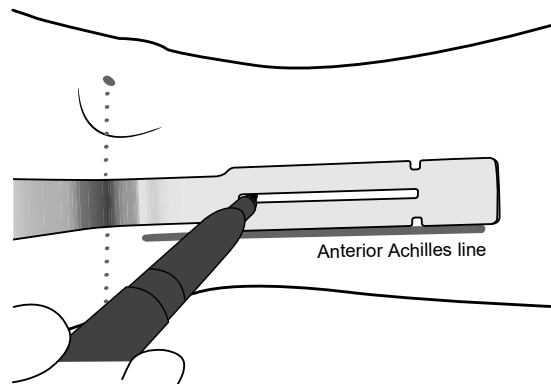


Figure 9. Marking the location of the tibial nerve

8. Make a mark on the skin at each of the notches on the outside of the pocket dissector handle (Figure 10).

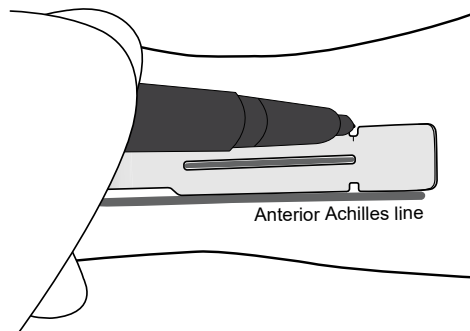


Figure 10. Marking the notches in the pocket dissector handle

9. Remove the pocket dissector and connect the two notch marks from step 8 with a line. This will be the location of the incision and insertion site for the neurostimulator (Figure 11).

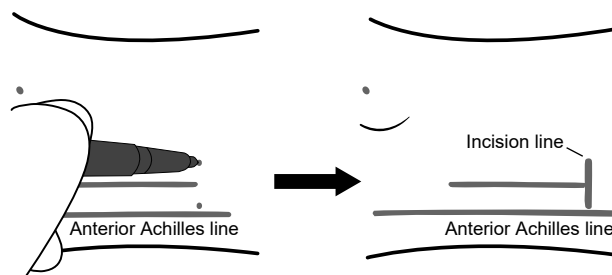


Figure 11. Connecting the marks to create the incision line

10. Administer subcutaneous local anesthetic to the incision site and pocket area.
Note: Do not inject local anesthetic below the fascia. Injecting below the fascia could result in anesthetizing the tibial nerve which may result in delayed post operative programming.
11. Incise the skin along the incision line marked in step 9, avoiding the Achilles tendon.
- Warning:** If cautery (electrocautery) is used to control bleeding, use care to limit tissue trauma. Excessive tissue trauma may lead to poor wound healing, increased risk of infection, and other wound complications such as inflammation that may require medical treatment or additional surgery.

Creating a pocket for the neurostimulator using the pocket dissector

1. Use blunt dissection to dissect down to but not through the deep fascia. The deep fascia is resistant to dissection and looks smooth and fibrous, with a color that ranges from white to pink, compared to the overlying subcutaneous tissue and fat.

Note: The depth of the deep fascia may vary from patient to patient depending on leg size.

Warning: Do not go through the deep fascia when dissecting. Going through the deep fascia could result in damage to the underlying structures or the neurostimulator being placed in the incorrect tissue plane. This may result in device migration requiring additional surgery or difficulty recharging.

2. Insert the blade of the pocket dissector perpendicular to the incision down to the deep fascia.

Caution: Ensure the pocket dissector is on the deep fascia. Failure to insert the pocket dissector down to the deep fascia may result in superficial neurostimulator placement. This may result in discomfort, bruising, or difficulty recharging, requiring additional surgery.

3. With the blade of the pocket dissector against the deep fascia, advance the blade distally along the fascia centered on the line marked in step 7 in "Locating the nerve and creating the incision using the pocket dissector".

Caution: Ensure the fully inserted blade is not over the Achilles tendon. Placing the neurostimulator over the Achilles tendon could result in uncomfortable stimulation or discomfort requiring additional surgery.

4. Continue advancing the blade until the blade is fully inserted, creating a pocket that is 5 cm in length (Figure 12).

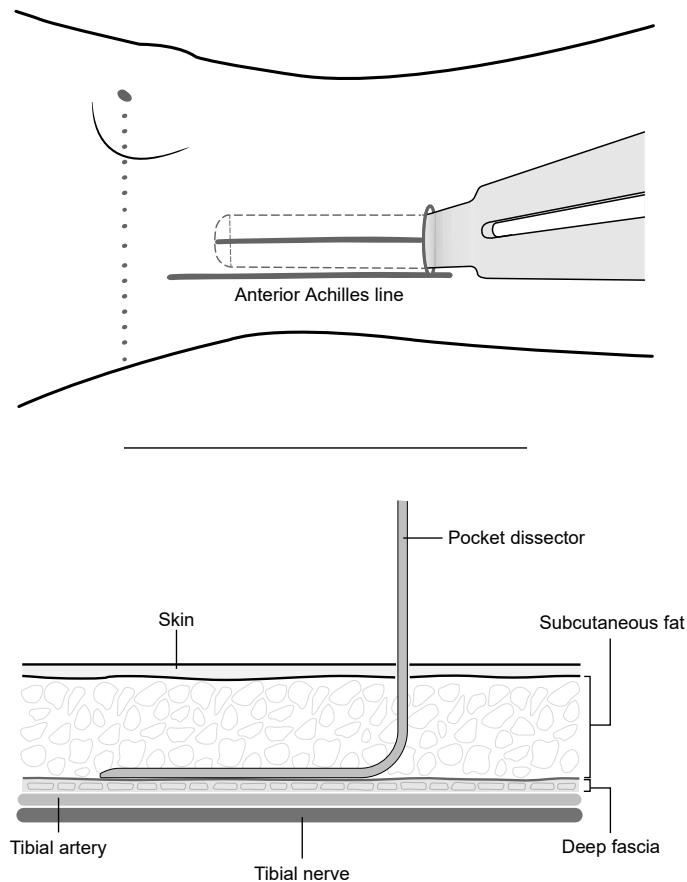


Figure 12. Inserting the pocket dissector to create the neurostimulator pocket

△ **Caution:** Insert the blade as a single pass to the bottom of the line. Do not make the neurostimulator pocket any larger than necessary. Sweeping the blade from side to side while inserting, lifting, or rocking the blade off the deep fascia, or making multiple passes can result in an oversized pocket. An oversized pocket can increase the likelihood of device movement in the pocket and inappropriate stimulation, requiring additional surgery.

5. Remove the blade of the pocket dissector and observe for bleeding from the pocket.

6. Preplace a loop of 2-0 nonabsorbable suture at the proximal end of the neurostimulator by passing the open end of the suture through the suture hole on the INS and leave untied (Figure 13). The suture is used to aid in removing the device from the pocket if repositioning is required, and to optionally secure the INS to the fascia for fixation.

△ **Caution:** To avoid damaging the insulation covering the neurostimulator, do not pass the suture needle through the suture hole. Damaging the insulation could result in inappropriate stimulation that may require additional surgery.

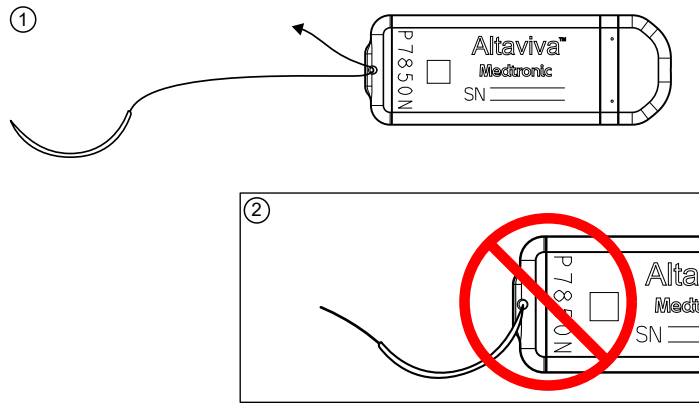


Figure 13. Preplace a loop of suture through the suture hole on the INS.

- ① Pass the open end of the suture through the suture hole. ② Do not pass the needle through the suture hole to pass the suture.

7. With the pocket dissector removed, insert the distal (stimulation electrode) end of the neurostimulator into the pocket with the Medtronic logo facing out towards the skin, and the "NERVE SIDE" logo facing towards the fascia and nerve (Figure 14). Advance the neurostimulator distally until the neurostimulator is not visible under the incision.

Note: "Altaviva™" or "TNM" may appear on the neurostimulator.

△ **Caution:** To avoid damaging the insulation covering the neurostimulator:

- Do not grab the neurostimulator with surgical instruments (such as thumb forceps, hemostats).
- Do not allow the neurostimulator to come in contact with metal instruments while inserting into the pocket (such as the pocket dissector or other metal instruments).

Contact with surgical instruments could damage the insulation covering the neurostimulator, resulting in inappropriate stimulation that may require additional surgery.

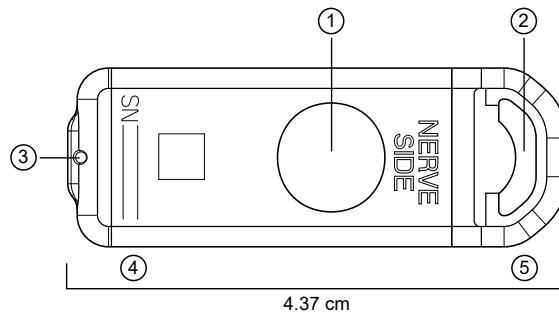


Figure 14. Features of the Model P7850N Altaviva neurostimulator

- ① Return electrode
② Stimulation electrode
③ Suture hole

- ④ Proximal end
⑤ Distal end

(Optional) Repositioning the neurostimulator

1. Pull on the preplaced suture on the INS (step 6 in "Creating a pocket for the neurostimulator using the pocket dissector") to remove the neurostimulator from the pocket.

△ **Caution:** To avoid damaging the insulation covering the neurostimulator, do not grab the neurostimulator with surgical instruments (such as thumb forceps, hemostats). Contact with surgical instruments could damage the insulation covering the neurostimulator, resulting in inappropriate stimulation that may require additional surgery.

2. Use the pocket dissector, inserted against the deep fascia, to adjust the distal end of the pocket for the desired neurostimulator position.
3. With the pocket dissector removed, insert the distal (stimulation electrode) end of the neurostimulator into the new pocket with the Medtronic logo facing out towards the skin, and the "NERVE SIDE" logo facing towards the fascia and nerve. Advance the neurostimulator distally until the neurostimulator is not visible under the incision.

△ **Caution:** Do not allow the neurostimulator to come in contact with metal instruments (such as the pocket dissector or other metal instruments) while repositioning it in the pocket. Contact with surgical instruments could damage the insulation covering the neurostimulator, resulting in inappropriate stimulation that may require additional surgery.

4. Repeat step 1 through step 3 until satisfied with neurostimulator placement.

(Optional) Fixating the neurostimulator

To secure the neurostimulator to the deep fascia using the suture hole and preplaced suture:

1. Tie the previously placed 2-0 nonabsorbable suture to the proximal suture hole on the neurostimulator.
2. Take a shallow bite into the deep fascia with the suture needle and tie, securing the neurostimulator to the deep fascia.

Closing the incision

1. If the preplaced suture was not used to fixate the neurostimulator, remove the suture from the suture hole.
2. Close the incision using a multilayer closure.
3. Apply a sterile dressing over the wound.
4. Apply the appropriately sized compression sock to the leg to minimize swelling and aid in healing. The sock should go above the implanted device and incision to apply compression to the implant site. Compression should be used for the first 72 hours or longer at the surgeon's discretion.

Post-implant care

Advise patients on care of the implant site per your standard of care. Refer to the Clinician Therapy and Programming Guide for the Altaviva System for guidance on use of compression and activity restrictions for proper healing and minimization of device movement.

Model P7850N Altaviva neurostimulator explant, replacement, or disposal

Explanting or replacing the neurostimulator

1. Create a skin incision through the original implant incision or through a new site near the proximal end of the neurostimulator.
2. Dissect down to the neurostimulator and open the tissue encapsulation surrounding the device.
3. Remove the neurostimulator from the pocket.
4. If replacing the neurostimulator, place the new neurostimulator in the existing pocket and proceed with step 6 in "Creating a pocket for the neurostimulator using the pocket dissector".
5. Close the incision using a multilayer closure.
6. Apply a sterile dressing over the wound.

Disposing of the neurostimulator

When disposing of the neurostimulator, follow these guidelines:

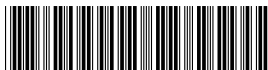
- Make sure patient-identifying information is removed from the device. See the Clinician Therapy and Programming Guide for the Altaviva System for instruction.
- If possible, return explanted neurostimulator with completed paperwork to Medtronic for analysis and disposal.
- To allow for device analysis, do not autoclave devices or expose devices to ultrasonic cleaners.
- Dispose of any components not returned to Medtronic according to local environmental regulations; in some countries, explanting a battery-operated implantable device is mandatory.

△ **Cautions:**

- Follow appropriate biohazard controls for all explanted components or components coming in to contact with bodily fluids.
- Do not incinerate or cremate the neurostimulator because it may explode if subjected to these temperatures.

Medtronic

Manufacturer 
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
Tel. 1-763-505-5000
Toll-free 1-800-328-0810



* M 0 2 8 9 3 0 C 0 0 1 *

© Medtronic 2025
All Rights Reserved
2025-09-16
M028930C001 Rev C



Clinician Therapy and Programming Guide for the Altaviva™ System

Tibial Neuromodulation Therapy

Model P7850N Altaviva Neurostimulator

Model P720R1 Recharger

Model CD9000A Recharger dock

Model P742A1 Ankle band

Model P7A2C11 Altaviva Clinician application version 1.1

Medtronic and Medtronic logo are trademarks of Medtronic.™ Third-party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Medtronic is under license.

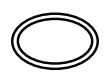
Android™ is a trademark of Google LLC.

Wi-Fi™ is a trademark of Wi-Fi Alliance®.

For U.S. Patents, see: www.medtronic.com/patents.

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.		Follow instructions for use
	Class II Equipment (IEC 60417-5172)		For USA audiences only
	Consult instructions for use		IEC 60601-1/EN60601-1, Type BF Equipment (IEC 60417-5333)
ISO 15223-1 [5.4.3]			Implantable neurostimulator
	Consult electronic instructions for use at this website		Keep dry
ISO 15223-1 [5.4.3]		ISO 15223-1 [5.3.4]	
	Date of manufacture		Lot number
ISO 15223-1 [5.1.3]		ISO 15223-1 [5.1.5]	
	Direct current (IEC 60417-5031)		Manufacturer
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.	ISO 15223-1 [5.1.1]	
2012/19/EU	See http://recycling.medtronic.com for instructions on proper disposal of product.		Magnetic Resonance (MR) Conditional
	Do not resterilize	ASTM F2503 [7.4.6]	
ISO 15223-1 [5.2.6]			Magnetic Resonance (MR) Unsafe
	Do not reuse	ASTM F2503 [7.4.10]	
ISO 15223-1 [5.4.2]			Medical device
	Do not use if package is damaged and consult instructions for use	ISO 15223-1 [5.7.7]	
ISO 15223-1 [5.2.8]			Model number
	Double sterile barrier system	ISO 15223-1 [5.1.10]	
ISO 15223-1 [5.2.12]			Package contents
	Authorized representative in the European Community/ European Union		PIN number
ISO 15223-1 [5.1.2]			Product documentation
			Reorder number
		ISO 15223-1 [5.1.6]	

SN

ISO 15223-1 [5.1.7]

Serial number

STERILE EO

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 (IP21: Protection level against solid foreign objects and falling water) (IEC 60601-1/EN 60601-1).

IP22

This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (IP22: Protection level against solid foreign objects and falling water) (IEC 60601-1/EN 60601-1)

UDI

ISO 15223-1 [5.7.10]

Unique device identifier



ISO 15223-1 [5.1.4]

Use by

Acronyms and definitions

Acronym	Definition
ABS	Acrylonitrile butadiene styrene
AC	Alternating current
ATA	Atmospheres absolute
Ah	Ampere-hour
App	Application
CT or CAT	Computerized axial tomography
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
HIFU	High-intensity focused ultrasound
Hz	Hertz
ID	Identification
INS	Implantable neurostimulator
mA	Milliamps
MEG	Magnetoencephalography
MR	Magnetic resonance
MRI	Magnetic resonance imaging
PC	Polycarbonate
PET	Positron emission tomography
SBR	Styrene-butadiene rubber
sec	Seconds
SN	Serial number
TENS	Transcutaneous electrical nerve stimulation
USB	Universal serial bus
UUI	Urge urinary incontinence
V	Volts
μs	Microseconds

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 description, product specifications, product-specific warnings, precautions, and instructions for use, and information about battery longevity and recharge interval.

! USA The clinical summary in the clinician therapy and programming guide provides information about the clinical study results for the neurostimulation system.

MRI guidelines provide information about any MRI conditions and MRI-specific contraindications, warnings, and precautions for MRI scans with the neurostimulation system. MRI Guidelines for the Altaviva Neurostimulator can be found by searching by neurostimulator model number at www.medtronic.com/mri.

The implant manual provides device description, package contents, product-specific warnings and precautions, instructions for use, and component disposal.

The pocket dissector manual provides device description, package contents, product specifications, product-specific warnings and precautions, instructions for use, and component disposal.

The EMC declaration outlines electromagnetic compatibility, disturbance, and wireless communication details for the recharger system and its interaction with an implanted neurostimulator and programming components.

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

Table of contents

Symbols.....	3
Acronyms and definitions	4
Table of contents	6
Introduction	8
About this guide	8
About Altaviva therapy.....	8
Indications	8
Contraindications	8
Patient selection.....	8
Use in specific populations	9
Warnings.....	9
Precautions	9
Clinician experience.....	11
Individualization of treatment	11
Possible adverse events.....	11
Patient counseling information post implant	11
Patient counseling information post explant	12
MRI information	13
X-ray identification.....	13
About the Altaviva system	14
System description	14
System components and compatibility	15
Model P7850N Altaviva neurostimulator	16
Model P720R1 recharger	16
Model CD9000A recharger dock.....	16
Model P742A1 ankle band	16
Model CT900F clinician tablet and Model P7A2C11 Altaviva clinician	

application	16
Model HH90 patient programmer and Model P7A2P11 Altaviva My	
Therapy application	16
How the system components interact.....	17
How the recharger functions within the system.....	18
Recharger modes	18
Changing recharger modes.....	18
Getting started with the clinician app	19
Accessing the clinician app	19
Icons	19
Navigating the startup screen.....	19
Initial system setup	20
Taking the recharger out of shipping mode	20
Charging the clinician tablet	20
Checking the clinician tablet clock.....	21
Pairing the clinician tablet to the recharger	21
Setting up the patient kit	21
Programming a new neurostimulator.....	22
Connect to the neurostimulator and begin programming	23
Express setup	23
Configure amplitude.....	24
Review and finish setup	25
Custom setup	25
Configure stimulation parameters	26
Configure therapy schedule	27
Configure patient and device information.....	29
Review and finish setup	29
Follow-up status check and programming.....	30
Connect to the neurostimulator and begin follow-up programming.....	30
Navigating the dashboard.....	31

Adjust therapy details	32	Therapy Settings Out of Range alert.....	47
Stop and resume schedule.....	32	Clinician Reset and Recharge workflow	47
End an active stimulation session	33	Troubleshooting during a recharging session	48
Refresh stimulation status.....	33	Recharger recovery mode.....	50
View therapy adherence.....	33	Troubleshooting for therapy (stimulation) issues	50
View recharge details.....	34	Clinician app notifications	51
Recharge interval.....	34	Troubleshooting patient app service codes.....	54
Checking recharge interval	34		
Reports	36	Product specifications	56
View and download reports	36	Neurostimulator.....	56
Viewing system information	38	Recharger	57
Software information	38	Recharger dock.....	57
Data security.....	38	Ankle band and adjusters.....	58
Network connectivity	38	Cleaning and care.....	59
Model A902 Patient Data Service Application.....	39	Return, replacement, and disposal.....	59
System updates.....	39	Recharger and dock disposal	59
Charging the recharger battery	39	Neurostimulator disposal	59
Recharging the neurostimulator	40	Removing identifying patient health information from the INS	59
Checking neurostimulator battery and recharger battery levels.....	40	Appendix A: Continuous stimulation	60
Recharging the neurostimulator before implant.....	41	Appendix B: Clinical study summary	61
Recharging the neurostimulator after implant.....	41	Introduction.....	61
(Optional) Using the ankle band	42	A. Study Design	61
(Optional) Using the ankle band adjusters	42	B. Accountability of PMA Cohort.....	64
View and adjust recharger settings	43	C. Study Population Demographics and Baseline Parameters.....	65
Recharge coupling status.....	43	D. Safety and Effectiveness Results	66
Recharge speed.....	43	References.....	75
Recharger volume	44	How to contact Medtronic	76
Troubleshooting.....	45		
System component and connection issues	45		

Introduction

The Medtronic Model P7A2C11 Altaviva 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 Altaviva 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 Altaviva system, the therapy risks, and programming and recharging the neurostimulator. This guide also includes product specifications and neurostimulator lifetime information.

- 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 Altaviva System*.
- The patient guide along with other patient information are available at www.medtronic.com/patientmanuals.
- To access additional copies of this guide or other information, go to www.manuals.medtronic.com.

Note: For help getting started, view a how-to video at www.medtronic.com/helloAltaviva.

Contact Medtronic to report issues with product documentation.

About Altaviva therapy

Indications

The Medtronic Altaviva system is indicated for treatment of urge urinary incontinence (UUI) in patients who failed or could not tolerate more conservative treatments.

Contraindications

The Altaviva system is contraindicated for the following patients:

- Poor surgical candidates, including:
 - Patients with skin lesions or compromised skin integrity
 - Patients with a current or recent history of venous insufficiency and/or venous stasis ulcers in the lower leg
 - Patients with anatomical defects or previous surgeries at the implant site which preclude use of the device
- Patients who are not able to operate or receive assistance in operating the system

Patient selection

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

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

- Severe, uncontrolled diabetes
- Clinically significant edema in the lower leg
- Clinically significant peripheral neuropathy, nerve damage, or a neurological condition affecting the lower leg

 **Warning: Metal implants: Do not implant the neurostimulator within 5 cm of another metal implant** – If the patient has a metal implant within 5 cm proximally or distally from the edge of the neurostimulator in the planned implant location, choose the other leg for implant. If the patient has metal implants within 5 cm of the implant location in both legs, do not implant the neurostimulator. Implanting the neurostimulator within 5 cm of another metal implant may cause recharge heating leading to tissue damage and possible surgical intervention.

 **Warning: Mechanical obstruction** – This therapy is not intended for patients with current and unresolved mechanical obstruction such as caused by benign prostatic hypertrophy, cancer, or urethral stricture.

 **Warning: Allergic reaction** – This therapy is not intended for patients with known allergies to any of the materials in the neurostimulator.

Use in specific populations

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

- Pregnant women
- Patients under the age of 18
- Patients with progressive, systemic neurological disease
- Patients with history of urinary retention

Warnings

Therapy-level warnings:

Continuous stimulation – Continuous stimulation should not be used as the safety and effectiveness of continuous stimulation of the tibial nerve have not been established.

Bilateral leg stimulation – Safety and effectiveness of bilateral leg stimulation have not been established.

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: Shortwave and microwave – Shortwave diathermy and microwave diathermy are medical treatments that deliver 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 or microwave diathermy on patients implanted with a neurostimulator. Energy from shortwave diathermy or microwave diathermy can be transferred through the implanted device and can cause tissue damage. Shortwave diathermy or microwave diathermy can also damage the neurostimulator, requiring removal.

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

Interaction with implanted cardiac devices – The Altaviva implant may interfere with the operation of the implanted cardiac device (for example, pacemaker, defibrillator). The effect of Altaviva on implanted cardiac devices is unknown. Clinicians should evaluate any potential interference before recommending Altaviva.

Metal implants: Assess proximity to neurostimulator before recharging – No metal implant should be placed within 5 cm of the neurostimulator. If for any reason, such as an accident requiring surgery, metal is implanted near the neurostimulator, the clinician will need to assess proximity of the neurostimulator to the metal implant and counsel the patient regarding recharging risk. Recharging a neurostimulator within 5 cm of a metal implant may cause recharge heating leading to tissue damage.

Contact Medtronic for more information about metal implants in proximity to the neurostimulator.

System component 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.

Precautions

Therapy-level precautions:

Electromagnetic interference (EMI) and therapeutic ultrasound – Certain types of medical equipment generate high levels of electromagnetic energy or therapeutic ultrasound energy, 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
- Electrosurgery

- High-output ultrasound and high-intensity focused ultrasound (HIFU)
- Physiotherapeutic ultrasound, including ultrasound diathermy
- Lithotripsy

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 Altaviva system.

Other medical procedures – EMI from the following medical procedures is unlikely to affect this neurostimulation system. 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

Images may be distorted if scanning near the neurostimulator.

External defibrillation – Application of external defibrillation is unlikely to damage the neurostimulator. Energy from external defibrillation may cause temporary changes in stimulation delivery. After a defibrillation procedure, confirm that the neurostimulator is functioning as intended.

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. Other situations that can result in unexpected stimulation include:

- Daylight saving time or time zone changes – The implant clock will not automatically update for daylight saving time or time zone changes.
- Incorrect time setting on the clinician tablet – 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.

As patients become accustomed to how the system feels and operates, they should be mindful of when stimulation sessions are scheduled. Remind patients to consider limiting activities until they are familiar enough to determine whether stimulation could be distracting or make an activity (for example, driving) dangerous.

System component precautions:

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.

Discomfort during recharge – Turn down the recharge speed if the patient experiences discomfort or changes in stimulation sensations during a recharging session. The recharger may induce heat or stimulation on the implanted neurostimulator, leading to heating or uncomfortable stimulation.

External metal objects and recharge – Do not use the recharger over any external metal object. Using the recharger over any external metal object could cause the metal object to heat up, resulting in heating sensation or tissue damage.

Neurostimulator battery charge level – Inform the patient to check the battery level and recharge the neurostimulator battery when needed. The neurostimulator battery depletes slowly, even when stimulation is off. If the neurostimulator battery level falls too low, the patient will not receive therapy sessions and symptoms will likely return, until the neurostimulator has been recharged.

Neurostimulator battery depleted, therapy remains disabled – If the neurostimulator battery is not recharged, it can become depleted to the point that therapy remains disabled even after the battery is recharged, because the implant clock is no longer accurate. 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). Examples of EMI sources include wireless charging devices (Qi), radio-frequency identification (RFID) systems (such as, access control systems for buildings with ID badges, inventory management in retail, animal and pet ID tag readers), computer monitors, and motorized wheelchairs. 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.

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

Notes:

- For MRI information see “MRI information”, page 13, and the *MRI Guidelines for the Altaviva Neurostimulator*.
- To avoid an unwanted stimulation session during a medical procedure, turn therapy off.

Clinician experience

- **Prescribing clinicians** should be experienced in the diagnosis and treatment of urge urinary incontinence (UUI), and should be familiar with using the Altaviva system. Medtronic will provide required training on programming.
- **Implanting clinicians** should be experienced in general surgical procedures, including perioperative infection control, and should review the procedures described in the Altaviva implant manual before surgery. Medtronic will provide required training on the implant procedure.

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.

Possible adverse events

Altaviva therapy is intended to improve symptoms of UUI to a more manageable level enabling patients to participate in regular activities. Therapy may not relieve symptoms for everyone and is not a cure for UUI.

In addition to the risks normally associated with surgery, the following adverse events may occur with the use of an implanted Altaviva system. Potential adverse events for an implanted Altaviva system will vary from person to person. Some of these potential adverse events may require surgical intervention.

Risks (potential adverse events) related to the Altaviva 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 Altaviva neurostimulator:

- Allergic or immune system reaction

- Lower leg pain or discomfort
- Infection
- Neurostimulator movement or skin erosion at implant site
- Uncomfortable or unintended stimulation or an inappropriate shock sensation
- Adverse change in bowel or urinary function
- Worsening of underlying progressive diseases
- Nerve injury
- Discomfort during recharge (such as heating or uncomfortable stimulation sensations)
- Technical device problems
- Loss of therapeutic effect

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

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

- 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's discretion.

For 4 weeks after the procedure, advise patients of the following:

 **Caution: 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.

For 4 weeks after the procedure, advise patients to also:

- Avoid soaking the incision site (for example, swimming, hot tub, or taking a bath).
- Avoid footwear that may rub or is constrictive around the implant.
- 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.

Additional counseling information for patients:

 **Caution: 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. Other situations that can result in unexpected stimulation include:

- **Daylight saving time or time zone changes** – The implant clock will not automatically update for daylight saving time or time zone changes.
- **Incorrect time setting on the clinician tablet** – 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.

As patients become accustomed to how the system feels and operates, they should be mindful of when stimulation sessions are scheduled. Remind patients to consider limiting activities until they are familiar enough to determine whether stimulation could be distracting or make an activity (for example, driving) dangerous.

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 Altaviva system components to follow-up appointments, and make sure that all system components are charged.
- 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.

Metal implants

Instruct patients to contact their clinician if they receive or plan to receive any metal implant below the knee in the same leg as their neurostimulator, such as a metal pin, screw, or plate. The clinician will need to assess the proximity of the INS to metal.

 **Warning: Metal implants: Assess proximity to neurostimulator before recharging** – No metal implant should be placed within 5 cm of the neurostimulator. If for any reason, such as an accident requiring surgery, metal is implanted near the neurostimulator, the clinician will need to assess proximity of the neurostimulator to the metal implant and counsel the patient regarding recharging risk. Recharging a neurostimulator within 5 cm of a metal implant may cause recharge heating leading to tissue damage.

Contact Medtronic for more information about metal implants in proximity to the neurostimulator..

Scuba diving or hyperbaric chambers

The Altaviva 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

The Altaviva neurostimulator has been tested to a low pressure of 0.42 atmospheres absolute (ATA). Pressures below 0.42 ATA have not been tested and could damage the neurostimulator. Activities such as hiking or mountain climbing at altitudes up to 20,000 feet (approximately 6100 meters) should not affect the Altaviva neurostimulator.

Patient counseling information 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 clinician's 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 explant site.

- Contact their clinician if they notice any unusual signs or symptoms while the explant site is healing such as redness, drainage, swelling, opening of the incision, or fever.

MRI information

MR **Magnetic Resonance (MR) Conditional** – Non-clinical testing has demonstrated that the Model P7850N Altaviva 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 Altaviva 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 medical 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 in the *MRI Guidelines for the Altaviva Neurostimulator* found at www.medtronic.com/mri.

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 Altaviva neurostimulator, the designated characters are NTL.

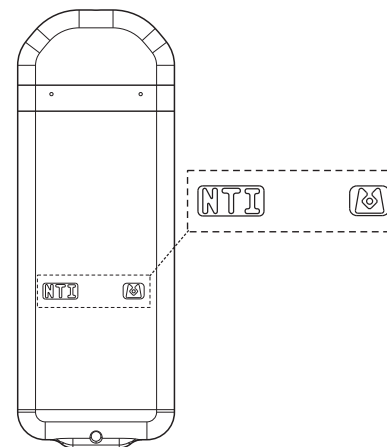


Figure 1. The Model P7850N Altaviva neurostimulator with radiopaque code block (visible with x-ray)

About the Altaviva system

System description

The Altaviva system is a programmable neurostimulation system that delivers electrical stimulation to the tibial nerve for tibial neuromodulation therapy. The Altaviva system includes a leadless neurostimulator, recharger and recharger dock, 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 urge urinary incontinence (UUI) by sending electrical pulses to the tibial nerve. The INS is intended to be programmed by the health care provider including both stimulation parameters and therapy schedules. It also 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

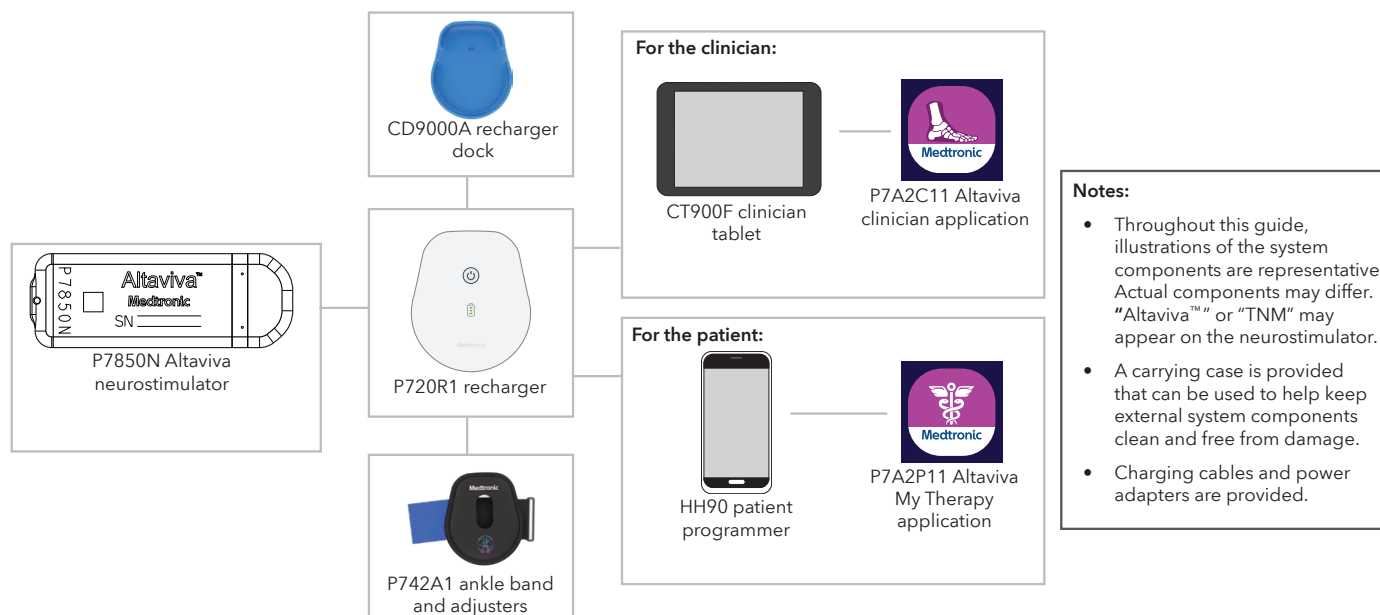


Figure 2. The Altaviva system

Follow these guidelines when selecting system components:

- Medtronic components** - For proper therapy, use only components that are compatible with the Altaviva 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 Altaviva 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 Altaviva 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 Altaviva neurostimulator

The Model P7850N Altaviva 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 tibial neuromodulation 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.

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 clinician kit.

Model P742A1 ankle band

The Model P742A1 ankle band is intended to hold the recharger over the implant for convenience during recharging or programming. Ankle band use is optional. 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 Altaviva clinician application

The Model CT900F clinician tablet, with Android-based operating system, is used in conjunction with the Model P7A2C11 Altaviva clinician application (app) to program the INS and collect system information for tibial neuromodulation therapy. Throughout this guide, “the app” refers to the clinician app, unless stated otherwise.

A tablet quick start guide is also provided, which contains instructions for the initial configuration of the tablet.

Model HH90 patient programmer and Model P7A2P11 Altaviva My Therapy application

The Model HH90 patient programmer is used in conjunction with the Model P7A2P11 Altaviva My Therapy application (app) to allow the patient to make adjustments to stimulation and to obtain system information from the implant.

How the system components interact



Figure 3. How the Altaviva 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 system

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

Recharger modes

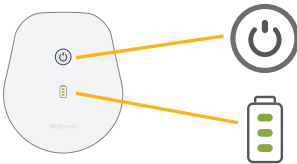
The recharger has 2 operating modes:

- **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:** Press the power button to switch the recharger between modes.
- **Turning off the recharger:** To turn off the recharger, press and hold the power button until the power button light and battery light turn off.

Table 1. Recharger modes

Recharging mode	Communication-only mode
	

Recharging mode	Communication-only mode
In recharging mode, the recharger searches for an implant (spinning green light on the power button with tones, battery light on). When the recharger connects to the implant, the recharger starts recharging the implant (pulsing green light on the power button). 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 button light off, battery light on), you can use the recharger to communicate with the implant without recharging the implant. In communication-only mode, you can use the recharger to program and make adjustments such as changing therapy settings, changing start time, or ending an active stimulation session.

Getting started with the clinician app

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

- Accessing the clinician app (page 19)
- Icons (page 19)
- Navigating the startup screen (page 19)
- Demo mode (page 19)

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 the app is opened, it will request permission(s). Accept all permissions. Tap **OK** to continue. Then tap **ALLOW** on the next message.

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.

Icon	Description
	Home: Tap to return to the Home screen.
	Exit session: Tap to exit the current programming session and return to the startup screen.

Navigating the startup screen

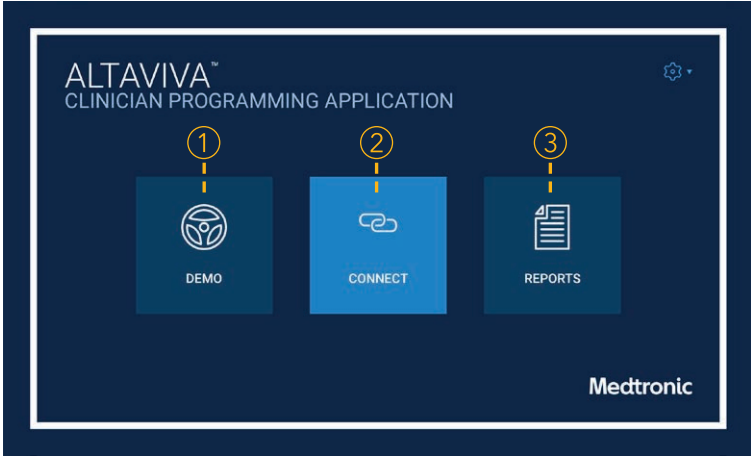


Figure 5. Startup screen

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 20.
- If you have already completed the initial system setup, see the table below for workflow options:

Workflow	Description
Express Setup (page 23)	A basic setup process that allows you to program a new INS with default settings
Custom Setup (page 25)	A step-by-step process that allows you to program a new INS with custom settings
Follow-up (page 30)	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 36, for more information.

Initial system setup

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

- Take the recharger out of shipping mode (page 20).
- Charge the clinician tablet (page 20).
- Check the clinician tablet clock (page 20).
- Pair the clinician tablet to the recharger (page 21).
- Set up the patient kit (page 21).

Taking the recharger out of 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 wall outlet using the USB charging cable and power adapter provided by Medtronic.
2. Place the recharger, blue side facing down, on the plugged-in dock. Do not remove for at least 30 seconds to ensure that the recharger establishes proper connection to the dock.
3. When the recharger is successfully out of shipping mode, it will emit 3 quick tones 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 set up for operation after pairing.

Charging the clinician tablet

Charge the tablet with the USB charging cable and power adapter provided by Medtronic.

Note: Clinician tablet battery percentage is shown in the app About screen, under the Tablet tab.

Checking the clinician tablet clock

Check and correct the time setting on the clinician tablet before connecting to a patient's 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 app, 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 the recharger from the plugged-in dock.
2. Turn on the tablet.
3. Open the Altaviva 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).

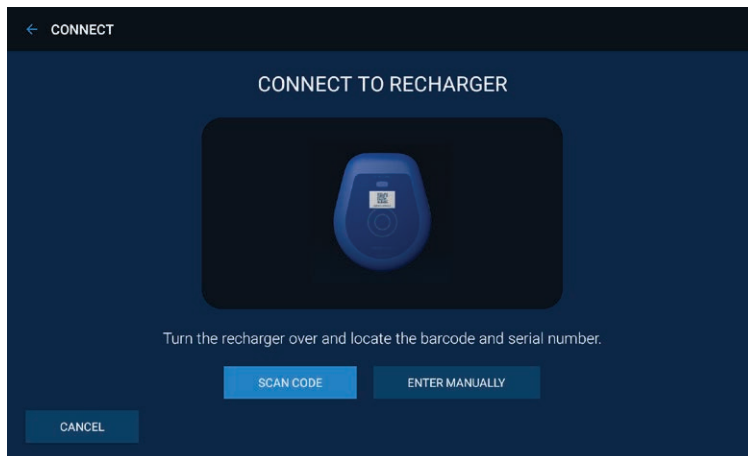


Figure 6. Connect to Recharger screen

6. After the barcode has been scanned or serial number has been entered, the app will attempt to connect to the recharger.
7. Once connected to the recharger, you will see the Search for Altaviva Implant screen (Figure 7), or a list of INSs for you to select from.

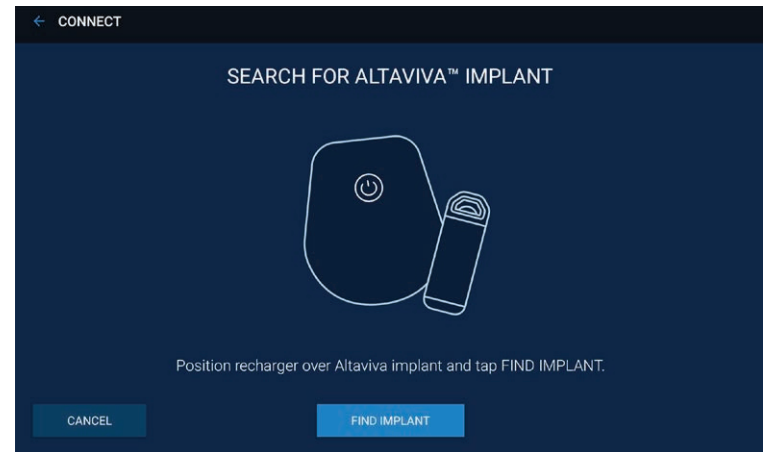


Figure 7. Search for Altaviva Implant screen

8. Continue to "Connect to the neurostimulator and begin programming", page 23, to finish the connection process.

Setting up the patient kit

Before sending the patient home with the Altaviva 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 Altaviva System*.

Programming a new neurostimulator

To program a new INS, you will need to specify the following:

- Stimulation parameters, which determines the strength of the patient's stimulation. Table 3 lists the available stimulation parameter settings and their descriptions.
- Therapy schedule, which determines when stimulation is on and off. Table 4 lists the 2 schedule types and their descriptions.

The TITAN 2 study included options for different schedule parameters. All patients started with a schedule of 30 minutes every other day, and the majority of patients stayed on this schedule through the 12 month visit. The Altaviva system is demonstrated to be safe and effective when scheduled therapy sessions are used.

Continuous stimulation should not be used as the safety and effectiveness of the device were not evaluated for continuous stimulation.

Before each programming session, check the battery level of the tablet and recharger. If charging is needed, see "Charging the clinician tablet", page 20, or "Charging the recharger battery", page 39, 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 21.

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. Stimulation parameter descriptions

Stimulation parameter setting	Description
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 (µs).
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.

Table 4. Therapy schedule descriptions

Therapy schedule type	Description
Scheduled Stimulation	Stimulation is active based on programmed schedule parameters including: • Schedule start date • Repeat cadence • Therapy length • Therapy start time For example, every Monday, Wednesday, and Friday at 9:00 PM starting October 1, 2024.
Continuous stimulation	Continuous stimulation should not be used as the safety and effectiveness were not evaluated in the TITAN 2 study. Refer to "Appendix A: Continuous stimulation" for details.

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 Altaviva clinician app.
3. Tap **CONNECT** on the startup screen.
4. Tap **FIND IMPLANT** (Figure 8).

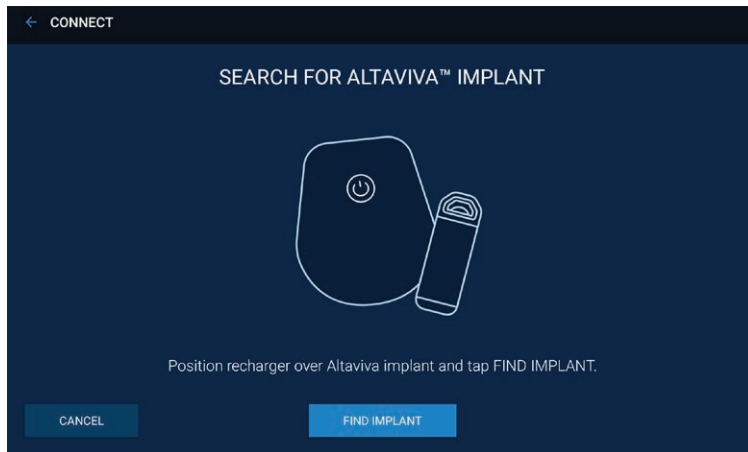


Figure 8. Search for Altaviva Implant screen

5. Select the appropriate INS according to the serial number (found on the patient ID card or patient records) and tap **CONTINUE** (Figure 9). If the neurostimulator serial number is not listed, tap **REFRESH LIST** (🔄).

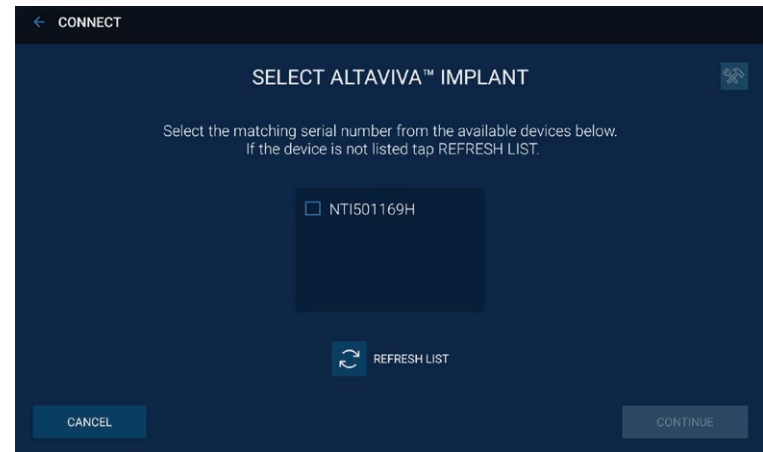


Figure 9. Select Altaviva Implant screen (serial number shown is for example only)

6. Once the app is connected, the Home screen will be displayed (Figure 10).

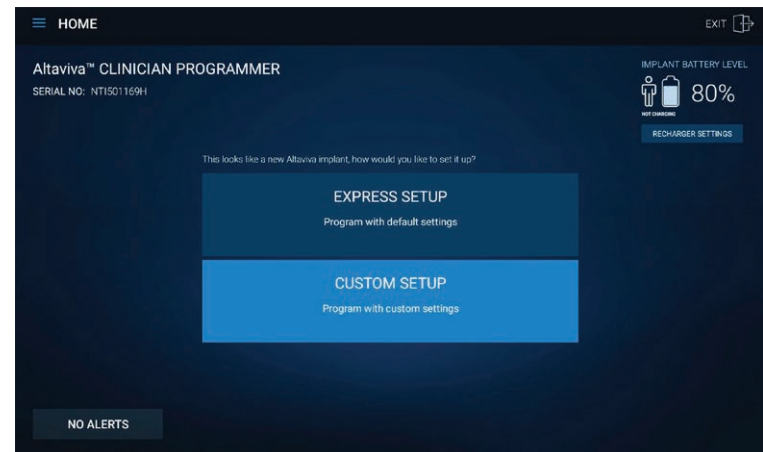


Figure 10. Home screen (serial number shown is for example only)

7. Select the setup workflow you want to use by tapping either **EXPRESS SETUP** or **CUSTOM SETUP**.
 - For **Express Setup**, proceed to page 23.
 - For **Custom Setup**, proceed to page 25.

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 a schedule of Monday, Wednesday, Friday (three 30-minute therapy sessions per week) starting at 9:00 PM. Note that patients can change the schedule therapy start time using their patient app.

Table 5. Default settings

Stimulation parameter	Setting
Amplitude	0.1 mA
Pulse Width	200 μ s
Rate	20 Hz
SoftStart/Stop	On, with a 4 second 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 25, for instructions.

Configure amplitude

1. Adjusting amplitude requires stimulation to be turned on. From the Basic Stimulation screen, tap the up arrow button (Figure 11) to turn on stimulation.

Note: Stimulation is on only while adjusting stimulation parameters. Afterwards, stimulation will be turned off automatically. See Step 8, page 25.

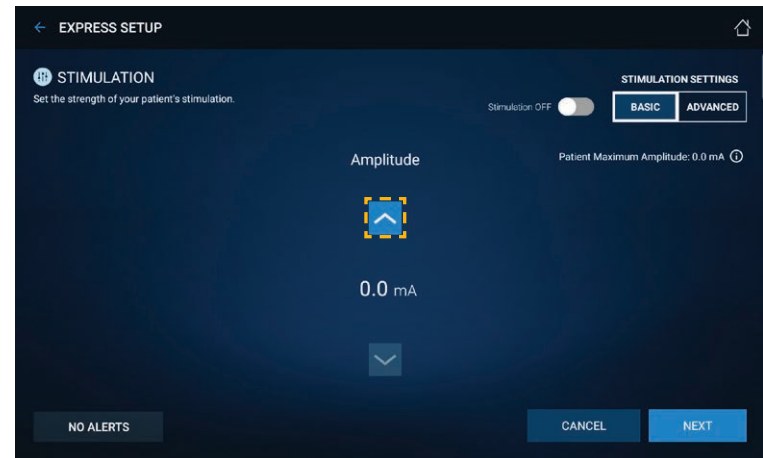


Figure 11. Express Setup: Basic Stimulation screen

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 12).
- Note:** It is important for the time on the clinician tablet clock to be correct 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 12).

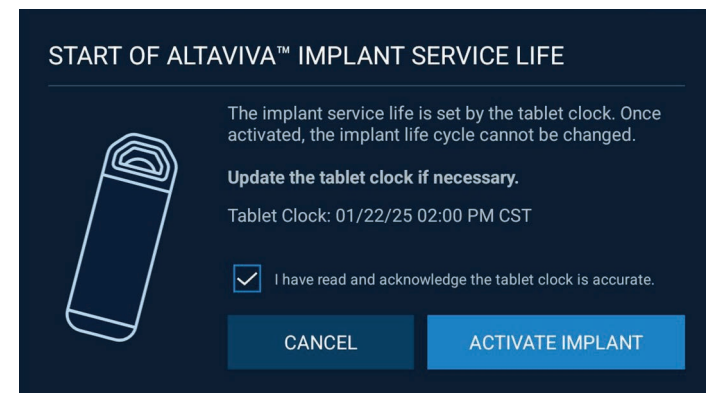


Figure 12. Start of Altaviva Implant Service Life notification

- Use the arrow buttons to set the amplitude (Figure 13). 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.

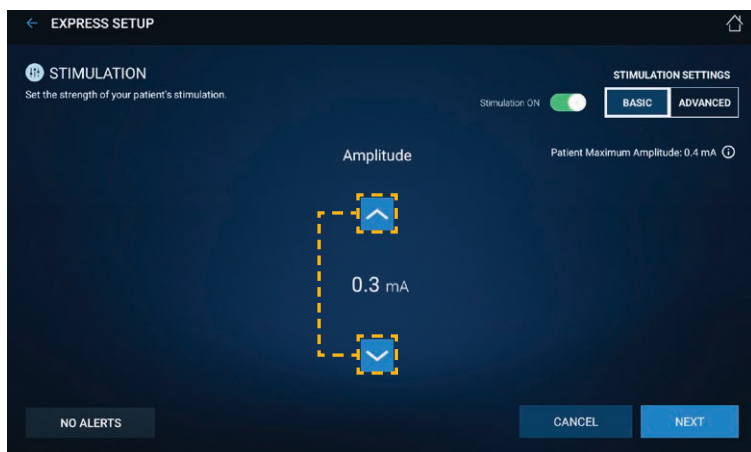


Figure 13. Express Setup: Basic Stimulation screen

- 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 responses	Sensory responses
Tibial	Observed as flexion, fanning, or movement of the toes or foot	Described as tingling, tapping, buzzing, pressure, pulsing, numbness, or similar sensations in the sole, heel, toes, or lower leg

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

Note: The amplitude is automatically saved to the neurostimulator.
- A confirmation notification will appear. Tap **OK** to continue to the Review and Finish Setup screen. Stimulation will be turned off until the next scheduled therapy session.

Review and finish setup

The Review and Finish Setup screen (Figure 14) allows you to review the default settings and amplitude entered.

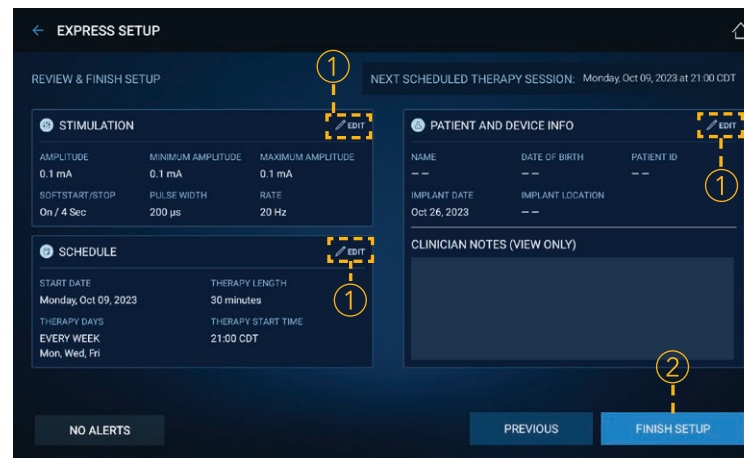


Figure 14. Express Setup: Review and Finish Setup screen

- If adjustments are needed, tap **EDIT** (Figure 14-①) 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.
- Make the adjustments needed on the appropriate screen(s) and navigate back to the Review and Finish Setup screen using the **NEXT** buttons.
- To complete the programming session, tap **FINISH SETUP** Figure 14-②).
- A confirmation notification will appear. Tap **OK**.
- After the setup process is complete, you will return to the Home screen which will now display a dashboard.
- 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 turned on. From the Basic Stimulation screen, tap the up arrow button (Figure 15) to turn on stimulation.

Note: Stimulation is on only while adjusting stimulation parameters. Afterwards, stimulation will be turned off automatically. See Step 10, page 27.

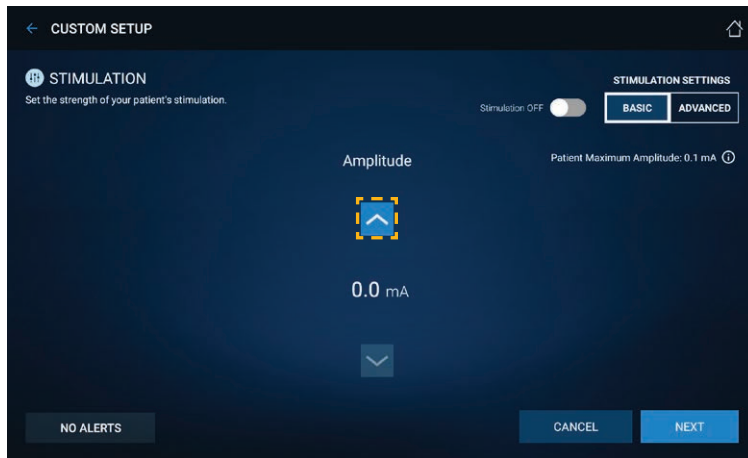


Figure 15. Custom Setup: Basic Stimulation screen

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 16).
- Note:** It is important for the time on the clinician tablet clock to be correct 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 16).

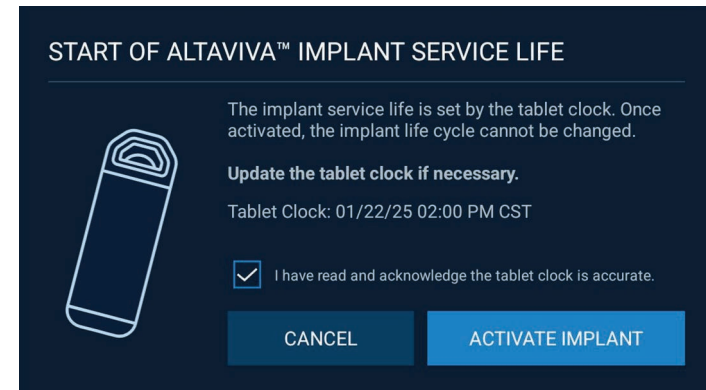


Figure 16. Start of Altaviva Implant Service Life notification

5. Use the arrow buttons to set the amplitude (Figure 17). 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.

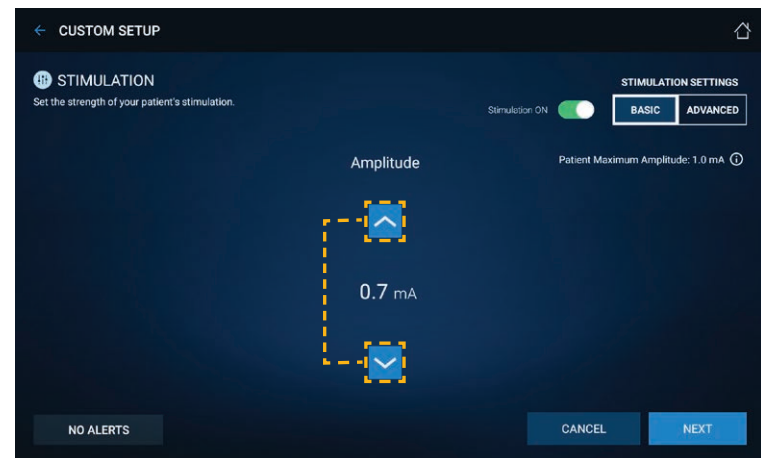


Figure 17. Custom Setup: Basic Stimulation screen

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 7). 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 7. Common motor and sensory responses to tibial neurostimulation

Nerve	Motor responses	Sensory responses
Tibial	Observed as flexion, fanning, or movement of the toes or foot	Described as tingling, tapping, buzzing, pressure, pulsing, numbness, or similar sensations in the sole, heel, toes, or lower leg

7. For more settings, tap **ADVANCED** (Figure 18).



Figure 18. 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 confirmation 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” or “Custom” 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

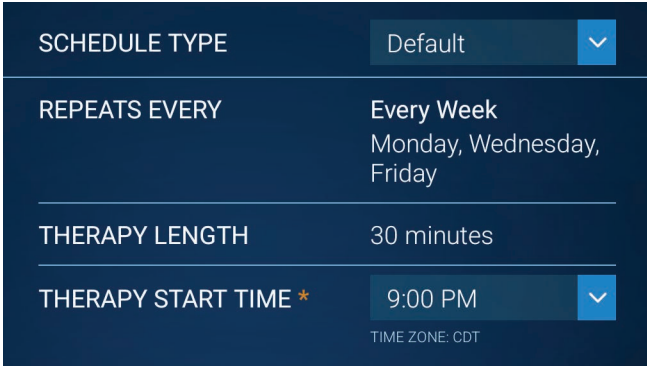


Figure 19. “Default” Schedule screen

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

With “Custom” selected as the schedule type (Figure 20-①), you can fully customize and configure the following parameters:

- Start Date, Figure 20-②
- Repetition, Figure 20-③. For example, you could set stimulation sessions to repeat every 1 day (Figure 21) or Monday, Thursday, Friday every 2 weeks (Figure 22)

- Days of the Week, Figure 20-④
- Therapy Length, Figure 20-⑥
- Therapy Start Time, Figure 20-⑦

Figure 20. "Custom" Schedule screen

After making your selections, you can preview the schedule by tapping **PREVIEW CURRENT SCHEDULE** (Figure 20-⑤). Tap **NEXT** to continue.

Figure 21. Sample Custom Schedule – Daily

Figure 22. Sample Custom Schedule – Weekly

(Optional) Maintenance schedule

The custom schedule type also includes an option to configure a second schedule for the patient (Figure 20). The first schedule that you create is referred to as the **CURRENT** schedule. The second (optional) schedule is the **MAINTENANCE** schedule.

The TITAN 2 study did not include the **MAINTENANCE** schedule feature. Accordingly, the safety and effectiveness of automatic changes to length and frequency of stimulation sessions have not been evaluated.

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.

The **MAINTENANCE** schedule is intended to support patient convenience when changes to session start time or day of week are desired. For example, this may be desired to support patients who will have a shift in their routine such as a seasonal change to work, daily activities, or place of residence.

To add a maintenance schedule:

1. From the Schedule screen, tap **MAINTENANCE** (+) to open a new schedule form.
2. Set the schedule parameters for the **MAINTENANCE** schedule. 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 **NEXT** 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 23).

Figure 23. View CURRENT and MAINTENANCE schedule details

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** (Figure 25-①) found in the upper right-hand corner of each panel.
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 25-②).
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.

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 programmed. If you have not programmed the INS, see page 22 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 Altaviva clinician app.
3. Tap **CONNECT** on the startup screen.
4. Tap **FIND IMPLANT** (Figure 26).

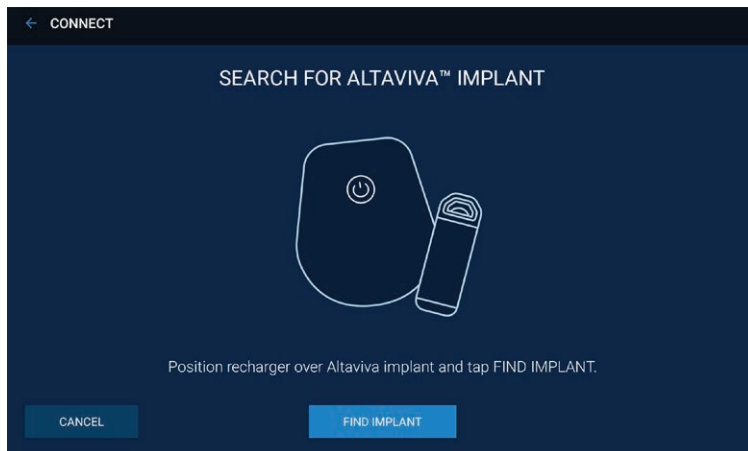


Figure 26. Search for Altaviva implant screen

5. Select the appropriate INS according to the serial number (on the patient ID card or in patient records) and tap **CONTINUE** (Figure 27). If the neurostimulator serial number is not listed, tap **REFRESH LIST** (↻).

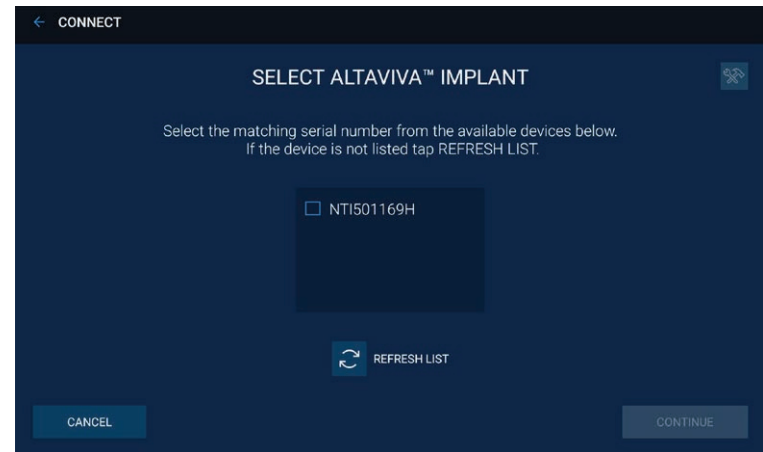


Figure 27. Select Altaviva Implant screen (serial number shown is for example only)

6. Once the app is connected to the INS, the dashboard will be displayed (Figure 29).

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 **5 minutes or less** 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 **more than 5 minutes** between the clinician tablet and the INS, a notification will appear alerting you to the discrepancy (Figure 28).

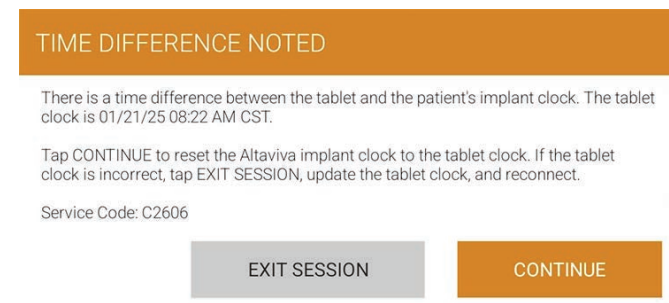


Figure 28. Time Difference Noted notification

Navigating the dashboard



Figure 29. 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 do the following:

- ① Edit patient and device information (page 29).
- ② Adjust programmed stimulation settings (page 32).
- ③ Adjust programmed therapy schedule (page 32).
- ④ Stop or resume a patient's therapy schedule (page 36).
- ⑤ Refresh stimulation status (page 33).
- ⑥ View therapy adherence details (page 33).
- ⑦ End an active stimulation session (page 33).
- ⑧ Download usage data (page 33).
- ⑨ View and adjust recharger settings (page 43).
- ⑩ View recharge details (page 34).
- ⑪ Check recharge interval (page 34).
- ⑫ Exit session and return to startup screen.

Adjust therapy details

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



Figure 30. Therapy Details: Stimulation and Schedule panels

To adjust programmed stimulation settings:

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

Notes:

- Adjusting stimulation parameters requires that stimulation be turned on.
 - Stimulation may be on or off depending on the schedule setting. If you turned it on to adjust stimulation parameters, upon exiting the Stimulation Edit screen, stimulation will be automatically turned off until the next scheduled therapy session.
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.
2. Adjust settings as needed.
3. Tap **SAVE** to save the changes and return to the dashboard.

Stop and resume schedule

The **STOP SCHEDULE** button allows you to stop the therapy schedule for a patient until it is re-enabled by you or your patient. Stopping the patient’s schedule will stop the current session and all future scheduled sessions.

To stop your patient’s schedule:

1. On the dashboard, tap **STOP SCHEDULE** (Figure 31).

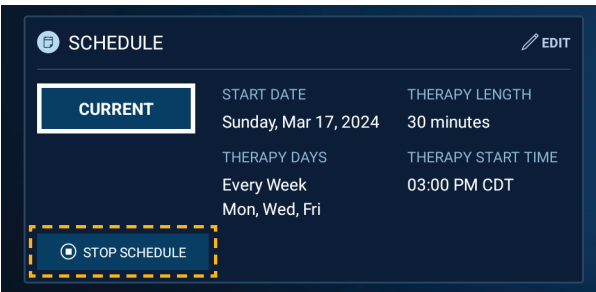


Figure 31. STOP SCHEDULE button located on dashboard

2. Follow the instructions provided on the screen.
3. The dashboard will be updated to indicate that the schedule is stopped (Figure 32).



Figure 32. Schedule panel 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.
3. The dashboard will be updated to indicate the next scheduled therapy session.

End an active stimulation session

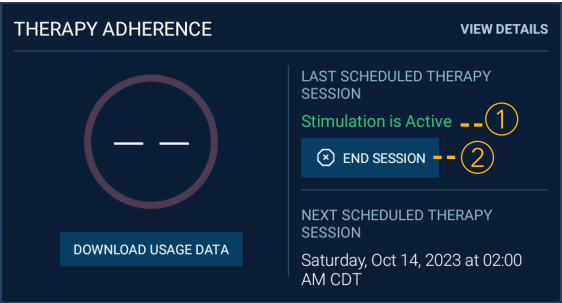


Figure 33. Therapy Adherence panel when stimulation is active

During an active session, the dashboard will show “Stimulation is Active” in the Therapy Adherence panel (Figure 33 -①).

To end an active stimulation session:

- Tap **END SESSION** on the Therapy Adherence panel (Figure 33 -②).

Notes:

- When stimulation is active, the dashboard will also show a green active indicator on the Stimulation panel (Figure 34).

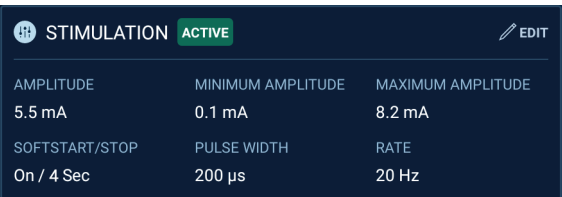


Figure 34. Stimulation panel when stimulation is active

- Turning the Stimulation toggle off does not end the current scheduled stimulation session.

Refresh stimulation status

The clinician app displays the last known stimulation status of the neurostimulator. Refresh to see the most current stimulation status (Figure 29-⑤).

View therapy adherence

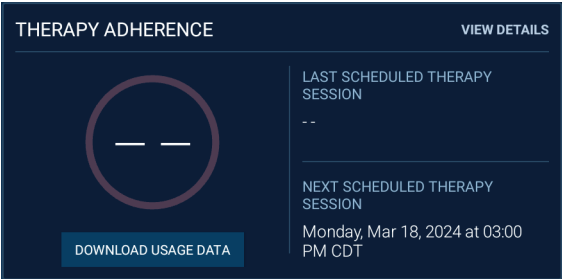


Figure 35. Therapy Adherence panel before data is downloaded

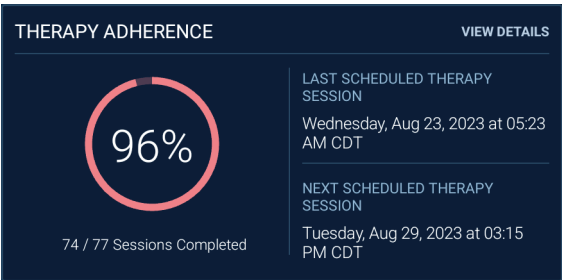


Figure 36. Therapy Adherence panel after data is downloaded

On the dashboard, the Therapy Adherence panel (Figure 36) shows information about therapy adherence (as a percentage determined by the number of sessions fully completed/total number of sessions initiated) over the last 6 months.

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.

To display therapy adherence information on the dashboard:

- Tap **DOWNLOAD USAGE DATA** on the Therapy Adherence panel (Figure 35) to display data (Figure 36).
- Tap **VIEW DETAILS** to open the Therapy History screen to see more detailed information

Once data is downloaded, it will be included in the session report. For more information about therapy reports, see page 36.

The Therapy History screen (Figure 37) 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)

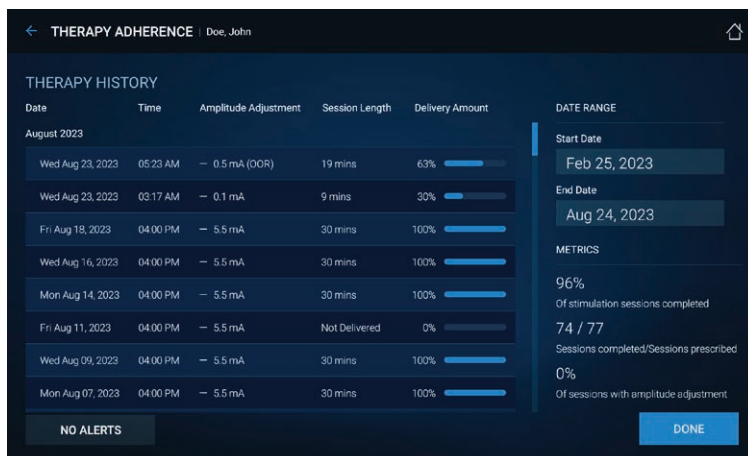


Figure 37. Therapy History screen

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 “System component and connection issues”, page 45, for more information.

View recharge details

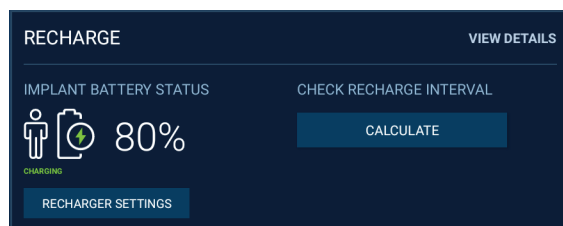


Figure 38. Usage Insights: Recharge panel

On the dashboard, the Recharge panel displays the current neurostimulator battery level and charging status (Figure 38). To see more details about recharge, tap **VIEW DETAILS** to open the Recharge Details screen (Figure 39).

The Recharge Details graph displays the following information for the last 10 recharging sessions:

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



Figure 39. Recharge Details screen

A summary of the metrics is also provided on the right side of the screen. This information can be used to assess and guide the patient on the future recharging needs and coupling status, if needed.

Recharge interval

The recharge interval is the time it takes a fully charged INS to reach a critically low battery level. The amount of time before the neurostimulator battery requires charging is affected by the following factors:

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

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

Checking recharge interval

From the dashboard, you can check how the current programmed settings will affect the recharge interval.

The recharge interval calculation will provide 2 calculation measurements; the first shows the “suggested recharge frequency” for your patient, the second shows the estimated interval from a fully-charged battery to a fully-discharged battery (Figure 42).

To guide your patient on how frequently to recharge their INS, encourage good recharge habits, and help avoid therapy disruptions, use the “suggested recharge frequency” on the recharge interval results (Figure 42).

To check recharge interval:

- 1. Tap **CALCULATE** found in the Recharge panel on the dashboard screen (Figure 40) to open the Recharge Interval screen.

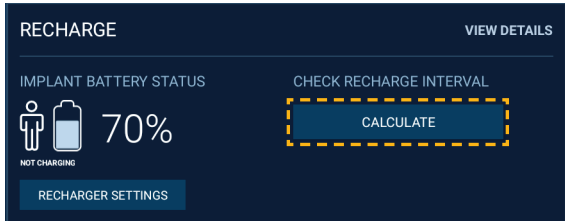


Figure 40. Recharge interval CALCULATE button

- 2. Tap **CALCULATE** on the Recharge Interval screen (Figure 41).

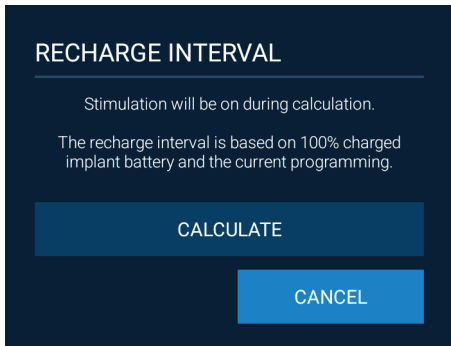


Figure 41. Recharge Interval screen

- 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 42).

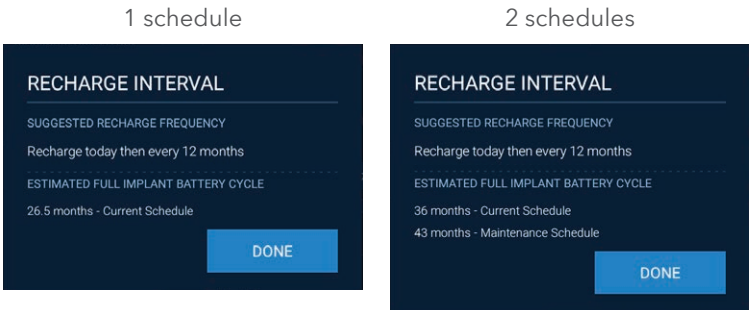


Figure 42. Recharge interval results for 1 or 2 schedules (examples)

- 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.
- 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 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 8 shows some suggested recharge intervals for a set of sample battery cycle times (the time it takes a fully charged implant battery to reach a low state that cannot support stimulation).

Table 8. Recharge interval suggestions

Battery cycle times	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 months or more	12 months

Reports

A therapy report is automatically generated each time you finish a programming session. All reports include patient and device information, stimulation and schedule settings, and impedance measurement (if taken).

Additional information is available in the report if you download data before exiting the programming session. You must download data to review the following:

- Therapy Adherence
- Battery Transitions
- System Events
- Therapy History
- Recharge Summary

Access therapy reports from the Reports screen (Figure 43).

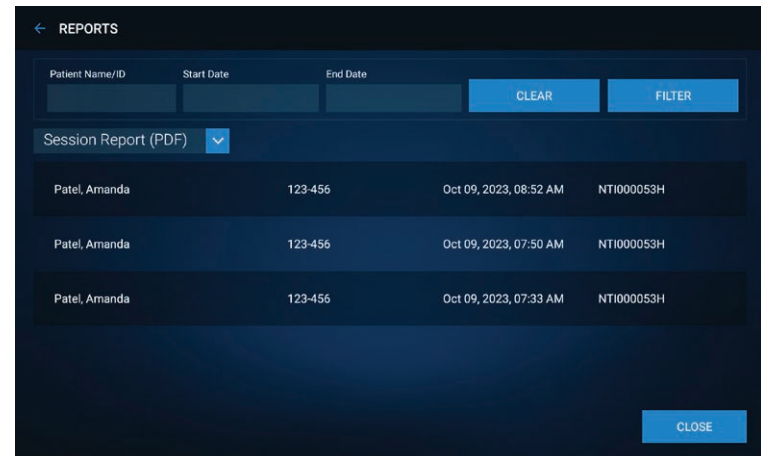


Figure 43. Reports screen

View and download reports

1. From the startup screen, tap **REPORTS** (Figure 44).

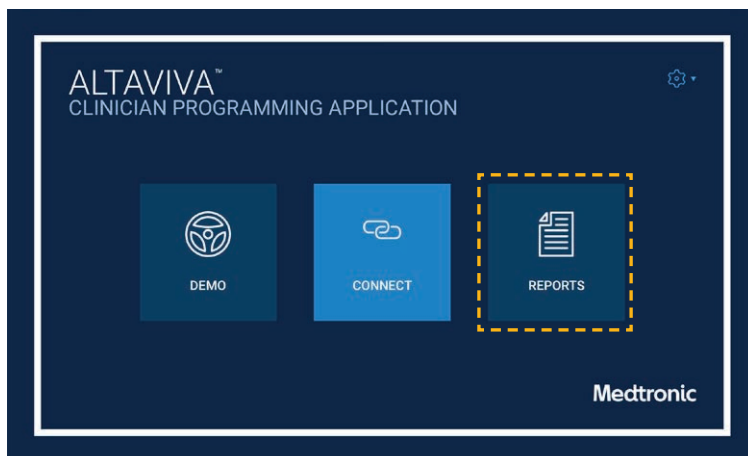


Figure 44. Reports button

2. (Optional) Filter reports using patient name/ID or a date range (Figure 45-①).

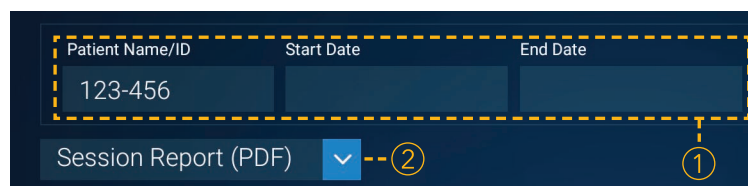


Figure 45. Options to filter located on the Reports screen

- 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 45-②).
4. Find and tap the desired report from the scrollable list. The most recent report appears at the top.
5. Tap one of the buttons shown in Table 9.

Table 9. Report icons and descriptions

Icon	Description
	View – to view the report. 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. This action takes you out of the clinician app. The app runs in the background and your session data remains intact.
	Download – to download and save the report on the clinician tablet. This action saves the report file in the default reports folder on the clinician tablet. Note: A notification will confirm download is complete and the file location on the clinician tablet.
	Delete – to delete the report.

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

Software 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.

Network connectivity

Network connectivity is required for initial app registration and for installation of Medtronic app 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. To avoid delays in programming, plan for updates accordingly.

Notes: 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 tablet is lost or stolen, contact Medtronic using the contact information listed at the end of this guide.

If more details are needed about the system software, hardware, or firmware (such as a Software Bill of Materials), contact Medtronic.

Model A902 Patient Data Service Application

The Model A902 Patient Data Service app works with the Model P7A2C11 Altaviva clinician app to store patient and therapy device records that are used when generating a report. You do not need to open or use the Patient Data Service app.

System updates

If system updates are necessary, you will be notified and provided with instructions.

Charging the recharger battery

If you have not set up the recharger for the first time, see “Taking the recharger out of shipping mode”, page 20.

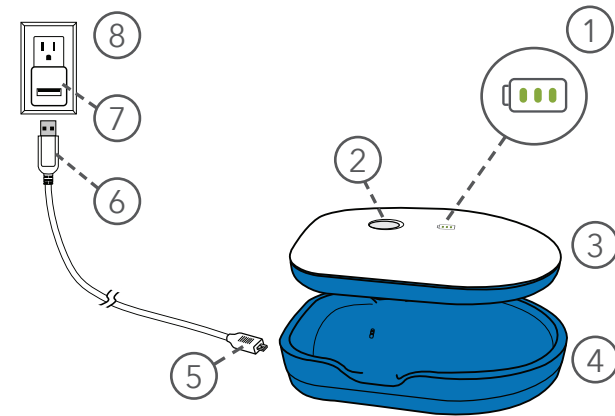


Figure 46. Charging the recharger battery

- | | |
|-----------------|-----------------------------|
| ① Battery light | ⑤ USB cable (micro-USB end) |
| ② Power button | ⑥ USB cable (USB-A end) |
| ③ Recharger | ⑦ Power adapter |
| ④ Dock | ⑧ Wall outlet (example) |

1. Plug in the dock to a wall outlet using the USB charging cable and power adapter provided by Medtronic. The dock must rest on a flat surface while plugged in.
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 facing down, on the plugged-in dock. Do not remove for at least 30 seconds to ensure that the recharger establishes proper connection to the dock.
Note: When the recharger is charging on the dock, it cannot recharge an INS.
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 (①).

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 40)
- Recharging the neurostimulator before implant (page 41) and after implant (page 41)
- Viewing and adjusting recharger settings (page 43)

Notes:

- Before you can recharge the neurostimulator, the tablet must be paired to the recharger. See “Pairing the clinician tablet to the recharger”, page 21.
- Once paired, you do not need the clinician tablet to recharge any Altaviva neurostimulator. You can use the recharger on its own.

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 level is on the Recharge panel. Tap **RECHARGER SETTINGS** to check recharger battery level.

Table 10 shows the neurostimulator battery icons and their associated meanings.

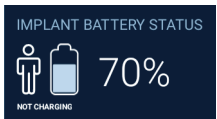
Table 10. Neurostimulator battery level displays

Percent Charged	Implant Battery Level
40% to 100% 	Implant Battery Level: OK
20% to 30% 	Implant Battery Level: LOW Recharge the implant.
0% to 10% 	Implant Battery Level: CRITICAL Recharge the implant. A programming session may be interrupted due to critically low battery level.

Note: Therapy may stop due to critically low battery level. In this case, you will need to connect to the patient's implant and update the implant clock to resume therapy.

When the neurostimulator battery is recharging, the display will show a lightning bolt symbol on top of the battery icon (Table 11.)

Table 11. Charging status of the neurostimulator battery

Recharging	Not Recharging
	

Note: During a recharging session, an orange indicator with an exclamation mark shows that the recharger position needs attention (⚠). See "Recharge coupling status", page 43 for details.

Recharging the neurostimulator before implant

The INS battery level prior to implant is available through connecting to the app. See the upper right-hand corner of the Home screen (Figure 10).

The target graphic (⊕) on the neurostimulator package indicates that the neurostimulator can be recharged and interrogated through the packaging.

To recharge the neurostimulator before implant:

1. Remove the recharger from the plugged-in dock.
2. 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 (⊕).
3. To start recharge, press the power button (⏻) on the recharger.
4. As the recharger searches for the neurostimulator, you will hear a repeating searching tone and the green light on the power button will spin (⦿).
5. When the recharger has found and connected to the neurostimulator, you will hear 2 tones rising in pitch and the power button will be solid green (●).
6. Once connected, the recharger will automatically begin recharging. While recharging is in progress, the recharger will show a slow pulsing green light (⦿).

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.

7. When recharging is complete, a series of tones rising in pitch will sound and the power button light will change to solid green (●).
8. Turn off the recharger by pressing and holding the power button.

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 searches for the INS, you will hear a repeating searching tone and the green light 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 42, for instructions.
When using the recharger in a clinic, place it outside a layer of patient clothing or a barrier to avoid cross contamination.
3. When the recharger has found and connected to the neurostimulator, you will hear 2 tones rising in pitch and the power button will be solid green (●).
4. Once connected, the recharger will automatically begin recharging. While recharging is in progress, the recharger will show a slow pulsing green light (⦿).

⚠ Caution: Discomfort during recharge – Turn down the recharge speed if the patient experiences discomfort or changes in stimulation sensations during a recharging session. The recharger may induce heat or stimulation on the implanted neurostimulator, leading to heating or uncomfortable stimulation.

See "Recharge speed", page 43, for instructions.

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

Notes:

- If the searching tones continue, reposition the recharger until the searching tones stop.
- During recharging, 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 “Troubleshooting during a recharging session”, page 48, for more information.

(Optional) Using the ankle band

Ankle band use is encouraged for convenience during recharging or programming. Use the ankle band to help maintain the correct recharger position for longer periods of time, as needed. Ankle band use is optional.

1. Insert the recharger into the ankle band pouch. The power button (Ⓢ) should be visible through the window in the pouch (Figure 47, Front view) and the 2 circles (⊙) on the back of the recharger should be aligned with the 2 circles on the ankle band (Figure 47, Back view).



Figure 47. Inserting the recharger into the ankle band pouch

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 48. Using a barrier in the clinic

3. Position the recharger so that the 2 circles (⊙) on the back of the ankle band are directly over the INS (Figure 49). Hold the recharger in this position as you continue.



Figure 49. Positioning the recharger over the INS

4. Secure the ankle band. The ankle band should be snug, but comfortable (Figure 50).

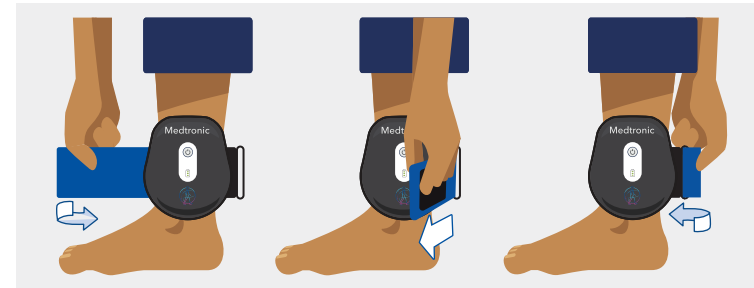


Figure 50. Securing the ankle band

(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.

To lengthen the ankle band:

1. Secure one or more adjusters to the end of the ankle band.
2. Thread the ankle band through the eyelet.

To shorten the ankle band:

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

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 51).

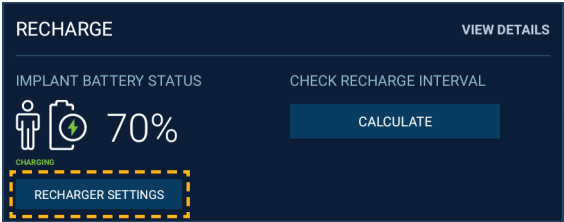


Figure 51. Recharge panel on dashboard

- 2. On the Recharger Settings screen (Figure 52), you can:
 - ① Check recharger and neurostimulator battery levels (page 40)
 - ② Check recharge coupling status (page 43)
 - ③ Adjust recharge speed (page 43)
 - ④ Adjust recharger volume (page 44)



Figure 52. Recharger Settings screen

Recharge coupling status

The Recharger Settings screen provides information about the recharger position and allows you to check the coupling status during a recharging session, an

indication of the strength of the connection between the recharger and the neurostimulator. Table 12 displays the coupling status indicators and their associated meaning.

Table 12. Recharger coupling status indicators and definitions

Indicator	Meaning
	Needs attention. Recharger requires repositioning.
	OK or Good coupling status. Acceptable recharger position for recharging and communicating.

If an orange indicator is displayed:

- 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 mode by default. If the implant site feels too warm for the patient’s comfort during a recharging session, change the recharge speed to slow.

To change the recharge speed, use the following steps:

- 1. From the Home screen (Figure 10) or the Recharge panel on the dashboard (Figure 51), tap **RECHARGER SETTINGS** to open the Recharger Settings screen.
- 2. On the Recharger Settings screen (Figure 52-③), select the speed (slow or fast) that is most comfortable.
- 3. 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.

Recharger volume

Adjustments to recharger volume are saved to each individual recharger.

In the clinician app, the volume settings for the recharger can be accessed from the Recharger Settings screen (Figure 52-(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 recharger volume. For instructions on adjusting recharger volume using the patient app, refer to the *Patient Guide for the Altaviva System*.
- Make sure that you use the recharger you want to adjust the volume settings for.
- If you turn off the volume completely, you will not be able to hear the audio feedback described in this guide.

Troubleshooting

System component and connection issues

Table 13. Clinician app, tablet, and recharger scenarios and solutions

Scenario	Explanations and solutions
The clinician tablet is 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. The recharger is not charged. Place the recharger on the plugged-in dock. Use the dock provided with recharger. Once charged, follow the connection steps to reconnect. The recharger is out of range. Position your tablet near the recharger. Once in range, follow the connection steps to reconnect. The clinician tablet is paired with a different recharger. 1. From the Recharger Not Found screen, tap RETRY. 2. If Step 1 was unsuccessful, tap CONNECT TO A DIFFERENT RECHARGER and follow the directions provided on the screen. The recharger and tablet failed to establish a Bluetooth connection. 1. Turn off the recharger by pressing and holding the power button, then turn it back on and reconnect. Note: If the recharger is unresponsive and does not turn off, hold down the power button for at least 20 seconds or until the battery lights begin to flash. This will reset the recharger. 2. If Step 1 was unsuccessful, turn off the tablet, turn it back on, and reconnect. 3. If the steps outlined above do not result in successful communication between the tablet and the recharger, contact Medtronic.
The recharger is unable to connect to and communicate with the neurostimulator	The recharger is out of range of the INS. Reposition the recharger over the neurostimulator and tap RETRY. The rechargeable neurostimulator battery is depleted. Recharge the neurostimulator. See "Recharging the neurostimulator after implant", page 41. The implant battery is drained to the point that it cannot communicate with the recharger and Unable to Connect comes on screen. Follow the on-screen instructions.
The tablet has no power or has lost power	The tablet battery is depleted. Charge the tablet using the charging cable and power adapter. The tablet is damaged or malfunctioning. Contact Medtronic.

Table 13. Clinician app, tablet, and recharger scenarios and solutions

Scenario	Explanations and solutions
The tablet will not charge	The tablet is not plugged into the power source. Make sure that the tablet is properly connected to the wall outlet, using the charging cable and power adapter provided. Tablet, charging cable, or power adapter may be defective, damaged, or malfunctioning. Contact Medtronic.
I cannot find the clinician app on the tablet	The clinician app may not have downloaded properly or may have been deleted from the tablet. Contact Medtronic.
The tablet or clinician app is unresponsive	The tablet may need to be restarted. 1. Turn off the tablet, then turn the power back on and reopen the app. 2. If that does not resolve the issue, use another tablet, if available. 3. If you are near possible sources of electromagnetic interference (EMI), move away from the source of EMI. If the issue persists, contact Medtronic.
I 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.
I 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  to connect to a different recharger.
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 to the implant. 3. If the app detects a time difference between the tablet and the implant of 5 minutes or less, it will automatically correct the implant clock. 4. If the app detects a time difference between the tablet and the implant of more than 5 minutes, 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 36) to understand the system event that interrupted the data collection. Discuss behaviors that will lead to better therapy adherence with your patient.

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

Perform the Clinician Reset and Recharge workflow if the clinician app or the recharger is unable to communicate with the neurostimulator or if troubleshooting indicates that a clinician 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 44 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.
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 to 2 seconds. A long button press is 3 to 5 seconds. The recharger will beep at the end of a correct duration button press.
4. The light on the power button will show a spinning orange light and the recharger will beep.
5. Remove the recharger from the plugged-in dock and hold it over the patient’s INS. Within 2 minutes, the power button will show a flashing orange light (🔴) and beeping will get faster. This means that the recharger is preparing to reset the neurostimulator.

6. Keep the recharger over the INS after the beeping stops. The reset will start after the beeping ends and will take up to 1 minute to complete. The light on the power button will change to an orange pulse and then a green pulse when the reset has completed.
7. After the reset, the recharger transitions to a special recharging session that may take up to 10 minutes if the neurostimulator battery needs to be recovered. Keep the recharger over the INS until it enters a recharging session.

Note: The light on the power button 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.

Troubleshooting during a recharging session

This section provides solutions to problems that you may encounter using the recharging system. Table 14 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 14. Recharging scenarios and solutions

Scenario or Alert	Cause and Action
 Lights: Spinning green Tones: Repeating tones of the same pitch	The recharger is searching for the implant. If the searching tones continue, the recharger’s position over the implant needs to be adjusted. 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.
 Lights: Solid green Tones: 2 tones rising in pitch	The recharger has found and connected to the implant. Maintain this position while you are using the recharger.
 Lights: Slowly pulsing green Tones: None	The recharger is recharging the implant. No action is needed.
 Lights: Solid green Tones: Series of tones, rising in pitch	Recharging session is complete. Return the recharger to the plugged-in dock.
 Lights: Spinning orange and green Tones: 2 tones falling in pitch	The recharger is indicating that you need to connect to the app. Open the clinician app and tap CONNECT.

Table 14. Recharging scenarios and solutions

Scenario or Alert	Cause and Action
 Lights: Flashing orange Tones: 2 tones, falling in pitch and repeating	The recharger has encountered an error and stopped recharging the implant. 1. Use the clinician app to resolve any error messages by following the directions provided on the app. 2. Turn off the recharger by pressing and holding the power button, then turn it back on. 3. Reposition the recharger over the neurostimulator and try again. If the alert or error persists: 1. Hold down the power button for at least 20 seconds or until the battery lights begin to flash. This will reset the recharger. 2. If alert or error persists, contact Medtronic.
 Lights: Solid orange briefly, then off Tones: 2 tones, falling in pitch (not repeating)	The tablet has not been paired to the recharger. Ensure the recharger is out of shipping mode, then pair the tablet to the recharger and try again. See "Pairing the clinician tablet to the recharger", page 21.
 Lights: Flashing orange Tones: 2 tones, falling in pitch and 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 39.
The patient experiences too much warmth, a heating sensation, discomfort, or redness near the implanted neurostimulator during recharging.	You may need to adjust the recharge speed. Assess the patient for the presence of metal near the implant. See "External metal objects and recharge", page 10 and "Metal implants", page 12. To adjust recharge speed, see "Recharge speed", page 43. Ensure the patient has taken the following steps: 1. Taken a break from recharging. 2. Moved to a comfortable position while recharging. 3. Loosened the ankle band (if used) so that it is comfortable and only tight enough to secure the recharger in place. 4. Placed a piece of clothing or a barrier between the patient's skin and the recharger or ankle band. 5. Stopped recharging if skin irritation persists or if symptoms are severe.
The tones from the recharger are too loud or too quiet.	The recharger volume may need to be adjusted. See "Recharger volume", page 44.

Table 14. Recharging scenarios and solutions

Scenario or Alert	Cause and Action
The battery light on the recharger is on, but it is not recharging the neurostimulator.	The recharger is in communication-only mode. To start recharging, position the recharger over the implant and press the power button to switch to recharging mode. If pressing the power button appears to do nothing, check if the recharger is connected to the clinician app on another tablet. If so, wait until the connected app is finished, and then start a recharge session. Note: It is not recommended to start recharge if extensive programming is needed.

Recharger recovery mode

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. Follow the directions provided in the alert.

Troubleshooting for therapy (stimulation) issues

Table 15. Troubleshooting for therapy (stimulation) issues

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 31; “End an active stimulation session”, page 33; “Reports”, page 36; or “Appendix A: Continuous stimulation”, page 60 for instructions.
The patient is not receiving symptom relief or has a return of symptoms.	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 32 for instructions. The neurostimulator battery may be depleted. The neurostimulator will need to be recharged.

Table 15. Troubleshooting for therapy (stimulation) issues

Scenario	Explanations and possible solutions
The patient's scheduled therapy sessions are not occurring, or are occurring at an unexpected time.	Therapy may be scheduled at a different time or the schedule was stopped by the patient or clinician. Check the status and therapy start time on the dashboard. The neurostimulator battery was fully depleted. Recharge the neurostimulator and reconnect. The patient traveled to a new time zone, or daylight saving time starts or ends, and the therapy schedule time has not yet been updated. 1. If daylight saving time has occurred, check and correct the time setting on the clinician tablet as needed. Then use the clinician tablet to connect to the implant and follow instructions on screen. 2. If the patient is traveling across time zone(s), the implant clock will not automatically adjust to the new time zone. Stimulation sessions will continue to occur based on the time zone set by the clinician. A system error occurred. Connect to the clinician app for additional information.
I 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 (⚙️) 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.

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 on-screen instructions carefully. If a notification says to contact Medtronic, provide the service code shown on the notification screen. Clinician app service codes are preceded by a "C". The notification color indicates its urgency. See Table 16.

Table 17 lists some important notifications and what to do if you see them.

Table 16. Types of notifications

Notification color and urgency	Explanations
Blue: Low 	Provides information about functionality or status. Follow the instructions in the notification message.
Orange: Medium 	Provides information about a system issue and action needed to resolve it. Follow the instructions in the notification message. Contact Medtronic if you cannot resolve the issue on your own.

Table 16. Types of notifications

Notification color and urgency	Explanations
Red: High 	Indicates a system error that may prevent the use of the clinician app. Follow the instructions in the notification message and contact Medtronic.

Table 17. Clinician app notifications and solutions

App notification	Service code(s)	Explanations and solutions
Recharger Docked	C4103	The recharger is on the dock. Remove the recharger from the dock and place it over the implant.
Communication to the Recharger Has Been Lost	C4101	The connection between the tablet and the recharger has been lost. Tap EXIT SESSION and reconnect. Ensure the recharger is turned on. If this issue persists, contact Medtronic.
Communication to the Altaviva Implant Unsuccessful	C4502	Communication to the Altaviva implant was unsuccessful. Tap EXIT SESSION and reconnect. If this issue persists, contact Medtronic.
Communication to the Altaviva Implant Has Been Lost	C4503	Communication to the Altaviva 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.
	C4505	Communication to the Altaviva implant was interrupted. The recharger may be too far away from the implant. Ensure the recharger is over the implant and tap RETRY , or tap EXIT SESSION and reconnect.
No Altaviva Implant Found	None	The recharger is out of range of the INS. Reposition the recharger over the neurostimulator and tap EXIT SESSION and reconnect.
	C4109	The neurostimulator battery is depleted and is not responding to the recharger. Recharge the neurostimulator. See "Recharging the neurostimulator", page 40. If unsuccessful, follow instructions for Clinician Reset and Recharge workflow, page 47. If this issue persists, contact Medtronic.
Permission Denied	C2602	The clinician application cannot run without permissions. 1. Tap GO TO SETTINGS . 2. Allow all permissions. If you need assistance, contact Medtronic.
Incompatible Altaviva implant	C4114	The recharger cannot connect to the neurostimulator. Ensure that the recharger is placed directly over the Altaviva implant. If this issue persists, contact Medtronic.

Table 17. Clinician app notifications and solutions

App notification	Service code(s)	Explanations and solutions
Recharger Low Battery	C2100 C4113	Recharger battery is low. Place the recharger on the plugged-in dock to charge. Note: The recharger should be left on the dock in between sessions when not in use so it remains charged.
Caution: Low Battery: Altaviva Implant	None	The Altaviva implant battery is low. Recharge the neurostimulator to avoid losing therapy.
Caution: Very Low Battery: Altaviva Implant	None	
Critically Low Altaviva Implant Battery	C2506	The current programming session has been interrupted due to a critically low Altaviva implant battery. Recharge the implant, then reconnect.
Therapy Disabled: Low Battery	C4504	Therapy was disabled due to low Altaviva implant battery. 1. Recharge the implant to re-enable therapy. 2. Check recharge history and discuss a sustainable recharge schedule with the patient.
Time Difference Noted	C2606	There is a time difference between the tablet and the patient's implant clock. Tap CONTINUE to reset the implant clock to match the tablet clock. If the tablet clock is incorrect, tap EXIT SESSION , update the tablet clock, and reconnect.
Time Updated	C2604	Time update of the tablet has been detected. Tap EXIT SESSION and reconnect.
Implant Security Error	C4204	An implant security error has been detected and neurostimulator programming is not possible. Tap EXIT SESSION and contact Medtronic.
Patient Data Service Error	C2610	Patient Data Service is disabled. Enable the application through the system settings.
Charge Density Threshold Exceeded	C4400	The stimulation parameters are set too high. From the Stimulation screen, lower the stimulation parameters to remain within safe limits. See "Configure stimulation parameters", page 26.
System Error	C2507 C4205 C4402	The system has encountered a problem that impacts therapy delivery. Follow the on-screen instructions. If the issue persists, contact Medtronic.

Table 17. Clinician app notifications and solutions

App notification	Service code(s)	Explanations and solutions
System Fault	C4200	An error occurred.
	C4201	Check programming if instructed. Follow instructions onscreen. If this issue persists, contact Medtronic.
	C4202	
	C4401	
Power-On Reset Detected	C2505	The Altaviva implant has reset. Tap EXIT SESSION and reconnect. Or If prompted, tap OK and continue with the session. Therapy adherence data could have been interrupted (see “View and download reports”, page 36).
Replacement Recommended	C2500	The Altaviva implant has reached the end of its service life. Schedule a replacement procedure.

Troubleshooting patient app service codes

The patient app displays notifications that provide instruction for the patient to contact their clinician. Table 18 provides explanations and solutions for you to troubleshoot patient app service codes. Patient app service codes are preceded by a “P”.

Table 18. Troubleshooting patient app service codes

Patient app service code(s)	Notification	Explanations and solutions for the clinician
P2200	System Error Detected	Therapy was automatically re-enabled. Connect to the patient’s INS and verify that the therapy schedule is correct.
P2502	Replacement Recommended	INS replacement is recommended. The patient’s INS has reached the end of its service life. Schedule time with patient to explant or replace the INS.
P2505	Therapy Disabled	Implant clock is no longer accurate. Connect to the patient’s INS, recharge, and update the implant clock to resume therapy.
P4110	Implant Unresponsive	The INS battery is depleted. Recharge the patient’s INS. If attempts to recharge at a different position are unsuccessful, follow the instructions for “Clinician Reset and Recharge workflow” on page 47.

Table 18. Troubleshooting patient app service codes

Patient app service code(s)	Notification	Explanations and solutions for the clinician
P4200	Stimulation Settings Error	Therapy settings are corrupt. Connect to the patient's INS and reprogram therapy settings.
P4401	Therapy Settings Error	Therapy Settings Out of Range. Connect to the patient's INS and follow the instructions for "Therapy Settings Out of Range alert" on page 47.
P4501	System Fault	INS memory invalid. Connect to the patient's INS and tap CONTINUE to clear invalid data.
P4502	INS Firmware Update	Firmware update needed. Connect to the patient's INS and update firmware.
P4101, P4102, P4503, P4504, P4505	Incompatible device, system fault, or error	System fault or error. Contact Medtronic for assistance.

Product specifications

Neurostimulator



Figure 53. Altaviva neurostimulator

The neurostimulator serial number (SN) can be found on the packaging, on the neurostimulator before implant (Figure 53), on the patient ID card, or in patient records after implant.

Note: “Altaviva™” or “TNM” may appear on the neurostimulator.

Table 19. Operating values for the Model P7850N Altaviva neurostimulator

Parameter	Operating values and ranges
Amplitude	0.1 mA to 25.5 mA
Pulse width	40 µs to 450 µs
Rate	3 Hz to 130 Hz
SoftStart/Stop	Off, On: 1 sec to 30 sec (with options of 1, 2, 4, 8, 15, 30 sec ramp duration)

Table 20. Physical characteristics of the Model P7850N Altaviva neurostimulator^a

Description	Specification
Width	15.7 mm
Length	43.7 mm
Thickness	4.4 mm
Mass	7.5 g
Volume	2.6 cm ³
Power source ^b	Medtronic lithium-ion rechargeable battery with Overdrive battery technology

Table 20. Physical characteristics of the Model P7850N Altaviva neurostimulator^a

Description	Specification	
Expected lifetime	15 years before recommended replacement notification ^c	
Serial number prefix ^d	NTI	
Radiopaque identification code	NTI	
Materials and substances to which the patient can be exposed ^e	Parylene C, titanium alloy, silicone medical adhesive, platinum-iridium alloy, liquid silicone rubber	
Transmitter and receiver	Carrier frequency	175 kHz
	Output power	<30 dBµA/m at 10 meters
Wireless technology type	Near-field magnetic inductive communication	

^a All measurements are approximate.

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

^c Clinical and bench data have demonstrated 15 years of expected stimulation delivery for therapy schedules with session durations up to 2 hours per day and associated settings of 11 mA, 200 µsec, 20 Hz.

^d 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.

^e Materials are listed from most to least amount by surface area.

Recharger

Table 21. Electrical, physical, and operating characteristics for the Model P720R1 recharger

Description	Specification
Power source	Internal rechargeable lithium-ion battery with a minimum capacity of 2.2 ampere-hour (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, approximate)	14.2 cm x 11.7 cm x 2.5 cm (5.6 in x 4.6 in x 0.98 in)
Weight, including battery (approximate)	363 g (0.80 lb)
Battery life	3 years ^d
Materials and substances to which the patient can be exposed ^e	Polycarbonate (PC)/acrylonitrile butadiene styrene (ABS), polycarbonate, polycarbonate with titanium dioxide, ink, gold-plated brass alloy
Radio types	Bluetooth 4.0 Near-field magnetic induction communication
Operating frequency band	Bluetooth: 2.4 to 2.4835 GHz ISM Near-field magnetic induction communication: 175 kHz
Effective range	Bluetooth: 2 meters (6 feet) - approximate maximum distance between the Model P720R1 recharger and the patient programmer Near-field magnetic communication: 4.0 cm (1.5 in) - approximate maximum distance between the Model P720R1 recharger and the neurostimulator

Table 21. Electrical, physical, and operating characteristics for the Model P720R1 recharger

Description	Specification
Electromagnetic compatibility (EMC) declaration	Recharger model P720R1 is compliant to IEC 60601-1-2:2014+AMD1:2020 for home healthcare environment and professional healthcare facility environment. For more details on EMC testing, refer to EMC Declaration available at www.manuals.medtronic.com .

^a At the upper range of operating temperature, the recharger may reach 43°C (109°F).

^b 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.

^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 Minimum battery life when recharger is kept fully charged between uses

^e Materials are listed from most to least amount by surface area.

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 22. Electrical, physical, and operating characteristics for the Model CD9000A recharger dock

Parameter	Operating values and ranges
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) ^b
Long-term storage temperature	Approximately room temperature

Table 22. Electrical, physical, and operating characteristics for the Model CD9000A recharger dock

Parameter	Operating values and ranges
Size (L x W x H, approximate)	16 cm x 16 cm x 3 cm (6.3 in x 6.3 in x 1.18 in)
Weight (approximate)	220 g (0.49 lb)
Input	5.0 V to 5.6 V  1.5 A
Output	4.5 V to 5.6 V
Materials and substances to which the patient can be exposed ^c	Polycarbonate (PC)/acrylonitrile butadiene styrene (ABS), silicone rubber, polycarbonate

^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 Materials are listed from most to least amount by surface area.

Table 23. Dock power adapter 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 Hz to 60 Hz
Output	5.0 V to 5.6 V  1.5 A
USB cable	USB-A to USB Micro

^a Do not connect other power adapters or equipment not provided by Medtronic to your system. The use of other power adapters or equipment not provided by Medtronic has not been tested for safety and could damage your system. Additionally, do not use the USB port of the recharger dock for anything but charging of the recharger to prevent malfunction.

Ankle band and adjusters

Table 24. Physical characteristics of the Model P742A1 ankle band and adjuster^a

Description	Specification
Ankle band length	300 mm (11.81 in)
Ankle band width	76.2 mm (3 in)
Ankle band thickness	3 mm to 5 mm (0.12 in to 0.20 in)
Adjuster length	152.4 mm (6 in)
Adjuster width	50.8 mm (2 in)
Adjuster thickness	2 mm (0.08 in)
Materials and substances to which the patient can be exposed ^b	Nylon, styrene-butadiene rubber (SBR), spandex, polypropylene, polyoxymethylene (acetal), silicone

^a All measurements are approximate.

^b Materials are listed from most to least amount by surface area.

Cleaning and care

- Use the system components only as instructed in this guide.
- The recharger and dock may be damaged if stored or used outside of the temperature ranges and other environmental conditions specified for the products. For specific storage and operating temperature ranges, see product specifications Table 21 and Table 22.
- 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 adapter are not waterproof. Do not allow moisture to get inside the components.
- To clean the ankle band, remove the recharger. Hand wash the ankle band with mild soap and warm water. Air dry.
 - 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.

Return, replacement, and disposal

If you need to return, replace, or dispose of any system component, contact Medtronic. Instructions will be provided.

Recharger and dock disposal

 **Caution: Component disposal** – Dispose of the recharger and dock according to local regulations, or consult <http://recycling.medtronic.com>. Failure to dispose of the recharger and dock correctly may lead to environmental damage.

Neurostimulator disposal

Refer to the *Model P7850N Altaviva Neurostimulator Implant Manual* for instructions on explant and disposal on the INS. Prior to explant, remove identifying patient health information from the INS.

Removing identifying patient health information from the INS

At explant and before disposal, ensure that 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.
3. Tap **SAVE** to save deletions to the INS.

Refer to the *Model P7850N Altaviva Neurostimulator Implant Manual* for instructions on explant and disposal.

Appendix A: Continuous stimulation

Safety and effectiveness were not evaluated for continuous stimulation, and consequently continuous stimulation should not be used.

If Continuous is selected from the Schedule Type dropdown menu and saved, then the patient's stimulation will be delivered with a therapy schedule length of 24 hrs/day (Figure 54).

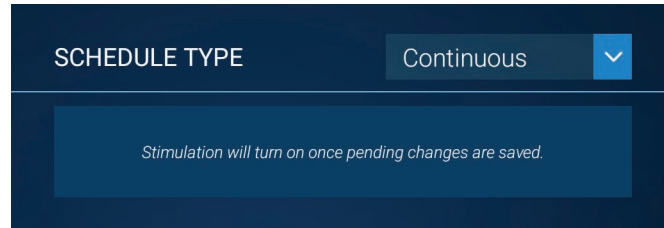


Figure 54. "Continuous" Schedule screen

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

To stop a patient's continuous stimulation:

1. On the dashboard, tap **EDIT** to open the Stimulation screen.
2. Tap the Stimulation toggle to turn stimulation **OFF**.
3. Tap **DONE**.

To resume a patient's continuous stimulation:

1. On the dashboard, tap **EDIT** to open the Stimulation screen.
2. Tap the Stimulation toggle to turn Stimulation **ON**.
3. Tap **DONE**.

Appendix B: Clinical study summary

Introduction

The TITAN 2 trial was a clinical study to demonstrate safety and effectiveness of the Medtronic Altaviva System for the treatment of urinary urge incontinence (UUI) in the US. A summary of the clinical study is presented below.

A. Study Design

Subjects were implanted with an investigational Altaviva system between 10-Mar-2022 and 27-Apr-2023. The last 12-month visit occurred on 10-May-2024, and the summary below reflects data collected through 18-Oct-2024 (data cutoff date). In total, 26 sites enrolled patients and 126 subjects were implanted.

The TITAN 2 study was a single arm, prospective, multicenter, pivotal study to assess safety and effectiveness for the Altaviva system in subjects with urge urinary incontinence. Enrolled subjects completed baseline procedures, including a baseline diary and assessment of medical history. Subjects who were consented and met all inclusion and no exclusion criteria were implanted with the neurostimulator following the implant methodology described in the study labeling. Subjects were instructed to initiate their therapy within 24 hours of implant and subjects were planned to complete follow-up visits at 7-days, 1-month, 2-months, 3-months, 6-months, 12-months, and 24-months post-implant. Subjects were instructed to complete voiding diaries at all follow-up visits following the 7-day visit. Patient questionnaires were completed at baseline, and all follow-up visits starting at 3-months post-implant. TITAN 2 safety and effectiveness data supporting the primary and secondary endpoints at 6-months post-implant and follow-up through 12 months are reported.

The primary endpoint was the percentage of implanted subjects considered a urinary urge incontinence (UUI) responder after 6 months of TNM therapy, defined as % of subjects having a reduction of 50% or more in daily UUI episodes; effectiveness at 12 months was also assessed. Secondary endpoints included: change in UUI episodes at 6 months compared to baseline, change in daily UF episodes at 6 months compared to baseline in subjects with UF at baseline (≥ 10 voids/day), change in urinary urgency assessed through the Urgency Perception Scale (UPS)^{1,2} at 6 months compared to baseline, and change in health-related quality of life (OAB-q HRQL)³ total score at 6 months compared to baseline. Additional measures to evaluate effectiveness which were pre-specified but not statistically powered included: proportion of subjects with OAB-q HRQL change ≥ 10 points, complete continence rate, 100% UUI responder rate, patient satisfaction, and patient global impression of improvement (PGI-I)^{4,5}. OAB-q HRQL responder rate is defined as % of subjects with ≥ 10 point or more improvement. Safety was evaluated by characterization of device-, procedure-, therapy-, or study-aid-related adverse events from implantation to 12-month follow-up visit. All adverse events were collected, and a Clinical Events Committee (CEC) reviewed and adjudicated all related adverse events and all serious adverse events.

1. Key Clinical Inclusion and Exclusion Criteria

Inclusion Criteria

1. Subjects 18 years of age or older
2. A 3-day voiding diary demonstrating a minimum of 3 episodes of urinary urge incontinence in 72 hours
3. Have a diagnosis of UUI for at least 6 months
4. No OAB pharmacotherapy for 2 weeks prior to completion of the baseline voiding diary and Overactive Bladder Quality of Life (OAB-q) questionnaire
5. Failed, or are not a candidate for, conservative non-pharmacologic treatment (e.g., pelvic floor training, biofeedback, behavioral modification)
6. Failed and/or are intolerant* to at least 2 overactive bladder medications (antimuscarinics or beta-3 agonist) or contraindicated to all pharmacological therapies for the treatment of overactive bladder
7. Willing and able to accurately complete study diaries, questionnaires, attend visits, operate the system, and comply with the study protocol
8. Willing and able to provide signed and dated informed consent

Exclusion Criteria

1. Have neurological conditions such as multiple sclerosis, clinically significant peripheral neuropathy or spinal cord injury (e.g., paraplegia)
2. Severe uncontrolled diabetes
3. History of urinary retention within the previous 6 months
4. Current symptomatic urinary tract infection
5. Have primary stress incontinence or mixed incontinence where the stress component overrides the urge component [see enrollment/baseline requirements for use of the Medical, Epidemiological, and Social Aspects of Aging urinary incontinence questionnaire (MESA) questionnaire]
6. Diagnosis of bladder pain syndrome, pelvic pain, or interstitial cystitis
7. Current urinary tract mechanical obstruction (e.g., benign prostatic enlargement or urethral stricture)
8. History of a prior implantable tibial neuromodulation system
9. Knowledge of planned diathermy procedures
10. Have had treatment of urinary symptoms with sacral neuromodulation in the past 6 months, botulinum toxin therapy in the past 9 months or percutaneous tibial nerve stimulation (PTNS)/percutaneous tibial neuromodulation (PTNM) in the past 3 months
11. Skin lesions or compromised skin integrity (e.g., skin atrophy, thinning, fragility, etc.) which may affect incision healing at the implant site
12. Current or a recent history (within the past 6 months) of a medical condition such as venous insufficiency and/or venous stasis ulcers, clinically significant malnutrition, immunocompromised state, or other relevant chronic disease which may indicate a higher risk for delayed or poor wound healing
13. Anatomical defects, clinically significant edema or previous surgeries which precludes use of the device (including any metal implant that is within 20 cm of the intended neurostimulator location)
14. Previous pelvic floor surgery in the last 6 months
15. Women who are pregnant or planning to become pregnant during the course of the study
16. Any subject who is considered to be part of a vulnerable patient population**
17. Characteristics indicating a poor understanding of the study or characteristics that indicate the subject may have poor compliance with the study protocol requirements
18. Concurrent participation in another clinical study that may add additional safety risks and/or confound study results***

* Defined as stopped taking medication due to lack of efficacy or intolerable side effects.

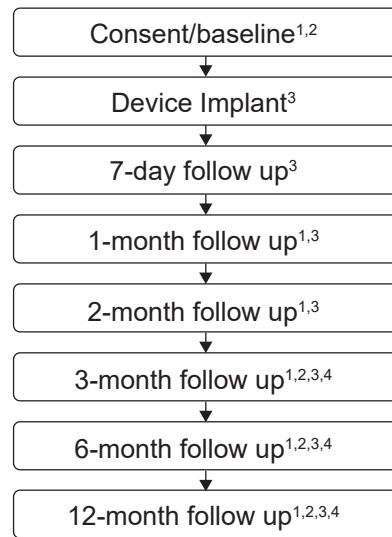
** Defined as subjects mentally incapable of giving consent, in the Investigator's opinion.

*** Subjects in concurrent studies can only be enrolled with permission from Medtronic.

Contact Medtronic's study manager to determine if the subject can be enrolled in both studies.

2. Follow Up Schedule

All subjects were scheduled to return for follow-up examinations at 7 days, 1-, 2-, 3-, 6-, 12-, and 24-months post-implant. Approval was based on data out to 12 months. Prior to the device implant, a 3-day urinary voiding diary, OAB-q, and UPS were completed. After device implant, 3-day urinary voiding diary, OAB-q, UPS, PGI-I, patient questionnaires, and device data were collected at various time points, as described in Figure 55.



Assessments at each visit: ¹Voiding diary, ²OAB-q/UPS, ³Device data, ⁴PGI-I/patient questionnaires

Figure 55. Subject Follow Up Schedule

3. Clinical Endpoints

Safety:

With regards to safety, adverse device effects (ADEs) from device implantation to 12 months after device implant were characterized. ADEs are all events related to the device (including external devices), procedure, therapy, or study aids. All adverse events were collected in the study and summarized.

Primary Effectiveness Endpoint:

Effectiveness - Proportion of TNM subjects experiencing a reduction of 50% or more in daily UUI episodes (UUI responder rate) at 6 months after device implant.

Secondary Effectiveness Endpoints:

- Change in UUI episodes at 6 months compared to baseline in subjects with UUI at baseline.
- Change in daily UF episodes at 6 months compared to baseline in subjects with UF at baseline.
- Change in urinary urgency assessed through the UPS at 6 months compared to baseline.
- Change in OAB-q HRQL (health related quality of life) Total Score at 6 months compared to baseline.

The primary and secondary effectiveness endpoints were also evaluated at 12 months.

Additional Measures included in this Summary (these endpoints were pre-specified but not statistically powered):

- OAB-q HRQL (change of score ≥ 10 points from the baseline)
- Complete continence rate

- 100% UUI responder rate
- Patient satisfaction/PGI-I

Several analysis sets were used. All Implanted includes subjects who are implanted. Complete Case includes subjects who are implanted and provided outcome measures at both baseline and follow-up visits. As Treated includes patients who received stimulation in the period prior to the visit.

B. Accountability of PMA Cohort

One hundred eighty-eight subjects were enrolled in the clinical study; patients were considered enrolled after signing the informed consent. Of the 188 enrolled subjects, 62 discontinued prior to implant (screen failures). Of the 126 subjects implanted, 1 (1%) discontinued prior to Month 6 and 4 (3%) discontinued prior to Month 12, as shown in Figure 56.

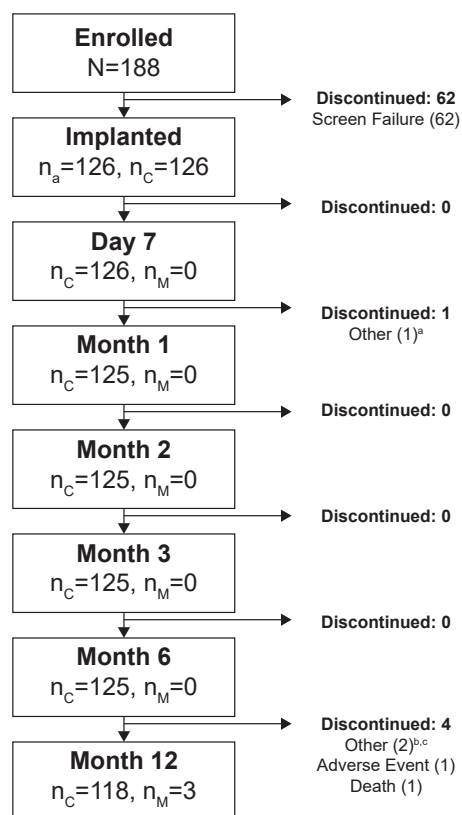


Figure 56. Disposition of Subjects

Note: n_a : number of attempted implants. n_C : number of subjects who completed the visit. n_M : number of subjects who missed the visit.

"Other" discontinuation reasons are:

- "device explant with no planned replacement" (discontinuation prior to the 1-month visit). The explant reason for this subject was due to an ADE of wound infection.
- "Subject is planning to have surgery with an implanted metal material within 20 cm of the INS."
- "Transitioned to urethral catheter/suprapubic tube in goals of care discussions with the patient and family."

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are within the range for studies evaluating therapy options for overactive bladder performed in the US^{6,7,8,9,10,11} and are provided in Table 25 and Table 26.

Table 25. Baseline Demographics (All Implanted Analysis Set)

Subject Characteristics	All Implanted (N=126)
Age (years)	
Measure Available	126
Mean (SD)	62.6 (13.68)
Median	65
Min to Max	27.0 to 90.0
Sex (n, %)	
Measure Available	126
Female	120 (95%)
Male	6 (5%)
Ethnicity (n, %)	
Measure Available	126
Not Hispanic or Latino	120 (95%)
Hispanic or Latino	5 (4%)
Not Reported	1 (1%)
Race (n, %)	
Measure Available	126
White	109 (87%)
Black or African American	16 (13%)
American Indian or Alaska Native	1 (1%)
Unknown	1 (1%)
BMI (kg/m²)	
Measure Available	126
Mean (SD)	34.8 (8.61)
Median	33.3
Min to Max	20.8 to 63.1
BMI>40	35 (28%)
BMI>30	84 (67%)

Abbreviations: BMI, body mass index.

Note: A subject may have more than one race.

Table 26. Baseline OAB Characteristics (All Implanted Analysis Set)

Symptom	N	Mean (SD)	Median	Min to Max
UUI (episodes/day)	126	5.1 (3.46)	4.5	0.6 to 25.3
UF [subjects with UF $\geq$ 10 only] (episodes/day)	59	12.9 (2.59)	12.1	10.0 to 22.3
OAB-q HRQL Total Score	126	45.6 (20.91)	44	6.4 to 98.4
UPS Degree of Urgency (n, %)	126	1.3 (0.50)	1	1.0 to 3.0

Abbreviations: UUI, urinary urge incontinence; OAB, overactive bladder; UF, urinary frequency; OAB-q HRQL, Overactive Bladder Symptom Quality of Life Questionnaire health-related quality of life; UPS, Urgency Perception Scale.

Implant procedures were performed in hospital operating rooms (29%), ambulatory surgical centers (35%), and outpatient clinic procedure rooms (37%).

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the implanted cohort of 126 subjects through 12-month follow-up visit. The key safety outcomes for this study are presented in Table 27 through Table 29.

The safety analysis assessed adverse device effects (ADE) and serious adverse events (SAE) through 12-months post-implant in all implanted subjects (n=126). From implant through the 12-month visit, a total of 30 ADEs were reported in 20% (25/126) of implanted subjects, all of which were anticipated. ADEs occurred at the highest rate immediately after implant with 25% of all ADEs occurring in the first month, and 53% within the first 3 months. Overall, the most frequently reported ADEs in the first 6 months were related to infection and pain. The most commonly reported preferred terms related to infection were implant site infection (4%) and incision site cellulitis (2%). The most commonly reported preferred terms related to pain were implant site pain (3%) and medical device site pain (2%). Suspected implant-related infections at the implant site (inclusive of multiple preferred terms) were reported at a rate of 7% (9/126). All resolved with antibiotic treatment except for one implant wound infection which resolved after device explant (1%). There was one serious adverse device effect (SADE) of *Clostridium difficile* colitis which was recovered/resolved. All ADEs were mild (grade 1) or moderate (grade 2) on the Common Terminology Criteria for Adverse Events (CTCAE) grading scale¹². Through 12 months, 3 subjects had their devices explanted: 2 explants were due to ADEs (1 due to infection, mentioned above, and 1 due to implant leg pain), and the 1 explant was due to a planned surgery. One subject had a device revision (explant with reimplant on the same day) due to an ADE post charging. Eight subjects (8/126, 6.3%) had the implant removed at or after 12 months due to subject reported lack of effectiveness.

There were no reported ADEs of device migration or erosion, and there were no unanticipated adverse device effects through 12-month follow-up.

There were 45 serious adverse events (SAE) occurring in 18% of subjects. One of the reported SAEs was adjudicated as related to the procedure (*Clostridium difficile* colitis). The most commonly reported serious adverse events after device implant were pyelonephritis (2%), angina pectoris (2%), and pneumonia (2%), with all other SAE preferred terms being attributed to 1 subject each.

Adverse Events

Table 27. Adverse Event Summary up to 12-months (All Implanted Analysis Set)

	# of events at 6 months	# of subjects (%) at 6 months	# of events at 12 months	# of subjects (%) at 12 months
Total AE	227	90 (71.4%)	437	107 (84.9%)
SAE	17	12 (9.5%)	45	23 (18.3%)
SADE	1	1 (0.8%)	1	1 (0.8%)
ADE	23	21 (16.7%)	30	25 (19.8%)

Table 28. Related Adverse Events by Type up to 12-months (All Implanted Analysis Set)

	Implant to 6 months		Implant to 12 months	
	ADE events (subjects, % of subjects)	SADE events (subjects, % of subjects)	ADE events (subjects, % of subjects)	SADE events (subjects, % of subjects)
Total	23 (21, 16.7%)	1 (1, 0.8%)	30 (25, 19.8%)	1 (1, 0.8%)
Procedure	10 (10, 7.9%)	1 (1, 0.8%)	10 (10, 7.9%)	1 (1, 0.8%)
Device	9 (9, 7.1%)	0 (0, 0.0%)	15 (14, 11.1%)	0 (0, 0.0%)
Therapy	5 (5, 4.0%)	0 (0, 0.0%)	6 (6, 4.8%)	0 (0, 0.0%)

Note: An ADE is any AE that was deemed related to the procedure, devices (neurostimulator/external TNM System devices), therapy, or study aids (Army Navy retractor, sterile ruler/marker, sterile bag, shower bag, compression sock). An event can be classified as more than 1 relatedness category, and a subject may have more than 1 event, so the sum of the related components may not add to the total. Because all related events are ADE, the related row values for Total are not displayed. Events are reported through 12 months. There were no study aid-related events.

All ADEs reported between implant and 12 months are summarized in Table 29 by System Organ Class and Preferred Term. Device- and therapy-related ADEs are shown in Table 30, and procedure-related ADEs are shown in Table 31.

Table 29. ADE by System Organ Class and Preferred Term - Implant to Month 12 (All Implanted Analysis Set)

System Organ Class Preferred Term All Adverse Events	Events (Subjects, % of Subjects)	
	Implant to Month 6 ADE (N = 126)	Implant to Month 12 ADE (N = 126)
All Adverse Events	23 (21, 16.7%)	30 (25, 19.8%)
Infections and infestations		
Clostridium difficile colitis	1 (1, 0.8%)	1 (1, 0.8%)
Implant site infection	5 (5, 4.0%)	5 (5, 4.0%)
Incision site cellulitis	3 (3, 2.4%)	3 (3, 2.4%)
Wound infection	1 (1, 0.8%)	1 (1, 0.8%)
Gastrointestinal disorders		
Anal incontinence	1 (1, 0.8%)	1 (1, 0.8%)
Musculoskeletal and connective tissue disorders		
Limb discomfort	1 (1, 0.8%)	1 (1, 0.8%)
Muscle tightness	1 (1, 0.8%)	1 (1, 0.8%)
Pain in extremity	1 (1, 0.8%)	2 (2, 1.6%)
General disorders and administration site conditions		
Implant site bruising	1 (1, 0.8%)	1 (1, 0.8%)
Implant site pain	2 (2, 1.6%)	4 (4, 3.2%)
Medical device pain	0 (0, 0%)	1 (1, 0.8%)
Medical device site pain	2 (2, 1.6%)	3 (3, 2.4%)
Oedema peripheral	1 (1, 0.8%)	1 (1, 0.8%)
Injury, poisoning and procedural complications		
Incision site complication	1 (1, 0.8%)	1 (1, 0.8%)
Incision site swelling	1 (1, 0.8%)	2 (1, 0.8%)
Product issues		
Device inappropriate shock delivery	1 (1, 0.8%)	2 (2, 1.6%)

Note: The event count may not be the same as the subject count, as a subject may have had more than 1 similar event. The sum of individual preferred terms may not add to the total of all adverse events, as a subject may have had more than 1 event.

Table 30. Device or Therapy ADE by System Organ Class and Preferred Term – Implant to Month 12
(All Implanted Analysis Set)

System Organ Class Preferred Term	Events (Subjects, % of Subjects)	
	Implant to Month 6 ADE	Implant to Month 12 ADE
	(N=126)	(N=126)
All Adverse Events	13 (12, 9.5%)	20 (16, 12.7%)
Gastrointestinal disorders		
Anal incontinence	1 (1, 0.8%)	1 (1, 0.8%)
Musculoskeletal and connective tissue disorders		
Limb discomfort	1 (1, 0.8%)	1 (1, 0.8%)
Muscle tightness	1 (1, 0.8%)	1 (1, 0.8%)
Pain in extremity	1 (1, 0.8%)	2 (2, 1.6%)
General disorders and administration site conditions		
Implant site bruising	1 (1, 0.8%)	1 (1, 0.8%)
Implant site pain	2 (2, 1.6%)	4 (4, 3.2%)
Medical device pain	0 (0, 0%)	1 (1, 0.8%)
Medical device site pain	2 (2, 1.6%)	3 (3, 2.4%)
Oedema peripheral	1 (1, 0.8%)	1 (1, 0.8%)
Injury, poisoning and procedural complications		
Incision site complication	1 (1, 0.8%)	1 (1, 0.8%)
Incision site swelling	1 (1, 0.8%)	2 (1, 0.8%)
Product issues		
Device inappropriate shock delivery	1 (1, 0.8%)	2 (2, 1.6%)

Note: The event count may not be the same as the subject count, as a subject may have had more than 1 similar event. The sum of individual preferred terms may not add to the total of all adverse events, as a subject may have had more than 1 event.

Table 31. Procedure ADE by System Organ Class and Preferred Term - Implant to Month 12
(All Implanted Analysis Set)

System Organ Class Preferred Term	Events (Subjects, % of Subjects)	
	Implant to Month 6 ADE	Implant to Month 12 ADE
	(N=126)	(N=126)
All Adverse Events	10 (10, 7.9%)	10 (10, 7.9%)
Infections and infestations		
Clostridium difficile colitis	1 (1, 0.8%)	1 (1, 0.8%)
Implant site infection	5 (5, 4.0%)	5 (5, 4.0%)
Incision site cellulitis	3 (3, 2.4%)	3 (3, 2.4%)
Wound infection	1 (1, 0.8%)	1 (1, 0.8%)

Note: The event count may not be the same as the subject count, as a subject may have had more than 1 similar event. The sum of individual preferred terms may not add to the total of all adverse events, as a subject may have had more than 1 event.

ADEs reported between implant and 12 months are summarized by when they occurred in Table 32 (device- or therapy-related ADEs) and Table 33 (procedure-related ADEs).

Table 32. Device- or Therapy-Related ADEs by Visit Window (All Implanted Analysis Set)

AE Preferred Term	Visit Window						
	Day 0	Day 1-7	Day 8-30	Day 31-90	Day 91-180	Day 181-365	Total
Anal incontinence	0	0	0	0	1	0	1
Device inappropriate shock delivery	0	0	0	1	0	1	2
Implant site bruising	0	0	0	1	0	0	1
Implant site pain	1	0	0	1	0	2	4
Incision site complication	0	0	0	0	1	0	1
Incision site swelling	0	0	0	1	0	1	2
Limb discomfort	1	0	0	0	0	0	1
Medical device pain	0	0	0	0	0	1	1
Medical device site pain	0	0	0	1	1	1	3
Muscle tightness	0	0	1	0	0	0	1
Oedema peripheral	0	0	0	1	0	0	1
Pain in extremity	0	0	0	0	1	1	2
Total	2	0	1	6	4	7	20

Table 33. Procedure-Related ADEs by Visit Window (All Implanted Analysis Set)

AE Preferred Term	Visit Window						
	Day 0	Day 1-7	Day 8-30	Day 31-90	Day 91-180	Day 181-365	Total
Clostridium difficile colitis	0	0	1	0	0	0	1
Implant site infection	0	0	2	3	0	0	5
Incision site cellulitis	0	0	2	1	0	0	3
Wound infection	0	0	1	0	0	0	1
Total	0	0	6	4	0	0	10

2. Effectiveness Results

The planned analysis set for primary and secondary objectives included all implanted subjects following intent-to-treat principle and required imputation if missing data exceeded 5% (All Implanted). The missing data threshold was not exceeded at 6 months, therefore the primary 6 month effectiveness analyses included subjects with data at baseline and follow up (Complete Case). As a sensitivity analysis, 6-month data will also be reported for the All Implanted set with imputation. At 12 months, missing data exceeded 5%, so 12-month analyses included all implanted subjects with imputation. All implant procedures in the TITAN 2 study were successful.

The TITAN 2 clinical study met the pre-specified primary and secondary objectives for effectiveness in an implanted cohort of 126 subjects at 6 months. There were 58% of subjects at 6 months and 61% of subjects at 12 months that had at least 50% reduction in UUI episodes. The primary objective exceeded the pre-specified performance goal of 40% response rate ($p < 0.0001$) at 6 months. Analyses of the primary objective at 6 and 12 months are shown in Table 34.

Table 34. UUI Responder Analyses at 6 and 12 Months

	All Implanted ^a (N=126)	Complete Case (N=123)	As Treated (N=119)
UUI Responder rate at 6 months			
Measure available	126	123	119
Responder n (%)	73.5 (58.3%)	72 (58.5%)	70 (58.8%)
P value ^b	<0.0001	<0.0001	<0.0001
95% confidence interval	(49.6%, 67.1%)	(49.3%, 67.3%)	(49.4%, 67.8%)
UUI Responder rate at 12 months			
Measure available	126	118	103
Responder n (%)	76.2 (60.5%)	72 (61.0%)	66 (64.1%)

^a Missing data imputed: All Implanted only, using multiple imputation.

^b All Implanted (Z-test), Complete Case and As Treated (Binomial test) comparing the responder rate to a performance goal of 40%; Missing data imputed: All Implanted only, using multiple imputation.

Note: The All Implanted group displays a sample size (n) which is not a whole number. This number has decimals because multiple imputation combines results from multiple imputed datasets, resulting in the average responder count shown.

Table 35 shows the results of UUI responder rate sensitivity analyses, including analyses in which subjects taking OAB medications were treated as failures.

Table 35. UUI Responder Rate Sensitivity Analyses-6 and 12 months
(All Implanted Analysis Set)

All Implanted (N=126)	6 Months	12 Months*
Imputing missing using Multiple Imputation (MI) ^a n/N ^b (%) 95% Lower Control Bound (LCB)	73.5/126 (58.3%) 49.6%	76.2/126 (60.5%)
Imputing missing using MI and OAB medications taken as failures UUI responder rate n/N (%)	72.7/126 (57.7%)	73.1/126 (58%)
Imputing both missing and OAB medications taken as failures UUI responder rate n/N (%)	71/126 (56.4%)	68/126 (54%)

*12-month data are considered post-hoc and no statistical inference can be made from these data.

^a MI followed ITT principals and was a prespecified primary analysis, which is presented as a sensitivity analysis due to less than 5% missing.

^b The All Implanted analysis set with MI analysis displays a sample size (n) which is not a whole number. This number has decimals because multiple imputation combines results from multiple imputed datasets, resulting in the average responder count shown.

Table 36 shows the results of a subgroup analyses of UUI responder rate for subgroups in which there were at least 10 subjects.

Table 36. UUI Responder Rate Subgroup Analyses-6 and 12 months (All Implanted Analysis Set)

All Implanted UUI Responder	Subgroup at 6 months	Subgroup at 12 months
Subgroup: Sex	Female	Female
Measure available	120	120
Responder (n, %)	71.5 (59.6%)	74.2 (61.8%)
95% confidence interval	(50.7%, 68.5%)	
Subgroup: Age 65	Age <65	Age <65
Measure available	58	58
Responder (n, %)	37.5 (64.7%)	44.3 (76.4%)
95% confidence interval	(52.0%, 77.3%)	
Subgroup: Age 65	Age ≥65	Age ≥65
Measure available	68	68
Responder (n, %)	36.0 (52.9%)	31.9 (46.9%)
95% confidence interval	(40.4%, 65.2%)	
Subgroup: Race	Black or African American	Black or African American
Measure available	16	16
Responder (n, %)	9.0 (56.3%)	10.2 (63.8%)
95% confidence interval	(29.9%, 80.2%)	
Subgroup: Race	White	White
Measure available	109	109
Responder (n, %)	63.5 (58.3%)	65.0 (59.6%)
95% confidence interval	(48.8%, 67.7%)	
Subgroup: Ethnicity	Not Hispanic or Latino	Not Hispanic or Latino
Measure available	120	120
Responder (n, %)	68.5 (57.1)	72.2 (60.2%)
95% confidence interval	(48.1%, 66.1%)	

Table 37. Summary of Secondary Objectives (All Implanted and Complete Case Analysis Set)

Measure	Change from Baseline to 6 mo Mean ± SD (N)		Change from Baseline to 12 mo Mean ± SD (N)	
	Complete Case	All Implanted	Complete Case	All Implanted
UUI episodes (per day)	-2.8 ± 3.13 (123) ^a	-2.7 ± 3.10 (126)	-2.7 ± 3.24 (118)	-2.7 ± 3.20 (126)
UF episodes (per day)	-2.5 ± 2.93 (58) ^b	-2.5 ± 2.91 (59)	-3.1 ± 3.46 (57)	-3.0 ± 3.54 (59)
Urgency Perception Scale (UPS)	0.4 ± 0.74 (125) ^a	0.4 ± 0.74 (126)	0.4 ± 0.72 (118)	0.4 ± 0.72 (126)
Overactive Bladder Symptom Quality of Life Questionnaire (OAB-q)	27.1 ± 25.79 (125) ^a	26.9 ± 25.81 (126)	25.8 ± 26.73 (118)	25.5 ± 27.04 (126)
^a p<0.0001, Wilcoxon Signed Rank test; Missing data imputed: no. ^b p<0.0001, t-test; Missing data imputed: No.				

Table 38. Assessment of Individual Symptoms at 12-months Follow-up (All Implanted, N=126)

Symptom	Baseline mean value of symptom/day (X)	Mean value of symptom/day at 12-months of device activation (Y)	Percentage mean improvement of symptom at 12-months of device activation compared to baseline = $\frac{X-Y}{X} \times 100\%$
UUI episodes/day	5.1	2.5	51%
Urgency episodes/day	9.8	7.9	19%
Urinary frequency (voids/day)	12.9	9.9	23%

Per the data shown in Table 37 and Table 38, the Altaviva System showed clinically meaningful improvements in UUI related symptoms at 12-months. In the AUA/SUFU guidelines¹³, there is no standard way to assess clinically meaningful improvement for UU and UF. In review with FDA, the reduction in urinary urgency and urinary frequency at 12 months was not considered to be clinically meaningful. Therefore, based on these data no claims regarding the improvement in urinary urgency and urinary frequency can be made.

An additional measure characterized the percentage of subjects who demonstrated clinically meaningful improvement in the OABq-HRQL (≥10 point change from baseline). There were 71% (89/126) of subjects at 6 months and 68% (86/126) of subjects at 12 months who had ≥10 point change in HRQL.

Furthermore, additional effectiveness data analyses which were pre-specified but not statistically powered were conducted for the Complete Case analysis set, including OAB-q HRQL (Overactive Bladder Questionnaire Health-Related Quality of Life) and 100% UUI responder rates. The OAB-q HRQL analysis showed that 71.2% (89/125) of subjects achieved a ≥10 point change at 6 months, which decreased to 69.5% (82/118) at 12 months. For the 100% urge urinary incontinence (UUI) responder rate, which evaluated complete resolution of all urgent leaks, 19% (23/123) of subjects showed 100% improvement for urgent leaks at 6 months, with 22% (26/118) at 12 months.

Patient satisfaction was assessed in the Complete Case analysis set through questions on whether a subject would recommend the therapy to a friend and by evaluating how satisfied or unsatisfied they were with how this therapy impacted their symptoms. On the patient satisfaction question rating, 76% of subjects would recommend the therapy to a friend or family member suffering from similar symptoms at both time points, and 74% and 65% of subjects were satisfied with TNM therapy at 6 and 12 months, respectively.

The validated PGI-I is a single question asking the patient to rate their urinary symptoms now as compared with prior to beginning treatment. After 6 months of TNM therapy, 82% of subjects reported that their condition had improved, and this stayed consistent through 12 months (80%).

Overall, these data support TNM delivered by the Medtronic Altaviva system being a safe and effective therapy for treating symptoms of UUI.

References

1. Freeman R, Hill S, Millard R, Slack M, Sutherst J. Reduced perception of urgency in treatment of overactive bladder with extended-release tolterodine. *Obstet Gynecol.* 2003;102(3):605-611. DOI: 10.1016/s0029-7844(03)00623-9.
2. Cardozo L, Coyne KS, Versi E. Validation of the urgency perception scale. *BJU Int.* 2005;95(4):591-596. DOI: 10.1111/j.1464-410X.2005.05345.x.
3. Coyne KS, Gelhorn H, Thompson C, Kopp ZS, Guan Z. The psychometric validation of a 1-week recall period for the OAB-q. *Int Urogynecol J Pelvic Floor Dysfunct.* 2011;22(12):1555-1563. DOI: 10.1007/s00192-011-1486-0.
4. Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. *Am J Obstet Gynecol.* 2003;189:98-101. DOI: 10.1067/mob.2003.379.
5. Tincello DG, Owen RK, Slack MC, Abrams, KR. Validation of the Patient Global Impression scales for use in detrusor overactivity: Secondary analysis of the RELAX study. *Am J Obstet Gynecol.* 2013;120:212-216. DOI: 10.1111/1471-0528.12069.
6. Kobashi K, Nitti V, Margolis E, et al. A prospective study to evaluate efficacy using the NURO percutaneous tibial neuromodulation system in drug-naïve patients with overactive bladder syndrome. *Urol* 2019;131:77-82. DOI: 10.1016/j.urology.2019.06.002.
7. Goudelocke C, Xavier K, Pecha B, et al. Evaluation of clinical performance and safety for the rechargeable InterStim Micro device in overactive bladder subjects: 6-month results from the global post-market ELITE study. *Neurol Urodyn.* 2023;42(4):761-769. DOI: 10.1002/nau.25171.
8. Siegel S, Noblett K, Mangel J, et al. Five-year follow-up results of a prospective, multicenter study of patients with overactive bladder treated with sacral neuromodulation. *J Urol.* 2018;199(1):229-236. DOI: 10.1016/j.juro.2017.07.010.
9. Siegel S, Kreder K, Takacs E, McNamara R, Kan F. Prospective randomized feasibility study assessing the effect of cyclic sacral neuromodulation on urinary urge incontinence in women. *Female Pelvic Med Reconstr Surg.* 2018;24(4):267-271. DOI: 10.1097/SPV.0000000000000457.
10. Blok B, Van Kerrebroeck P, de Wachter S, et al. A prospective, multicenter study of a novel, miniaturized rechargeable sacral neuromodulation system: 12-month results from the RELAX-OAB study. *Neurol Urodyn.* 2019;38(2):689-695. DOI: 10.1002/nau.23892.
11. Benson K, McCrery R, Taylor C, et al. One-year outcomes of the ARTISAN-SNM study with the Axonics System for the treatment of urinary urgency incontinence. *Neurol Urodyn.* 2020;39(5):1482-1488. DOI: 10.1002/nau.24376.
12. Common Terminology Criteria for Adverse Events (CTCAE) v5.0. Publish Date: November 27, 2017.
13. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder. *J Urol.* 2024 Jul;212(1):11-20. doi: 10.1097/JU.0000000000003985.

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 the U.S., call Medtronic Technical Services at 1-800-707-0933. Support is available Monday through Friday from 7:00 AM to 6:00 PM (Central Time).

Medtronic

Manufacturer

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
Tel. 1-763-505-5000
Toll-free 1-800-328-0810



* M 0 2 8 9 2 9 C 0 0 1 *

© Medtronic 2025
All Rights Reserved

M028929C001 Rev C
2025-09-16

Medtronic

P720R1 Recharger and Associated Medical Electrical System

Rx only

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

Wireless Communication Information and Electromagnetic Compatibility Declaration

IEC 60601-1-2:2014+AMD1:2020

Reference manual

Medtronic and the Medtronic logo are trademarks of Medtronic. All other brands are trademarks of a Medtronic company.

The Bluetooth®* word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Medtronic is under license.

Introduction

This manual provides quality of service and electromagnetic disturbance information for the P720R1 Recharger and its associated medical electrical system. The medical electrical system is comprised of the recharger, its power station and ancillary parts, and the programming components.

This document covers the following information:

- Electromagnetic compatibility and disturbance information for the conductance of recharging energy from the recharger (serving in its recharging mode) to the implanted neurostimulator.
- Electromagnetic compatibility and disturbance information for the wireless connection between the implanted neurostimulator, the recharger (serving in its communication mode), and the programming system.
- **Note:** Electromagnetic compatibility and disturbance information for the implanted device when communication with the recharger is provided in the labeling for the implanted device.
- Electromagnetic compatibility and disturbance information for the recharger when charging its battery (connected via power supply to mains electricity).
- Quality of service and coexistence information for the wireless connections within the system (wireless communication between the recharger and the implanted neurostimulator, and between the recharger and the programming system).

Wireless quality of service (QoS) and operating characteristics

Near-field magnetic induction communication

The Medtronic Model P720R1 recharger uses near-field magnetic induction communication to interact with compatible medical devices. Successful recharging of the compatible medical device requires close proximity between the Model P720R1 recharger and the medical device.

See Table 1 for the wireless operating characteristics.

Table 1. Wireless operating characteristics: Near-Field Magnetic Induction Communication for Model P720R1

Radio type	Near-field magnetic induction communication
Operating frequency band	175 kHz
Effective radiated power output	H-field strength of <30 dB μ A/m at 10 m
Receiving bandwidth	Up to 30 kHz (occupied bandwidth of the transmitter)
Modulation (modulation is model-specific)	On-off keying (OOK) burst
Effective range	4.0 cm (1.5 in) – approximate maximum distance between the Model P720R1 recharger and the compatible implantable rechargeable neurostimulator.

Bluetooth® wireless technology

The Medtronic Model P720R1 recharger uses Bluetooth wireless technology to exchange data and information with the commercial off-the-shelf patient programmer or clinician tablet. Bluetooth wireless technology is a wideband transmission system, which uses wideband modulation techniques. The use of the protocol by Medtronic includes forward error correction (FEC) on data packets, frequency hopping spread spectrum (FHSS) that aids in spectral co-existence, and a reliable data stream profile. Interrupted or partial messages are invalid and must be resent. If communication errors are detected, the system will automatically retransmit the interrupted message to guarantee delivery of the message. If the wireless connection does not automatically re-establish itself, the user should reposition the Model P720R1 recharger to re-establish communication.

See Table 2 for the wireless operating characteristics.

Table 2. Wireless operating characteristics: Bluetooth wireless technology for Model P720R1

Radio type	Bluetooth 4.0
Operating frequency band	2.4 to 2.4835 GHz ISM
Effective radiated power output	<10 mW e.i.r.p.
Receiving bandwidth	Less than 2 MHz per aggregated channels (occupied bandwidth of the transmitter)
Modulation (modulation is model-specific)	Gaussian frequency shift keying (GFSK)
Effective range	2 meters (6 feet) - approximate maximum distance between the Model P720R1 recharger and the patient programmer or clinician tablet.

Model P720R1 has been tested per ANSI 63:27:2021 Tier 1 level.

Wireless security

Near-field magnetic induction communication

The near-field magnetic induction communication uses a model-specific device access code to initiate a recharging session. Keep the Medtronic Model P720R1 recharger within 4 cm (about 1.5 inches) of the compatible medical device. This close contact will mitigate inadvertent programming, malicious programming, and eavesdropping.

Bluetooth® wireless technology

Pairing the Medtronic Model P720R1 recharger and a patient programmer or clinician tablet is the first step to begin communication using Bluetooth wireless technology between the two devices. Pairing can only be accomplished with physical access to the devices and is only available for a short period of time. During the pairing process, a link key is generated by both devices at the same time. This key is derived from a secret key known only to the pair. Once the link key is generated, both devices authenticate each other to verify that they have the same key. Once the communication session has been established, data traffic is encrypted to prevent eavesdropping of packet payloads.

Electromagnetic compatibility (EMC) declaration

The Medtronic Model P720R1 recharger (also referred to herein as "external device") is portable medical electrical equipment and has been tested and conforms to the requirements of IEC 60601-1-2:2014+AMD1:2020.

The P720R1 was tested according to the recommendations of IEC TR 60601-4-2: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be put into service according to the EMC information provided in this EMC declaration.

- For the environments in which the Model P720R1 recharger, its power supply components, and the components with which it communicates are intended to be used, refer to the information in Table 3 on page 10 of this EMC declaration.
- Portable and mobile radio-frequency (RF) communications equipment (for example, mobile or cellular phones and amateur radio equipment) can affect medical electrical equipment.
- Portable radio-frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Model P720R1 recharger, including cables specified by Medtronic. Otherwise, degradation of the performance of this external device could result.
- Use of this external device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this external device and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by Medtronic could result in increased electromagnetic emissions or decreased electromagnetic immunity of this external device and result in improper operation.
- For information about Model P720R1 compatibility with medical devices, equipment, and accessories, refer to other manuals provided with the Medtronic neuromodulation system.
- Other equipment could interfere with the external device, even if the other equipment complies with CISPR emission requirements.
- This external device is **MR Unsafe** and should not be allowed in the MRI scanner (magnet) room. This external device contains ferromagnetic material, which can be affected by the MRI magnet.
- The use of this external device can be affected by interference when in the vicinity of equipment that uses RF or microwave energy (such as diathermy, RF ablation, or an RFID reader).

For more information on MRI, diathermy, and other sources of electromagnetic interference (EMI), refer to other manuals provided with the Medtronic neuromodulation system. EAS and RFID frequencies recommendation not included in this document are found in the patient manual.

Tables 3, 4, and 5 apply to the Model P720R1 recharger, which is an external device powered by a rechargeable lithium-ion battery. A charging dock, USB 2.0 charging cable, and 5-V DC output AC adapter are included with the recharger for recharging the battery.

Table 3. Examples of environments of intended use

Electromagnetic environments	Examples
Home Healthcare Environment	Restaurants, cafes, shops, stores, markets, schools, places of worship, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), vehicles (cars, buses, trains, boats, planes, helicopters), bus stations, hotels, hostels, pensions, museums, theatres
Professional healthcare facility environment	Physician offices, dental offices, clinics, limited care facilities, freestanding surgical centers, freestanding birthing centers, multiple treatment facilities, hospitals – emergency rooms, patient rooms, intensive care, outside the RF shielded room of a medical electrical (ME) system for magnetic resonance imaging (MRI), surgery rooms except near high-frequency (HF) surgical equipment

Summary of test results

The essential and general performance of the P720R1 and its medical electrical system are its implant recharge and wireless communication functions. This essential and general performance has been verified to perform without degradation under the electromagnetic disturbances and conditions identified in this manual.

No deviations or allowances were used.

Table 4. Electromagnetic emissions: Test information and results

Emissions test method	Test level requirement and compliance test level	Test applicability, guidance, and comments
		Model P720R1 recharger (battery-powered, rechargeable using charging dock and power supply^a)
RF conducted emissions CISPR 11	Group 1, Class B	Applicable and compliant
RF radiated emissions CISPR 11	Group 1, Class B	Applicable and compliant
Harmonic emissions IEC 61000-3-2	Class A clause 7 of IEC 61000-3-2.	Applicable and compliant
Voltage fluctuations/flicker emissions IEC 61000-3-3	Test levels are according to clause 5 of IEC 61000-3-3.	Applicable and compliant

^a Power supply includes: 5.0-5.6 V DC, 1.5 A output AC adapter and USB 2.0 type-A to micro-B charging cable.

Table 5. Electromagnetic immunity: Test information and results

Immunity test method	Test level requirement and compliance test level	Test applicability, guidance, and comments
		Model P720R1 recharger (battery-powered, rechargeable using charging dock and power supply ^a)
Radiated RF IEC 61000-4-3	• 10 V/m: 80 MHz to 2.7 GHz 80% AM at 1 kHz	Applicable and compliant
Radiated RF – Proximity to portable and mobile radio communication equipment IEC 61000-4-3	Exposure to 385 MHz to 5785 MHz • 385 MHz: 27 V/m • 450 MHz: 28 V/m • 710, 745, 780 MHz: 9 V/m • 810, 870, 930 MHz: 28 V/m • 1720, 1845, 1970 MHz: 28 V/m • 2450 MHz: 28 V/m • 5240, 5500, 5800 MHz: 9 V/m	Applicable and compliant Recommended minimum separation distance is 30 cm (12 inches).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	• 30 A/m	Applicable and compliant
Conducted disturbances induced by RF IEC 61000-4-6	• 3 V rms: 150 kHz to 80 MHz, 80% AM at 1 kHz • 6 V rms in ISM and amateur radio bands from 150 kHz to 80 MHz	Applicable and compliant
Radiated RF - Proximity to Low Frequency Variable Magnetic Field and RFID technology	IEC 6100-4-39/RFID AIM 7351731:2021	Applicable and compliant

Table 5. Electromagnetic immunity: Test information and results (continued)

Immunity test method	Test level requirement and compliance test level	Test applicability, guidance, and comments
		Model P720R1 recharger (battery-powered, rechargeable using charging dock and power supply ^a)
Immunity to RFID	• AIM 7351731:2021 • 134.2 kHz (65 A/m) • 13.56MHz (7.5A/m) • 433.92MHz (3V/m) • 860-960MHz (54V/m) • 2.45GHz (54V/m)	Applicable and compliant
ISO 7137: Aircraft Environment	Portable medical electronic devices level for category R	Compliant by assessment
Electrostatic discharge (ESD) IEC 61000-4-2	• Contact: ± 2 kV, ± 4 kV, ± 8 kV • Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Applicable and compliant Enclosure and all ports were evaluated
LF Immunity Method: IEC 61000-4-39	• 30kHz CW 8 A/m • 134.2 kHz Pulse Modulation, 2.1 kHz, 50% Duty Cycle 65 A/m • 13.56 MHz Pulse Modulation, 50kHz, 50% Duty Cycle 7.5 A/m	Frequencies used by RFID emitters
Electrical fast transient/burst IEC 61000-4-4	• ± 2 kV for power supply lines	Applicable and compliant

Table 5. Electromagnetic immunity: Test information and results (continued)

Immunity test method	Test level requirement and compliance test level	Test applicability, guidance, and comments
		Model P720R1 recharger (battery-powered, rechargeable using charging dock and power supply ^a)
Surge IEC 61000-4-5	• ± 0.5 kV, ± 1 kV differential mode • ± 0.5 kV, ± 1 kV, ± 2 kV common mode	Applicable and compliant
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	• 0% U_T for 0.5 cycle • 0% U_T for 1 cycle • 70% U_T for 25/30 cycles • 0% U_T for 250/300 cycles NOTE: U_T is AC mains voltage prior to application of test level.	Applicable and compliant

^a Power supply includes: 5.0-5.6 V DC, 1.5 A output AC adapter and USB 2.0 type-A to micro-B charging cable.

Medtronic

Manufacturer

Medtronic, Inc.

710 Medtronic Parkway

Minneapolis, MN 55432

USA

www.medtronic.com

Tel. 1-763-505-5000

Toll-free 1-800-328-0810



* M 0 2 8 9 3 8 C 0 0 1 *

© Medtronic 2025
All Rights Reserved

2025-09-17
M028938C001 Rev C