Medtronic

Patient Guide for the Altaviva™ System

Tibial Neuromodulation Therapy

Model P7850N Altaviva Neurostimulator
Model P720R1 Recharger
Model CD9000A Recharger dock
Model P742A1 Ankle band
Model P7A2P11 Altaviva My Therapy application version 1.1

! USA Rx only

Refer to your patient programmer quick start guide for information about:

- Charging your patient programmer
- Patient programmer buttons and controls
- Setting your patient programmer language
- Wi-Fi™* connection

Symbols

Explanation of symbols on product or package labeling

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


Class II equipment


Consult instructions for use

Consult electronic instructions for use at this website


Date of manufacture


Direct current


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

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


Follow instructions for use

For USA audiences only


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


Keep dry

Lot number


Manufacturer

Magnetic Resonance (MR) Conditional

Magnetic Resonance (MR) Unsafe

Model number

PIN number

REF Reorder number

SN Serial number

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 Unique device identifier

 Use by

How to contact Medtronic

Medtronic is available to answer any technical or troubleshooting questions you may have about your system components. Keep the name and telephone number of your clinician on hand for any concerns. See the front cover of this guide for applicable model numbers and trade names.

! USA For assistance in the U.S., call Patient Services at 1-800-510-6735. Support is available Monday through Friday from 8:00 AM to 5:00 PM (Central Time).

If you lose your patient identification card:

Call 1-800-551-5544

Or contact:
Medtronic Inc., Patient Registration Services
Mail Stop RCW225
7000 Central Ave NE
Fridley, MN 55432

Table of contents

Glossary

The following list includes glossary terms that may be unfamiliar to you. These words are defined here for your convenience.

AC
Alternating current.

Altaviva neurostimulator
A rechargeable, implantable neurostimulator, also referred to as "implant" in this guide. The implant generates electrical pulses and delivers stimulation to the tibial nerve for tibial neuromodulation therapy.

Ankle band
An accessory that you can (optionally) use to hold your recharger over your Altaviva™ implant.

Application (app)
A software program designed for a specific use.

Barcode located on the recharger
A square code on the back of your recharger that the Altaviva My Therapy app scans to pair the app on your patient programmer to your recharger.

Caution
A statement that describes an action or situation which could harm you or damage the device.

Clinician
A medical professional such as a doctor, nurse, medical technician, or specialist.

Contraindications
A condition that indicates a particular treatment would be inappropriate for a potential patient because it could harm the patient.

Diathermy
A medical treatment applied to the outside of the body that delivers energy into the body. Three types of energy that can be used are shortwave, microwave, and ultrasound. Depending on the power level used, diathermy devices may or may not produce heat within the body. This treatment is typically used to relieve pain, stiffness and muscle spasms, reduce joint contractures, reduce swelling and pain after surgery, and promote wound healing.

Electromagnetic interference (EMI)
Effects on a device from a field of energy.

Explant
The removal of an implanted device. Explantation requires surgery.

Icon
A symbol or graphic on the app screen that represents an object or command.

Magnetic Resonance Imaging (MRI)
A type of medical procedure that scans your body using magnetic fields to provide detailed pictures of your anatomy.

Pair
Create a wireless connection between 2 devices, such as the patient programmer and the recharger.

Patient programmer
A hand-held device that allows you to manage your stimulation. The Altaviva My Therapy app is installed and runs on the patient programmer.

Precaution
See Caution.

Recharger
The component of the neurostimulation system that is used to recharge your neurostimulator battery and support communication between your patient programmer and neurostimulator.

Recharger dock
A component used to charge the internal battery of your recharger.

Recharging session
Time spent charging the rechargeable neurostimulator.

Schedule
The recurring days and times when stimulation will occur.

Stimulation
The delivery of electrical pulses.

Stimulation level
The strength or intensity of stimulation.

Stimulation session
One of the scheduled times when you receive stimulation.

Tibial neuromodulation (TNM)
Stimulation of the tibial nerve that is used to treat urge urinary incontinence (UUI) symptoms.

USB
Universal serial bus.

Urinary urge incontinence (UUI)
A strong sensation to empty the bladder associated with unintended loss of urine.

Warning
A statement that describes an action or situation that could seriously harm you.

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
mA	Milliamps
MEG	Magnetoencephalography
MR	Magnetic resonance
MRI	Magnetic resonance imaging
PC	Polycarbonate
PET	Positron emission tomography
RFID	Radio-frequency identification
SBR	Styrene-butadiene rubber
TENS	Transcutaneous electrical nerve stimulation
TNM	Tibial neuromodulation
USB	Universal serial bus

Acronym	Definition
UUI	Urge urinary incontinence
V	Volts
µs	Microseconds

About this guide

Read all information before using the Altaviva system.

- The illustrations in this guide are representative. The appearance of some of your system components may vary.
- Troubleshooting information is provided throughout this guide.
- Settings shown on the Altaviva My Therapy app screens throughout this guide are examples. Actual settings will differ based on how your clinician has set up your system.
- If you do not understand something or need more information about your system or your therapy, contact your clinician.
- To access additional copies of this guide or other information, go to www.medtronic.com/patientmanuals.
- To report issues with this guide or any of the documentation you received with this product, contact Medtronic.

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

Part 1: About Altaviva therapy

About your Altaviva system

The Altaviva system is a programmable neurostimulation system that delivers electrical stimulation to the tibial nerve near the ankle. The tibial nerve is part of the network of nerves that control the bladder. Electrical stimulation of the tibial nerve targets the miscommunication that occurs between the bladder and the brain.

System components

The Altaviva system includes the neurostimulator, recharger, patient programmer, and accessories.

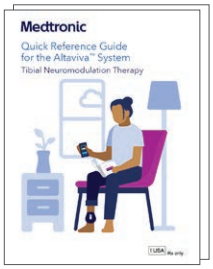
Figure 1. Altaviva system components

1. **Neurostimulator**
2. **Recharger dock**
3. **Charging cable and power adapter for the dock**
4. **Recharger**
5. **Ankle band and adjusters**
6. **Patient programmer**
7. **Charging cable and power adapter for patient programmer**
8. **Patient identification (ID) card and holder**
9. **Product literature**

Table 1. The parts of your system

	Model	Description
1	 Altaviva neurostimulator, Model P7850N	The implanted Altaviva neurostimulator (also referred to as "implant" in this guide) generates electrical pulses to provide stimulation to your tibial nerve.

Model	Description
②  Recharger dock, Model CD9000A	A recharger dock (referred to as “dock” for the rest of this guide) is used to charge the recharger.
③  Charging cable for the dock  Power adapter for the dock	A charging cable and power adapter are used to provide power to the dock.
④ Recharger, Model P720R1	The recharger is used to recharge and communicate with the Altaviva implant. **Note:** Unless you want to adjust your therapy, you do not need to use the recharger during stimulation sessions.
⑤  Ankle band and adjusters, Model P742A1	The ankle band is intended to hold the recharger over the implant for convenience during recharging or programming. Use of the ankle band is optional.
⑥  Patient programmer, Model HH90	The patient programmer hosts the Model P7A2P11 Altaviva My Therapy application (app). It is used to make adjustments to stimulation and to obtain system information from the implant. The recharger must be placed over the implant in order to use the app. **Notes:** • The patient programmer looks like a phone, but it cannot be used as a phone. It cannot be used for emergency calls. • Unless you want to adjust your therapy, you do not need to use the patient programmer during stimulation sessions.

Model	Description
⑦  Charging cable for patient programmer  Power adapter for patient programmer	A charging cable and power adapter are used to charge the patient programmer.
⑧  Patient ID card	The patient ID card contains information about your implant and MRI eligibility. You will receive a temporary card on the day of your procedure and a permanent card will be mailed to you. This card supplies information about you, your implant, and your clinician. It is important that you carry this card with you at all times and bring this card with you to your medical appointments. If you move, change clinicians, lose your card, or your card becomes worn, contact Medtronic to obtain a replacement. Your carrying case has a slot for holding your patient ID card.
⑨  Product literature	Product literature includes: • *Quick Reference Guide for the Altaviva System* which provides a quick reference for how to set up and use your Altaviva system. • Commercial regulation insert for the recharger. • Information about the patient programmer.
 Carrying case, Model P742P1	The Altaviva system components are provided in a carrying case. You may choose to use your carrying case to help keep the components clean and free from damage.

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.

Warnings related to implant procedure

This therapy is not intended for you if your doctor determines you may be at risk for complications from the implant procedure. This may include, but is not limited to:

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

Metal within 5 cm of implant site – Notify your doctor if you have or plan to have any metal implanted below the knee in the same leg as your neurostimulator, such as a metal pin, screw, or plate. If the neurostimulator is within 5 cm of another metal implant, this may cause recharge heating leading to tissue damage and possible surgical intervention.

Mechanical obstruction – This therapy is not intended for you if you have current and unresolved mechanical obstruction such as caused by benign prostatic hypertrophy, cancer, or urethral stricture.

Allergic reaction – This therapy is not intended for you if you have 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
- People under the age of 18
- People with progressive, systemic neurological disease
- People with history of urinary retention

Warnings

General warnings

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

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. You should not have shortwave diathermy or microwave diathermy. Having shortwave diathermy or microwave diathermy with an implanted neurostimulator can cause tissue damage. Shortwave diathermy or microwave diathermy can also damage the implant, requiring removal. Let clinicians know about your Altaviva implant.

Effects on other medical devices – Your Altaviva system may affect the operation of other implanted or external systems. If you have any other medical devices, your clinicians for both systems should work together to make sure that you will not have interactions between the systems. Let both clinicians know about your medical devices.

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. Your clinicians should evaluate any potential interference before recommending Altaviva.

Implant damage – If you have any accident or injury that you think may have physically damaged your implant, talk to your clinician right away. A damaged device may cause tissue damage from exposure to the internal battery, or may fail to operate properly.

Metal implants – Notify the clinician responsible for your system if you plan to receive a metal implant below the knee in the same leg as your neurostimulator, such as a metal pin, screw, or plate. If for an unanticipated reason you have received a new metal implant below the knee in the same leg as your neurostimulator, do not recharge your neurostimulator until your clinician has assessed the distance from the metal implant to the neurostimulator. Recharging a neurostimulator located within 5 cm of another metal implant may cause heating, leading to tissue damage and possible surgical intervention.

Recharger 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

General 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 medical procedures, make sure the providing clinicians know that you have an implanted neurostimulator so that they can take appropriate precautions:

- Radio frequency/microwave ablation - a medical procedure that uses high-frequency radio waves or microwaves to heat and destroy abnormal tissue, like tumors, inside the body
- Electrolysis - a technique where electrical current is used to break down substances or remove unwanted hair by destroying hair follicles
- Transcutaneous electrical nerve stimulation (TENS) - a therapy that uses small electrical currents delivered through electrodes on the skin to help relieve pain
- Laser procedures - medical treatments that use focused beams of light (lasers) to cut, destroy, or repair tissue, such as in eye surgery or skin treatments
- Radiation therapy - a medical procedure that uses high-energy radiation (like X-rays or gamma rays) to target and destroy abnormal cells, such as cancerous tumors
- Electrocautery - a technique where an electrically heated instrument is used to burn or seal tissue, often to stop bleeding during surgery
- Electrosurgery - a procedure that uses high-frequency electrical currents to cut or destroy tissue or stop bleeding during surgery
- High-output ultrasound and high-intensity focused ultrasound (HIFU) - medical procedures that use powerful sound waves to heat or destroy targeted tissue, such as tumors, inside the body
- Physiotherapeutic ultrasound, including ultrasound diathermy - a therapy that uses gentle sound waves to promote healing and relieve pain in muscles and joints
- Lithotripsy - a treatment that uses sound waves or shock waves to break up stones in the kidneys, bladder, or gallbladder so they can be passed out of the body

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 the 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. Although the procedures are not expected to affect your device, you should still let the providing clinician know that you have an implant.

External defibrillation – External defibrillation is a therapy that can deliver an electrical shock to the heart to convert an abnormal heart rhythm to a normal heart rhythm. Application of external defibrillation is unlikely to damage the neurostimulator. Energy from external defibrillation may cause temporary changes in stimulation delivery. If you receive a defibrillation procedure, ask your clinician to confirm that the Altaviva implant is functioning as intended after the defibrillation.

Communication interference from EMI sources – When using your patient programmer and recharger to communicate with your implanted neurostimulator, move away from equipment that may generate EMI or turn off the likely source of EMI. EMI may disrupt communication between the patient programmer, recharger, and implanted neurostimulator. 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.

Implant battery charge level – Check the implant battery level and recharge the battery when needed. The implant battery depletes slowly, even when stimulation is off. If the implant battery level falls too low, therapy will be disabled and your symptoms will likely return, until the battery is recharged.

Implant battery depleted, therapy remains disabled – If the implant battery is not recharged, it can become depleted to the point that

therapy will remain disabled even after the battery is recharged. Contact your clinician to have therapy re-enabled.

Four weeks after implant – 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 may cause discomfort or pain, complications at the surgical site (including reopening the surgical incision), or delayed healing.

Activities during stimulation sessions – As you become accustomed to how the system feels and operates, be mindful of when stimulation sessions are scheduled. Consider limiting activities until you are familiar enough to determine whether stimulation could be distracting or make an activity (for example, driving) dangerous.

Recharger precautions

Discomfort during recharge – Contact your clinician if you experience 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.

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.

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.

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 recharge or communicate with the neurostimulator and may result in exposure to chemicals or sharp edges.

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.

MRI information

Magnetic Resonance (MR) Conditional

You may have a full-body MRI scan only under specific conditions. Scanning under different conditions may result in serious injury to you or damage to your device. If a clinician prescribes an MRI examination for you, ensure that you take these steps:

- **Bring** your Medtronic Patient ID card to your MRI appointment. Information on the card is needed to determine your ability to have an MRI scan.
- **Inform** your implanting clinician or the clinician responsible for your implant that you have been prescribed an MRI.
- **Inform** the MRI-prescribing clinician and MRI technicians that you have an implanted medical device before your MRI examination appointment.
- **Tell** the MRI technician if you think you have a fever. Having a fever may affect your ability to have an MRI scan.
- **Tell** the MRI technician if you experience any heating of the device, shocking sensations, uncomfortable stimulation, or unusual sensations during the MRI scan.

Your clinician will find the latest MRI guidelines for the Altaviva implant at www.medtronic.com/mri.

Magnetic Resonance (MR) Unsafe

External devices such as your patient programmer and recharger are unsafe in the MR environment. Do not take any external devices into the MRI scanner (magnet) room.

Possible complications

Altaviva therapy is intended to improve your symptoms of urge urinary incontinence to a more manageable level enabling you to participate in your regular activities. Therapy may not relieve symptoms for everyone and is not a cure for urge urinary incontinence.

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

Possible complications related to implanting or explanting the Altaviva neurostimulator:

- 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)

Possible complications after implantation of the Altaviva neurostimulator:

- Allergic or immune system reaction
- Lower leg pain or discomfort
- Infection
- Implant could shift from the original implant site or wear through the skin
- 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 you are concerned or feel that you might be experiencing any of these conditions, contact your clinician.

Reporting a serious incident

If you experience any unusual side effects related to your therapy or encounter a serious incident with your device, report it to your clinician immediately. Your clinician will help manage your symptoms and should report the incident to Medtronic and to the applicable competent authority.

⚠ **Warning: Implant damage –** If you have any accident or injury that you think may have physically damaged your implant, talk to your clinician right away. A damaged device may cause tissue damage from exposure to the internal battery, or may fail to operate properly.

Clinical study summary

Safety and effectiveness of the Medtronic Altaviva system for tibial neuromodulation therapy is demonstrated by the TITAN 2 clinical study that evaluated the system for the treatment of urge urinary incontinence (UUI).

Who was included in the study?

Enrollment in the Medtronic clinical study included women and men 18 years of age or older with a diagnosis of UUI for at least 6 months. Patients had to demonstrate at least 3 episodes of UUI in 72 hours in a diary and be without specific medications to control UUI for 2 weeks prior to participating in the study. Patients must have failed or were not a candidate for or did not tolerate more conservative treatments, which includes medications to control UUI.

Who was excluded from the study?

People could not participate in the clinical study if they had severe uncontrolled diabetes or certain conditions affecting the nervous system such as multiple sclerosis, significant peripheral neuropathy (nerves outside of the brain or spinal cord with significant disease or damage), or spinal cord injury. People with certain skin problems or other medical conditions which may affect wound healing were unable to participate. People were also excluded if they had any of the following bladder or pelvic conditions: history of urinary retention in the past 6 months, bladder pain syndrome, pelvic pain, interstitial cystitis, a blockage of the urinary tract, symptomatic urinary tract infection, or a primary diagnosis of stress or mixed (stress and urgency) incontinence where the stress component overrides the urge component. People who had certain anatomical abnormalities (for example due to previous surgery, trauma, or scarring) or significant swelling at the site for implant of the device which could interfere with use of the device were excluded.

Other reasons for exclusion from the study included the history of certain other treatments for their bladder symptoms, such as a prior implantable tibial neuromodulation system, sacral neuromodulation in the past 6 months, botulinum toxin therapy in the past 9 months, or percutaneous tibial nerve stimulation in the past 3 months.

Key safety and effectiveness results

In the Medtronic clinical study, 126 people were implanted with the Altaviva device. Of these, 125 people completed a 6-month follow-up and 118 people completed a 12-month follow-up.

Safety overview

Through 12 months of the clinical study, 25 people (20%) reported complications (adverse events) related to the device, procedure, or therapy. Table 2 provides an overview of reported events that occurred during the 12-month clinical study period.

Table 2. Overview of reported events during the first 12 months of the clinical study

Types of events	Percentage of people who reported the event
Infections where the neurostimulator is placed	7.1%
Pain where the neurostimulator is placed	4.8%
Other pain/discomfort[a]	3.2%
Other[b]	6.3%

a This includes pain in other parts of the foot or leg not at the site of device placement.

b In the "Other" category, the following events each occurred in less than 2% of people: other infection, bowel changes, bruising where the neurostimulator is placed, swelling, buzzing sensation at incision site, and shocking feeling from the recharging device.

Overall, the most frequently reported events were related to infection and pain. There were 9 people who had a suspected infection at the implant site. All these infections were resolved with antibiotic treatment except for one which resolved after the device was removed. One person experienced a serious adverse event of Clostridium difficile infection of the colon which was related to the implant procedure. This event was also resolved. Three people had their neurostimulator either removed or replaced to resolve an adverse event.

Effectiveness overview

The overall clinical success rate for UUI was 59% at 6 months and 61% at 12 months. This means that 59% of people at 6 months and 61% of people at 12 months saw at least a 50% reduction in the number of UUI episodes per day compared to baseline. This analysis included patients with data at baseline and follow-up.

People also experienced approximately 3 fewer UUI episodes per day (2.8 fewer at 6 months and 2.7 fewer at 12 months).

The percentage of patients who experienced clinically meaningful improvement in quality of life was 71% at 6 months and 70% at 12 months. After 6 months of TNM therapy, 82% of patients reported that their condition had improved compared to before treatment, and this stayed consistent through 12 months (80%). The percentage of patients who were completely continent (no leaks) was 17% at 6 months and 23% at 12 months.

Part 2: Living with your system

After the implant procedure

Talk with your clinician about how to care for your implant site after your implant procedure.

Initial healing period

For at least 72 hours after your implant procedure (or longer based on your clinician's advice):

- Keep the implant site dry and covered.
- Wear a compression sock to minimize swelling and aid in healing.

First 4 weeks after implant

△ **Caution:** 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 may cause discomfort or pain, complications at the surgical site (including reopening the surgical incision), or delayed healing.

For the first 4 weeks after the implant procedure you should 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 your clinician if you notice any unusual signs or symptoms while the implant site is healing such as redness, drainage, swelling, opening of the incision, or fever.

Life with your implant

Remember to:

- Avoid physically manipulating the implanted neurostimulator.
- Contact your clinician if you notice any unusual signs or symptoms at the implant site such as discomfort, redness, the implant showing through the skin, or if you begin to notice changes in your urinary symptoms.
- Contact your clinician if you notice any unintended changes in stimulation.

Daily and recreational activities

△ **Caution: Activities during stimulation sessions –** As you become accustomed to how the system feels and operates, be mindful of when stimulation sessions are scheduled. Consider limiting activities until you are familiar enough to determine whether stimulation could be distracting or make an activity (for example, driving) dangerous.

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. A damaged device may cause tissue damage from exposure to the internal battery, or may fail to operate properly. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your clinician.

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.

Managing your therapy

Therapy is stimulation that occurs on a schedule. You will receive therapy in sessions called "stimulation sessions." During active stimulation, your implant will deliver stimulation to your tibial nerve.

Your clinician will program your stimulation schedule and determine how frequently you receive stimulation, how long stimulation stays on, and the start date and time. Once set up, stimulation will be delivered automatically.

Talk to your clinician to make sure that you understand how your stimulation schedule works and how to manage your stimulation schedule.

You can do the following:

- Change the schedule start time (see page 61).
- Adjust the stimulation level within clinician-defined limits (see page 56).
- End an active stimulation session (see page 58).
- Stop and resume stimulation schedule (see page 59).

Notes:

- Unless you want to adjust your therapy, you do not need to use the patient programmer or recharger during stimulation sessions.
- You may not need to feel stimulation in order for your therapy to relieve your symptoms. The sensation of stimulation may change; however, if you have symptom relief, there is no need to adjust your stimulation.
- If you have questions about your therapy, contact your clinician.

Travel and time change questions

Frequently asked questions about traveling and timekeeping with the Altaviva system are answered below. If you have additional questions, contact your clinician.

Should I take my patient programmer and recharger with me when I travel?

Yes. For convenience and device protection, you can store your patient programmer and recharger in your carrying case during travel.

What do I do at the airport or near theft detectors?

If you are in an active stimulation session, you do **not** need to turn off stimulation to go through airport security or theft detectors. Do not linger or lean near the security gate or theft detectors and do not start a recharging or programming session near this equipment. Always carry your patient ID card.

Will my patient programmer work during air travel?

Yes. You can use the patient programmer to adjust therapy during a flight. While in flight, use Airplane Mode. Consult with the airline for their policy on using your recharger or patient programmer on board their aircraft.

What happens to my stimulation session time when I enter a new time zone?

The clock in your implant will **not** automatically adjust to the new time zone. Stimulation sessions will continue to occur based on the time zone set by your clinician. To see when your next session begins, check the Home screen.

What happens to my stimulation session time when daylight saving time occurs?

The clock in your implant will **not** automatically update the time when daylight saving time occurs. To ensure your implant clock adjusts, connect to the app after daylight saving time has taken place. Tap **UPDATE NOW** on the Daylight Saving Time Update notification. Your system will move the implant clock forward or back by 1 hour accordingly. Once you have tapped **UPDATE NOW** you do not need to make any additional changes.

What happens if I notice that my stimulation session time is starting a little earlier or later than expected?

It is normal for the clock in your implant to lose or gain a few minutes over time. If needed, your clinician can correct the time set on your implant clock at your next appointment.

Follow-up appointments

Bring all Altaviva system components to your follow-up appointments.

Make sure that your system components are charged.

In addition, bring your patient ID card to share information with clinicians who may not be familiar with the Altaviva system.

Future medical procedures

Before you have any medical procedure, always inform health care professionals that you have an implanted Altaviva neurostimulator.

To avoid an unwanted stimulation session during a medical procedure, turn off your therapy. After the procedure, remember to turn therapy back on.

Metal implants

If you receive or plan to receive any metal implant below the knee in the same leg as your neurostimulator, let your clinician know.

⚠ **Warning: Metal implants –** Notify the clinician responsible for your system if you plan to receive a metal implant below the knee in the same leg as your neurostimulator, such as a metal pin, screw, or plate. If for an unanticipated reason you have received a new metal implant below the knee in the same leg as your neurostimulator, do not recharge your neurostimulator until your clinician has assessed the distance from the metal implant to the neurostimulator. Recharging a neurostimulator located within 5 cm of another metal implant may cause heating, leading to tissue damage and possible surgical intervention.

Part 3: Getting started with the Altaviva system

System description

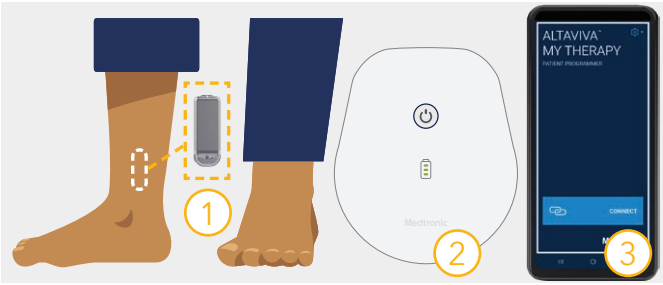


Figure 2. Altaviva system components

① The implanted Altaviva neurostimulator.

② The recharger.

③ The patient programmer and Altaviva My Therapy app. The app comes pre-installed on the patient programmer.

The Altaviva My Therapy app is used to view details about your therapy and make adjustments as needed.

Once paired, you do not need the patient programmer to recharge your implant. You can use the recharger on its own.

If you are making adjustments to stimulation settings, you need both the recharger and the patient programmer. Anytime you want to use the app to adjust your stimulation, you will need to position the recharger over the implant (see "Positioning your recharger", page 77).

How the system components interact

Figure 3. How the Altaviva system components interact

① **The patient programmer connects to the recharger using Bluetooth®*.**

② **The recharger connects to the implanted neurostimulator using near-field magnetic induction communication.**

The patient programmer uses Bluetooth®* wireless communication to connect to the recharger. The recharger uses near-field magnetic induction communication to connect to the implanted neurostimulator.

The Altaviva My Therapy app on the patient programmer communicates with the implant through the recharger.

Note: If your system components were set up at the clinic, you can skip the "Taking the recharger out of shipping mode" and "Pairing the system components" sections.

How the recharger functions within the system

The recharger is used to recharge and communicate with your Altaviva implant.

There are other Medtronic rechargers and docks that look like your Altaviva components. If you have more than one recharging system, confirm that the model number "P720R1" recharger is used with the "CD9000A" dock. Model numbers are found on the back of these components.

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

Table 3. Recharger modes

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 make adjustments such as change stimulation level, change start time, or end an active stimulation session.**

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.

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 dock 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 ().

After removing the recharger from shipping mode, continue to "Pairing the system components", page 46, to complete the system setup.

Pairing the system components

Before you can use the system to recharge or view and adjust therapy details, you will need to pair the patient programmer to the recharger and the implant.

Pairing the patient programmer to the recharger

1. Remove the recharger from the plugged-in dock.
2. Turn on your patient programmer.

   Tap the Altaviva My Therapy app icon (Figure 4) to open the app.

Figure 4. Altaviva My Therapy 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**.

3. Tap **CONNECT** on the startup screen (Figure 5) and turn the recharger over to view the backside.

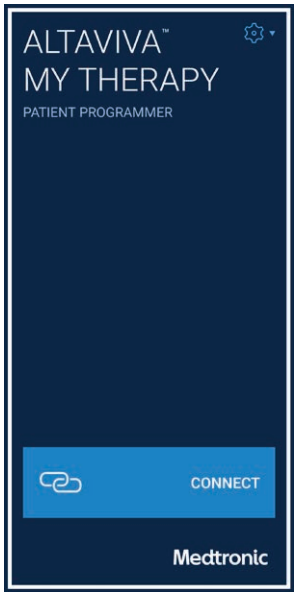


Figure 5. Startup screen

4. Tap **SCAN CODE** and scan the barcode on the back of the recharger, **or** enter the serial number manually using your patient programmer (Figure 6).

Figure 6. Connect to Recharger screen

To scan the barcode:

a. Tap **SCAN CODE**.

b. Tap **CONTINUE** (Figure 7).

c. Using the camera on the patient programmer, center the barcode found on the back of the recharger (Figure 7).

d. The patient programmer will beep when the barcode is read.

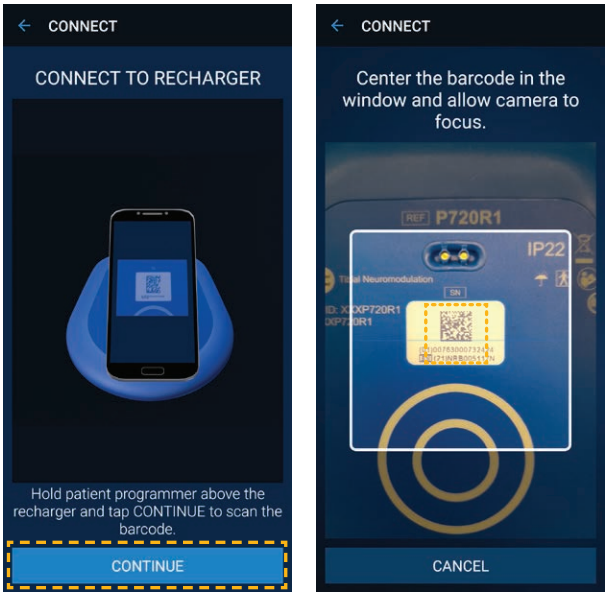


Figure 7. Scan the barcode (serial number shown is for example only)

To enter the serial number manually:

a. Tap **ENTER MANUALLY.**

b. Using the patient programmer, enter the number on the back of your recharger (Figure 8).

c. Tap **CONTINUE**.

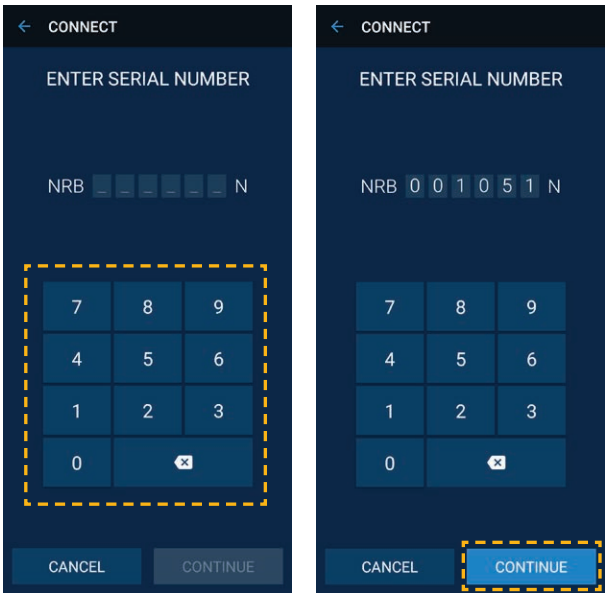


Figure 8. Manually enter the serial number (serial number shown is for example only)

5. Wait for the recharger to connect (Figure 9).

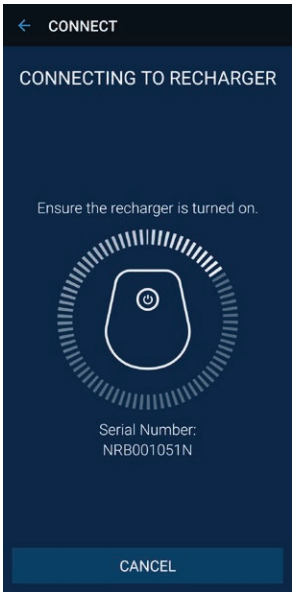


Figure 9. Connecting to Recharger screen (serial number shown is for example only)

6. Once the patient programmer has connected to the recharger, you will see the Searching for Altaviva Implant screen (Figure 10).

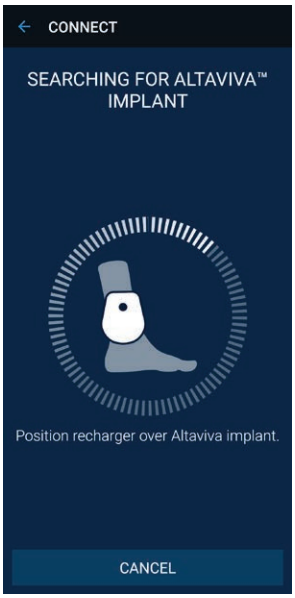


Figure 10. Searching for Altaviva Implant screen

7. Continue with "Pairing the patient programmer to the implant", page 50, to finish the pairing process.

Pairing the patient programmer to the implant

1. While the Searching for Altaviva Implant screen is visible, position your recharger over the implant.

   Note: For details about how to position the recharger, see page 77.

2. Tap to select the box next to your implant's serial number, then tap **CONTINUE** (Figure 11).

   Note: You can confirm your implant's serial number using your patient ID card.

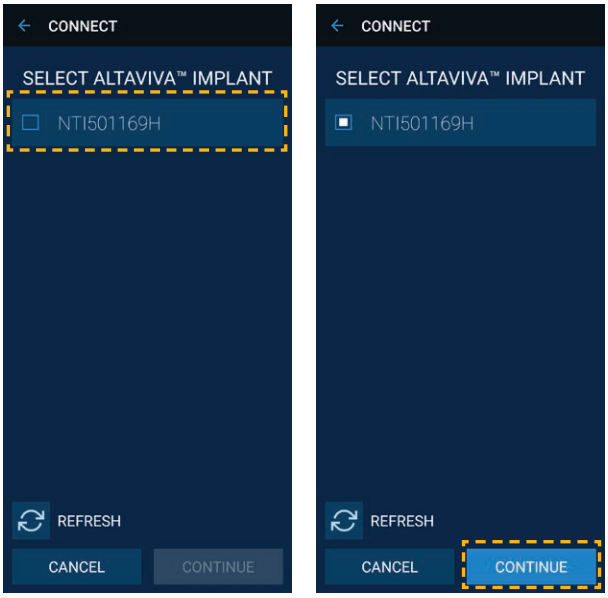


Figure 11. Implant selection (serial number shown is for example only)

3. Once the patient programmer has successfully connected to the implant, you will see the Home screen.

Part 4: Using the Altaviva My Therapy application

Connecting to the implant using the app

Once the system is set up, you can connect to your implant using the app as needed.

1. Remove the recharger from the plugged-in dock.
2. Position the recharger over your implant. See "Positioning your recharger", page 77, for instructions.
3. Open the Altaviva My Therapy app on the patient programmer and tap **CONNECT**.

Once connected, you will be taken to the Home screen. See "Home screen", page 53.

Home screen

When you have connected to your implant, you will see the Home screen of the app.

From the Home screen, you can do the following:

- Access menu options (page 55)
- Check implant battery
- Check your stimulation status (active versus not active)
- End a scheduled stimulation session that is currently active (page 58)
- Stop and resume scheduled stimulation sessions (page 59)
- View and adjust stimulation level (page 56)
- View your schedule and change the start time for scheduled stimulation sessions (page 61)

Your Home screen will look like Figure 12 depending on the status of your stimulation.

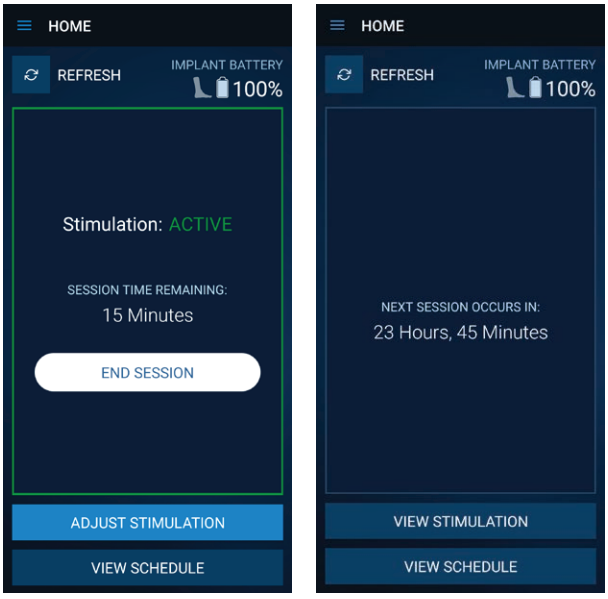


Figure 12. Home screen when your scheduled stimulation is active (left) and inactive (right)

Notes:

Figure 13. REFRESH icon located on the Home screen

- If you are already on the Home screen when a stimulation session begins, tap the **REFRESH** icon (↻) to update the stimulation status and start the auto-countdown of session time remaining.
- If you stay on the Home screen after the stimulation session ends, tap the **REFRESH** icon (↻) to see the time until your next scheduled session.

Accessing menu options

From the Home screen, you can access the menu options.

1. Tap the menu icon ☰ to display the menu options (Figure 14).

Figure 14. Home screen menu access

2. Select from the list of options to access an area of the app:
   - **Recharger** – to view battery and recharge details (page 64)
   - **Stop Schedule** – to stop your stimulation schedule (page 59)
   - **About** – to view system information
   - **Exit Application** – to quit the app

Adjusting stimulation level

Your clinician has established the range within which you can adjust your stimulation level. You can only adjust stimulation when you are in an **active** stimulation session.

To change the stimulation level:

1. Position the recharger over your implant and connect to the app.
2. Tap **ADJUST STIMULATION** on the Home screen (Figure 15).

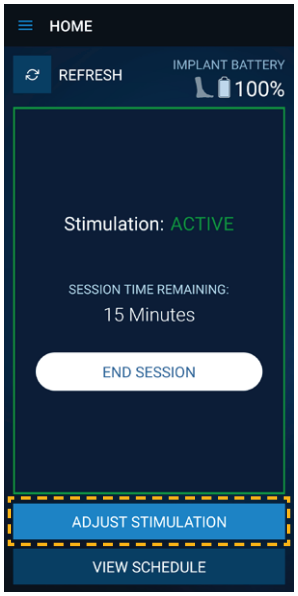


Figure 15. Home screen when stimulation is active

The Stimulation screen will be displayed (Figure 16).

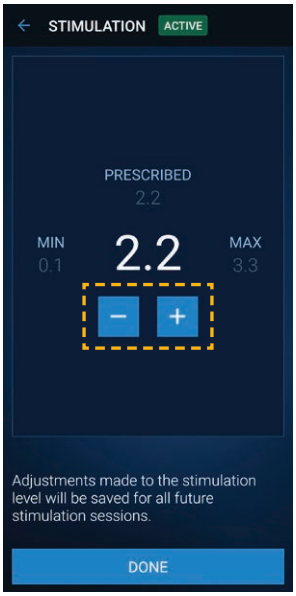


Figure 16. Stimulation screen

3. Tap **−** to decrease stimulation level (Figure 16).
4. Tap **+** to increase stimulation level (Figure 16).
5. When you have reached the desired level, tap **DONE**.

Notes:

- Adjustments to stimulation will be saved for all future stimulation sessions.
- If your stimulation becomes uncomfortable and you cannot adjust your stimulation, stop your stimulation and contact your clinician.

Ending an active stimulation session

1. Position the recharger over your implant and connect to the app.
2. When in an active stimulation session, tap **END SESSION** on the Home screen to end the stimulation session (Figure 17).

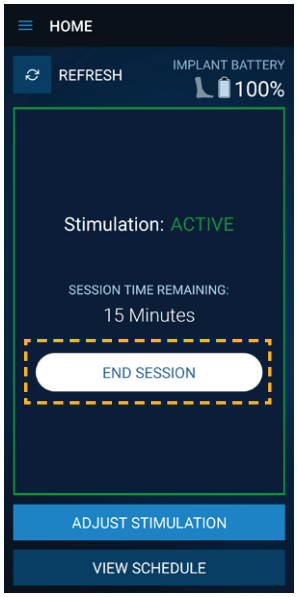


Figure 17. Home screen when stimulation is active

3. A confirmation notification will appear. Tap **CONFIRM**.
4. Stimulation will resume at your next scheduled session and the Home screen will now show the amount of time until that next scheduled session.

Stopping and resuming scheduled stimulation

If you want to interrupt your stimulation schedule so that stimulation does not occur at your next scheduled time, use the "Stop Schedule" menu item.

Stopping your stimulation schedule

1. Position the recharger over your implant and connect to the app.
2. Tap ☰ in the top-left corner of the Home screen to open the menu.
3. Select **Stop Schedule** from the list of options.
4. The Stop Schedule screen will appear (Figure 18). Tap **STOP SCHEDULE**.

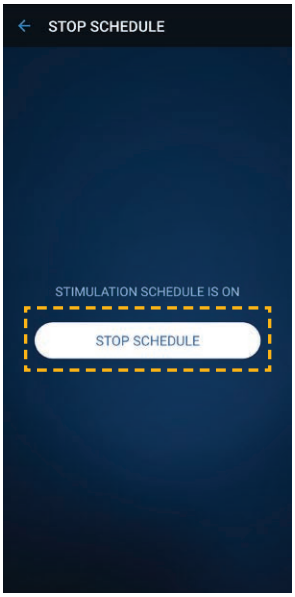


Figure 18. Stop Schedule screen

5. A confirmation notification will appear. Tap **CONFIRM**.
6. Your Home screen will now show that your stimulation schedule is stopped.

   Note: When your stimulation schedule is stopped, stimulation sessions will not occur until you or your clinician resumes the schedule.

Resuming your stimulation schedule

1. On the Home screen, tap **RESUME SCHEDULE** to resume your schedule (Figure 19).

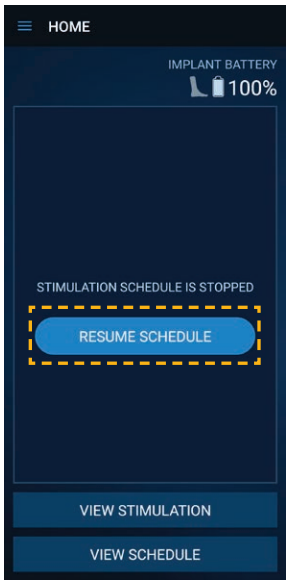


Figure 19. Home screen when scheduled stimulation is stopped

2. A confirmation notification will appear. Tap **CONFIRM** to resume your schedule.

   Note: Your stimulation schedule will resume after you tap **CONFIRM**.

Viewing schedule and changing the scheduled start time

If you receive **scheduled** stimulation, you can view your schedule and change your scheduled start time, if needed.

To view your schedule:

1. Position the recharger over your implant and connect to the app.
2. From the Home screen, tap **VIEW SCHEDULE** (Figure 20).

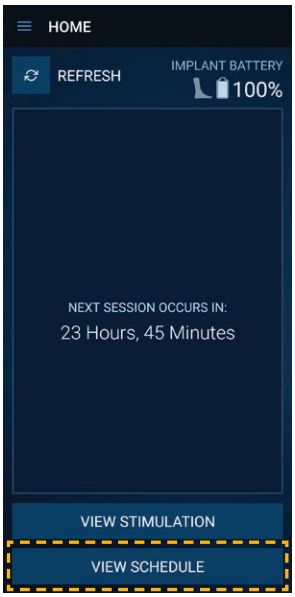


Figure 20. Home screen between sessions

3. The Schedule screen will appear.

To change the scheduled start time:

1. On the Schedule screen, tap **CHANGE START TIME** (Figure 21).

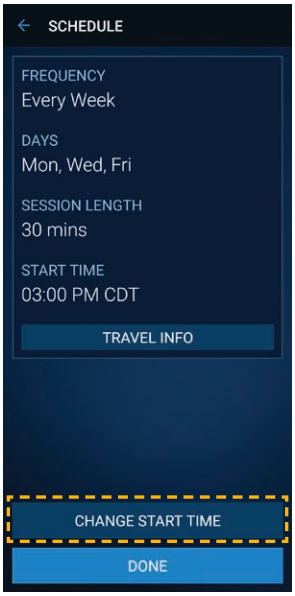


Figure 21. Schedule screen

2. On the Change Start Time screen, scroll up and down on the hour, minutes, and AM/PM settings to set the new start time for your stimulation sessions. Then tap **SAVE** (Figure 22).

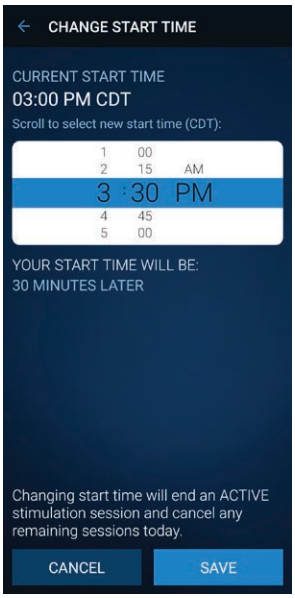


Figure 22. Change Start Time screen

3. A confirmation notification will appear. Tap **CONFIRM** to confirm the change to your stimulation schedule.

Note: After you tap **CONFIRM**, your scheduled start time will be updated for all future sessions.

4. If you are keeping notes on your stimulation schedule, be sure to also update that record to reflect your new start time.

Checking implant and recharger battery levels

Check the implant battery level and recharge the battery when needed. Talk to your clinician to get an estimate for how often you need to recharge your implant battery. The recharge frequency for the implant battery will depend on your stimulation settings and schedule.

Your implant battery level is displayed on the top-right corner of the Home screen (Figure 23).

Figure 23. Implant battery level display on the Home screen

Tapping the **IMPLANT BATTERY** area of the Home screen will take you to the Recharger screen where you can see both your implant and recharger battery levels.

You can also access the Recharger screen using the menu:

1. Tap ☰ in the top-left corner of the Home screen to open the menu.
2. Select **Recharger** from the list of options.

Figure 24 shows an example of the Recharger screen.

Figure 24. Recharger screen

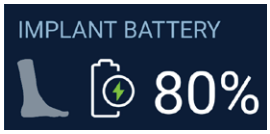
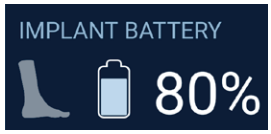
Table 4 shows implant battery level displays. Battery levels are displayed in increments of 10%.

Table 4. Implant 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.

When the implant battery is recharging, the display will show a lightning bolt symbol on top of the battery icon (Table 5).

Table 5. Charging status of the implant battery

Recharging	Not recharging
	

Note:

Figure 25. Recharger position needs attention

- During a recharging session, an orange indicator with an exclamation mark shows that your recharger position needs attention (Figure 25). See "Improving recharger position", page 83 for details.

For instructions on recharging the implant battery, see page 80. For instructions on charging your recharger, see page 75.

Software information

Data security

The Altaviva My Therapy app uses and stores data about your health and medical device. This information is protected by the app and patient programmer. Personal files or data you choose to store or access elsewhere on the patient programmer are not protected. You are ultimately responsible for protecting the data that is stored on the patient programmer.

The recharger does not store any personal information.

Network connectivity

You do not need to connect to a network to use your patient programmer. Network connectivity is required only in the event of a software update for your patient programmer or recharger.

Medtronic recommends the following for network connectivity:

- Secure your patient programmer by disabling the Wi-Fi connection when using the Altaviva My Therapy app.
- Use a trusted Wi-Fi network when internet access is needed.
- Connect the patient programmer to a Wi-Fi network periodically to check for update notifications.

System updates

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

During updates, you temporarily will not be able to make changes to your therapy. Plan for updates accordingly.

Additional security measures

If your patient programmer or recharger is lost or stolen, contact Medtronic right away.

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

If you no longer need the patient programmer or recharger to manage your therapy, refer to "Return, replacement, and disposal", page 95.

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

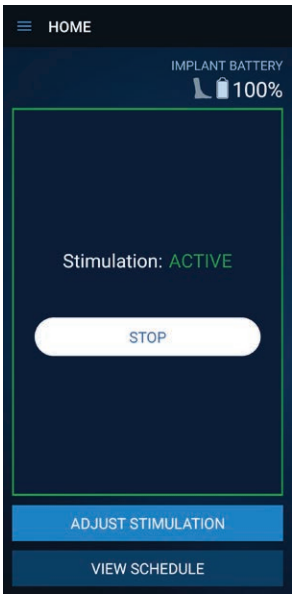
Troubleshooting

Therapy (stimulation) issues

Table 6 provides troubleshooting scenarios that you may encounter, as well as explanations and solutions to resolve issues you are experiencing with your therapy.

Table 6. Possible scenarios and solutions for therapy (stimulation) issues

Scenario	Explanations and solutions
Uncomfortable or intolerable stimulation	**You may be experiencing side effects or discomfort from the stimulation.** 1. Decrease the stimulation level, end the active stimulation session, or stop the stimulation schedule. To adjust stimulation level, see page 56. To end an active stimulation session, see page 58. To stop the stimulation schedule, see "Stopping and resuming scheduled stimulation", page 59. 2. Electromagnetic interference (EMI) from sources like electronic theft detectors, large electrical engines or generators, welding equipment, radio transmitters, and high-power lines may temporarily disrupt therapy, cause uncomfortable stimulation, or interfere with communication during an ongoing stimulation session. If this happens, move away from the EMI source. Exposure to these sources is unlikely to damage your implant. 3. If you are still experiencing uncomfortable stimulation, call your clinician.
During a scheduled stimulation session, the Home screen does not update the time remaining in the session	**The Home screen needs to be refreshed.** Tap the **REFRESH** icon (↻) in the top-left corner of the screen to update the Home screen.
After a scheduled stimulation session, the Home screen does not show the time remaining until next session	**The Home screen needs to be refreshed.** Tap the **REFRESH** icon (↻) in the top-left corner of the screen to update the Home screen.

Scenario	Explanations and solutions
My scheduled stimulation is happening at an unexpected time	**Your scheduled start time may need to be updated.** 1. If daylight saving time has occurred, connect to the app and tap **UPDATE NOW** on the Daylight Saving Time Update notification to ensure your scheduled start time adjusts accordingly. 2. If you are traveling across time zone(s), the clock in your implant will not automatically adjust to the new time zone. Stimulation sessions will continue to occur based on the time zone set by your clinician. To see when your next session begins, check the Home screen. If you have questions or concerns about the timing of your scheduled stimulation, contact your clinician.
Return of symptoms	**Your stimulation schedule may be turned off.** 1. Connect to the app. 2. Resolve any notifications. 3. Ensure your stimulation schedule is not stopped and your stimulation sessions are scheduled as expected. Contact your clinician if you have concerns about your therapy.
The white button on my Home screen says STOP instead of END SESSION 	**Your stimulation is being delivered continuously which should not be used.** You should stop the stimulation by using the app and contact your clinician. Contact Medtronic if you have questions about turning continuous stimulation off.

App notifications

When you are using the app, notifications may appear to notify you of issues with your system. When a notification screen pops up, read the notification and follow the instructions. If a notification screen says to contact your clinician or Medtronic, provide the service code shown on the notification screen.

The notification color indicates its urgency, as shown in Table 7. Contact your clinician if you have any questions about notifications.

Table 7. Types of notifications

Notification color and urgency	Explanation
Blue: Low 	Provides information about your system. Follow the instructions in the notification.
Orange: Medium 	Follow the instructions in the notification. Contact your clinician or Medtronic if you cannot resolve the issue on your own.
Red: High 	Follow the instructions in the notification. Contact your clinician or Medtronic as directed.

Table 8 lists some important notifications along with explanations and what to do if you see them.

Table 8. Possible notifications and solutions

App notification	Explanations and solutions
Recharger Connection Lost	**The connection between the patient programmer and the recharger has been lost.** 1. Position the recharger near your patient programmer and press the power button on the recharger. 2. Tap **EXIT SESSION** and reconnect. 3. If this issue persists, contact Medtronic.
Communication to the Altaviva Implant Has Been Lost	**Communication to the implant was lost.** Ensure the recharger is over the implant and tap **RETRY**, or tap **EXIT SESSION** and reconnect. If this issue persists, contact Medtronic.

App notification	Explanations and solutions
Recharger Low Battery	**Recharger battery is low.** Place recharger on the plugged-in dock to charge. **Note:** The recharger should be left on the plugged-in dock between recharging sessions when not in use so it remains charged.
Low Battery: Implant	**Your implant battery is low.** Recharge your implant to avoid losing stimulation. **Note:** Check your battery level and keep your implant charged to avoid interruptions in stimulation. If the implant battery is not recharged, it can become depleted to the point that therapy will remain disabled even after the battery is recharged.
Therapy Disabled	**Your therapy was disabled due to very low implant battery level.** Contact your clinician to have therapy re-enabled.
Stimulation Schedule Disabled	**Your stimulation schedule was disabled due to a system error.** Recharge your implant and reconnect to the app to re-enable stimulation. If the issue persists, contact Medtronic.
Stimulation Schedule Stopped	**Your stimulation schedule was stopped due to a system error.** This error has been corrected. Check that your stimulation schedule settings are as expected and resume the schedule.
Therapy Settings Error	**Stimulation settings error detected.** Your stimulation will still occur but settings may need to be adjusted. Contact your clinician.
Replacement Recommended	**Your implant has reached the end of its service life.** Contact your clinician.

Other troubleshooting scenarios

Table 9 provides additional troubleshooting scenarios and solutions.

If these troubleshooting steps do not resolve your issues, try turning the patient programmer off and then turning it back on. Then retry the steps as described in this guide. If the issue persists, contact Medtronic.

Table 9. Other troubleshooting scenarios and solutions

Scenario	Explanations and solutions
I cannot find the app on the patient programmer	**The Altaviva My Therapy app may not have downloaded properly or may have been deleted from the patient programmer.** Contact Medtronic.
The patient programmer, or the app is unresponsive	**Your patient programmer may need to be restarted.** 1. Turn off the patient programmer, then turn the patient programmer back on and reopen the app. 2. If the issue persists, contact your clinician.
The patient programmer has no power or has lost power	**The patient programmer battery may be depleted.** Charge the patient programmer using the charging cable and power adapter provided by Medtronic. If the issue persists, contact Medtronic.
The patient programmer will not charge	**The patient programmer is not plugged into the power source.** Make sure that the patient programmer is properly connected to the wall outlet, using the charging cable and power adapter provided.
	The patient programmer, charging cable, or power adapter may be defective, damaged, or malfunctioning. Contact Medtronic.

Scenario	Explanations and solutions
The patient programmer is unable to connect to the recharger	**The recharger is not turned on (the power button light and battery light are both off).** Position your patient programmer near the recharger and press the power button to turn on the recharger. Once the recharger is turned on, try reconnecting.
	The recharger is not charged. Place the recharger on the plugged-in dock. Once charged, follow the connection steps to reconnect.
The patient programmer is unable to connect to the recharger (continued)	**The recharger is out of range.** Position your patient programmer near the recharger and ensure that your recharger is turned on. Once in range, try reconnecting.
	Your patient programmer is paired with a different recharger. 1. From the Recharger Not Found screen, tap **RETRY**. 2. If unsuccessful, tap **CONNECT TO A DIFFERENT RECHARGER** and follow the directions provided on the screen.
	The recharger and patient programmer 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 lights begin to flash. This will reset the recharger. 2. If Step 1 was unsuccessful, turn off the patient programmer, turn it back on, and reconnect. 3. If the steps outlined above do not result in successful communication between the patient programmer and the recharger, contact Medtronic.

Part 5: Using the Altaviva recharger

Charging your recharger battery

If the recharger was not set up or you have a replacement recharger, see "Taking the recharger out of shipping mode", page 45.

The internal battery of the recharger uses a dock to charge (Figure 26).

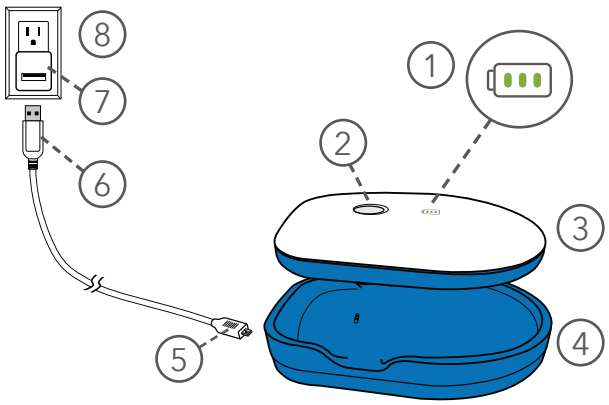


Figure 26. Charging the recharger battery

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

1. Plug in the dock to the wall outlet using the dock charging cable (USB 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 your implant.

3. While the recharger is charging, the battery light will slowly flash green. When the recharger is fully charged, you will see 3 solid green bars on the battery light (Table 10).

Table 10. Recharger battery light display

Charging	Fully Charged
	

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.

Positioning your recharger

Position your recharger over your implant to:

- Recharge the implant.
- View and change your stimulation schedule or settings using the app.

To position the recharger, locate the circles shown on the back of the recharger (◎) and place them directly over your implant (Figure 27). Maintain this position while you are using the recharger.

Figure 27. Positioning the recharger

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.

Note: While your wound is healing, use a sterile bandage or barrier between the wound and the recharger or ankle band to reduce the risk of an infection.

To position the recharger using the ankle band:

1. Insert the recharger into the ankle band pouch so that the power button (⏻) is visible through the window in the pouch (Figure 28).

Figure 28. Inserting the recharger into the ankle band pouch

2. Place the 2 circles (◎) on the back of the ankle band directly over your implant. Hold the recharger in this position as you continue (Figure 29).

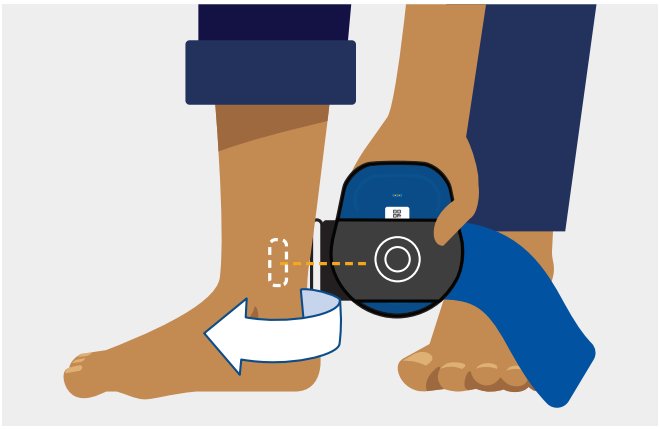


Figure 29. Positioning the recharger over the implant

3. Wrap the ankle band around the back of your ankle and thread the ankle band through the eyelet (Figure 30).

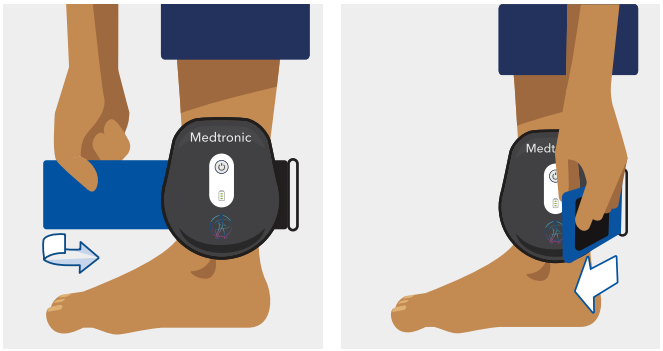


Figure 30. Wrapping and threading the ankle band

4. Fold the ankle band back around your ankle and then pull it forward and secure it in place (Figure 31).

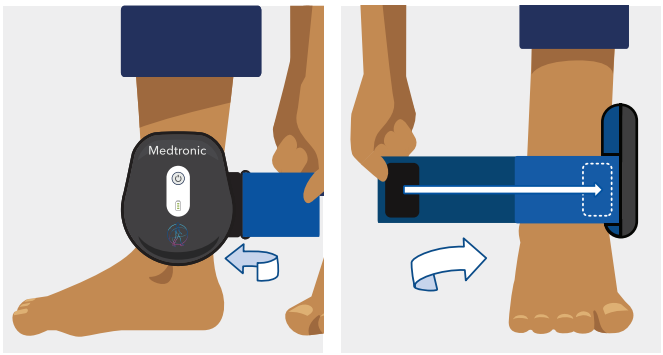


Figure 31. Securing the ankle band

Using the ankle band adjusters

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

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 one adjuster to the end of the ankle band.
3. Thread the ankle band through the eyelet.

Recharging the implant

Notes:

- Before you can recharge the implant, the patient programmer must be paired to the recharger. See "Pairing the patient programmer to the recharger", page 46.
- Once paired, you do not need the patient programmer to recharge your implant. You can use the recharger on its own.

To begin your recharging session, follow these steps:

1. Remove the recharger from the plugged-in dock.
2. Press the power button (⏻) on the recharger.

   As the recharger searches for the implant, you will hear searching tones and the green light on the power button will spin.
3. Position the recharger over your implant with or without the ankle band (Figure 32).

Figure 32. Recharger is searching for the implant

4. If the searching tones continue, reposition the recharger until the searching tones stop.
5. When the recharger has found and connected to the implant, you will hear 2 tones rising in pitch and the power button light will be solid green.
6. Once connected, the recharger will automatically start recharging the implant. While recharging is in progress, the recharger will show a slow pulsing green light (Figure 33).

Figure 33. Recharge in progress

7. Keep the recharger over your implant for the duration of the recharging session.
8. When recharging is complete, a series of tones rising in pitch will sound and the power button light will change to solid green (Figure 34).

Figure 34. Recharge complete

9. Remove the recharger from the ankle band (if using) and return the recharger to the plugged-in dock.

Note: If the recharger power button is displaying an orange light, indicating an error, see "Table 12. Recharging scenarios or alerts", page 86.

Viewing recharger details in the app

Although use of the patient programmer is not required to recharge your implant, you can use the patient programmer and app to view details about your recharger positioning, view your recharge status, and adjust the recharger volume. Make sure that you have connected to your implant using your patient programmer while you are recharging to view this information.

View recharger positioning status

The Recharger screen in the app displays information about the strength of the connection between the recharger and the implant by measuring the recharger position.

Your recharger can be in a position that is “Needs attention”, “OK”, or “Good” (Figure 35).

Table 11 shows the recharger status indicators that you may see on the Recharger screen and their definitions.

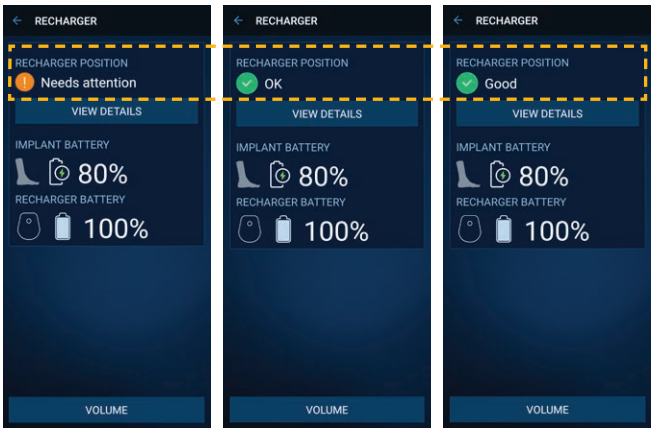


Figure 35. Examples of recharger positioning status shown on the Recharger screen

Table 11. Recharger status indicators and definitions

Indicator	Meaning
	The recharger requires repositioning.
	The recharger is in an OK or Good position for recharging and communicating.

Improving recharger position

Follow these steps if you see an orange indicator and “Needs attention” displayed under “Recharger Position”:

1. Tap **VIEW DETAILS** to open the Recharger Details screen (Figure 36).

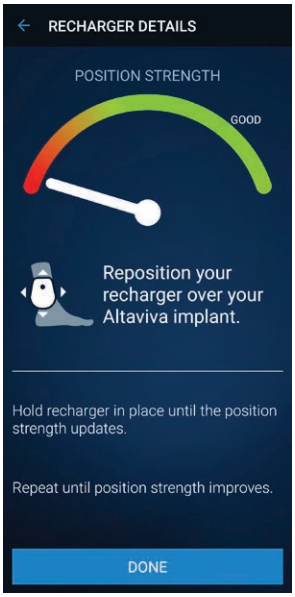


Figure 36. Recharger Details screen

2. Reposition your recharger over your implant and hold it in place until the position strength updates.
3. Once your recharger is in an “OK” or “Good” position, maintain that position for the rest of the recharging session. See Figure 37 for recharger position examples.

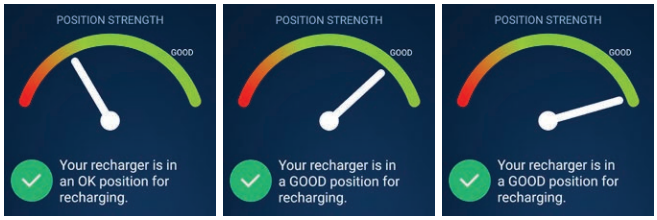


Figure 37. Indication of an acceptable recharger position

4. Tap **DONE**.

Adjusting recharger volume

To adjust recharger volume, you will need to connect to your app.

1. Once connected, tap ☰ in the top-left corner of the Home screen to open the menu.
2. Select **Recharger** from the list of options to open the Recharger screen.
3. Tap **VOLUME** to open the Recharger Volume screen (Figure 38).

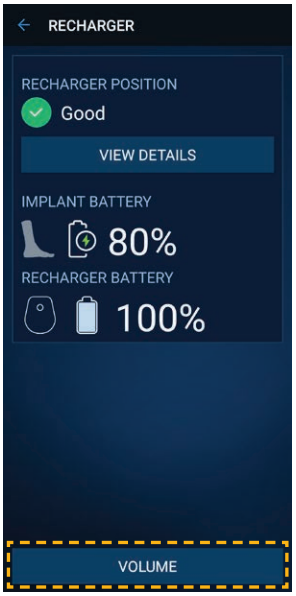


Figure 38. Recharger screen

4. Use the arrow buttons (∧ ∨) to adjust the volume as desired (Figure 39). As you change the volume, the recharger will make a tone to demonstrate the current volume setting.

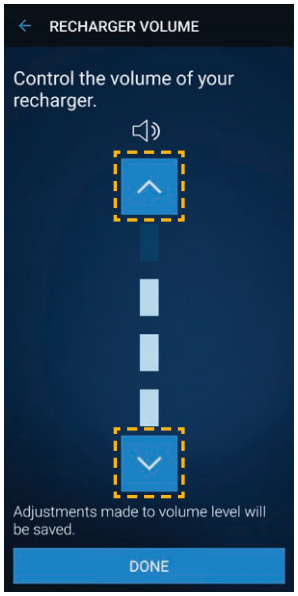


Figure 39. Recharger Volume screen

5. Tap **DONE** to return to the Recharger screen. From the Recharger screen, tap the back arrow (←) at the top-left corner of the screen to return to the Home screen.

Note: If you turn off the volume completely, you will not be able to hear the audio feedback described in this guide.

Troubleshooting the recharger

This section provides solutions to problems that you may encounter while using your recharging system. If you cannot solve a problem or it is not described here, contact your clinician.

Table 12 lists some problems and alerts and what to do if you encounter them.

Table 12. Recharging scenarios or alerts

Scenario or alert	Cause and action
The recharger is unresponsive or will not turn on.	**Cause:** The recharger battery may need to be charged, or the recharger may be in shipping mode. **Action:** Try charging the recharger. See "Charging your recharger battery", page 75. If the recharger is still unresponsive, it may need to be taken out of shipping mode. See "Taking the recharger out of shipping mode", page 45.
 **Lights:** Spinning green **Tones:** Repeating tones of the same pitch	**Cause:** The recharger is searching for the implant. If the searching tones continue, the recharger's position over the implant needs to be adjusted. **Action:** 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	**Cause:** The recharger has found and connected to the implant. **Action:** Maintain this position while you are using the recharger.
 **Lights:** Slowly pulsing green **Tones:** None	**Cause:** The recharger is recharging the implant. **Action:** No action is needed.
 **Lights:** Solid green **Tones:** A series of tones, rising in pitch	**Cause:** Recharging session is complete. **Action:** Return the recharger to the plugged-in dock.

Scenario or alert	Cause and action
 **Lights:** Spinning orange and green **Tones:** 2 tones, falling in pitch	**Cause:** Connection with the app is needed. **Action:** Open the app and tap **CONNECT** for more information.
 **Lights:** Flashing orange **Tones:** 2 tones, falling in pitch and repeating	**Cause:** The recharger has encountered an error and stopped recharging the implant. **Action:** • Open the app and tap **CONNECT** to resolve any error messages by following the directions provided in the app. • If the error continues, turn off the recharger by pressing and holding the power button. Press the power button to resume recharging. • If the error persists, hold down the power button for at least 20 seconds or until the lights begin to flash. This will reset the recharger. If not resolved, contact your clinician.
 **Lights:** Solid orange, then off **Tones:** 2 tones, falling in pitch (not repeating)	**Cause:** Your patient programmer has not been paired to the recharger. **Action:** Pair the patient programmer to the recharger and try again. See "Pairing the patient programmer to the recharger", page 46.
 **Lights:** Flashing orange **Tones:** 2 tones, falling in pitch and repeating	**Cause:** The recharger battery is low. **Action:** Charge the recharger by placing it on the plugged-in dock before attempting further use. See "Charging your recharger battery", page 75.

Scenario or alert	Cause and action
You experience too much warmth, a heating sensation, discomfort, or redness near the implant during recharging.	**Cause:** It is normal to feel warmth at the implant site during a recharging session. **Action:** Confirm you are not recharging over any metal object. If there is discomfort, recharge speed can be turned down by your clinician or you can try the following actions: • Take a break from recharging. • Move to a comfortable position while recharging. • If you are using the ankle band, loosen it so that it is comfortable and only tight enough to secure the recharger in place. • If you are not using the ankle band, place a piece of clothing or barrier between your skin and the recharger. If skin irritation persists or if symptoms are severe, stop recharging and contact your clinician.
The tones from the recharger are too loud or too quiet.	**Cause:** The recharger volume may need to be adjusted. **Action:** See "Adjusting recharger volume", page 83.
The battery light on the recharger is on, but it is not recharging your implant.	**Cause:** The recharger is in communication-only mode. **Action:** To start recharging, position the recharger over your implant and press the power button to switch to recharging mode. **Note:** For more information about the recharger modes, see page 43.
I cannot switch between recharger modes.	**Cause:** The recharger button press has been temporarily disabled while the app is communicating with your implant. **Action:** 1. Wait for the app to finish communicating with the implant and try again. 2. If Step 1 was unsuccessful, turn off the recharger by pressing and holding the power button, then turn it back on.

Specifications for the recharging system

Table 13. Recharger specifications

Item	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 V–4.1 Volts (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
Recharger size (approximate)	14.2 cm x 11.7 cm x 2.5 cm (5.6 in x 4.6 in x 0.98 in)
Recharger 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[f]	Bluetooth 4.0 Near-field magnetic induction communication
Operating frequency band[f]	Bluetooth: 2.4 to 2.4835 GHz ISM Near-field magnetic induction communication: 175 kHz
Effective range[f]	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
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.medtronic.com/patientmanuals.

[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.

[f] For detailed Bluetooth®* and EMC information, refer to EMC Declaration available at www.medtronic.com/patientmanuals.

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.

Table 14. Dock specifications

Item	Specification
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
Dock size (approximate)	16 cm x 16 cm x 3 cm (6.3 in x 6.3 in x 1.18 in)
Dock 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 15. Dock power adapter and USB cable specifications[a]

Item	Specification
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 Hertz (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.

Table 16. Ankle band and adjuster specifications[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.

Part 6: Other information

Cleaning and care

- Keep your system components out of the reach of children or pets.
- Use the system components only as explained to you by your clinician or as discussed in this guide.
- The recharger and dock may be damaged if stored or used outside of the temperature ranges and other environmental conditions specified. See "Specifications for the recharging system", page 89 and package labels.
- Keep the patient programmer charged between uses. Plug in the patient programmer to the wall outlet using the charging cable and power adapter provided. For more information, refer to the patient programmer quick start guide.
- Handle the recharger with care. Do not drop, strike, or step on the device.
- Do not dismantle or tamper with the recharger and dock.
- Clean the recharger with a damp cloth when necessary. Mild household cleaners will not damage the device.
- The recharger, dock, USB cable, and AC power adapter are not waterproof. Do not allow moisture to get inside the components.
- To clean your 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 damage the ankle band.

Removal of your implant

The Altaviva implant has an expected lifetime of 15 years. 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 stimulation settings of 11 mA, 200 µsec, 20 Hz.

If your Altaviva implant is removed, follow the post-explant procedure guidance described in this section.

For at least 72 hours after your explant procedure (or longer based on your clinician's advice):

- Keep the explant site dry and covered.
- Wear a compression sock to minimize swelling and aid in healing.

For the first 2 weeks after the explant procedure:

- Avoid soaking the 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 your clinician if you notice any unusual signs or symptoms while the explant site is healing such as redness, drainage, swelling, opening of the incision, or fever.

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:** 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

An implanted neurostimulator should be removed before burial or cremation. In some countries, removal of a battery-powered implantable device is required before burial because of environmental regulations.

Personal health information should be removed from the implant before disposal. Contact your clinician.

Medtronic

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M028917C001 Rev C
2025-09-16

Medtronic

Quick Reference Guide for the Altaviva™ System

Tibial Neuromodulation Therapy

! USA Rx only

This guide provides a quick reference for:

- The items in your Altaviva™ patient kit
- How to recharge and use your Altaviva system

Refer to the *Patient Guide for the Altaviva System* for complete instructions, including:

- Warnings and precautions
- Post-implant care
- Managing your therapy schedule
- Recharger details
- Pairing system components
- Possible complications

Read all information before using the Altaviva system. If you do not understand something or need more information about your system or your therapy, contact your clinician.

To view a how-to video about your system

Go to **www.medtronic.com/helloAltaviva**.

To access your complete patient guide

Go to the patient manuals website to view, download, print, or order manuals.

1. Open your internet browser and in the address bar at the top of the screen type:

www.medtronic.com/patientmanuals

2. On the patient manuals website, type in your model number (P7850N) or product name (Altaviva) to search.

Call Patient Services at 1-800-510-6735 for help, or to order printed copies of your manuals.

How to contact Medtronic

Medtronic is available to answer any technical or troubleshooting questions you may have about your system components.

! USA For assistance in the U.S., call Patient Services at **1-800-510-6735**. Support is available Monday through Friday from 8:00 AM to 5:00 PM (Central Time).

If you lose your patient identification card:

Call **1-800-551-5544**

Or contact:
Medtronic Inc., Patient Registration Services
Mail Stop RCW225
7000 Central Ave NE
Fridley, MN 55432

Your Altaviva patient kit

1

Recharger dock

2

Dock charging cable and power adapter

3

Recharger

4

Ankle band and adjusters

5

Patient programmer

6

Patient programmer charging cable and power adapter

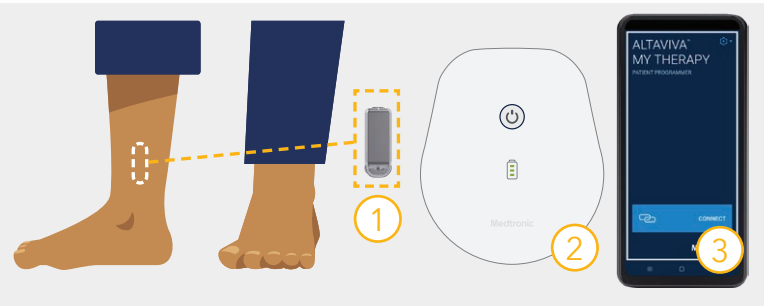
7

Card holder, patient identification (ID) card, and product literature

Note: Throughout this guide, the illustrations are representative. The appearance of some of your system components may vary.


1
2
3
4
5
6
7

The Altaviva system includes:



① The implanted Altaviva neurostimulator (referred to as "the implant" in this guide).

② The recharger.

③ The patient programmer and Altaviva My Therapy application (app). The app comes pre-installed on the patient programmer.

You can use the Altaviva My Therapy app to:

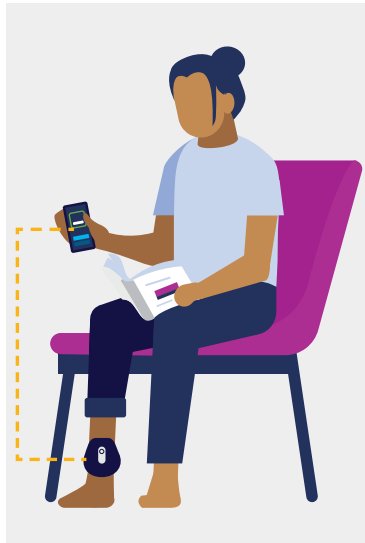
- View and change your stimulation schedule.
- End active stimulation.
- Change your stimulation level during stimulation sessions, if needed.

See the patient guide for more information about how you can use the app.

The recharger has 2 purposes. You can use it to:

- Recharge the implant.
- Provide communication between the Altaviva My Therapy app and the implant.

The recharger relays any changes that you make on the patient programmer to your implant.



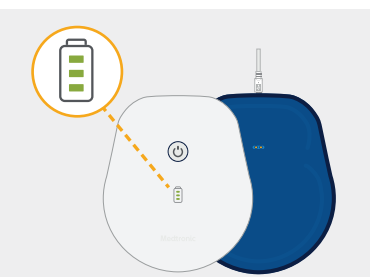
Whether you are using the recharger to recharge your implant or to communicate between your patient programmer and the implant, your recharger must be **properly positioned** over the implant as described later in this guide.

If you are just recharging the implant, you do not need the patient programmer. You can recharge the implant using the recharger on its own.

How to charge the items in your kit

It is important to keep your patient programmer, recharger, and implant charged.

- To charge the patient programmer, plug in the patient programmer to the wall outlet using the programmer charging cable and power adapter provided. Keep the patient programmer charged between uses.
- To charge the recharger, plug in the dock to a wall outlet using the dock charging cable and power adapter provided and place the recharger on the dock until it is fully charged (showing 3 solid green bars).



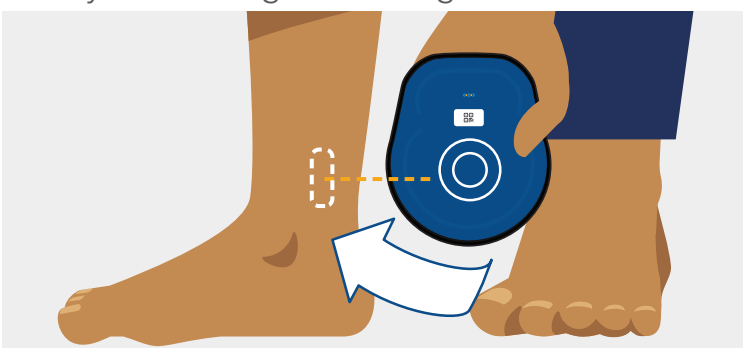
  Store your recharger on the plugged-in dock between uses.
- To recharge the implant, see the steps on the following pages.

How to position your recharger

Position your recharger over your implant to:

- Recharge the implant.
- View and change your stimulation schedule or settings in the app on the patient programmer.

To position the recharger, locate the circles shown on the back of the recharger (◎) and place them directly over your implant. Maintain this position while you are using the recharger.



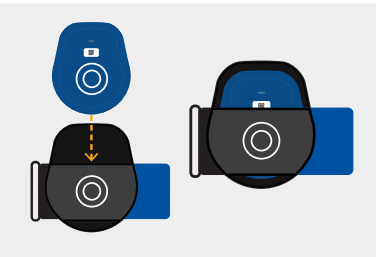
Use the provided ankle band to help maintain the correct recharger position for longer periods of time, as needed. Ankle band use is optional.

Note: While your wound is healing, use a sterile bandage or barrier between the wound and the recharger or ankle band to reduce the risk of an infection.

Using the ankle band to position the recharger:

1. Insert the recharger into the ankle band pouch so that the power button (⏻) is visible through the window in the pouch.

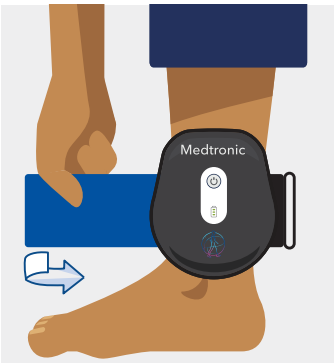
Front view



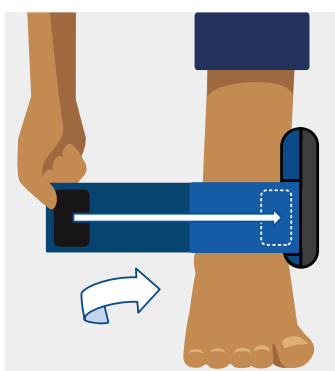
Back view

2. Place the 2 circles (◎) on the back of the ankle band directly over your implant. Hold the recharger in this position as you continue.

3. Wrap the ankle band around the back of your ankle and thread the ankle band through the eyelet.



4. Fold the ankle band back around your ankle and then pull it forward and secure it in place.



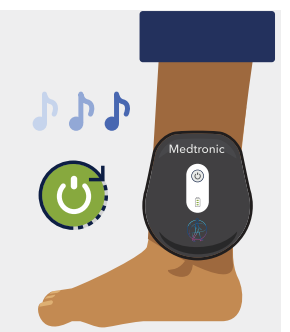
How to recharge your implant

Talk to your clinician about how often you should recharge your implant. The recharge frequency for the implant will depend on your stimulation settings and schedule. See the patient guide for details.

Connecting the recharger to your implant and recharging

1. Remove the recharger from the plugged-in dock.
2. Press the power button (⏻) on the recharger.

   As the recharger searches for the implant, you will hear searching tones and the green light on the power button will spin.



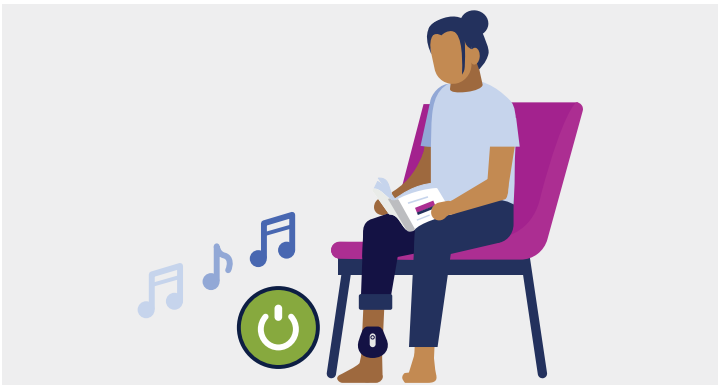
3. Position the recharger over your implant with or without the ankle band (as shown on page 9).
4. If the searching tones continue, reposition the recharger until the searching tones stop.
5. When the recharger has found and connected to the implant, you will hear 2 tones rising in pitch and the power button light will be solid green.

6. Once connected, the recharger will automatically start recharging the implant. While recharging is in progress, the recharger will show a slow pulsing green light.

7. Keep the recharger over your implant for the duration of the recharging session.

Recharging is complete

1. When recharging is complete, a series of tones rising in pitch will sound. The power button light will change to solid green.



2. Remove the recharger from the ankle band (if using) and return the recharger to the plugged-in dock.

Recharger lights and tones

Lights	Tones	Meaning
 Spinning green	Repeating tones, same pitch	Recharger is searching for the implant.
 Solid green	2 tones, rising in pitch	Implant has been found and the recharger has connected to the implant.
 Slowly pulsing green	None	Recharging the implant.
 Solid green	A series of tones, rising in pitch	Recharging session is complete.
 Spinning orange and green	2 tones, falling in pitch	Open the Altaviva My Therapy app; tap **CONNECT** for more information.
 Flashing orange	2 tones, falling in pitch and repeating	There has been a problem. Recharging has stopped.
 Solid orange, then off	2 tones, falling in pitch (not repeating)	Your patient programmer has not been paired to the recharger.
 Flashing orange	2 tones, falling in pitch and repeating	Recharger battery is low.
 Solid green +  Off	None	Recharger is in communication-only mode (not recharging).

See the patient guide for more information.

How to connect to your implant using the Altaviva My Therapy app

The Altaviva My Therapy app can be used to view details about your therapy and make adjustments as needed. You do not need to use the app to recharge the implant or to receive therapy. Stimulation will be delivered automatically.

1. Remove the recharger from the plugged-in dock.
2. Position the recharger over your implant (as shown on page 9).
3. Turn on your patient programmer.
4. Tap the Altaviva My Therapy app icon to open the app.

5. Tap **CONNECT** (

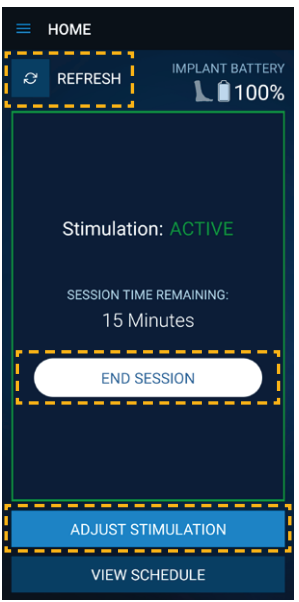
).
6. Follow the instructions on the patient programmer to complete connection.

Adjusting stimulation

You may not need to feel stimulation in order for your therapy to work. If you have symptom relief, there is no need to adjust your stimulation.

From the Home screen in the app, you can:

- Tap **REFRESH** to update the information on this screen to reflect the current status of your stimulation session.
- Tap **END SESSION** to stop the active stimulation session.
- Tap **ADJUST STIMULATION** to change your stimulation level.



See the patient guide for details.

Schedule 1 Details

M T W Th F S Sun

Length of session: _____ minutes

Start time: _____

Start date: _____

Schedule 2 Details

M T W Th F S Sun

Length of session: _____ minutes

Start time: _____

Start date: _____

Notes

Medtronic

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M028919C003

Medtronic

MRI Guidelines for the Altaviva™ Neurostimulator

P7850N

Tibial Neuromodulation Therapy

Instructions for use

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

Explanation of symbols


Manufacturer

For USA audiences only

Magnetic Resonance (MR) Conditional

Magnetic Resonance (MR) Unsafe

Table of contents

Introduction to MRI and the Altaviva™ neurostimulator

Read this manual before conducting a 3-Tesla (T) or 1.5-T magnetic resonance imaging (MRI) scan of a patient with the Medtronic Model P7850N Altaviva neurostimulator. These instructions do not apply to other implantable products, or other devices, products, or items. The Medtronic Model P7850N neurostimulator is an MR Conditional device and, as such, is designed to allow patients to be safely scanned on any part of the anatomy by a magnetic resonance imaging (MRI) machine when used according to the specified MRI conditions for use.

IMPORTANT: Always obtain the latest MRI guidelines. Go to www.medtronic.com/mri and search by neurostimulator model number P7850N. Read the entire manual, then see the section on "Confirming MRI eligibility for the Model P7850N Altaviva neurostimulator" before conducting an MRI scan on a patient with this device.

Contact Medtronic at the appropriate address or phone number listed at the end of this manual if you have questions.

Scheduling an MRI

Information for schedulers: The Model P7850N Altaviva neurostimulator is MR Conditional, full body scan eligible using 3-T or 1.5-T scanners. To schedule an MRI for a patient with a Model P7850N neurostimulator:

- Confirm the model number of the implanted Medtronic neurostimulator. You can confirm that the patient has the Model P7850N neurostimulator using the Medtronic patient ID card OR patient records OR via x-ray of the implanted device. The implant is a leadless device. (See section on "Confirming MRI eligibility for the Model P7850N Altaviva neurostimulator" on page 6 for more information about identifying neurostimulator model number.)
- If the neurostimulator model number is not known, check with the clinician who manages the patient's Altaviva system.

Before the MRI appointment, remind patients to do the following:

- Consult with the clinician who manages their Altaviva system.
- Bring their most up-to-date Medtronic patient ID card to the MRI appointment for identification of the implanted neurostimulator and MRI information.
- Inform the MRI clinician that they have an implanted device.

MR Conditional

MR Conditional. Non-clinical testing has demonstrated that the Medtronic Model P7850N Altaviva neurostimulator is MR Conditional. Follow these MRI guidelines to determine whether and how to perform an MRI scan safely on a patient with a fully implanted Model P7850N neurostimulator.

General information on MRI procedures and neurostimulation system interactions

MRI systems generate electromagnetic fields that may interact with implanted components of the neurostimulation system. The following information describes the potential interactions and control measures that should be taken to minimize the risks from these interactions. Exposing a patient with an implanted neurostimulator to MRI settings other than those listed in this manual may potentially seriously injure the patient or damage the neurostimulator.

Information for prescribers

Risks associated with implanted neurostimulators in the MRI environment

The known potential risks for implanted neurostimulators in the MRI environment are as follows:

- **Heating –** RF induced currents may cause heating of the tissue surrounding the device resulting in tissue damage. In addition, the time varying magnetic field gradient may result in heating of the neurostimulator.
- **Induced stimulation –** The gradient magnetic and RF fields produced by an MRI scanner induce energies onto an implanted neurostimulation system that may potentially cause unintended stimulation to the patient such as a tingling, shocking, or jolting sensation.
- **Magnetic field interactions –** The magnetic material of an implanted system may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. Patients may feel a mild tugging or vibration sensation at the site of the device implant, or the neurostimulator may move within the implant pocket and align itself with the magnetic field, which may cause patient discomfort. Patients being scanned with recent implant incisions should be monitored for any surgical wound discomfort.
- **Device damage –** The static magnetic field, pulsed gradient magnetic field, or the pulsed RF field generated by MRI may permanently damage the neurostimulator, requiring explant or replacement.
- **Device interactions –** MRI may affect the operation of the neurostimulator and require reprogramming of the neurostimulator with the clinician tablet after the MRI scan. Reprogramming with the clinician tablet after the MRI scan may also be needed if the MRI scan resets the parameters.

General Warnings

Assess other implanted devices — Prior to an MRI scan, determine whether the patient has multiple active or abandoned medical device implants (such as sacral neurostimulation systems, deep brain stimulation systems, implantable cardiac defibrillators, and others). The most restrictive MRI exposure requirements must be used if the patient has multiple active or abandoned medical device implants.

MRI scans with another metal implant less than 3 cm away from the Model P7850N neurostimulator have not been tested. Scanning patients with another metal implant less than 3 cm from any part of the neurostimulator may cause excessive tissue heating surrounding the device, resulting in tissue damage and possible surgical intervention.

See specific procedural cautions and conditions throughout these MRI guidelines.

Precautions

External devices are MR Unsafe in the scanner (magnet) room — Do not allow the following Medtronic external devices of the Altaviva system into the MRI scanner (magnet) room. These devices are MR Unsafe:

- Patient control devices
- Recharger and dock
- Ankle band
- Clinician tablet

Confirming MRI eligibility for the Model P7850N Altaviva neurostimulator

Do not proceed with the instructions for MRI before identifying that the patient has the Model P7850N Altaviva neurostimulator using the following "Eligibility identification checklist".

Eligibility identification checklist

Choose ONE of the following three methods to identify the neurostimulator before scanning.

☐	**Medtronic patient ID card:** Use the most up-to-date Medtronic patient ID card to verify that the patient has the Model P7850N neurostimulator. The patient ID card must be complete and accurate if it is to be used for the identification of the device. The patient may have other implanted devices that are not noted on the Medtronic patient ID card.
☐	**Patient records:** Use the patient records to verify that the patient has the Model P7850N neurostimulator. The patient records must be complete and accurate if they are to be used for the identification of the device.
☐	**X-ray of the implanted device:** Take an x-ray of the implant to verify that it is the Model P7850N neurostimulator. See "Appendix A: X-ray identification – Model P7850N Altaviva neurostimulator" of these MRI Guidelines for more information. An x-ray also indicates whether the patient has any other implanted devices that require assessment for MRI.

Note: If none of these three methods are available for identification of the neurostimulator, then STOP. Neurostimulator identification is required to confirm eligibility for MRI. Unless the implanted neurostimulator is known and it is determined to be safe to perform an MRI under specific conditions, an MRI scan should not be conducted. For assistance, contact the clinician managing the patient's Altaviva system.

After eligibility identification is determined, proceed to "MRI Safety Information for the Model P7850N Altaviva neurostimulator" on page 7.

MRI Safety Information for the Model P7850N Altaviva neurostimulator

MR Conditional
Full Body Scan Eligible

Before proceeding with an MRI scan, confirm via the "Eligibility identification checklist" section that the patient's implanted system is a Model P7850N neurostimulator.

A patient with an implanted Model P7850N neurostimulator can have 3-T and 1.5-T scans of any part of the anatomy when all the specific conditions in this MRI Safety Information section are met.

△ **Cautions:**

- Failure to follow all the conditions within this MRI Safety Information section may result in patient discomfort, device damage, or serious patient injury due to excessive heating or other risks associated with implanted neurostimulation systems in the MRI environment.
- Do not perform an MRI scan if the patient’s body temperature is above 38°C (100°F). Do not cover the patient with blankets or heated blankets. Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which may cause tissue damage.
- Do not position patients in positions other than prone or supine, such as on their side within the MRI bore. Scanning patients in positions other than prone or supine is untested and may cause excessive tissue heating during an MRI scan.
- Use insulation padding to avoid skin-to-skin contact, especially near implant site at ankle. Skin-to-skin contact may cause excessive tissue heating during an MRI scan.

Conditions for use - Model P7850N neurostimulator

Proceed with Table 1 on page 7.

Table 1. Conditions for use - Model P7850N neurostimulator

Parameter	Condition
Model Number and Device Name	Model P7850N Altaviva neurostimulator
Device Manufacturer	Medtronic
Programming Settings (Device Configurations)	No restrictions Devices configured to ON or ACTIVE, OFF, a non-responsive device, unknown status device, or a device that has reached the end of its service life can be scanned at these parameters.
MRI System Types	▪ 3-T horizontal cylindrical system for hydrogen imaging, approximately 128 MHz Or ▪ 1.5-T horizontal cylindrical system for hydrogen imaging, approximately 64 MHz
RF Excitation	▪ 3-T systems: Circularly Polarized (CP) or 2-Channel Multi-Transmit (MC-2) configuration[a] Or ▪ 1.5-T systems: Circularly Polarized (CP)
Maximum Spatial Field Gradient (SFG) [T/m] and [gauss/cm]	20 T/m (2000 gauss/cm)
Maximum Gradient Slew Rate	≤ 200 T/m/s per axis
RF Transmit Coil Type(s)	Use any of the following three types: ▪ RF Whole-Body Transmit Coil (Integrated Transmit Coil) ▪ Detachable Head Transmit/Receive Volume Coil ▪ Detachable Lower Extremity Transmit/Receive Volume Coil
RF Receive Coil	No Restrictions-Any type of receive coil may be used
Scanner Operating Mode	▪ First Level Controlled Operating Mode ▪ Normal Operating Mode
RF Exposure Level	First Level Controlled Operating Mode limits: ▪ ≤ 4.0 W/kg Whole Body SAR ▪ ≤ 3.2 W/kg Head SAR
Maximum B1+rms	No Restrictions

Table 1. Conditions for use - Model P7850N neurostimulator (continued)

Scan Time Limit	Detachable Head or Lower Extremity Transmit/Receive Volume Coil: No Restrictions
	RF Whole-Body Transmit Coil (Integrated Transmit Coil): ▪ Hip and above (at or superior to the anterior superior iliac spine): No Restrictions ▪ Below the hip (inferior to the anterior superior iliac spine): MRI scan durations should not exceed a total of 60 minutes of active scan time.
Patient Positioning	▪ Prone Or ▪ Supine
Insulation Padding	Use insulation padding to avoid skin-to-skin contact, especially near implant site at ankle.
Scan Regions	No Restrictions
MR Image Artifact	Image distortion can result from the presence of the Model P7850N device within the field of view. Image artifacts and distortion resulting from the presence of the neurostimulator when in the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.
Anatomical Location of Implant	When implanted per approved indications, the Model P7850N neurostimulator is located in the lower leg just anterior to the Achilles tendon. The implant is a leadless device.
Post-Exam Instructions	After the MRI scan, verify that the patient has not experienced adverse effects as a result of the MRI. Contact Medtronic and the clinician who manages the Altaviva system to report any adverse effects. Instruct the patient to see the clinician who manages their Altaviva system if the patient has any questions about neurostimulator function.
Notes: ▪ If possible, do not sedate the patient so that the patient can provide feedback during the examination. ▪ Inform the patient of all the risks of undergoing an MRI examination. ▪ Verify that the patient is feeling normal and is stable and responsive between each individual scan sequence of the MRI examination. ▪ Discontinue the MRI immediately if the patient experiences any heating, pain, shocking sensations, uncomfortable stimulation, or unusual sensations.	

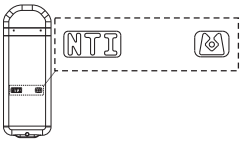
[a] Systems that use more than two transmit channels have not been studied, but such systems could be operated in CP or MC-2 configurations, if available.

Appendix A: X-ray identification – Model P7850N Altaviva neurostimulator

X-ray identification permits the determination of the manufacturer and the neurostimulator model number using standard x-ray procedures. The Medtronic symbol Ⓜ identifies Medtronic as the manufacturer.

Model P7850N neurostimulator x-ray identification

Table 2. Neurostimulator ID code and x-ray identification

INS radiopaque ID code	Model P7850N neurostimulator
 ID code NTI	

Note: When implanted per approved indications, the Model P7850N neurostimulator is located in the lower leg just anterior to the Achilles tendon. The implant is a leadless device.

Medtronic

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