NeuroSphere™ Patient Controller

Eterna™ Spinal Cord Stimulation System
Model 55500

User's Guide

Abbott

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

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

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Pat. http://www.abbott.com/patents

Contents

About This Guide

This guide explains how to use the NeuroSphere™ Patient Controller application (model 55500) with your Eterna™ Spinal Cord Stimulation (SCS) System. If you have any questions about your system, contact Technical Support.

Terms Used in This Document

This section contains definitions of some of the terms used in this document.

Magnetic Resonance (MR) Conditional system. A group of implanted parts that allows a patient to receive a magnetic resonance imaging (MRI) scan safely if all the requirements for the implanted parts and for scanning are met.

Perception. Perception strength is the value at which stimulation is first felt.

Program. A combination of one or more subprograms (areas).

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The clinician programmer and patient controller applications and accessories are intended to communicate with pulse generators to manage stimulation programs. The applications allow clinicians to create customized therapy and help patients manage their prescribed stimulation programs.

Indications for Use

This neurostimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.

Contraindications

This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

MRI Safety Information

You may be implanted with the parts that make up a Magnetic Resonance (MR) Conditional system, which allows you to receive an MRI scan if all the requirements for the implanted parts and for scanning are met. Scanning under different conditions may cause device malfunction, severe injury, or death. Contact your physician before receiving an MRI scan to find out if you can undergo the procedure and to learn more about any risks. Additionally, before receiving an MRI scan, inform the healthcare professional that you are implanted with a neurostimulation system. If you do not have an MR Conditional system, you cannot receive an MRI.

Do not bring your patient controller into the scanner magnet room. It can be affected by the MRI magnet, may present a projectile hazard, and is MR Unsafe.

For more information about what you need to do to prepare for an MRI scan, refer to “Setting Your Generator to MRI Mode” (page 18) in this guide.

Warnings

The following warnings apply to these components.

NOTE: For nontherapy-related warnings regarding the patient controller, refer to the user guide available at support.apple.com/guide for the Apple‡ iOS‡ device you are using to run the patient controller app.

System Warnings

Diathermy therapy. You cannot have any diathermy (a type of medical treatment that generates heat) if you have any part of a neurostimulation system implanted. This includes short-wave, microwave, or therapeutic ultrasound diathermy. Diathermy can cause injury near your implanted electrodes, resulting in severe injury or death. Diathermy may also damage your neurostimulation system, resulting in loss of therapy and the need for replacement surgery. Inform your healthcare professional that you cannot have diathermy treatment.

Operation of machines, equipment, and vehicles. Neurostimulation systems can cause tingling sensations throughout parts of your body. If you feel tingling sensations, turn off stimulation before operating motorized vehicles or potentially dangerous machinery and equipment. Sudden changes in your stimulation settings or physical position may make tingling worse and distract you from properly operating machines and equipment. Current data show that most patients using BurstDR™ stimulation therapy do not experience tingling sensation.

Implanted cardiac systems. Be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems (minimum separation distance of approximately 8 cm (3 in.) between lead ends is recommended); (2) verify that the neurostimulation system is not interfering with the function of the implanted cardiac system; and (3) consider bipolar programming of both devices and use neurostimulation system settings that do not interfere with the function of the implantable cardiac system.

Electrosurgery devices. Electrosurgery devices may harm you or damage your neurostimulation system. Inform your healthcare professional that only bipolar electrosurgery devices should be used and electrosurgery devices should be kept as far away as possible from your neurostimulation system. Additionally, your healthcare professional must confirm the neurostimulation system is functioning correctly after your procedure.

Lead movement. Avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) for six to eight weeks after implantation. These activities may cause lead movement,

resulting in understimulation or overstimulation. Excessive lead migration may require reoperation to replace the leads.

Emergency procedures. Designate a representative (family member or close friend) to notify any emergency medical personnel of your implanted neurostimulation system if emergency care is required. You will receive an identification card to carry that will inform emergency medical personnel of your implanted system. Use caution when undergoing any procedure that could include radiofrequency (RF) or microwave ablation, defibrillation, or cardioversion.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Cardioverter defibrillators. Neurostimulation systems may adversely affect the programming of implanted cardioverter defibrillators.

Device Warnings

Explosive or flammable gases. Do not use your patient controller around explosive or flammable gas fumes or vapors. This includes oxygen-enriched environments such as hyperbaric chambers. Operating the device near gas fumes or vapors could cause them to catch fire. If gas fumes or vapors catch fire, it could cause severe burns, injury, or death.

Interference with other devices. This equipment can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other active implanted devices. Avoid placing equipment components directly over other electronic devices. To correct the effect of interference with other devices, turn off the equipment or increase the distance between the equipment and the device being affected.

Device modification. This patient controller is not serviceable by the customer. To prevent injury or damage to the system, do not modify the patient controller.

Application modification. To prevent unintended stimulation, do not modify the operating system or application in any way.

Strangulation. The cords in this system pose a strangulation risk. Keep cords out of the reach of children.

Keep dry to avoid damage. Your patient controller is not waterproof. Keep it dry to avoid damage. Do not use the patient controller when engaging in activities that might cause it to get wet, such as swimming or bathing.

Precautions

The following precautions apply to these components.

NOTE: For nontherapy-related precautions for the patient controller, refer to the user guide available at support.apple.com/guide for the Apple‡ iOS‡ device you are using to run the patient controller app.

System Precautions

Medical tests and procedures. Before undergoing medical tests or procedures (such as therapeutic radiation or electrolysis), contact your physician to determine if the

procedure will cause you injury or damage your neurostimulation system. Specifically, you should be aware that medical devices such as electrohydraulic lithotriptors, therapeutic X-rays, computerized tomography (CT) scans, cobalt machines, and linear accelerators may cause damage to the electronic circuitry of an implanted neurostimulation system. Damage to the system may not be immediately detectable.

Component manipulation. Do not rub or press on implanted components through the skin. This may cause the leads to move, inducing stimulation at the implant site; generator inversion can occur, leading to the inability to communicate with the generator or skin erosion that can lead to another surgical procedure or possible infection.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations, motor disturbances, or make it difficult to control the generator using the patient controller. If unpleasant sensations occur, turn off stimulation immediately.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Postural changes. Changes in posture or abrupt movements can change the level of stimulation and potentially cause unpleasant sensations. Turn stimulation off or lower the stimulation strength before stretching, lifting your arms over your head, or exercising. If unpleasant sensations occur, turn off stimulation.

Security, antitheft, and radiofrequency identification (RFID) devices. Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which some patients have described as uncomfortable or jolting. Use caution when approaching such a device and request assistance to bypass the device. If you must proceed through a gate or doorway containing this type of device, turn off stimulation and proceed with caution, being sure to move through the device quickly.

Scuba diving or hyperbaric chambers. Before diving or using a hyperbaric chamber, you should contact your physician to discuss the effects of high pressure on your implanted system. Implanted systems with non-Abbott Medical leads have not been evaluated for safety while scuba diving or in hyperbaric chambers. Patients with implanted Abbott Medical leads should avoid scuba diving in more than 30 m (100 ft) of water or entering hyperbaric chambers above 4.0 atmospheres absolute (ATA) for any length of time, as this may damage the neurostimulation system. For less than 30 m (100 ft) of water or pressures below 4.0 ATA, durations of less than 60 minutes are recommended.

Physician instructions. Always follow the programs and therapy instructions established for you by your physician. If you do not, the therapy may be less effective in providing pain relief.

Patient training. Patients should use their neurostimulation system only after an authorized clinician has programmed their generator and has trained them on how to safely control stimulation and to charge the system.

Device components. The use of components not approved for use by Abbott Medical may result in damage to the system and increased risk of injury.

Magnet usage. The magnet provided with the system is a high-powered magnet intended for use solely with the system. Keep it away from watches, credit cards, computer disks, and other magnetically sensitive items to avoid damaging them. Always place the keeper bar on the magnet when not in use.

Consumer goods and electronic devices. Magnetic interference with consumer goods or electronic devices that contain magnets, such as mobile phones and smart watches, may unintentionally cause the neurostimulation system to turn on or turn off or affect communication between the patient controller and generator; however, it will not change the prescribed programmed parameters. To prevent accidental interference, keep your smart device at least 15 cm (6 in.) away from the generator, and do not carry any smart device in a pocket near the generator. Contact Technical Support or your physician to discuss modifying the magnet mode setting on your neurostimulation system or if you have any other questions.

High-output ultrasonics and lithotripsy. The use of high-output therapeutic treatments, such as ultrasound and lithotripsy, may damage the generator. Inform your healthcare professional if lithotripsy treatment must be used.

Ultrasonic scanning equipment. The use of ultrasound may cause damage to a neurostimulation system if used directly over the generator. Inform your healthcare professional if ultrasound must be used.

Home use. This product is intended for home use per physician instruction. To avoid damage and other potential hazards, keep this product away from children and pets.

Infection. Follow proper infection control procedures. Also avoid showering and touching the bandages while your incisions are healing. If you need to charge your generator before your incisions have healed completely, take care not to disturb the bandages and follow your physician's guidance on charging.

Household appliances. Household appliances that contain magnets (such as refrigerators, freezers, inductive cooktops, stereo speakers, mobile telephones, cordless telephones, standard wired telephones, AM/FM radios, and some power tools) may unintentionally cause the neurostimulation system to turn on or turn off or affect communication between the patient controller and generator.

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this patient controller, please ask for authorization to use it before turning it on.

External defibrillators. Safety for use of external defibrillator discharges on a patient receiving neurostimulation has not been established. External defibrillation can cause

induced currents in the lead-extension portion of the neurostimulation system. After defibrillation, confirm the neurostimulation system is still working.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted generator should be shielded with lead. Damage to the system may not be immediately detectable.

Overcommunicating with the generator. Use your patient controller to communicate with your generator only when needed because excessive communication with the generator can shorten the battery life.

Device Precautions

Keep the patient controller away from extreme temperatures. The patient controller may not function when the patient controller is very hot or very cold.

Handle the device with care. The patient controller is a sensitive electronic device that can be damaged by rough handling, such as dropping it on the ground.

Battery precaution. This patient controller contains a lithium ion battery and other potentially hazardous materials. Do not crush, puncture, or burn the patient controller because explosion or fire may result.

Component disposal. Do not dispose of the patient controller or charging system in fire. Dispose of the patient controller and charging system components according to local regulations. Do not incinerate or cremate the generator. The generator should be explanted and returned to Abbott Medical.

Control of your patient controller. Keep your patient controller out of the hands of children to avoid potential damage or unauthorized change in stimulation parameters.

Adverse Effects

The use of a neurostimulation system involves risks. In addition to those risks commonly associated with surgery, the following risks are also associated with use of a neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off stimulation immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration, causing changes in stimulation or reduced pain relief
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode or generator site

- Seroma (mass or swelling) at the implant site
- Allergic or rejection response to device or implant materials
- Implant migration or skin erosion around the implant
- Battery failure

Product Description

The NeuroSphere™ Patient Controller communicates wirelessly through Bluetooth® wireless technology with the Eterna™ implantable pulse generator (also called a generator or IPG) and charger. The NeuroSphere™ Patient Controller application (app) (model 55500) allows you to view, select, and control the programs that your physician has prescribed. The patient controller app also allows you to monitor charging sessions for your generator and charger and modify charger settings.

NOTE: In this document, the term “patient controller” refers to the NeuroSphere™ Patient Controller device and “patient controller app” refers to the NeuroSphere™ Patient Controller application (app).

About Your System

The Eterna™ SCS System is designed to deliver low-intensity electrical pulses to nerve structures. This neurostimulation system includes the following components:

- **Implantable pulse generator (IPG).** The generator delivers electrical pulses through the leads to electrodes near selected nerve fibers in order to provide therapeutic stimulation.
- **Leads.** Thin wires that deliver pulses from the generator to nerves along the spinal cord.
- **Extensions/Adapters.** An added extension or adapter that connects to an implanted lead.
- **Patient magnet.** The patient magnet can be used to turn your generator on and off if your physician enables this functionality.
- **Charger and accessories.** The rechargeable charger is used to charge your generator wirelessly.

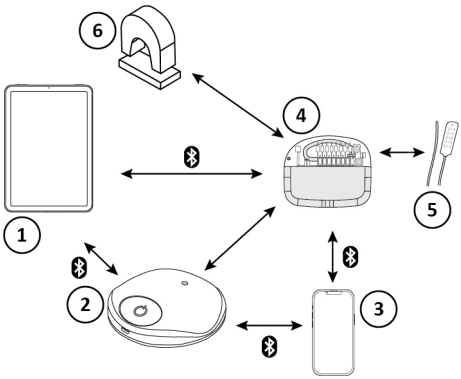
- **Patient controller (a device provided by Abbott Medical or a compatible personal Apple‡ iOS‡ device) and patient controller app.** The patient controller, with the patient controller app, is used to view, select, and control the programs that your physician has prescribed. The patient controller app also allows you to monitor charging sessions for your generator and charger and modify charger settings.

  NOTE: For more information on compatible devices, see “Appendix A: Downloading the Patient Controller App” (page 40).

Your physician uses the clinician programmer to create and modify your stimulation programs.

The following image shows how the major system components are intended to interact.

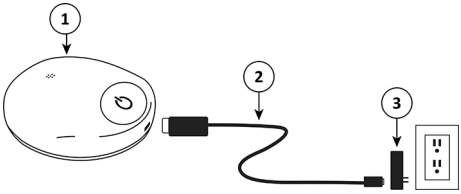
Figure 1. System components



1. Clinician programmer
2. Charger
3. Patient controller
4. Implantable pulse generator
5. Leads/Extensions/Adapters
6. Magnet

ᛒ indicates devices communicate through Bluetooth® wireless technology

Figure 2. Charging system components



1. Charger
2. Charging cable
3. Power adapter

Overview of the Patient Controller

Your patient controller may be a device provided by Abbott Medical or a compatible personal Apple‡ iOS‡ device.

Before you begin, be sure you are familiar with how to perform basic operational functions on your patient controller.

- Turning the patient controller on and off
- Putting the patient controller to sleep
- Waking the patient controller
- Locking and unlocking the patient controller

- Using touchscreen functions such as tap and screen swipe actions
- Returning to the Home screen

NOTE:

- If a passcode is not set for the device, a message will appear advising you to consider adding a passcode. Open the device's settings to add a passcode to secure the device.
- For nontherapy-related information on how to use the patient controller, refer to the user guide available at support.apple.com/guide for the Apple‡ iOS‡ device you are using to run the patient controller app.

The patient controller app is available from the Apple App Store and can be downloaded to your device using your Apple ID. See “Appendix A: Downloading the Patient Controller App” (page 40) for more information on compatible devices and for instructions on downloading the patient controller app.

Items You Will Receive

If you are using a patient controller provided by Abbott Medical, you will receive the following items to use with your system:

- Patient controller and charging cord
- Protective case for the patient controller
- Patient magnet
- Product documentation

If you are using a compatible personal device, you will receive the following items:

- Patient magnet
- Product documentation

Your Personal Identification Card

A personal medical identification card is included with your physician's product documentation. Your physician will complete the card and give it to you. This card does the following things:

- Identifies you as having an implanted medical device
- Identifies the model numbers and locations of your implanted system parts to help determine if you can safely receive an MRI scan
- Helps you pass through security systems like those in airports
- Provides information that allows your physician to be contacted in an emergency

If you have subsequent surgeries for your neurostimulation system, please bring your identification card to the surgery.

If you have questions about your card or need to request a replacement card, contact your physician.

Getting Started

If using a device provided by Abbott Medical, the patient controller app should be available on the Home screen when you turn on your patient controller. If you do not see the app, refer to “Appendix A: Downloading the Patient Controller App” (page 40).

If using your own device, you will need to download the patient controller app. Refer to “Appendix A: Downloading the Patient Controller App” (page 40).

Figure 3. Patient controller app icon

1. Tap the patient controller app icon. The Startup screen appears.

Figure 4. Patient controller app startup screen

2. The first time you launch the patient controller app, the Terms of Use and Privacy Policy popovers open. Tap **Accept** to accept the terms of use and tap Acknowledge to acknowledge the privacy policy to use the app.

   NOTE: Each time the terms of use or privacy policy is updated, you will receive a notification. The terms of use and privacy policy can be viewed at any time by tapping the Information icon.

Managing Your Therapy

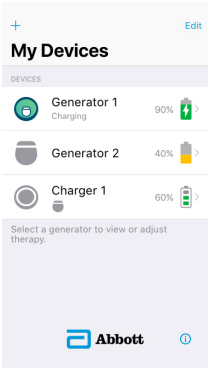
On the My Devices screen, you can view the devices, such as your generator (IPG) and charger, that have been paired with your patient controller and the battery status of each device.

NOTE: If you do not see your generator in the My Devices list, you will need to pair your patient controller and generator, see “Appendix B: Pairing the Patient Controller With the Generator” (page 41) for instructions.

For the connected devices:

- To view and edit therapy programs for your generator, tap the generator name or icon.
- To view and edit charger settings, tap the charger name.
- To view system information, tap ⓘ.

Figure 5. My Devices screen



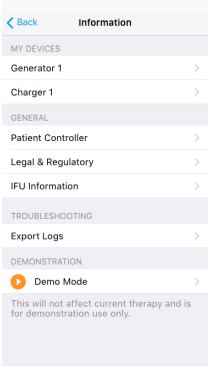
NOTE:

- Before the app can establish communication with the generator a prompt may display requesting the user to allow Bluetooth® wireless technology access. Tap **OK** to allow Bluetooth® wireless technology access. Otherwise, the app will be unable to communicate with the generator.
- In some cases, use of Bluetooth® wireless technology media devices (such as headphones or speakers) may prevent the patient controller from connecting to your generator. Abbott Medical recommends disconnecting these accessories before you attempt to adjust your therapy.

To view information about your system, tap ⓘ. The Information screen appears.

From the Information screen, you can view general information, such as software and device information and the terms of use and privacy statements. You can also export logs for troubleshooting and access a demonstration mode.

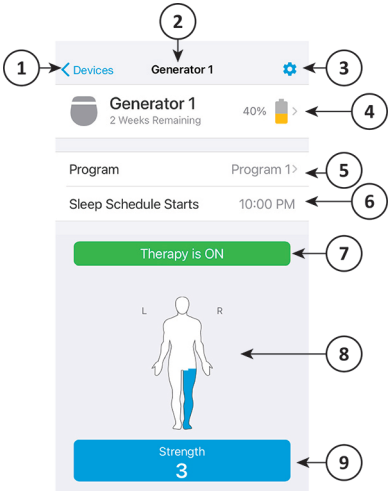
Figure 6. Information screen



Managing Your Generator

When you tap a generator in My Devices, the Therapy screen appears for that generator. The Therapy screen provides information about whether stimulation is on or off, the generator battery level, the remaining stimulation time based on generator battery (if enabled by your clinician, and only for the first 10 years of device life), and the area and strength of stimulation.

Figure 7. Therapy screen



1. Devices (back) button
2. Screen title
3. Settings icon
4. Generator battery information
5. Program name
6. Sleep schedule
7. Therapy button
8. Stimulation map
9. Strength button

Table 1. Therapy screen descriptions

Screen Section or Button Name	Description
Devices (back) button	Tap the Devices button to return to the My Devices screen.
Screen title	Displays the name of the device you are viewing.

Table 1. Therapy screen descriptions

Screen Section or Button Name	Description
Settings icon	Tap the Settings icon to display the Mode screen.
Generator battery information	Displays the percentage of charge in the generator and an estimate for how much stimulation time that percentage of charge can provide.
Program name	Displays the name of the active program. Tap to display the Programs screen for that program.
Sleep schedule	Displays whether sleep schedule is turned on or off. Sleep schedule is visible from the Therapy screen if a sleep schedule has been configured. Tap to turn sleep schedule on or off.
Therapy button	Displays whether therapy is on or off. Tap to turn therapy on or off.
Stimulation map	Displays the body area currently receiving stimulation.
Strength button	Displays the active program stimulation strength level. Tap to display the Strength screen.

Starting and Stopping Therapy

You may start and stop stimulation using the patient controller app or using the magnet if your physician has enabled magnet use.

Starting and Stopping Therapy Using the Patient Controller

To start or stop stimulation using the patient controller app:

- Tap the Therapy is ON button to turn off stimulation.
- Tap the Therapy is OFF button to turn on stimulation.

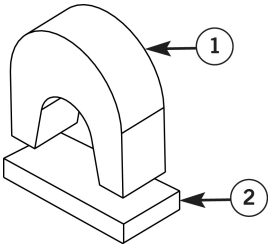
Starting and Stopping Therapy Using the Magnet

If your physician has enabled magnet use, you may use it to start and stop stimulation.

To start or stop stimulation using the magnet:

1. Take the keeper bar off the magnet.

Figure 8. Magnet and keeper bar

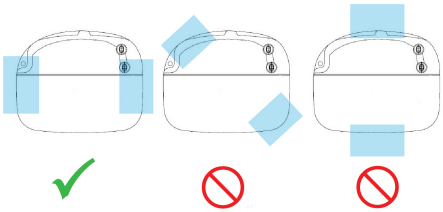


1. Magnet
2. Keeper bar

2. Hold the magnet centered directly over the generator for 1 to 2 seconds and then remove it.

   NOTE: Ensure the two ends of the magnet are horizontal and level with the generator.

Figure 9. Correct versus incorrect magnet orientation



3. Place the magnet on the keeper bar and store the magnet. Stimulation will either start (using the most recently used program settings) or stop.

   CAUTION: Do not use the magnet provided with the system around magnetically sensitive items to avoid damaging them.

Managing Therapy Programs

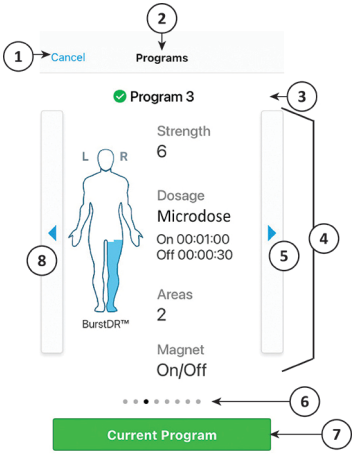
This section provides information and instructions for viewing, selecting, and adjusting your prescribed therapy programs.

NOTE: To avoid interruption while adjusting your therapy, Abbott Medical recommends enabling Do Not Disturb mode on your patient controller prior to connecting to your generator. Instructions for doing so have been published by Apple, which can be found on their support website.

To view and select programs:

1. From **My Devices**, tap your generator. The Therapy screen appears with your active program.
2. Tap the program name. Your active program appears.

Figure 10. Current active program



1. Cancel button
2. Screen title
3. Selected program name
4. Selected program details
5. Right arrow
6. Page indicator
7. Current Program/Select this Program button
8. Left arrow

NOTE: For Tonic programs, the number of areas is displayed. For BurstDR™ programs, the number of pulses is displayed.

3. Tap the right or left arrow to view or select other saved programs, if available.
4. If desired, tap **Select this Program**. Once selected, this becomes the active program. The Therapy screen updates and the strength will gradually increase to the perception strength level set for the selected program or to the last saved amplitude value.

Table 2. Programs screen descriptions

Screen Section or Button Name	**Description**
Cancel button	Tap **Cancel** to return to the Therapy screen. No program changes will be made.
Selected program name	Displays the program name of the current program. A check mark next to the program name indicates the active program.
Selected program details	Displays the information about the selected program.
▪ Strength	The current strength within a prescribed amplitude range. Amplitude is a measure of the strength of stimulation applied to the leads by the generator.
▪ Stimulation map	Displays the area the stimulation covers.
▪ Dosage	▪ Continuous – provides nonstop stimulation. ▪ Microdose – automatically alternates stimulation on and off for the preset periods in the selected program; displays the remaining time in the current on or off period.

Table 2. Programs screen descriptions

Screen Section or Button Name	Description
▪ Pulses	The number of pulses in a BurstDR™ stimulation therapy program.
▪ Areas	The number of areas in a Tonic stimulation therapy program.
▪ Magnet	Displays whether the magnet can turn the generator on and off if the clinician enabled this functionality.
Left arrow	Tap the left arrow to scroll through your saved programs (if you have more than one program).
Right arrow	Tap the right arrow to scroll through your saved programs (if you have more than one program).
Page indicator	Displays the number of programs available and indicates which program is on the screen.
Current Program button	Tap Current Program to return to the Therapy screen.
Select this Program button	Tap Select This Program to make a program the active program and return to the Therapy screen

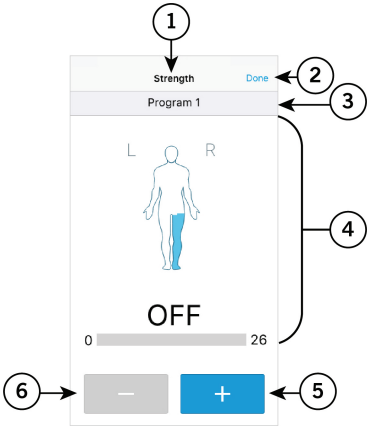
Adjusting Program Strength

To adjust the strength of a Tonic or BurstDR™ stimulation therapy program:

1. Tap **Strength** on the Therapy screen. The Strength screen appears.
2. Tap the + or – buttons to increase or decrease the strength. The green bar will increase or decrease as you increase or decrease strength.

   NOTE: If you tap + while stimulation is off, stimulation turns on. If you tap – when the strength is at **1**, stimulation turns off.

Figure 11. Strength screen – Tonic or BurstDR™ stimulation therapy program



1. Screen title
2. Done button
3. Program name
4. Selected program details
5. Increase button
6. Decrease button

Adjusting Tonic Area Strength

If a Tonic program has multiple areas, you can modify the stimulation strength for each area. Use this feature when you want to increase or decrease the strength of an individual area.

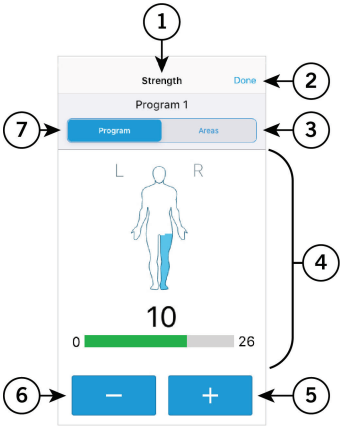
To adjust the area strength of the active program:

1. On the Therapy screen, tap **Strength**. The Strength screen appears.
2. Tap **Areas**. The Areas portion of the Strength screen appears.

   NOTE: If the program only has one area, the Areas tab will not appear on the screen.

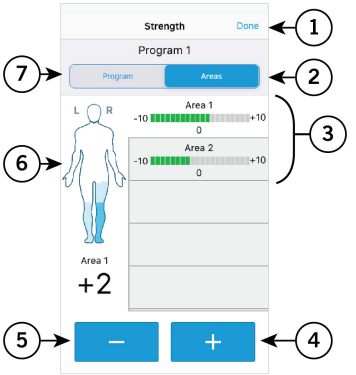
3. Tap + or – to increase or decrease the strength for the selected area. The green bar will increase or decrease as you adjust strength.
4. Modify other areas as needed.
5. When you are finished adjusting the area strength, tap **Done** to return to the Therapy screen.

Figure 12. Strength screen Program tab – Tonic program with multiple areas



1. Screen title
2. Done button
3. Areas tab
4. Selected program details
5. Increase button
6. Decrease button
7. Program tab

Figure 13. Strength screen Areas tab



1. Done button
2. Areas tab
3. Selected area
4. Increase button
5. Decrease button
6. Stimulation map
7. Program tab

Table 3. Areas screen descriptions

Screen Section or Button Name	Description
Done button	Tap **Done** to save changes and return to the Therapy screen.
Program tab	Tap the Program tab to open the Strength screen for the program.
Areas tab	Modify the strength of each area in the active program on this screen.
Selected area	Tap to select the area you want to modify. The stimulation map displays the affected area.
Stimulation map	View the program areas.
Increase button	Tap to increase the strength for the selected area.
Decrease button	Tap to decrease the strength for the selected area.

Setting Your Generator to MRI Mode

This section provides information and instructions about what you need to do before and after an MRI scan if you are implanted with a system that is Magnetic Resonance (MR) Conditional. An MR Conditional system allows you to receive an MRI scan if all the requirements for the implanted parts and scanning are met.

NOTE:

- Contact your clinician before receiving an MRI scan to find out if you can undergo the procedure and to learn more about any risks.
- Before scheduling an MRI appointment, it is recommended to place your system in MRI mode to confirm your system is MR Conditional and then exit to resume stimulation.

You have two ways to learn if the implanted parts of your system are MR Conditional:

- Your personal identification card, which your clinician or MRI technologist will use
- Your patient controller app
  - Tap ⓘ on the My Devices screen, and then tap the name of the generator you want to view to display the system information. The top of the screen displays a System is MR Conditional message if implanted parts of your system are approved MR Conditional models.
  - Tap ⚙ on the Therapy screen to display the Mode screen. The MRI Mode option is available if implanted parts of your system are approved MR Conditional models.

Preparing for an MRI Scan

If you have an MR Conditional system and will receive an MRI scan:

- Charge your generator and patient controller fully before you set your generator to MRI Mode.

- Set your generator to MRI Mode within one day of your MRI scan.

  NOTE: If you have more than one generator implanted, each generator must be set to MRI Mode. While a generator is in MRI Mode, stimulation will be off.

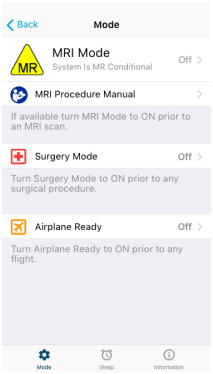
- Bring your identification card and patient controller to the MRI scan.

  CAUTION: Do not bring your patient controller or charger into the scanner magnet room since they may be affected by the MRI magnet, may present a projectile hazard, and are MR Unsafe.

To set your generator to MRI Mode:

1. In the Therapy screen, tap ⚙. The Mode screen appears.

Figure 14. Mode screen



2. Tap **MRI Mode** to view the MRI Mode screen.
3. Tap the **Turn MRI Mode On** button.
4. When a Set Generator to MRI Mode message appears, tap Continue. Stimulation turns off, and the patient controller app checks the system for any issues.

   NOTE: If a warning message appears instead of a Proceed with MRI message, you cannot set the generator to MRI Mode and cannot receive an MRI scan. Refer to “Troubleshooting” (page 35) for more information.

5. If the checks are successful, a Proceed with MRI message appears and the MRI Mode is on. Tap **OK**.

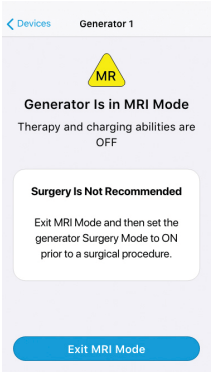
   CAUTION: Do not remove the Bluetooth® wireless technology pairing between the generator and the patient controller and do not delete the generator from the Generators list while the system is in MRI Mode. Doing so will require communication to be established again and may delay disabling MRI Mode and resuming therapy.

Disabling MRI Mode

After your MRI scan, you need to disable MRI Mode to restart stimulation. To disable MRI Mode:

1. Launch the patient controller app and connect with your generator. You should see the following screen, showing that the generator is in MRI Mode.

Figure 15. MRI Mode screen



2. Tap **Exit MRI Mode**. The patient controller app disables MRI Mode. The Therapy screen appears, showing that stimulation therapy is off.
3. To start stimulation, tap **Therapy is OFF**.

Setting Your Generator to Surgery Mode

This section provides information and instructions about what you need to do before and after a surgical procedure.

NOTE:

- Using the Surgery Mode feature turns therapy off while you undergo your procedure.
- Contact your clinician before your procedure to learn more about any risks. If you feel uncomfortable completing the following steps, contact Technical Support before your procedure.

Preparing for a Surgical Procedure

If you are planning to undergo a surgical procedure:

- Charge your generator and patient controller fully before you set your generator to Surgery Mode.
- Set your generator to Surgery Mode before your procedure.

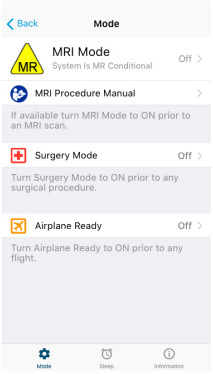
  NOTE: If high current is detected, the generator turns on Surgery Mode automatically.

- Bring your identification card and patient controller to the procedure.

To set your generator to Surgery Mode:

1. In the Therapy screen, tap . The Mode screen appears.

Figure 16. Mode screen



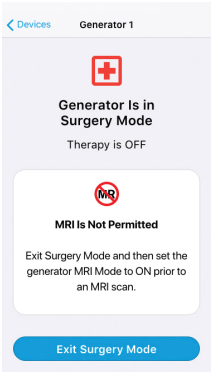
2. Tap **Surgery Mode** to display the Surgery Mode screen.
3. Tap **Turn Surgery Mode ON**. When the generator is placed in Surgery Mode, the Surgery Mode ON button turns green briefly and stimulation turns off.

Disabling Surgery Mode

After your procedure, you need to disable Surgery mode to restart stimulation. To disable Surgery mode:

1. Launch the patient controller app and connect with your generator. You should see the following screen, showing that the generator is in Surgery mode.

Figure 17. Generator is in Surgery Mode screen



2. Tap **Exit Surgery Mode**. The patient controller app disables Surgery mode. The Therapy screen appears, showing that stimulation therapy is off.

   NOTE: If the generator detects high current, you will not be able to exit Surgery mode. When you leave the high current environment and high current is no longer detected, you will be able to exit Surgery mode.

3. To start stimulation, tap **Therapy is OFF**.

Setting Your Generator to Airplane Ready Mode

If traveling by airplane, you may be asked to place electronic devices in airplane mode. Follow all flight precautions regarding Bluetooth® wireless technology connections. You can place your patient controller in airplane mode by going to your patient controller iOS‡ settings and turning on airplane mode.

You can also place the generator in airplane mode, which disables Bluetooth® wireless technology between the generator and patient controller.

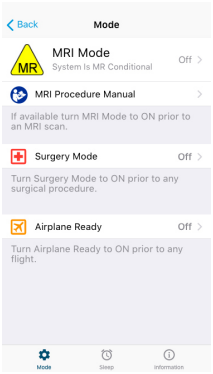
NOTE:

- Stimulation stays on even after disabling Bluetooth® wireless technology.
- Be sure to bring your magnet with you when you travel.

To place your generator in airplane mode, also known as Airplane Ready Mode:

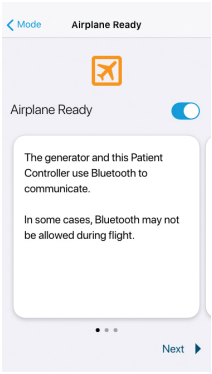
1. In the Therapy screen, tap ⚙. The Mode screen appears.

Figure 18. Mode screen



2. Tap Airplane Ready. The Airplane Ready screen appears.
3. Tap the Airplane Ready toggle button. The toggle button moves from left to right and turns blue.

Figure 19. Airplane Ready Mode screen



NOTE: The Airplane Ready screens contain additional information about what to do before and after your flight.

To adjust your system with your patient controller during flight, both airplane mode and Airplane Ready Mode need to be deactivated using the magnet.

To deactivate Airplane Ready Mode:

1. Hold your magnet over the generator for 5 seconds to enable Bluetooth® wireless technology connection.

   NOTE: Ensure the two ends of the magnet are horizontal and level with the generator.

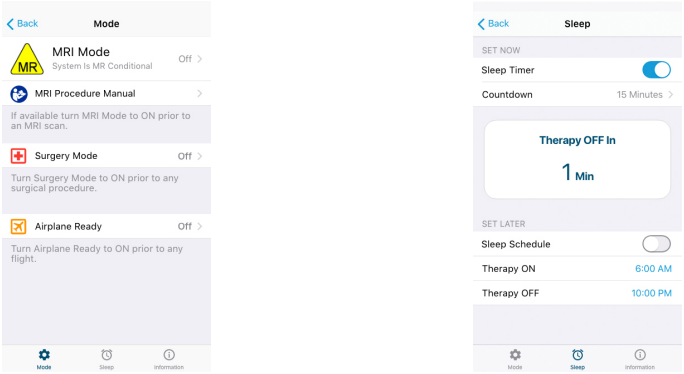
2. Remove the magnet and place it on the keeper bar.
3. In My Devices, tap your generator. The Therapy screen appears.
4. Tap ⚙. The Mode screen appears.
5. Tap Airplane Ready.
6. Tap the Airplane Ready toggle button. The button moves to the left and turns gray.

Setting Sleep Mode

This section provides information and instructions for using the optional Sleep Mode features, which can be used separately or together. You can use the sleep timer to schedule stimulation to turn off at a set time for each program. If your clinician enables the sleep schedule feature, you can use the sleep schedule to turn stimulation on and off automatically at a set time for each program.

- Sleep Timer – allows you set stimulation to turn off in 15, 30, 45, or 60 minutes.
- Sleep Schedule – allows you to set a time for stimulation to automatically turn on or off each day.

Figure 20. Mode screen and Sleep screen



To turn on the sleep timer:

1. In the Therapy screen, tap . The Mode screen appears.
2. Tap . The Sleep screen appears.
3. Tap the **Sleep Time**r toggle button. The toggle button moves from left to right and turns blue.
4. To set the amount of time until therapy turns off, tap Countdown. The **Countdown** popover opens.
5. Select when you want stimulation to turn off.

NOTE: The Sleep screen displays the time remaining before stimulation turns off.

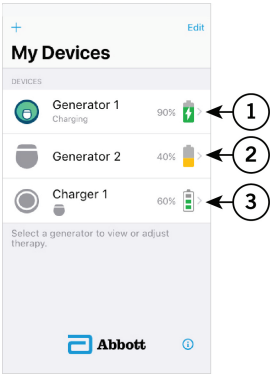
To set a sleep schedule:

1. In the Therapy screen, tap . The Mode screen appears.
2. Tap . The Sleep screen appears.
3. Choose one or both of the following options:
   - Tap **Therapy ON** to select the time you want stimulation to turn on.
   - Tap **Therapy OFF** to select the time you want stimulation to turn off.
4. Tap the **Sleep Schedule** toggle button. The toggle button moves from left to right and turns blue.

Viewing Generator, Charger, and Patient Controller Battery Status

Your generator, charger, and patient controller contain rechargeable batteries. You can view the charge level of your generator and charger batteries on the My Devices screen. The charge level of each device listed is displayed on the right with a percentage and battery icon. If a listed device is charging, you can view the charging status. The generator icon that appears under the charger name indicates how much charge the charger can provide the generator.

Figure 21. Device charge level and charging status



1. Generator 1 battery is charging and is 90% full
2. Generator 2 battery is 40% full
3. Charger 1 battery is 60% full and can charge a generator fully

Viewing Generator Battery and Charging Status

The patient controller app provides information about your generator's battery. Your clinician will also give you guidance to determine a charging schedule. For the best charging experience, charge the generator until generator charging is complete at least once per year.

If your clinician has enabled this feature and the generator and patient controller are connected, you can view the estimated stimulation time remaining in the Therapy screen (only available for the first 10 years of device life). The estimated stimulation time remaining appears below the name of the connected generator.

When your patient controller indicates your generator battery is low, you should charge the generator to maintain therapy.

The patient controller provides alert messages when the charge level of the generator is below 20% and you should charge your generator. It also displays an alert message when therapy is turned off due to a low generator battery, and the generator must be charged to resume therapy. When the generator battery is too low to provide therapy, or if therapy has turned off due to a low battery, the battery status on the patient controller displays as N/A.

NOTE: With rechargeable batteries, charging may become more frequent with use over time as the battery will no longer hold as much power as it used to. If the charging frequency becomes inconvenient, you should contact your physician.

When the generator reaches 10 years of life, the patient controller app displays a Battery Reminder message, indicating you should contact your physician if charging frequency is inconvenient. This reminder message will appear every 90 days.

Viewing Generator Charging Sessions

You can use your patient controller to monitor generator charging sessions. If enabled by your clinician, you can modify Charging Mode settings.

To view the charging status in detail:

1. From the My Devices screen, tap the name of the generator that is being charged. The Therapy screen appears.

2. Tap the generator name or battery icon. The Charge screen appears.

The screen may show the generator is charging, the time remaining until the generator is fully charged (if enabled, and only for the first 10 years of device life), and when generator charging is complete. It may also display when generator charging has slowed or stopped.

Table 4. Generator charge screens

Screen Icon	Screen Message	Description
	Charging	Generator battery is charging.
	Battery Full In x Hours x Mins	Time remaining until generator battery is fully charged.
	Charging Slowed System is Cooling	Generator battery charging slowed because the system is cooling.
	Charging Stopped Allow System to Cool	Generator battery charging stopped. System must cool for charging to continue.
	Not Charging	Generator battery not charging.
	Complete	Generator battery charging is complete.

During generator charging sessions, it is normal to feel warming around the generator location. If the warming becomes uncomfortable, remove the charger and wait until the sensation is gone before charging again or set the Charging Mode to a lower setting.

You can also choose the charging setting that is most comfortable if your clinician has enabled the Charging Mode feature. It is recommended to choose a setting based on the typical length of your charging session.

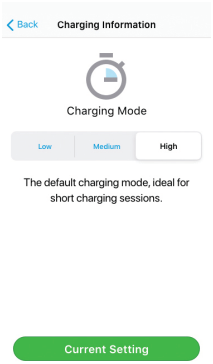
- Low is recommended for longer charging sessions.
- Medium is recommended for average-length charging sessions.
- High is recommended for short charging sessions.

NOTE: You can change your Charging Mode during charging sessions.

To change the Charging Mode:

1. From the My Devices screen, tap your generator. The Generator screen appears.
2. Tap on the generator name. The Charge screen appears.
3. Tap ⓘ. The Charging Information screen appears.
4. Tap the desired mode.
5. Tap **Save This Setting**.

Figure 22. Charging Mode settings



Viewing the Charger Battery Status

If your charger is in range of your patient controller or connected to it, you can view the battery status of your charger on the My Devices screen of your patient controller. The charger battery level is indicated by a battery icon with colored lights. See the following table.

Table 5. Charger battery status

Battery Icon	Bar Color	Charging Status
	Three gray bars	Charger is off or charger battery is depleted.
	One yellow bar	Charger will not fully charge a depleted generator.
	One green bar	Charger may not be able to fully charge a depleted generator.
	Two green bars	Charger can fully charge a depleted generator.
	Three green bars	Charger can fully charge a depleted generator.

NOTE: One yellow bar indicates you have 30 minutes or less remaining before the charger turns off due to low battery.

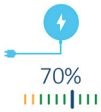
Viewing Charger Charging Sessions

To view the charging status in detail:

1. From the My Devices screen, tap the name of the charger that is being charged. The Charger screen appears.
2. Tap the charger name or battery icon. The Charge screen appears.

The screen may show the charger is charging, the time remaining until the charger is fully charged, and when charging is complete. It may also display when the charger is not charging or is out of range.

Table 6. Charger charge screens

Screen Icon	Screen Message	Description
	Battery Full In x Hours x Mins	Screen shows the charger battery currently charging, the percentage of charge the battery has, and the time remaining until the battery is fully charged.
	Complete	Charger battery fully charged.
	Not Charging	Charger battery not charging.
	Out of Range	Charger is out of range of the patient controller.

Managing Other Charger Settings

From the Charger screen, you can change the charger name and volume settings.

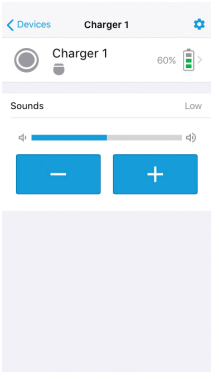
To edit the name of your charger:

1. From My Devices, tap your charger. The Charger screen appears.
2. Tap ⚙. The Settings screen appears.
3. Tap the Charger Name field. The on-screen keypad appears.
4. Edit the charger name.

To edit the volume of your charger:

1. From My Devices, tap your charger. The Charger screen appears.
2. Tap + or – buttons to increase or decrease the charger volume. The blue bar will increase or decrease as you increase or decrease the volume.

Figure 23. Charger screen



Viewing the Patient Controller Battery Status

Be sure to monitor the patient controller battery status ⁎ 100% ▬ (indicated in the top right corner of the screen, varies by Apple‡ device version). As the battery is used, the battery indicator shows the remaining charge. Recharge the patient controller using the charging cord and wall outlet plug provided with your device.

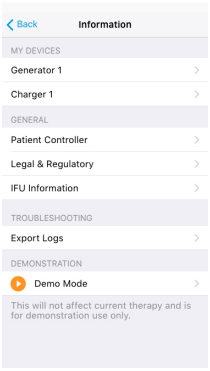
NOTE: Keep the patient controller charged or have a power supply nearby. Familiarize yourself with the patient controller's battery life so you can anticipate its charging needs. For more information, refer to the user guide available at support.apple.com/guide for the Apple‡ iOS‡ device you are using to run the patient controller app.

Viewing, Updating, and Exporting Device Information

From the Information screen, you can view information about your connected devices, such as model and software version; general information about the patient controller; and legal and regulatory information. From this screen, you can also update the patient controller app, generator, and charger software (when available) and export the patient controller logs.

To view general device and system information, tap ⓘ in the My Devices screen or in the Mode screen.

Figure 24. Information screen



Updating Generator Software

When a software update is available for your generator, you can perform the software update from the My Devices screen or from the Therapy screen. To update the software:

From the My Devices screen

1. Tap the generator you want to view. If a software update is available, the Update Available popover opens.

   CAUTION: Do not remove the Bluetooth® wireless technology pairing between the generator and the patient controller and do not delete the generator from the My Devices list while the software updates. Doing so may prevent the generator from establishing communication and prevent therapy from being turned on again.

2. Select **Dismiss** or **Update**. If Dismiss is selected, you will return to the Therapy screen. If Update is selected, the Update Software screen appears.

   NOTE:

   - The Update button is only visible when an update is available.
   - During a software update, stimulation will be turned off temporarily.

3. Tap **Download Update.**
4. Place the magnet over the generator to confirm the software update.

   NOTE:

   - Ensure the two ends of the magnet are horizontal and level with the generator.
   - Once the magnet confirms the update, the update cannot be canceled.
   - If the magnet is not placed over the generator to confirm the update within 60 seconds, a Software Update Canceled message appears. If you receive this message, try updating the software again.

From the Therapy screen

1. Tap ⚙. The Mode screen appears.
2. Tap ⓘ. A list of your paired devices appears.
3. Tap the connected generator you want to view.

4. Tap **Update**. The Update Software screen appears.
5. Tap **Download Update**.
6. Place the magnet over the generator to confirm the software update.

   NOTE:

   - Ensure the two ends of the magnet are horizontal and level with the generator.
   - Once the magnet confirms the update, the update cannot be canceled.
   - If the magnet is not placed over the generator to confirm the update within 60 seconds, a Software Update Canceled message appears. If you receive this message, try updating the software again.

Updating Charger Software

When a software update is available for your charger, you can perform the software update from the My Devices screen or from the Charger screen. To update the software:

From the My Devices screen

1. Tap the charger you want to view. If a software update is available, the Update Available popover opens.
2. Select **Dismiss** or **Update**. If Dismiss is selected, you will return to the charger screen. If Update is selected, the Update Software screen appears.

   CAUTION: Do not remove the Bluetooth® wireless technology pairing between the charger and the patient controller and do not delete the charger from the My Devices list while the software updates. Doing so may prevent the charger from establishing communication.
3. Tap **Start Update**.

   NOTE: The Update button is only visible when an update is available.
4. To confirm the software update, press the Power button on the charger.

   NOTE:

   - Once the Power button is pressed to confirm the update, the update cannot be canceled.
   - If the Power button on the charger is not pressed within 60 seconds, a Software Update Canceled message appears. If you receive this message, try updating the software again.

From the Charger screen

1. Tap ⚙. The Mode screen appears.
2. Tap ⓘ. A list of your paired devices appears.
3. Tap the connected charger you want to view.
4. Tap **Update**. The Update Software screen appears.
5. Tap **Start Update**.

   NOTE: The Update button is only visible when an update is available.

6. To confirm the software update, press the Power button on the charger.

   NOTE:

   - Once the Power button is pressed to confirm the update, the update cannot be canceled.
   - If the Power button on the charger is not pressed within 60 seconds, a Software Update Canceled message appears. If you receive this message, try updating the software again.

Updating Patient Controller App Software

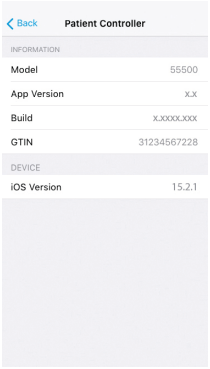
When a software update is available for the patient controller app, follow these steps to update the software:

1. From the My Devices screen or the Mode screen, tap ⓘ. The Information screen appears.
2. Tap Patient Controller. The Patient Controller screen appears.
3. Tap **Update**. The Confirm Update popover opens.

   NOTE: The Update button is only visible when an update is available.

4. Tap **Confirm Update**.
5. To confirm that the software was updated, see the app version on the patient controller device information screen.

Figure 25. Patient controller device information screen



Exporting the Patient Controller Log

Your generator performs a series of self-diagnostic tests to verify that the generator firmware and hardware are operating according to specifications. The generator saves the test results in a log file. If Technical Support asks you to obtain the troubleshooting logs:

1. From the My Devices screen or the Mode screen, tap ⓘ. The Information screen appears.

2. Under Troubleshooting, tap **Export Logs**. The Export Log screen appears.

   NOTE:

   - When exporting the patient controller log, you must select whether to Remove or Include Personally Identifiable Information (PII). It is recommended to select Remove unless directed by your clinician or Technical Support.
   - If using the AirDrop feature of the patient controller, be aware that PII in the patient controller may be accessible.

3. Tap **Export**.

Caring for the Patient Controller

If you are using a patient controller provided by Abbott Medical, clean the protective case by wiping off the outer surface using a moist cloth and a small amount of mild soap. Do not use a cloth that is saturated. Do not use alcohol, ammonia-based cleaning agents, cleaning solutions, or solvents to clean the case.

NOTE: For more information on how to care for the patient controller, refer to the user guide available at support.apple.com/guide for the Apple‡ iOS‡ device you are using to run the patient controller app. If using a device from a different manufacturer, refer to the manufacturer's user guide for that device.

Cybersecurity

To protect the devices, products, and systems that connect patients to healthcare professionals and institutions, Abbott takes a broad and deep approach to ensuring safety, privacy, and security. Visit the information page available at www.NMCybersecurity.Abbott to learn more about the Abbott Medical neuromodulation cybersecurity program. Periodically, Abbott may update this website with important messages related to the cybersecurity of your patient device.

Protecting Access to the Patient Controller

To prevent unauthorized access to your Apple‡ device, set up a passcode or other supported method of biometric security (such as a Touch ID). For instructions, refer to the user guide available at support.apple.com/guide for the Apple‡ iOS‡ device you are using to run the patient controller app.

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator and charger encrypt wireless communication with the patient controller using a key that is unique to that link.
- Only one patient controller or clinician programmer may communicate with the generator or charger at a time.
- Standard Bluetooth® Low Energy (LE) pairing methods ensure valid and legitimate pairing among devices.

- Proprietary authentication for patient controller app or clinician programmer app in addition to the pairing procedure specified in Bluetooth LE, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized user from attempting to pair with the generator or charger.
- Whitelisting methods that prevent unauthorized devices from using Bluetooth LE scanning to interfere with communication from the generator or charger to a legitimate patient controller or clinician programmer.

Guidelines for Secure Use

Users should adhere to the following guidelines when using the system:

- Do not use the app if the operating system is compromised (for example, jailbroken).
- Do not share your Apple‡ ID login information or device passcode.
- Do not leave the device unattended or allow other users to access the patient controller.
- Do not install untrusted apps on the patient controller.
- Secure your home network with a Wi-Fi‡ password, and only connect to trusted secured networks when not at home.
- If your patient controller is lost or stolen before your generator has been paired, follow the instructions at support.apple.com.
- If your patient controller is lost or stolen after your generator has been paired, use your replacement device to delete the previous patient controller and generator pairing. See Removing a Pairing Between a Generator and an Unused Patient Controller (page 42).
- If you receive a “Device Not Secure” notification in the patient controller app, contact Technical Support.
- When notified on the patient controller, upgrade to the latest available software version for the patient controller app.
- Install iOS‡ software upgrades on your device as they are made available by Apple‡, after verifying iOS software version compatibility with the patient controller app via www.NMmobiledevicesync.com/int/cp.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Legal and Privacy Notice

The terms of use and privacy policy are displayed the first time the patient controller app is launched after installing or updating the app. To view this information again, tap ⓘ on the patient controller app My Devices screen.

Abbott Medical is committed to protecting the privacy of our customers and patients. This privacy statement summarizes how we protect, gather, and use personal information of users. For more information, view our US or Global Privacy Policies online at www.abbott.com/privacy-policy.html.

We may amend these terms of use, privacy statements, and privacy policies from time to time, so please check for updates.

Troubleshooting

This section provides troubleshooting procedures to help you identify and solve problems that may occur.

NOTE:

- If you encounter problems other than those described in this section, contact “Technical Support” (page 34).
- Refer to the terms and conditions for repair or replacement of Abbott Medical neurostimulation system components as stated in the Limited Warranty card included in your product documentation.

Table 7. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Patient Controller Device		
Patient controller is not accessible.	Patient controller is lost or damaged.	Contact Technical Support. If you receive a replacement patient controller, delete all previous connections when prompted.
Patient controller is not communicating with the generator.	The generator is not sensing the magnet.	Position the magnet toward the top and close to the side of the generator. Ensure the two ends of the magnet are horizontal and level with the generator.
Patient controller has no power or has lost power.	Patient controller’s battery is drained.	Charge the patient controller.
	Patient controller is damaged or malfunctioning.	Contact Technical Support.
Patient controller will not charge.	Patient controller charging cable is loose or not well connected.	Connect the charging cable to the patient controller.
	Correct plug adapter (voltage converter) is not connected to the charging cable.	Connect the appropriate plug adapter (voltage converter) to the charging cable.
	Plug adapter or charging cable is defective.	Replace the plug adapter or charging cable.
	Patient controller is damaged or malfunctioning.	Contact Technical Support.

Table 7. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Nothing is displayed on the screen.	Patient controller is off or is in Sleep mode.	Turn on the patient controller.
	Patient controller's battery is drained.	Charge the patient controller.
	Screen is damaged or malfunctioning.	If the patient controller appears to be powered on but without display, the screen may be defective. Contact Technical Support.
Patient controller will not respond to input.	Patient controller has locked up.	Perform a soft reset by turning the patient controller off and back on.
	Touchscreen interface is damaged or malfunctioning.	If the patient controller appears to be powered on but will not respond to input, the screen may be defective. Contact Technical Support.
Cannot find or connect to the generator or charger.	The patient controller battery is low.	Charge the patient controller.
	Unsupported device.	Download and install the patient controller app for the Eterna™ SCS system. See "Appendix A: Downloading the Patient Controller App" (page 40). If you encounter problems installing the app, contact Technical Support.
	The patient controller pairing with the generator or charger was lost or removed.	1. Follow the alert message to remove the existing pairing from the patient controller iOS‡ settings. 2. Pair the patient controller with the generator or charger. See "Appendix B: Pairing the Patient Controller With the Generator" (page 41) or "Appendix C: Pairing the Patient Controller With the Charger" (page 42).
Patient Controller App		
Cannot locate patient controller app.	Patient controller app is not on patient controller Home screen.	Swipe through screens from the patient controller Home screen to locate app.
		Search for the app using the iOS‡ search function.
		Ensure you have the patient controller app for the Eterna™ SCS system and see this icon: 
		Download and install the patient controller app for the Eterna™ SCS system. See "Appendix A: Downloading the Patient Controller App" (page 40). If

Table 7. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
		you encounter problems installing the app, contact Technical Support.
		Enable notifications.
Bluetooth® Wireless Technology Communication or Connection		
Patient controller cannot establish Bluetooth connection with the generator or charger, or ▪ connection was lost or is intermittent. ▪ app returns to home screen. ▪ patient controller does not respond to input.	Interference in the environment, including temporary interference (for example, from microwave ovens and Wi-Fi‡ routers, or voltage surge produced by lightning).	Move to a different area or room away from the interference.
		Reconnect the patient controller with the generator or charger. Start new session.
	Patient controller is off or has timed out and is in standby mode.	Wake up the patient controller.
	Patient controller battery is drained.	Charge the patient controller battery.
	Generator battery is low or depleted.	Charge the generator battery.
	Bluetooth® wireless technology is not connected.	Remove and reenable the Bluetooth® wireless technology pairing.
		In the device settings, select the patient controller app. Tap the toggle button to enable Bluetooth® wireless technology.
	The magnet was used and Bluetooth® wireless technology was disabled.	Hold your magnet over the generator for 5 seconds to enable Bluetooth® wireless technology.
	The user's hand is blocking the Bluetooth® wireless technology antenna.	Try holding the patient controller differently.
	Bluetooth® wireless technology connection is not strong.	Decrease the distance between the devices. Ensure the patient controller is in Bluetooth® wireless technology range of the generator within 0.9 m (3 ft) or charger within 2 m (6.5 ft).
		Turn on Bluetooth® wireless technology on your patient controller if communication is disabled. 1. Return to the patient controller Home screen and tap **Settings**. 2. Tap **Bluetooth**, then tap the Bluetooth toggle button. NOTE: If you turn Bluetooth® wireless technology off and on or reset the app, it will take longer to reconnect to your generator.

Table 7. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
		Move to another location so the patient controller, generator, and charger are away from other devices that may be causing interference.
		Move the patient controller and generator or charger so they have line of sight and maintain an uninterrupted path for the Bluetooth® wireless technology signal.
		If the generator is being charged, stop charging and move the charger away from the generator.
		Disable Wi-Fi‡ in the iOS‡ settings.
		Do not operate other wireless devices at the same time.
		Disconnect any Bluetooth® wireless technology media accessories (such as headphones or speakers, AirPlay‡, AirDrop‡, CarPlay‡, or Hotspot‡).
Therapy		
A program is invalid or not available.	The program is missing information.	Talk to your physician about reprogramming your therapy.
No stimulation.	Stimulation is off, possibly due to a generator reset or magnet application.	Turn on stimulation using the patient controller app or magnet (if enabled).
Stimulation turns off unexpectedly.	Stimulation has stopped according to the therapy schedule.	Check the therapy schedule.
	The system impedance is measuring impedance and has stopped stimulation temporarily.	Stimulation will resume when the impedance measurement is completed.
	A magnet was used to turn off stimulation.	Turn on stimulation to resume therapy.
	The generator performed a reset.	Select a program and turn on stimulation to resume therapy.
	The generator battery depleted.	Charge the generator.
	The generator entered Surgery mode.	If Surgery mode was triggered in error, follow the on-screen notification to exit Surgery mode.
		If the generator detected high current, move the source of the high current away from the generator or move the generator away from the source of the high current. When the generator no longer detects high current, follow the steps to exit Surgery mode.

Table 7. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Program strength is off.	The generator could not deliver the desired program strength.	Try adjusting the program strength. If the problem persists, contact your clinician.
Increasing Strength is Not Recommended message appears.	The program may need to be modified.	Contact your clinician.
MRI Mode		
MRI is Not Permitted is displayed instead of the MRI Mode option on the Mode screen.	A part of the system is not MR Conditional.	Contact your clinician for help identifying the models of your system. If you have any implanted parts that are not MR Conditional, you cannot receive an MRI scan.
	The generator battery is low and cannot enter MRI mode.	Check the generator battery status and charge the generator if the battery is low. Then try entering MRI mode again.
MRI is Not Advised message appears.	The generator battery voltage is too low.	Contact your clinician.
	There may be a problem with the implanted lead or leads.	Contact your clinician.
Cannot put the generator in MRI mode.	The generator is not connected to the patient controller.	Try connecting to the generator again. If the problem persists, contact Technical Support.
	The generator is in Surgery mode.	Exit Surgery mode to set MRI mode.
Cannot access the Mode screen.	The generator is not connected to the patient controller.	Try connecting to the generator again.
Surgery Mode		
Cannot put the generator in Surgery mode.	The generator is not connected to the patient controller.	Try connecting to the generator again. If the problem persists, contact Technical Support.
	The generator is in MRI mode.	Exit MRI mode to set Surgery mode.
Generator automatically enters Surgery mode and Surgery mode cannot be removed or turned off.	The generator has detected high current.	If possible, move the source of the high current away from the generator, or move the generator away from the source of the high current. When the generator no longer detects high current, follow the steps to exit Surgery mode.
Battery		
Battery percentage for the generator changes unexpectedly when starting or stopping charging.	Generator battery may need to be calibrated.	Charge the generator fully to calibrate the battery percentage.
Generator requires frequent charging.	The programs may need to be adjusted or the generator may be approaching its end of service.	Talk to your physician about reprogramming or replacing the generator.
Battery Reminder message appears.	The generator has reached 10 years of device life and may not be holding as much power as it used to.	If the generator requires frequent charging, talk to your physician about reprogramming or replacing the generator.

Table 7. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Battery Reminder message appears unexpectedly, before 10 years of device life.	Date of the patient controller was manually changed.	Turn on automatic date control or correct the date and time for the patient controller.
Replace Charger Soon message appears.	The charger may be approaching its end of service.	Contact Abbott Medical Technical Support to schedule replacement.
Charger		
Charging is uncomfortable.	Charging mode may need to be adjusted.	Change the Charging mode (if enabled). See "Viewing Generator Charging Sessions" (page 25). Or talk to your physician about enabling Charging mode or adjusting settings.
		Stop charging until the discomfort subsides and then resume charging.
Software Update		
Generator or charger software update was not successful.	Generator or charger software update was interrupted.	Try installing the generator or charger software again. If unsuccessful, wait a while and try again. If you cannot locate the generator or charger on the patient controller app, contact Technical Support.
	Pairing was removed between the patient controller and the generator or charger.	Do not remove a pairing during a software update.
	Patient controller app must be updated to work with the newer generator software.	Perform the steps in "Appendix A: Downloading the Patient Controller App" (page 40) to update the app.
	Generator or charger battery is too low to update the software.	Charge the generator or charger.
Cannot locate programs after updating generator software.	After installing generator software, the previous program data was lost.	Contact your physician for reprogramming.
Software update is not available.	An update is not available at this time.	You should see a notification when a software update is available.

Appendix A: Downloading the Patient Controller App

If your patient controller does not have the patient controller app for the system, you must download the app to your patient controller (either a device provided by Abbott Medical or a compatible personal Apple‡ iOS‡ device) in order to use the patient controller with your generator. The patient controller app is compatible with Apple‡ iOS‡ mobile digital devices as specified on the Abbott Neuromodulation patient resources page at www.NMmobiledevicesync.com/int/cp. Be sure your patient controller is running an Apple-released iOS version before downloading the patient controller app.

If you do not have an Apple ID, you can create one while setting up the device or before installing the app. For instructions, refer to the Apple ID support page at support.apple.com/apple-id.

To download the patient controller app:

1. Make sure the device is turned on and connected to the internet.
2. Tap the App Store icon on the patient controller.
3. Tap **Search** and enter **Patient Controller RC** in the Search field.
4. Once you locate the correct app, tap **GET** and follow the onscreen prompts.

   NOTE: If you encounter problems downloading the app, contact Technical Support for assistance.

Appendix B: Pairing the Patient Controller with the Generator

The following instructions outline the steps for pairing the patient controller to the generator.

1. Tap the patient controller app icon to open the app. The Startup screen appears.

   NOTE: The first time you launch the patient controller app, the Terms of Use popover opens. Tap **Accept**. The Privacy Policy popover opens. Tap **Acknowledge** to use the app.

2. If no generator is listed, place the magnet over the generator for 10 to 15 seconds and then remove it.

   NOTE: Ensure the two ends of the magnet are horizontal and level with the generator.

3. When the My Devices screen appears, Tap +.
4. Tap the appropriate generator in the Select Devices list.

   NOTE: If no generators are found, you will see a No Generators Found message. Tap ↻ to search for available generators again.

5. Enter the date of birth associated with the generator in the Patient field.
6. Tap **Register** to pair the patient controller and generator.

You may pair the patient controller with up to four different generators. If you reach the maximum number of paired devices, a message appears instructing you to delete a device.

The following instructions outline the steps for deleting a generator from a patient controller.

1. On the My Devices screen, tap **Edit**.
2. Tap ⊖ next to the generator you want to delete. The Delete button appears next to the generator.
3. Tap **Delete**. A confirmation message appears.
4. Tap **Delete** to remove the generator.

Removing a Pairing Between a Generator and an Unused Patient Controller

If you lost or are no longer using a patient controller or if you have exceeded the number of devices you can pair with your generator, you can remove a pairing.

To remove pairing information between a generator and an unused patient controller:

1. Connect the patient controller to your generator.
2. Tap ⚙. The Mode screen appears.
3. Tap ⓘ. The Information popover opens.
4. Tap **Delete Connections**. The Delete Connections screen appears.
5. Tap **Delete Others**. All patient controller pairing information is deleted from the generator except for the patient controller that is currently connected.

Appendix C: Pairing the Patient Controller With the Charger

To charge the generator, the charger does not need to be connected through Bluetooth® wireless technology to the patient controller. However, a Bluetooth® wireless technology connection with the patient controller allows you to monitor charger charging sessions and perform charger software updates.

Before you can establish a Bluetooth® wireless technology connection between the patient controller and the charger, a one-time Bluetooth® wireless technology pairing must be performed. If the charger is paired to the patient controller, it will be listed in My Devices on the patient controller app.

If Bluetooth® wireless technology pairing is needed:

1. Launch the patient controller app.
2. Place the charger within Bluetooth® wireless technology range of the patient controller.
3. Turn on the charger by pressing the Power button. The charger emits a tone.
4. To begin pairing, press the Power button for approximately 5 seconds.
5. Confirm the charger is in a pairing state by observing the blinking light on the Power button and that it is in close proximity to the patient controller.

   NOTE: Once the charger is in a pairing state and in close proximity to the patient controller, the charger light blinks, the charger beeps once, and pairing is completed automatically. The charger beeps again when charging is complete.

6. To confirm that pairing has been successful, locate the charger under My Devices on the patient controller app.
7. Power off the charger by pressing the Power button for approximately 5 seconds.

   NOTE:

   - If the pairing does not occur within 5 minutes, the charger exits pairing mode and then automatically turns off after 90 seconds of inactivity.
   - If the charger is not paired with the patient controller, retry steps 1-3.

You may pair the patient controller with up to four different chargers. If you reach the maximum number of paired devices, a message appears instructing you to delete a device.

The following instructions outline the steps for deleting a charger from a patient controller.

1. On the My Devices screen, tap **Edit**.
2. Tap ⊖ next to the charger you want to delete. The Delete button appears next to the charger.
3. Tap **Delete**. A confirmation message appears.
4. Tap **Delete** to remove the charger.

Appendix D: Regulatory Statements

These statements are applicable to the generator. For Regulatory Statements regarding the patient controller, refer to the user guide available at support.apple.com/guide for the Apple‡ iOS‡ device you are using to run the patient controller app; or, on the patient controller Home screen, tap **Settings > General > Legal & Regulatory**.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Statement of Compliance With License-Exempt RSS Standard (Canada)

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Declaration of Conformity (Industry Canada) Notice to Users of Radio and Television

This Class B digital apparatus meets all the requirements of the Canadian interference-causing equipment regulations.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format.

Table 8. Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2-GMIPG1
IC Registration Number	30752-GMIPG1

Product Classification Statement (CISPR 11, Class B)

This product is class B equipment, which is intended primarily for use in the domestic environment.

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® wireless technology as it is implemented in the device.

Table 9. Bluetooth® Low Energy (LE) wireless technology information

Antenna type	Modified monopole
Antenna dimensions	10.7 mm x 4.3 mm x 3.0 mm
Modulation	GFSK
Output power (EIRP*)	2 mW (+3 dBm) typical
Duty cycle	14.1% or less over 6 min period
Range	Up to 2 m typical
Center frequency	2.44 GHz
Channel frequency range	2.402 GHz to 2.480 GHz

Table 9. Bluetooth® Low Energy (LE) wireless technology information

Channel	40 logical channels using AFH**
Bandwidth per channel	2 MHz
Data flow	Bi-directional
Protocol	Bluetooth LE wireless technology
Semi-duplex capability	Yes

*EIRP = Equivalent isotropically radiated power (not duty cycle adjusted)

**AFH = Adaptive frequency hopping

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.

Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the generator or charger and the clinician programmer or patient controller. The quality of the wireless communication link varies depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer or patient controller is paired with a generator or charger, the Bluetooth® wireless technology symbol is visible on the clinician programmer or patient controller in the upper right corner of the screen. When the Bluetooth wireless connection is not active, the symbol appears dimmed.

The standard Bluetooth® wireless technology data rate is 1 Mbit/s. The quality of service (QoS) should allow wireless data to be transferred at a net rate of 2.5 kB/sec. Each connection interval includes a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not successfully received. Each key press may transmit up to 4 data packets with up to 20 bytes per packet, depending on the number of packets that need to be transmitted (that is, if there is only one packet to transmit, only one packet will be transmitted). If the interference is high (for example, the bit error rate exceeds 0.1%), the user may experience what appears to be a slow connection, difficulty pairing devices, and a need to decrease the distance between connected devices. For information on how to improve connection issues, please refer to Troubleshooting for Wireless, Coexistence, or Interference Issues (page 46).

Troubleshooting for Wireless, Coexistence, or Interference Issues

If you experience issues with interactions within the neurostimulation system, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Close the patient controller app; then turn the patient controller off and on.
- Wait a few minutes and try connecting again.
- Avoid operating other consumer electronic devices, such as a laptop, tablet, mobile phone, or cordless phone at the same time.

NOTE: Equipment such as the following can interfere with the neurostimulation system: wireless home network devices, mobile and cordless telephones, and consumer electronic devices.

Appendix E: Radio Frequency Information

The effective radiated power is below the limits as specified in:

- USA: FCC 47 CFR Part 15
- Canada: RSS-247 Issue 2

NOTE: Maintain a reasonable distance between other electronic equipment and the device.

CAUTION: The ISM band used by this device has been approved by the Federal Communications Commission for unlicensed use. However, there is no guarantee that this device will not receive interference or that any particular transmission from this device will be free from interference.

Appendix F: Electromagnetic Compatibility Guidelines

The patient controller app (Model 55500) operates on an Apple‡ iOS‡ device as part of the Eterna™ SCS system. Refer to the precautions in this guide for information on sources of EMI, the effect of EMI on the patient and the Eterna™ SCS system, and instructions on how to reduce the risk of EMI (see “Precautions” (page 3)). Failure of the Apple‡ iOS‡ device will not result in an unacceptable risk to the user.

The Eterna™ SCS system has undergone electromagnetic disturbance testing to confirm essential performance of the associated medical equipment as defined by IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2). Refer to the user's guide for the charging system for information regarding electromagnetic declaration and intended use environments.

NOTE:

- Apple‡ iOS‡ devices were included in the Eterna™ SCS system testing for electrostatic discharge (ESD), power frequency, radiated electric fields, and radiated magnetic fields.
- The non-Abbott accessories supporting the patient controller, such as charging cords, adapters, should not be used while running the patient controller app. The effect of use of such accessories while running the app has not been evaluated.

Appendix G: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

NOTE: For symbols and definitions for the patient controller, refer to the user guide available at support.apple.com/guide for the Apple‡ iOS‡ device you are using to run the patient controller app; or, on the patient controller Home screen, tap ⓘ > **Legal & Regulatory**.

Table 10. Symbols and definitions

Symbol	Definition
	Caution
	Contains hazardous substances
	Refer to instruction manual/booklet
	Consult instructions for use
	Follow instructions for use on this website
	Type BF Applied Part
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe

Table 10. Symbols and definitions

Symbol	Definition
	NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.
	Non-ionizing electromagnetic radiation
	Keep dry; keep away from rain
IP22	Ingress protection rating for a device that is protected from the intrusion of solid foreign objects as small as 12.5 mm in diameter and is protected from vertically dripping water when the device is tilted at an angle up to 15 degrees
	Use-by date
	Date of manufacture
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturing facility
	Temperature
	Temperature limit
	Excursion temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Manufacturer

Table 10. Symbols and definitions

Symbol	Definition
	Do not use if package is damaged
	Packaging unit
	Programmer
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Medical Device
	Prescription use only
	Patient identification
	Physician telephone
	Date
	Healthcare center or physician
	Location of implant
	Patient Information Website
	This product shall not be treated as household waste. Instead it is the user's responsibility to return this product to Abbott Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by

Table 10. Symbols and definitions

Symbol	Definition
	inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Abbott Medical.
EC REP	Authorized representative in the European Community
CH REP	Swiss Representative
	Importer
CE 2797	European conformity, affixed in accordance with the relevant provisions of European Council Regulation 2017/745 (NB 2797). Hereby, Abbott Medical declares that this device is in compliance with the relevant provisions of this regulation.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law
	Korean Radio Communications License (KC Mark)
UK CA 0086	United Kingdom Conformity Assessed
UKRP	Responsible person in the United Kingdom

Additional Symbols for Product Labels

The following table shows additional symbols that may appear on the product labels for parts related to this kit.

Table 11. Additional symbols for product labels

Symbol	Description
Patient Magnet	Patient Magnet
Patient Manual Kit	Patient Manual Kit

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

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