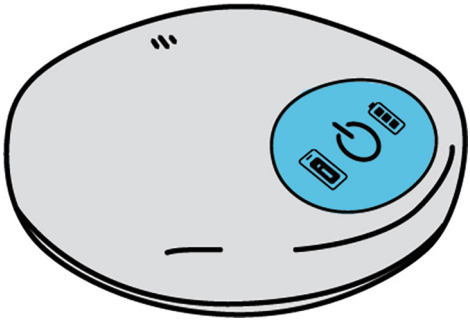
Charging System

Eterna™ Spinal Cord Stimulation System
Model 16000



User's Guide

Abbott

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

⚠ WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Contents

About This Guide

This guide explains how to use the charging system (model 16000 and charging system accessories). Follow the information in this guide to correctly use your charging system. If you have any questions about your system, contact Technical Support.

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The charging system is intended to be used to charge the Eterna™ implantable pulse generator (IPG), also referred to as a generator.

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.

Additional Prescription Information

Refer to the user's guide for your patient controller for instructions for use and other important information, including indications for use, contraindications, warnings, precautions, adverse effects, and the personal identification card related to your neurostimulation system.

MRI Safety Information

Do not bring your charger into the scanner magnet room. It can be affected by the magnetic resonance imaging (MRI) magnet, may present a projectile hazard, and is considered MR Unsafe.

Warnings

The following warnings apply to this charging system.

Device inspection. Before using the charging system, check the charger, charging cable, and power adapter for visible damage or indication of prior disassembly. If any damage or prior disassembly is observed, do not use the charging system and contact Technical Support.

Device modification. This charger is not serviceable by the customer. To prevent injury to yourself or damage to the charging system, do not modify the charger. If needed, return the charger to Abbott Medical for service.

Battery warning. The charger contains a lithium-ion battery and other potentially hazardous materials. Do not crush, puncture, or burn the charger because explosion or fire may result.

Battery care. Batteries should not come in contact with metal or be exposed to high temperature or fire. Batteries can explode, leak, or melt if disassembled, shorted (when battery connections contact metal), or exposed to high temperature or fire.

Power adapter and charging cable compatibility. Use only power adapters and charging cables that meet the ratings specified in the appendix for technical specifications. Use of accessories, transducers, and cables other than those specified or provided by Abbott Medical could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation of the system.

Power adapter handling. Do not position the power adapter in such a way that it is difficult to disconnect from an electrical outlet.

Explosive or flammable gases. Do not use your charger 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.

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

Choking. Small parts in this charging system pose a choking risk. Keep small system parts out of the reach of children.

Keep dry to avoid damage. Your charger is not waterproof. Keep it dry to avoid damage. Never use the charger in or around water. If the charger becomes wet, allow it to dry completely before use.

Precautions

The following precautions apply to this charging system.

Device components. The charging system is for use with the Eterna™ implantable pulse generator only. You may use a commercially available power adapter and charging cable as long as it meets the technical specifications listed in the appendix.

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

Review your user's guide. Before using your charger, review the system information in the applicable patient controller user's guide.

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.

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

Pain-relief patches. Avoid using pain-relief patches or topical anesthetics, such as pain-relieving creams or medicated balms, over your generator site before or during charging. These pain-relief patches or topical anesthetics may reduce your ability to perceive discomfort due to charging.

Alcohol consumption. Avoid drinking alcoholic beverages before or during charging because they may reduce your ability to perceive discomfort due to charging.

Charging system immunity. Wireless communication equipment, such as wireless home network devices, mobile and cordless telephones, and walkie-talkies, can interfere with the charging system. To correct the effects of typical system interference, keep the charging system at least 0.5 m (1.6 ft) from these types of wireless communication equipment. If you continue to have problems with interference, further increase the distance between the equipment and your charging system.

Charge your charger. The charger should be fully charged after every generator charging session.

Unplug the cable carefully. To avoid damaging the charging cable, do not pull on cable when unplugging it from the charger or power adapter. Grasp the connector and pull carefully.

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.

Adverse Effects

The following adverse effects are associated with using this charging system. Refer to the patient controller user's guide for a list of adverse effects related to the use of the Eterna™ SCS system.

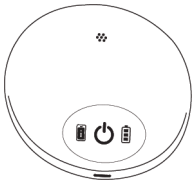
- Heating or discomfort at the pocket while charging. If you feel discomfort at the implant site while charging your generator, stop using the charger. Use your patient controller to change the charging mode or contact your physician.
- Heating or discomfort at surgical staples while charging. Charging should not be carried out while surgical staples are in place.
- Interference with another implanted medical device. This equipment generates, uses, and can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other implanted medical devices. To try to correct the effect of any interference with other devices, turn off the charging equipment or increase the distance between the charging equipment and the device being affected.

Product Description

The charging system consists of a charger, a charging cable, a power adapter, charging apparel, and a travel case for storing the charging system. The charger is used to charge the Eterna™ implantable pulse generator wirelessly. The charger interfaces with the patient controller application wirelessly through Bluetooth® wireless technology. The patient controller application allows you to modify charger settings, view the battery level of your charger and generator, and view the charging status of your charger and generator.

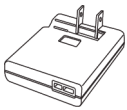
Charger

The charger is used to wirelessly charge your Eterna™ implantable pulse generator.



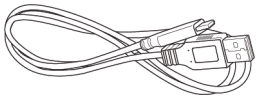
Power adapter

The power adapter connects with an electrical outlet and with the charging cable to charge the charger battery. The power adapter provided varies depending on country or region.



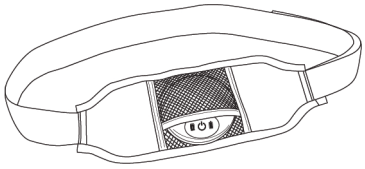
Charging cable

The charging cable connects with the power adapter and with the charger to charge the charger battery.



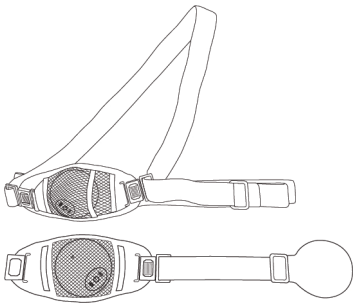
Charging apparel – lumbar

Charging apparel is used to position and stabilize the charger over your generator and charge the generator without having to manually hold the charger in place. The lumbar apparel is worn like a belt around your waist.



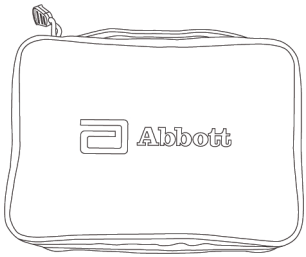
Charging apparel – pectoral

Charging apparel is used to position and stabilize the charger over your generator and charge the generator without having to manually hold the charger in place. The pectoral apparel can be worn in multiple configurations using the double strap or the counterweight.



Charger travel case

The travel case is used to store the parts of the charging system.



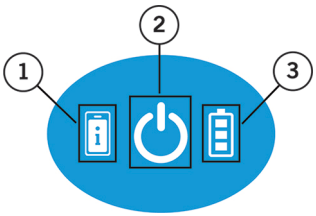
Charger Indicators

The charger has a power icon, a battery icon, and a patient controller alert icon as shown in the figure below. The charger provides indicator lights and sounds that show the charger status and the action being performed.

- **PC Alert icon.** The PC alert icon illuminates when the charger has encountered an error. You may view more information about the error on your patient controller.
- **Power icon.** The power icon illuminates when the charger is turned on. When the charger is charging the generator, the power icon blinks slowly. When the charger is in pairing mode, the power icon blinks quickly.
- **Battery icon.** The battery icon illuminates in segments to indicate the charger battery level. While the charger is being charged, a segment of the battery icon blinks.

  NOTE: The indicator lights on the charger may be difficult to see if under direct sunlight.

Figure 1. Charger icons



1. PC Alert icon
2. Power icon
3. Battery icon

Table 1. Charger sounds

Event	Charger sound
Power on	1 beep
Volume on	1 beep
Power off	2 beeps
Error	3 beeps every 5 seconds
Low battery	3 beeps every 5 minutes
Generator found	Short, repeating beeps
Generator charging started	2 beeps low tone then high tone
Generator charging stopped (not aligned)	2 beeps high tone then low tone
Generator charging complete (fully charged)	3 beeps low tone, high tone, then low tone

Using Your Charger

The instructions in this section explain how to use your charging system to charge your generator battery and charger battery, how to use the charging apparel, and how to care for and travel with your charging system.

NOTE: Each time before using the system, inspect the device and its accessories for damage. Avoid using a damaged device or accessory. If your device is damaged, contact Technical Support.

Pairing the Charger with the Patient Controller

Before you use your charger for the first time, you may want to pair the charger with your patient controller. Pairing refers to setting up communication between the charger and the patient controller. When these devices are paired, you can use your patient controller to monitor charging sessions, adjust charger settings, such as volume control, and perform charger software updates. Refer to your patient controller user guide for more information.

NOTE: Your charger and patient controller do not need to be paired or connected to Bluetooth® wireless technology in order to charge your generator.

To prepare the charger for pairing:

1. Ensure that your patient controller and charger are charged.
2. Place the patient controller near the charger.
3. Turn on the charger.
4. Press and hold the power icon on the charger for 5 seconds, and then release the button. The power icon and the battery icon blink once. Then the power icon blinks quickly, indicating the charger is in the pairing state.
5. On the patient controller, select the charger you are pairing. Refer to your patient controller manual for more information.

   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.

When to Charge Your Generator

Your clinician will help you plan a charging schedule that will work best for you to maintain effective therapy. For example, you may establish a charging routine of once per week.

The following are additional considerations to help you decide when to charge your generator:

- Prior to an MRI
- Prior to an upcoming surgery
- In anticipation of travel
- When the next charging opportunity is uncertain
- When the patient controller application displays a low battery notification for your generator

- When stimulation has stopped due to generator battery depletion

Your patient controller indicates the battery level of your generator. The level ranges from 0% charge to 100% charge. The patient controller also indicates the approximate stimulation time remaining based on the generator's current battery level and therapy settings.

When your implanted generator battery is low, your patient controller displays a low battery message. When this message appears, you should charge your generator at your earliest convenience. If you do not charge your generator after the low battery message appears, your stimulation will eventually stop. When stimulation stops, your controller will display an alert indicating therapy was turned off due to a low generator battery. You should charge your generator battery so that therapy can be restored.

NOTE:

- To maintain therapy without interruption and improve battery longevity, always charge your generator before it is depleted completely. If your generator is repeatedly allowed to deplete completely, its performance or longevity may be reduced over time.
- If your generator is depleted completely, it will take a few minutes for the generator to turn on again and communicate with your patient controller once you start charging.

Charging Your Charger

Like your generator, your charger contains a rechargeable battery that needs to be charged on a regular basis. The battery icon on the charger displays the charger battery level. The patient controller also displays the charger battery level. If the charger is in range of the patient controller or connected to it, the battery level is indicated by a battery icon with colored lights. See the following table.

Table 2. 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.
- When the charger battery is low, the charger beeps three times every 5 minutes until the battery is depleted.

To charge your charger:

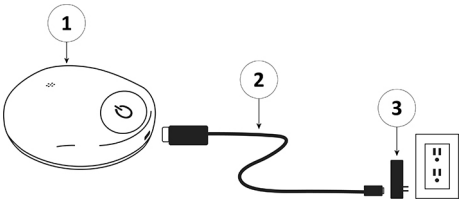
1. If the charger is in the charging apparel, remove the charger from the apparel before charging.

   NOTE: The charging apparel is not intended to be used while charging the charger.

2. Plug the power adapter into an electrical outlet.
3. Connect the charging cable and power adapter.
4. Plug the charging cable into the charger. If the charger is connected successfully to the charging cable and power adapter, the charger beeps once and a segment of the battery icon blinks and then turns off. Once the charger is fully charged, all the segments of the battery icon illuminate for 60 seconds and then turn off.

   NOTE: While the charger is charging, it should be placed on a stable surface, such as a table, counter, or floor.

Figure 2. Connecting components to charge the charger



1. Charger
2. Charging cable
3. Power adapter

NOTE:

- While the charger is charging, it cannot be used to charge the generator.
- If your charger is not charging, you may be using an incorrect cable or power adapter. Refer to the appendix for technical specifications.

5. When you are ready to use the charger, unplug the charging cable from the charger. The power adapter connected to the charging cable can remain plugged into the electrical outlet.

While the charger is being charged, the charger is able to communicate with the patient controller. The patient controller indicates the charger battery level and when the charger is being charged.

Setting Up the Charging Apparel

Your charging system comes with reusable charging apparel that you can use, if desired, to help stabilize the charger over your generator during a charging session. Depending on the implant location of your generator, you will receive either pectoral charging apparel or lumbar charging apparel. The charging apparel can be configured to be worn in different ways, depending on your preference and implant location. For example, patients with generators implanted in the lower back may choose to use the lumbar

charging apparel like a belt. If you choose to use your charging apparel, you should adjust it for comfort and fit before charging your generator.

Your clinician will help you find the configuration that is most comfortable and suitable for your generator charging sessions.

NOTE: The charger and accessories are to be used with light clothing (<5 mm). If your clothing is very thick, the charger may not effectively charge your generator.

Placing Lumbar Charging Apparel

To set up your lumbar charging apparel, gather the charger and the charging apparel:

1. If the charger is connected to the charger cable, disconnect it.

   NOTE: While the charger is charging, it cannot be used to charge the generator.

2. Press the power icon to turn on the charger. The three charger icons illuminate briefly and the charger beeps once if sound is enabled.
3. Insert the charger fully into the mesh pocket of the charging apparel with the icons facing the opening of the pocket.
4. Ensure the elastic edges of the pocket overlap, fully covering the charger.
5. Wrap the charging apparel around your waist so the charger is over your generator.
6. Adjust the velcro strap so the apparel is secure around your waist and the charger is on top of your generator.

   NOTE:

   - When the generator enters the charging zone, it beeps continuously until charging begins.
   - If the charger does not find the generator within 90 seconds, the charger turns off automatically. You can press the power icon through the mesh pocket to turn on the charger and align the charger over your generator.
7. Once you have adjusted the charging apparel to a comfortable fit around your waist, you can trim the excess strap length, if desired.

Placing Pectoral Charging Apparel

To set up your pectoral charging apparel, gather the charger and the charging apparel:

1. If the charger is connected to the charging cable, disconnect it.

   NOTE: While the charger is charging, it cannot be used to charge the generator.

2. Press the power icon to turn on the charger. The three charger icons illuminate briefly and the charger beeps once if sound is enabled.
3. With the charger icons facing the opening of the pocket, insert the charger into the mesh pocket of the charging apparel by lifting one side of the opening and then pulling the other side over the charger.
4. Ensure the elastic edges of the pocket overlap, fully covering the charger.

   NOTE:

   - When the generator enters the charging zone, it beeps continuously until charging begins.

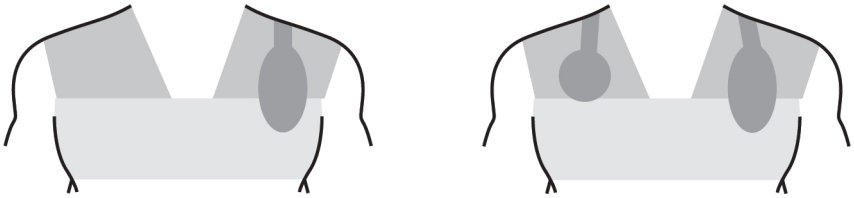
- If the charger does not find the generator within 90 seconds, the charger beeps two times and then turns off automatically. You can press the power icon through the mesh pocket to turn on the charger and align the charger over your generator.

Counterweight configurations

1. If connected, release the long strap from the charger pocket. The counterweight should remain buckled to the charger pocket.
2. Position the charger over your generator.
3. Place the counterweight over your shoulder so it rests on your back or around your neck so the counterweight rests on your opposite shoulder.

NOTE: You may need to adjust the length of the strap to fit properly.

Figure 3. Charger positioned over generator (left); counterweight positioned over opposite shoulder (right)



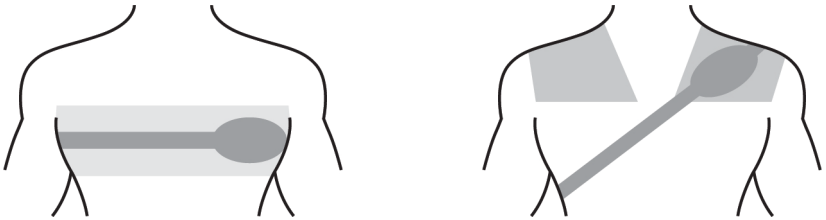
Single-strap configurations

1. Release the counterweight from the charger pocket.
2. Wrap the charging apparel around your chest or over your shoulder and fasten the buckle.

NOTE: If needed, use the excess strap near the buckle to tighten or loosen the apparel.

3. Adjust the strap until the charger is comfortably positioned over your generator.

Figure 4. Single-strap around chest (left); single-strap around one shoulder (right)



Double-strap configurations

Option 1 – Loop and charger on opposite sides

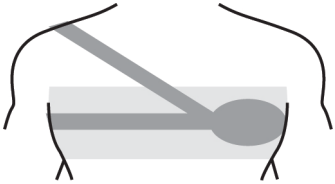
1. Release the counterweight from the charger pocket.

2. Grasp the plastic buckle so the charger pocket is hanging toward your feet.

   NOTE: If your generator is located on the right side of your body, grasp the buckle with your right hand. If your generator is on your left side, grasp the buckle with your left hand.

3. Put the arm on the opposite side of your generator through the loop.

Figure 5. Arm through loop on opposite side of generator



4. Adjust the charging apparel so that a strap is comfortably over your shoulder and the other strap is under your armpit. The buckle should be in front of you.
5. Ensure that the charger is positioned over your generator.
6. Fasten the buckle.

   NOTE: If needed, use the excess strap near the buckle to tighten or loosen the apparel.

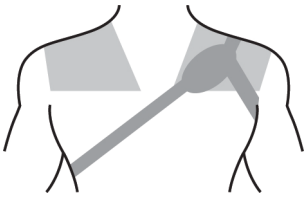
Option 2 – Loop and charger on same side

1. Release the counterweight from the charger pocket.
2. Grasp the charger pocket so the long strap is hanging toward your feet.

   NOTE: If your generator is located on the right side of your body, hold the pocket with left hand. If your generator is on your left side, hold the pocket with your right hand.

3. Insert the opposite arm (the arm that is not holding the charger pocket) through the loop.

Figure 6. Arm through loop on same side as generator



4. Adjust the charging apparel so that a strap is comfortably over your shoulder and the other strap is under your armpit. The buckle should be in front of you.
5. Ensure that the charger is positioned over your generator.
6. Fasten the buckle.

   NOTE: If needed, use the excess strap near the buckle to tighten or loosen the apparel.

Charging Your Generator

After you have charged your charger and have set up the charging apparel (if desired), you are ready to charge your generator. It is recommended to charge your generator frequently and to charge before stimulation turns off due to a low battery.

NOTE:

- You can receive stimulation while charging your generator. The patient controller can still communicate with the generator while charging. However, the charger software cannot be updated while the generator is charging.
- If you have more than one Eterna™ implantable pulse generator implanted, you can use the same charger to charge your generators.

WARNING: You may perceive an increase in temperature at the generator site while you charge. Ensure that the area around the charger is well ventilated and not covered by an insulating material such as a blanket. If you feel discomfort while recharging your generator, stop using the charger and refer to "Troubleshooting" (page 16). If the discomfort persists, contact your clinician. Only charge your generator while you are awake so that you can stop the charger if charging becomes uncomfortable.

To charge your generator:

1. Ensure the charger is not connected to an electrical outlet.

   NOTE: If the charger is connected to an electrical outlet, it will not charge the generator.

2. Turn on the charger. The three icons on the charger illuminate and the charger beeps once if the sound is enabled in the patient controller.
3. Place the charger directly over the generator, using the charging apparel to hold the charger in place if desired. Charging begins automatically when the charger is positioned correctly over the generator. If charging has not begun, try the following, one at a time, until charging begins:
   - Ensure the charger and charging apparel are used with light clothing (<5 mm). If the clothing over the generator is very thick, the charger may not effectively charge the generator.
   - Ensure that the charger is centered over the top half of your generator.
   - Move the charger slowly in a circular motion over the generator location, slowly increasing the size of the circle until you hear the beeps begin, indicating the charger is aligned with the generator and charging has begun.
   - Slowly swipe the charger across the generator in a single direction until you hear the beeps begin, indicating the charger is aligned with the generator and charging has begun.

4. To confirm charging is occurring, note the following. If you do not note any of the indicators listed below, charging is not occurring.
   - If the charger sound is enabled in the charger settings on the patient controller, the charger beeps when charging begins. When charging is in progress, the charger will not beep.
   - The charger power icon begins blinking slowly.
   - The patient controller displays the charging status and the generator battery level.

     NOTE: If the charger loses alignment with the generator for 10 seconds, the charger will beep until alignment with the generator is restored or the charger is turned off. Try repositioning the charger so it is positioned over the generator.
5. Verify that charging is complete. When the generator is fully charged, the charger beeps 3 times every 10 seconds if the sound is enabled. You can also view charging status on the patient controller.

   NOTE:
   - The charger automatically turns off after 90 seconds once charging is complete.
   - While the charger is charging the generator, the charger cannot be turned off. If you need to turn off the charger while it is charging the generator, move it away from the generator site.
6. Turn off the charger and remove the charging apparel.

Caring for and Maintaining Your Charger and Charging Apparel

To keep your charger running its best, follow these guidelines:

- Keep the charger dry. Do not use the charger in or around water.
- Clean the charger as needed. You can use a dry cloth or a cloth slightly dampened with water or isopropyl alcohol. Ensure the charger is completely dry before use.

  NOTE: To avoid damaging the charger, do not insert anything in the speaker holes.

- Clean the charging apparel as needed.
  - Hand wash in cold water.
  - Use mild soap.
  - Lay flat to dry.

    NOTE: Do not machine wash or machine dry.

- Charge your charger and store your charging system in the travel case after each use.
- Store and use your charging system within the range of conditions as shown in the following table.

Table 3. Storage, transportation, and operating conditions

Storage and transportation conditions	
Long-term storage temperature	23°C (73°F)

Table 3. Storage, transportation, and operating conditions

Temperature excursions	Excursions below 15°C (59°F) or above 30°C (86°F) should be <24 hours in duration
Temperature excursion limits	-20°C to 60°C (-4°F to 140°F)
Humidity	5% to 90% RH
Pressure	70 kPa to 106 kPa
Operating conditions	
Temperature	5°C to 35°C (41°F to 95°F)
Humidity	10% to 90% RH
Pressure	70 kPa to 106 kPa

NOTE: If the charger was stored in an environment that is outside of normal operating temperature, allow it to acclimate to the current environment for approximately 30 minutes.

- When the charger is approaching its end of service, an alert message displays on the patient controller. This message indicates that you should contact your physician for a replacement charger.

Traveling with Your Charging System

If traveling with your charging system, follow these guidelines:

- Use the travel case to store your charging system.
- Be sure to pack the charging cable and power adapter.

  NOTE: For short trips, if you plan to travel without the charging cable and power adapter, check the battery level of the generator and the charger to ensure continued therapy during your trip.

- If you are traveling to an international location, you may need a country-specific power adapter.
- The charger contains a lithium-ion battery. If traveling by air, the charger should be placed and kept in your carry-on baggage during flight, not in your checked baggage.
- When traveling, follow all guidelines and restrictions for use of electronic devices.

Troubleshooting

This section provides information for solving problems you may have using your charging system.

NOTE:

- If the PC Alert icon illuminates, check your patient controller for more information.
- If problems occur other than those described in this section, contact Technical Support.

- 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.

Troubleshooting Charging Issues

The following table lists possible charging system problems and possible solutions.

Table 4. Troubleshooting charging issues

Problem	Possible Solution
The charger will not turn on.	Ensure the power cable is disconnected from the charger.
	Ensure the charger has sufficient charge.
The charger is not able to establish or maintain charging of the generator.	Use light clothing to reduce the distance between the charger and the surface of the skin as much as possible.
	Position the charger flat against your clothing.
	Locate the generator under your skin and center the charger over the top of your generator.
	Enable sound on the charger to use audible tones while aligning the charger over the generator. A series of tones will indicate that charging has begun.
	Avoid sitting on or against hard surfaces that may push the charger out of position during charging.
	Ensure the charger is not plugged into an electrical outlet.
	If you do not feel the generator close to your skin, center the charger over the generator site and move the charger in small circles until the charger emits a tone and charging begins.
	If none of the charger icons are illuminated, ensure the power cable is disconnected and turn the charger off and on.
The temperature of the generator becomes uncomfortable during charging.	Stop charging until the discomfort subsides and then resume charging.
	If your clinician has enabled the Charging mode feature, change the Charging mode to low. See the patient controller manual for more information about this feature.
	Ensure the area around your generator is well ventilated.

Table 4. Troubleshooting charging issues

Problem	Possible Solution
	Reposition the charger, aligning the bottom of the charger with the bottom edge of the generator. 
	Ensure the charging apparel is centered over the generator.
	Tighten the charging apparel to ensure the charger is positioned correctly over the generator.
	If you can feel the generator close to your skin, try adding a thin material on your skin over the implant site.
	Consider recharging more frequently for less time.
	If the temperature continues to be uncomfortable, contact your physician.
The charger is not charging.	Ensure the charging cable is fully inserted and USB-IF certified. To determine if a cable is USB-IF certified, look for markings such as the following:
	Ensure the power adapter is fully inserted and has one or more of the following certification markings:
The charger is not making sounds.	The charger volume may be set too low. Turn the volume up. See your patient controller user's guide for instructions.
	The charger volume may be turned off. Turn the volume on. See your patient controller user's guide for instructions.
The charger is too loud.	The charger volume may be set too high. Turn the volume down. See your patient controller user's guide for instructions.

Table 4. Troubleshooting charging issues

Problem	Possible Solution
The charger is not staying in the pocket of the charging apparel.	Ensure that the top flap of the charging apparel is over the charger.
The charger is not able to maintain Bluetooth® wireless connection with the patient controller.	▪ Avoid charging your patient controller while charging your generator. ▪ Decrease the distance between the devices. Ensure the patient controller is in Bluetooth wireless range of the charger within 2 m (6.5 ft). ▪ Move the patient controller and charger so they have a line of sight and maintain an uninterrupted path for the Bluetooth wireless signal. ▪ Try holding the patient controller differently. ▪ Reconnect the patient controller with the charger. ▪ Move to a different area or room away from interference in the environment or interference from other devices. ▪ Avoid operating other wireless devices at the same time. ▪ Disconnect any Bluetooth wireless media accessories (such as headphones or speakers, AirPlay‡, AirDrop‡, CarPlay‡ or Hotspot‡). ▪ Remove and reenable the Bluetooth® wireless technology pairing.
The charger will not turn off.	Contact Technical Support.

Service and Ordering Information

This section provides information for contacting Technical Support and for ordering replacement parts and accessories.

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.

Ordering Information

To order parts, contact Technical Support. Refer to the following list for order numbers.

Table 5. Ordering information for the charging system

Description	Model
Charger kit - lumbar	36000
Charger	16000
Charging apparel - lumbar	16750
Charging apparel - pectoral	16760
Travel case	16730
Charging cable	16710
Power adapter	16720

Appendix A: Regulatory Statements

Please note the following regulatory statements related to the charging system.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. The device and its battery should be disposed of according to local laws and regulations.

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. This device has been tested and found to comply with the limits of an industrial, scientific, and medical (ISM) equipment, pursuant to part 18 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.

Product Classification Statement (CISPR 11, Class B)

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

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.

The device meets regulatory requirements for nerve stimulation exposure and SAR (thermal exposure) limits when held directly over the skin.

Statement of Compliance With Interference-Causing Equipment Standard (Canada)

This ISM device complies with Canadian ICES-001.

Identification Information for Product Registration

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

Table 6. Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2-GMCHG1
IC Registration Number	30752-GMCHG1

Wireless Technology Information

The following table summarizes technical details of the wireless technology of the charging system.

Table 7. Wireless technology information for charging system

Charging frequency	266 kHz to 320 kHz
Charging distance	0.5 cm to 2.5 cm

NOTE: Refer to Charging Your Generator (page 13) for instructions to successfully align and charge your generator.

Table 8. Bluetooth® Low Energy (LE) wireless technology information

Antenna type	Chip Antenna
Antenna dimensions	7.00 mm x 2.00 mm x 1.20 mm
Modulation	GFSK
Output power (EIRP*)	1.5 mW (+2 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
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.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the 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 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 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, refer to Troubleshooting for Wireless, Coexistence, or Interference Issues (page 22).

Wireless Security Measures

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

- The charger encrypts its wireless communication with the programming device using a key that is unique to that link.
- Only one patient controller or clinician programmer may communicate with the charger at a time.
- Standard Bluetooth® Low Energy (LE) pairing methods ensure valid and legitimate pairing among devices.
- Proprietary authentication for the patient controller or clinician programmer applications in addition to the pairing procedure specified in Bluetooth LE protocol, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized application from communicating with the charger.
- Whitelisting methods that prevent unauthorized devices from using Bluetooth LE scanning to interfere with communication from the charger to a legitimate patient controller or clinician programmer.

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 B: Product Specifications

The charging system has the following product specifications and compatibility information.

Table 9. Product specifications

Charger input	5 V, 0.5 A
Charger connector type	USB Type C
Charger power source	Rechargeable lithium ion cell battery
Charger IP code	IP22
Charger communication protocol	Bluetooth® Low Energy
Charger expected service life	5 years
Charging accessories expected service life	5 years

NOTE:

- The charger is considered an applied part per the 60601-1 standard when it comes into physical contact with the user during charging.
- The USB port in the charger is restricted for charging the charger and is not intended to perform any communication per the USB protocol.

Table 10. Implantable pulse generator compatibility for the charging system

Description	Model
Eterna™ implantable pulse generator	32400

Appendix C: Technical Specifications

Use the charging cable and power adapter included with this system. You may also use a charging cable and power adapter with the following ratings.

Table 11. Technical specifications

Charging cable ratings	
Voltage rating	Minimum 20 V
Current rating	Up to 3 A
Cable length	1 m

Table 11. Technical specifications

USB-IF	Certified Only use an Abbott Medical charging cable (model 16710) or a cable marked with USB-IF certification such as the following: 
Power adapter ratings	
Power	5.25 W maximum
Input voltage	100 to 240 VAC
Input frequency	50 to 60 Hz
Output voltage	5 VDC
Output current	up to 1 A
Power adapter certification marking	Power adapter should have one or more of the following certification markings: 

Appendix D: Electromagnetic Compatibility Guidelines

The charging system (model 16000), hereafter the device, is medical equipment and should be used with the following guidance.

The device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The device has essential performance, as defined by IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2). Performance of the device was maintained during electromagnetic disturbance testing.

The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

CAUTION:

- **The device complies with the limits for medical devices contained in IEC 60601-1-2:2014+AMD1:2020 (Ed 4.1) and CISPR11:2015+AMD1:2016+AMD2:2019 (BS EN 55011:2016+A2:2021). However, the device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device.**
- **To avoid increasing emissions or decreasing immunity from a device or system, use only components approved by Abbott Medical with this system. Do not use Abbott Medical components with devices or systems that are not approved by Abbott Medical.**

Table 12. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device produces RF emissions as a result of its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A*	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class 5 Full Compliance*	

*Only applicable to power adapter (model 16720)

Table 13. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 10%.
Electrical fast transient/burst IEC 61000-4-4*	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial, hospital, or home environment.
Surge IEC 61000-4-5*	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial, hospital, or home environment.
Voltage dips, short interruptions IEC 61000-4-11*	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial, hospital, or home environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an

Table 13. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital, or home environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. Recommended minimum separation distance for higher immunity test levels $E = \frac{6}{d}\sqrt{P}$ where P is the maximum power in watts (W), d is the recommended separation distance in meters (m), and E is the immunity test level in volts per meter (V/m).
	6 Vrms ISM/Radio bands between 150 kHz to 80 MHz 80% AM at 1 kHz	6 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	

* Only applicable to power adapter (model 16720)

NOTE:

- U_T is the AC mains voltage prior to application of the test level.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 14. Guidance and Manufacturer's Declaration - Proximity Fields from RF Wireless Communication Equipment

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended minimum separation distance d = 0.3 m

Table 14. Guidance and Manufacturer's Declaration - Proximity Fields from RF Wireless Communication Equipment

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
	450 MHz: 28 V/m @ FM modulation	28 V/m	
	710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	2450 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	

WARNING: Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 in.) to any part of the device, including cables specified by Abbott Medical. Otherwise, performance degradation may occur.

Table 15. Guidance and Manufacturer's Declaration - Enclosure Port Immunity to RF Wireless Communication Equipment

Immunity Test	Band (MHz)	Maximum Power (W)	Immunity Test Level (V/m)
IEC 61000-4-3	380 to 390	1.8	27
	430 to 470	2	28
	704 to 787	0.2	9
	800 to 960	2	28
	1700 to 1900	2	28
	2400 to 2570	2	28
	5100 to 5800	0.2	9

Table 16. Guidance and Manufacturer's Declaration - Enclosure Port Immunity to Proximity Magnetic Fields

Immunity Test	Test Frequency	Modulation	Immunity Test Level (A/m)
IEC 61000-4-39	30.0 kHz	Continuous wave	8
	134.2 kHz	Pulse modulation 2.1 kHz	65
	13.56 MHz	Pulse modulation 50 kHz	7.5

Appendix E: 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.

Table 17. Symbols and definitions

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use
	Follow instructions for use on this website
	Type BF Applied Part
	MR Unsafe 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
	Use-by date
	Class II Equipment
	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
	Date of manufacture

Table 17. Symbols and definitions

Symbol	Definition
	Manufacturing facility
	Long term storage temperature
	Temperature limit
	Excursions permitted within this range
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
MD	Medical Device
REF	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	Charger
+	Accessories
SN	Serial number
LOT	Batch code
UDI	Unique Device Identifier
$\mathrm{Rx}_{\mathrm{ONLY}}$	Prescription use only

Table 17. Symbols and definitions

Symbol	Definition
	This product shall not be treated as household waste. The product and its battery should be disposed of according to local laws and regulations. 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 inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.
EC REP	Authorized representative in the European Community
CH REP	Swiss Representative
	Importer
CE 2797	European conformity, affixed according to the relevant provisions of European Council Regulation 2017/745 (NB 2797) and RE directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the relevant provisions of this regulation and directive. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.neuromodulation.abbott/euconformity.
	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
	Intertek Listed US and Canada. Conforms to UL STD 60601-1 Certified to CAN/CSA C22.2 STD No.601.1.
	This device is listed by the Canadian Standards Association (CSA) International as certified
	This device is a recognized component by Underwriters Laboratories (UL) Inc.
	This device complies with part 18 of the FCC rules.

Table 17. Symbols and definitions

Symbol	Definition
	Korean Radio Communications License (KC Mark)
	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 18. Additional symbols for product labels

Symbol	Definition
Charger Kit, Lumbar	Charger Kit, Lumbar
Charger	Charger
Lumbar Charging Apparel	Lumbar Charging Apparel
Pectoral Charging Apparel	Pectoral Charging Apparel
Travel Case	Travel case
Charging Cable	Charging Cable
AC Power Adapter	AC Power Adapter

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