Patient Manual

! USA

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CE Mark effective on 4 May 2010

Nevro hereby declares that the Senza® system is in compliance with the essential requirements and other relevant provisions of the Radio Equipment Directive (2014/53/EU).

IMPORTANT: Do not change or modify any component of the Nevro® Senza system, unless expressly approved by Nevro Corp.

Explanation of symbols on the product or package labeling. Refer to the product for symbols that apply.

Symbol	Description
SN	Serial number
LOT	Batch code
	Date of Manufacture
	Manufacturer
	Caution
REF	Catalog number
XX C XXX F XX C XX F	Temperature limitation (storage)
www.nevro.com	Consult Electronic Instructions for Use
NON STERILE	Non-sterile
	Non-ionizing radiation
	Type B Applied Part
	Type BF Applied Part
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.

MR Conditional	MR Conditional
MR	MR unsafe
CE 0086	CE Marking of Conformity
EC REP	Authorized representative in the European Community
! USA	For USA audiences only

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INTRODUCTION

This booklet was written for people who are considering or have received a Nevro® Senza® Spinal Cord Stimulator (SCS) system to help treat pain. Every person is unique and your medical needs differ from those of others, even people with the same condition and the same SCS system. For this reason, always talk to your doctor if you have questions about your condition. This booklet presents general information and can help you better communicate with your doctor.

The first part of this booklet discusses chronic pain, spinal cord stimulation, and the Senza system. It is based on common questions that patients have about their condition, this particular treatment option, and the Senza system.

The second part of this booklet explains how to use the devices.

In the back of the booklet, we have added some information in the appendices. The first appendix contains technical information about this product. This information may be useful to you, but it is not necessary for you to understand it in order to use your device. The second appendix shows pictures of the parts of the Senza system.

Throughout the booklet, we have provided definition of medical or electronic terms in a shaded box with a definition.

STIMULATION. Small electrical pulses produced by the SCS system delivered to your spinal cord to provide therapy for your pain. Spinal cord stimulation is sometimes called “therapy delivery.”

ABOUT CHRONIC PAIN

Everybody feels pain when there is a painful external stimulus such as a pinprick or touching something hot. This is referred to as acute pain and is an important normal sensation that helps protect against injury. **Chronic** pain is very different. People with chronic pain may also feel pain when there is no obvious reason or may have pain that does not go away long after an injury.

CHRONIC. Something that persists or lasts for more than 3 months. Chronic pain is pain that does not go away with the passage of time or as the body heals from an injury.

Chronic pain can be **intractable**, which is the medical term meaning that it is hard to treat. You have probably tried many treatments to control your pain and found that they did not work well or perhaps they did not work at all.

INTRACTABLE. Any condition, such as chronic pain, which is very difficult to control or treat effectively.

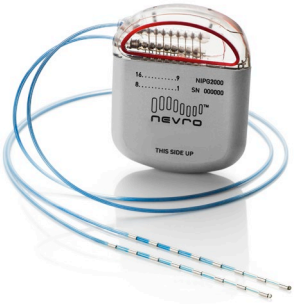
YOUR SENZA SYSTEM

The Senza system works by delivering electrical energy from a device to an area around your spine. The system is capable of delivering HF10® therapy, a therapy that does not produce tingling sensations called paresthesia. It is also capable of providing stimulation that produces paresthesia at some therapy settings. You will first go through a **trial phase** where you and your doctor evaluate the therapy to see if it is right for you. The Senza system trial phase consists of several components:

- **Trial Stimulator** is a temporary device that you use outside the body to test to see if the therapy is helpful to you.
- **Lead** is a thin insulated wire that connects to the Trial Stimulator at one end and with small electrodes on the other end placed near your spine. A small amount of electrical energy from the device travels through the lead and near the spine.
- **OR Cable** is an insulated wire used outside the body to temporarily connect the leads to the Trial Stimulator.
- **Remote Control** is a unit that can turn the stimulator ON or OFF and allows for some adjustments of therapy settings.

PARESTHESIA. A sensation of tingling, “pins and needles,” prickling, or even burning. Paresthesia may be brief or it may last a long time.

TRIAL PHASE. A time during which a person with chronic pain tests SCS therapy to see if and how well it works. During the trial phase, the person will temporarily use a Trial Stimulator, which is not implanted in the body.



If the Senza system is right for you, your doctor will discuss with you the implantation of a battery-powered device after the trial phase. The Senza system components will include:

- **Implantable pulse generator (IPG)** is a small, battery-powered electronic device that is implanted inside the body (see IPG in the diagram above).
- **Lead**, same as in the trial phase. However, instead of connecting to an external stimulator as occurred during the trial phase, will connect to the implanted IPG. After implantation there are no external wires or connections as occurred during the trial phase (see lead wires in diagram above).
- **Charger** recharges the IPG after it is implanted.
- **Power Adaptor** recharges the Charger.
- **Charger Belt and Charger Holster** holds the Charger during recharging.
- **Remote Control** is a unit that can turn the IPG ON or OFF and allows for some adjustments of therapy settings.

For pictures of the Charger, Power Adaptor, Charger Belt and Remote Control, please see the "System Components" section at the end of this manual.

IMPLANTABLE PULSE GENERATOR or IPG. A self-contained battery-powered device that is small enough to fit in a person's hand and delivers small amounts of electrical energy or pulses.

You will first use the Trial Stimulator and Remote Control. If the Senza system is right for you, your doctor will then implant the IPG. You control the implanted device with the same Remote Control.

INDICATIONS

The Senza system is not right for everyone. **Indications** for the use of this device are as follows:

The Senza neuromodulation 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, intractable low back pain, and leg pain.

INDICATIONS. Reasons that you should get a device, drug, or treatment. Indications are determined by medical experts, clinical studies, and the Food & Drug Administration (FDA).

CONTRAINDICATIONS

CONTRAINDICATIONS. Situations in which the device should not be used because the risk of use clearly outweighs any possible benefit. Contraindications are determined by medical experts, clinical studies, and the Food & Drug Administration (FDA).

The Senza system is contraindicated (not appropriate) for certain patients. Contraindications for the Senza system include:

- Not being able to operate the Senza system
- Not being able to have the SCS surgery
- Failing to receive effective pain relief during trial stimulation.

Your doctor can tell you if the Senza system might be appropriate for you. If you have questions about whether the Senza system may be right for you, ask your doctor.

WARNINGS

Warnings are statements about safety of your device that you should take very seriously. If you do not follow these warnings, it is possible that you could be hurt and/or the device could be damaged. The following are some warnings for the Senza system:

Stimulation Frequencies – Stimulation frequencies in the range of 2 Hz to 1,200 Hz are indicated for paresthesia-based therapy and the system must be configured to produce paresthesia. Stimulation at 10,000 Hz is indicated as

paresthesia-free therapy and the system must be configured to deliver paresthesia-free stimulation. Stimulation between 1,200 Hz and 10,000 Hz has not been evaluated for safety, effectiveness and perception of paresthesia. Specifically, for stimulation frequencies above 1,200 Hz, amplitudes that produce paresthesias have not been evaluated and therefore it is unknown whether injury may occur.

Stimulation at vertebral levels above T8 – The safety of program settings above 1,200 Hz have not been studied above the T8 vertebral level.

Pediatric Use – The safety and effectiveness of spinal cord stimulation has not been established for use in children.

Other Active Implanted Devices – Please let your doctor know if you have any other active implanted devices in your body. The Senza system may interfere with other implanted stimulators, such as cardiac pacemakers and defibrillators which have sensing features, and may result in sensing problems or inappropriate responses. The effect of other implanted devices, including deep brain stimulators, peripheral nerve stimulators, implanted drug delivery pumps, and cochlear implants on the Senza system are unknown.

Sleep – If you are using therapy that generates paresthesia (tingling sensations caused by stimulation) you may choose to turn stimulation off to avoid uncomfortable sensations during sleep (see Warning regarding Stimulation Frequency). If you are using therapy at 10 kHz which does not generate paresthesia, stimulation can remain on during sleep.

Operation of Vehicles (e.g., driving) or Machinery – If you are using therapy that generates paresthesia you should not operate motorized vehicles such as automobiles or potentially dangerous machinery and equipment with the stimulation on when using paresthesia-causing programs. Stimulation must be turned off first in such cases. Any sudden stimulation changes may distract you from proper operation of the vehicle, machinery, or equipment. If you are using therapy at 10 kHz which does not generate paresthesia, it is less likely that sudden stimulation changes resulting in distraction could occur.

Heat from Charging – You will have to recharge the battery in your device. Always use the special Charger Belt when recharging. During recharging, the Charging Coil may become warm or even burn you. If you feel warmth or discomfort when recharging the device, stop recharging and contact your doctor. Do not place the charger over an area of skin where you do not feel any sensation.

Electromagnetic Interference (EMI) – Ordinary household appliances, magnets, and devices encountered in everyday life will not affect your implanted Senza device. However, some equipment generates **electromagnetic interference (EMI)** which may affect your Senza system.

ELECTROMAGNETIC INTERFERENCE (EMI). Invisible signals generated by some equipment, appliances, and devices, also known as noise or static. Even if you cannot hear this noise, it may be picked up by your implanted SCS system and can affect it.

Electromagnetic interference (EMI) can affect the implanted Senza system in ways that are hard to predict. For example, EMI might:

- Turn your Senza system ON or OFF
- Cause your Senza system to give you more stimulation (a “shock”)
- Cause damage to the system that may result in loss of therapy and require reoperation to replace the system

There are many sources of EMI today so it is not possible to give exact instructions as to how to avoid them. Listed below are some well-known sources of EMI that you should avoid:

- Power lines and power generators
- Arc welders
- Large, magnetized stereo speakers
- Radiofrequency identification devices (RFID)

Exposure to strong EMI can result in serious patient injury or death, resulting from heating of the implanted components of the SCS system and damage to the surrounding tissue.

The Remote Control, Charger and Trial Stimulator are suitable for use in a residential environment (Per CISPR 11 class B).

WARNING: Use of the Senza system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Senza system and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories other than those specified or provided by Nevro could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Senza system and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 15 cm (6 inches) to any part of the Senza system, including cables specified by Nevro. Otherwise, improper operation of the Senza system could result.

Theft Detectors and Security Screening Devices – Security checkpoints, metal detectors, screening systems at airports, and theft detectors all produce EMI. If you must pass through such a system, tell the personnel that you have an implanted medical device and show them your patient ID card. They may be able to help you get through the checkpoint without going through the scanner. If that is not possible, you may be able to pass through the scanner or detector by turning the device OFF and moving through the scanner as quickly as possible.

Theft detection systems may also produce EMI. While some theft detection systems are obvious and are located at store exits, others may be concealed within the store. If you are in a store or other environment and suspect EMI is affecting your device, turn OFF the Senza system and move out of the area. Once you are out of the area, check whether therapy is ON or OFF. You may have to recharge the device. If you have specific questions about EMI sources, talk to your doctor.

Strong electromagnetic fields arising from closeness to electrical equipment such as mobile phones, satellite phones and radio systems may interfere with the radio communication between the Remote Control and IPG. As described in the "Troubleshooting" section of this manual, communication failure is indicated by three beeps. Communication can be restored by moving away from the interfering electrical equipment and retrying the operation.

Electrostatic Discharge (ESD) is a common source of electromagnetic interference that can occur when a person or object accumulates a static charge. ESD is made worse by low humidity and synthetic materials.

- If the battery terminals of the Trial Stimulator are exposed to ESD, the device may reset and stop stimulation. Stimulation can be restarted by following the instructions in the "How to Turn ON Stimulation" section of

this manual. To avoid unintentionally stopping stimulation, do not open the battery compartment while stimulation is ongoing.

- ESD may cause the Charger to stop charging the IPG. If this happens, charging can be resumed by repeating the steps in the "How to Charge the Implantable Pulse Generator" section of this manual. ESD events can be minimized by keeping the charger in the Charger Holster while recharging the IPG.

WARNINGS ABOUT OTHER MEDICAL TREATMENTS

Always tell your doctors, nurses, and other clinicians (including dentists, physical therapists, occupational therapists, and others) that you have the Senza Spinal Cord Stimulation system implanted in your body. There are some procedures that are not recommended for people with the Senza system, and there are other procedures which may be possible for you only with certain precautions. If you ever need any of these treatments, be sure to discuss them with your pain doctor as well as with the clinical team doing the procedure.

Procedures that are not recommended for you with an implanted SCS system include:

- **Diathermy**
- Computed tomography (**CT scans**)
- Magnetic resonance imaging (**MRI scans**)
- **Lithotripsy**
- **External defibrillation**
- **Ultrasound procedures**
- **Radiation**
- **Radio-Frequency or Microwave Ablation**

DIATHERMY. A medical treatment in which heat energy from shortwaves, microwaves, or ultrasounds are used as treatment or in surgery.

Diathermy Therapy - Energy from the diathermy device can be transferred to the SCS system and can cause the lead to overheat, which may cause damage to the device, heating and damage to the body, severe injury, and even death.

CT SCAN. A type of technology in which x-ray-like images are taken in sections (slices) and then re-assembled by computer to provide detailed two- and three-dimensional pictures of inside the body.

Computed Tomography (CT) – Please inform your doctor and medical personnel conducting your CT scan that you have an implanted SCS system. You must turn your device off temporarily while the scan is being conducted. It is important that the person conducting your CT scan does the following:

- Determines the device type;
- If practical, tries to move external devices out of the scan range;
- Minimizes x-ray exposure to the implanted or externally worn electronic medical device by:
  - Using the lowest possible x-ray tube current consistent with obtaining the required image quality; and
  - Making sure that the x-ray beam does not dwell over the device for more than a few seconds;

Important note: For CT procedures that require scanning over the medical device continuously for more than a few seconds, as with CT perfusion or interventional exams, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

After CT scanning directly over the implanted or externally worn electronic medical device:

- You should turn your Senza system device back on.
- Check that the Senza system is working properly.
- Contact your doctor as soon as possible if you suspect the Senza system is not functioning properly after a CT scan.

MRI SCAN. A type of technology in which electromagnetic energy is used to take images of soft tissue in the body.

Magnetic Resonance Imaging (MRI) - The Senza system is MR Conditional which means that safety has been demonstrated only within specifically defined conditions. Scanning under different conditions may result in severe injury, death or device malfunction. If your doctor determines it is safe for you to have an MRI, your doctor will have you turn off the device before the scan and turn it back on when the scan is complete. This should be done with extreme caution, since these scans may injure you or damage the device. Never undergo an MRI scan without making sure the team doing the scan knows you have an SCS device.

If your doctor recommends an MRI, inform the doctor that you have the Senza Spinal Cord Stimulation system and show him/her your patient ID card (refer to Your Patient ID section in this manual). The doctor will need to take specific

precautions (as identified in the MRI Guidelines located at: http://www.nevro.com/manuals) to prevent patient injury and device damage. Do not take the trial stimulator, patient remote, or charger into the MRI scan room. They are not considered safe for MRI and may be rapidly pulled into the MRI scanner. In doing so, they may strike and injure a person.

Before undergoing these or any other procedures, discuss them with your doctor to be sure they are safe for you.

LITHOTRIPSY. The use of sound waves to help break up calcified stones in the body.

EXTERNAL DEFIBRILLATION. The emergency use of two large paddles placed on the chest to deliver a large amount of electrical energy to "re-start" the heart.

ULTRASOUND PROCEDURES. Any number of procedures that use sound waves to get images of the soft tissue in the body.

RADIATION. The use of radiation energy for therapy. There are many types of radiation treatments. Radiation can be as simple as an x-ray of the body or it can be targeted therapy to kill cancer cells (radio therapy).

Lithotripsy, External Defibrillation, Ultrasound Procedures and Radiation - If you are required to undergo lithotripsy, external defibrillation, high-output ultrasound, radiation therapy, or ultrasonic scanning, inform the medical personnel conducting the procedure that you have an implanted SCS system and follow these precautions:

- Turn off the IPG before the procedure.
- Have medical personnel use the equipment as far away from the IPG as possible.
- Have medical personnel keep fields, such as current, radiation, or high-output ultrasonic beams, away from the IPG.
- Equipment should be set to the lowest energy setting possible.
- After the therapy or procedure, check to see that the IPG is functioning properly by gradually increasing the IPG's stimulation to the desired level.

- If you suspect that the device is not functioning properly after the use of these therapies or procedures, please contact your doctor.

RADIO-FREQUENCY OR MICROWAVE ABLATION – An electrical current produced by a radio/micro wave is used to heat up a small area of nerve tissue, thereby decreasing pain signals from that specific area.

Radio-Frequency or Microwave Ablation – Safety has not been established for Radio-Frequency or Microwave Ablation in people who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

PRECAUTIONS

Precautions are instructions about your device you should follow to avoid damage to the device, so that it will function correctly and last longer.

- Store the Trial Stimulator and Remote Control at normal temperatures in the range of -20°C to 60°C (-4°F to 140° F).
- Store the Charger at normal temperatures in the range of 0°C to 45°C (32°F to 113°F).
- The operating temperature range for the Patient Remote Control is 10°C to 40°C (50°F to 104°F). The operating temperature range for the Trial Stimulator is 10°C to 38°C (50°F to 100 °F). The operating temperature range for the Charging System is 10°C to 40°C (50°F to 104°F).
- Keep the Charger, Trial Stimulator and Remote Control dry.
- Do not drop the Charger, Trial Stimulator and Remote Control. Although these devices are built for constant use, they could break if dropped onto a hard surface.
- Do not plug your Charger into a power source near water.
- Use only Nevro or Nevro-approved accessories with your Senza system.

Caring for the Trial Stimulator, Remote Control, and Charging System – You can care for your Trial Stimulator, Remote Control, and Charger by cleaning them with a soft, damp (not wet) cloth and mild detergent. Do not use alcohol or any harsh or abrasive cleansers and never let moisture get inside these items.

Pregnancy and Nursing – This device is not to be used in pregnant/nursing women, or women who may become pregnant.

Patient Activities – Some therapy settings are known to cause tingling sensations (called "**paresthesias**"). With such settings, you may feel a sudden increase in these sensations when you change your posture or make large or sudden movements. You can lower the amplitude or turn off the stimulation before making posture changes. If you are using stimulation at 10 kHz which does not generate paresthesia, these postural changes should not affect you.

Patient Activities Related to Lead Movement – Do not make sudden and excessive bending, stretching, or twisting movements, particularly within the first

weeks after the surgery. An implanted lead can move from its original location during such movements, which might affect delivery of therapy. In such cases, your system may need to be reprogrammed or the lead may need to be repositioned through another operation.

Scuba Diving and Hyperbaric Chambers – Your Senza system is sensitive to high pressure. To prevent possible damage to the device, prior to beginning these activities turn OFF the Senza system and:

- Do not scuba dive to depths greater than 115 feet (35 meters)
- Do not enter a **hyperbaric chamber** with pressure above 4.5 atmospheres

HYPERBARIC CHAMBER. A special chamber or compartment in which 100% oxygen is delivered to a person under very high pressures, far above the normal atmospheric pressure. Hyperbaric therapy is used for some medical treatments, such as wound healing.

Transcranial Magnetic Stimulation (TMS) and Electroconvulsive Therapy (ECT) – Safety has not been established for TMS or ECT in people who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

TMS. A non-invasive way that uses magnetic fields to stimulate nerve cells in the brain.

ECT. A procedure in which electric currents are passed through the brain to intentionally cause a seizure.

Transcutaneous Electrical Nerve Stimulation – Do not place transcutaneous electrical nerve stimulation (TENS) electrodes so that the TENS current passes over any part of the neurostimulation system. If you feel that the TENS may be interfering with the implanted neurostimulator, discontinue using the TENS and consult with your doctor.

TENS. A TENS unit is a device that sends small electrical currents to targeted body parts. These currents are used to relieve pain.

Post-Operative Pain – In the days after the surgery, you may experience pain in the implant area, which is typical in SCS surgeries.

IPG Location and Patient Manipulation – Do not to twist or rotate the IPG. If the IPG flips over in the body, the Charger may not be able to charge the IPG. Manipulation of the IPG in your body may cause the skin over the IPG to become thinner over time.

Infection – If you experience persistent discomfort or excessive redness around the wound areas, please advise your physician. You may need to be checked for infection. Infections related to the SCS system may require the implanted components to be explanted. Do not use the Charger if the incision is not sufficiently healed. The Charger and the charging belt are not sterile and should not be in contact with the incision.

Cell Phones – The impact of cell phones on the neuromodulation system is unknown at this time.

IPG Failure – If your IPG does not provide stimulation even after complete charging of the IPG or replacement of the batteries in the Patient Remote Control, turn off the IPG and contact your physician. When frequency of recharging becomes too inconvenient for you, the IPG may need to be replaced. You should contact your physician if this occurs.

Device Disposal – If you want to dispose of any components in your system, it is best to bring them back to your doctor. Do not throw them (or any electronic components, including batteries) in the regular household trash. Your local community will have regulations and advice as to how to dispose of batteries and other components.

Never put these device components in fire as they may explode.

If an IPG and/or lead is ever removed from your body, your doctor will return it to Nevro Corp. This helps Nevro monitor its products and is required by U.S. law.

In the event of death and cremation, the implanted IPG should be removed prior to cremation.

Long-term effectiveness of neurostimulation – The long-term effectiveness of spinal cord stimulation has been documented. Not all patients realize long-term

benefits from spinal cord stimulation. Stimulation effectiveness at 10 kHz has been established for one year.

ADVERSE EVENTS

Adverse events, or side effects, are risks associated with the use of this or any other SCS system. There are adverse events associated with the implant procedure, with stimulation, and with the device itself. Please contact your physician if you experience any adverse events associated with the device.

Possible Adverse Events Associated with the Implant Procedure and Additional Medical Risks

- Risks associated with anesthesia, including cardiac arrest
- Surgical complications, such as infection, fever, or bleeding
- Leaking of the cerebrospinal fluid (CSF)
- Intracranial hypotension
- Hematoma, seroma, or thrombosis
- Epidural hemorrhage
- Impaired or inadequate wound healing
- Temporary or persistent tenderness or pain at implant site
- Lead movement leading to ineffective pain control or other undesirable changes in stimulation
- Suboptimal placement or movement of the IPG or lead, requiring another surgery or explant
- Pressure on the spinal cord, or injury to the spinal cord, nerve, or nerve root
- Paralysis
- Death

Possible Adverse Events Associated with Stimulation

- Loss of pain relief or unpleasant paresthesia, such as tingling or prickling
- Jolting or shocking sensation associated with changes in posture or sudden movements
- Increased pain
- Changes over time in the cells around the electrodes of the leads, or changes in the electrode, lead, or its connection, leading to undesirable stimulation
- Uncomfortable stimulation of tissue (such as skin or muscle) around the leads
- Weakness, clumsiness, or numbness

Possible Adverse Events Associated with the Implanted Device Components

- Tissue reaction or allergy to implanted materials
- Persistent pain at the lead or IPG implant site(s)
- Failure of device components or the battery, including lead breakage or movement (migration), hardware malfunctions, loose connections, electrical shorts, or open circuits and lead insulation breaches
- Failure or malfunction, resulting in ineffective pain control or other undesirable changes in stimulation, possibly requiring explant and another surgery
- Skin erosion or seroma at the lead or IPG site
- Pressure sores
- External sources of electromagnetic interference that could affect stimulation and/or cause the device to malfunction
- Infection
- Exposure to magnetic resonance imaging (MRI) can result in heating of tissue, image artifacts, induced voltages in the IPG and/or leads, and lead dislodgement
- Epidural Mass Formation at Lead: Though incidence is rare (14 cases over 30 years; see reference below), over the course of months or years, permanent implantation of an SCS paddle lead or percutaneous lead can result in epidural mass formation around the lead, which could compress the spinal cord. The effect of spinal cord compression can range from muscle weakness to progressive quadriparesis. If a patient with a SCS lead presents with a new neurological deficit, spinal cord compression due to reactive tissue mass formation should be considered as a potential cause. If an epidural mass is identified in a patient who is asymptomatic, periodic monitoring should be considered. For more information please visit:
  http://professional.medtronic.com/wcm/groups/mdtcom_sg/@mdt/@neuro/documents/documents/scs-compression-ltr-feb2014.pdf

Adverse Events Associated with the External Device Components

- Tissue reaction or allergy to external materials
- Uncomfortable heating effects, discomfort, or burn

If you have questions or are experiencing adverse events, contact your doctor.

WHAT TO EXPECT WITH SCS THERAPY

If you and your doctor decide to proceed with SCS therapy, the first step is a trial phase. Typically, your doctor will first place a lead in your body. This procedure may be done under local anesthetic, so you are awake and aware of what is going on. You may be given medication to help you relax and some numbing medicine for the insertion site. The lead is placed in your body during a minor procedure usually without an incision. Most patients are able to leave the hospital the same day, depending on physical condition, the procedure, and doctor's preferences. Once the lead is in the body, you will typically use the device over a period of days as decided by your doctor. This provides an opportunity for you and your doctor to experience the system on a temporary basis and evaluate how well the device might work for you.

If your SCS therapy works for you, you will move to the implant phase, during which an IPG will be implanted in your body. Your doctor will select the implant site based on your individual body type and need. This procedure may be done under local or general anesthesia.

Following either of the implant procedures, you will be given instructions on how to care for the wound. You may experience some pain and tenderness around the implant site. Tell the clinical team if you are uncomfortable or in pain.

Following the IPG surgery, you may find you are very aware of the implanted device and may want to touch it. Try to avoid twisting or fiddling with the IPG. If you manage to flip the implanted device over in your body, it will not work properly. Do not pull on the lead, which can cause it to loosen or even come out. Touching the implant site too much can cause your skin to get very thin in that area.

In the first weeks after surgery, avoid big and sudden movements, bending over, lifting heavy objects, and stretching. Your IPG and lead(s) need a few weeks in the body to become secure. Your doctor or nurse will advise you on what you should and should not do in these first weeks after implantation.

TRIAL PHASE

If you are in the Trial Phase of getting the Senza system, this is an exciting and important time. The Senza system may offer you a way to control your pain without taking more drugs. In fact, you may be able to discontinue some of your drugs and still get pain control. To get the best results during this important time, please follow your doctor's advice closely.

When you are in the trial phase, you will receive a Trial Stimulator and a Remote Control so you have a chance to see if the Senza system works for you. If it works

well for you, you will have an IPG implanted in the body to replace the Trial Stimulator. This trial phase typically lasts several days.

For your trial, your doctor has set up a special stimulation program for you. He or she has adjusted the device's features specifically for you. You will be given the external Trial Stimulator, a Remote Control, and some cables. Using this system, you can test the stimulation system to see how it works for you. At the end of the trial phase, you will discuss with your doctor whether or not a device should be implanted in your body to take the place of the Trial Stimulator.

How to Set Up and Use Your Equipment

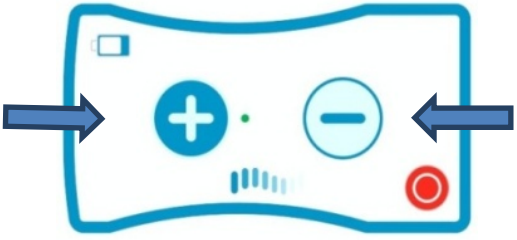
This section discusses the Trial Stimulator, Cables, and Remote Control that you are using during the trial phase.

The Trial Stimulator

The Trial Stimulator provides stimulation during the trial phase. You can increase or decrease stimulation by pressing the big plus (Stimulation Start/Increase) and minus (Stimulation Decrease) buttons on the face of the Trial Stimulator. To turn the Trial Stimulator OFF, press the red Stimulation OFF Button in the corner. Your Trial Stimulator may be locked for your safety and you will be asked to control your system using the Remote Control.

The Trial Stimulator has a special safety feature that locks it to prevent you from accidentally turning the stimulation feature too far up or down. The Trial Stimulator can be used when it is locked—in fact, that is the way it is supposed to be used. You should only unlock the Trial Stimulator when you are with your clinician.

- To unlock the Trial Stimulator, press both the plus and minus buttons at the same time and hold them down for at least two full seconds. The Trial Stimulator will beep once for one second to confirm it is unlocked.



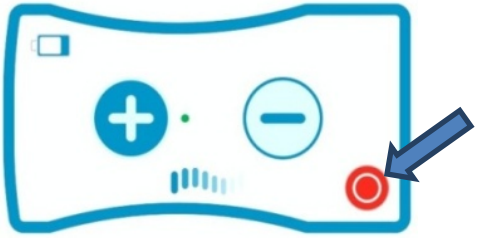
- When the Trial Stimulator is unlocked, you can use the plus and minus buttons to make adjustments to the stimulation strength.

- The Trial Stimulator will lock itself again automatically if you do not press any button on it for a minute or more.

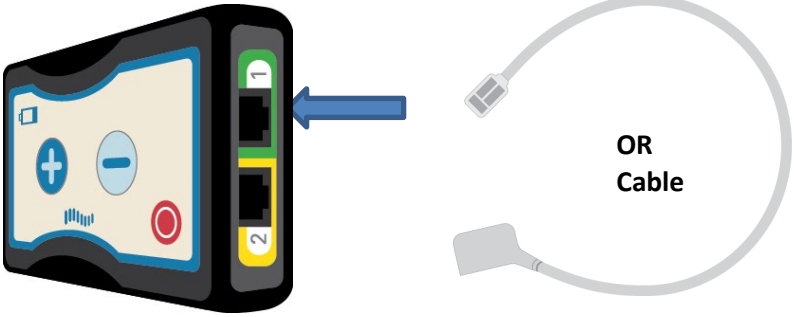
Plugging OR Cables into the Trial Stimulator

You will receive the Trial Stimulator with OR Cables. A diagram of these cables and the Trial Stimulator appears in the Appendix. To plug them into the Trial Stimulator, follow these steps:

1. Make sure the Trial Stimulator is turned OFF by pressing the red Stimulation OFF Button.



2. Select one of the OR Cables (it does not matter which one you start with). Check the color of the sticker at the end of the cable that plugs into the Trial Stimulator.



3. Plug that end of the OR Cable into the Trial Stimulator port of the same color. You will hear a click when the cable is fully inserted into the port.
4. Repeat for the other OR Cable.

Trial Stimulator Alert

If the Trial Stimulator is set up but cannot deliver therapy, it will sound an alert. This alert will sound until you press the red Stimulation OFF Button on the Trial Stimulator. Pressing the red button turns therapy OFF.

A frequent reason for the Trial Stimulator alert is one or more loose connections. Check that both OR Cables are properly in place and securely plugged in. If a cable is loose or disconnected, plug it in securely. Double-check that the OR Cables are in the correct port (match colors on the cable to color of the port). Once you are sure that the OR Cables are correctly in place, turn stimulation ON by pressing the plus sign Stimulation Increase Button and try again.

If you still get the alert sound, then the Trial Stimulator cannot deliver therapy. Contact your doctor.

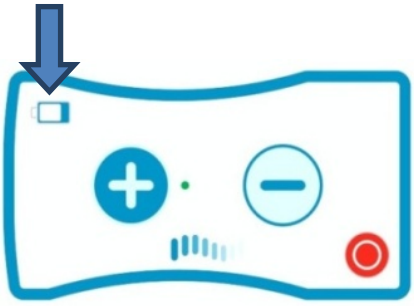
Trial Stimulator Batteries

Your Trial Stimulator uses a special type of battery that is provided by Nevro. These batteries have a distinctive purple color. **Do not use any other batteries in the Trial Stimulator.** Use only the batteries provided by your doctor or a technician. If you use another type of battery, you may damage the Trial Stimulator.

WARNING: Do not use any batteries in the Trial Stimulator except the purple batteries from Nevro.

The Trial Stimulator will warn you when the batteries are running low. When the Low Battery Indicator Light flashes, you have 10 minutes or less of battery life available. If the Low Battery Indicator Light stops flashing and remains lit, the battery is exhausted and has to be replaced.

Low Battery Indicator



The arrow points to the Low Battery Indicator Light. The Low Battery Indicator Light will flash for about 10 minutes before the batteries wear out.

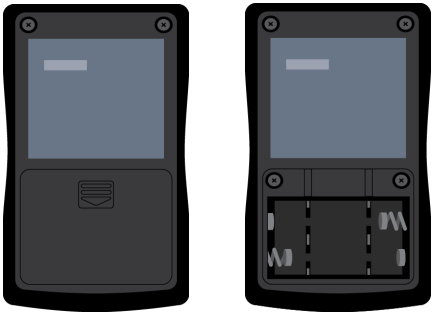
Replace the batteries when the Low Battery Indicator light first begins to flash so that you can avoid interrupting your therapy.

When this indicator light is lit, the Trial Stimulator can no longer provide stimulation. Replace the batteries at once.

How to Change the Batteries in the Trial Stimulator

You will regularly need to replace the batteries in your Trial Stimulator. Use only the special Nevro batteries provided. A spare set of batteries will be provided with the Trial Kit. If needed, additional batteries can be obtained from your physician. Typically, batteries last for approximately five days.

1. Turn OFF the Trial Stimulator by pressing the red Stimulation OFF Button on the lower right.
2. Turn the Trial Stimulator over and remove the battery cover.
3. Remove the two old batteries.
4. Double check that the new batteries are the special Nevro batteries. They should be purple.
5. Insert the batteries as you would in any device, matching the positive ends of the battery to the positive symbol in the battery compartment. You may need to use a little force to get the new batteries into the battery compartment.
6. Replace the cover; the battery compartment should always be covered.



The Remote Control (RC1000)

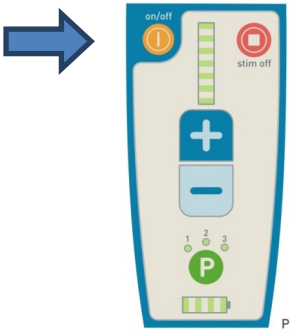
RC1000

The Remote Control communicates wirelessly with the Trial Stimulator when you hold the Remote Control near it. The Remote Control turns itself OFF when it is not in use. To turn it ON, just press the yellow ON/OFF Button on the upper left-hand corner. Once the Remote Control is ON, you can increase or decrease stimulation by pressing the big plus (Stimulation Start/Increase) and minus (Stimulation Decrease) buttons on the front of the Remote Control. To turn the device OFF, press the red Stimulation OFF Button on the upper right-hand corner. If you want to turn the Remote Control OFF immediately instead of waiting for it to respond, press the yellow ON/OFF Button on the upper left-hand corner again.

How to Turn on the Remote Control

Most of the time, your Remote Control will be OFF to help save battery life. The Remote Control needs to be turned ON in order for it to communicate with the Trial Stimulator.

1. Press the small yellow ON/OFF Button on the upper left-hand corner of the Remote Control.



2. Hold it down for up to five seconds.
    - If the Remote Control turns on, you will hear a long beep.
    - Lights will flash as the Remote Control tries to establish communication with the Trial Stimulator.
        - If communication with the Trial Stimulator is established, the lights stop flashing
        - If communication with the Trial Stimulator cannot be established, the Remote Control will beep three times and turn itself OFF

If the Remote Control cannot communicate with the Trial Stimulator, make sure the Trial Stimulator is close to the Remote Control. You may need to move the Remote Control closer to the Trial Stimulator. If this does not work, check the batteries in the Trial Stimulator—if the Trial Stimulator needs new batteries, it will not be able to communicate with the Remote Control.

The Remote Control is also battery powered. When the batteries get low, the Remote Control will beep six times when it is turned ON. When this occurs, change the batteries.

The Remote Control will turn itself OFF anytime it is not in use for two or more minutes. Simply turn it back on when you are ready to use it again.

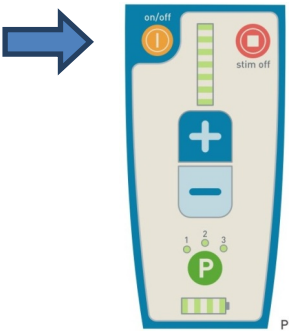
Remote Control Batteries

Your Remote Control should come with batteries already installed. It uses two AA alkaline batteries. **Never use any other type of battery with your Remote Control because this could damage the device**.

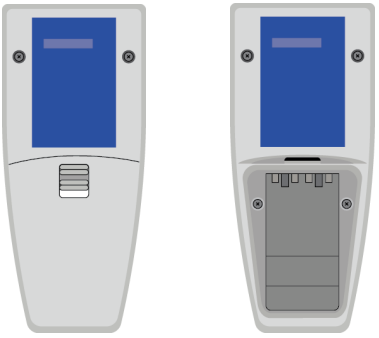
WARNING: Use only two AA alkaline batteries in the Remote Control; any other type of battery could damage the device.

How to Change the Batteries in the Remote Control

Make sure the Remote Control is OFF; it turns itself OFF automatically if it is not touched for two minutes. Pushing the yellow ON/OFF Button on the top left corner also turns off the Remote Control.



1. Turn the Remote Control over and remove the battery compartment cover.
2. Remove the two old batteries.
3. Double check that the new batteries are AA alkaline batteries. Do not use any other type of battery.
4. Insert the batteries as you would in any device, matching the positive ends of the battery to the positive symbol in the battery compartment.
5. Replace the cover; the battery compartment should always be covered.



Adjusting Stimulation

Once the Remote Control is ON and has established communication with the Trial Stimulator, you can use the Remote Control to turn the stimulation ON and OFF, or increase/decrease the strength of the stimulation.

How to Turn OFF Stimulation

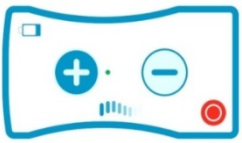
If you are using the Trial Stimulator, you can turn stimulation OFF by pressing the round red Stimulation OFF Button on the lower right-hand corner. This button is always active and can be pressed at any time, even if the Trial Stimulator is locked.

You can also turn stimulation OFF with the Remote Control, but the Remote Control must be turned ON first (press the yellow ON/OFF Button on the upper left). Turn stimulation OFF from the Remote Control by pressing the round red Stimulation OFF Button on the upper right-hand corner.

You can use either method to turn stimulation OFF.

Note: The red OFF buttons do not turn stimulation back ON.

Trial Stimulator



Turn stimulation OFF: Press the red button on the lower right-hand corner

Remote Control

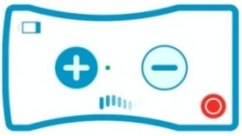
Turn stimulation OFF: Press the red button on the upper right-hand corner

How to Turn ON Stimulation

To turn stimulation ON, press the Stimulation Start/Increase Button (the plus sign) on the Trial Stimulator or the Remote Control. If you are using the Remote Control, turn it on first (use the yellow ON/OFF Button on the upper left) and then turn stimulation ON by pressing the plus sign. When the device stimulates, it will indicate this by flashing (Trial Stimulator) or lighting up at least one LED light (Remote Control).

Your doctor has set up your stimulation program for you already. When you turn stimulation ON, it will stimulate as programmed. The Trial Stimulator will stimulate based on the last program it used.

Trial Stimulator



Turn stimulation ON: Press the plus sign. The lights will flash when it is stimulating.

Remote Control

Turn stimulation ON from the Remote Control, first turn the Remote Control on by pressing the yellow ON/OFF Button for up to five seconds. One long beep sounds to tell you the Remote Control is on.

Once the Remote Control is ON; Turn stimulation ON: press the plus sign. When the device is stimulating, you will see at least one of the LED lights turn on.

Increasing or Decreasing Stimulation Strength

Follow the directions given to you by your doctor when changing the stimulation strength. The stimulation you receive can be made more or less intense using the Trial Stimulator or the Remote Control. To increase stimulation strength, press the plus sign button repeatedly until you reach the stimulation strength you want. Your doctor has programmed a maximum stimulation strength into the device and it cannot be made to stimulate more intensely than that. To decrease the stimulation strength, press the minus sign button.

When you change stimulation levels, you will hear beeps. The table below defines the beep counts and type.

What You Hear	What It Means
One single soft beep	This confirms that the plus sign or minus sign button has been pressed.
One single regular beep	Stimulation has increased or decreased by one level.
Two regular beeps	You have reached the highest or lowest stimulation level possible.
Three regular beeps	The device cannot respond the way you want.
Continuous beeping	One of the cables on the Trial Stimulator is loose.

<u>Three regular beeps</u> means the device cannot accommodate your request. The following may be the reason:

- The Remote Control is too far away from the Trial Stimulator
- The Remote Control has another problem communicating with the Trial Stimulator

Move the Remote Control closer to the Trial Stimulator and try again.

Your device is adjustable so that you can find the right level of stimulation to control your pain. If your pain remains uncontrolled, even at the maximum level, or if you are having difficulty getting pain relief with this system, tell your doctor.

Switching Between Programs

Your doctor may have set up your stimulator to offer one, two, or three different stimulation programs. Follow the directions given to you by your doctor when switching the program. If you have more than one stimulation program available, you can change programs by pressing the green P button on the Remote Control. The number of the program you have selected will light up. The button runs through the numbers in order and then starts over, so keep pressing until you reach the number you want.

1. Turn the Remote Control on by pressing and holding the yellow ON/OFF Button on the upper left-hand corner for up to five seconds. You will hear one long beep to tell you that the Remote Control is on.
2. Press the green P button to change the stimulation program. The programs go in order (1, 2, 3, then 1, 2, 3, and so on).
3. Stop when light by the desired number is lit.

If only one program is available, the number 1 will remain lit and you will not be able to change programs.

IMPLANTED STIMULATOR PHASE

After your Trial Phase using the Trial Stimulator and the Remote Control, you and your doctor will decide if SCS therapy is right for you. During the trial phase, you learned to use the Remote Control. You will use either the same or a similar Remote Control with the IPG. You also learned what it felt like to receive therapy and how it worked to control your pain. It is expected that the therapy will work the same way after the IPG implantation. There may come a time when your IPG no longer holds a charge well. When your therapy cannot be maintained with daily charging, the IPG may need to be replaced. At that point, the doctor can remove your old IPG and replace it with a new one. This involves another surgical procedure. This second procedure is usually faster and more straightforward than the original implant surgery. The rechargeable battery in your IPG should last many years. How long it lasts will depend on many factors, including how often the IPG stimulates. Ask your doctor how long the battery might be expected to last for you.

You may be able to resume many of the everyday things you are used to. Talk with your doctor about appropriate activities. With the Senza system you may be able to resume:

- Driving
- Going to work
- Travel
- Many leisure activities
- Moderate exercise (ask your doctor)
- Normal sexual activity

Your doctor will want to see you regularly for check-ups. These are important not only for your health, but also to monitor how the device is working.

How to Set Up and Use Your Senza Omnia™ Remote Control (RC2500 – 5 Program Remote)

If you have already gone through the trial phase, you know how to turn the Remote Control ON, turn stimulation ON and OFF, increase and decrease stimulation strength, and switch between stimulation programs. These are done exactly the same way as before using the Remote Control.

This section discusses the Senza Omnia Remote Control that you may have received for the implanted stimulator phase.

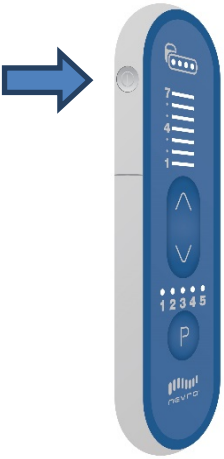
RC2500 – 5 Program Remote

The Remote Control communicates wirelessly with the IPG when you hold the Remote Control near it. The Remote Control turns itself OFF when it is not in use. To turn it ON, just press the ON/OFF Button on the upper left-hand side. Once the Remote Control is ON, you can increase or decrease stimulation by pressing the ‘up’ (Stimulation Start/Increase) and ‘down’ (Stimulation Decrease) arrow buttons on the front of the Remote Control. To turn the device OFF, press the red Stimulation OFF Button on the back of the Remote Control. If you want to turn the Remote Control OFF immediately instead of waiting for it to respond, press the ON/OFF Button on the upper left-hand side again.

How to Turn On the Remote Control

Most of the time, your Remote Control will be OFF to help save battery life. The Remote Control needs to be turned ON in order for it to communicate with the IPG.

1. Press the small ON/OFF Button on the upper left-hand side of the Remote Control.



2. Hold it down for up to five seconds.
    - If the Remote Control turns on, you will hear a long beep.
    - Lights will flash as the Remote Control tries to establish communication with the IPG.
        - If communication with the IPG is established, the lights stop flashing
        - If communication with the IPG cannot be established, the Remote Control will beep three times and turn itself OFF

If the Remote Control cannot communicate with the IPG, make sure the IPG is close to the Remote Control. You may need to move the Remote Control closer to the IPG. If this does not work, check the batteries in the IPG — it may need to be recharged before being able to communicate with the Remote Control.

The Remote Control is also battery powered. When the batteries get low, the Remote Control will beep six times when it is turned ON. When this occurs, change the batteries.

The Remote Control will turn itself OFF anytime it is not in use for two or more minutes. Simply turn it back on when you are ready to use it again.

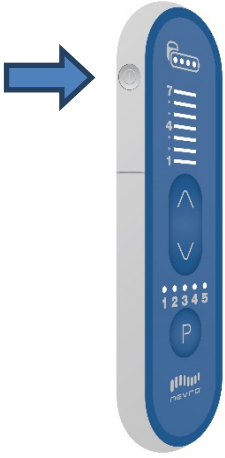
Remote Control Batteries

Your Remote Control should come with batteries already installed. It uses two AAA alkaline batteries. **Never use any other type of battery with your Remote Control because this could damage the device**.

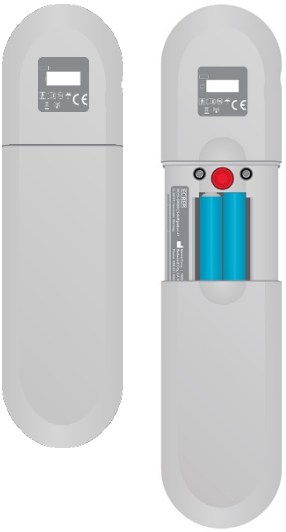
WARNING: Use only two AAA alkaline batteries in the Remote Control; any other type of battery could damage the device.

How to Change the Batteries in the Remote Control

Make sure the Remote Control is OFF; it turns itself OFF automatically if it is not touched for two minutes. Pushing the ON/OFF Button on the top left side also turns off the Remote Control.



1. Turn the Remote Control over and remove the battery compartment cover.
2. Remove the two old batteries.
3. Double check that the new batteries are AAA alkaline batteries. Do not use any other type of battery.
4. Insert the batteries as you would in any device, matching the positive ends of the battery to the positive symbol in the battery compartment.
5. Replace the cover; the battery compartment should always be covered.



Adjusting Stimulation

Once the Remote Control is ON and has established communication with the IPG, you can use the Remote Control to turn the stimulation ON and OFF, or increase/decrease the strength of the stimulation.

How to Turn OFF Stimulation

You can turn stimulation OFF with the Remote Control, but the Remote Control must be turned ON first (press the ON/OFF Button on the upper left side). Slide open the back door of the Remote Control slightly till the red Stimulation OFF Button is visible. Turn stimulation OFF from the Remote Control by pressing the round red button.

Turn stimulation OFF: Press the red button on the back of the Remote Control

NOTE: The red OFF button does not turn stimulation back ON.

How to Turn ON Stimulation

To turn stimulation ON, turn on the Remote Control first (use the ON/OFF Button on the upper left) and then turn stimulation ON by pressing the ‘up’ arrow. When the IPG stimulates, it will indicate this by lighting up at least one LED light (Remote Control).

Your doctor has set up your stimulation program for you already. When you turn stimulation ON, it will stimulate as programmed.

Turn stimulation ON from the Remote Control: Turn the Remote Control on by pressing the ON/OFF Button for up to five seconds. One long beep sounds to tell you the Remote Control is on.

When the Remote Control is powered ON; Turn stimulation ON by pressing the ‘up’ arrow. When the device is stimulating, you will see at least one of the LED lights turn on.

Increasing or Decreasing Stimulation Strength

Follow the directions given to you by your doctor when changing the stimulation strength. The stimulation you receive can be made more or less intense using the Remote Control. To increase stimulation strength, press the plus sign or ‘up’ arrow button repeatedly until you reach the stimulation strength you want. Your doctor has programmed a maximum stimulation strength into the device and it cannot be made to stimulate more intensely than that. To decrease the stimulation strength, press the minus sign or ‘down’ arrow button.

When you change stimulation levels, you will hear beeps. The table below defines the beep counts and type.

What You Hear	What It Means
One single soft beep	This confirms that the plus or minus sign or the up- or down-arrow button was pressed.

One single regular beep	Stimulation has increased or decreased by one level.
Two regular beeps	You have reached the highest or lowest stimulation level possible.
Three regular beeps	The device cannot respond the way you want.
Continuous beeping	One of the cables on the Trial Stimulator is loose.

Three regular beeps means the device cannot accommodate your request**.** The following may be the reason:

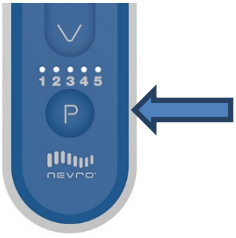
- The Remote Control is too far away from the IPG
- The IPG is not sufficiently charged
- The Remote Control has another problem communicating with the IPG

Move the Remote Control closer to the IPG and try again.

Your device is adjustable so that you can find the right level of stimulation to control your pain. If your pain remains uncontrolled, even at the maximum level, or if you are having difficulty getting pain relief with this system, tell your doctor.

Switching Between Programs

Your doctor may have set up your stimulator to offer between one and five different stimulation programs. Follow the directions given to you by your doctor when switching the program. If you have more than one stimulation program available, you can change programs by pressing the P button on the Remote Control.



The number of the program you have selected will light up. The P button runs through the numbers in order and then starts over, so keep pressing until you reach the number you want.

1. Turn the Remote Control on by pressing and holding the ON/OFF Button on the upper left-hand side for up to five seconds. You will hear one long beep to tell you that the Remote Control is on.
2. Press the green P button to change the stimulation program. The programs go in order (1, 2, 3, 4, 5, then 1, 2, 3, 4, 5, and so on).
3. Stop when light by the desired number is lit.

If only one program is available, the number 1 will remain lit and you will not be able to change programs.

Battery Status (CRG1000, RC1000, RC2500)

Your IPG is a battery-powered device, and it can be recharged. This will help you get maximum service from your system. Your care team should show you how to recharge your IPG. The best way to recharge is to get into the habit of recharging once a day, although you may be able to charge it less often. Many factors can affect how often you need to recharge the IPG (such as how much you use it, how intensely it stimulates, how old the system is).

You have a Charger, a Charger Belt, and a Charger Holster for recharging the IPG. These are shown in the Appendix.

You also have equipment to recharge the Charger. This is shown in the Appendix. It is recommended that you recharge the Charger after every use.

There are Battery Level Indicators on the Charger and on the Remote Control.

Battery Level Indicators (CRG1000)

The Battery Level Indicators on the Charger report the battery level of the implanted device.

The right-sided battery level indicator on the charger tells you the status of the IPG battery.

If you see two or fewer bars, then your IPG needs to be recharged.

Battery Level Indicators (RC1000)

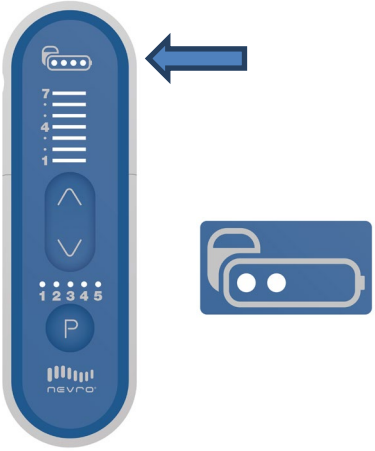
The Remote Control also has a Stimulator Battery Level Indicator.

The Stimulator Battery Level Indicator on the Remote Control tells you the status of the IPG battery.

If you see two or fewer bars, then your IPG needs to be recharged.

Battery Level Indicators (RC2500 – 5 Program Remote)

The Remote Control also has a Stimulator Battery Level Indicator.



The Stimulator Battery Level Indicator on the Remote Control tells you the status of the IPG battery.

If you see two or fewer dots, then your IPG needs to be recharged.

How to Charge the Implantable Pulse Generator

You can still get stimulation from your device even during charging. Follow these steps to charge the IPG.

1. Place the Charging Coil (the big blue circle) into the mesh pouch of the Charger Belt. The mesh pouch is the part of the Charger Belt that has the Nevro logo.

WARNING: Use only the Power Adaptor, Charging Coil, and accessories from Nevro Corp. Always recharge using the Charger Belt provided. Failure to use the Charger Belt may result in a burn.

2. Identify the area where the IPG is implanted. When charging, the Charging Coil in the mesh pouch of the Charger Belt should be lined up so the center of the Charging Coil covers the top of the IPG. You do not need to remove any clothing—you can recharge through a thin layer of fabric. **However, make sure that there is no metal between the Charging Coil and the IPG or near the Charging Coil because it could result in serious burns.** (Metal might be in jewelry, a belt, buttons, zipper, and so on.) Fasten the belt to hold the Charging Coil in place; you may want to use the optional Charger Holster to help hold the Charger.

WARNING: If you feel warmth or discomfort when recharging the device, stop recharging and contact your doctor.

WARNING: Never charge your IPG when the Charger is plugged into a wall outlet. Always remove the Power Adaptor before pressing the Charge Start Button.

3. Press the arrow Charge Start Button to turn on the Charger.
4. The Charger will start to look for the IPG. It beeps as it searches.
5. When the Charger finds the IPG, you will see at least two bars on the Antenna Strength Indicator. (If you do not have at least two bars, move the Charging Coil slightly until you get sufficient antenna strength.) You can charge successfully with two or more bars. If the antenna strength still is 1 (the yellow bar) or no bars, then please advance to the "Optimizing Charging." The more bars you see, the better the communication you have and the more efficient the charging session will be.
6. When the Charger is in the correct position, the IPG Battery Level Indicator will light up. These are the status bars to the right and left of the Charge Start Button .

The Charger has two battery status bars:

The status bar on the left of the arrow button is the battery status of the Charger.

The status bar on the right of the arrow button is the battery status of the IPG.

7. Keep the Charging Coil steady in the same position. The Charger will keep charging until the IPG is fully charged (or until the Charger runs out of its own charge).

NOTE: If the Charging Coil is moved during the charging session, it may lose communication with the IPG. If this occurs, you will see one orange bar on the Antenna Strength Indicator and you will hear intermittent beeps. Slowly move the Charging Coil back into proper position, wait about three seconds, and confirm that the antenna strength shows at least two bars. Keep moving slightly and pausing, checking until you re-establish communication. If the Charging Coil and the IPG lose communication for a long period of time, the Charger will sound one long beep and turn itself off. If this happens, re-start the charging process. The IPG can still be charged even if the charging session is interrupted.

8. When the IPG is fully charged, the Charger will sound a long beep and the IPG's Battery Level Indicator (the ones on the right) will show four bars. The Charger turns itself off automatically.

NOTE: If you ever need to turn off the Charger during a recharging session, just move the Charging Coil away from the IPG. If the Charger cannot locate the IPG after 10 seconds, it turns itself off automatically.

CAUTION: Do not charge your IPG while you are drowsy, sleeping, or sedated, as this may result in a burn. If you feel warmth or discomfort around the Charging Coil, discontinue the charging process and contact your doctor.

9. Once the charging is complete, turn ON the Remote Control (by following the instructions in the 'How to Turn On the Remote Control' section of this manual) and verify that therapy is ON.

NOTE: The IPG will continue to provide therapy while being recharged.

The battery life of the IPG is estimated to be 10 years but the battery life may be more or less depending on the stimulation parameters used. The battery will eventually need to be replaced in a surgical procedure.

How to Charge the Charger

You should recharge the Charger after every use. The best way to remember to do this is to get into a daily routine of charging the IPG and then recharging the Charger. You can find a diagram of the Charger parts in the Appendix.

WARNING: Never charge the IPG at the same time you are recharging the Charger.

1. The Charger has a Power Adaptor Port. Plug the Power Adaptor Port plug into the Power Adaptor Port.
2. This initiates the charge. You will see a red light on the Power Adaptor light up. This means the Charger is being recharged.
3. Allow the recharging to continue until the light turns green. The green light indicates that the recharging is complete.

NOTE: Once the Charger is fully charged, you do not have to unplug it until you the next time you charge the IPG. There is no harm in continuously charging the Charger. You may also remove the plug, if you prefer.

Optimizing Charging

In order to charge the IPG, the Charging Coil must establish good communication with the IPG. There may be times when you have trouble getting the Charger and the IPG to communicate.

If there is no communication at all, the Antenna Strength Indicator will show one single orange bar and beep occasionally. The Charger will eventually turn itself off.

1. Make sure that there is no metal near the Charging Coil. (Be sure to check for jewelry, metal buttons, belt buckles, watches, zippers, and so on.)
2. The Charger will work through a thin layer of fabric. Remove any thick or heavy clothing.
3. Make sure the Charging Coil is lined up with the top of the implanted device (IPG). You may need to use your fingers to feel the shape of the device through your skin.
4. Check to see that the Charger has enough charge to work (you should see at least two status bars to the left of the arrow on the charger). If the Charger does not have enough charge, recharge it first and then try to charge the IPG.

If there is poor communication, you will see one orange bar but there will not be any beeping. The Charging Coil can still recharge the IPG, but it will happen slowly. You may be able to get better communication by moving the Charging Coil slightly, waiting about three seconds, and seeing if this improves the antenna strength.

If communication is lost during a recharging session, simply move the Charging Coil back into position until you see at least two bars on the Antenna Strength Indicator. An interruption in charging will not hurt the system.

Charging Tips

It is very important that you get familiar and comfortable with charging your system and develop a routine so that your device is charged every day. This assures that you can get the pain control therapy you need when you need it.

- Charging times will vary for each session. Things that can affect charging time include battery status, how much therapy you have had, therapy strength, and time elapsed from the last charge. Do not be concerned if the charging process seems to take longer some days than others.
- If the charging time is very short, check that the IPG is turned on.

- Ensure the Charger is charged by viewing the Battery Status indicator on the left side of the Charger. It is recommended that at least two bars are indicated. If no lights are indicated then see “How to Charge the Charger”.
- The more bars shown on the Antenna Strength Indicator, the better communication the Charging Coil has with the IPG. The better the communication, the less likely that your charge session will be interrupted.
- To find the top of the implanted device, use your fingers to gently feel for the device through the skin. Your doctor can assist you in learning how to do this.
- Keep the Charging Coil steady in position as you charge. If the Charging Coil moves, it may lose communication with the IPG. If this happens, you will hear a long beep and the Charger will turn itself off. Simply put the Charging Coil back in position and start again.
- If you need to turn OFF the Charger during a charging session, just move it away from the IPG. It will turn itself OFF automatically in about 10 seconds.
- You can still get therapy while the device is recharging.
- Do not press the red Stimulation OFF Button on the Charger unless you want to turn therapy OFF. There is no need to do this during charging. If you should ever press the red button on the Charger, turn therapy back ON using the Remote Control (by following the instructions in the ‘How to Turn ON Stimulation’ section of this manual).

YOUR PATIENT ID CARD

You will receive a temporary patient identification (ID) card during the trial phase. If you have the device implanted, you will get a permanent ID card from Nevro through the mail in several weeks.

Carry this patient ID card with you at all times. It identifies you as a device patient and it may be important for you in a medical emergency. If you ever need to go through a security checkpoint, you should show your Patient ID card.

If you move or if your personal information changes, be sure to let your doctor know. It is important to update your contact information with your doctor and Nevro.

ASK YOUR DOCTOR

SCS therapy has helped many people, but you must be willing to share information with your doctor for best results. You should have the name and phone number of your doctor and/or healthcare professional (technician) handy at home and at work, so that you can get in touch with him or her quickly if need be. Tell your family and individuals close to you about your Senza system in the event that they will ever have to speak for you.

Contact your doctor at once if:

- You feel unusual pain or discomfort during stimulation. (Turn stimulation OFF at once.)
- The implant site is swollen, reddened, irritated, tender, or painful.
- You experience any unusual symptoms that you think may be related to the device.

If you have a medical emergency, do not call your doctor. Call 911 and seek emergency help.

Ask your doctor or other healthcare professional for help if you have trouble with any of the following:

- Using the Remote Control
- Using the Trial Stimulator
- Charging the IPG
- Charging the Charger
- Changing batteries
- Understanding how to increase/decrease stimulation strength

Discuss with your doctor changes in your condition and how you are responding to therapy.

TROUBLESHOOTING

If you should experience problems with your Senza system, please see if any of these troubleshooting recommendations might address that problem. Many times, problems with the device turn out to have simple solutions. If you cannot fix your problem with these recommendations or if you are having a problem not described here, contact your doctor.

Troubleshooting Therapy

<u>If therapy has stopped</u>:

- Check that therapy has not been inadvertently turned OFF. Turn therapy ON by following the instructions in the 'How to Turn ON Stimulation' section of this manual.
- If you are using the Trial Stimulator, there may be a loose connection. Check that the OR Cables are in the right ports (match the colors) and make sure they are fully inserted into the port. You will hear a click when the cable is fully inserted into the port.
- Check battery status.
    - On the Trial Stimulator, look if the Low Battery Indicator Light is on or flashing.
    - Listen for six beeps when you turn ON the Remote Control.
    - If necessary, replace batteries.
- If you have an IPG, check the battery status and recharge, if necessary.

Troubleshooting the Remote Control (RC1000)

<u>If you press the buttons on the Remote Control and nothing happens:</u>

- Make sure the Remote Control is ON. You must turn ON the Remote Control before you use it; it automatically turns itself OFF when not in use. To turn it ON, press and hold the yellow ON/OFF Button on the upper left for up to five seconds.
- If this does not fix the problem replace the batteries in the Remote Control with two AA alkaline batteries. Batteries should be replaced every three months. When replacing batteries, replace both at the same time and ensure that the orientation of the batteries is correct.

- If you are using the Trial Stimulator, look at the Trial Stimulator to see if the Low Battery Indicator Light (upper left-hand corner) is flashing or lit. If the light is flashing or lit, replace the Trial Stimulator battery. **Use only the special batteries provided by Nevro for use in your Trial Stimulator.**
- Move the Remote Control to make sure it is close enough to the Trial Stimulator or IPG to work. It may be out of range.
- If none of these steps restores the Remote Control to normal operation, contact your doctor.

If you have an IPG and the Remote Control sounds three beeps to indicate that a command was not accepted:

- Move the Remote Control closer to the Trial Stimulator or IPG and try again.
- Move away from possible sources of electromagnetic interference, such as electrical equipment and radio systems, and try again.
- If you notice that the Remote Control is turned off after the three beeps, the IPG battery is low. Recharge the IPG.

Troubleshooting the Senza Omnia Remote Control (RC2500)

If you press the buttons on the Remote Control and nothing happens:

- Make sure the Remote Control is ON. You must turn ON the Remote Control before you use it; it automatically turns itself OFF when not in use. To turn it ON, press and hold the ON/OFF Button on the upper left side for up to five seconds.
- If this does not fix the problem replace the batteries in the Remote Control with two AAA alkaline batteries. Batteries should be replaced every three months. When replacing batteries, replace both at the same time and ensure that the orientation of the batteries is correct.
- Move the Remote Control to make sure it is close enough to the IPG to work. It may be out of range.
- If none of these steps restores the Remote Control to normal operation, contact your doctor.

If you have an IPG and the Remote Control sounds three beeps to indicate that a command was not accepted:

- Move the Remote Control closer to the IPG and try again.
- Move away from possible sources of electromagnetic interference, such as electrical equipment and radio systems, and try again.

- If you notice that the Remote Control is turned off after the three beeps, the IPG battery is low. Recharge the IPG.

Troubleshooting the Trial Stimulator

<u>If the Trial Stimulator beeps continuously</u>:

- There may be a loose connection. Double check that the OR Cables are in the correct ports (match the colors) and that they are securely inserted. You should feel a click when the cables are inserted the right way.
- Once you are sure the cables are properly inserted, turn therapy ON again.

<u>If the Trial Stimulator does not seem to be responding to the Remote Control</u>:

- Using the Remote Control, notice if you hear three beeps after pressing a button. Three beeps means the command was not accepted. If this happens:
    - Move the Remote Control closer to the Trial Stimulator and try again.
    - If this does not help, the Trial Stimulator batteries may be low. In this case, you will hear three beeps and notice the Low Battery Indicator Light on the Trial Stimulator. Replace the batteries in the Trial Stimulator.
- The batteries may also be low in the Remote Control. Replace the batteries.
- If you go through these steps and it does not help, contact your doctor.

Troubleshooting the Recharging Process

<u>If your device needs very frequent recharging:</u>

- After each charging session, check to see that the IPG is fully charged.
- If frequent charging persists, contact your doctor.

<u>If you ever charge your device and it does not provide stimulation:</u>

- Check to see that the IPG is fully charged.
- Replace batteries in the Remote Control
- Check that stimulation is turned ON; if it is not, turn on stimulation by following the instructions in the 'How to Turn ON Stimulation' section of this manual.
- If these do not work, contact your doctor.

If you are trying to recharge the IPG and you have low antenna strength that you cannot improve:

- Slowly move the Charging Coil slightly. The goal is that the center of the Charging Coil circle is lined up over the top of the implanted device. Wait about three seconds and observe if the antenna strength improves.
- You may have to do this a few times—make sure your movements are slow and small.
- You can still charge if you have two bars on the Antenna Strength Indicator.

All of the Lights are Blinking!

If you ever see all of the lights blinking or hear long beeps or a series of many rapid short beeps, your device may require service. Contact your doctor.

APPENDICES

Device Specifications

System Specifications

Parameter	Range
Frequency	2 – 10,000 Hz
Pulse Width	20µsec – 1msec
Amplitude	0 – 15mA

Charger Specifications

The following table contains technical specifications for the Charger.

AC input for the charger:	
Parameter	Specification
Frequency	50 to 60 Hz
Voltage	100 to 240 VAC
Input Current	0.2 A max

Additional technical information, including the Guidance and Manufacturer's Declarations on electromagnetic emissions and immunity, is available. To request this information, please contact Nevro Corp.

Stimulation Parameter Ranges
The following table summarizes the maximum impedance for which the maximum current of 15 mA can be delivered at the maximum pulse width (1 msec, at a maximum frequency of 400 Hz) and maximum frequency (10,000 Hz, at a maximum pulse width of 30 µsec).

Frequency	Maximum Amplitude	Maximum Pulse Width	Maximum Impedance
400 Hz	15 mA	1 msec	1,270 Ω
10,000 Hz	15 mA	30 µsec	1,080 Ω

Quality of Wireless Service
The Senza system uses a wireless communication system in the MedRadio frequency band (402-405 MHz). This band is reserved for implantable medical devices. The typical communication range is less than 5 feet (1.5 meters) between the Remote Control/Programmer Wand and Implantable Pulse Generator (IPG)/Trial Stimulator. Before each communication, the Remote Control/Programmer Wand scans 8 channels in the band and selects the least interfered channel for communication. All communication is verified for accuracy. Any communication containing uncorrectable errors are rejected and communication is retried automatically. If the retries fail, the user is notified of the communication failure.

Wireless Security
The Senza system has a telemetry range of less than 5 feet (1.5 meters). The Remote Control is uniquely paired to a specific IPG or Trial Stimulator and can only communicate with that device. The IPG or Trial Stimulator will not respond to any communication that does not come from a linked device (a device that is paired with the IPG). There are additional mechanisms that ensure the integrity of the communicated data.

Telemetry Information
The Senza system uses a wireless communication system in the MedRadio frequency band (402-405 MHz). The wireless communication system implements Frequency Shift Keying (FSK) modulation. The bandwidth of each of the 8 frequency channels does not exceed 300 kHz, and the Transmitter Effective Isotropic Radiated Power (EIRP) does not exceed -16 dBm (25 µW).

Refer to the troubleshooting sections in this manual if communication difficulties are encountered.

This device complies 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 radio frequency energy and , if not installed and

used in accordance with the instructions, may cause harmful interference to radio communications. Changes or modifications of any kind not expressly approved by Nevro could void the user's authority to operate this device.

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation.

This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

Refer to the tables in the "Electromagnetic Interference" section to determine the recommended separation distances between the Senza system and other transmitters.

Wireless Charging Information

The Senza system uses charging frequency of 408-477 kHz. The charging distance between the Charger and the IPG is between 0 to 2.5 cm.

Electromagnetic Interference

Guidance and Manufacturer's Declaration - electromagnetic emissions		
The Senza system is intended for use in the electromagnetic environment specified below. The customer or user of the Senza system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guide**
RF emissions CISPR 11	Group 1	The Senza system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B Class A (Programmer Wand)	The Senza system 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. The Programmer Wand is suitable for use in all establishments other than domestic and those
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations /	Complies	

Flicker emissions IEC 61000-3-3		directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration - electromagnetic immunity			
The Senza system is intended for use in the electromagnetic environment specified below. The customer or user of the Senza system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2/4/8/15 kV Air ±8 kV Contact	±2/4/8/15 kV Air ±8 kV Contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2kV, 100 kHz PRR	2kV, 100 kHz PRR	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle, 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚ 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles	0 % U_T for 0.5 cycle, 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚ 0 % U_T for 1 cycle 70 % U_T for 25 cycles 0 % U_T for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of Nevro SCS system requires continued operation during power mains interruptions, it is recommended that the Nevro SCS system be powered from an 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 or hospital environment.
NOTE U_T *is the a.c. mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - electromagnetic immunity			
The Senza system is intended for use in the electromagnetic environment specified below. The customer or user of the Senza system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment guidance**
Conducted RF IEC 61000-4-6	3V RMS 6V RMS in ISM + Amateur Radio Bands 150 kHz to 80 MHz 3V RMS, 6V RMS in ISM Bands 150 kHz to 80 MHz (Programmer Wand)	3V RMS 6V RMS in ISM + Amateur Radio Bands 150 kHz to 80 MHz 3V RMS, 6V RMS in ISM Bands 150 kHz to 80 MHz (Programmer Wand)	Portable and mobile RF communications equipment should be used no closer to any part of the Senza system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d=1.2$\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 3 V/m 80 MHz to 2.7 GHz (Programmer Wand)	10 V/m 80 MHz to 2.7 GHz 3 V/m 80 MHz to 2.7 GHz (Programmer Wand)	d=1.2 $\sqrt{P}$ 80 MHz to 800 MHz d=2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz

			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the symbol shown below:

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Senza system is used exceeds the applicable RF compliance level above, the Senza system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Senza system.

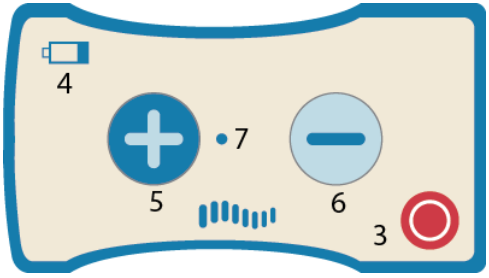
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

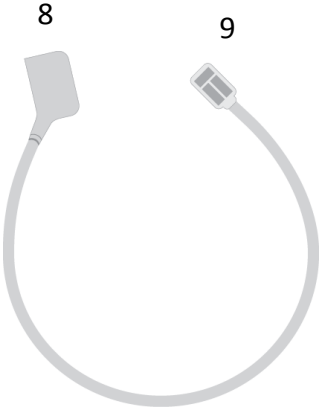
Recommended separation distances between portable and mobile RF communications equipment and the Senza system			
The Senza system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Senza system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Senza system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (meters)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

System Components

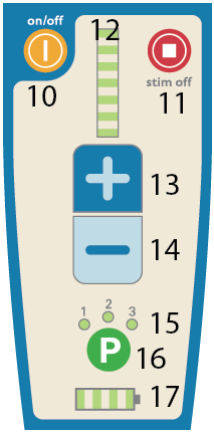
TRIAL STIMULATOR AND OR CABLE

1. Right Cable Port
2. Left Cable Port
3. Stimulation OFF Button
4. Low Battery Indicator Light
5. Stimulation Increase Button
6. Stimulation Decrease Button
7. Stimulation ON Indicator Light
8. OR Cable, the lead end
9. OR Cable, the Trial Stimulator end



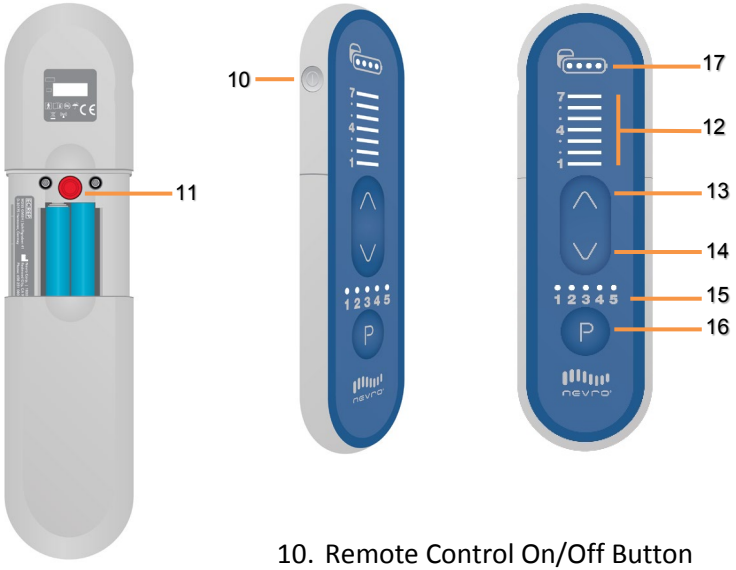


REMOTE CONTROL (RC1000)



10. Remote Control On/Off Button
11. Stimulation OFF Button
12. Stimulation Level Indicator
13. Stimulation Start/Increase Button
14. Stimulation Decrease Button
15. Program Indicator
16. Program Selection Button
17. Stimulation Battery Level Indicator (Charge level of the IPG or Trial Stimulator)

SENZA OMNIA REMOTE CONTROL (RC2500 – 5 Program Remote)



10. Remote Control On/Off Button
11. Stimulation OFF Button
12. Stimulation Level Indicator
13. Stimulation Start/Increase Button
14. Stimulation Decrease Button
15. Program Indicator – 5 Programs
16. Program Selection Button
17. Stimulation Battery Level Indicator (Charge level of the IPG)

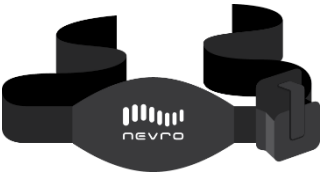
CHARGER

1. Stimulation OFF Button
2. Antenna Strength Indicator
3. Charger Battery Level Indicator
4. Charge Start Button
5. Implanted Stimulator's Battery Level Indicator
6. Charging Coil
7. Power Adaptor Port

POWER ADAPTOR

8. Power Adaptor Wall Plug
9. Power Adaptor Port Plug

CHARGING BELT



CHARGER HOLSTER

NEVRO CORP.

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