Physician Implant Manual

Senza®
Senza II™
Senza Omnia™

! USA

℞ ONLY

NEVRO CORP.
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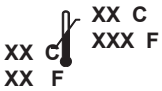
CE Mark effective on 4 May 2010

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 a Senza, Senza II, or Senza Omnia Spinal Cord Stimulation system, unless expressly approved by Nevro Corp.

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

Explanation of symbols. Refer to the product for symbols that apply.

Symbols	Description
SN	Serial number
LOT	Batch code
	Date of Manufacture
	Manufacturer
	Caution
REF	Catalog number
	Temperature limitation (storage)
STERILE EO	Sterilized using ethylene oxide
	Use by
	Do not use if package is damaged
	Do not reuse
	Do not re-sterilize
	Keep dry
	Prescription only
	Consult Electronic Instructions for Use
	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.

Conditional

MR Conditional

MR unsafe

CE Marking of Conformity

Authorized representative in the European Community

For USA audiences only

Table of Contents

1. Device Description

The Senza®, Senza II™, and Senza Omnia™ Spinal Cord Stimulation (SCS) Systems are neuromodulation devices designed to deliver electrical stimulation for the treatment of chronic intractable pain of the trunk and/or limbs.

The Senza, Senza II, and Senza Omnia Systems are implantable systems and deliver stimulation using implantable leads and a rechargeable, implantable pulse generator (IPG). The IPG is implanted in a subcutaneous pocket and is capable of stimulating the spinal cord nerves when used with one or more leads. The IPG is controlled by a Patient Remote and/or the Clinician Programmer. Other components of the Senza, Senza II, and Senza Omnia Systems include an external Trial Stimulator capable of delivering the same stimulation as the IPG, Lead Extensions, Adaptors, Charger and charging system, operating room (OR) cables and surgical accessories. Details regarding the Senza, Senza II, and Senza Omnia Systems are as follows:

Senza System Details – Major Components

- **Implantable Pulse Generator (Models Senza, Senza II and Senza Omnia):** The Implantable Pulse Generator (IPG) is a rechargeable implantable device with 16 output channels capable of stimulating the spinal cord nerves through electrode leads. The IPG is designed to produce current-regulated, charge-balanced, biphasic, capacitively-coupled, rectangular output pulses. The IPG header contains the charging coil and two ports to allow the insertion of leads. The rechargeable battery is contained in a hermetically sealed housing, which is inside the hermetic IPG Titanium enclosure.
- **Trial Stimulator:** The Trial Stimulator is a battery-powered, handheld device capable of providing the same stimulation as the IPG. During the Trial Phase of SCS, the subject wears this external Trial Stimulator for a period of time to evaluate the effectiveness of the stimulation prior to receiving a permanent implant. The Trial Stimulator is connected to the subject's implanted leads by the use of OR cables.
- **IPG or Trial Stimulator interface with other Senza components**: The Charger transmits energy transcutaneously to recharge the IPG battery. The IPG and Trial Stimulator communicate with the Patient Remote or Clinician Programmer via the Programmer Wand. Patients are also able to send commands to the IPG or Trial Stimulator directly using the Patient Remote. The IPG also includes a magnetic switch for turning the therapy off by using an external magnet.
- **Patient Remote:** The Patient Remote is a handheld battery operated unit able to communicate with the IPG or Trial Stimulator. The Patient Remote includes multiple controls and indicators for the purpose communicating with these components.
- **Charger:** This Charger is used by the subject to transcutaneously charge the IPG battery. It is a portable device powered by a rechargeable battery and can be held in one hand.
- **Programmer**: The Clinician Programmer programs the IPG or Trial Stimulator via the Programmer Wand via a graphical user interface (GUI).
- **Programmer Wand:** The Programmer Wand is the Clinician Programmer interface that allows the communication with the IPG or Trial Stimulator.
- **Leads, Lead Extensions and Lead Adaptors:** There are two types of leads: Percutaneous and Surgical. The Nevro Leads are intended to be used with an IPG or Trial Stimulator for use in

delivering stimulation. The Leads are for single use and interface with the IPG, Lead Extensions, OR Cable, and lead accessories.

The Percutaneous Lead has an isodiametric body made out of Pellethane 55D, which carries eight low impedance cables. The proximal connector end has eight (8) individual contacts which interface with the Nevro IPG and Lead Extensions.

The proximal end of the Surgical Lead has two legs each with 8 contacts. The proximal end of the Surgical Lead is identical to the proximal end of the Percutaneous Lead. The distal end of the lead is molded out of Silicone material and has 10 or 16 distal electrodes depending on the configuration.

The proximal end of the Lead Extension is identical to the proximal ends of the Percutaneous and Surgical Leads. The distal end of the Lead Extension is designed to accept the proximal end of the Percutaneous or Surgical Lead. The construction of the Lead Extension is identical along its length to the Percutaneous Lead.

The M8 and S8 Lead Adaptors allow a physician to connect a specific implanted Medtronic or St. Jude Medical/Abbott lead, respectively, with the Nevro Lead Extension or IPG. The construction of the Lead Adaptors is identical to the Lead Extension.

Senza System Details - Surgical Accessories

- **Torque Wrench:** The Torque Wrench is used to tighten the setscrews that lock the Lead into the IPG, to lock the Lead into a Lead Extension/Adaptors, or to activate the retention mechanism on the Active Anchors.

- **Lead anchors:** The Lead Anchors are used to anchor the Lead to the fascia or supraspinous ligament.

- **Insertion Needle:** The Insertion Needle is used during implant surgery to introduce the Percutaneous Lead between the vertebrae into the epidural space.

- **Coiled Lead Blank:** The Coiled Lead Blank is optionally used during surgery to clear a path for the introduction of the Percutaneous Lead into the epidural space.

- **Stylets:** The Stylets are used to maneuver the Lead through the epidural space to the desired implant location.

- **IPG Port Plug:** The IPG Port Plug is provided to seal the port of the IPG that is not in use when only one Lead is implanted.

- **OR Cables:** The Operating Room (OR) Cables make electrical and mechanical connections between the Trial Stimulator and the Leads or Lead Extensions.

- **Tunneling Tool:** The Tunneling Tool creates a subcutaneous tunnel for the leads from the IPG site to the midline incision.

- **IPG Template:** The IPG Template acts as an optional aid for physicians in proper sizing of the IPG implant pocket.

- **Mx Trial Adaptor:** The Mx Trial Adaptor is intended to connect a Medtronic OR cable to the Nevro Trial Stimulator.

- **Passing Elevator Accessory Tool:** The Passing Elevator Accessory Tool is an optional surgical accessory tool, intended to assist implanting physicians in assessing and verifying that the epidural space is appropriately sized for placement of the Surgical Lead. Material is a Nylon 6 Base with 30% barium sulfate-filled compound.

2. Indications for Use

The Senza®, Senza II™ and Senza Omnia™ neuromodulation systems are indicated as aids 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.

The Senza®, Senza II™ and Senza Omnia™ neuromodulation systems, when programmed to include a frequency of 10 kHz, are indicated as aids in the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with diabetic neuropathy.

3. Contraindications

The Senza, Senza II, and Senza Omnia Systems should not be used for those patients who:

- Are poor surgical candidates, including those with poor glycemic control in whom the safety of the device has not yet been characterized, i.e. HbA1C >10%".
- Fail to receive effective pain relief during trial stimulation.
- Are unable to operate the SCS system.

4. Warnings

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 pediatric use.

Other Active Implanted Devices – The Senza, Senza II, and Senza Omnia Systems 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, Senza II, and Senza Omnia Systems are unknown.

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

Operation of Vehicles (e.g., driving) or Machinery – Patients using therapy that generates paresthesia (see Warning regarding Stimulation Frequencies) should not operate motorized vehicles such as automobiles or

potentially dangerous machinery and equipment with the stimulation on. Stimulation must be turned off first in such cases. For these patients, any sudden stimulation changes may distract patients from proper operation of the vehicle, machinery, or equipment.

Therapy at 10 kHz does not generate paresthesia and it is less likely that sudden stimulation changes resulting in distraction could occur while having stimulation on when operating moving vehicles, machinery, and equipment.

Heat From Charging – The charging coil may become warm while charging. Patients may experience discomfort or burn if they charge while sleeping or do not use the provided charging belt. Additionally, the charger should not be placed over insensate skin.

Diathermy Therapy – Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy on patients implanted with a neuromodulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. The neuromodulation system, whether it is turned on or off, may be damaged.

Computed Tomography (CT) – Before beginning a CT scan, the operator should use CT scout views to determine if implanted or externally worn electronic medical devices are present and if so, their location relative to the programmed scan range.

For CT procedures in which the medical device is in or immediately adjacent to the programmed scan range, the operator should:

- Determine the device type;
- If practical, try to move external devices out of the scan range;
- Ask patients with neurostimulators to shut off the device temporarily while the scan is performed;
- Minimize 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:

- Have the patient turn the device back on if it had been turned off prior to scanning.
- Have the patient check the device for proper functioning, even if the device was turned off.
- Advise patients to contact their healthcare provider as soon as possible if they suspect their device is not functioning properly after a CT scan.

Magnetic Resonance Imaging (MRI) – The Senza, Senza II, and Senza Omnia Systems are MR Conditional which means that safety has been demonstrated only within specifically defined conditions. Scanning under different conditions may result in severe patient injury or device malfunction. Refer to the Nevro MRI guidelines manuals (available at www.nevro.com/physicianmanuals) for detailed information on MRI safety and conditions for MRI scanning of patients implanted with Nevro products.

Devices in Hospital/Medical Environments – The use of following medical devices or procedures may damage the SCS system or turn the stimulation off. After usage of these devices or procedures, the IPG may need to be explanted as a result of permanent damage.

- Electrocautery: The IPG should not be exposed to electrocautery. If electrocautery is necessary with the IPG implanted, use bipolar electrocautery. Do not use monopolar electrocautery.
- External defibrillation: The safety of discharge of an external defibrillator on patients implanted with an SCS system has not been established.
- Lithotripsy or high-output ultrasonics: Do not use these devices in patients with an implanted IPG.
- Radiation therapy: If radiation therapy is needed near the IPG, shield the area over the IPG.
- Ultrasonic scanning: Do not use it over the IPG.

If a patient is required to undergo lithotripsy, high-output ultrasound, electrocautery, external defibrillation, radiation therapy, or ultrasonic scanning, follow these precautions.

- Turn off the IPG before the procedure.
- Use the equipment as far away from the IPG as possible.
- 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 the patient suspects that the device is not functioning properly after the use of these therapies or procedures, advise the patient to contact his or her healthcare provider.

Electromagnetic Interference (EMI) – Electromagnetic energy is generated by equipment found in the home, work, medical or public environments. Electromagnetic interference may occur when the energy is strong enough to interfere with neurostimulator function. Most electrical devices and magnets that patients will encounter in a normal day are unlikely to affect the operation of the SCS system. However, some equipment may generate strong electromagnetic fields that can turn the stimulator (IPG or TSM) off or cause shocks or jolts (see below). Patients should keep away from areas of EMI and turn off the stimulator if they are in such an area. The following are examples of sources that can potentially generate strong EMI.

- Theft detectors or security screeners such as airport security screening devices, retail store, and libraries.

  Note: It is recommended that patients request assistance to bypass the theft detector or security screener. If they must go through a screening device, the patient should turn off the stimulator and go through the area as quickly as possible and as far away from the theft detector or security screener as possible.

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

If EMI is suspected or encountered, patients will need to turn off the stimulator. Then, the patients will need to move away from the EMI area and check whether the therapy is on or off. Before therapy can be turned on, the batteries may need to be replaced in the TSM or recharged in the IPG.

Strong electromagnetic interference can result in the following:

- **Serious patient injury,** resulting from heating of the implanted components of the neurostimulation system and damage to surrounding tissue.
- **System damage,** resulting in a loss of or change in symptom control and requiring surgical replacement.
- **Operational changes to the neurostimulator,** causing it to turn on or off
- **Unexpected changes in stimulation,** causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure the patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured.

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. 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 Simulator 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 the Patient 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 should be restarted. ESD events can be minimized by keeping the charger in the Charger Holster while recharging the IPG.

Radio-frequency or microwave ablation – Safety has not been established for radiofrequency (RF) or microwave ablation in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Patients with diabetes – This device was only studied in patients with HbA1C up to 10%. In general, patients with diabetes have a higher risk of surgical complications, especially those who are at high risk for ischemic heart disease and those with autonomic neuropathy or renal failure. Appropriate patient selection, pre-operative risk assessment, and reasonable optimization of glycemic control are recommended"

5. Precautions

Patients Who Are Poor Surgical Candidates – Do not implant an SCS system if a patient is considered a poor surgical candidate. Implanting an SCS system has risks similar to surgical procedures of the spine, including spinal fluid leak, headaches, swelling, bruising, bleeding, infection, or paralysis.

Pregnancy – The safety and effectiveness of spinal cord stimulation has not been established for use during pregnancy or nursing.

Patient Activities – Patients using therapy that generates paresthesia (see Warning regarding Stimulation Frequencies) may experience increased paresthesia when changing posture or making abrupt movements. Such patients should lower the amplitude or turn off the stimulation before making posture changes, such as stretching and moving their arms over their head. If unpleasant sensations occur, the IPG should be turned off.

Stimulation at 10 kHz does not generate paresthesia, so patients should not experience unpleasant sensations caused by posture changes or movement. As such, patients would not need to change amplitudes in their programs in response to posture changes or movement.

Patient Activities Related to Lead Movement – Advise patients to 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, the patient may need to be reprogrammed or the lead may need to be repositioned through another operation.

Scuba Diving and Hyperbaric Chambers – Patients should avoid scuba diving to depths greater than 35 meters and hyperbaric chambers with pressure greater than 4.5 ATM. Pressure greater than 35 meters or 4.5 ATM may damage the Senza, Senza II, or Senza Omnia systems.

Storage – Store the system components and accessories between the prescribed temperatures. Excessively hot or cold temperatures may damage the components, particularly high heat. Devices should be kept in temperature regulated areas within the acceptable temperature range. Do not expose the components to liquids or excessive moisture.

- The storage temperature for the IPG, Lead, Lead Extension, and Charger should not exceed the range of 0° C to 45° C (32° F to 113° F).
- The storage temperature for the Trial Stimulator and the Patient Remote Control should not exceed the range of -20 to 60 °C (-4 to 140 °F).

Sterilization – This device is for single use only and is not intended to be re-sterilized.

- Prior to opening the sterile package, inspect the sterilization indicator and the sterile package.
- Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
- Do not use any component that shows signs of damage.
- Do not re-sterilize the package or the contents. There is risk of infection and device malfunction.
- Do not use if "Use by" date has passed.
- All implanted components are intended for single use only. Do not re-use.

Handling – Use care when handling the system components and accessories. Do not drop them or submerge them in water. Do not impact the system components against hard surfaces and avoid rough handling.

Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water or other rough handling, can permanently damage the components and accessories. Do not plug the charger into a power source near water.

Handling the Leads and Lead Extensions - Follow these guidelines when handling the Leads or Lead Extensions:

- Lead and lead extension should be handled with care at all times.
- Do not make sharp bends to the lead or lead extension.
- Do not severely kink, crush or stretch the lead or lead extension.
- Do not apply severe torque (twist) to the lead or lead extension. Do not tie suture directly to the lead or the lead extension.
- When placing a suture around the lead, use the provided lead anchors.
- Do not force the lead into the epidural space. Use the lead blank prior to inserting the lead.
- Create a stress relief loop to minimize tension on the lead.
- Do not stretch the lead.
- Do not use sharp instruments to handle the lead or lead extension.
- Wipe off any bodily fluids (e.g. blood) from the lead's proximal end before connecting it to any other component.
- Wipe off any bodily fluids (e.g. blood) from the lead stylet before inserting or reinserting it into the lead.
- When inserting the stylet into the lead, do not use excessive force.

Handling the IPG - Follow these guidelines when handling the IPG:

- Avoid rough handling of the IPG.
- Take care not to drop the IPG. If it has been dropped to a hard surface, do not use the device and send it back to Nevro Corp.

System Compatibility – Do not use any cables or adaptors unless they are explicitly approved by Nevro Corp.

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

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 patients feel that the TENS may be interfering with the implanted neurostimulator, patients should discontinue using the TENS until they talk with their doctor.

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

IPG Location and Patient Manipulation – Advise patients 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. The patient's manipulation of the IPG in his or her body may cause the skin over the IPG to become thinner over time.

Infection – Use proper infection control procedures. If a patient experiences persistent discomfort or excessive redness around the wound areas, the patient may need to be checked for infection. Infections related to the SCS 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.

Operating Temperature – The operating temperature range for the Patient Remote Control is 10 to 40 °C (50 to 104 °F). The operating temperature range for the Trial Stimulator is 10 to 38 °C (50 to 100 °F). While the Charger is plugged into the wall and charging itself, the operating temperature range for the Charging System is 10 to 40 °C (50 to 104 °F). While the Charger is charging the IPG, the operating temperature for the Charging System is 10 to 30 °C (50 to 86 °F).

Caring for the Trial Stimulator, Remote Control, and Charging System – These components can be cleaned by rubbing all surfaces without undue pressure with soft cloth damped with water, isopropyl alcohol or mild detergent. The remaining residue should be removed by wiping the surfaces with a dry cloth. Do not use abrasive cleansers for cleaning. Do not allow moisture to get inside the components.

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

IPG Failure – If the patient's 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 Nevro Corp. When frequency of recharging becomes too inconvenient for your patient, the IPG may need to be replaced. Contact Nevro Corp.

Device Disposal – Do not dispose the IPG, Patient Remote Control or Charger in fire. The battery in these devices can explode in fire. The IPG should be explanted in the case of cremation. All explanted IPGs should be returned to Nevro Corp. Do not dispose of electrical components, including batteries, in the unsorted municipal waste stream. Dispose of electrical components, including batteries, according to local regulations.

Long-Term Effectiveness of Spinal Cord Stimulation – 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.

FCC Statements: Senza IPG, Trial Stimulator and Patient Remote -
Senza IPG FCC ID: XKYIPG1000, XKYIPG1500, XKYIPG2000
Trial Stimulator FCC ID: XKYEXTS1000
Patient Remote FCC ID: XKYPTRD1000, XKYPTRD2500

Note:

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
    - Reorient the receiving antenna.
    - Increase the separation between the equipment and the antenna.
    - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
    - Consult the dealer or an experienced radio/TV technician for help.

- This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.
- Do not change or modify any component of the Senza, Senza II, or Senza Omnia Spinal Cord Stimulation systems, unless expressly approved by Nevro Corp.

FCC Statements: Programmer Wand -
Programmer Wand FCC IDs: XKYWAND1000, XKYWAND1001

Note:

- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The equipment generates, uses and can radiate radio frequency energy and may cause harmful interference to radio communications if it is not installed and used in accordance with the instruction manual. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.
- This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.
- Do not change or modify any component of the Senza, Senza II, or Senza Omnia Spinal Cord Stimulation systems, unless expressly approved by Nevro Corp.

6. Adverse Effects

There are potential risks associated with the use of any SCS system. Potential risks may be related to the implant procedure, the stimulation, or a component of the device system. Instruct the patient to contact their physician should they experience any device related adverse event. Possible risks include the following:

Implant Procedure and Medical Risks

- Risks associated with anesthesia, including cardiac arrest
- Surgical complications, such as infection, cellulitis, abscess, fever, sepsis, bleeding
- Cerebrospinal fluid leak
- Intracranial hypotension
- Hematoma, seroma or thrombosis
- Epidural hemorrhage
- Impaired or inadequate wound healing, wound dehiscence
- Temporary or persistent tenderness or pain at implant site
- Lead migration leading to ineffective pain control or other undesirable changes in stimulation
- Suboptimal lead or IPG placement or migration requiring revision or explant
- Spinal cord compression; nerve, nerve root, or spinal cord injury
- Paralysis
- Death

Stimulation

- Loss of pain relief, loss of paresthesia, unpleasant paresthesia
- Increased pain

- Undesirable stimulation due to cellular changes over time in tissue around electrodes, changes in electrode position, loose electrical connections, or lead failure
- Uncomfortable stimulation of tissue around the leads including skin and muscle
- Other undesirable sensation such as tingling or prickling
- Weakness, clumsiness or numbness

Implanted Device Components

- Tissue reaction or allergy to implanted materials
- Persistent pain at implant site (lead or IPG)
- 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, and possibly requiring explant and re-implantation
- Skin erosion or seroma at the lead or IPG site
- Pressure sores
- External sources of electromagnetic interference that cause the device to malfunction and could affect stimulation
- 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
- Infection
    - 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. (professional.medtronic.com/wcm/groups/mdtcom_sg/@mdt/@neuro/documents/documents/scs-compression-ltr-feb2014.pdf)

External Device Components

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

Please consult the Clinical Summary (P/N 12057) for additional information regarding clinical studies of the Senza system and safety and effectiveness data.

7. Technical Specifications

a. System Specifications

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

b. 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.

c. 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

d. Quality of Wireless Service

The Senza, Senza II, and Senza Omnia Systems use 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 Patient Remote/Programmer Wand and Implantable Pulse Generator/Trial Stimulator. Before each communication, the Patient Remote/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.

e. Wireless Security

The Senza, Senza II, and Senza Omnia Systems have a telemetry range of less than 5 feet (1.5 meters). The Patient Remote is uniquely paired to a specific Implantable Pulse Generator or Trial Stimulator and can only communicate with that device. The Implantable Pulse Generator 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.

f. Telemetry Information

The Senza, Senza II, and Senza Omnia Systems use 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 Patient Manual for more information on optimizing communication.
Refer to the tables in the "Electromagnetic Interference" section to determine the recommended separation distances between the Senza, Senza II, or Senza Omnia system and other transmitters.

g. Wireless Charging Information

The Senza, Senza II, and Senza Omnia Systems use charging frequency of 410 - 485 kHz. The charging distance between the Charger and the IPG is between 0 to 2.5 cm. Refer to the instructions provided in the Patient Manual to optimize charging.

h. Electromagnetic Interference

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The Senza, Senza II, and Senza Omnia Systems are intended for use in the electromagnetic environment specified below. The customer or user of the Senza, Senza II, or Senza Omnia System should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment Guide</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The Senza, Senza II, and Senza Omnia Systems use 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B
Class A (Programmer Wand)</td><td rowspan="3">The Senza, Senza II, and Senza Omnia Systems are 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 directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class B</td></tr>
<tr><td>Voltage fluctuations / Flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and Manufacturer's Declaration - electromagnetic immunity			
The Senza, Senza II, and Senza Omnia Systems are intended for use in the electromagnetic environment specified below. The customer or user of the Senza/Senza II/Senza Omnia 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	± 8 kV contact ± 2/4/8/15 kV air	± 8 kV contact ± 2/4/8/15 kV air	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	± 2 kV, 100 kHz PRR	± 2 kV, 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 Senza/Senza II/Senza Omnia System requires continued operation during power mains interruptions, it is recommended that the Senza/Senza II/Senza Omnia 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, Senza II, and Senza Omnia Systems are intended for use in the electromagnetic environment specified below. The customer or user of the Senza/Senza II/Senza Omnia 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	3 Vrms 6 Vrms in ISM + Amateur Radio Bands 150 kHz to 80 MHz 3 Vrms 6 Vrms in ISM Bands 150 kHz to 80 MHz (Programmer Wand)	3 Vrms 6 Vrms in ISM + Amateur Radio Bands 150 kHz to 80 MHz 3 Vrms 6 Vrms 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/Senza II/Senza Omnia 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, (a) 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/Senza II/Senza Omnia System is used exceeds the applicable RF compliance level above, the Senza/Senza II/Senza Omnia 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/Senza II/Senza Omnia 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/Senza II/Senza Omnia System			
The Senza, Senza II, and Senza Omnia Systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Senza/Senza II/Senza Omnia System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Senza/Senza II/Senza Omnia 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.			

The Senza, Senza II, and Senza Omnia systems are expected to operate normally in the presence of electromagnetic interference. If an interruption in communication is encountered, the user is advised to re-orient or re-locate the Programmer Wand or Patient Remote. If the user experiences an unexpected change in stimulation, the stimulation may be adjusted or turned off. See Section 4 for additional warnings.

8. Patient Identification

Please ensure that the patient receives a completed identification card following surgery.

9. Instructions for Use

The physicians providing SCS therapy with the Senza, Senza II, and Senza Omnia Systems should be experienced in the diagnosis and treatment of chronic pain and have proper surgical and clinical training. See sections 10 and 11 below on details for instructions for use.

10. Guidelines for Trial-phase Implantation

This section details the recommended procedures for trial-phase implantation of lead(s).

a. Temporary vs. Permanent Trials

- Physicians may elect to perform a trial in one of two ways, temporary or permanent. Nevro devices can be used with either method.
- In a **temporary trial**, the lead is placed in the patient, and the proximal end is externalized and connected to the Trial Stimulator using a connecting cable, which is referred to as the OR Cable. When the trial is over, the lead is removed from the patient. Subsequently, when a permanent system is implanted, the patient receives a new lead and IPG.
    - To perform a temporary trial, use the directions in the following sections in the order below:
        1. Pre-op Instructions
        2. Lead Placement
        3. Performing Intra-operative Testing
        4. Preparing for Temporary Trial
        5. Connecting the Lead or Extension to the Trial Stimulator
- In a **permanent trial**, the lead is placed in the patient and then fully implanted. The lead is attached to a lead extension, which is externalized and connected to the Trial Stimulator using an OR Cable. With this approach, the implanted lead remains sterile. When a permanent system is implanted, the extension is discarded and the implanted lead is connected to an IPG. Depending on the patient body and the lead length that was used, a new lead extension may be necessary to connect the lead to the selected IPG site.
    - To perform a permanent trial, use the directions in the following sections in the order below:
        1. Pre-op Instructions
        2. Lead Placement
        3. Performing Intra-operative Testing
        4. Anchoring the Lead
        5. Connecting an Extension to the Lead
        6. Percutaneous Tunneling of the Extension
        7. Closing the Incision Sites
        8. Connecting the Lead or Extension to the Trial Stimulator

b. Pre-op Instructions

- Before opening the packages, verify the use-by date and the description of the component, such as length and type.
- Do not use any component that shows signs of damage.

- NOTE:
    - Confirm that the Trial Stimulator has batteries. When inserting batteries into the Trial Stimulator, match the positive (+) end of the battery to the positive (+) symbol inside the battery compartment.
    - Turn off the Trial Stimulator before taking out the batteries.
    - The Trial Stimulator's battery compartment must remain closed unless the batteries are actively being replaced.
    - The M8 Adaptor (MADP-25B) can be used to connect specific Medtronic leads to the Nevro Trial Stimulator/IPG. The S8 Adaptor (SADP-25B) can be used to connect specific St. Jude Medical/Abbott leads to the Nevro Trial Stimulator/IPG. For a list of compatible leads, please consult the M8 Adaptor/S8 Adaptor Instructions for Use.
    - Adaptors are not required to connect compatible Boston Scientific leads to the Trial Stimulator. The following Boston Scientific neuromodulation leads and extensions can be used interchangeably with Nevro's leads and extensions during the trial phase implantation and permanent implantation.[1] (Note: xx = length (cm))
        - SC-2016-xx Infinion™ 16 Lead and Splitter 2x8 Kit[2]
        - SC-2016-xxE Infinion 16 Lead and Splitter 2x8 Trial Kit
        - SC-2138-xx Linear™ xxcm 8 Contact Lead
        - SC-2158-xx Linear xxcm 8 Contact Lead
        - SC-2158-xxE Linear xxcm 8 Contact Lead
        - SC-2208-xx Linear ST xxcm 8 Contact Lead
        - SC-2218-xx Linear ST xxcm 8 Contact Lead
        - SC-2218-xxE Linear ST xxcm 8 Contact Lead
        - SC-2352-xx Linear 3-4 xxcm 8 Contact Lead
        - SC-2352-xxE Linear 3-4 xxcm 8 Contact Lead
        - SC-2366-xx Linear 3-6 xxcm 8 Contact Lead
        - SC-2366-xxE Linear 3-6 xxcm 8 Contact Lead
        - SC-3138-xx xxcm 8 Contact Extension
        - SC-3304-xx D4 Splitter 2x4
        - SC-3354-xx W4 Splitter 2x4
        - SC-2316-xx Infinion 16 xxcm 16 Contact Lead Kit
        - SC-2316-xxE Infinion 16 xxcm 16 Contact Trial Lead Kit
        - SC-3400-xx xxcm Splitter 2x8 Kit
        - SC-3138-xx xxcm 8 Contact Extension
        - SC-8120-xx Artisan 2x8 Surgical Lead
        - SC-8216-xx Artisan 2x8 Surgical Lead

c. Percutaneous Lead Placement

- Prep the skin and drape the patient in a usual sterile fashion.
- Confirm pre-operative antibiotic prophylaxis if deemed appropriate.
- Inject a local anesthetic at the desired needle insertion site.
- Insert the needle at an angle of 45° or less (pointing the needle in the direction of the target location) into the posterior ligamentous complex at the desired vertebral level using fluoroscopic guidance.

[1] Verification documentation is on file at Nevro Corp.

[2] To use Infinion Leads with the Senza/Senza II/Senza Omnia System, connect the Infinion Lead to the Splitter 2x8.

- Remove the needle-stylet from the needle cannula and confirm entry into the epidural space using standard methods such as loss of resistance. Verify needle location using fluoroscopy.
- In order to advance the lead easier, you may insert the lead blank through the needle and then withdraw it. Use fluoroscopic guidance.
- Prior to inserting the lead into the needle, ensure that the stylet is fully inserted and extended to the tip of the lead to ensure optimal steering of the lead.
- With the stylet in the lead, slowly advance the lead into the epidural space.
- Advance the lead to the appropriate vertebral level using fluoroscopic guidance. Rotate the stylet as necessary to steer the lead.
- NOTE:
    - Needles not provided by Nevro Corp. may damage Nevro leads.
    - Inserting the lead while the needle is at an angle of greater than 45° may increase difficulty in placing the lead or damage the lead.
    - If you are inserting a second lead, insert the second needle in such a way that doesn't damage the first lead.
    - If sedation or Monitored Anesthesia Care is used, it is recommended that the patient remain communicative during needle and lead placement to help mitigate any risk of neural injury.

d. Surgical Lead Placement

- Refer to the relevant Surgical Lead Manual.

e. Performing Intra-operative Testing

- After the lead is in the desired location, you are ready to attach the OR Cable to the lead.
- If two leads are used, the leads may be marked using a sterile surgical marker, to distinguish between the two leads.
- Open the connector box of the OR Cable by pushing the two tabs away from each other. Insert the proximal end of the lead (or the lead extension) into the connector box.
- When the most proximal contact of the lead is seen in the first notch of the connector box, close the connector box by pushing the two tabs towards each other.
- The OR Cable is usually not long enough to reach outside the sterile field, so an OR Cable Extension may need to be attached. The OR Cable Extension is designed for temporary connection to the OR Cable to facilitate stimulation testing outside of the sterile field.
- Ensure that the Trial Stimulator is off.
- Connect the OR Cable or the OR Cable Extension to the Trial Stimulator.
- Conduct impedance testing.
- Verify lead position. Paresthesia mapping is not required for 10 kHz programming.
    - If frequencies up to 1200 Hz are used for programming, paresthesia mapping is needed. For paresthesia mapping, use the following directions.
        1. Ensure that the patient can give immediate feedback.
        2. Conduct test stimulation. Select contacts and adjust amplitude, pulse width, and pulse rate until patient has satisfactory paresthesia coverage of the pain areas.
        3. If satisfactory paresthesia coverage cannot be achieved, reposition the leads as necessary and repeat stimulation.
        4. Repeat steps 2-3 as needed.
- Turn off the Trial Stimulator and disconnect the lead from the OR Cable.
- At this point, you can opt to do a temporary lead trial or a permanent lead trial.
- CAUTION:

- Do not immerse the OR cable connector or plug in water or other liquids. Wipe fluids (e.g. blood) off the exposed lead connections to ensure that it is dry.
- The OR Cable Assembly is intended for one-time only use. Do not re-sterilize.
- Always turn the Trial Stimulator off before connecting or disconnecting the Cable Assemblies.
- Do not pull on the OR cable while it is connected to the placed lead.

f. Preparing for Temporary Trial

- Using minimal force, carefully withdraw the insertion needle from the patient while holding the percutaneous lead.
- Using minimal force, carefully withdraw the stylet while holding the percutaneous lead.
- After removing the needle and the stylet, it is recommended that you confirm the location of the lead using fluoroscopy.
- Secure the lead to the skin using sterile tape or suturing to the skin. If you are suturing the lead to the skin, use a non-absorbable suture and the supplied anchoring device. Tying sutures directly to the lead can damage the lead.
- NOTE: Percutaneous leads are suggested for temporary trial use when implantation of a surgical lead for permanent stimulation is planned. Refer to the Surgical Lead Manual for details on surgical lead placement.

g. Anchoring the Lead

- After assuring appropriate anesthesia, make a longitudinal incision around the needle and use a combination of sharp and blunt dissection to access the supraspinous ligament.
- Using minimal force, carefully withdraw the insertion needle from the patient while holding the lead.
- Using minimal force, carefully withdraw the stylet while holding the lead.
- After removing the needle and the stylet, it is recommended that you confirm the location of the lead using fluoroscopy. Place suture(s) over the anchor.
    - For a silicone anchor:

      At least one suture is needed (two are recommended) to tie the lead anchor to the lead, and another suture is needed to attach the lead anchor and lead to the patient's tissue.
        1. Slide the lead anchor over the lead and to the supraspinous ligament.
        2. Use a non-absorbable suture(s) to tie the lead anchor to the lead. Tie the suture around a groove or over the bumps on the lead anchor to prevent the lead from sliding.
        3. Suture the lead anchor to the supraspinous ligament or deep fascial tissue. Run the suture through the eyelets on the lead anchor or around the bumps or grooves of the lead anchor. Make sure the suture is firm enough to hold the anchor to the tissue.
    - For an active anchor:

      At least one suture is needed (two is recommended) to attach the lead anchor to the tissue.
        1. Slide the lead anchor over the lead and to the supraspinous ligament.
        2. Use non-absorbable suture(s) to attach the lead anchor to the patient's tissue. Suture the lead anchor to the supraspinous ligament or deep fascial tissue. Run the suture through the eyelets on the lead anchor or around the grooves of the lead anchor. Make sure the suture is firm enough to hold the lead anchor to the tissue.

3. Use the supplied torque wrench to tighten the anchor to the lead. Tighten the torque wrench in clockwise direction until the audible click is heard.

- CAUTION:
  - Tying sutures directly on the lead can damage the lead. Always use a lead anchor(s).
  - Do not use polypropylene sutures as they may damage the lead anchor.
  - Do not use a hemostat on the lead body. This may damage the lead insulation.
  - If needed, it is recommended that bipolar electrocautery is used for hemostasis around the epidural needles. Energy from monopolar cauterization could conduct down the needle to the epidural space and damage the neural structures.
  - If the lead does not fully insert into the active anchor, loosen the anchor by turning the torque wrench counter-clockwise and then re-insert the lead.
  - Use only the appropriate torque wrench provided by Nevro Corp.

h. Connecting an Extension to the Lead

- Wipe fluids (e.g. blood) from the proximal end of the lead. Then fully insert the proximal end of the lead into the lead extension's connector.
- Do an impedance check.
- Do not tighten the setscrew on the extension until all of the impedances are in the normal range.
- Fully insert the torque wrench into the setscrew.
- Rotate the torque wrench handle to turn the lead extension connector's setscrew clockwise until it clicks. Clicking indicates that it is fully tightened.
- NOTE:
  - Ensure that the setscrew is not removed from the connector.
  - If the lead does not fully insert into the lead extension's connector, check to see whether the setscrew is impeding the progress of the lead. If it is, use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-insert the lead.
  - If the setscrew does not tighten smoothly, try the following:
    1. Use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-tighten by turning it clockwise.
    2. Check to see that the lead is fully inserted into the lead extension's connector before tightening.
  - The wrench is torque-limited and cannot be over tightened if you use the handle.
  - Use only the appropriate Nevro torque wrench to ensure that the proper torque is applied to the setscrews.

i. Percutaneous Tunneling of the Extension

- Assemble the tunneling tool by screwing in one of the tips on the end of the shaft. Make sure the straw is on the shaft prior to screwing in the tip.
- Plan the desired route of the tunnel and mark the route and the destination point at least 10-15 cm from the incision.
- Give appropriate local anesthetic along the tunneling route.
- Create a small incision at the planned extension exit site.
- Insert the tunneling tool from the lead insertion site and create a subcutaneous tunnel to the extension exit site until the straw can be seen.
- Hold the tunneling tip firmly and then unscrew and remove the tunneling tip. Take care not to drop the tunneling tip.
- Remove the tunneling tool while leaving the straw in the tunnel.

- Insert the proximal end of the lead extension(s) through the straw.
- Push the lead extension(s) until they come out of the straw's other end.
- Gently pull the extension(s) to get as much of the extension(s) that you need through the straw, and then withdraw the straw from the exit site. It is recommended that a strain relief loop is left in the dorsal wound.
- Make sure that the lead location has not changed.
- NOTE: In place of the tunneling tool, the following Codman Disposable Catheter Passers may be used using the standard technique: REF 82-1515 (36cm); REF 82-1516 (55cm); REF 82-1517 (65cm).

j. Closing the Incision Sites

- At the lead insertion site, use blunt dissection to create a pocket large enough to place excess lead. Coil excess lead into small loops and place them in the pocket.
- Gently pull on the lead extension from the exit site to remove excess slack.
- Close the incision at the lead insertion site.
- A small suture may be used to close the incision at the exit site. Do not tighten a suture around the lead or lead extension.
- Create a stress relief loop outside the body and tape it to the skin.
- Appropriate sterile dressings must be applied to the site where the lead or lead extension exits the body.

k. Connecting the Lead or Extension to the Trial Stimulator

- Appropriate sterile dressings must be applied to the site where the lead or lead extension exits the body. Tape the lead securely to the skin.
- Connect the lead or lead extension to the OR Cable.
- Create a loop of the OR Cable for strain relief and then tape the OR Cable to the skin.
- Connect the OR Cable to the Trial Stimulator.

11. Guidelines for Permanent Implantation

This section details the recommended procedures for permanent implant-phase.

a. Pre-op instructions

- Before opening the packages, verify the use-by date and the description of the component, such as length and type.
- Do not use any component that shows signs of damage.
- Ensure that the IPG is charged prior to implant

b. If the patient was given a temporary trial

- NOTE: At the end of a temporary trial, remove the temporary trial lead(s) as described below and follow the "IPG Implantation" section below. The leads will typically be removed before a patient comes in for the permanent implant.
- Removing the temporary trial lead(s):
    - Clip sutures if they were used to secure the lead(s) in place.
    - Remove the lead(s) and discard.
- Place lead(s) by following previous sections for:
    1. Pre-op Instructions
    2. Lead Placement

3. Performing Intra-operative Testing
4. Anchoring the Lead

- Prepare the IPG implant site and tunnel the lead to the IPG site by following the instructions below:
    - Prepare the skin and drape in the usual sterile fashion.
    - With consideration for patient comfort and infection control, identify a desired IPG implant site away from the exit site for the lead extension used for the trial.
    - Anesthetize the site for the IPG pocket.
    - Use the IPG template to estimate the size of the pocket. Mark the IPG implant site and make an incision that would be adequate to insert the IPG.
    - Create a subcutaneous pocket using blunt dissection. The pocket should be no larger than the IPG and no deeper than a depth of 2 cm from the skin.
    - NOTE:
        1. For optimal charging, the IPG must be no more than 2 cm from the surface of the skin.
        2. Deep tunneling is not recommended.
    - Assemble the tunneling tool by screwing in one of the tips on the end of the shaft. Make sure the straw is on the shaft.
    - Mark the desired tunneling route.
    - Give appropriate local anesthetic along the tunneling route.
    - If necessary, gently bend the shaft of the tunneling tool to conform to the patient's anatomy.
    - Create a subcutaneous tunnel between the IPG implant site and the lead anchor site. Insert the tunneling tool until the tip of the straw is out of the tunnel.
    - Hold the tunneling tip firmly and then unscrew and remove the tunneling tip. Take care not to drop the tunneling tip.
    - Remove the tunneling tool's tip. Remove the tunneling tool, while leaving the straw in the tunnel.
    - If necessary, use a lead extension. (Refer to the previous section on "Connecting an Extension to the Lead")
    - Insert the proximal end of the lead(s) or lead extension(s) through the straw.
    - Push the lead(s) or lead extension(s) until they come out of the straw's other end.
    - Gently pull the lead to get as much of the lead that you desire through the straw, and then carefully withdraw the straw. It is recommended that a strain relief loop is left in the dorsal wound.
    - Make sure that the lead location has not changed.
- Follow the instruction on ***IPG Implantation*** below.

c. If the patient was given a Permanent trial

- NOTE: At the end of a permanent trial, remove the lead extension(s) as described below and follow the "IPG Implantation" section below.
- Removing the lead extension(s):
    - Prepare the skin and prep the patient in the usual sterile fashion. It is recommended to prep the midline incision in the sterile field and leave the extension site outside the sterile field so that it can be removed by an OR assistant.
    - Open the midline incision.
    - Cut the lead extension at the connector at the lead insertion site. Confirm that you are cutting the lead extension, not the lead.

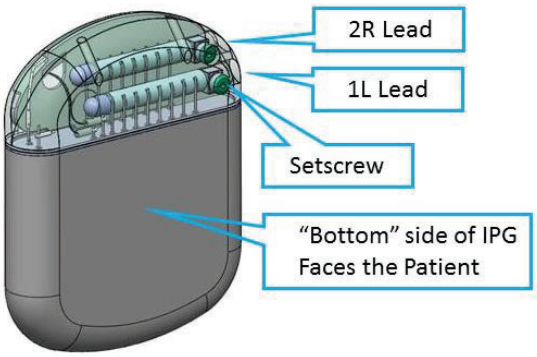
- Use the torque wrench to loosen the setscrew in the lead extension connector. Disconnect the head of the lead extension.
- Remove the lead extension by pulling on the portion of the lead extension that is already externalized. This will be done outside the sterile field.
- Discard the head of the lead extension.

- Prepare the IPG implant site and tunnel the lead to the IPG site by following the instructions below:
  - With consideration for patient comfort and infection control, identify a desired IPG implant site away from the exit site for the lead extension used for the trial.
  - Anesthetize the site for the IPG pocket
  - Mark the IPG implant site and make an incision equal to the IPG's width.
  - Create a subcutaneous pocket using blunt dissection. The pocket should be no larger than the IPG and no deeper than a depth of 2 cm from the skin.
  - NOTE:
    1. For optimal charging, the IPG must be no more than 2 cm from the surface of the skin.
    2. Deep tunneling is not recommended.
    3. In place of the tunneling tool, the following Codman Disposable Catheter Passers may be used using the standard technique: REF 82-1515 (36cm); REF 82-1516 (55cm); REF 82-1517 (65cm).
  - Assemble the tunneling tool by screwing in one of the tips on the end of the shaft. Make sure the straw is on the shaft.
  - Mark the desired tunneling route.
  - Give appropriate local anesthetic along the tunneling route.
  - If necessary, gently bend the shaft of the tunneling tool to conform to the patient's anatomy.
  - Create a subcutaneous tunnel between the IPG implant site and the lead anchor site. Insert the tunneling tool until the tip of the straw is out of the tunnel.
  - Hold the tunneling tip firmly and then unscrew and remove the tunneling tip. Take care not to drop the tunneling tip.
  - Remove the tunneling tool's tip. Remove the tunneling tool, while leaving the straw in the tunnel.
  - If necessary, use a lead extension. (Refer to the previous section on "Connecting an Extension to the Lead")
  - Insert the proximal end of the lead(s) or lead extension(s) through the straw.
  - Push the lead(s) or lead extension(s) until they come out of the straw's other end.
  - Gently pull the lead to get as much of the lead or lead extension that you desire through the straw, and then carefully withdraw the straw. It is recommended that a strain relief loop is created.
  - Make sure that the lead location has not changed.
- Follow the instruction on ***IPG Implantation*** below.

d. IPG Implantation

- Confirm that no hemostasis is required.
- The IPG should not be exposed to electrocautery. If the use of electrocautery is necessary, turn off the IPG and use bipolar electrocautery. Do not use monopolar electrocautery.
- Wipe the proximal end of the lead(s) or lead extension(s).

- The most cephalad or left lead or lead extension connects to IPG port 1L. The most caudal or right lead or lead extension connects to IPG port 2R.



- Place the lead(s) or lead extension(s) fully into the header port and perform impedance check.
- NOTE:
    - When using two leads, connect the left lead or lead extension to IPG port 1L. Then, connect the right lead or lead extension to IPG port 2R.
    - When using one lead, start by placing the port plug in the 2R port of the IPG and tighten the setscrew. Then insert the lead into IPG port 1L. It is recommended not to tighten the setscrew until the lead is fully inserted in the 1L port and impedance check has been performed.
    - If any of the contacts have unusually high impedance, re-insert the lead or lead extension into the header.
- Insert the torque wrench through the septum in the IPG header and fully into the setscrew socket. The torque wrench will be exactly perpendicular to the broad side of the IPG when properly aligned.
- Turn the torque wrench's handle clockwise until it clicks. Clicking indicates that it is fully tightened.
- NOTE:
    - Ensure that the setscrew is not removed from the header.
    - If the lead or lead extension does not fully insert into the IPG header, check to see whether the setscrew is not impeding the progress of the lead or lead extension. If it is, use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-insert the lead or lead extension. Check every full turn of the torque wrench to guard against completely pulling out the setscrew.
    - If the setscrew does not tighten smoothly, try the following:
        1. Use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-tighten by turning it clockwise.
        2. Check to see that the lead or lead extension is fully inserted into the IPG header before tightening. Check impedance again before tightening.
    - The wrench cannot be over tightened if you use the handle.
    - The lead or lead extension could be damaged if the setscrew is tightened without being fully inserted.
    - Use only the appropriate Nevro torque wrench.
- Place the IPG in the subcutaneous pocket with "This Side Up" facing towards the skin.
- It is recommended that non-absorbable sutures are placed through the suture holes in the IPG header and attached to the patient.
- Check communications between the IPG and the programmer prior to closing the IPG pocket wound. This can be done by taking an impedance measurement.
- Close all wounds and apply dressings in the usual surgical manner.

e. IPG Explant or Replacement

- Turn off the IPG.
- Surgically open the IPG pocket and withdraw the device.
- It is recommended that electrocautery not be used until the IPG is removed from the patient and the leads or extensions disconnected from the IPG. If the use of electrocautery is necessary while the IPG is still implanted, use bipolar electrocautery. Do not use monopolar electrocautery.
- Unscrew the connector setscrews to release and disconnect the leads or extensions.
- For replacement, connect a new IPG to the leads or extensions. To discontinue therapy, surgically remove the implanted lead system.
- NOTE:
    - Be careful not to cut the lead(s) or extension(s) when making an incision to remove the IPG.

12. Additional considerations for patients with diabetes

To identify suitable patients for device implantation and manage patient risks before, during, and after the procedure, consider the following:

Stage of Care	Considerations for Patients with Diabetes
Pre-operative	• Patients suitable for HF10 therapy with painful diabetic neuropathy symptoms that are refractory to or intolerant of conventional medical therapies, including medications recommended for pain by the American Diabetes Association's Standards of Medical Care in Diabetes.[3] • Attempts to optimize the patient's glycemic control should be made prior to the procedure. • Pre-operative risk assessment should be performed for patients with diabetes and any other comorbidities. • Coordination among healthcare providers involved in the patient's care team may aid in risk mitigation. • Appropriate patient counselling regarding potential surgical risks should be communicated.

Perioperative	• Consider the Perioperative Care guidelines as established in American Diabetes Association's Standards in Medical Care in Diabetes,[3] especially:
	  ○ appropriate target blood glucose range for perioperative period whilst balancing potential risks of hypoglycemia
	• Additional guidance can be found:
	  ○ Society for Ambulatory Anesthesia's consensus statement on perioperative blood glucose management in patients with diabetes undergoing ambulatory surgery[4]

[3] American Diabetes Association Standards of Medical Care in Diabetes-2021. *Diabetes Care*. 2021;44(Suppl 1):S1-S232

[4] Joshi GP, Chung F, Vann MA, Ahmad S, Gan TJ, Goulson DT, et al. Society for Ambulatory Anesthesia consensus statement on perioperative blood glucose management in diabetic patients undergoing ambulatory surgery. *Anesth Analg*. 2010;111(6):1378-87

	○ Centers for Disease Control and Prevention guideline for the prevention of surgical site infection[5]
Post-operative	• Due to the potential for increased risk of infection in patients with diabetes, careful oversight of wound healing may help identify potential infections early to initiate treatment. • Continued careful management of blood glucose during healing may reduce risk of infection. • Close collaboration between the referring physician and the implanting physician will aid in optimal post-operative management.

Data from Senza-PDN study and overall risk-benefit determination [Section II.C Senza PDN Study in Clinician Summary Manual] provide evidence that the Senza SCS device, providing HF10 therapy, is safe and effective for the treatment of chronic intractable pain in the lower limbs due to diabetic neuropathy. Careful and appropriate patient selection is needed to reduce the known risks, such as surgical site infection, associated with implantation of SCS devices and to avoid complications associated with poor glycemic control.

Note: For detailed inclusion/exclusion criteria for patients included in the Senza-PDN study, refer to Study Design Section under Senza-PDN Study in Clinician Summary Manual.

13. Device Information for the Clinical Staff

a. Trial Stimulator

Locking and Unlocking the Trial Stimulator

- NOTE: When the buttons on the Trial Stimulator are not pressed for longer than 1 minute, the Trial Stimulator will "lock". Only the red button, which turns the stimulation off, is operable when the Trial Stimulator is in the locked mode.
- Unlocking the Trial Stimulator: To unlock, press and hold both the '+' and '-' buttons simultaneously on the Trial Stimulator for longer than 2 seconds. The Trial Stimulator will beep once for 1 second when it is unlocked.

b. Rechargeable IPG

- The Senza, Senza II, Senza Omnia IPGs are rechargeable. Nevro recommends a recharge schedule that fits the patient's schedule and lifestyle while maintaining sufficient charge to deliver a desired level of stimulation.
- The rechargeable implant battery should provide at least 10 years of service on typical 10 kHz program stimulation settings.[6] If lower power stimulation parameters are used to deliver therapy, the battery should provide service for a longer period of time. At power levels higher than typical settings, the years of service may be shorter for the IPG.
- With repeated charging over time, the IPG battery will gradually lose its ability to recover its full capacity. When the patient cannot maintain therapy with daily charging, the IPG may need to be replaced.

[5] Berríos-Torres et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg

[6] Testing on file at Nevro Corp.

Refer to the Patient Manual (Document number: 11052) available at www.nevro.com/manuals for detailed instructions on the Trial Stimulator, Patient Remote Control, and Charging system.

Refer to the Nevro MRI guidelines manuals (available at www.nevro.com/physicianmanuals) for detailed information on MRI safety and conditions for MRI scanning of patients implanted with Nevro products.

Refer to Clinician Summary Manual (available at www.nevro.com/physicianmanuals) for details on the Senza clinical studies' design and results.

NEVRO CORP.

All questions or concerns about Nevro Corp. products should be forwarded to:

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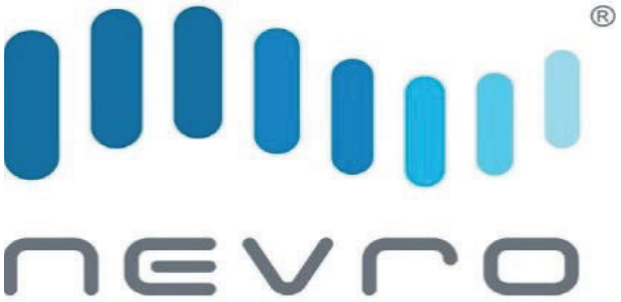

INFORMATION FOR PRESCRIBERS

Senza® Bluetooth® Trial System

Effective April 2021

10001045 Rev C

All questions or concerns about Nevro Corp. products, including any serious incident that has occurred in relation to the device, should be forwarded to:

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Nevro® hereby declares that the Senza® Bluetooth® System is in compliance with the essential requirements and other relevant provisions of the Radio Equipment Directive (2014/53/EU) and U.S. FCC CFR 47 Part 15.

IMPORTANT: Do not change or modify any component of the Senza® Bluetooth® Spinal Cord Stimulation System, unless expressly approved by Nevro Corp.

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

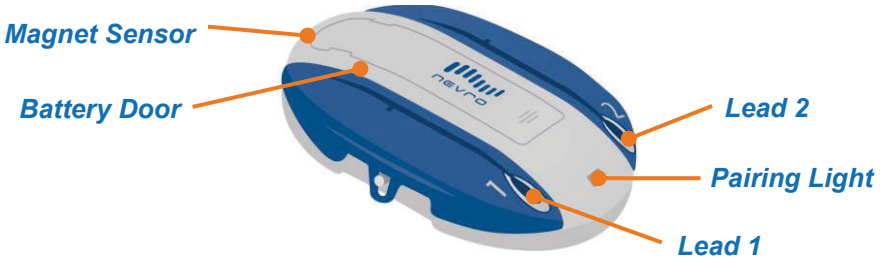
CONTENTS

1 DEVICE AND PRODUCT DESCRIPTION

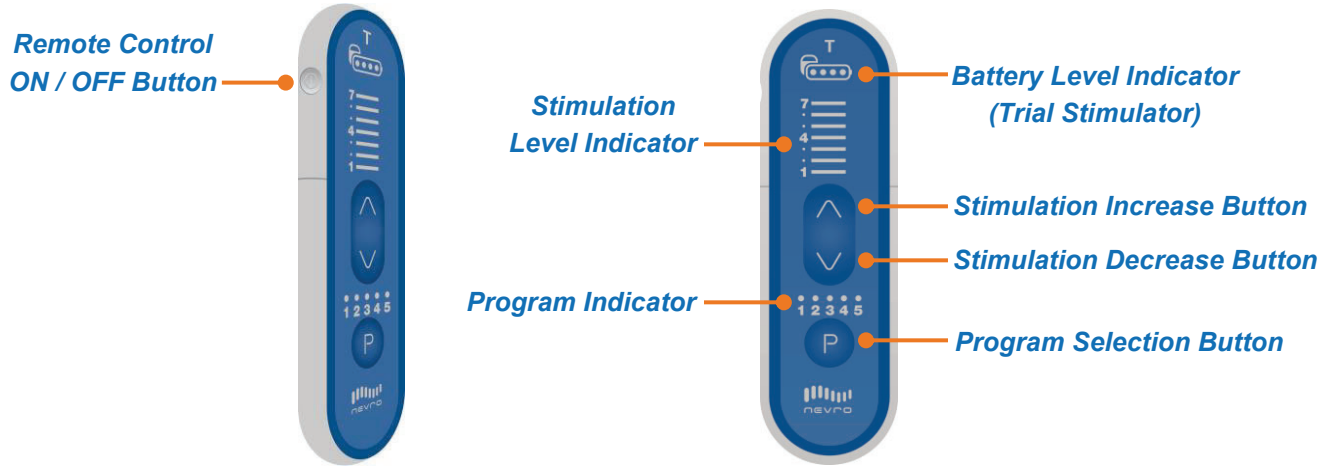
The Nevro® Senza® BLUETOOTH® enabled Spinal Cord Stimulator (SCS) Trial System works by delivering electrical energy from a stimulator to an area around the spine. The system is capable of delivering HF10® therapy, a therapy that does not produce tingling sensations called paresthesia. It is also capable of providing stimulation that produces paresthesia at some therapy settings. For SCS therapy, a patient will typically first go through a trial phase to evaluate the therapy to see if it is right for them.

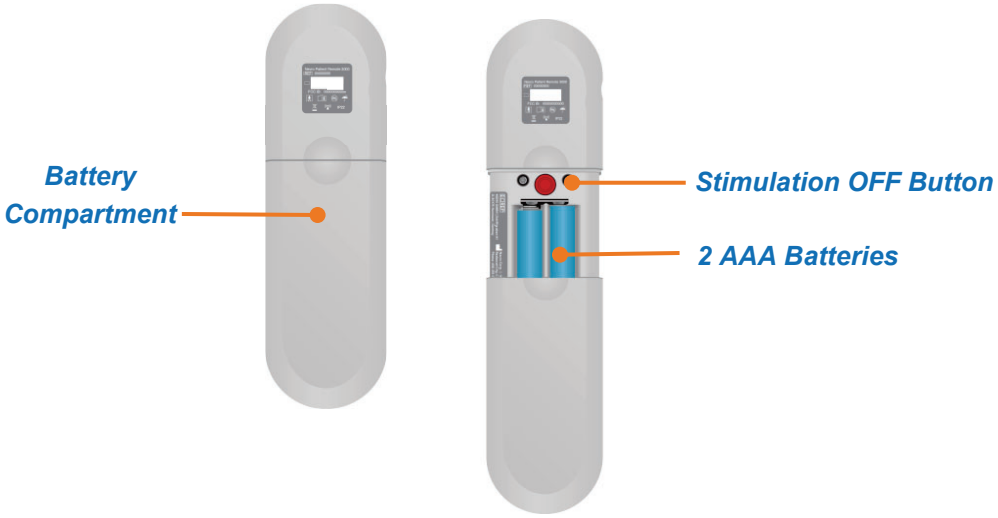
1.1 Major Components

Trial Stimulator: The Trial Stimulator (model EXTS3000) is a battery-powered, single-use, externally worn device, used by the patient to evaluate the effectiveness of the stimulation therapy prior to getting a permanent implant. The Trial Stimulator has connections for up to 2 leads with 8 electrodes each and can be programmed to stimulate the nerves in the spinal cord through the electrodes on these leads.



Remote Control: The Remote Control (model PTRC3000T) is a handheld, battery-operated unit that communicates with the Trial Stimulator using Bluetooth® wireless technology. The patient can use the Remote Control to turn stimulation on or off and adjust certain therapy settings, as well as retrieve the current stimulation level and battery status from the Trial Stimulator.





Leads: Leads are thin insulated wires that connect to the Trial Stimulator at one end and have small electrodes on the other end placed near the spine. A small amount of electrical energy from the device travels through the leads and to the electrodes near the spine.

1.2 Surgical Accessories

Torque Wrench: The Torque Wrench is used to tighten the setscrews that lock the Lead into the Lead Extension/Adaptors, or to activate the retention mechanism on the Active Anchors.

Lead Anchors: The Lead Anchors are used to anchor the Lead to the fascia or supraspinous ligament.

Insertion Needle: The Insertion Needle is used during implant surgery to introduce the Percutaneous Lead between the vertebrae into the epidural space.

Coiled Lead Blank: The Coiled Lead Blank is optionally used during surgery to clear a path for the introduction of the Percutaneous Lead into the epidural space.

Stylets: The Stylets are used to maneuver the Lead through the epidural space to the desired implant location.

Magnet: The Magnet is used to power on the Trial Stimulator and pair the Patient Remote to the Trial Stimulator.

1.3 Compatible Leads

1.3.1 Compatible Nevro Leads and Extensions

The table below provides a list of all Nevro leads and extensions that are compatible with the Trial Stimulator.

Part Number	Name	Description
TLEAD1058-xx	Trial Percutaneous Lead Kit	1x8, 5 mm spacing xx = 50, 70, and 90 cm lengths
LEAD1058-xx	Percutaneous Lead Kit	1x8, 5 mm spacing xx = 50, 70, and 90 cm lengths
LEAD3005-xx	Surpass Surgical Lead Kit	2x8 paddle xx = 50, 70, and 90 cm lengths
LEAD2005-xx	Surpass-C Surgical Lead Kit	2x5 paddle xx = 70 and 90 cm lengths
LEAD2008-xx	Lead Extension Kit	1x8 extension xx = 35, 45, and 60 cm lengths
MADP-25B	M8 Adaptor Kit	Medtronic lead adaptor, 25 cm
SADP-25B	S8 Adaptor Kit	St. Jude Medical / Abbott lead adaptor, 25 cm

1.3.2 Compatible Competitor Leads

The table below provides a list of all competitor leads that are compatible with the Trial Stimulator.

Competitor Leads	Adaptor Required	Compatible Leads
Medtronic	M8 Adaptor	For a list of compatible leads, consult the M8 Adaptor Instructions for Use (P/N 10000124).
St. Jude Medical / Abbott	S8 Adaptor	For a list of compatible leads, consult the S8 Adaptor Instructions for Use (P/N 10000125).

Competitor Leads	Adaptor Required	Compatible Leads	
Boston Scientific[1]	None	SC-2016-xx	Infinion™ 16 Lead and Splitter 2x8 Kit[2]
		SC-2016-xxE	Infinion 16 Lead and Splitter 2x8 Trial Kit
		SC-2138-xx	Linear™ xxcm 8 Contact Lead
		SC-2158-xx	Linear xxcm 8 Contact Lead
		SC-2158-xxE	Linear xxcm8 Contact Lead
		SC-2208-xx	Linear ST xxcm 8 Contact Lead
		SC-2218-xx	Linear ST xxcm 8 Contact Lead
		SC-2218-xxE	Linear ST xxcm 8 Contact Lead
		SC-2352-xx	Linear 3-4 xxcm 8 Contact Lead
		SC-2352-xxE	Linear 3-4 xxcm 8 Contact Lead
		SC-2366-xx	Linear 3-6 xxcm8 Contact Lead
		SC-2366-xxE	Linear 3-6 xxcm 8 Contact Lead
		SC-3138-xx	xxcm 8 Contact Extension
		SC-3304-xx	D4 Splitter 2x4
		SC-3354-xx	W4 Splitter 2x4
		SC-2316-xx	Infinion 16 xxcm 16 Contact Lead Kit
		SC-2316-xxE	Infinion 16 xxcm 16 Contact Trial Lead Kit
		SC-3400-xx	xxcm Splitter 2x8 Kit
		SC-3138-xx	xxcm 8 Contact Extension
		SC-8120-xx	Artisan 2x8 Surgical Lead
		SC-8216-xx	Artisan 2x8 Surgical Lead
		(Note: xx = length in cm)	

[1] Verification documentation is on file at Nevro Corp.
[2] To use the Infinion Lead with the Trial Stimulator, connect the lead to the Splitter 2x8

2 INDICATIONS

The Senza® Bluetooth® Trial 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
- Leg pain

The Senza® Bluetooth® Trial System when programmed to include a frequency of 10 kHz, is indicated as an aid in the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with diabetic neuropathy.

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

3 CONTRAINDICATIONS

The SCS System is contraindicated for the following patients:

- Are poor surgical candidates, including those with poor glycemic control in whom the safety of the device has not yet been characterized, i.e. HbA1C >10%”
- Are unable to operate the SCS system
- Fail to receive effective pain relief during trial stimulation

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).

Patients that have questions about whether the Senza® Bluetooth® Trial System is right for them should consult with their doctor.

4 WARNINGS

WARNINGS. Statements about the use of the device that patients and doctors should take very seriously. If patients and doctor do not follow these warnings, it is possible that the patient could be hurt, and / or the device could be damaged.

4.1 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, or perception of paresthesia. Specifically, for stimulation frequencies above 1,200 Hz, amplitudes that produce paresthesia have not been evaluated and therefore it is unknown whether injury may occur.

PARESTHESIA. Tingling sensations caused by stimulation.

4.2 Stimulation at Vertebral Levels Above T8

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

4.3 Patients Who Are Poor Surgical Candidates

The SCS system should not be implanted in a patient that is considered a poor surgical candidate. Implanting an SCS system has risks similar to surgical procedures of the spine, including spinal fluid leak, headaches, swelling, bruising, bleeding, infection, or paralysis.

4.4 Patients with diabetes

This device was only studied in patients with HbA1C up to 10%. Some patients, including patients with diabetes may be at higher risk of surgical complications, especially those who are at high risk for ischemic heart disease and those with autonomic neuropathy or renal failure. Patients should discuss with their physicians to assess the risks involved.

4.5 Pregnancy and Nursing

The safety and effectiveness of spinal cord stimulation has not been established for use during pregnancy or nursing.

4.6 Pediatric Use

The safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

4.7 Other Active Implanted Devices

Patients must let their physicians know if they have any other active implanted devices. The Senza® Bluetooth® Trial 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® Bluetooth® Trial System is unknown.

4.8 Sleep

Patients using the Senza® Bluetooth® Trial System that generates paresthesia (tingling sensations caused by stimulation) may choose to turn stimulation off to avoid uncomfortable sensations during sleep. Therapy at 10 kHz does not generate paresthesia and therefore stimulation can remain on during sleep.

4.9 Operation of Vehicles (Driving) or Machinery

If patients are using therapy that generates paresthesia, they should not operate motorized vehicles such as automobiles or potentially dangerous machinery and equipment with the stimulation on. Stimulation must first be turned off in such cases. For these patients, sudden stimulation changes may distract them from proper operation of the vehicle, machinery, or equipment. Therapy at 10 kHz does not generate paresthesia and therefore sudden stimulation changes that result in distraction are less likely.

4.10 Electromagnetic Interference (EMI) and Electrostatic Discharge (ESD)

Electromagnetic energy is generated by equipment found in home, work, medical or public environments. Electromagnetic interference may occur when the energy is strong enough to interfere with the function of the Trial Stimulator.

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

Most electrical devices and magnets that patients will encounter in a normal day are unlikely to affect the operation of the Senza® Bluetooth® Trial System. However, some equipment may generate strong electromagnetic fields that can turn the Trial Stimulator off or cause shocks or jolts. Patients should keep away from areas of EMI and turn off the Trial Stimulator if they are in such an area.

The following are examples of sources that can potentially generate strong EMI:

- Theft detectors or security screeners such as airport security screening devices, retail store, and libraries
- Power lines and power generators
- Arc welders
- Large, magnetized stereo speakers
- Radiofrequency identification devices (RFID)

If EMI is suspected or encountered, patients will need to turn off the Trial Stimulator. The patient will then need to move away from the EMI area and check whether the therapy is on or off. Before therapy can be turned on, the battery may need to be replaced in the Trial Stimulator.

The following are effects that can result from exposure to strong EMI:

- **Serious patient injury,** resulting from heating of the implanted components of the SCS system and damage to the surrounding tissue.

- **System damage**, resulting in a loss of or change in symptom control and requiring surgical replacement.
- **Operational changes to the Trial Stimulator**, causing stimulation to turn ON or OFF.
- **Unexpected changes in stimulation**, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure the patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen and been injured.

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 the Trial Stimulator. Communication can be restored by moving away from the interfering electrical equipment or repositioning the Remote Control.

WARNING: Use of the Senza® Bluetooth® Trial 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® Bluetooth® Trial System and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories and cables other than those specified or provided by Nevro could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Senza® Bluetooth® Trial 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® Bluetooth® Trial System, including cables specified by Nevro. Otherwise, degradation of the performance of the Senza® Bluetooth® Trial System could result.

Electrostatic Discharge (ESD) is another common source of electromagnetic interference. ESD can occur when a person or object accumulates a static charge. ESD is intensified by low humidity and synthetic materials. If the battery terminals of the Trial Simulator are exposed to ESD, the device may reset and stop stimulation. To avoid unintentionally stopping stimulation, do not open the battery compartment while stimulation is ongoing.

4.11 Theft Detectors and Security Screening Devices

Security checkpoints, metal detectors, screening systems at airports, and theft detectors all produce EMI. If patients must pass through such a system, they should tell the personnel that they have an implanted medical device and show them their Patient ID Card. Patients may be able to go through the checkpoint without going through the scanner. If that is not possible, patients should turn the device off and move through the scanner as quickly as possible.

While some theft detection systems are obvious and are located at store exits, others may be concealed within the store. If a patient is in a store or other environment and suspect EMI is affecting their device, the patient should turn off their Senza® Bluetooth® Trial System and move out of the area. Once the patient is out of the area,

they should check whether therapy is on or off. Before therapy can be turned on, the battery may need to be replaced in the Trial Stimulator.

Patients that have specific questions about EMI sources should talk to their doctor.

5 WARNINGS ABOUT OTHER MEDICAL TREATMENTS

There are some procedures that should not be performed or are not recommended for patients with the Senza® Bluetooth® Trial System and there are other procedures which may be possible only with certain precautions. Patients that need any of these treatments should discuss the treatment with their doctor and other clinicians (including dentists, physical therapists, occupational therapists) as well as with the medical personnel performing the procedure.

Procedures that are not recommended for patients if any part of a SCS system is implanted include:

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

5.1 Diathermy Therapy

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

Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with any part of a neuromodulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. The Senza® Bluetooth® Trial System, whether it is turned on or off, may be damaged.

5.2 Magnetic Resonance Imaging (MRI)

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

Patients in the trial phase should not undergo an MRI scan. Refer to the Nevro MRI guidelines manuals (available at www.nevro.com/physicianmanuals) for detailed information on MRI safety and conditions for MRI scanning of patients implanted with Nevro products.

Never take the Trial Stimulator and Remote Control into an MRI scan room. The Trial Stimulator and Patient Remote 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.

5.3 Computed Tomography Scans

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.

Before beginning a CT scan, the operator should use CT scout views to determine if implanted or externally worn electronic medical devices are present and if so, its location relative to the programmed scan range.

For CT procedures in which the medical device is in or immediately adjacent to the programmed scan range, the operator should:

- Determine the device type;
- Ask patients to turn off the device temporarily while the scan is performed;
- Disconnect the Trial Stimulator from the implanted leads and remove it from the area.
- Minimize x-ray exposure to the implanted or externally worn medical device by:
    - Using the lowest possible x-ray tube current consistent with obtaining the required image quality
    - Making sure that the x-ray beam does not dwell over the device for more than a few seconds

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 medical device, patients should:

- Turn their Senza® Bluetooth® Trial System device back on.
- Check that their Senza® Bluetooth® Trial System is working properly.
- Contact their doctor as soon as possible if they suspect the Senza® Bluetooth® Trial System is not functioning properly after a CT scan.

5.4 Devices in Hospital and Medical Environments

The use of the following medical devices or procedures may damage the Senza® Bluetooth® Trial System or turn the stimulation off. After usage of these devices or procedures, the implanted or externally worn SCS system may need to be replaced as a result of permanent damage:

- Electrocautery
- External defibrillation
- Lithotripsy or high-output ultrasonic
- Radiation therapy
- Ultrasonic scanning

ELECTROCAUTERY. The technique of burning the skin or flesh of a wound by means of an instrument heated by an electric current, typically to stop bleeding or prevent the wound from becoming infected.

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.

LITHOTRIPSY. The use of sound waves to help break up calcified stones 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).

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

If a patient is required to undergo electrocautery, lithotripsy, high-output ultrasound, radiation therapy, or ultrasonic scanning, the following precautions should be taken:

- Disconnect the Trial Stimulator from the implanted leads and remove it from the area
- All equipment, including ground plates and paddles, must be used as far away as possible from all external devices
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from all external devices.
- Equipment should be set to the lowest energy setting clinically indicated.

After the therapy or procedure, the patient should check that the Trial Stimulator is functioning properly by gradually increasing stimulation to the desired level. If a patient suspect that the Trial Stimulator is not functioning properly after the use of these medical devices or procedures, the patient should contact their doctor.

5.5 Radiofrequency Ablation and Microwave Ablation

Safety has not been established for radiofrequency (RF) or microwave ablation in patients that have implanted leads as part of an SCS system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

RADIOFREQUENCY OR MICROWAVE ABLATION. An electrical current produced by a radio / microwave is used to heat up a small area of nerve tissue, thereby decreasing pain signals from that specific area.

6 PRECAUTIONS

PRECAUTIONS. Instructions about the device patients and doctors should follow to avoid damage to the device, so that it will function correctly and last longer.

6.1 Storage

Store the Senza® Bluetooth® Trial System components and accessories at the prescribed temperatures, whether in transport or storage. Excessively hot or cold temperatures may damage the components, particularly high heat. Devices should be kept in temperature regulated areas within the acceptable temperature range. Do not expose the components to liquids or excessive moisture.

- The storage temperature range for the Trial Stimulator is 0°C to 45°C (32°F to 113°F).
- The storage temperature range for the Remote Control is -20°C to 60°C (-4°F to 140°F).

6.2 Operating Temperatures

- The operating temperature range for the Remote Control is 5°C to 40°C (41°F to 104°F).
- The operating temperature range for the Trial Stimulator is 5°C to 40°C (41°F to 104°F).
- Device surface temperatures may reach a couple of degrees above ambient conditions. Therefore at 40°C, the maximum operating surface temperature for the Patient Remote & Trial Stimulator may exceed 41°C, up to 43°C (109°F).

6.3 Sterilization

The Trial Stimulator and all implanted components are intended for single use only.

- Prior to opening the sterile package, inspect the sterilization indicator and the sterile package.
- Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
- Do not use any component that shows signs of damage.
- Do not re-sterilize the package or the contents. There is risk of infection and device malfunction.
- Do not use if "Use by" date has passed.
- Do not re-use the Trial Stimulator or any of the implanted components.

6.4 Handling

Use care when handling the Senza® Bluetooth® Trial System's components and accessories. Do not drop them or submerge them in water. Do not impact the system components against hard surfaces and avoid rough handling. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water or other rough handling, can permanently damage the components and accessories.

6.4.1 Handling the Leads and Lead Extensions

Follow these guidelines when handling the leads or lead extensions:

- Leads and lead extensions should always be handled with care.
- Do not make sharp bends to the lead or lead extension.
- Do not severely kink, crush or stretch the lead or lead extension.
- Do not apply severe torque (twist) to the lead or lead extension. Do not tie suture directly to the lead or the lead extension.
- When placing a suture around the lead, use the provided lead anchors.
- Do not force the lead into the epidural space. Consider use of the optional lead blank prior to inserting the lead.
- Create a stress relief loop to minimize tension on the lead.
- Do not stretch the lead.
- Do not use sharp instruments to handle the lead or lead extension.
- Wipe off any bodily fluids (e.g. blood) from the lead's proximal end before connecting it to any other component.
- Wipe off any bodily fluids (e.g. blood) from the lead stylet before inserting or reinserting it into the lead.
- When inserting the stylet into the lead, do not use excessive force.

6.4.2 Handling the Trial Stimulator

Follow these guidelines when handling the Trial Stimulator:

- Avoid rough handling of the Trial Stimulator.
- Avoid water around the Trial Stimulator.
- Take care not to drop or hit the Trial Stimulator. If it has been dropped to a hard surface, do not use the device and send it back to Nevro Corp.

6.5 System Compatibility

Use only Nevro or Nevro-approved accessories with the Senza® Bluetooth® Trial System. A complete list of compatible leads and accessories can be found in section 1 of this manual.

6.6 Cleaning

The Remote Control can be cleaned as needed by wiping the surface with a soft cloth damped with water or mild detergent. The remaining residue should be removed by wiping the surfaces with a dry cloth. Do not use alcohol or any harsh or abrasive cleaners and never let moisture get inside the Remote Control.

6.7 Patient Activities

Patients using therapy that generates paresthesia may experience increased paresthesia when changing posture or making abrupt movements. These patients should lower the amplitude or turn off the stimulation before making posture changes such as stretching or moving their arms over their head. If unpleasant sensations occur, the Trial Stimulator should be turned off.

Stimulation at 10 kHz does not generate paresthesia, so patients should not experience unpleasant sensations caused by posture changes or movement. As such, patients would not need to change amplitudes in their programs for posture changes or abrupt movements.

6.8 Patient Activities Related to Lead Movement

Patients should not make sudden and excessive bending, stretching, or twisting movements. An implanted lead can move from its original location during such movements, which might affect delivery of therapy. In such cases, the Trial Stimulator may need to be reprogrammed or the lead(s) may need to be repositioned through another operation.

6.9 Hyperbaric Chambers

The Senza® Bluetooth® Trial System is sensitive to high pressure. Patients should not enter hyperbaric chambers with pressure greater than 4.5 ATM. Pressure greater than 4.5 ATM may damage the Senza® Bluetooth® Trial System.

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.

6.10 Transcranial Magnetic Stimulation and Electroconvulsive Therapy

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

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

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

6.11 Transcutaneous Electrical Nerve Stimulation

Do not place transcutaneous electrical nerve stimulation (TENS) electrodes so that the TENS current passes over any part of the SCS system. If a patient feel that the TENS may be interfering with the implanted SCS system, the patient should discontinue using the TENS and consult with their doctor.

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

6.12 Post-Operative Pain

In the days after the surgery, patients may experience pain in the implant area. This is typical in SCS surgeries.

6.13 Infection

If a patient experiences persistent discomfort or excessive redness around the wound areas, the patient may need to be checked for infection by their doctor. Infections related to the Senza® Bluetooth® Trial System may require the implanted components to be explanted.

6.14 Long-Term Effectiveness of Spinal Cord Stimulation

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 two years.

6.15 Mobile Phones and Other Bluetooth®-enabled Devices

Mobile phones and other Bluetooth®-enabled devices are not anticipated to interfere with the Senza® Bluetooth® Trial System. However, technology continues to change and interactions between the Senza® Bluetooth® Trial System and mobile phones or other Bluetooth®-enabled devices are possible. Patients should contact their doctor if they are concerned about mobile phones or other Bluetooth®-enabled devices interacting with their neuromodulation system.

6.16 Limitations on Wireless Use

In some environments, such as aboard airplanes, in hospitals, near explosives, or in hazardous locations, the use of wireless functions (e.g., Bluetooth® wireless technology) may be restricted. If patients are unsure of the policy that applies to the use of their Senza® Bluetooth® Trial System in a particular environment, the patient should ask for authorization before turning it on.

In environments where many Bluetooth®-enabled devices or other devices that use wireless radio are active nearby, the Remote Control and Trial Stimulator may have problems connecting, and/or communicating with each other. Due to signal interference, multiple attempts may be required. Refer to the Troubleshooting section of the Senza® Bluetooth® Trial System Patient's Manual (P/N: 10000890).

6.17 Maintenance

Apart from replaceable batteries for the Remote Control, the Senza® Bluetooth® Trial System does not contain any user serviceable parts.

If any part of the Senza® Bluetooth® Trial System becomes damaged, loose, or does not function properly, patients should discontinue therapy and contact their doctor. The system may require maintenance at the clinic or may need to be replaced.

6.18 Device Disposal

Patients that want to dispose of any components in their system should return them to their doctor. Do not dispose of the Trial Stimulator or Remote Control in fire as the batteries in these devices may explode. Do not

dispose of electrical components, including batteries, in the unsorted municipal waste stream. Dispose of electrical components, including batteries, according to local regulations.

Whenever a lead or Trial Stimulator is removed from a patient and a product issue is suspected, it should be returned to Nevro Corp. This helps Nevro monitor its products and is required by U.S. law.

7 Additional considerations for patients with diabetes

To identify suitable patients for device implantation and manage patient risks before, during, and after the procedure, consider the following:

Stage of Care	Considerations for Patients with Diabetes
Pre-operative	• Patients suitable for HF10 therapy with painful diabetic neuropathy symptoms that are refractory to or intolerant of conventional medical therapies, including medications recommended for pain by the American Diabetes Association's Standards of Medical Care in Diabetes.[3] • Attempts to optimize the patient's glycemic control should be made prior to the procedure. • Pre-operative risk assessment should be performed for patients with diabetes and any other co-morbidities. • Coordination among healthcare providers involved in the patient's care team may aid in risk mitigation. • Appropriate patient counselling regarding potential surgical risks should be communicated.

Perioperative	• Consider the Perioperative Care guidelines as established in American Diabetes Association's Standards in Medical Care in Diabetes,[3] especially:
	  ○ appropriate target blood glucose range for perioperative period whilst balancing potential risks of hypoglycemia
	• Additional guidance can be found:
	  ○ Society for Ambulatory Anesthesia's consensus statement on perioperative blood glucose management in patients with diabetes undergoing ambulatory surgery[4]
	  ○ Centers for Disease Control and Prevention guideline for the prevention of surgical site infection[5]

Post-operative	• Due to the potential for increased risk of infection in patients with diabetes, careful oversight of wound healing may help identify potential infections early to initiate treatment. • Continued careful management of blood glucose during healing may reduce risk of infection. • Close collaboration between the referring physician and the implanting physician will aid in optimal post-operative management.

[3] American Diabetes Association Standards of Medical Care in Diabetes-2021. *Diabetes Care*. 2021;44(Suppl 1):S1-S232
[4] Joshi GP, Chung F, Vann MA, Ahmad S, Gan TJ, Goulson DT, et al. Society for Ambulatory Anesthesia consensus statement on perioperative blood glucose management in diabetic patients undergoing ambulatory surgery. *Anesth Analg*. 2010;111(6):1378-87
[5] Berríos-Torres et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg

Data from Senza-PDN study and overall risk-benefit determination [Section II.C Senza PDN Study in Clinician Summary Manual] provide evidence that the Senza SCS device, providing HF10 therapy, is safe and effective for the treatment of chronic intractable pain in the lower limbs due to diabetic neuropathy. Careful and appropriate patient selection is needed to reduce the known risks associated with implantation of SCS devices and to avoid complications associated with poor glycemic control.

Note: For detailed inclusion/exclusion criteria for patients included in the Senza-PDN study, refer to Study Design Section under Senza-PDN Study in Clinician Summary Manual.

8 ADVERSE EVENTS

Adverse events, or side effects, are risks associated with the use of the Senza® Bluetooth® Trial System or any other SCS system. There are adverse events associated with the lead implant procedure, with stimulation, and with the device itself. Patients should contact their doctor if they experience any adverse events associated with their device.

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

- Risks associated with anesthesia, including cardiac arrest
- Surgical complications, such as infection, cellulitis, abscess, fever, sepsis, bleeding
- Cerebrospinal fluid leak
- Intracranial hypotension
- Hematoma, seroma or thrombosis
- Epidural hemorrhage
- Impaired or inadequate wound healing, wound dehiscence
- Temporary or persistent tenderness or pain at implant site
- Lead migration leading to ineffective pain control or other undesirable changes in stimulation
- Suboptimal lead placement or migration requiring revision or explant
- Spinal cord compression; nerve, nerve root, or spinal cord injury
- Paralysis
- Death

8.2 Possible Adverse Events Associated with Stimulation

- Loss of pain relief, loss of paresthesia, or unpleasant paresthesia
- Jolting or shocking sensation associated with changes in posture or sudden movements
- Increased pain
- Undesirable stimulation due to changes over time in tissue around electrodes, changes in electrode position, loose electrical connections, or lead failure
- Uncomfortable stimulation of tissue around the leads including skin and muscle
- Other undesirable sensation such as tingling or prickling
- Weakness, clumsiness or numbness

8.3 Possible Adverse Events Associated with Implanted Device Components

- Tissue reaction or allergy to implanted materials
- Persistent pain at lead implant site
- Failure of device components 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, and possibly requiring trial lead removal
- Skin erosion or seroma at the lead site
- Pressure sores
- External sources of electromagnetic interference that cause the device to malfunction and could affect stimulation
- Exposure to magnetic resonance imaging (MRI) can result in heating of tissue, image artifacts, induced voltages in the leads, and lead dislodgement
- Infection
- Epidural mass formation around the lead

8.4 Risks Associated with External Device Components

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

9 TECHNICAL SPECIFICATIONS

9.1 Electromagnetic Interference

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Senza® Bluetooth® Trial System is intended for use in the electromagnetic environment specified below. The customer or user of the Senza® Bluetooth® Trial 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® Bluetooth® Trial 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	The Senza® Bluetooth® Trial 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.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Senza® Bluetooth® Trial System is intended for use in the electromagnetic environment specified below. The customer or user of the Senza® Bluetooth® Trial 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
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.*			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and Amateur Radio Bands 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and Amateur Radio Bands 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Senza® Bluetooth® Trial System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d=1.2\sqrt{P}$

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Senza® Bluetooth® Trial System is intended for use in the electromagnetic environment specified below. The customer or user of the Senza® Bluetooth® Trial System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	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, (a) 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: 
Proximity Fields IEC 61000-4-3	28 V/m	28 V/m	
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® Bluetooth® Trial System is used exceeds the applicable RF compliance level above, the Senza® Bluetooth® Trial 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® Bluetooth® Trial 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® Bluetooth® Trial System

The Senza® Bluetooth® Trial System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Senza® Bluetooth® Trial System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Senza® Bluetooth® Trial 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.

The Trial Stimulator (model EXTS3000) and Remote Control (model PTRC3000T) are Type BF Applied Parts and are compliant with IEC/EN 60601-1. The Trial Stimulator (model EXTS3000) is a Continuous Operation and Remote Control (model PTRC3000T) is a Non-Continuous Operation. The Trial Stimulator (model EXTS3000) and Remote Control (model PTRC3000T) are both Internally Powered.

9.2 FCC Statements

Trial Stimulator FCC ID: XKYEXTS3000

Remote Control FCC ID: XKYPR1D3000

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The equipment generates, uses and can radiate radio frequency energy and may cause harmful interference to radio communications if it is not installed and used in accordance with the instruction manual.

There is no guarantee that interference will not occur in a particular installation. If this equipment causes interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

Changes or modifications of any kind not expressly approved by Nevro could void the user's authority to operate this device.

9.3 Quality of Wireless Service

The Senza® Bluetooth® Trial System uses a wireless communication system in the ISM frequency band (2400 to 2483.5 MHz). This band is not reserved for implantable medical devices. The typical communication range is less than 5 feet (1.5 meters) between the Remote Control and Trial Stimulator.

9.4 Telemetry Information

The Senza® Bluetooth® Trial System uses a wireless communication system in the ISM frequency band (2400 to 2483.5 MHz). The wireless communication system implements Gaussian Frequency Shift Keying (GFSK) modulation. The bandwidth of each of the 40 possible frequency channels does not exceed 2MHz, and the Transmitter Effective Isotropic Radiated Power (EIRP) does not exceed +6dBm (Trial Stimulator) and +6dBm (Remote Control).

Refer to the tables in the Electromagnetic Interference section to determine the recommended separation distances between the Senza® Bluetooth® Trial System and other transmitters.

9.5 System Specifications

The following table contains the stimulation parameter ranges for the Trial Stimulator.

Parameter	Range
Frequency	2 – 10,000 Hz
Pulse Width	20 – 1000 µs
Amplitude	0 – 15 mA

The following table summarizes the maximum amplitude, pulse width, and impedance at two frequency settings.

Frequency* (Hz, Hertz)	Maximum Amplitude (mA, milliamps)	Maximum Pulse Width (µs, microseconds)	Maximum Impedance (Ω, Ohms)
2	9	1000	1000
10,000	10	30	1000

*Therapy settings between frequencies of 2 Hz -10 KHz can vary depending on actual values for Impedance, Current and Pulse Width

9.6 Expected Service Life

The Trial Stimulator should have an expected service life of 2 months using nominal stimulation settings and allowing for a replaceable battery. The Remote Control should have an expected service life of 3 years allowing for replaceable batteries.

10 SECURITY FEATURES AND DECLARATIONS

1.1 Wireless Security

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

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NEVRO CORP.

All questions or concerns about Nevro Corp. products, including any serious incident that has occurred in relation to the device, should be forwarded to:

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