



PHYSICIAN IMPLANT MANUAL

Senza BLUETOOTH® Trial System

Effective May 2020

10000891 Rev 02

R_x ONLY



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

Nevro Corp.

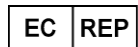
1800 Bridge Parkway

Redwood City, CA 94065 USA

Tel: +1.650.251.0005

Fax: +1.650.251.9415

info@nevro.com



MDSS GMBH

Schiffgraben 41

D-30175 Hannover

Germany

Australian Sponsor

Emergo Australia

201 Sussex Street, Darling Park, Tower II, Level 20

Sydney, NSW 2000

Australia

© Copyright 2020, Nevro Corp. All rights reserved.

No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system or translated into any language or computer language, in any form or by any means, including, but not limited to, electronic, magnetic, optical, chemical, manual, or otherwise without written permission of Nevro Corp.

Registered Trademarks: Nevro, Senza, Senza II, Omnia, Senza Bluetooth®, HF10, and the Nevro Logo are trademarks of Nevro Corp. The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Nevro Corp. is under license. Other trademarks and trade names are those of their respective owners.

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

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.















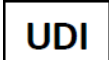
CONTENTS

1 EXPLANATION OF SYMBOLS ON THE PRODUCT OR LABELING	4
2 INTRODUCTION	7
2.1 ABOUT THIS BOOKLET	7
3 DEVICE DESCRIPTION	8
3.1 MAJOR COMPONENTS.....	8
3.2 SURGICAL ACCESSORIES.....	9
3.3 COMPATIBLE LEADS	9
4 INSTRUCTIONS FOR USE	12
4.1 PRE-OPERATIVE INSTRUCTIONS	12
4.2 LEAD PLACEMENT.....	15
4.3 PERFORMING INTRA-OPERATIVE TESTING	16
4.4 TEMPORARY TRIAL	18
4.5 PERMANENT TRIAL	18
4.6 CONNECTING THE LEAD OR EXTENSION TO THE TRIAL STIMULATOR.....	21
4.7 ATTACHING THE TRIAL STIMULATOR TO THE PATIENT	22
4.8 ABOUT THE TRIAL STIMULATOR	23
5 TROUBLESHOOTING	26
5.1 TROUBLESHOOTING PAIRING.....	26
5.2 TROUBLESHOOTING LEAD CONNECTIONS	27
6 PATIENT IDENTIFICATION CARD	29
7 ADDITIONAL INFORMATION	30

1 EXPLANATION OF SYMBOLS ON THE PRODUCT OR LABELING

SYMBOLS	DESCRIPTION
	Serial number
	Caution
	Batch number
	Date of manufacture
	Manufacturer
	Expiration date
	Catalog number
	Physician only
	Temperature limit
	Consult instructions for use
 www.nevro.com	Consult electronic instructions for use

SYMBOLS	DESCRIPTION
	Sterilized using ethylene oxide
	Non-sterile
<p data-bbox="418 657 529 709">IP22</p>	Degree of ingress protection provided by enclosure
	Keep dry
	Do not re-use
	Do not re-sterilize
	Do not use if package damaged
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.
	Magnetic resonance (MR) unsafe
	Non-ionizing electromagnetic radiation
	Type BF applied part.

SYMBOLS	DESCRIPTION
	Authorized European representative
	Medical device
	Unique device identification



2 INTRODUCTION

2.1 About This Booklet

This booklet was written for doctors that may prescribe the Nevro® Senza® Bluetooth® Spinal Cord Stimulator (SCS) System to help their patients treat chronic pain. For information about indications, contraindications, warnings, precautions, and technical specifications, refer to the Information for Prescribers (P/N 10001045).

3 DEVICE DESCRIPTION

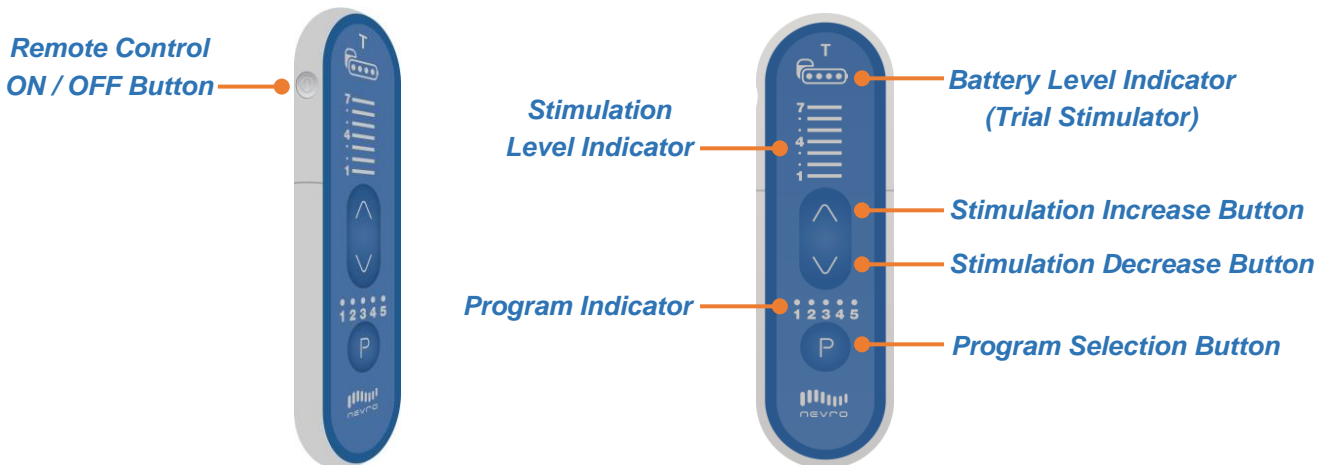
The Senza Bluetooth Trial System works by delivering electrical energy from a stimulator to an area around the spine. The system is capable of delivering HF10® therapy, a therapy that does not produce tingling sensations called paresthesia. It is also capable of providing stimulation that produces paresthesia 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.

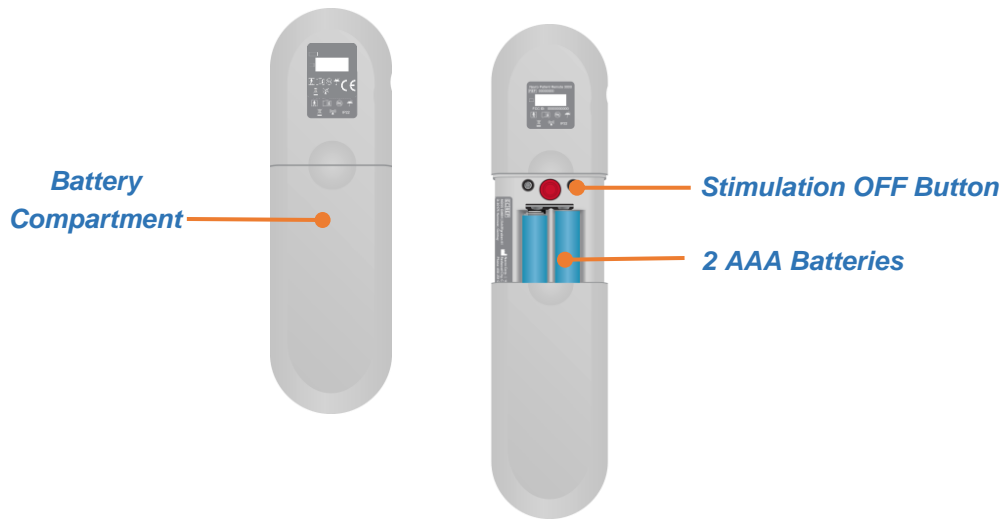
3.1 Major Components

- 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.

3.2 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.

3.3 Compatible Leads

3.3.1 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

3.3.2 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

4 INSTRUCTIONS FOR USE

Physicians providing SCS therapy with the Senza Bluetooth Trial System should be experienced in the diagnosis and treatment of chronic pain and have proper surgical and clinical training.

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 implanted in the patient, and the proximal end is externalized and connected to the Trial Stimulator. When the trial period is over, the lead is removed from the patient. When the patient receives a permanent system, the patient receives a new lead with their IPG. The procedure for the temporary trial is detailed in [section 4.4](#).
- 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. With this approach, the implanted lead remains sterile, and the extension can be discarded at the end of the trial period. When the patient receives a permanent system, the implanted lead can be connected to the IPG. The procedure for the permanent trial is detailed in [section 4.5](#).

4.1 PRE-OPERATIVE INSTRUCTIONS

4.1.1 Check Trial Stimulator and Leads

CAUTION: Do not use any component that shows signs of damage, or that is contained within a visibly damaged package.

CAUTION: Exercise caution when taking the Trial Stimulator out of its packaging as it is sterile.

1. Before opening the packages, verify the use-by date and the description of each component, such as length and type.
2. Confirm that leads and lead extensions are approved by Nevro for use with the Trial Stimulator. See of this manual for list of compatible leads.

4.1.2 Pairing the Trial Stimulator with the Clinician Programmer

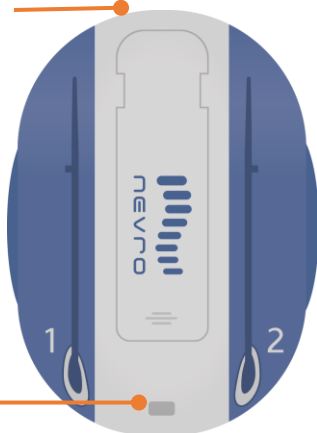
CAUTION: Do not store the Trial Stimulator around magnets as it may unintentionally wake the device.

1. Orient the Trial Stimulator packaging so the Trial Stimulator is visible through the window on the outer box. The Trial Stimulator can remain in its packaging for the following steps.
2. Prepare the Trial Stimulator for pairing by holding the magnet over the magnet sensor on the Trial Stimulator. The magnet sensor symbol will be found on the Trial Stimulator packaging. The Pairing LED should light up solid blue once the magnet is properly aligned with the magnet sensor.

Magnet Sensor Symbol



Magnet Sensor

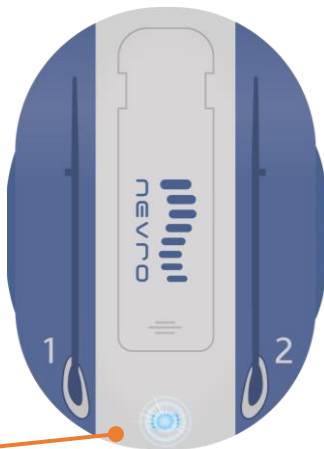


Pairing Light



*Pairing Light:
Magnet Aligned*

3. Hold the magnet over the magnet sensor until the pairing light starts blinking to indicate it is ready to be paired with the Clinician Programmer.



*Pairing Light Blinking:
Ready to be Paired*

NOTE: Once the Trial Stimulator is woken up with the magnet, there is a 2-minute window for pairing. If nothing pairs with the Trial Stimulator during the 2-minute window, it will go back to sleep.

4. On the Clinician Programmer, scan for stimulators and select the serial number of the Trial Stimulator you wish to pair with. Refer to the Clinician Programmer (P/N 10000906) for additional details.
5. If pairing is successful, the pairing light on the Trial Stimulator will light up solid briefly and then turn off. Once the Trial Stimulator is successfully paired with the Clinician Programmer, it will remain awake.
6. Use the Clinician Programmer to confirm that the battery in the Trial Stimulator is full. For detailed instructions, refer to the Clinician Programmer Manual (P/N 10000906).

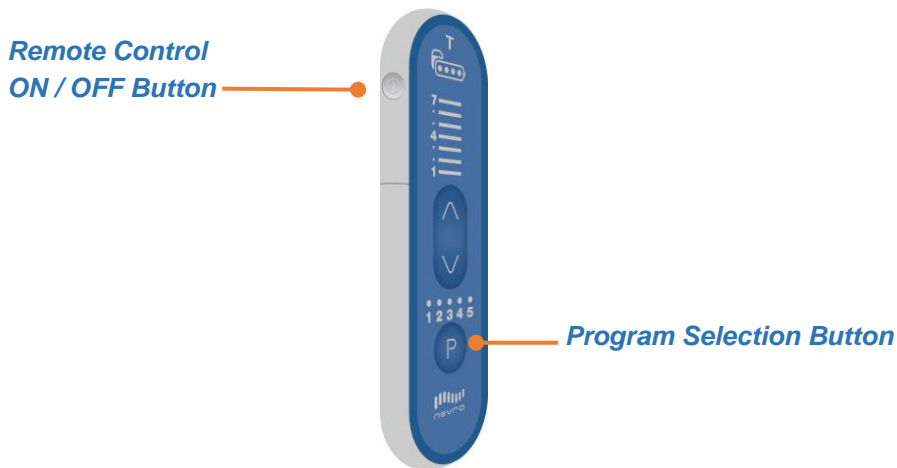
4.1.2 Pairing the Trial Stimulator with the Remote Control

- Orient the Trial Stimulator packaging so the Trial Stimulator is visible through the window on the outer box. The Trial Stimulator should remain in its packaging for the following steps.
- Prepare the Trial Stimulator for pairing by placing the magnet over the magnet sensor on the Trial Stimulator packaging window. The magnet sensor symbol can be found on the Trial Stimulator packaging, indicating the magnet sensor position. The Pairing LED should light up solid blue once the magnet is properly aligned with the magnet sensor.



NOTE: If the Trial Stimulator was previously paired with a Clinician Programmer, you may use the Clinician Programmer to prepare the Trial Stimulator for pairing with the Remote Control instead of using the magnet. For details, refer the Programmer Manual (P/N 10000906).

- Keep the magnet over the magnet sensor until the Pairing LED starts blinking to indicate it is ready to be paired with the Remote Control.
- For the Remote Control to pair with the Trial Stimulator, first make sure the Remote Control is OFF by pressing the gray ON / OFF Button on the upper left side of the device. The Remote Control is OFF when all stimulation indicator level lights are off.
- On the Remote Control, hold the Program Selection Button down, then press the ON / OFF Button for up to 5 seconds. The Remote Control will start beeping to indicate it is searching for the Trial Stimulator.



What You Hear	What It Means
One long beep	The Remote Control successfully paired with the Trial Stimulator.
Three regular beeps	The Remote Control did not find the Trial Stimulator. Make sure the Trial Stimulator Pairing Light is still blinking and try again. Refer to the Troubleshooting section of this manual.
Four regular beeps	The Remote Control found more than one Trial Stimulator ready for pairing. Only one Trial Stimulator should be ready for pairing at a time. Refer to the Troubleshooting section of this manual.

4.2 LEAD PLACEMENT

4.2.1 Percutaneous Lead Placement

NOTE: 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.

1. Prep the skin and drape the patient in a usual sterile fashion.
2. Confirm pre-operative antibiotic prophylaxis if deemed appropriate.
3. Inject a local anesthetic at the desired needle insertion site.

CAUTION: Needles not provided by Nevro Corp. may damage Nevro leads.

4. 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.

CAUTION: Inserting the lead while the needle is at an angle of greater than 45° may damage the lead or increase the difficulty of lead placement.

5. Remove the needle-styleset 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.
6. With the stylet in the lead, slowly advance the lead into the epidural space.
7. Advance the lead to the appropriate vertebral level using fluoroscopic guidance. Rotate the stylet as necessary to steer the lead.

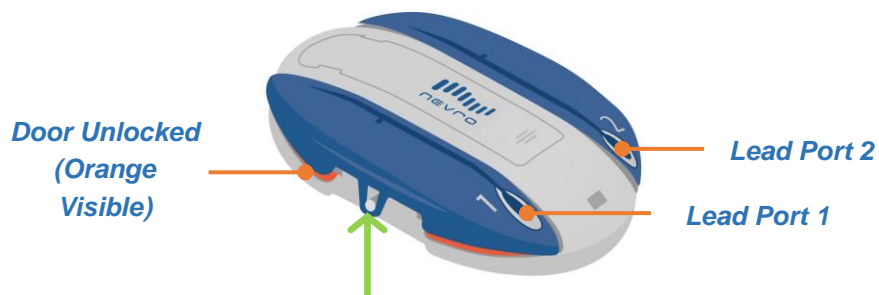
CAUTION: If implanting a second lead, use care when inserting the second needle to prevent damage the first lead.

4.2.2 Surgical Lead Placement

Refer to the Surgical Lead Manual (PN 12027) for instructions regarding surgical lead placement.

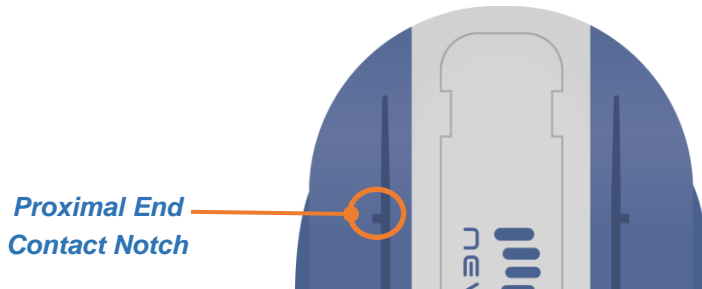
4.3 PERFORMING INTRA-OPERATIVE TESTING

1. After the lead is in the desired location, you can attach the leads to the Trial Stimulator to perform intra-operative testing. Ensure the Trial Stimulator is OFF.
2. Make sure Lead Door 1 is unlocked (orange markings below the door are visible). If Lead Door 1 is locked, push the door up using the lip at the edge of the door to unlock it.

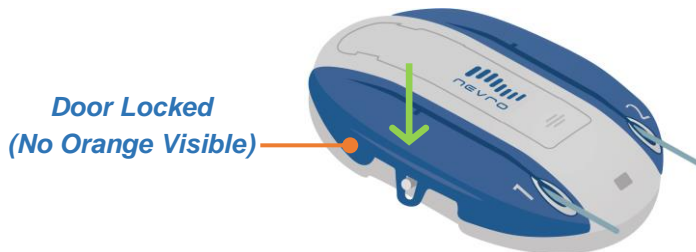


CAUTION: Make sure the lead door is unlocked (orange markings below door are visible) before inserting the lead to prevent damage to the lead.

3. Insert the first lead into Lead Port 1 until the most proximal contact of the lead is aligned with the notch on the Trial Stimulator lead door.



4. Press Lead Door 1 on the Trial Stimulator until there is an audible click (orange markings below the door are no longer visible). Gently tug on the lead to verify the door is locked.



5. Repeat the three (3) preceding steps for the second lead and Trial Stimulator Lead Port 2. When two leads are used, the leads may be marked using a sterile surgical marker to distinguish between the two leads.
6. Conduct impedance testing. Refer to the Clinician Programmer Manual (PN 10000906) for detailed instructions. Do not continue until all the impedances are in the normal range.
7. Verify lead position. Paresthesia mapping is not required for 10 kHz programming. However, if frequencies up to 1200 Hz are used for programming, paresthesia mapping is needed:
 - Ensure that the patient can give immediate feedback.
 - Conduct test stimulation. Select contacts and adjust amplitude, pulse width, and pulse rate until patient has satisfactory paresthesia coverage of the pain areas.
 - If satisfactory paresthesia coverage cannot be achieved, reposition the leads as necessary and repeat stimulation.
 - Repeat steps as needed.
8. Turn the Trial Stimulator OFF and then disconnect the lead.

CAUTION: Always turn the Trial Stimulator OFF using the Programmer or Remote Control before connecting or disconnecting the leads.

9. At this point, you may opt to continue with either a **Temporary Trial** (*continue to 4.4*), or a **Permanent Trial** (*continue from 4.5*).

4.4 TEMPORARY TRIAL

4.4.1 Preparing for Temporary Trial

1. Using minimal force, carefully withdraw the insertion needle from the patient while holding the percutaneous lead.
2. Using minimal force, carefully withdraw the stylet while holding the percutaneous lead.
3. After removing the needle and the stylet, it is recommended that you confirm the location of the lead using fluoroscopy.
4. 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.
5. *Continue from [Section 4.6](#), Connecting the Lead or Extension to the Trial Stimulator*

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 (P/N 12027) for details on surgical lead placement.

4.5 PERMANENT TRIAL

4.5.1 Anchoring the Lead

1. 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.
2. Using minimal force, carefully withdraw the insertion needle from the patient while holding the lead.
3. Using minimal force, carefully withdraw the stylet while holding the lead.
4. 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.

CAUTION: Tying sutures directly on the lead can damage the lead. Always use a lead anchor.

CAUTION: Do not use polypropylene sutures as they may damage the lead anchor.

CAUTION: Do not use a hemostat on the lead body, as this may damage the lead insulation.

CAUTION: If needed, it is recommended that bipolar electrocautery be 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.

4.5.2 Instructions Specific to Silicone Anchors

For silicone anchors, 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.

CAUTION: Use only the appropriate torque wrench provided by Nevro Corp. to tighten the anchor to the lead.

4.5.3 Instructions Specific to Active Anchors

For active anchors, 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.

NOTE: 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.

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: Use only the appropriate torque wrench provided by Nevro Corp. to tighten the anchor to the lead.

4.5.4 Connecting an Extension to the Lead

1. 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.

NOTE: If the lead does not fully insert into the lead extension's connector, check 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. Ensure that the setscrew is not removed from the connector.

2. Conduct impedance testing. Refer to the Clinician Programmer Manual (P/N 10000906) for detailed instructions. Do not tighten the setscrew on the extension until all the impedances are in the normal range.
3. Check that the lead is fully inserted into the lead extension's connector before tightening.
4. Fully insert the torque wrench into the setscrew.
5. Rotate the torque wrench handle to turn the lead extension connector's setscrew clockwise until the audible click is heard. The clicking indicates that it is fully tightened.

NOTE: If the setscrew does not tighten smoothly, use the torque wrench to loosen the setscrew by turning it counter-clockwise and then re-tighten by turning it clockwise. Ensure that the setscrew is not removed from the connector.

CAUTION: Use only the appropriate torque-limited torque wrench provided by Nevro Corp. to ensure that the proper torque is applied to the setscrews and prevent overtightening.

4.5.5 Percutaneous Tunneling of the Extension

1. 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.
2. Plan the desired route of the tunnel and mark the route and the destination point at least 10-15 cm from the incision.
3. Give appropriate local anesthetic along the tunneling route.
4. Create a small incision at the planned extension exit site.
5. 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.
6. Hold the tunneling tip firmly and then unscrew and remove the tunneling tip. Take care not to drop the tunneling tip.
7. Remove the tunneling tool while leaving the straw in the tunnel.
8. Insert the proximal end of the lead extension(s) through the straw.
9. Push the lead extension(s) until they come out of the straw's other end.
10. 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.
11. Make sure that the lead location has not changed.

NOTE: Instead 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).

4.5.6 Closing the Incision Sites

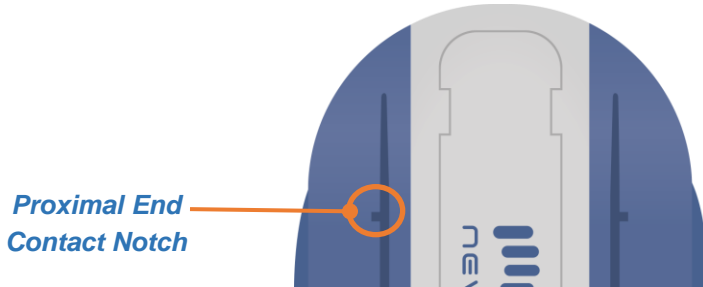
1. At the lead insertion site, use blunt dissection to create a pocket large enough to place excess lead. Coil excess lead into small loops and place them in the pocket.
2. Gently pull on the lead extension from the exit site to remove excess slack.
3. Close the incision at the lead insertion site.
4.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

4.6 CONNECTING THE LEAD OR EXTENSION TO THE TRIAL STIMULATOR

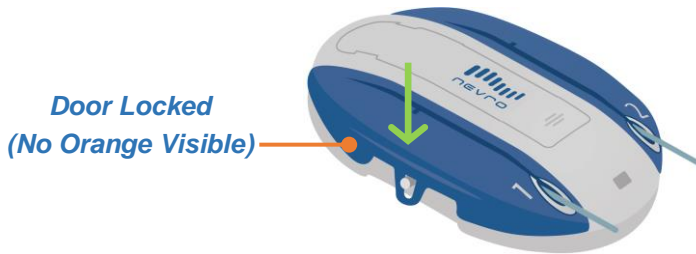
1. Apply appropriate sterile dressings to the site where the lead or lead extension exits the body. Tape the lead securely to the skin.
2. Create a loop of the lead for strain relief and then tape the lead to the skin.
3. Conduct impedance testing. Refer to the Clinician Programmer Manual (P/N 10000906) for detailed instructions. Do not attach the Trial Stimulator to the patient until all the impedances are in the normal range.
4. Once the impedances are confirmed, you can attach the leads to the Trial Stimulator. Ensure the Trial Stimulator is OFF.
5. Make sure Lead Door 1 is unlocked (orange markings below the door are visible). If Lead Door 1 is locked, push the door up using the lip at the edge of the door to unlock it.



6. Insert the first lead into Lead Port 1 until the most proximal contact of the lead is aligned with the notch on the Trial Stimulator lead door.



7. Press Lead Door 1 on the Trial Stimulator until there is an audible click (orange markings below the door are no longer visible). Gently tug on the lead to verify the door is locked.

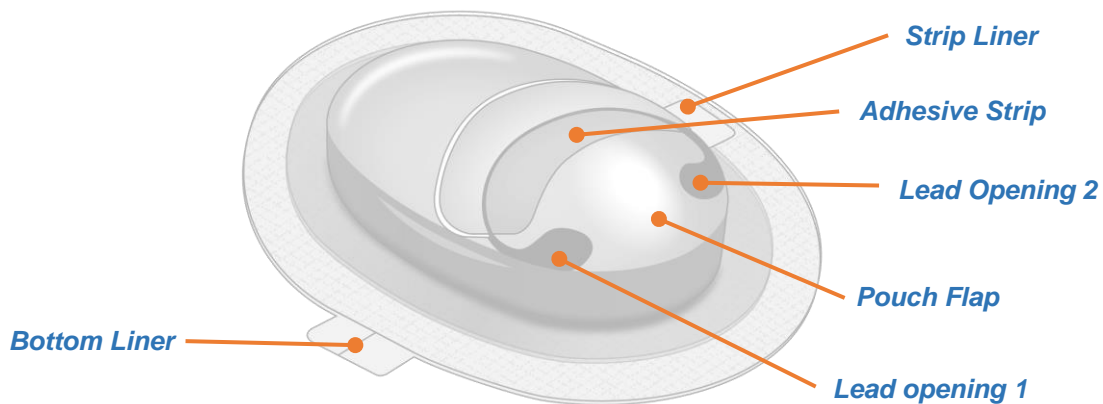


8. Repeat the three (3) preceding steps for the second lead and Trial Stimulator Lead Port 2. When two leads are used, the leads may be marked using a sterile surgical marker to distinguish between the two leads.

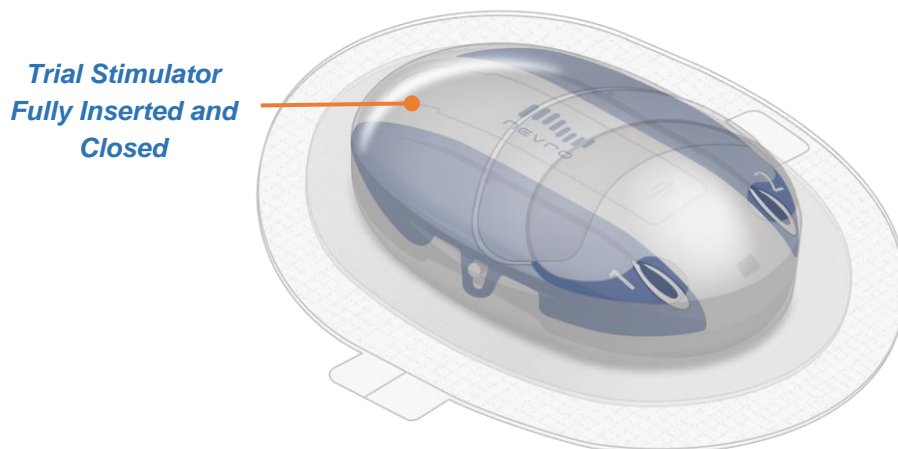
4.7 ATTACHING THE TRIAL STIMULATOR TO THE PATIENT

The Senza Bluetooth Trial System includes an optional Adhesive Pouch for the Trial Stimulator. Make sure the leads are securely locked in the Trial Stimulator before inserting it into the Pouch. If the optional Adhesive Pouch is not used, please secure the Trial Stimulator to the patient's body per physician's discretion.

WARNING: The Adhesive Pouch is NOT sterile. Do not bring it into contact with the lead insertion site.



1. To use the Pouch, insert the Trial Stimulator with leads into the Pouch by lifting the pouch flap and shimmying the Trial Stimulator into the Pouch.
2. Pull leads through lead openings 1 and 2 of the pouch after sliding the Trial Stimulator into the pouch. Make sure that the leads at the incision site has not shifted as a result.
3. Conduct impedance testing. Refer to the Clinician Programmer Manual (P/N 10000906) for detailed instructions. Do not attach the Trial Stimulator to the patient until all the impedances are in the normal range.
4. Attach the Pouch to the patient by removing the liner from the bottom adhesive and pressing the Pouch and Trial Stimulator onto the patient.
5. Close the Pouch by removing the liner from the adhesive strip on the top flap of the Pouch and pressing the adhesive strip to the Pouch.



NOTE: The Pouch may also be used by first attaching it to the patient, and then inserting the Trial Stimulator.

4.8 ABOUT THE TRIAL STIMULATOR

4.8.1 Adjusting Therapy on the Trial Stimulator

For instructions on how to turn stimulation ON and OFF, and adjust therapy on the Trial Stimulator, refer to the Senza Bluetooth Trial System Patient Manual (P/N 10000890).

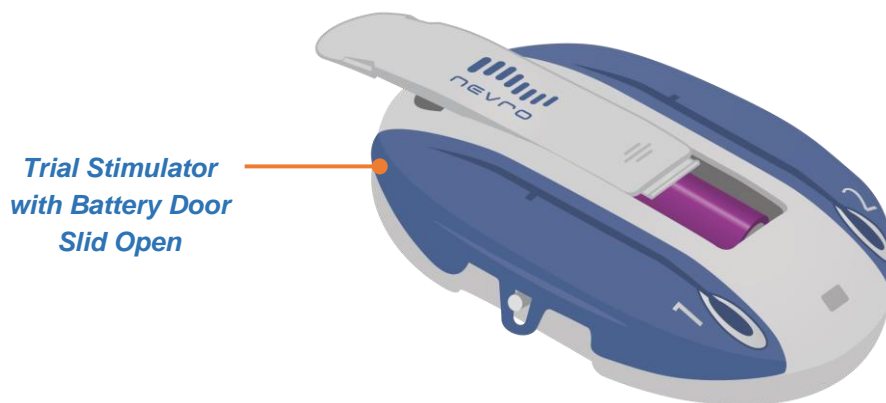
4.8.2 Replacing the Trial Stimulator Battery

1. Turn the Trial Stimulator OFF using the Remote Control or Clinician Programmer.

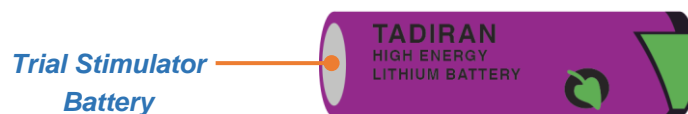
CAUTION: Always turn the Trial Stimulator OFF using the Programmer or Remote Control before replacing the battery.

2. If the Pouch was used to adhere the Trial Stimulator to the patient, carefully lift the pouch flap to open the Pouch and pull the Trial Stimulator out. Otherwise, carefully lift the dressing used to secure the Trial Stimulator to the patient.
3. Slide the battery door off the Trial Stimulator and remove the old battery.

CAUTION: Do not remove the battery in the Trial Stimulator unless the battery is being replaced. Removing and reinserting the same battery may cause the battery level read by the Trial Stimulator to be incorrect.



4. Insert a new battery matching the positive terminal of the battery to the positive symbol in the battery compartment. You may need to use a little force to get the new battery into the battery compartment.



CAUTION: The Trial Stimulator uses a Tadiran TL-5903 Lithium-Thionyl Chloride (Li-SOCl₂) battery that must be replaced with the same type of battery for the Trial Stimulator to work.

CAUTION: Always use a new battery when replacing the battery in the Trial Stimulator. The Trial Stimulator requires a new battery to properly determine its battery level.

5. Slide the battery door back onto the Trial Stimulator. The Trial Stimulator battery compartment should remain closed unless the battery is being replaced.
6. If the Pouch was used, insert the Trial Stimulator with leads back into the Pouch by lifting the pouch flap and shimmying the Trial Stimulator into the Pouch.
7. Conduct impedance testing. Refer to the Clinician Programmer Manual (PN 10000906) for detailed instructions. Do not replace the dressing until all the impedances are in the normal range.

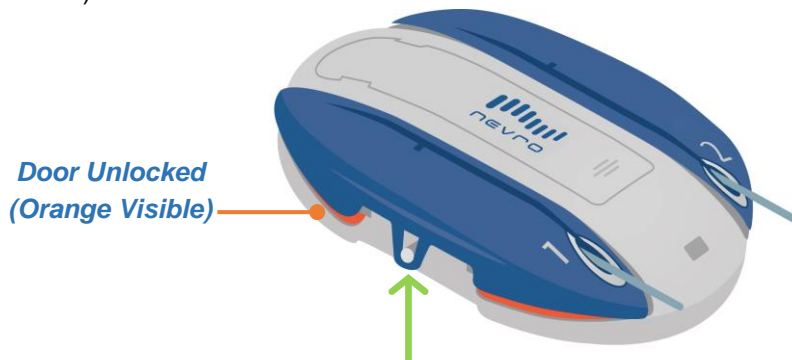
8. Close the Pouch by pressing the adhesive strip to the Pouch. Add additional tape if necessary.
9. Turn the Trial Stimulator ON using the Remote Control or Clinician Programmer.

4.8.3 Disconnecting the Trial Stimulator

1. Turn the Trial Stimulator OFF using the Remote Control or Clinician Programmer.

CAUTION: Always turn the Trial Stimulator OFF using the Programmer or Remote Control before connecting or disconnecting the leads.

2. Push the lead door up using the lip at the edge of the door to unlock it (orange marking below the door are visible).



3. Pull the lead out from the Trial Stimulator.

5 TROUBLESHOOTING

5.1 TROUBLESHOOTING PAIRING

5.1.1 *If the Clinician Programmer cannot pair with the Trial Stimulator*

- Make sure the Trial Stimulator is awake and ready for pairing.
 - Prepare the Trial Stimulator for pairing by holding the magnet over the magnet sensor on the Trial Stimulator. The Pairing LED should light up solid blue once the magnet is properly aligned with the magnet sensor.
 - Hold the magnet over the magnet sensor until the Pairing LED starts blinking to indicate it is ready to be paired with the Clinician Programmer.
 - On the Clinician Programmer, press the Scan Button to search for stimulators.
- Make sure the Clinician Programmer has Bluetooth turned on. For instructions on how to turn Bluetooth on, refer to the Clinician Programmer Manual (P/N 10000906).
- Move the Clinician Programmer closer to the Trial Stimulator and try again. The Clinician Programmer may be out of range.
- Move away from areas where there may be a lot of Bluetooth devices such as department stores or large, open office buildings and try again.
- Move away from possible sources of electromagnetic interference, such as electrical equipment and radio systems and try again.

5.1.2 *If the Remote Control cannot pair with the Trial Stimulator*

- Make sure the Remote Control is ready for pairing with the Trial Stimulator.
 - For the Remote Control to pair with the Trial Stimulator, first make sure the Remote Control is OFF by pressing the gray ON / OFF Button on the upper left side of the device.
 - On the Remote Control, hold the Program Selection Button down, then press the ON / OFF Button for up to 5 seconds. The Remote Control will start beeping to indicate it is searching for the Trial Stimulator.
- If the Remote Control beeps three times when it is done searching, the Remote Control was not able to find the Trial Stimulator. Make sure the Trial Stimulator is ready for pairing.
 - Prepare the Trial Stimulator for pairing by holding the magnet over the magnet sensor on the Trial Stimulator. The Pairing LED should light up solid blue once the magnet is properly aligned with the magnet sensor.
 - Hold the magnet over the magnet sensor until the Pairing LED starts blinking to indicate it is ready to be paired with the Remote Control.

What You Hear	What You See	What It Means
Three regular beeps	All lights are off	The Remote Control did not find the Trial Stimulator.

- If the Remote Control beeps four times when it is done searching, the Remote Control found more than one Trial Stimulator ready for pairing. The Remote Control can only pair when only one Trial Stimulator is found. Wait 2 minutes and try again.

What You Hear	What You See	What It Means
Four regular beeps	All lights are off	The Remote Control found more than one Trial Stimulator ready for pairing.

- If the Remote Control beeps six times when you turn it ON, the Remote Control batteries may be low.

What You Hear	What You See	What It Means
Six beeps	All lights are off	The Remote Control batteries are low.

- Replace the batteries in the Remote Control (see Patient Manual P/N 10000890). Normally, batteries should be replaced at least once a month. When replacing batteries, replace both at the same time and check that the orientation of the batteries is correct.
- Move the Remote Control closer to the Trial Stimulator and try again. The Remote Control may be out of range.
- Move away from areas where there may be a lot of Bluetooth devices such as department stores or large, open office buildings, and try again.
- Move away from possible sources of electromagnetic interference, such as electrical equipment and radio systems and try again.
- If you still hear three beeps when you press a button, use the gray button on the upper left side to power OFF the Remote Control, wait 10 seconds, then power it back ON again.

5.2 TROUBLESHOOTING LEAD CONNECTIONS

5.2.1 *If Impedances are not within the normal range*

- Make sure there are no fluids (e.g. blood) or debris at the proximal end of the lead. Remove the lead from the Trial Stimulator, wipe the proximal end of the lead and reinsert into the lead port.
- Make sure the lead is fully inserted into the Trial Stimulator. Remove the lead from the Trial Stimulator and reinsert it into the lead port. The first contact on the proximal end of the lead should line up with the notch on the lead door.

- Make sure the lead doors on the Trial Stimulator are locked by pressing down on the doors until there is an audible click and the orange markings below the door are no longer visible. Gently tug on the leads to verify the doors are locked.

6 PATIENT IDENTIFICATION CARD

Doctors should provide patients with a temporary Patient Identification (ID) Card during the trial phase. Patients should always carry their Patient ID Card with them. The card identifies someone as a device patient, and it may be important for the patient in a medical emergency. If a patient ever needs to go through a security checkpoint, they should show their Patient ID Card.

Patients should let their doctor know if they move or their personal information changes. It is important that patients update their contact information with their doctor and Nevro.



7 ADDITIONAL INFORMATION

Refer to the Clinical Summary (P/N 12057) for additional information regarding clinical studies of the Senza System and safety and effectiveness data.

Refer to the Information for Prescribers (P/N 10001045) for indications, contraindications, warnings, warnings about other medical treatments, precautions, adverse events, technical specifications, and security features and declarations.

Refer to the Nevro MRI Guidelines Manuals (P/N 11096) for detailed information on MRI safety and conditions for MRI scanning of patients implanted with Nevro products.

Additional information may be found in other documentation available at www.nevro.com/manuals.

This page is intentionally left blank.



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:

Nevro Corp.
1800 Bridge Parkway
Redwood City, CA 94065
USA

Tel: +1.650.251.0005
Fax: +1.650.251.9415
Email: info@nevro.com