



PATIENT MANUAL

Senza BLUETOOTH® Trial System

Effective May 2020

10000890 Rev 02



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.

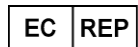
1800 Bridge Parkway

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, Senza Bluetooth, Omnia, 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 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.



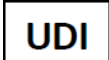
CONTENTS

1 EXPLANATION OF SYMBOLS ON THE PRODUCT OR LABELING	4
2 INTRODUCTION	7
3 DEVICE DESCRIPTION	9
3.1 MAJOR COMPONENTS.....	9
4 INSTRUCTIONS FOR USE	11
4.1 USING THE REMOTE CONTROL	11
4.2 ABOUT THE TRIAL STIMULATOR	16
4.3 ASK YOUR DOCTOR	ERROR! BOOKMARK NOT DEFINED.
5 TROUBLESHOOTING	18
5.1 TROUBLESHOOTING THERAPY.....	18
5.2 TROUBLESHOOTING THE REMOTE CONTROL.....	18
6 PATIENT IDENTIFICATION	22
7 ADDITIONAL INFORMATION	24

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="415 657 529 709">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 people who are considering or have received a Nevro® Senza® Bluetooth® Spinal Cord Stimulator (SCS) Trial System to help treat pain. Every person is unique, and your medical needs differ from those of others, even people with the same condition and the same SCS system. For this reason, always talk to your doctor if you have questions about your condition. This booklet presents general information and can help you better communicate with your doctor. For information about indications, contraindications, warnings, precautions, and technical specifications, refer to the Information for Prescribers (P/N 10001045).

The first part of this booklet discusses the Senza Bluetooth Trial System, including a visual guide to the system components. It is based on common questions that patients have about their condition, this particular treatment option, and the Senza Bluetooth Trial System.

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

Throughout the booklet, we have provided definitions of medical or electronic terms in shaded boxes like this:

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

2.2 About Chronic Pain

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

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

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

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

2.3 What to Expect with SCS Therapy

If you and your doctor decide to proceed with SCS therapy, the first step is a trial phase. Typically, your doctor will first place a lead in your body. This procedure may be done under local anesthetic, so you are awake and aware

of what is going on. You may be given medication to help you relax and some numbing medicine for the insertion site. The lead is placed in your body during a minor procedure usually without an incision. Once the lead has been attached to the Trial Stimulator, the Trial Stimulator will either be placed in a pouch or wrapped in bandages to your back. Most patients are able to leave the hospital the same day, depending on physical condition, the procedure, and doctor's preferences. Once the lead is in the body, you will typically use the Trial Stimulator over a period of days as decided by your doctor. This provides an opportunity for you and your doctor to experience the system on a temporary basis and evaluate how well the device might work for you.

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

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

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

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

2.4 Trial Phase

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

When you are in the Trial Phase, you will receive a Trial Stimulator and a Remote Control so you have a chance to see if SCS therapy works for you. If it works well for you, you will have an IPG implanted in the body to replace the Trial Stimulator. This trial phase typically lasts several days.

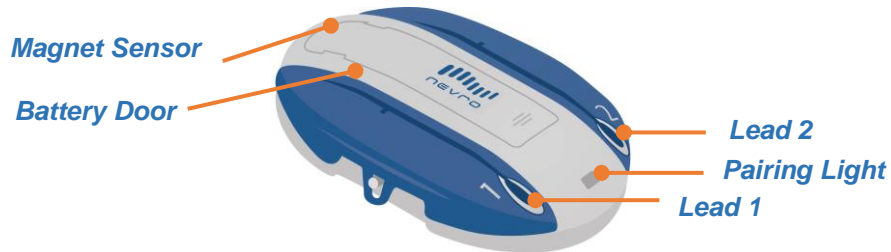
For your trial, your doctor has set up a stimulation program for you. He or she has adjusted the device's features specifically for you. You will be given the external Trial Stimulator and a Remote Control. Using this system, you can test the stimulation system to see how it works for you. At the end of the trial phase, you will discuss with your doctor whether a device should be implanted in your body to take the place of the Trial Stimulator.

3 DEVICE DESCRIPTION

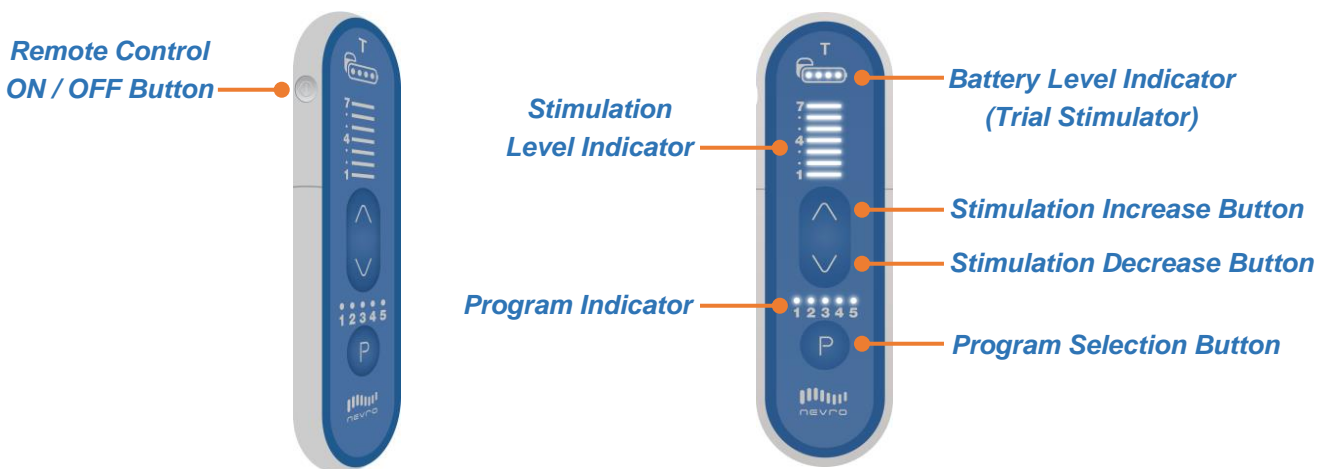
The Senza Bluetooth Trial System works by delivering electrical energy from a stimulator to an area around the spine. The system is capable of delivering HF10® therapy, a therapy that does not produce tingling sensations called paresthesia. It is also capable of providing stimulation that produces paresthesia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

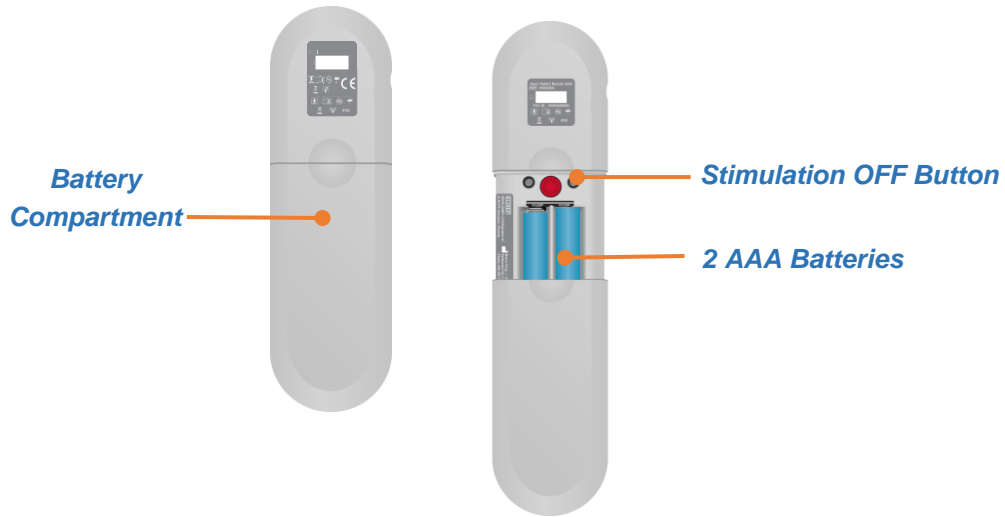
3.1 Major Components

- 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.

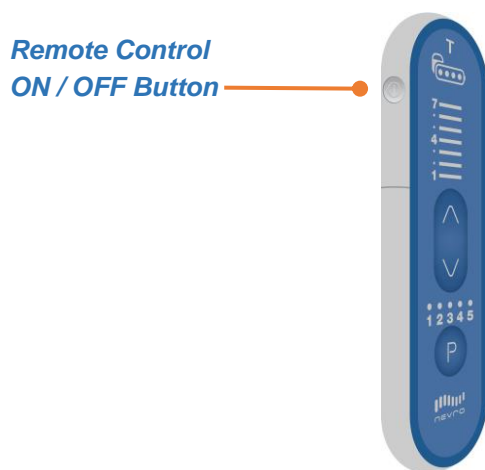
4 INSTRUCTIONS FOR USE

4.1 USING THE REMOTE CONTROL

4.1.1 Turning ON the Remote Control

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

1. Press and hold the small gray ON / OFF Button on the upper left side of the Remote Control for up to five seconds



2. If the Remote Control turns ON, you will hear one long beep and it will flash all its lights once.
3. The lights on the Remote Control will continue to flash as it tries to establish communication with the Trial Stimulator.
 - If the Remote Control successfully establishes communication with the Trial Stimulator, the lights will stop blinking and be updated to indicate the current stimulation of your Trial Stimulator.
 - If the Remote Control cannot establish communication with the Trial Stimulator, the Remote Control will beep 3 times, then turn itself off. If this happens, repeat step 1.
 - Refer to the [Troubleshooting Section](#) of this manual to learn why the Remote Control may be having difficulties connecting to the Trial Stimulator and what you can do about it.

4.1.2 Turning OFF the Remote Control

The Remote Control turns itself OFF automatically if no buttons are pressed for two minutes. You can also turn the Remote Control OFF yourself by pressing the gray ON / OFF Button on the upper left side of the device. Note that even while the Remote Control is OFF, it can still receive alerts from the Trial Stimulator and notify you of the Trial Stimulator stimulation status.

4.1.3 Turning OFF Stimulation

1. Press and hold the small gray ON / OFF Button on the upper left side of the Remote Control for up to five seconds to turn the Remote Control ON.
2. Press the round red Stimulation OFF Button located inside the Remote Control battery compartment to turn stimulation OFF. The Stimulation is OFF when all stimulation level indicator lights are off.



4.1.4 Turning ON Stimulation

1. Press and hold the small gray ON / OFF Button on the upper left side of the Remote Control for up to five seconds to turn the Remote Control ON.
2. Press the Stimulation Increase Button on the Remote Control to turn stimulation ON (if stimulation was turned off previously). Your doctor has set up your stimulation program for you already. When you turn stimulation ON, it will stimulate as programmed. The Stimulation is ON when stimulation level indicator lights turn on.

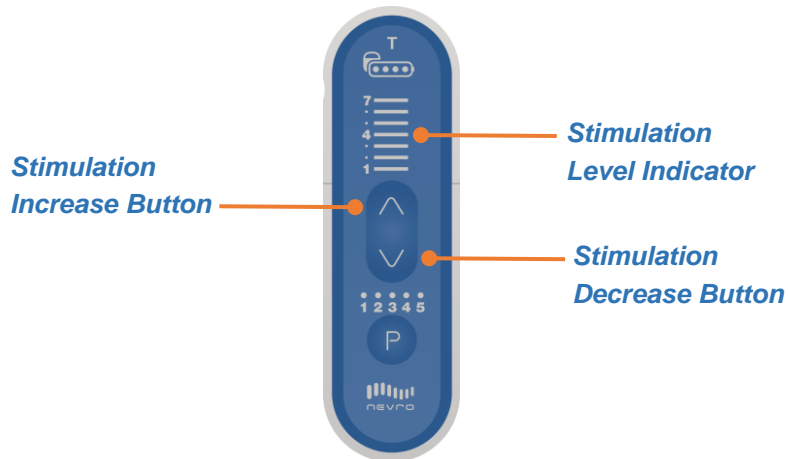


4.1.5 Changing Stimulation Level

Follow the directions given to you by your doctor when changing the stimulation level. The stimulation you receive can be increased or decreased using the Remote Control.

1. Press and hold the small gray ON / OFF Button on the upper left side of the Remote Control for up to five seconds to turn the Remote Control ON.

- To increase stimulation strength, press the Stimulation Increase Button repeatedly until you reach the stimulation strength you want. To decrease the stimulation strength, press the Stimulation Down Button.

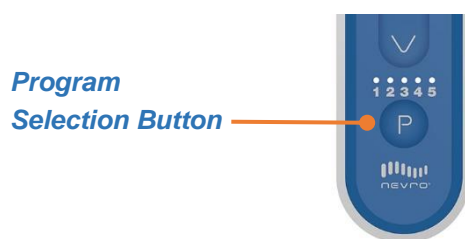


Your doctor has programmed a maximum stimulation strength into the device and it cannot be made to stimulate more intensely than what was programmed.

4.1.6 Switching Between Programs

Your doctor may have set up your stimulator to offer up to 5 different programs. Follow the directions given to you by your doctor when switching the program. If you have more than one stimulation program available, you can change programs as follows:

- Press and hold the small gray ON / OFF Button on the upper left side of the Remote Control for up to five seconds to turn the Remote Control ON.
- Press the Program Selection Button. Each time you press the button, the next available program light will turn on.



- When the light above your desired program turns on, stop pressing the Program Selection Button.

If only one program is available, the number for that program will remain lit and you will not be able to change

programs.

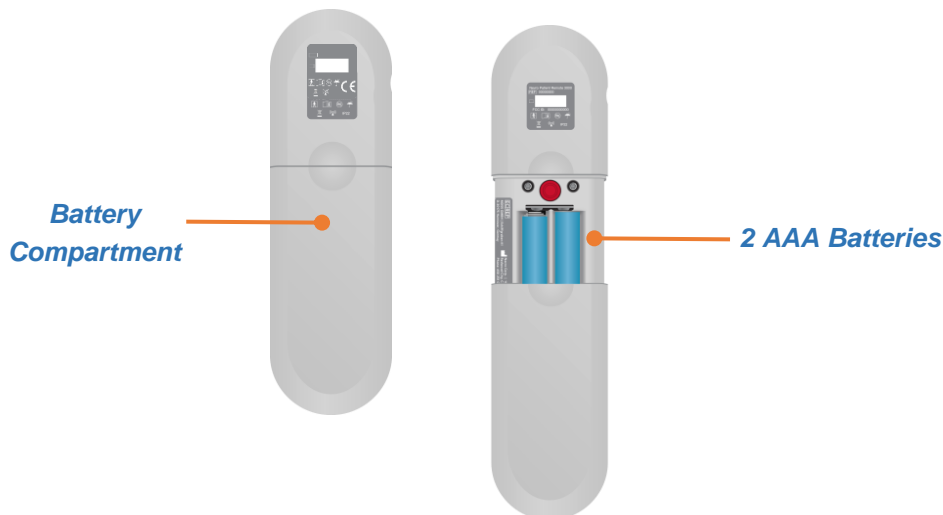
4.1.7 Changing the Batteries in the Remote Control

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

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

Make sure the Remote Control is OFF; it turns itself OFF automatically if no buttons are pressed for two minutes. You can also press the gray ON / OFF Button on the top left side of the Remote Control to turn it off yourself.



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



4.1.8 Understanding Signals from the Remote Control

Your Remote Control will beep and light up to keep you informed about your Senza Bluetooth Trial System status.

The following table provides the most common signals you will see and hear from your Remote Control. If you encounter something that is not shown here, Refer to the [Troubleshooting Section](#) of this manual, or contact your doctor.

What You Hear	What You See	What It Means
One single soft beep	No change in lights.	One of the buttons on the Remote Control was pressed.
One single regular beep	The therapy level lights or programs lights change.	Stimulation has increased or decreased by one level or a new program has been selected.
Two regular beeps	No change in lights.	You have reached the highest or lowest stimulation level possible.
Three regular beeps	No change in lights.	The Remote Control is not able to communicate with the Trial Stimulator. Refer to the Troubleshooting Section of this manual.
Continuous beeping for 60 seconds	All battery lights are blinking. 	The Trial Stimulator battery is low or completely empty. Refer to the Troubleshooting Section of this manual.
Continuous beeping for 60 seconds	All therapy level lights are blinking. 	One of the leads on the Trial Stimulator is loose. Refer to the Troubleshooting Section of this manual.

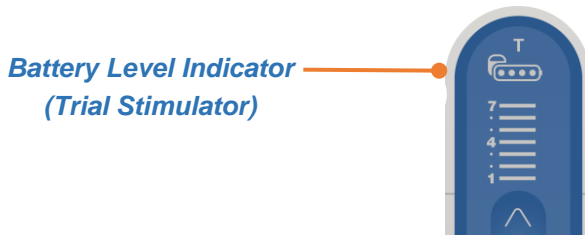
4.2 ABOUT THE TRIAL STIMULATOR





The Trial Stimulator is an externally worn SCS device that delivers therapy, stops delivering therapy, increases or decreases therapy intensity, or changes therapy types (“programs”) in response to commands that you send it using the Remote Control. You should avoid interacting directly with the Trial Stimulator, touching it, or applying pressure to it, as these activities could cause the Trial Stimulator that is attached to your body to come loose. It could also interfere with the lead connections to the Trial Stimulator or with the lead position in your spine.




4.2.1 Understanding Trial Stimulator Battery Status

Your Remote Control provides the battery level of your Trial Stimulator on the Trial Stimulator Battery Level Indicator. The Remote Control will notify you when the battery in the Trial Stimulator is low or completely empty by blinking all its battery lights and beeping continuously for 60 seconds (see the [Troubleshooting Section](#) for specific details). Contact your doctor if you receive any of these battery notifications.



The table below describes the different battery levels for the Trial Stimulator.

Battery Level	What You See	What It Means
4 lights on		Trial Stimulator battery is full. 100% battery capacity remaining.
3 lights on		75% battery remaining.

Battery Level	What You See	What It Means
2 lights on		50% battery capacity remaining.
1 light on		25% battery capacity remaining.
All lights blinking		The Trial Stimulator battery is low or completely empty. Refer to the Troubleshooting Section of this manual.

4.2.2 Replacing the Trial Stimulator Battery

Your Trial Stimulator has a battery that can be replaced by your doctor if necessary. Do not attempt to replace the battery in the Trial Stimulator yourself.

WARNING: The Trial Stimulator uses a special purple battery from Nevro that must be replaced with the same type of battery for the Trial Stimulator to work. Do not attempt to replace the battery and consult your doctor if the battery needs to be replaced.

4.2.3 Understanding the Optional Adhesive Pouch

The Trial Stimulator may be secured to the patient's back using an Optional Adhesive Pouch, per the discretion of the doctor. If used, the patient should avoid opening or taking the Trial Stimulator out of the Optional Adhesive Pouch.

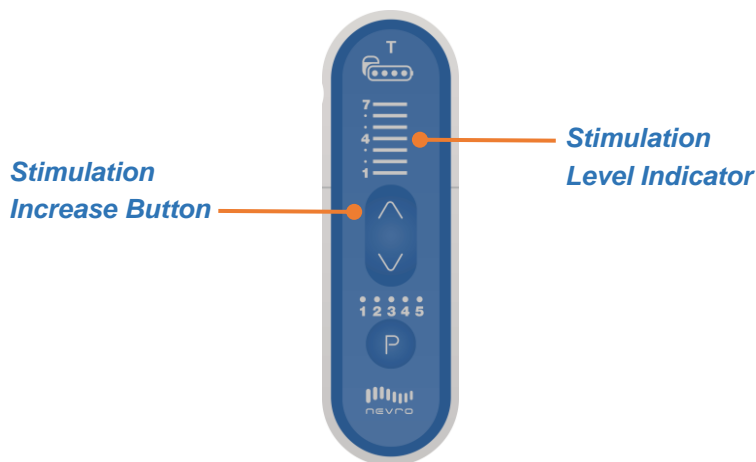
5 TROUBLESHOOTING

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

5.1 TROUBLESHOOTING THERAPY

5.1.1 If therapy has stopped:

- Check that therapy has not been inadvertently turned OFF.
 - Press and hold the gray ON / OFF Button on the upper left side of the Remote Control for up to five seconds to turn the Remote Control ON.
 - Wait for the Remote Control to connect with the Trial Stimulator.
 - Check that at least one of the Stimulation Level Indicator lights is on.
 - If none of the Stimulation Level Indicator lights is on, press the Stimulation Increase Button to turn stimulation ON.
 - Check that at least one of the Stimulation Level Indicator level lights is on.



- If the Remote Control cannot connect with the Trial Stimulator, it is possible the Trial Stimulator battery is completely empty.

5.2 TROUBLESHOOTING THE REMOTE CONTROL

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

- Make sure the Remote Control is ON. You must turn ON the Remote Control before you use it (the Remote Control automatically turns itself OFF when not in use). To turn it ON, press and hold the gray ON / OFF button on the upper left side of the Remote Control for up to five seconds.
- 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 “Using the Remote Control”). 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. The Remote Control may be out of range.

5.2.2 If you press a button on the Remote Control and it beeps three times:


- If the Remote Control beeps three times when you press a button, it may be having trouble communicating with the Trial Stimulator.

What You Hear	What You See	What It Means
Three beeps	No change in lights	The Remote Control is not able to communicate with the Trial Stimulator.

- 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.

5.2.3 If Remote Control is beeping continuously and/or all the Stimulation Level Indicator lights on the Remote Control are blinking:


- If the Remote Control is beeping continuously and/or the Stimulation Level Indicator lights are blinking, there may be a loose connection between a lead and the Trial Stimulator.

What You Hear	What You See	What It Means
Continuous beeping for 60 seconds	All the Stimulation Level Indicator lights are blinking 	There may be a loose connection between a lead and the Trial Stimulator. Contact your doctor.

- Dismiss the beeping and blinking by pressing and holding the ON / OFF button for up to five seconds.
- Contact your doctor to schedule an appointment to check your leads.

5.2.4 If the Remote Control is beeping continuously and/or all the Battery Level lights on the Remote Control are blinking:

- If the Remote Control beeps continuously and/or the battery lights are blinking, the Trial Stimulator battery may be low or completely empty.

What You Hear	What You See	What It Means
Continuous beeping for 60 seconds	All the Battery Level lights are blinking 	The Trial Stimulator battery is low or completely empty. Contact your doctor.

- Dismiss the beeping by pressing and holding the ON /OFF button for up to five seconds. The battery lights will continue to flash.
- Turn on your Remote Control:
 - If the Remote Control turns ON and the therapy level and program are displayed, the battery in your Trial Stimulator is low but therapy is still ON. Your Trial Stimulator battery has less than 48 hours (2

days) of therapy left. You may continue to use your Trial Stimulator but should schedule an appointment with your doctor to have your battery replaced.

- If the Remote Control beeps 10 times when you turn it ON, the Trial Stimulator battery is completely empty, and therapy has been turned OFF. You will not be able to use your Trial Stimulator until the battery is replaced.

What You Hear	What You See	What It Means
Ten beeps	All lights are off	The Trial Stimulator battery is completely empty. Contact your doctor.

- Contact your doctor to schedule an appointment to change your battery.



6 ASK YOUR DOCTOR

SCS therapy has helped many people, but you must be willing to share information with your doctor for best results. Keep the name and phone number of your doctor and/or healthcare professional (technician) near you, at home, and at work, so that you or others can get in touch with him or her quickly if need be. Tell your family and other individuals close to you about your Senza Bluetooth Trial System in the event that they ever have to assist you or become involved on your behalf during a medical event.

Contact your doctor promptly if:

You feel unusual pain or discomfort during stimulation. (Turn stimulation OFF right away).

The implant site is swollen, reddened, irritated, tender, or painful.

You experience any unusual symptoms that you think may be related to the device.

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

Ask your doctor or other healthcare professional for help if you have any trouble:

Using the Remote Control

Using the Trial Stimulator

Adjusting your therapy

Discuss with your doctor any changes in:

Your condition

Your response to therapy

7 PATIENT IDENTIFICATION CARD

Patients will be provided 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.



8 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.

The Trial Stimulator is unsafe for an MRI. Please 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