

Senza Remote Control Quick Start Guide



How to use the Remote Control (PTRC1000)

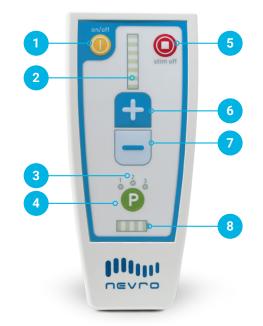


How to use the Charger (CHGR1000)



HEX How to use the Remote Control (PTRC1000) For Patients in the Implant Phase

- 1. Remote Control ON/OFF Button
- 2. Stimulation Level Indicator
- 3. Program Indicator
- 4. Program Selection Button
- 5. Stimulation OFF Button
- 6. Stimulation Start/Increase Button
- 7. Stimulation Decrease Button
- 8. Battery Level Indicator (Charger level of Trial Device or Implant)



Tips

Guidance on using your Remote Control will be provided by your HFX Care Team. You may not need to make any programming changes during the temporary trial. To achieve optimal relief, make sure you work closely with your HFX Care Team.

Replace the batteries in the Remote Control if any of the following situations arise:

- The Remote Control beeps 6 times when turned on.
- The Remote Control will not turn on.

The Remote Control uses 2 AA batteries, alkaline only. DO NOT USE lithium or rechargeable batteries.

When the Battery Level Indicator shows 2 bars or fewer, the batteries in the Trial Device need to be replaced. See Trial Device Guide.

Turning the Remote Control ON

Press () and hold until you see lights turn on and hear a beep.

- You may need to press \bigcirc for up to 5 seconds.
- If the Remote Control syncs with the Trial Device or Implant, your Program Indicator (1, 2, or 3) will light up. You'll also see lights on the Stimulation Level Indicator indicating the stimulation is ON.
- If the Remote Control cannot sync with the Trial Device or Implant, you will hear 3 beeps and the lights on the Remote Control will turn OFF.
- Repeat these until you have a link with the Trial Device or Implant. Moving the Remote Control closer to the Trial Device or Implant will help.
- Other buttons on the Remote Control will respond only when the Remote Control is ON and linked to the Trial Device or Implant.

Turning Remote Control OFF

Press 🕕 to turn OFF the Remote Control.

- Stimulation continues even when the Remote Control is OFF.
- DO NOT press O to turn OFF the Remote Control.
 turns stimulation OFF.
- Remote Control will turn off by itself after 2 minutes of inactivity.

Turning stimulation OFF

Once the Remote Control is ON, press 🔘 to turn stimulation OFF.

- The lights on the Stimulation Level Indicator will be OFF when stimulation is OFF.
- This button only turns stimulation OFF. It does not turn stimulation ON.

Turning stimulation ON and changing program

To turn stimulation ON, press 🕂 . The Remote Control must be ON.

- Stimulation is ON unless it has been turned OFF.
- When stimulation is turned ON (after it was turned OFF), the Trial Device or Implant will be on the starting level for the last active program used.

To change the program, press P

- Program Indicator light will start blinking.
- Press **P** repeatedly until the light is at the desired program number.
- Once desired program is selected, do not press any buttons until the light stops blinking. The Remote Control will sound one long beep, confirming the new program setting. Verify that the light above the desired program number is steadily illuminated.
- If the Remote Control beeps 3 times and the Program Indicator goes back to the previous program, then the program was not successfully changed. Place the Remote Control closer to the Trial Device or Implant and repeat previous steps.

Changing stimulation level

The remote should be turned ON before adjusting the stimulation level.



s 🛨 to increase stimulation level.

ss 📒 to decrease stimulation level.

- For each 🛨 or 🚍 , 1 beep will sound.
- The level of stimulation can be seen in the Stimulation Level Indicator.
- When stimulation level for selected program is at the maximum or minimum level AND you try to go one level up or down, 2 beeps sound, indicating that you are at the currently programmed limit.

Impedance Check Instructions (PTRC1000)



An Impedance Check for your system is required to be performed prior to you receiving an MRI scan. Before initiating an Impedance Check, be sure to note the program and number of levels you are on in order to confirm there are no changes to your settings made during the process.

Below are step by step instructions on how to perform the check. Contact your HFX Care Team before conducting an Impedance Check on your device.

In some situations, the Impedance Check can be performed by your HFX Care Team if needed.

Turn on your Remote Control

• Press and hold the yellow on/off button 🕕 at the top left corner of the Remote Control for 5 seconds, or until you hear a long beep indicating the Remote Control has connected to your implant device.

Turn off Stimulation and Initiate Impedance Check

- Next, press and hold the stimulation off button 🔘 at the top right corner of the Remote Control for at least 10 seconds.
- The Remote Control will beep and the ladder lights will turn off, confirming that stimulation has been turned OFF.
- While you continue to hold down the stimulation' off button 🔘 the ladder lights will begin to light up from bottom to top. indicates the impedance check is in process.
- The remote will then beep when the impedance check is complete. Once you hear another beep or series of beeps, you can release the O. These beeps (described below) indicate whether you had a successful or unsuccessful Impedance Check.

Successful Impedance Check Indicators

• To be eligible for an MRI procedure, all of your impedances need to be within an acceptable range. The impedances are within an acceptable range when you hear one long beep and see all ladder lights on your Remote Control, including the battery bar, light up solid after holding the stimulation off button O for more than 10 seconds after following the instructions above.

Unsuccessful Impedance Check Indicators

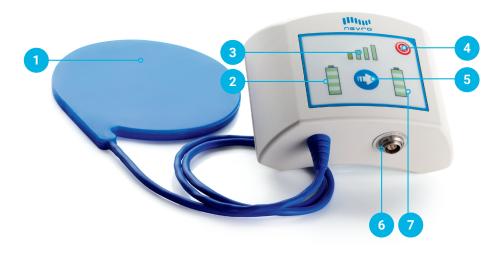
- If the Impedance Check was unsuccessful, you will hear 3 short beeps after holding the O stimulation off button for 10 seconds after following the instructions above. Move the Remote Control closer to your device and press and hold the O for 10 seconds to re-run the Impedance Check.
- If you hear 4 short beeps followed by one or more of the ladder lights or battery level indicator flashing, this indicates one or more of the electrode impedances are not within acceptable range and an MRI cannot be completed. Please contact a HFX Coach at 844-331-1001 for support.
- If none of the number levels on your remote are lit up or blinking, the Impedance Check was not performed. Follow the instructions listed above in "Turn off Stimulation and Initiate Impedance Check," being sure to hold the stimulation off button for at least 10 seconds.

Exit Impedance Check Instructions and Turn Stimulation Back On

- To exit the Impedance Check mode, press the yellow on/off button 🕕 on the Remote Control for 5 seconds until all lights on the Remote Control turn off. When the Remote Control is turned on next, it will return to the normal mode.
- To turn stimulation back ON, first turn the Remote Control on using the yellow on/off button (●), then press the '+' button (●) once. You will now see lights on your ladder indicating stimulation is ON and you can adjust program settings as needed.



- 1. Charging Coil
- 2. Charger Battery Level Indicator
- 3. Antenna Strength Indicator
- 4. Stimulation OFF Button
- 5. Charge Start Button
- 6. Power Adapter Port
- 7. Implant Battery Level Indicator



Tips

Do not press **O** unless you want to turn OFF the stimluation. To turn the stimulation ON, use your Remote Control.

Charging times may vary for each session, depending on factors such as recharging frequency and stimulation settings.

If the Charging Coil has an insufficient link (shown by the Antenna Strength Indicator), reposition the Charging Coil slowly and wait 3 seconds. The Antenna Strength Indicator may take up to 3 seconds to update the new Charging Coil position. Repeat as necessary.

If charging time is shorter than expected, your Implant may have been turned OFF. Make sure your Implant is turned ON with the Remote Control.

Important reminders

Do not charge the Implant while the Charger is plugged into the wall. Always remove the Power Adapter before pressing the Charge Start Button.

Recharge the Implant regularly to develop an easy-to-remember routine.

While charging, the implant site may become warm. If pain or discomfort is felt, stop charging and contact your doctor or HFX Coach.

After recharging the Implant, plug the Charger back into the wall so the Charger will be ready for your next recharging session.

Use the Remote Control after charging to verify that the stimulation is ON. If charging times dramatically increase, please notify your HFX Coach.

Video instructions are available at www.NevroHFX.com/Resources.

Charging preparation

Place the center of the circular Charging Coil over the top of your Implant.

- Figure 1 shows that the top of the Implant (in yellow box) is at the center of the Charging Coil.
- Figure 2 shows an Implant just below the beltline. Your Implant may be in a different location, such as on your front side, in the abdomen (not shown).



Initiate charging

Press 🕪 and hold until beeping starts, then release.

- 1. Beeping and blinking of green lights continues until the Charger links with the Implant.
- 2. If 10 to 12 seconds pass without a link, the Charger will sound one long beep and shut off. Reposition the Charging Coil and press hold 🐢 again.
- 3. When lights appear on the Antenna Strength Indicator, a link has been made. More lights mean a better link, and make it less likely that charging will be interrupted by movements.
- 4. If the link is insufficient or lost, the Antenna Strength Indicator will show only the small orange bar and beep intermittently.

If the link is not made, is insufficient, or is lost, reposition the blue Charging Coil slowly and repeat Steps 1 and 2.

Charging

Charging is in progress when you see lights blinking on both the Charger Battery Level Indicator and the Implant Battery Level Indicator. As charging progresses, the number of lights on the Charger Battery Level Indicator will decrease and the number of lights on the Implant Battery Level Indicator will increase.

• If the link is lost, the Charger will beep. Reposition the Charging Coil and repeat Steps 1 and 2.

Complete charging

When charging is complete, one long beep will sound and the lights on the Charger will turn OFF. Check the Implant Battery Level to make sure the battery is fully charged.

Use the Remote Control to check that the Implant is turned ON.

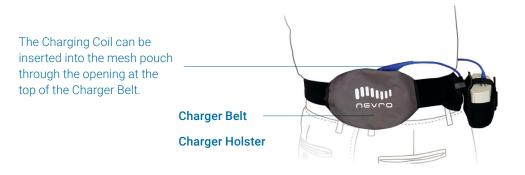
Plug the Charger into the wall socket to ensure the Charger will be ready for the next charging session.

- To plug the Charger into the wall socket, connect the Power Adapter into the Charger's Power Adapter Port, then plug the Power Adapter into the wall socket.
- It's okay to continuously charge the Charger. The battery will not be damaged.

Using the Charger Belt

Once you know where to place the Charging Coil to achieve a strong link with the Implant, use the Charger Belt to secure the Charging Coil's location on your body before charging.

- 1. Place the blue Charging Coil in the mesh pouch on the Charger Belt and securely attach belt around the waist.
- 2. Initiate charging and move the Charging Coil until it links with the Implant.
- 3. If you want to be mobile during charging, insert the Charger into the holster. Then clip the holster to your belt or pants.



Video instructions are available at www.NevroHFX.com/resources

For full instructions on the accessories, warnings, and precautions, please refer to the Patient Manual.

Important information: Rx Only: Patient experiences with the Senza® spinal cord stimulation (SCS) system vary by individual, including the amount of pain relief. The occurrence of adverse events associated with SCS implant surgery or use also varies by patient. Please see www.Nevro.comHFX/safety for complete safety, indications for use, and contraindications information.

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1800 Bridge Parkway Redwood City, CA 94065 USA www.NevroHFX.com Tel. 1.650.251.0005 Toll-free 1.888.956.3876