



HFX™ Accessory Guides



How to use the Trial Device



*How to use the Remote Control
(PTRC1000)*



*How to use the Remote Control
(PTRC2300 - 3 Program Remote)*



*How to use the Omnia™ Remote Control
(PTRC2500 - 5 Program Remote)*



*How to use the Charger
(CHGR1000)*



*How to use the Charger
(CHGR2500)*

HFX is a comprehensive solution that includes a Senza spinal cord stimulation system and support services for the treatment of chronic pain.

1. Stimulation Increase Button
2. Low Battery Indicator Light
3. Stimulation ON Indicator Light
4. Stimulation Decrease Button
5. Stimulation OFF Button



Tips



- Your Trial Device delivers the stimulation to the leads.
- Although many buttons are present on this device, you will make nearly all stimulation changes using your Remote Control.
- Remember, to achieve optimal relief, make sure you work closely with your HFX Care Team before making changes to the settings.
- Be sure to keep the Trial Device dry.
- Check the Stimulator ON Indicator Light two times per day to confirm the stimulation is on.

Default mode of the Trial Device

- In the default mode, the plus and minus buttons are locked. This feature prevents accidental pressing of the buttons, which can change the settings.
- When locked, only the Stimulation OFF Button will respond.
- In the locked state, you can still receive HFX.
- Stimulation settings can be changed with the Remote Control.

Turning stimulation OFF

Press 

- Stimulation ON Indicator Light will turn OFF.
-  only turns stimulation OFF. It does not turn stimulation ON.
-  will turn stimulation OFF, even while the Trial Device's buttons are locked.



Turning stimulation ON



- Refer to the Remote Control Guide.

Changing stimulation level

- Refer to the Remote Control Guide.

Ensuring cable connection


If one of the cables is disconnected from the Trial Device, it will beep continuously. Reinsert the cable using the following steps:

1. Ensure that stimulation is OFF. Press  to stop the alarm and stimulation.
2. Check the color of the sticker at the  Trial Device end of the OR cable.
3. Plug the OR cable into Trial Device port that matches the color of the OR cable sticker. A click will sound once the cable is fully inserted into the Trial Device.
4. Use Remote Control to turn stimulation back on.

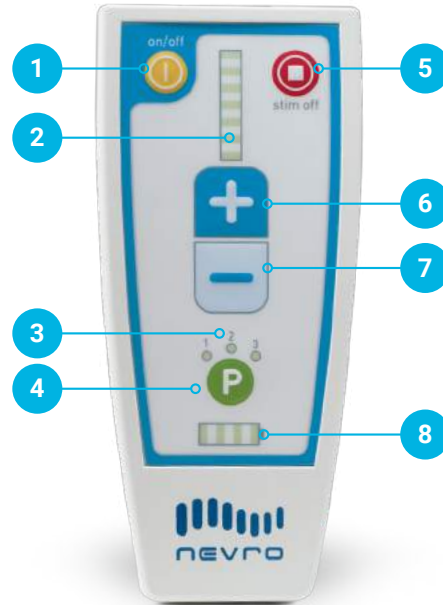
Replacing the batteries

When the Low Battery Indicator Light  is flashing or ON, the Trial Device's batteries need to be replaced.

To change the batteries, follow these steps:

1. Turn the Trial Device OFF by pressing .
2. Remove the battery cover on the back of unit and remove the 2 batteries.
3. Confirm the new batteries are the purple batteries provided by Nevro[®]. (These batteries should not be used for any other purpose.) DO NOT use AA batteries.
4. Insert the new purple batteries into the battery compartment. Be sure to match (+) and (-) ends of batteries with the corresponding connectors inside battery compartment.
5. Replace the cover and restart stimulation using the Remote Control.

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 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  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 .



- Program Indicator light will start blinking.
- Press  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

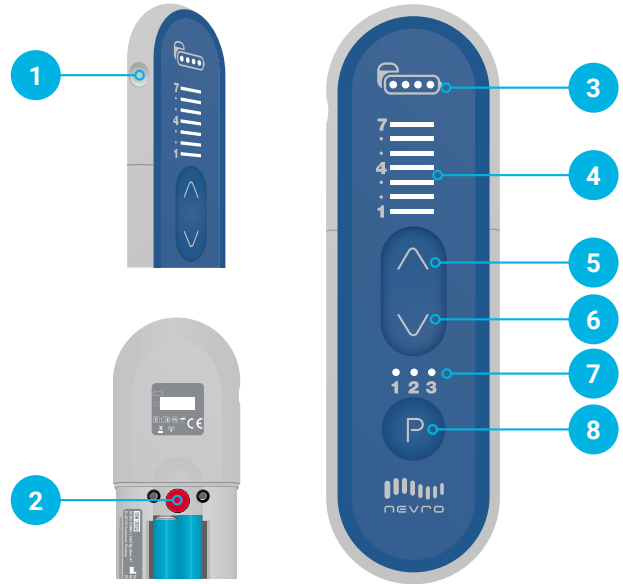
The remote should be turned ON before adjusting the stimulation level.

Press  to increase stimulation level.

Press  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.

1. Remote Control ON/OFF Button
2. Stimulation OFF Button
3. Battery Level Indicator (Charge Level of Implant)
4. Stimulation Level Indicator Ladder lights
5. Stimulation Start/Increase Button
6. Stimulation Decrease Button
7. Program Indicator
8. Program Selection Button



Tips

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.
- It has been 3 months since the last battery change.

To achieve optimal relief, make sure you work closely with your HFX Care Team to identify which programs work best for you. They will provide guidance on how and when to use the Remote Control.

The Remote Control uses 2 AAA batteries, alkaline only.


DO NOT USE lithium or rechargeable batteries.

When the Battery Level Indicator shows 2 dots or less, your Implant battery needs to be recharged using the Charger.

Video instructions are available at www.NevroHFX.com/en/resources/existing-patients.

Turning the Remote Control ON

Press and hold side button  until you hear a long beep.

- You may need to press  for up to 5 seconds.
- If the Remote Control syncs with the Implant, at least one LED light on the Remote Control will light up.
- If the Remote Control cannot sync with the Implant, you will hear 3 beeps and the lights on the Remote Control will turn OFF.
- Repeat these steps until you have a link with the Implant. Moving the Remote Control closer to the Implant will help.
- Other buttons on the Remote Control will respond only when the Remote Control is ON and linked to an Implant.


Turning Remote Control OFF

Press side button  to turn off the Remote Control.


- Stimulation continues even when the Remote Control is OFF.
- Remote Control will turn off by itself after 2 minutes of inactivity.

Turning stimulation ON and changing program

To turn stimulation ON, make sure the Remote Control is ON.

- Stimulation is ON unless it has been turned OFF.
- If Stimulation Level Indicator is not illuminated, stimulation is OFF. Press  once to turn stimulation ON to predetermined level.
- When stimulation is turned ON (after it was turned OFF), the Implant will be on the starting level for the last active program used.

To change the program, press the Program Selection Button .



- Press  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 1 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 Implant and repeat previous steps.

Changing stimulation level

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


Press  to increase stimulation level.

Press  to decrease stimulation level.

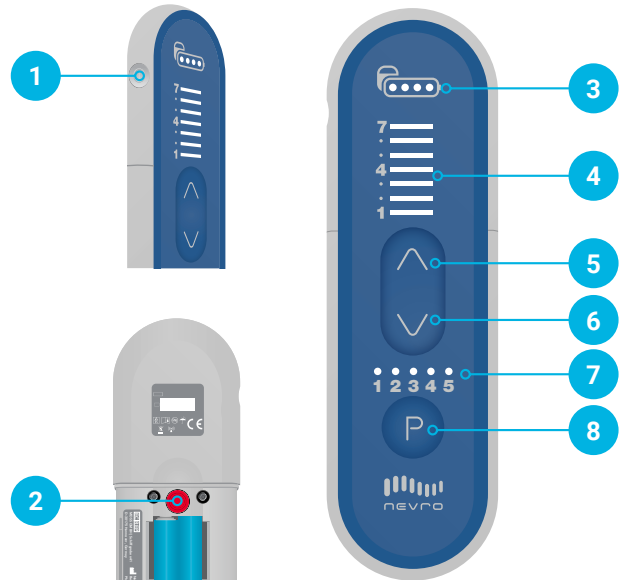
- For each  or , 1 beep will sound.
- The level of stimulation can be seen in the Stimulation Level Indicator.
- When stimulation level for selected program is at the maximum or minimum level AND you try to go one level up or down, 2 beeps sound, indicating that you are at the currently programmed limit.

Turning stimulation OFF

Once the Remote Control is ON, press the  under the battery door to turn stimulation OFF.

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

1. Remote Control ON/OFF Button
2. Stimulation OFF Button
3. Battery Level Indicator (Charge Level of Implant)
4. Stimulation Level Indicator Ladder lights
5. Stimulation Start/Increase Button
6. Stimulation Decrease Button
7. Program Indicator
8. Program Selection Button



Tips

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.
- It has been 3 months since the last battery change.

To achieve optimal relief, make sure you work closely with your HFX Care Team to identify which programs work best for you. They will provide guidance on how and when to use the Remote Control.

The Omnia Remote Control uses 2 AAA batteries, alkaline only.


DO NOT USE lithium or rechargeable batteries.

When the Battery Level Indicator shows 2 dots or less, your Implant battery needs to be recharged using the Charger.

Video instructions are available at www.NevroHFX.com/en/resources/existing-patients.

Turning the Remote Control ON

Press and hold side button  until you hear a long beep.

- You may need to press  for up to 5 seconds.
- If the Remote Control syncs with the Implant, at least one LED light on the Remote Control will light up.
- If the Remote Control cannot sync with the Implant, you will hear 3 beeps and the lights on the Remote Control will turn OFF.
- Repeat these steps until you have a link with the Implant. Moving the Remote Control closer to the Implant will help.
- Other buttons on the Remote Control will respond only when the Remote Control is ON and linked to an Implant.


Turning Remote Control OFF

Press side button  to turn off the Remote Control.


- Stimulation continues even when the Remote Control is OFF.
- Remote Control will turn off by itself after 2 minutes of inactivity.

Turning stimulation ON and changing program

To turn stimulation ON, make sure the Remote Control is ON.

- Stimulation is ON unless it has been turned OFF.
- If Stimulation Level Indicator is not illuminated, stimulation is OFF. Press  once to turn stimulation ON to predetermined level.
- When stimulation is turned ON (after it was turned OFF), the Implant will be on the starting level for the last active program used.

To change the program, press the Program Selection Button .



- Press  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 1 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 Implant and repeat previous steps.

Changing stimulation level

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


Press  to increase stimulation level.

Press  to decrease stimulation level.

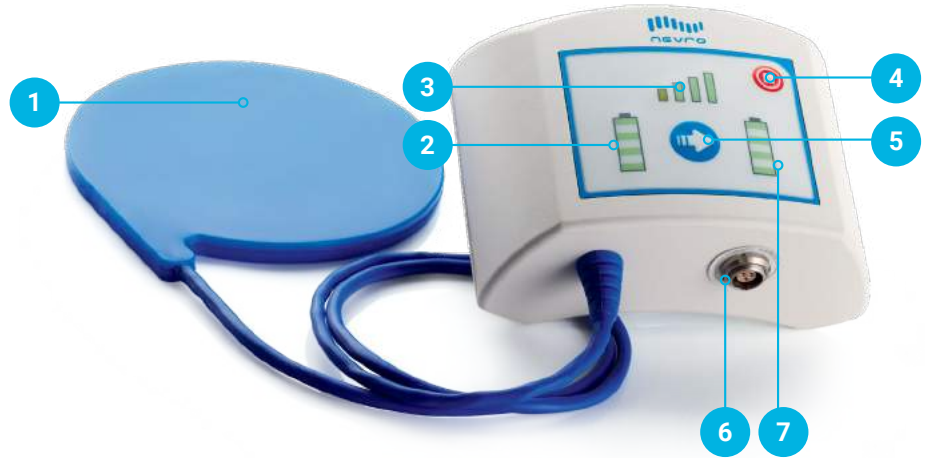
- For each  or , 1 beep will sound.
- The level of stimulation can be seen in the Stimulation Level Indicator.
- When stimulation level for selected program is at the maximum or minimum level AND you try to go one level up or down, 2 beeps sound, indicating that you are at the currently programmed limit.

Turning stimulation OFF


Once the Remote Control is ON, press the  under the battery door to turn stimulation OFF.

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

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  unless you want to turn OFF the stimulation. 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/en/resources/existing-patients.

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).

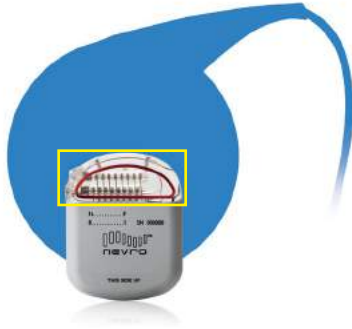


Figure 1

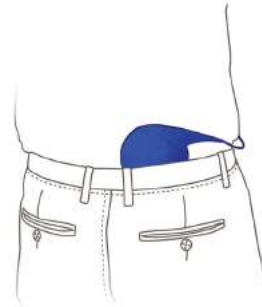



Figure 2

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.

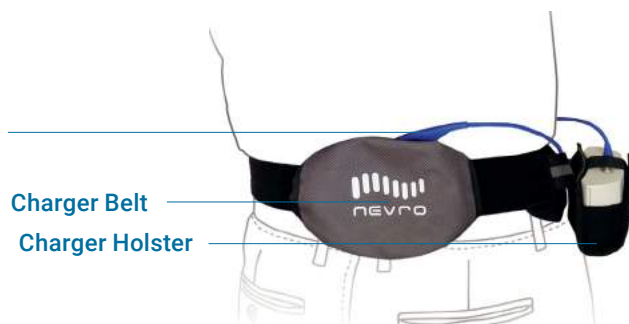
- To plug the Charger into the wall socket, connect the Power Adapter into the Charger's Power Adapter Port, then plug the Power Adapter into the wall socket.
- It's okay to continuously charge the Charger. The battery will not be damaged.

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.

The Charging Coil can be inserted into the mesh pouch through the opening at the top of the Charger Belt




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



Tips


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 circle lights), reposition the Charging Coil slowly and wait 3 seconds. The Antenna Strength Indicator circle lights 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. You will know stimulation is ON if you see the lights illuminated above the  arrow.

Important reminders

You can still get stimulation from your Implant even during charging.

Do not charge the Implant while the Charger is plugged into the wall. Always remove the Power Adapter before pressing the Charge Start Button . Unplug the Power Adapter from the wall each time you use the Charger on your Implant. Once you are finished charging, plug the Charger back into the Power Adapter and then the Power Adapter into the wall so the Charger will be ready for your next recharging session.

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

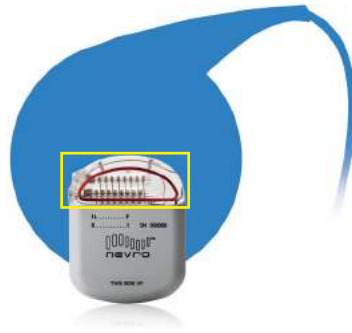
While charging, the implant site may become warm. If pain or discomfort is felt, stop charging and contact your doctor or HFX Coach.

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


Charging preparation


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

- The figure below shows that the top of the Implant (in yellow box) is at the center of the Charging Coil.



Initiate charging

Press the Charge Start Button  to turn on the Charger. The light on the side of the device (Charger Battery Level Indicator) will illuminate to confirm the Charger is on. The Charger will start to beep and look for the Implant.

1. Beeping continues until the Charger links with the Implant.
2. If 10 seconds pass without a link, the Charger will sound one long beep and shut off. Reposition the Charging Coil and press the Charge Start Button  again.
3. When at least one lighted circle appears on the Antenna Strength Indicator, a link has been made. More circles mean a better link, and make it less likely that charging will be interrupted by movements. If only the middle dot is illuminated, this indicates poor connection and the Implant and the Charger will not link.
4. When the Charger is in the correct position, the IPG Battery Level Indicator will light up.



If the link is not made, is insufficient, or is lost, reposition the blue Charging Coil slowly and repeat the above steps.

Charging

Charging is in progress when you see the IPG Battery Level Indicator and the circles on the Antenna Strength Indicator are lit. As charging progresses, the number of lit dots on the IPG Battery Level Indicator will increase.

- If the link is lost, the Charger will beep. Reposition the Charging Coil and repeat steps under the “Initiate Charging” section.

Complete charging

When charging is complete, one long beep will sound and the Charger will turn itself off automatically. There is no off button on the Charger. Check the Implant Battery Level to make sure the battery is fully charged (four dots).

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. The orange light indicates the Charger is being recharged. Recharging is complete when the orange light turns off.



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 pouch on the Charger Belt and securely attach belt around the waist. Use the hook and loop near the pouch to secure the cable of the Charging Coil.
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/en/resources/existing-patients.

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

Rx Only: Patient experiences with the Senza®, Senza II™ and Senza Omnia™ neuromodulation systems vary by individual, including the amount of pain relief. The occurrence of adverse effects associated with SCS implant surgery or use also varies by patient.

Brief Summary: A summary of important information follows. Please see www.NevroHFX.com/safety and the Senza®, Senza II™ and Senza Omnia™ Patient Manual (at <https://www.Nevro.com/manuals>) for complete information. Please consult your doctor to fully understand Senza®, Senza II™ and Senza Omnia™ benefits and risks.

Indications for Use: The Senza, Senza II, and Senza Omnia neuromodulation systems are intended to 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, upper back pain, leg pain, upper limb and neck pain.

Warnings/Precautions: There are warnings or precautions against or regarding: Senza®, Senza II™ and Senza Omnia™ use in patients who are or may become pregnant; patients undergoing diathermy or with other active implanted devices, or those undergoing CT scans, ultrasound or other procedures, among others. **Adverse Effects:** Senza®, Senza II™ and Senza Omnia™ are implanted surgically, so surgical complications are possible, such as infection, pain, bleeding and, very rarely, paralysis or death. After Senza®, Senza II™ and Senza Omnia placement, potential side effects include allergy or infection, loss of pain relief, pain or uncomfortable stimulation, burns or device or component malfunction resulting in corrective surgery, lead replacement or device removal.



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