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## PATIENT MANUAL

Senza® HFX iQ™ System

Effective August 2021



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.

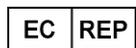
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Nevro® hereby declares that the Senza® HFX iQ™ System and Senza® HFX™ Trial System is in compliance with the essential requirements and other relevant provisions of the Radio Equipment Directive (2014/53/EU) and U.S. FCC CFR 47 Part 15.

**IMPORTANT:** Do not change or modify any component of the Senza® HFX iQ™ System and Senza® HFX™ Trial 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.



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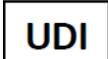
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## 1 EXPLANATION OF SYMBOLS ON THE PRODUCT OR LABELING

SYMBOLS	DESCRIPTION
	Serial number
	Caution
	Batch number
	Date of manufacture
	Manufacturer
	Expiration date
	Catalog number
	Physician only
	Temperature limit
	Consult instructions for use
 <a href="http://www.nevro.com">www.nevro.com</a>	Consult electronic instructions for use

SYMBOLS	DESCRIPTION
	Sterilized using ethylene oxide
	Non-sterile
<p data-bbox="415 657 529 709"><b>IP22</b></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
	Refer to Instruction manual/booklet
	AAA Battery



## 2 INTRODUCTION

### 2.1 ABOUT THIS BOOKLET

This booklet was written for people who are considering or have received a Nevro Senza® HFX iQ™ 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 spinal cord stimulator (SCS) system. For this reason, always talk to your physician if you have questions about your condition. This booklet presents general information and can help you better communicate with your physician. For information about indications, contraindications, warnings, precautions, and technical specifications, refer to the Information for Prescribers (P/N 10001223).

The first part of this booklet discusses the HFX iQ™ IPG, 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 HFX iQ IPG.

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 physician decide to proceed with SCS therapy, the first step is a trial phase. Typically, your physician 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 physician'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 physician. This provides an opportunity for you and your physician 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 physician 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 physician 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 HFX Trial Stimulator 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 physician's advice closely.

When you are in the Trial Phase, you will receive a HFX 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 HFX Trial Stimulator. This trial phase typically lasts several days.

For your trial, your physician 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 HFX 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 physician whether a device should be implanted in your body to take the place of the Trial Stimulator. For instructions specific to the Trial Phase, please refer to the Patient Trial Manual (P/N: 10001230).

## **2.5 IMPLANTED STIMULATOR PHASE**

After your Trial Phase using the HFX Trial Stimulator and the Remote Control, you and your physician will decide if SCS therapy is right for you. During the trial phase, you learned to use the Remote Control and/or HFX iQ App. You will use either the same or a similar Remote Control and/or HFX iQ App with the HFX iQ IPG. You also



learned what it felt like to receive therapy and how it worked to control your pain. It is expected that the therapy will work the same way after the HFX iQ IPG implantation. There may come a time when your HFX iQ IPG no longer holds a charge well. When your therapy cannot be maintained with daily charging, the HFX iQ IPG may need to be replaced. At that point, the physician can remove your old HFX iQ IPG and replace it with a new one. This involves another surgical procedure. This second procedure is usually faster and more straightforward than the original implant surgery. The rechargeable battery in your HFX iQ IPG should last many years. How long it lasts will depend on many factors, including how often the HFX iQ IPG stimulates. Ask your physician how long the battery might be expected to last for you.

You may be able to resume many of the everyday things you are used to. Talk with your physician about appropriate activities. With the Senza system you may be able to resume:

- Driving
- Going to work
- Travel
- Many leisure activities
- Moderate exercise (ask your physician)
- Normal sexual activity

Your physician will want to see you regularly for check-ups. These are important not only for your health, but also to monitor how the device is working.

### 3 DEVICE DESCRIPTION

The Senza® HFX iQ™ System works by delivering electrical energy from a stimulator to an area around the spine. The system is capable of delivering 10kHz stimulation, a therapy that does not produce tingling sensations called paresthesia. It is also capable of delivering stimulation that produces paresthesia.

#### 3.1 MAJOR COMPONENTS

The Senza® HFX iQ™ System components will include:

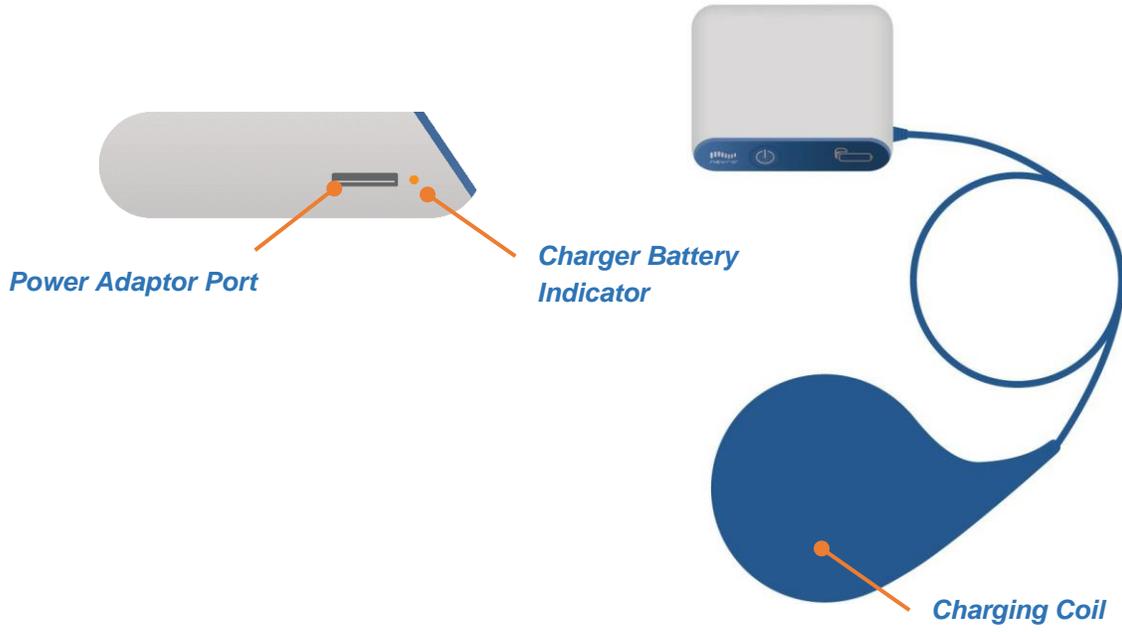
**HFX iQ™ Implantable Pulse Generator (HFX iQ IPG):** The HFX iQ IPG is a small, battery-powered electronic device that is implanted inside the body



**Leads:** Instead of connecting to an external stimulator as occurred during the trial phase, will connect to the implanted HFX iQ IPG. After implantation there are no external wires or connections as occurred during the trial phase.

**HFX™ Charger:** The Charger recharges the HFX iQ IPG after it is implanted.





**Power Adaptor:** Recharges the Charger.



**Charger Belt and Charger Holster:** Holds the Charger during recharging.

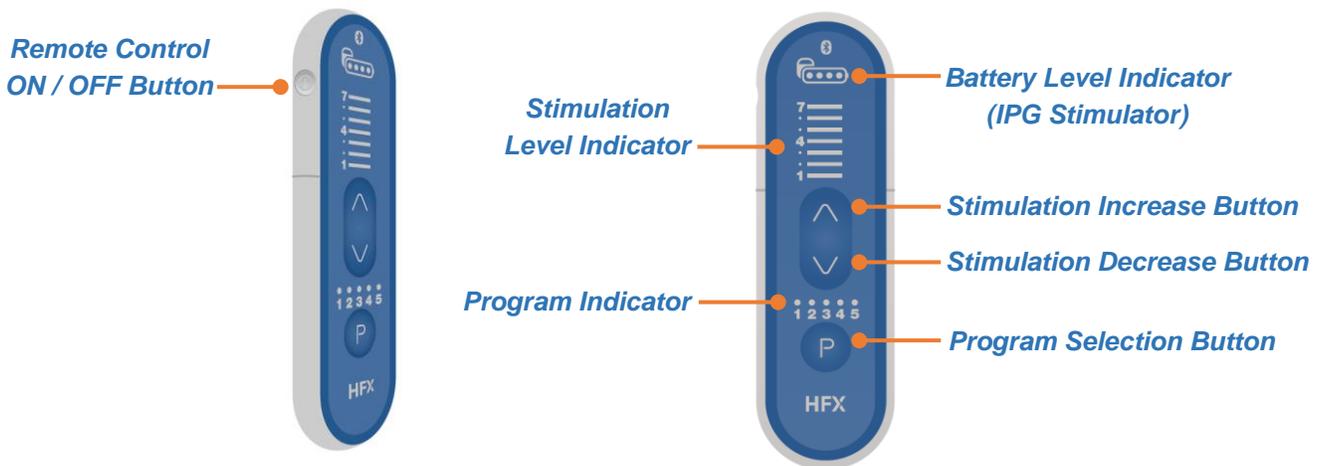


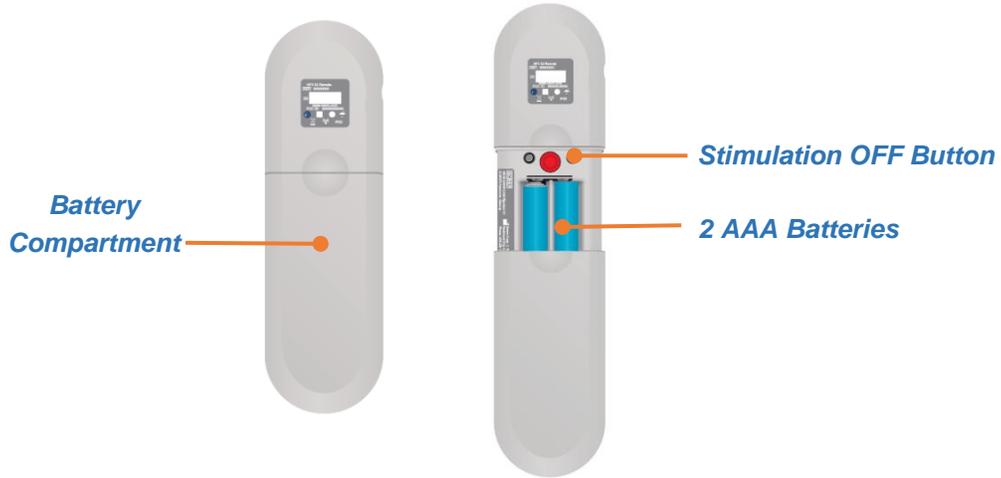
*Charging Belt (CGR2500)*



*Charging Case (for CGR2500)*

**HFX™ Remote (Remote Control):** The Remote Control (model PTR3000) is a handheld, battery-operated unit that communicates with the HFX iQ IPG 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 HFX iQ IPG.





**HFX iQ™ Patient Application:** The HFX iQ Patient Application is a mobile application that communicates with the HFX iQ IPG using Bluetooth® wireless technology. The patient can use the HFX iQ Patient Application to turn stimulation on or off, adjust certain therapy settings, retrieve current stimulation level, and take daily assessments to better track their pain progress. For additional information and troubleshooting, refer to the HFX iQ Patient Application Manual (P/N 10001171)



## 4 INSTRUCTIONS FOR USE

### 4.1 ABOUT THE HFX IQ IPG



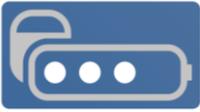
The HFX iQ IPG is an implanted SCS device that delivers therapy, stops delivering therapy, increases or decreases therapy intensity, or changes therapy types (“programs”) in response to commands that you send it using the Remote Control. You should avoid interacting directly with the HFX iQ IPG, touching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

#### 4.1.1 Understanding Stimulator Battery Status

Your Remote Control provides the battery level of your HFX iQ IPG on the Battery Level Indicator. The table below describes the different battery levels for the HFX iQ IPG.



Battery Level	What You See	What It Means
4 lights on		HFX iQ IPG battery is full. 100% battery capacity remaining.

Battery Level	What You See	What It Means
3 lights on		75% battery remaining.
2 lights on		50% battery capacity remaining. If you see two or fewer dots, then your HFX iQ IPG should be recharged.
1 light on		25% battery capacity remaining.

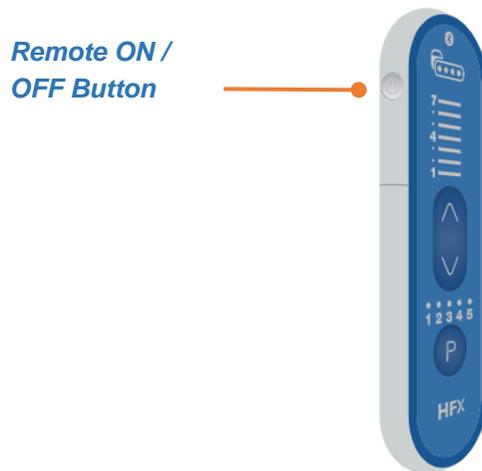
## 4.2 USING THE REMOTE CONTROL

This section discusses the Bluetooth® Remote Control that you have received for the implanted stimulator phase.

### 4.2.1 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 HFX iQ IPG.

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 HFX iQ IPG.

- If the Remote Control successfully establishes communication with the HFX iQ IPG, the lights will stop blinking and be updated to indicate the current stimulation of your HFX iQ IPG.
- If the Remote Control cannot establish communication with the HFX iQ IPG, 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 HFX iQ IPG and what you can do about it.

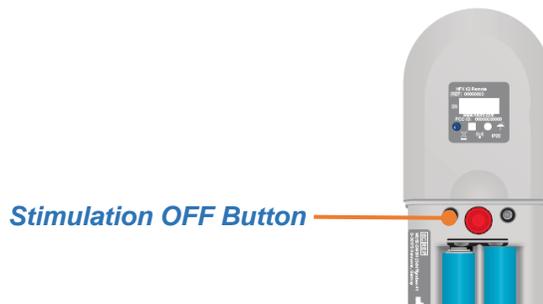
#### 4.2.2 Turning OFF the Remote Control

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 HFX iQ IPG and notify you of the HFX iQ IPG stimulation status.

#### 4.2.3 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.

**NOTE:** Avoid touching the battery when turning off stimulation.



#### 4.2.4 Turning ON Stimulation

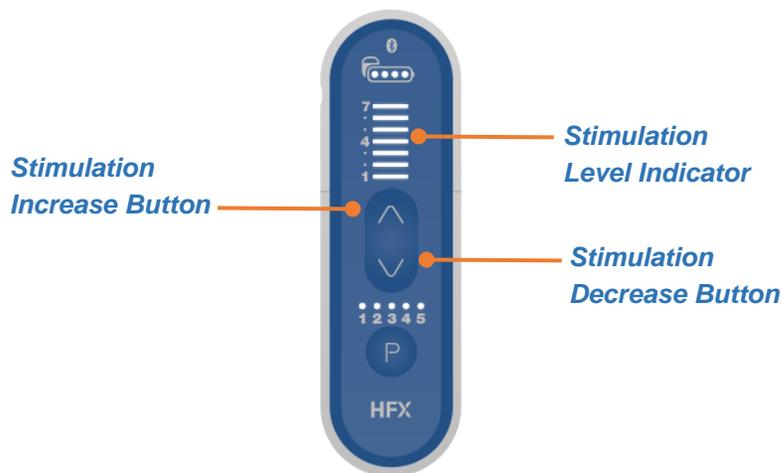
1. Press and hold the small gray ON / OFF Button on the upper left side of the Remote Control for up to five seconds to turn the Remote Control ON.
2. Press the Stimulation Increase Button on the Remote Control to turn stimulation ON (if stimulation was turned off previously). Your physician has set 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.



#### 4.2.5 Changing Stimulation Level

Follow the directions given to you by your physician 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.
2. 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.



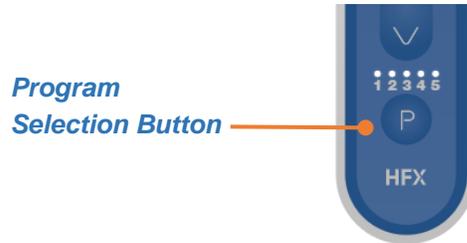
Your physician has programmed a maximum stimulation strength into the device and it cannot be made to stimulate more intensely than what was programmed.

#### 4.2.6 Switching Between Programs

Your physician may have set up your stimulator to offer up to seven (7) groups of up to five (5) different programs. Follow the directions given to you by your physician when switching the program. If you have more than one

stimulation program available, you can change programs as follows:

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 Program Selection Button. Each time you press the button, the next available program light will turn on.



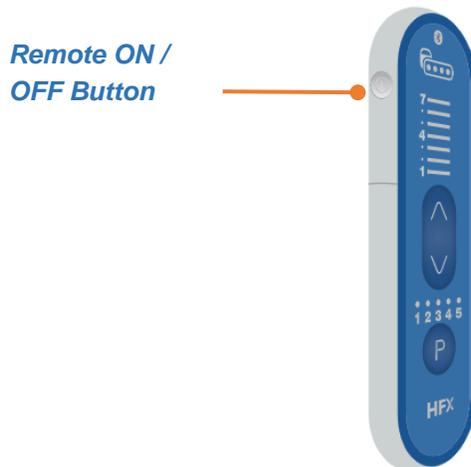
3. When the light above your desired program turns on, stop pressing the Program Selection Button. If only one program is available, the number for that program will remain lit and you will not be able to change programs.

#### 4.2.7 Switching Between Groups

Additionally, your physician may have set up your stimulator to offer between one and seven different groups of stimulation programs.

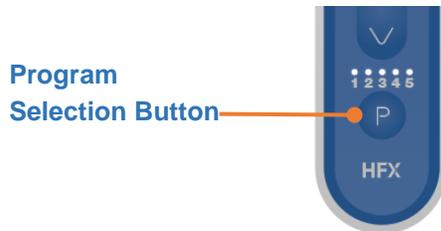
Perform the following steps to switch between groups:

1. Turn the Remote Control on by pressing and holding the ON/OFF button on the upper left-hand side for up to five seconds. You will hear one long beep to tell you that the Remote Control is on.



2. Press and hold the Program Selection button (P button) for at least 3 seconds to enter Group Change

Mode. You will hear one long beep to indicate you have successfully entered the mode.



3. Upon entering the mode, you will see one of the amplitude lights above the UP arrow (1 – 7) blinking to indicate the current group.



4. You can now adjust the current group by pressing the UP or DOWN arrows.
5. Accept the group selection by pressing and holding the P button for at least 3 seconds. You will hear one long beep to indicate that the group selection was successful.
6. After the group change has been accepted you can adjust your desired program within that group by pressing the P button. Note that the current group number will display while you are changing programs.

#### 4.2.8 Changing the Batteries in the Remote Control

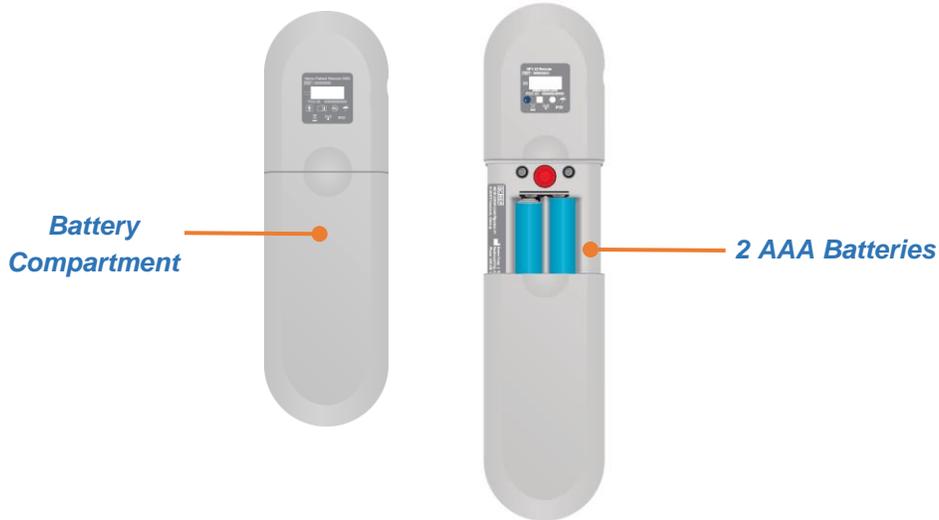
Your Remote Control should come with batteries already installed. It uses two AAA alkaline batteries. Never use any other type of battery with your Remote Control because this could damage the device.

**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.



#### 4.2.9 Understanding Signals from the Remote Control

Your Remote Control will beep and light up to keep you informed about your Senza® HFX iQ 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 physician.

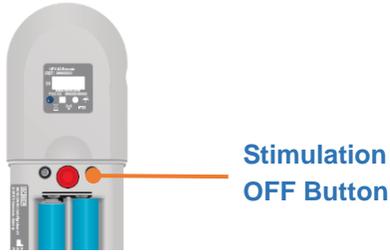
What You Hear	What You See	What It Means
One single soft beep	No change in lights.	One of the buttons on the Remote Control was pressed.
One single regular beep	The therapy level lights or programs lights change.	Stimulation has increased or decreased by one level or a new program has been selected.
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 HFX iQ IPG. Refer to the <a href="#">Troubleshooting Section</a> of this manual.

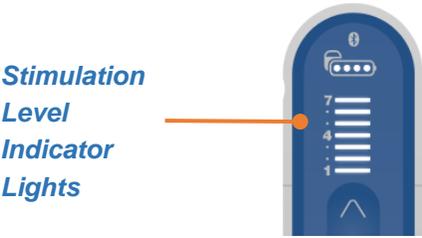
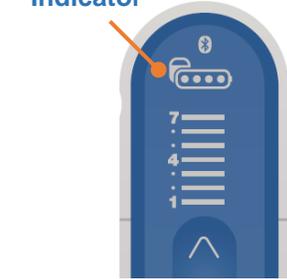
#### 4.2.10 Impedance Check

An impedance check may be required prior to certain activities such as receiving an MRI. The impedance check measures to see if your impedances are in an acceptable range for activities such as receiving an MRI. Consult with your Nevro representative, physician, or MRI provider to determine if an impedance check is needed. Your physician or MRI center can provide more information on when to perform an impedance check prior to receiving an MRI.

Instructions for performing an impedance check with your Remote Control are provided below. Contact your HFX Care Team if you have any questions.

Step	Result
<p>1. Power on the Remote Control. Press the ON/OFF button for up to five seconds until the remote beeps and turns on.</p>  <p>The diagram shows a blue remote control with various buttons. A red arrow points to a small circular button at the top, labeled "Remote Control ON / OFF Button". The remote control also features a volume knob, a power button, and a button with the HFX logo.</p>	<p>The Remote Control will beep and turn on.</p>

Step	Result
<p>2. Turn the Remote Control over and slide open the battery door.</p> 	<p>The Stimulation Off Button will be accessible.</p>
<p>3. Press and hold the Stimulation OFF Button until you hear beeping. This should take 10 seconds.</p> 	<p>After holding the Stimulation OFF Button for 10 seconds, the Remote Control will beep and display the results of the impedance check.</p> <p><b>PASS:</b> If you hear a <u>single long beep</u>, move forward to Step 4.</p> <p><b>FAIL:</b> If you hear <u>4 short beeps</u>. Contact your HFX Care Team or physician for further instructions.</p> <p>If after 10 seconds, no beeps are heard, the impedance check was not performed. Hold the Stimulation Off Button until a long beep or 4 short beeps are heard.</p>

Step	Result
<p data-bbox="203 352 597 422">4. Interpret results – Stimulation Level Indicator Lights</p>  <p data-bbox="175 537 321 680"><i>Stimulation Level Indicator Lights</i></p>	<p data-bbox="678 352 1386 422"><b>PASS:</b> If all 7 stimulation level indicator lights above the 'Up' button are <u>lit and not blinking</u>, move forward to Step 5.</p> <p data-bbox="678 478 1463 590"><b>FAIL:</b> If ANY of the 7 stimulation level indicator lights above the 'Up' button are <u>blinking</u>, do not perform an MRI Scan. Contact your HFX Care Team or physician for further instructions.</p> <p data-bbox="678 646 1393 751">If any of the 7 stimulation level indicator lights are NOT lit, an impedance check was not performed. Call Nevro Technical Services for assistance.</p>
<p data-bbox="203 858 634 928">5. Interpret Results – Battery Level Indicator</p>  <p data-bbox="245 1010 415 1073"><i>Battery Level Indicator</i></p>	<p data-bbox="678 858 1409 928"><b>PASS:</b> All 4 of the battery level indicator lights at the top of the remote are <u>lit and not blinking</u>.</p> <p data-bbox="678 989 1451 1094"><b>FAIL:</b> If any of the battery level indicator lights at the top of the Remote Control are <u>blinking</u>, do NOT perform an MRI scan. Contact your HFX Care Team or physician for further instructions.</p> <p data-bbox="678 1150 1430 1220">If Steps 3, 4 and 5 all had <u>passing</u> results, the impedance check has passed.</p> <div data-bbox="803 1234 1333 1346" style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;"> <p data-bbox="824 1251 1312 1320">If unsure of the impedance check results, call HFX Care Team for assistance.</p> </div>



### 4.3 CHARGING THE IMPLANTABLE PULSE GENERATOR

Your HFX iQ IPG is a battery-powered device, and it can be recharged using the Charger. This will help you get maximum service from your system. Your care team should show you how to recharge your HFX iQ IPG. The best way to recharge is to get into the habit of recharging once a day, although you may be able to charge it less often. Many factors can affect how often you need to recharge the HFX iQ IPG (such as how much you use it, how intensely it stimulates, how old the system is).

You have a Charger, a Power Adaptor, a Charger Belt, and a Charger Holster or Case for recharging the HFX iQ IPG. You also have equipment to recharge the Charger. It is recommended that you recharge the Charger after every use.

You can still get stimulation from your device even during charging. Follow these steps to charge the HFX iQ IPG.

1. Place the Charging Coil (the big blue circle) into the mesh pouch of the Charger Belt.

**WARNING:** Use only the Power Adaptor, Charging Coil, and accessories from Nevro Corp. Always recharge using the Charger Belt provided.

2. Identify the area where the HFX iQ IPG is implanted. When charging, the Charging Coil in the mesh pouch of the Charger Belt should be lined up so the center of the Charging Coil covers the top of the HFX iQ IPG. You do not need to remove any clothing—you can recharge through a thin layer of fabric.

**WARNING:** Make sure that there is no metal (such as jewelry, a belt, buttons, zipper etc.) between the Charging Coil and the HFX iQ IPG or near the Charging Coil because it could result in serious burns.

3. Fasten the belt to hold the Charging Coil in place; you may want to use the optional Charger Holster to help hold the Charger.

**WARNING:** If you feel warmth or discomfort when recharging your HFX iQ IPG, stop recharging and contact your physician.

**WARNING:** You will not be able to charge your HFX iQ IPG when the Charger is plugged into a wall outlet. Always remove the Power Adaptor before pressing the Charge Start Button.

4. Press the Charge Start Button to turn on the Charger.
5. The Charger will start to look for the HFX iQ IPG. It beeps as it searches.
6. When the Charger finds the HFX iQ IPG, you will see at least the outer circle light up on the Antenna Strength Indicator. (If you do not have at least the outer circle, move the Charging Coil slightly until you get sufficient antenna strength). You can charge successfully with one or more circles. If the antenna strength still is blinking in the center, then please advance to the section “Optimizing Charging”. The more circles you see, the better the communication you have, and it will be less likely that your charge session will be interrupted.

7. When the Charger is in the correct position, the HFX iQ IPG Battery Level Indicator will light up. The Charger shows the battery status of the HFX iQ IPG.



8. Keep the Charging Coil steady in the same position. The Charger will keep charging until the HFX iQ IPG is fully charged (or until the Charger runs out of its own charge).

**NOTE:** If the Charging Coil is moved during the charging session, it may lose communication with the HFX iQ IPG. If this happens, re-start the charging process. The HFX iQ IPG can still be charged even if the charging session is interrupted.

9. When the HFX iQ IPG is fully charged, the Charger will sound a long beep and the HFX iQ IPG Battery Level Indicator will show four dots. The Charger turns itself off automatically.

**NOTE:** If you ever need to turn off the Charger during a recharging session, just move the Charging Coil away from the HFX iQ IPG. If the Charger cannot locate the HFX iQ IPG after 10 seconds, it turns itself off automatically.

**CAUTION:** Do not charge your HFX iQ IPG while you are drowsy, sleeping, or sedated, as this may result in a burn. If you feel warmth or discomfort around the Charging Coil, discontinue the charging process and contact your physician.

10. Once the charging is complete, turn ON the Remote Control (see section 4.2.1 of this manual) and verify that therapy is ON.

**NOTE:** The HFX iQ IPG will continue to provide therapy while being recharged.

The battery life of the HFX iQ IPG is estimated to be 10 years but the battery life may be more or less depending on the stimulation parameters used. The battery will eventually need to be replaced in a surgical procedure.

#### 4.4 CHARGING THE CHARGER

You should recharge the Charger after every use. The best way to remember to do this is to get into a daily routine of charging the HFX iQ IPG and then recharging the Charger.

**WARNING:** You will not be able to charge the HFX iQ IPG at the same time you are recharging the Charger.

1. The Charger has a USB-C Power Adaptor Port. Plug the Power Adaptor Port plug into the Power Adaptor Port.



2. You will see the orange light on the side of the Charger light up. The orange light indicates the Charger is being recharged.



3. Allow the recharging to continue until the orange light turns off. This indicates that the recharging is complete.

**NOTE:** Once the Charger is fully charged, you do not have to unplug it the next time you charge the HFX iQ IPG. There is no harm in continuously leaving the Charger plugged to the outlet. You may also remove the plug if you prefer.

#### 4.5 OPTIMIZING CHARGING

In order to charge the HFX iQ IPG, the Charging Coil must establish good communication with the HFX iQ IPG. There may be times when you have trouble getting the Charger and the HFX iQ IPG to communicate.

If there is no communication at all, the Antenna Strength Indicator will blink the center light and beep occasionally. The Charger will eventually turn itself off.

- Make sure that there is no metal near the Charging Coil. (Be sure to check for jewelry, metal buttons, belt buckles, watches, zippers, and so on).
- The Charger will work through a thin layer of fabric. Remove any thick or heavy clothing.

- Make sure the Charging Coil is lined up with the top of the implanted device (HFX iQ IPG). You may need to use your fingers to feel the shape of the device through your skin.
- Check to see that the Charger has enough charge to work. Connect it to the Power Adaptor and wait till the orange light on the side of the Charger turns off, and then try to charge the HFX iQ IPG.

If there is poor communication, you will see the center light of the Antenna Strength Indicator only, but there will not be any beeping. The Charging Coil can still recharge the HFX iQ IPG. You may be able to get better communication by moving the Charging Coil slightly, waiting about three seconds, and seeing if this improves the antenna strength.

If communication is lost during a recharging session, simply move the Charging Coil back into position until you see at least the outer circle on the Antenna Strength Indicator. An interruption in charging will not hurt the system.

#### **4.5.1 Charging Tips**

It is very important that you get familiar and comfortable with charging your system and develop a routine so that your device is charged every day. This assures that you can get the pain control therapy you need when you need it.

- Charging times will vary for each session. Things that can affect charging time include battery status, how much therapy you have had, therapy strength, and time elapsed from the last charge. Do not be concerned if the charging process seems to take longer some days than others.
- If the charging time is very short, check that the HFX iQ IPG is turned on.
- The more circles shown on the Antenna Strength Indicator, the better communication the Charging Coil has with the HFX iQ IPG. The better the communication, the less likely that your charge session will be interrupted.
- To find the top of the implanted device, use your fingers to gently feel for the device through the skin. Your physician can assist you in learning how to do this.
- Keep the Charging Coil steady in position as you charge. If the Charging Coil moves, it may lose communication with the HFX iQ IPG. If this happens, you will hear a long beep and the Charger will turn itself off. Simply put the Charging Coil back in position and start again.
- If you need to turn OFF the Charger during a charging session, just move it away from the HFX iQ IPG. It will turn itself OFF automatically in about 10 seconds.
- You can still get therapy while the device is recharging

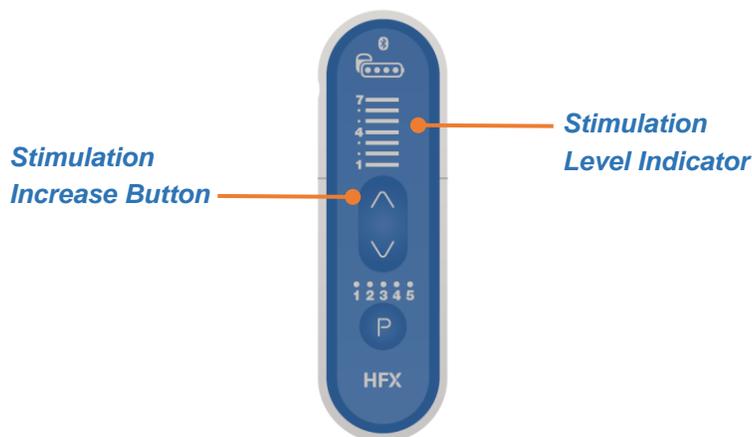
## 5 TROUBLESHOOTING

If you experience any problem with your HFX iQ 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 physician.

### 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 HFX iQ IPG.
- 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 HFX iQ IPG, it is possible the HFX iQ IPG 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 HFX iQ IPG. The Remote Control may be out of range.

**5.2.2 If more than one of the Program lights on the Remote Control are lit:**

- If the Program lights 1, 3, and 5 are lit up, your HFX iQ IPG is in MRI Mode. Contact your HFX Care Team for instructions on how to take the HFX iQ IPG out of MRI Mode.

What You Hear	What You See	What It Means
Two beeps	Program lights 1, 3, and 5 are lit up 	The HFX iQ IPG is in MRI Mode.

**5.2.3 If all the Program lights on the Remote Control are lit:**

- The HFX iQ IPG is running programs set up and best managed with your HFX iQ App.

What You Hear	What You See	What It Means
Varies depending on which buttons are pressed	All Program lights are lit up 	The stimulator is running programs best controlled through the HFX iQ App. The Remote Control can still turn stimulation on and off.

**5.2.4 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 HFX iQ IPG.

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 HFX iQ IPG.

- Move the Remote Control closer to the HFX iQ IPG 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.
- Use the gray button on the upper left side to power OFF the Remote Control, wait 10 seconds, then power it back ON again.
- If you still hear three beeps when you press a button, remove the batteries from the Remote Control, wait 10 seconds, then reinsert the batteries (or replace with new batteries).

### 5.3 TROUBLESHOOTING THE RECHARGING PROCESS

#### 5.3.1 If your HFX iQ IPG needs very frequent recharging:

- After each charging session, check to see that the HFX iQ IPG is fully charged.
- If frequent charging persists, contact your physician.

#### 5.3.2 If you charge your HFX iQ IPG and it does not provide stimulation:

- Check to see that the HFX iQ IPG is fully charged.
- Replace batteries in the Remote Control.
- Check that stimulation is turned ON; if it is not, turn on stimulation by following the instructions in the section 4.2.1 of this manual.
- If these do not work, contact your physician.

#### 5.3.3 If you are trying to recharge the HFX iQ IPG and you have low antenna strength:

- Slowly move the Charging Coil slightly. The goal is to line up the center of the Charging Coil circle with the top of the HFX iQ IPG. Wait about three seconds and observe if the antenna strength improves.
- You may have to do this a few times—make sure your movements are slow and small.
- You can still charge if you have at least the outermost circle on the Antenna Strength Indicator.

## 6 ASK YOUR PHYSICIAN

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

Contact your physician 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 HFX iQ IPG.

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

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

- Using the Remote Control
- Charging the HFX iQ IPG
- Charging the Charger
- Adjusting your therapy

Discuss with your physician any changes in:

- Your condition
- Your response to therapy



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## 7 PATIENT IDENTIFICATION CARD

Patients will be provided with a temporary Patient Identification (ID) Card at the time of implant and will get a permanent ID card at a later date from Nevro.

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



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## 8 ADDITIONAL INFORMATION

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

Refer to the Information for Prescribers (P/N 10001223) for indications, contraindications, warnings, warnings about other medical treatments, precautions, adverse events, technical specifications, and security features and declarations.

The HFX iQ IPG is MR Conditional. Please refer to the Nevro MRI Guidelines Manual (P/N 10001162) 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](http://www.nevro.com/manuals).

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