

*dance*

*take a trip*

*go camping*

*ride a bike*

*play catch*

*hit the gym*

*have fun*

*shop*

*go out on the town*

*host a dinner party*

*hike*

*walk on the beach*

*go jogging*

*Free to*



LIBERATE YOURSELF FROM CHRONIC PAIN WITH HF10®

# Congratulations

*The HF10 trial has helped many people discover relief from debilitating chronic pain.*



Trying HF10 is an important step toward being free to do the things you once enjoyed. You'll use the trial system for about a week. If you and your doctor are satisfied with the results, you can arrange to keep using HF10.

*This booklet will help you make the most of your HF10 trial by reminding you what to do and what to expect.*

- *HF10 benefits*
- *Your HF10 trial*
- *Tips to make your trial a success*
- *Write down your goals for HF10*
- *Accessory guides for the trial*
- *Frequently asked questions about the HF10 trial*

***“I know this sounds dramatic, but HF10 made me feel like I did before I ever hurt my back. It makes me feel normal.”***

*— HF10 user*

# *9 out of 10 people who try HF10 choose to stay with it<sup>1</sup>*

- *HF10 is proven to deliver superior long-term relief of chronic back and leg pain.<sup>2</sup>*
- *HF10 allows you to get back to doing the things you miss.*
- *It works by safely delivering mild and undetectable electrical pulses to the nerves, but still allows you to feel everything else as you should.*
- *HF10 does not require drugs to provide pain relief, as it is not a medication based treatment. However, it is possible your doctor may continue to prescribe medications based on your pain condition.*





## Your HF10 trial.

The HF10 trial system makes it easy for you and your doctor to assess how well it manages your pain.

- *Thin, flexible wires, called leads, are placed beneath the skin and next to the spine.*
- *You wear a temporary device under your clothes or on a belt that delivers HF10 stimulation to the leads.*
- *The system is customised for your pain. You then assess the pain relief and improvement to your daily activities.*

*“ I have a real smile, versus hiding behind the, 'No, I'm not in pain' smile, which is nice. I can be more spontaneous with my activities. I feel like I'm more in the game and now I actually have a fighting chance—and I wouldn't have life any other way.”*

*— HF10 user*



## Tips to make your trial a success.

Your HF10 representative will contact you during the trial to assess your pain reduction and, if necessary, optimise HF10 settings to meet your needs.

### Here's what you should do during your trial:

- *Generally, limit physical activities that require lifting, bending, twisting, and raising your arms above your head.*
- *Make notes about your pain levels, so you and your doctor can assess your pain relief and other factors.*
- *Follow your stimulation instructions carefully. You should only be making changes on your Remote Control if you have first discussed this with your HF10 representative or your doctor.*
- *Keep the procedure site and Trial Device dry.*

## Write down your goals for HF10.

Write down the goals you hope to achieve with the help of HF10. Include details about daily tasks and activities.

**Goal examples:** Reduce my pain, make it easier to fall asleep, improve my ability to walk around the neighborhood.

Date: \_\_\_\_\_

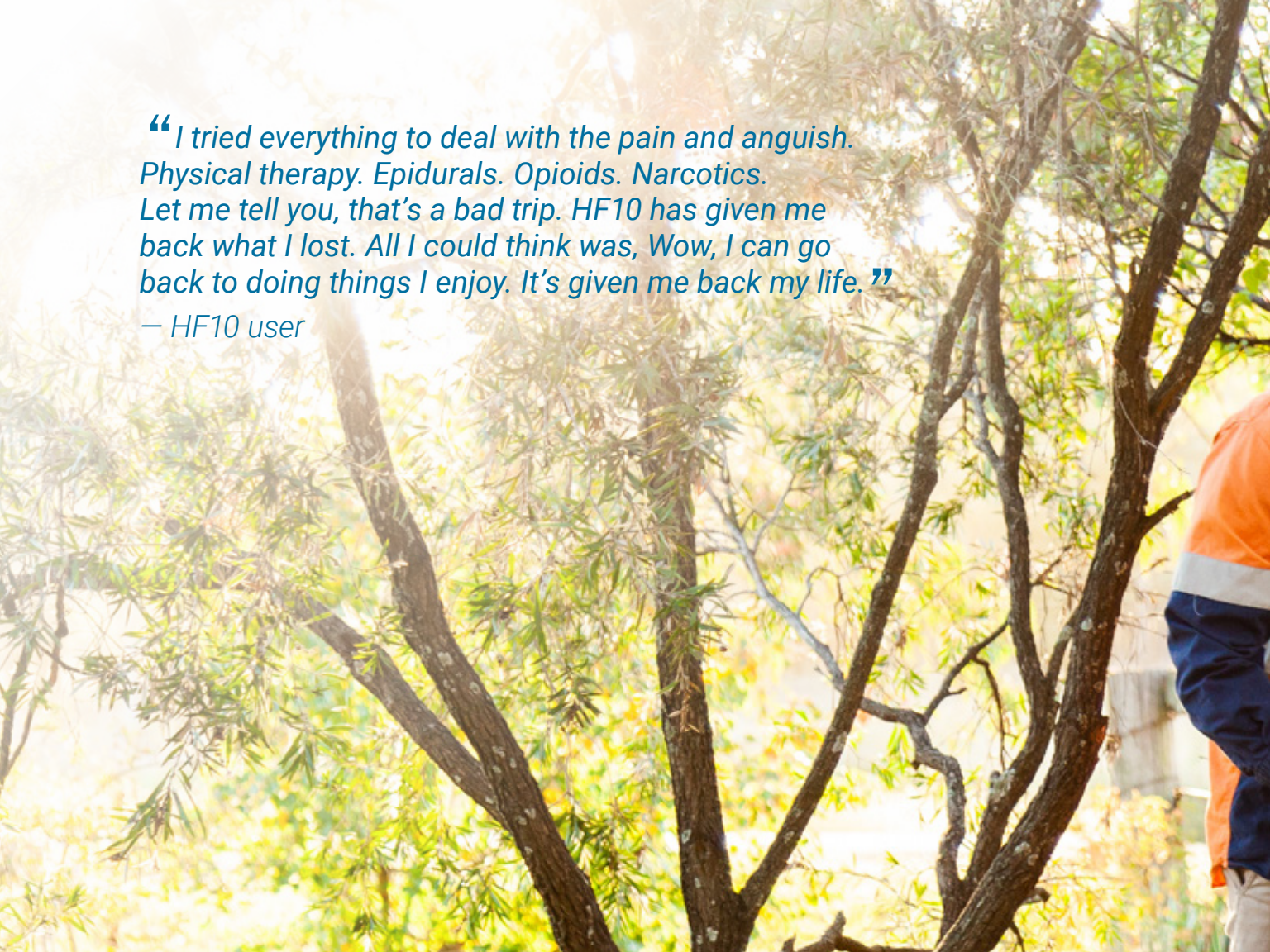
Name: \_\_\_\_\_

Goals: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



A person wearing an orange and blue high-visibility jacket is partially visible on the right side of the frame. They are standing in a sunlit area with many trees and branches, some of which are in the foreground and slightly out of focus. The lighting is bright and warm, suggesting a sunny day. The text is overlaid on the upper left portion of the image.

*“I tried everything to deal with the pain and anguish. Physical therapy. Epidurals. Opioids. Narcotics. Let me tell you, that’s a bad trip. HF10 has given me back what I lost. All I could think was, Wow, I can go back to doing things I enjoy. It’s given me back my life.”*

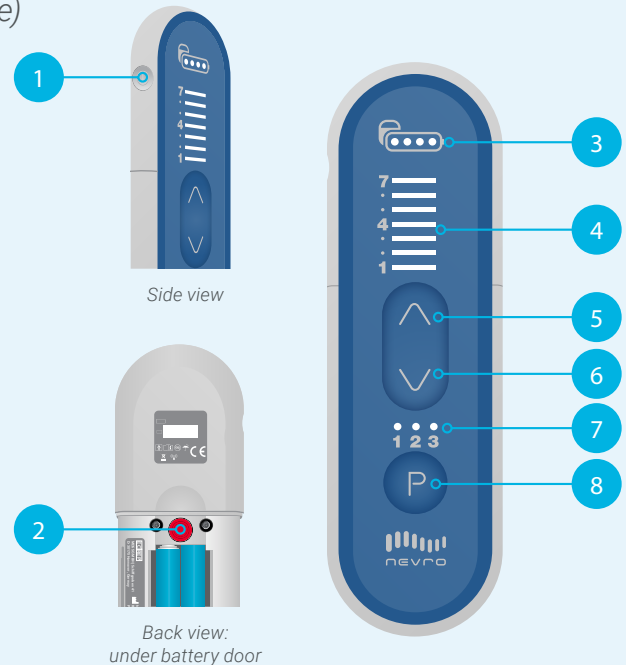
*— HF10 user*





# Your Remote Control Guide

1. Remote Control ON/OFF Button
2. Stimulation OFF Button
3. Battery Level Indicator (Charge Level of Trial Device)
4. Stimulation Level Indicator
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.

To achieve optimal relief, make sure you work closely with your HF10 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, the batteries in the Trial Device need to be replaced. Please contact your HF10 representative.



## *Turning the Remote Control ON*

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

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


## *Turning the Remote Control OFF*


Press the 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 remains ON unless it has been turned OFF.
- If Stimulation Level Indicator is not illuminated, stimulation is OFF. Press the  button once to turn stimulation ON to predetermined level.
- When stimulation is turned ON (after it was turned OFF), the Trial Device 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.

## *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  button under the battery door on the back side of the remote 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.

## *Understanding the beeps*

If you are attempting to turn stimulation ON, change the program, change stimulation level, or turn stimulation OFF, and the Remote Control beeps 3 times and there is no change to display, then the action was not successfully completed. Place the Remote Control closer to the Trial Device and repeat previous steps.

## *Your HF10 Trial Device Guide*

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 HF10 representative 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 HF10 is on.
- If the Low Battery Indicator Light (#2 in diagram above) is a solid amber color, please contact your HF10 representative.

## 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 HF10.
- 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.

If this happens, please contact your HF10 representative.



*Frequently asked questions  
about the HF10 trial*



### *How long will the trial period last?*

The trial period is typically 7 to 14 days. Timing depends on your response to HF10 and your doctor's recommendation.

### *Are there any restrictions after the trial procedure?*

Your doctor will tell you what you can and cannot do after the procedure. In general, the device and dressings must remain dry to avoid infection. To ensure the leads stay in the right place, you should not lift your arms above your shoulders or lift heavy objects. Please consult your doctor before engaging in any physical activity.

### *Will I feel anything?*

No. Unlike other spinal cord stimulation systems, HF10 does not create a tingling sensation, known as paresthesia. You may have some procedural pain, but this should subside.

### *How do I know if the device is working?*

When the green light on your Trial Device is flashing, HF10 is ON.

### *What should I do if I pull the connection out by accident?*

The white OR cables are attached to the Trial Device, and they may disconnect if pulled or caught. If a disconnection occurs, an alarm will sound. Please reference the Trial Device Guide located in this booklet, or contact your HF10 representative for reconnection instructions.

### *How do I charge the system?*

The Trial Device uses special batteries that do not need to be recharged.

### *Can I turn the system OFF if I need to?*

Yes. You can turn OFF HF10 by pressing the red button on the Trial Device or the Remote Control. However, your pain relief will go away if the stimulation is turned off.

### *Can I drive?*

Yes. Unlike other spinal cord stimulation systems, HF10 does not have driving restrictions. However, after surgery, your doctor may advise you to refrain from driving until you have recovered from the procedure.

### *Do I need to change my medication?*

You should always discuss medications with your doctor prior to making adjustments. HF10 is not a medication based treatment, however some patients continue to take prescription pain medications based on their doctor's guidance.

### *How will I sleep?*

Unlike other spinal cord stimulation systems, you can keep your system turned on while you sleep. You can place the Trial Device to the front or side of your body depending on your sleeping position.

For more information, visit [www.HF10.com](http://www.HF10.com).

Contact HF10 Technical Services with any questions: (02) 8091 2878.



Nevro Corp.  
1800 Bridge Parkway  
Redwood City, CA 94065 USA  
[www.HF10.com](http://www.HF10.com)  
Tel. +1.650.251.0005

FOLLOW THE INSTRUCTIONS FOR USE. Rx Only: Patient experiences with the Senza spinal cord stimulation (SCS) system vary by individual, including the amount of pain relief. IF SYMPTOMS PERSIST SEE YOUR DOCTOR/HEALTHCARE PROFESSIONAL. 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.HF10.com/safety](http://www.HF10.com/safety) for complete information. Please consult your doctor to fully understand Senza benefits and risks. Indications for Use: The Senza spinal cord stimulation system is an 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 and leg pain. Contraindications: These include patients not fit for surgery. ALWAYS READ THE INSTRUCTIONS FOR USE. Warnings/Precautions: There are warnings or precautions against or regarding: Senza 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 is implanted surgically, so surgical complications are possible, such as infection, pain, bleeding and, very rarely, paralysis or death. After Senza 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.

All superiority and paresthesia-free claims are supported by the Senza Summary of Safety and Effectiveness Data (SSED). Published May 8, 2015.

#### References:

1. Tiede J, Brown L, Gekht G, Vallejo R, Yearwood T, Morgan D. Novel spinal cord stimulation parameters in patients with predominant back pain. *Neuromodulation*. 2013;16:370-375.
2. Kapural L, Yu C, Doust MW, et al. Comparison of 10-kHz high-frequency and traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: 24-month results from a multicenter, randomized, controlled pivotal trial. *Neurosurgery*. 2016;79:667-677.

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2020100 Rev. A (AUS)  
ML-00013 Rev A