INFORMATION FOR PRESCRIBERS

Senza® HFX iQ™ System
Senza® HFX™ Trial 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.

1800 Bridge Parkway

Redwood City, CA 94065 USA

Tel: +1.650.251.0005

Fax: +1.650.251.9415

info@nevro.com

EC REP

MDSS GMBH
Schiffgraben 41
D-30175 Hannover
Germany

Australian Sponsor
Emergo Australia
201 Sussex Street, Darling Park, Tower II, Level 20
Sydney, NSW 2000
Australia

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.

CONTENTS

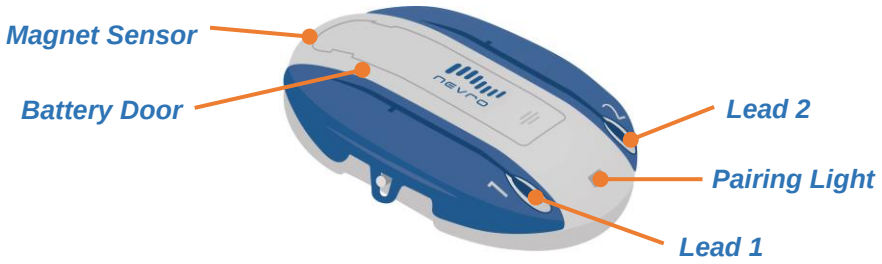
1 DEVICE AND PRODUCT DESCRIPTION

The Nevro Senza® HFX iQ™ System and Senza® HFX™ Trial System work by delivering electrical energy from a stimulator to an area around the spine. The system is capable of delivering 10kHz therapy, a therapy that does not produce tingling sensations called paresthesia. It is also capable of providing stimulation that produces paresthesia at some therapy settings. For spinal cord stimulation (SCS) therapy, a patient will typically first go through a trial phase to evaluate the therapy to see if it is right for them. If the HFX iQ System is right for the patient, the physician will proceed with the implantation of a battery-powered device after the trial phase.

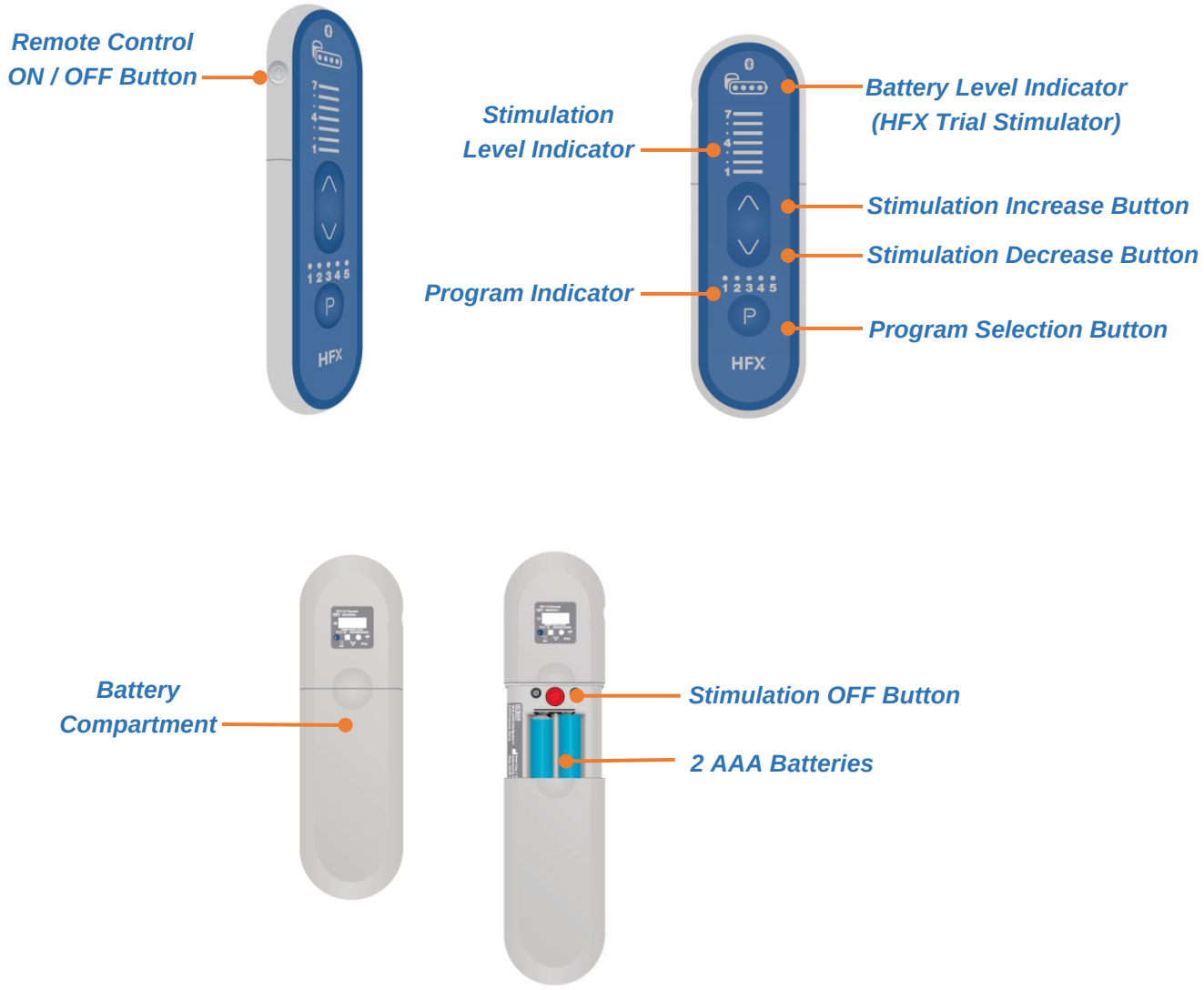
1.1 TRIAL PHASE MAJOR COMPONENTS

The Senza® HFX™ Trial System components will include:

HFX™ Trial Stimulator: The HFX Trial Stimulator (model EXTS3500) is a battery-powered, single-use, externally worn device, used by the patient to evaluate the effectiveness of the stimulation therapy prior to getting a permanent implant. The HFX Trial Stimulator has connections for up to 2 leads with 8 electrodes each and can be programmed to stimulate the nerves in the spinal cord through the electrodes on these leads.



HFX™ Remote (Remote Control): The Remote Control (model PTR3000) is a handheld, battery-operated unit that communicates with the HFX Trial Stimulator using Bluetooth® wireless technology. The patient can use the Remote Control to turn stimulation on or off and adjust certain therapy settings, as well as retrieve the current stimulation level and battery status from the HFX Trial Stimulator.



Leads: Leads are thin insulated wires that connect to the HFX Trial Stimulator at one end and have small electrodes on the other end placed near the spine. A small amount of electrical energy from the device travels through the leads and to the electrodes near the spine.

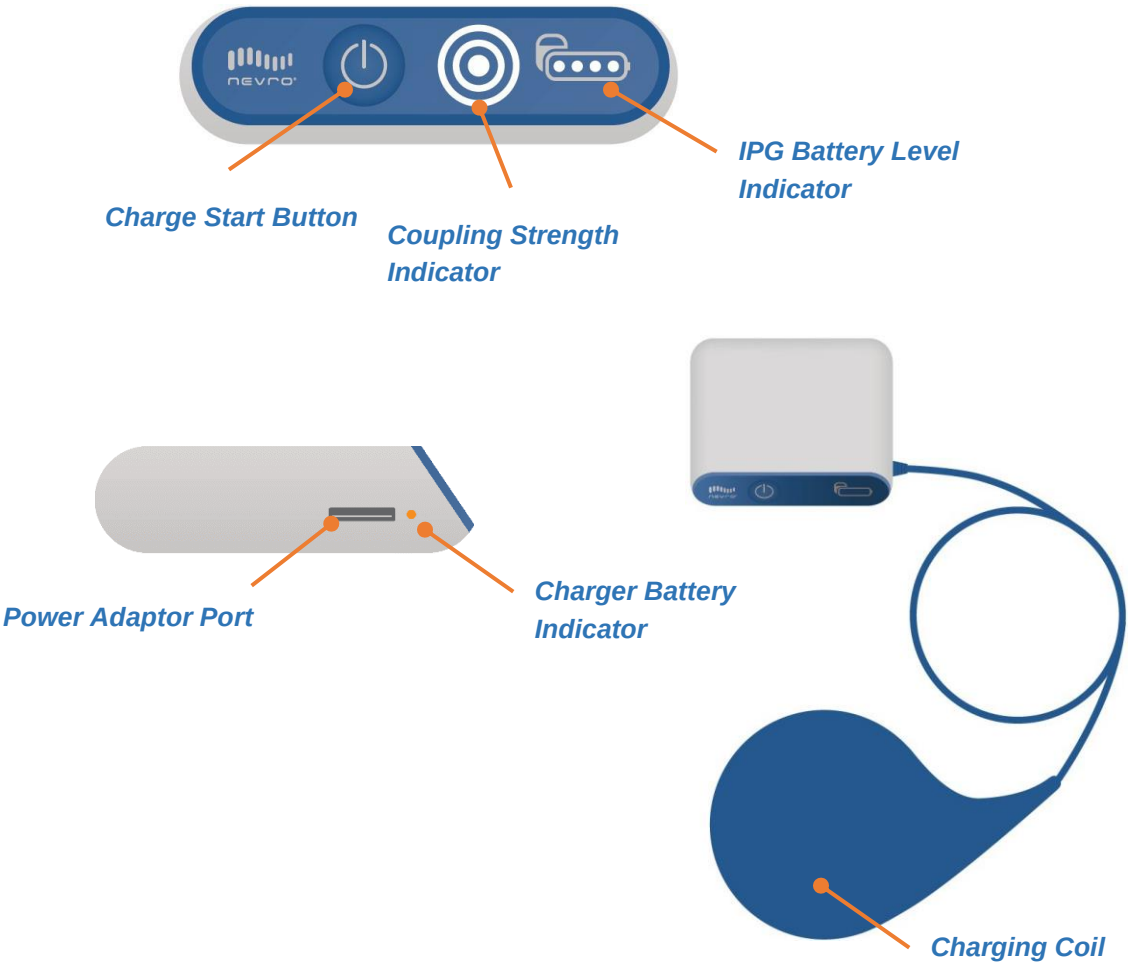
1.2 IMPLANTED PHASE MAJOR COMPONENTS

The HFX iQ™ System components will include:

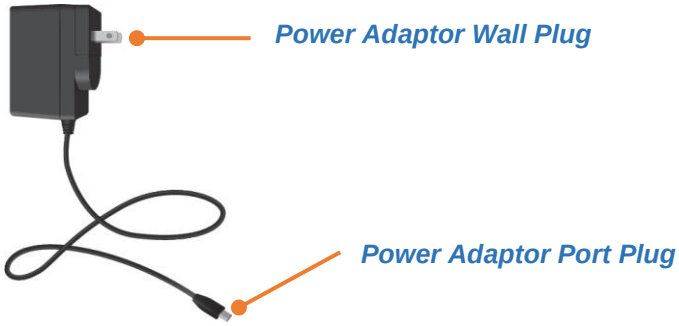
HFX iQ™ Implantable Pulse Generator (HFX iQ IPG): The Implantable Pulse Generator (model IPG3000) is a rechargeable implantable device with 16 output channels capable of stimulating the spinal cord nerves through electrode leads. The HFX iQ IPG is designed to produce current-regulated, charge-balanced, biphasic, capacitively-coupled, rectangular output pulses. The HFX iQ IPG header contains the charging coil and two ports to allow the insertion of leads. The rechargeable battery is contained in a hermetically sealed housing, which is inside the hermetic HFX iQ IPG Titanium enclosure.

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 is used by the patient to transcutaneously charge the HFX iQ IPG battery. It is a portable device powered by a rechargeable battery and can be held in one hand. It will also be used to put the HFX iQ IPG into elected mode in order to associate the HFX iQ IPG with the HFX Remote and HFX iQ Patient Application.



Power Adaptor: Recharges the Charger.

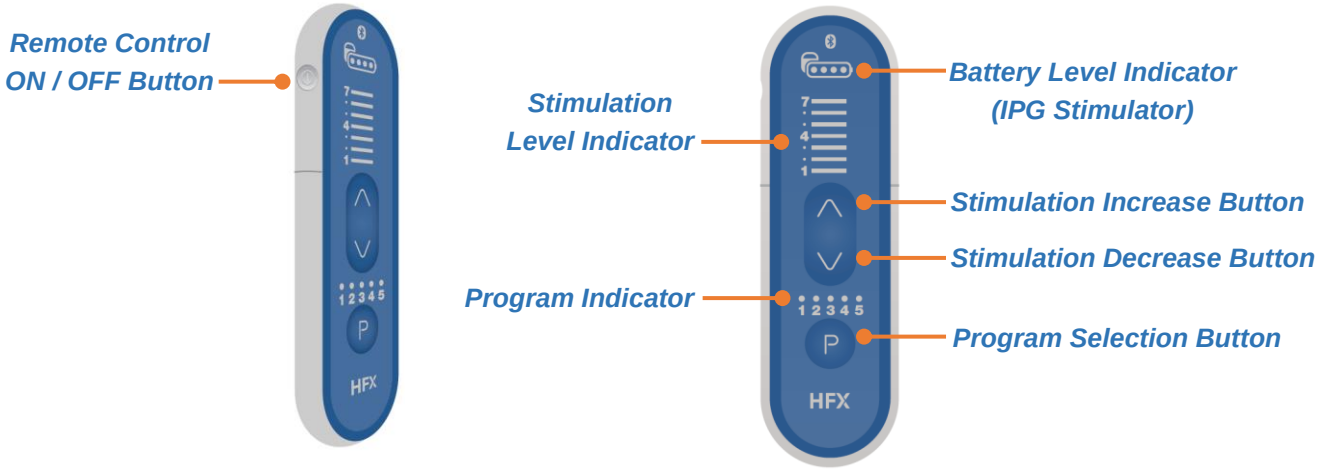


Charger Belt and Charger Holster: Holds the Charger during recharging.

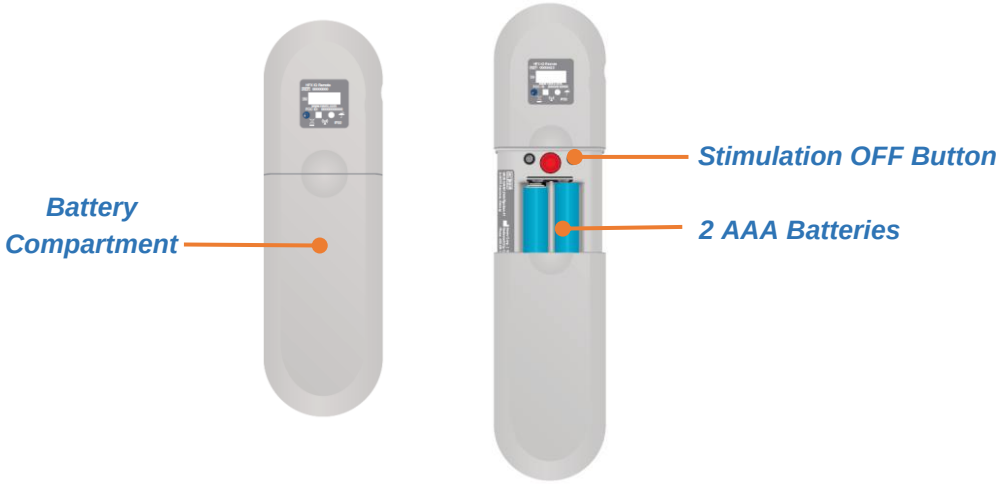
Charging Belt (CGR2500)

Charging Case (for CGR2500)

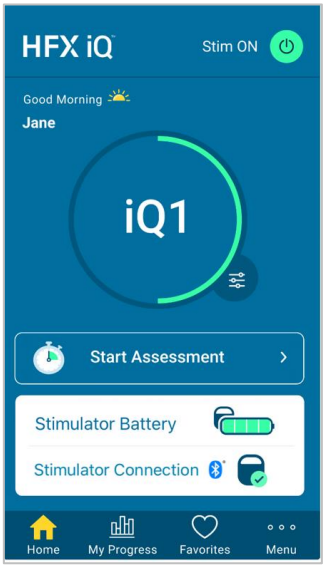
HFX™ Remote (Remote Control): The Remote Control (model PTR3000) is a handheld, battery-operated unit that communicates with the HFX iQ IPG using Bluetooth® wireless technology. The patient can use the Remote



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 (HFX iQ App): 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)



1.3 SURGICAL ACCESSORIES

Torque Wrench: The Torque Wrench is used to tighten the setscrews that lock the Lead into the Lead Extension/Adaptors, or to activate the retention mechanism on the Active Anchors.

Lead Anchors: The Lead Anchors are used to anchor the Lead to the fascia or supraspinous ligament.

Insertion Needle: The Insertion Needle is used during implant surgery to introduce the Percutaneous Lead between the vertebrae into the epidural space.

Coiled Lead Blank: The Coiled Lead Blank is optionally used during surgery to clear a path for the introduction of the Percutaneous Lead into the epidural space.

Stylets: The Stylets are used to maneuver the Lead through the epidural space to the desired implant location.

Magnet: The Magnet is used to power on the HFX Trial Stimulator and pair the Remote Control to the HFX Trial Stimulator.

HFX iQ IPG Port Plug: The HFX iQ IPG Port Plug is provided to seal the port of the HFX iQ IPG that is not in use when only one Lead is implanted.

OR Cables: The Operating Room (OR) Cables make electrical and mechanical connections between the HFX Trial Stimulator and the Leads or Lead Extensions.

Tunneling Tool: The Tunneling Tool creates a subcutaneous tunnel for the leads from the HFX iQ IPG site to the midline incision.

IPG Template: The IPG Template acts as an optional aid for physicians in proper sizing of the HFX iQ IPG implant pocket.

M8 Trial Adaptor: The Mx Trial Adaptor is intended to connect a Medtronic OR cable to the Nevro HFX Trial Stimulator.

S8 Trial Adaptor: The Sx Trial Adaptor is intended to connect a St. Jude Medical OR cable to the Nevro HFX Trial Stimulator.

1.4 COMPATIBLE LEADS

1.4.1 Compatible Nevro Leads and Extensions

The table below provides a list of all Nevro leads and extensions that are compatible with the HFX iQ System and HFX Trial System.

Part Number	Name	Description
TLEAD1058-xx	Trial Percutaneous Lead Kit	1x8, 5 mm spacing xx = 50, 70, and 90 cm lengths

Part Number	Name	Description
LEAD1058-xx	Percutaneous Lead Kit	1x8, 5 mm spacing xx = 50, 70, and 90 cm lengths
LEAD3005-xx	Surpass Surgical Lead Kit	2x8 paddle xx = 50, 70, and 90 cm lengths
LEAD2005-xx	Surpass-C Surgical Lead Kit	2x5 paddle xx = 70 and 90 cm lengths
LEAD2008-xx	Lead Extension Kit	1x8 extension xx = 35, 45, and 60 cm lengths
MADP-25B	M8 Adaptor Kit	Medtronic lead adaptor, 25 cm
SADP-25B	S8 Adaptor Kit	St. Jude Medical / Abbott lead adaptor, 25 cm

1.4.2 Compatible Competitor Leads

The table below provides a list of all competitor leads that are compatible with the HFX System.

Competitor Leads	Adaptor Required	Compatible Leads
Medtronic	M8 Adaptor	For a list of compatible leads, consult the M8 Adaptor Instructions for Use (P/N 10000124).
St. Jude Medical / Abbott	S8 Adaptor	For a list of compatible leads, consult the S8 Adaptor Instructions for Use (P/N 10000125).

Competitor Leads	Adaptor Required	Compatible Leads	
Boston Scientific[1]	None	SC-2016-xx	Infinion™ 16 Lead and Splitter 2x8 Kit[2]
		SC-2016-xxE	Infinion 16 Lead and Splitter 2x8 Trial Kit
		SC-2138-xx	Linear™ xxcm 8 Contact Lead
		SC-2158-xx	Linear xxcm 8 Contact Lead
		SC-2158-xxE	Linear xxcm8 Contact Lead
		SC-2208-xx	Linear ST xxcm 8 Contact Lead
		SC-2218-xx	Linear ST xxcm 8 Contact Lead
		SC-2218-xxE	Linear ST xxcm 8 Contact Lead
		SC-2352-xx	Linear 3-4 xxcm 8 Contact Lead
		SC-2352-xxE	Linear 3-4 xxcm 8 Contact Lead
		SC-2366-xx	Linear 3-6 xxcm8 Contact Lead
		SC-2366-xxE	Linear 3-6 xxcm 8 Contact Lead
		SC-3138-xx	xxcm 8 Contact Extension
		SC-3304-xx	D4 Splitter 2x4
		SC-3354-xx	W4 Splitter 2x4
		SC-2316-xx	Infinion 16 xxcm 16 Contact Lead Kit
		SC-2316-xxE	Infinion 16 xxcm 16 Contact Trial Lead Kit
		SC-3400-xx	xxcm Splitter 2x8 Kit
		SC-3138-xx	xxcm 8 Contact Extension
		SC-8120-xx	Artisan 2x8 Surgical Lead
		SC-8216-xx	Artisan 2x8 Surgical Lead
		(Note: xx = length in cm)	

1.4.3 Senza System Models

The following table provides a general overview of the differences between the Senza Systems.

	Senza I	Senza II	Senza Omnia	HFX
Built-in therapy programs	3	3	5	35
IPG size	34 CC	26 CC	26 CC	26 CC
Remote Control	PTRC1000	PTRC1000	PTRC2500	PTRC3000
Patient charger	CHGR1000	CHGR1000	CHGR2500	CHGR2500

[1] Verification documentation is on file at Nevro Corp.
[2] To use the Infinion Lead with the HFX Trial Stimulator, connect the lead to the Splitter 2x8

	Senza I	Senza II	Senza Omnia	HFX
Compatible with Programmer	✓	✓	✓	✓

2 INDICATIONS

The HFX iQ System and HFX Trial System is indicated as 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
- Leg pain

INDICATIONS. Reasons to get a device, drug, or treatment. Indications are determined by medical experts, clinical studies, and the Food & Drug Administration (FDA).

3 CONTRAINDICATIONS

The HFX iQ System and HFX Trial System is contraindicated for the following patients:

- Are poor surgical candidates
- Are unable to operate the SCS system
- Fail to receive effective pain relief during trial stimulation

CONTRAINDICATIONS. Situations in which the device should not be used because the risk of use clearly outweighs any possible benefit. Contraindications are determined by medical experts, clinical studies, and the Food & Drug Administration (FDA).

Patients that have questions about whether the HFX iQ System and HFX Trial System is right for them should consult with their physician.

4 WARNINGS

WARNINGS. Statements about the use of the device that patients and physicians should take very seriously. If patients and physician do not follow these warnings, it is possible that the patient could be hurt, and / or the device could be damaged.

4.1 STIMULATION FREQUENCIES

Stimulation frequencies in the range of 2 Hz to 1,200 Hz are indicated for paresthesia-based therapy and the system must be configured to produce paresthesia. Stimulation at 10,000 Hz is indicated as paresthesia-free therapy and the system must be configured to deliver paresthesia-free stimulation. Stimulation between 1,200 Hz and 10,000 Hz has not been evaluated for safety, effectiveness, or perception of paresthesia. Specifically, for stimulation frequencies above 1,200 Hz, amplitudes that produce paresthesia have not been evaluated and therefore it is unknown whether injury may occur.

PARESTHESIA. Tingling sensations caused by stimulation.

4.2 STIMULATION AT VERTEBRAL LEVELS ABOVE T8

The safety of program settings above 1,200 Hz have not been studied above the T8 vertebral level.

4.3 PATIENTS WHO ARE POOR SURGICAL CANDIDATES

The SCS system should not be implanted in a patient that is considered a poor surgical candidate. Implanting an SCS system has risks similar to surgical procedures of the spine, including spinal fluid leak, headaches, swelling, bruising, bleeding, infection, or paralysis.

4.4 PREGNANCY AND NURSING

The safety and effectiveness of spinal cord stimulation has not been established for use during pregnancy or nursing.

4.5 PEDIATRIC USE

The safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

4.6 OTHER ACTIVE IMPLANTED DEVICES

Patients must let their physicians know if they have any other active implanted devices. The HFX iQ System and HFX Trial System may interfere with other implanted stimulators, such as cardiac pacemakers and defibrillators which have sensing features and may result in sensing problems or inappropriate responses. The effect of other implanted devices, including deep brain stimulators, peripheral nerve stimulators, implanted drug delivery pumps, and cochlear implants on the HFX iQ System and HFX Trial System is unknown.

4.7 SLEEP

Patients using the HFX iQ System and HFX Trial System that generates paresthesia (tingling sensations caused by stimulation) may choose to turn stimulation off to avoid uncomfortable sensations during sleep. Therapy at 10 kHz does not generate paresthesia and therefore stimulation can remain on during sleep.

4.8 OPERATION OF VEHICLES (DRIVING) OR MACHINERY

If patients are using therapy that generates paresthesia, they should not operate motorized vehicles such as automobiles or potentially dangerous machinery and equipment with the stimulation on. Stimulation must first be turned off in such cases. For these patients, sudden stimulation changes may distract them from proper operation of the vehicle, machinery, or equipment. Therapy at 10 kHz does not generate paresthesia and therefore sudden stimulation changes that result in distraction are less likely.

4.9 ELECTROMAGNETIC INTERFERENCE (EMI) AND ELECTROSTATIC DISCHARGE (ESD)

Electromagnetic energy is generated by equipment found in home, work, medical or public environments. Electromagnetic interference may occur when the energy is strong enough to interfere with the function of the HFX iQ System and HFX Trial System.

ELECTROMAGNETIC INTERFERENCE (EMI). Invisible signals generated by some equipment, appliances, and devices, also known as noise or static. Even if the noise cannot be heard, it may be picked up by the SCS system and affect it.

Most electrical devices and magnets that patients will encounter in a normal day are unlikely to affect the operation of the HFX iQ System and HFX Trial System. However, some equipment may generate strong electromagnetic fields that can turn off stimulation or cause shocks or jolts. Patients should keep away from areas of EMI and turn off the HFX iQ System and HFX Trial System if they are in such an area.

The following are examples of sources that can potentially generate strong EMI:

- Theft detectors or security screeners such as airport security screening devices, retail store, and libraries
- Power lines and power generators
- Arc welders
- Large, magnetized stereo speakers
- Radiofrequency identification devices (RFID)

If EMI is suspected or encountered, patients will need to turn off the HFX iQ System and HFX Trial System. The patient will then need to move away from the EMI area and check whether the therapy is on or off. Before therapy can be turned on, the battery may need to be replaced in the HFX Trial Stimulator or recharged in the HFX iQ IPG.

The following are effects that can result from exposure to strong EMI:

- **Serious patient injury,** resulting from heating of the implanted components of the SCS system and damage to the surrounding tissue.
- **System damage**, resulting in a loss of or change in symptom control and requiring surgical replacement.

- **Operational changes to the HFX Trial Stimulator**, causing stimulation to turn ON or OFF.
- **Unexpected changes in stimulation**, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure the patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen and been injured.

Strong electromagnetic fields arising from closeness to electrical equipment such as mobile phones, satellite phones and radio systems may interfere with the communication between the Remote Control, HFX Trial Stimulator or HFX iQ IPG. Communication can be restored by moving away from the interfering electrical equipment or repositioning the Remote Control.

WARNING: Use of the HFX iQ System and HFX Trial System adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the HFX iQ System and HFX Trial System and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories and cables other than those specified or provided by Nevro could result in increased electromagnetic emissions or decreased electromagnetic immunity of the HFX iQ System and HFX Trial System and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 15 cm (6 inches) to any part of the HFX iQ System and HFX Trial System, including cables specified by Nevro. Otherwise, degradation of the performance of the HFX iQ System and HFX Trial System could result.

Electrostatic Discharge (ESD) is another common source of electromagnetic interference. ESD can occur when a person or object accumulates a static charge. ESD is intensified by low humidity and synthetic materials.

- If the battery terminals of the Trial Simulator are exposed to ESD, the device may reset and stop stimulation. Stimulation can be restarted by following the instructions in the “How to Turn ON Stimulation” section of the Patient Manual. To avoid unintentionally stopping stimulation, do not open the battery compartment while stimulation is ongoing.
- ESD may cause the Charger to stop charging the HFX iQ IPG. If this happens, charging should be restarted. ESD events can be minimized by keeping the charger in the Charger Holster while recharging the HFX iQ IPG.

4.10 THEFT DETECTORS AND SECURITY SCREENING DEVICES

Security checkpoints, metal detectors, screening systems at airports, and theft detectors all produce EMI. If patients must pass through such a system, they should tell the personnel that they have an implanted medical device and show them their Patient ID Card. Patients may be able to go through the checkpoint without going

through the scanner. If that is not possible, patients should turn the device off and move through the scanner as quickly as possible.

While some theft detection systems are obvious and are located at store exits, others may be concealed within the store. If a patient is in a store or other environment and suspect EMI is affecting their device, the patient should turn off their HFX iQ System and HFX Trial System and move out of the area. Once the patient is out of the area, they should check whether therapy is on or off. Before therapy can be turned on, the battery may need to be replaced in the HFX Trial Stimulator or recharged in the HFX iQ IPG.

Patients that have specific questions about EMI sources should talk to their physician.

4.11 HEAT FROM CHARGING

The charging coil may become warm while charging. Patients may experience discomfort or burn if they charge while sleeping or do not use the provided charging belt. Additionally, the charger should not be placed over insensate skin.

5 WARNINGS ABOUT OTHER MEDICAL TREATMENTS

There are some procedures that should not be performed or are not recommended for patients with the HFX iQ System and HFX Trial System and there are other procedures which may be possible only with certain precautions. Patients that need any of these treatments should discuss the treatment with their physician and other clinicians (including dentists, physical therapists, occupational therapists) as well as with the medical personnel performing the procedure.

5.1 DIATHERMY THERAPY

DIATHERMY. A medical treatment in which heat energy from shortwaves, microwaves, or ultrasounds are used as treatment or in surgery.

Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with any part of a neuromodulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. The HFX iQ System and HFX Trial System, whether it is turned on or off, may be damaged.

5.2 MAGNETIC RESONANCE IMAGING (MRI)

MRI SCAN. A type of technology in which electromagnetic energy is used to take images of soft tissue in the body.

The HFX iQ System is MR Conditional which means that safety has been demonstrated only within specifically defined conditions. Scanning under different conditions may result in severe patient injury or device malfunction. Refer to the Nevro MRI guidelines manuals (available at www.nevro.com/physicianmanuals) for detailed information on MRI safety and conditions for MRI scanning of patients implanted with Nevro products.

Never take the Charger, HFX Trial Stimulator or Remote Control into an MRI scan room. The Charger, HFX Trial Stimulator and Remote Control are not considered safe for MRI and may be rapidly pulled into the MRI scanner. In doing so, they may strike and injure a person.

5.3 COMPUTED TOMOGRAPHY SCANS

CT SCAN. A type of technology in which x-ray-like images are taken in sections (slices) and then re-assembled by computer to provide detailed two- and three-dimensional pictures of inside the body.

X-ray and CT scans may damage the Stimulator if stimulation is on. X-Ray and CT Scans are unlikely to damage the Stimulator if stimulation is turned off. Before beginning a CT scan, the operator should use CT scout views to determine if implanted or externally worn electronic medical devices are present and if so, its location relative to the programmed scan range.

For CT procedures in which the medical device is in or immediately adjacent to the programmed scan range, the operator should:

- Determine the device type
- Ask patients to turn off the device temporarily while the scan is performed
- For patients during a trial and if practical, disconnect the HFX Trial Stimulator from the implanted leads and remove external devices out of the scan range.
- Minimize x-ray exposure to the implanted or externally worn medical device by:
    - Using the lowest possible x-ray tube current consistent with obtaining the required image quality
    - Making sure that the x-ray beam does not dwell over the device for more than a few seconds

NOTE: For CT procedures that require scanning over the medical device continuously for more than a few seconds, as with CT perfusion or interventional exams, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

After CT scanning directly over the implanted or externally worn medical device, patients should:

- Turn their HFX iQ System or HFX Trial System device back on.
- Check that their HFX iQ System or HFX Trial System is working properly.
- Contact their physician as soon as possible if they suspect the HFX iQ System or HFX Trial System is not functioning properly after a CT scan.

5.4 DEVICES IN HOSPITAL AND MEDICAL ENVIRONMENTS

The use of the following medical devices or procedures may damage the HFX iQ System or HFX Trial System. After usage of these devices or procedures, the implanted or externally worn SCS system may need to be replaced as a result of permanent damage:

- **Electrocautery:** The HFX iQ IPG should not be exposed to electrocautery. If electrocautery is necessary with the HFX iQ IPG implanted, use bipolar electrocautery. If monopolar electrocautery is required, position the grounding pad so that the current pathway does not pass through or near the implanted pulse generator system.
- **External defibrillation:** The safety of discharge of an external defibrillator on patients implanted with an SCS system has not been established.
- **Lithotripsy or high-output ultrasonics:** Do not use these devices in patients with an implanted HFX iQ IPG.
- **Radiation therapy:** If radiation therapy is needed near the HFX iQ IPG, shield the area over the HFX iQ IPG.
- **Ultrasonic scanning:** Avoid use over the HFX iQ IPG.

ELECTROCAUTERY. The technique of heating tissue, usually by means of an instrument heated by resistance to an electric current, typically to achieve hemostasis or to cause varying degrees of tissue destruction.

EXTERNAL DEFIBRILLATION. The emergency use of an externally applied, controlled electric shock to restore normal cardiac rhythm.

LITHOTRIPSY. The use of sound waves to help break up calcified stones in the body.

RADIATION. The use of radiation energy for therapeutic or diagnostic purposes. There are many types of radiation treatments and the risk to the HFX iQ IPG varies depending on the strength and duration of the applied field

ULTRASONIC SCANNING. Any number of procedures that use sound waves to obtain images of the soft tissue in the body.

If a patient is required to undergo electrocautery, lithotripsy, high-output ultrasound, radiation therapy, or ultrasonic scanning, the following precautions should be taken:

- Turn off the HFX iQ IPG or disconnect the HFX Trial Stimulator from the implanted leads. Remove the HFX Trial Stimulator from the area
- All equipment, including ground plates and paddles, must be used as far away as possible from all implanted and external devices
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from all implanted and external devices.
- Equipment should be set to the lowest energy setting clinically indicated.

After the therapy or procedure, the patient should check that the HFX iQ IPG or HFX Trial Stimulator is functioning properly by gradually increasing stimulation to the desired level. If a patient suspect that the HFX iQ IPG or HFX Trial Stimulator is not functioning properly after the use of these medical devices or procedures, the patient should contact their physician.

5.5 RADIOFREQUENCY ABLATION AND MICROWAVE ABLATION

Safety has not been established for radiofrequency (RF) or microwave ablation in patients that have implanted leads as part of an SCS system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

RADIOFREQUENCY OR MICROWAVE ABLATION. An electrical current produced by a radio / microwave is used to heat up a small area of nerve tissue, thereby decreasing pain signals from that specific area.

6 PRECAUTIONS

PRECAUTIONS. Instructions about the device patients and physicians should follow to avoid damage to the device, so that it will function correctly and last longer.

6.1 STORAGE

Store the HFX iQ System and HFX Trial System components and accessories at the prescribed temperatures, whether in transport or storage. Excessively hot or cold temperatures may damage the components, particularly high heat. Devices should be kept in temperature regulated areas within the acceptable temperature range. Do not expose the components to liquids or excessive moisture.

- The storage temperature range for the HFX Trial Stimulator, HFX iQ IPG, Lead, Lead Extension, and Charger is 0°C to 45°C (32°F to 113°F).
- The storage temperature range for the Remote Control is -20°C to 60°C (-4°F to 140°F).

6.2 OPERATING TEMPERATURES

- The operating temperature range for the Remote Control is 5°C to 40°C (41°F to 104°F).
- The operating temperature range for the HFX Trial Stimulator is 5°C to 40°C (41°F to 104°F).
- While the Charger is plugged into the wall and charging itself, the operating temperature range for the Charging System is 10 to 40 °C (50 to 104 °F).
- While the Charger is charging the HFX iQ IPG, the operating temperature for the Charging System is 10 to 30 °C (50 to 86 °F).
- Device surface temperatures may reach a couple of degrees above ambient conditions. Therefore at 40°C, the maximum operating surface temperature for the Remote Control & HFX Trial Stimulator may exceed 41°C, up to 43°C (109°F).

6.3 STERILIZATION

The HFX Trial Stimulator, HFX iQ IPG and all implanted components are intended for single use only.

- Prior to opening the sterile package, inspect the sterilization indicator and the sterile package.
- Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
- Do not use any component that shows signs of damage.
- Do not re-sterilize the package or the contents. There is risk of infection and device malfunction.
- Do not use if "Use by" date has passed.
- Do not re-use the HFX Trial Stimulator, HFX iQ IPG or any of the implanted components.

6.4 HANDLING

Use care when handling the HFX iQ System and HFX Trial System’s components and accessories. Do not drop them or submerge them in water. Do not impact the system components against hard surfaces and avoid rough handling. Although reliability testing has been performed to ensure quality manufacturing and performance,

dropping the devices on hard surfaces or in water or other rough handling, can permanently damage the components and accessories.

6.4.1 Handling the Leads and Lead Extensions

Follow these guidelines when handling the leads or lead extensions:

- Leads and lead extensions should always be handled with care.
- Do not make sharp bends to the lead or lead extension.
- Do not severely kink, crush or stretch the lead or lead extension.
- Do not apply severe torque (twist) to the lead or lead extension. Do not tie suture directly to the lead or the lead extension.
- When placing a suture around the lead, use the provided lead anchors.
- Do not force the lead into the epidural space. Consider use of the optional lead blank prior to inserting the lead.
- Create a stress relief loop to minimize tension on the lead.
- Do not stretch the lead.
- Do not use sharp instruments to handle the lead or lead extension.
- Wipe off any bodily fluids (e.g. blood) from the lead's proximal end before connecting it to any other component.
- Wipe off any bodily fluids (e.g. blood) from the lead stylet before inserting or reinserting it into the lead.
- When inserting the stylet into the lead, do not use excessive force.

6.4.2 Handling the HFX Trial Stimulator or HFX iQ IPG

Follow these guidelines when handling the HFX Trial Stimulator or HFX iQ IPG:

- Avoid water around the HFX Trial Stimulator.
- Avoid rough handling of the HFX Trial Stimulator or HFX iQ IPG.
- Take care not to drop or hit the HFX Trial Stimulator or HFX iQ IPG. If it has been dropped to a hard surface, do not use the device and send it back to Nevro Corp.

6.5 SYSTEM COMPATIBILITY

Use only Nevro or Nevro-approved accessories with the HFX iQ System and HFX Trial System. A complete list of compatible leads and accessories can be found in section 1 of this manual.

6.6 CLEANING

The Remote Control and Charger can be cleaned as needed by wiping the surface with a soft cloth damped with water or mild detergent. The remaining residue should be removed by wiping the surfaces with a dry cloth. Do not use alcohol or any harsh or abrasive cleaners and never let moisture get inside the Remote Control or Charger.

6.7 PATIENT ACTIVITIES

Patients using therapy that generates paresthesia may experience increased paresthesia when changing posture or making abrupt movements. These patients should lower the amplitude or turn off the stimulation before making posture changes such as stretching or moving their arms over their head. If unpleasant sensations occur, the HFX iQ IPG or HFX Trial Stimulator should be turned off.

Stimulation at 10 kHz does not generate paresthesia, so patients should not experience unpleasant sensations caused by posture changes or movement. As such, patients would not need to change amplitudes in their programs for posture changes or abrupt movements.

6.8 PATIENT ACTIVITIES RELATED TO LEAD MOVEMENT

Patients should not make sudden and excessive bending, stretching, or twisting movements, particularly within the first weeks after the surgery. An implanted lead can move from its original location during such movements, which might affect delivery of therapy. In such cases, the HFX iQ IPG or HFX Trial Stimulator may need to be reprogrammed or the lead(s) may need to be repositioned through another operation.

6.9 HYPERBARIC CHAMBERS

The HFX iQ System and HFX Trial System is sensitive to high pressure. Patients should avoid scuba diving to depths greater than 35 meters and not enter hyperbaric chambers with pressure greater than 4.5 ATM. Pressure greater than 4.5 ATM may damage the HFX iQ System and HFX Trial System.

HYPERBARIC CHAMBER. A special chamber or compartment in which 100% oxygen is delivered to a person under very high pressures, far above the normal atmospheric pressure. Hyperbaric therapy is used for some medical treatments, such as wound healing.

6.10 TRANSCRANIAL MAGNETIC STIMULATION AND ELECTROCONVULSIVE THERAPY

Safety has not been established for Transcranial Magnetic Stimulation (TMS) or Electroconvulsive Therapy (ECT) in patients who have an implanted SCS system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

TRANSCRANIAL MAGNETIC STIMULATION. A non-invasive therapy that uses magnetic fields to stimulate nerve cells in the brain.

ELECTROCONVULSIVE THERAPY. A procedure in which electric currents are passed through the brain to intentionally cause a seizure.

6.11 TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION

Do not place transcutaneous electrical nerve stimulation (TENS) electrodes so that the TENS current passes over any part of the SCS system. If a patient feel that the TENS may be interfering with the implanted SCS system, the patient should discontinue using the TENS and consult with their physician.

TENS. A TENS unit is an external device that sends small electrical currents through the skin to targeted body parts. These currents are used to relieve pain.

6.12 POST-OPERATIVE PAIN

In the days after the surgery, patients may experience pain in the implant area. This is typical in SCS surgeries.

6.13 INFECTION

If a patient experiences persistent discomfort or excessive redness around the wound areas, the patient may need to be checked for infection by their physician. Infections related to the HFX iQ System and HFX Trial System may require the implanted components to be explanted.

6.14 HFX IQ IPG LOCATION AND PHYSICAL MANIPULATION

Patients should not twist or rotate the HFX iQ IPG. If the HFX iQ IPG flips over in the body, the charger may not be able to charge the HFX iQ IPG. The patient's manipulation of the HFX iQ IPG in his or her body may cause the skin over the HFX iQ IPG to become thinner over time.

6.15 LONG-TERM EFFECTIVENESS OF SPINAL CORD STIMULATION

The long-term effectiveness of spinal cord stimulation has been established. Not all patients realize long-term benefits from spinal cord stimulation. Stimulation effectiveness at 10 kHz has been established for two years[1].

6.16 MOBILE PHONES AND OTHER BLUETOOTH®-ENABLED DEVICES

Mobile phones and other Bluetooth®-enabled devices are not anticipated to interfere with the HFX iQ System and HFX Trial System. However, technology continues to change and interactions between the HFX iQ System and HFX Trial System and mobile phones or other Bluetooth®-enabled devices are possible. Patients should contact their physician if they are concerned about mobile phones or other Bluetooth®-enabled devices interacting with their neuromodulation system. See Sections on Electromagnetic Interference (EMI) for additional information.

6.17 LIMITATIONS ON WIRELESS USE

In some environments, such as aboard airplanes, in hospitals, near explosives, or in hazardous locations, the use of wireless functions (e.g., Bluetooth® wireless technology) may be restricted. If patients are unsure of the policy that applies to the use of their HFX iQ System and HFX Trial System in a particular environment, the patient should ask for authorization before turning it on.

In environments where many Bluetooth®-enabled devices or other devices that use wireless radio are active nearby, devices may have problems connecting, and/or communicating with each other. Due to signal interference, multiple attempts may be required. Refer to the Troubleshooting section of the HFX iQ System Patient's Manual (P/N: 10001170).

6.18 MAINTENANCE

Apart from replaceable batteries for the Remote Control, the HFX iQ System and HFX Trial System does not contain any user serviceable parts.

1. Al-Kaisy A, Van Buyten J-P, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients

If any part of the HFX iQ System and HFX Trial System becomes damaged, loose, or does not function properly, patients should discontinue therapy and contact their physician. The system may require maintenance at the clinic or may need to be replaced.

6.19 DEVICE DISPOSAL

Patients that want to dispose of any components in their system should return them to their physician. Do not dispose of the HFX iQ IPG, HFX Trial Stimulator, Charger or Remote Control in fire as the batteries in these devices may explode. The HFX iQ IPG should be explanted in the case of cremation. All explanted HFX iQ IPGs should be returned to Nevro Corp. Do not dispose of electrical components, including batteries, in the unsorted municipal waste stream. Dispose of electrical components, including batteries, according to local regulations.

Whenever a lead or HFX Trial Stimulator is removed from a patient and a product issue is suspected, it should be returned to Nevro Corp. This helps Nevro monitor its products and is required by U.S. law.

7 ADVERSE EVENTS

Adverse events, or side effects, are risks associated with the use of the HFX iQ System and HFX Trial System or any other SCS system. There are adverse events associated with the lead implant procedure, with stimulation, and with the device itself. Patients should contact their physician if they experience any adverse events associated with their device.

7.1 POSSIBLE ADVERSE EVENTS ASSOCIATED WITH THE IMPLANT PROCEDURE AND ADDITIONAL MEDICAL RISKS

- Risks associated with anesthesia, including cardiac arrest
- Surgical complications, such as infection, cellulitis, abscess, fever, sepsis, bleeding
- Cerebrospinal fluid leak
- Intracranial hypotension
- Hematoma, seroma or thrombosis
- Epidural hemorrhage
- Impaired or inadequate wound healing, wound dehiscence
- Temporary or persistent tenderness or pain at implant site
- Lead migration leading to ineffective pain control or other undesirable changes in stimulation
- Suboptimal lead or HFX iQ IPG placement or migration requiring revision or explant
- Spinal cord compression; nerve, nerve root, or spinal cord injury
- Paralysis
- Death

7.2 POSSIBLE ADVERSE EVENTS ASSOCIATED WITH STIMULATION

- Loss of pain relief, loss of paresthesia, or unpleasant paresthesia
- Jolting or shocking sensation associated with changes in posture or sudden movements
- Increased pain
- Undesirable stimulation due to changes over time in tissue around electrodes, changes in electrode position, loose electrical connections, or lead failure
- Uncomfortable stimulation of tissue around the leads including skin and muscle
- Other undesirable sensation such as tingling or prickling
- Weakness, clumsiness or numbness

7.3 POSSIBLE ADVERSE EVENTS ASSOCIATED WITH IMPLANTED DEVICE COMPONENTS

- Tissue reaction or allergy to implanted materials
- Persistent pain at lead or HFX iQ IPG implant site.
- Failure of device components including lead breakage or movement (migration), hardware malfunctions, loose connections, electrical shorts or open circuits, and lead insulation breaches

- Failure or malfunction resulting in ineffective pain control or other undesirable changes in stimulation, and possibly requiring trial lead removal
- Skin erosion or seroma at the lead site or HFX iQ IPG site
- Pressure sores
- External sources of electromagnetic interference that cause the device to malfunction and could affect stimulation
- Exposure to magnetic resonance imaging (MRI) can result in heating of tissue, image artifacts, induced voltages in the HFX iQ IPG and/or leads, and lead dislodgement
- Infection
- Epidural mass formation around the lead

7.4 RISKS ASSOCIATED WITH EXTERNAL DEVICE COMPONENTS

- Tissue reaction or allergy to external materials
- Uncomfortable heating effects, discomfort or burn

8 TECHNICAL SPECIFICATIONS

8.1 ELECTROMAGNETIC INTERFERENCE

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The HFX iQ System and HFX Trial System is intended for use in the electromagnetic environment specified below. The customer or user of the HFX iQ System and HFX Trial System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guide**
RF emissions CISPR 11	Group 1	The HFX iQ System and HFX Trial System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The HFX iQ System and HFX Trial System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The HFX iQ System and HFX Trial System is intended for use in the electromagnetic environment specified below. The customer or user of the HFX iQ System and HFX Trial System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T *is the A.C. mains voltage prior to application of the test level.*			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and Amateur Radio Bands 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and Amateur Radio Bands 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the HFX iQ System and HFX Trial System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d=1.2\sqrt{P}$

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The HFX iQ System and HFX Trial System is intended for use in the electromagnetic environment specified below. The customer or user of the HFX iQ System and HFX Trial System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	d=1.2 $\sqrt{P}$ 80 MHz to 800 MHz d=2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the symbol shown below: 
Proximity Fields IEC 61000-4-3	28 V/m	28 V/m	
NOTE: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HFX iQ System and HFX Trial System is used exceeds the applicable RF compliance level above, the HFX iQ System and HFX Trial System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HFX iQ System and HFX Trial System. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

Recommended separation distances between portable and mobile RF communications equipment and the HFX iQ SCS System

The HFX iQ System and HFX Trial System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HFX iQ System and HFX Trial System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HFX iQ System and HFX Trial System as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter (meters)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The HFX Trial Stimulator (model EXTS3500) and Remote Control (model PTRC3000) are Type BF Applied Parts and are compliant with IEC/EN 60601-1. The HFX Trial Stimulator (model EXTS3500) is a Continuous Operation and Remote Control (model PTRC3000) is a Non-Continuous Operation. The HFX Trial Stimulator (model EXTS3500) and Remote Control (model PTRC3000) are both Internally Powered.

8.2 FCC STATEMENTS

Trial Stimulator FCC ID: XKYEXTS3000

Remote Control FCC ID: XKYPR1D3000

Implantable Pulse Generator (IPG) FCC ID: XKYIPG3000

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The equipment generates, uses and can radiate radio frequency energy and may cause harmful interference to radio communications if it is not installed and used in accordance with the instruction manual.

There is no guarantee that interference will not occur in a particular installation. If this equipment causes interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna.
- Increase the separation between the equipment and the antenna.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications of any kind not expressly approved by Nevro could void the user's authority to operate this device.

8.3 QUALITY OF WIRELESS SERVICE

The HFX iQ System and HFX Trial System uses a wireless communication system in the ISM frequency band (2400 to 2483.5 MHz). This band is not reserved for implantable medical devices. The typical communication range is less than 5 feet (1.5 meters) between the Remote Control and Stimulator.

8.4 TELEMETRY INFORMATION

The HFX iQ System and HFX Trial System uses a wireless communication system in the ISM frequency band (2400 to 2483.5 MHz). The wireless communication system implements Gaussian Frequency Shift Keying (GFSK) modulation. The bandwidth of each of the 40 possible frequency channels does not exceed 2MHz, and the Transmitter Effective Isotropic Radiated Power (EIRP) does not exceed +6dBm (HFX Trial Stimulator and HFX iQ IPG) and +6dBm (Remote Control).

Refer to the tables in the Electromagnetic Interference section to determine the recommended separation distances between the HFX iQ System and HFX Trial System and other transmitters.

8.5 SYSTEM SPECIFICATIONS

The following table contains the stimulation parameter ranges for the HFX Trial Stimulator and HFX iQ Implantable Pulse Generator.

Parameter	Range
Frequency	2 – 10,000 Hz
Pulse Width	20 – 1000 µs
Amplitude	0 – 15 mA

The following table summarizes the maximum amplitude, pulse width, and impedance at two frequency settings.

Frequency* (Hz, Hertz)	Maximum Amplitude (mA, milliamps)	Maximum Pulse Width (µs, microseconds)	Maximum Impedance (Ω, Ohms)
2	9	1000	1000
10,000	10	30	1000

*Therapy settings between frequencies of 2 Hz -10 KHz can vary depending on actual values for Impedance, Current and Pulse Width

8.6 EXPECTED SERVICE LIFE

The service 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 HFX Trial Stimulator should have an estimated service life of 2 months using nominal stimulation settings and allowing for a replaceable battery. The Remote Control should have an expected service life of 3 years allowing for replaceable batteries.

9 SECURITY FEATURES AND DECLARATIONS

9.1 WIRELESS SECURITY

The HFX iQ System and HFX Trial System has a telemetry range of less than 5 feet (1.5 meters). The Remote Control and HFX iQ App is uniquely paired to a specific HFX iQ IPG or HFX Trial Stimulator and can only communicate with that device. The HFX iQ IPG or HFX Trial Stimulator will not respond to any communication that does not come from a linked device (a device that is paired with the HFX iQ IPG or HFX Trial Stimulator). There are additional mechanisms that ensure the integrity of the communicated data.

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NEVRO CORP.

All questions or concerns about Nevro Corp. products, including any serious incident that has occurred in relation to the device, should be forwarded to:

Nevro Corp.
1800 Bridge Parkway
Redwood City, CA 94065
USA

Tel: +1.650.251.0005
Fax: +1.650.251.9415
Email: info@nevro.com