MiniStim PNS User Manual

Caution: Federal law restricts this device to sale by or on the order of a physician.

MiniStim PNS ETx KIT (MNRO-915-1K)

EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE

Refer to the appropriate product for symbols that apply.

Symbol	English – EN
	Device reference identification
	Lot number
	Quantity of product included in package
	Consult instructions for use
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Store in a cool, dark, dry place
	Caution
	Warning
	MR Conditional
	MR Unsafe
	Use by
	Manufacturing date
	Manufacturer
	Device length
	Sterilization: ethylene-oxide gas
	Temperature limits

TABLE OF CONTENTS

HOW TO USE THIS MANUAL

This manual will help you understand how to use and care for your neurostimulator system. It also provides you with warnings and precautions you should know about. You should discuss with your clinician any questions or concerns you have after reading this manual. Please refer to the MiniStim PNS Product Safety Guide for EMC related safety information.

INDICATIONS FOR USE

MiniStim PNS is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. MiniStim PNS is not intended to treat pain in the craniofacial region.

PARTS OF YOUR STIMULATION SYSTEM

Percutaneous Implanted Pulse Generator (pIPG) – Also known as the "implant," is a set of thin wires and a miniature pulse generator receiver, covered with a protective casing. The pIPG has small metal electrodes near the tip that are set to different electrical polarities. An electrical field of energy is created when power is applied to the electrodes. The electrical field aids in blocking the pain signals coming from certain nerves. The pIPG receives energy wirelessly from the ETx.

ETx – ETx is an electronic device used to power the pIPG that contains a rechargeable battery with an antenna cable port and micro USB port (for charging). The ETx is worn near the area where the pIPG is implanted. The ETx communicates with your pIPG by sending radiofrequency signals wirelessly. Your pIPG only accepts communication from your ETx. The ETx antenna sends out the wireless signal. The antenna is permanently attached to the antenna cable. The antenna connects to the ETx with the antenna cable.

OVERVIEW OF ETX USER CONTROLS

BUTTONS	
Key	**Action Description**
	Increase Power Button – Used to increase stimulation strength.
	ON/OFF Button – Used to turn the ETx ON or OFF. Green LED is a default indicator and will blink to indicate power status.
	Decrease Power Button – Used to decrease stimulation strength.
Change Program Selection – Depress Increase Power Button and Decrease Power Button at the same time to alternate programmed setting to either I, II, or III.	

LEDS			
Action Description		**Pattern and Color**	**Description of Pattern**
	**Charging**		Solid Blue
	OFF, Not Charging		None
	Charged		Blinking Blue
	**ON Program I**		Blinking Green (single)
	ON Program II		Blinking Green (double)
	ON Program III		Blinking Green (triple)
	**Minimum Index**		Blinks Once Yellow
	Maximum Index		Blinks Once Yellow
	**Antenna Disconnected**		Solid Yellow

POSITIONING THE ETX

WARNING:

- Do not place the ETx directly on your skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The ETx must be placed overtop a thin layer of clothing at all times.
- Do not turn the ETx on without the antenna cable attached. Do not remove the antenna from the ETx during operation. This will damage the ETx. Charging is okay to perform without the antenna cable.

Steps:

1. The antenna must be placed over the general region of the pIPG in order to transfer the optimal amount of energy.
2. The ETx and antenna cable do not need to be placed over the pIPG. Your clinician will assist you to find the optimal placement for effective therapeutic relief.

STARTING STIMULATION

Note*: *ETx automatically starts at lowest power setting when turned on.

Steps:

1. Place the ETx Antenna directly over the pIPG.
2. Turn on the ETx by pressing ON/OFF until the green Light activates.
3. Adjust power by using the Increase or Decrease Power Buttons.

SELECTING STIMULATION PROGRAM

The ETx has three programs described below.

Program	Frequency (Hz)	Pulse Width (µs)	Amplitude (mA)
I	1500	50	0
II	500	200	0
III	60	200	0

Steps:

1. After powered "On," the ETx defaults to the last program used.
2. Press "+" and "–" buttons at the same time to switch programs.
3. The LED pattern will blink to signify which program is active.

INCREASING OR DECREASING POWER

⚠ CAUTION:
Turn the power off or decrease the power before changing the position of the ETx Antenna to prevent possible uncomfortable stimulation.

Note: ETx must be turned on to increase or decrease the power.

Steps: Press (+) button to increase power or (–) button to decrease power.

To receive the most effective therapy you may need to adjust your power levels throughout the day. Your clinician will provide guidelines about adjustments. The following table provides general guidelines on how to adjust your stimulation.

Situation	Action
Stimulation is too strong	Decrease power with Decrease Power Button
Stimulation is not strong enough	Increase power with Increase Power Button
You have unexpected changes in stimulation	Remove ETx and antenna from your body. Reposition the antenna, restart ETx starting at zero power increase slowly.
You have tried adjusting stimulation but are unable to find effective setting	Remove ETx and antenna from your body. Reposition the antenna, restart ETx starting at zero power increase slowly.

MAINTENANCE

BATTERY CHARGING

Notes:

- *Use only the USB Charger and cable provided to perform charging.*
- *Contact your clinician if you experience poor battery life.*
- *The antenna does not need to be connected during charging.*

Steps:

1. Remove the ETx from your body.
2. Connect the USB cable to the power adapter.
3. Plug the power adapter into a wall outlet.
4. Connect opposite end of USB cable to micro-USB port on the ETx.
5. Charging Indicator Light will stay solid on while the battery is charging.
6. Allow the battery to charge for at least four hours.
7. Charging Indicator Light will blink when the battery is fully charged.
8. ETx is now ready to be used again.

CLEANING AND CARE PRECAUTIONS

Notes:

- Clean the outside of the device with a damp cloth when necessary. Mild household cleaners will not damage the device or labels.
- Device is not waterproof. Do not allow moisture inside the device.
- Keep the device out of the reach of children and pets.
- Use the device only as explained to you by your clinician.
- Handle the device with care. Do not drop, strike, or step on the device.
- Do not dismantle or tamper with the device.

WHEN TO CALL YOUR CLINICIAN

Contact your clinician if any of the following events occur:

- You have pain, redness, or swelling later than 6 weeks after procedure.
- The stimulation is causing you to have pain or discomfort.
- The system is not working properly.
- You cannot adjust stimulation using the user controls.
- You cannot place the ETx in optimal position to communicate with the pIPG.

Your clinician will schedule follow-up visits to make sure your device is working properly and that the stimulation is managing your pain.

Common Questions	Response
How long will it take to recharge a "dead" or depleted battery?	It normally takes an average of four (4) hours to recharge the battery.
When is the battery near depletion, and how will I know?	The ETx will turn off and not respond to user controls.
What happens if I deplete the battery completely?	You cannot damage the ETx by depleting the battery. The device has safeguards to prevent battery harm.
How long will a fully charged battery provide power?	Eight (8) hours on average. Performance is affected by the amount of power used on average.
When is the battery done charging?	The battery is done charging when the Charging Indicator Light (blue) blinks on/off.
Can I charge while the device is turned on?	No, you cannot charge the device while it is turned on. The device cannot be used while connected to the charger.
Must I disconnect the device from the charger when full?	It is not necessary to disconnect the device from the charger when full.
Will the ETx feel warm during or after charging?	The ETx may feel warm during or immediately after charging.

SAFETY INFORMATION

CONTRAINDICATIONS

- **Poor surgical risks –** MiniStim PNS should not be used on patients who are poor surgical risks, have multiple illnesses, active infections, or who need anticoagulation therapy that cannot be temporarily halted to accommodate the implant procedure.
- **Pregnancy –** Safety and effectiveness of MiniStim PNS for use during pregnancy and nursing have not been established.
- **Inability to operate System –** MiniStim PNS should not be used on patients who are unable to operate the device.
- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated within the vicinity of a patient implanted with a pIPG or when wearing the ETx. The energy from diathermy can be transferred through the pIPG or ETx and cause tissue damage, resulting in potential injury.
- **Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy –** Users who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with MiniStim PNS. The energy in high-level areas can be transferred through the pIPG and cause tissue damage, resulting in injury. Examples of environments having high level non-ionizing radiation includes radio or cell phone transmission stations, facilities using radiofrequency heat sealers or induction heaters, electric power infrastructure-controlled environments (i.e. step down transformers or high voltage power lines) .

- **Implanted cardiac systems –** Patients who have implanted cardiac systems should not use MiniStim PNS. Electrical pulses from the device may interact with the sensing operation of an implanted cardiac system, causing inappropriate responses.

WARNINGS

Electromagnetic interference (EMI) – EMI is a field of energy that can be generated by certain equipment found in home, work, medical or public environments. Strong EMI signals have the ability to cause interference with MiniStim PNS operation. Most electrical devices and magnets encountered in a normal day will not affect the operation of MiniStim PNS. However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in MiniStim PNS operation;
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or cause a patient direct injury. In rare cases, as a result of the unexpected changes in stimulation, patients have injured themselves.

If you suspect that equipment is interfering with device function:

- Immediately move away from the equipment or object;
- Remove the ETx from the vicinity of the patient.

Electromagnetic equipment/environments – The product is suitable for use in home environments and public areas. Avoidance of high electromagnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation;
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics;
- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics;
- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area);
- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area);
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area);
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or

other electronic equipment;
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals.

Adjacent to or Stacked with Equipment – Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications Equipment – Portable RF communications equipment (including external antennas) should be used no closer than 30 cm (12 inches) to any part of the System. Otherwise, degradation of the performance of this equipment could result.

Active Implantable or Body Worn Medical Devices – Safety has not been established for patients who use MiniStim PNS with other active implantable or body worn medical devices. These devices include other neurostimulation systems, insulin pumps, automated external defibrillators (AED), cochlear implants, and wearable medical sensors. Malfunction and/or damage could occur to either system resulting in harm to patient or other people nearby.

Radiofrequency (RF) ablation – Safety has not been established for radiofrequency (RF) ablation in patients with a pIPG. RF ablation may cause induced electrical currents that result in heating and tissue damage. Do not use RF ablation anywhere near the pIPG. If RF ablation is used, ensure that ablation is not performed over or near the pIPG.

Magnetic resonance imaging (MRI) – **MiniStim PNS is MR Unsafe.** Since MiniStim PNS is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage device, and in the process cause serious harm to the patient or other people or damage to the MR system.

ETx component is MR Unsafe; ensure that the ETx does not enter the MR system room. Since the ETx is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the ETx, and in the process cause serious harm to the patient or other people or damage to the MR system.

Machinery or heavy equipment – Machinery and heavy equipment (including vehicles) should not be operated while using MiniStim PNS. Malfunction could result in loss of body control, body function, or a feeling that could render the patient incapable of controlling equipment.

Bone growth stimulators – Safety has not been established for bone growth stimulator systems within the vicinity of MiniStim PNS. Use of a bone growth stimulator may result in damage to the device or harm to the patient.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic

interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have pIPGs. Induced electrical currents can cause heating that may result in tissue damage.

Dental drills and ultrasonic probes – Safety has not been established for dental drills or ultrasonic probes within the vicinity of MiniStim PNS. Use of drills or probes may result in damage to the device or harm to the patient.

Electrolysis – Safety has not been established for electrolysis within the vicinity of MiniStim PNS. Use of electrolysis may result in damage to the device or harm to the patient.

Electrocautery – If electrocautery tools are used near the pIPG then the insulation can be damaged. The pIPG may fail or conduct induced currents. Induced electrical currents can cause heating that results in tissue damage.

When electrocautery is necessary, these precautions must be followed:

- The ETx should be taken off.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
    - Only low-voltage modes should be used;
    - The lowest possible power setting should be used;
    - The current path (ground plate) should be kept as far away as possible from pIPG;
    - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm that the pIPG is working as intended.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with a pIPG. X-rays from the scan could cause unintended shocks or malfunctions of the pIPG. The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the ETx from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
    - Use lowest possible X-ray current to obtain the required image quality;
    - Making sure that the X-ray beams do not dwell over the device for more than a few seconds.

After CT scanning directly over the implanted device:

- Place the ETx and turn on stimulation.
- Check for proper stimulation and that indicator lights are operating as expected.
- Shut off the ETx if it is suspected that the device is not functioning properly.

High-output ultrasonics / lithotripsy – Safety has not been established for high-output ultrasonics or lithotripsy when implanted with MiniStim PNS. Use of lithotripsy may result in damage to the device or harm to the patient.

Radiofrequency Identification (RFID) Emitters - Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems – Tests have been performed with an array of simulated RFID emitter systems, and have demonstrated that MiniStim PNS (implanted pIPG and ETx) are not affected by separation distances between MiniStim PNS and the RFID emitter of less than 3 m (~10 ft.). More powerful RFID Emitters might cause effect at farther distances. RFID emitters can be hidden or portable and not obvious to the patient. Any RFID emitter may temporarily interrupt stimulation or cause elevated levels of stimulation. It is recommended that if a patient feels a change in stimulation near a potential RFID emitter, they promptly move away from the area and remove the ETx from the body.

When possible, it is best to avoid RFID emitters or remove the ETx while passing near RFID emitters. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing any RFID emitter. If unavoidable, the patient should walk through the RFID emitter and promptly move away from the area. Patients should not lean on scanners or linger in the area of RFID emitters.

Device fracture – If the pIPG insulation is ruptured or pierced due to extensive forces, unexpected changes in stimulation could result.

Laser procedures – Safety has not been established for lasers within the vicinity of MiniStim PNS. Use of lasers may result in damage to the device or harm to the patient.

Radiation therapy – Safety has not been established for high radiation sources such as cobalt 60 or gamma radiation when implanted with MiniStim PNS. Use of radiation therapy could cause damage to the device or harm to the patient.

Transcutaneous electrical nerve stimulation – Safety has not been established for use of transcutaneous electrical nerve stimulation (TENS) when implanted with MiniStim PNS. Use of TENS could cause the device to turn off or intermittent/increased stimulation.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps,

elbow wraps) – Keep the magnet away from the pIPG site. Magnetic fields will generally not affect the pIPG.

ETx Skin Contact – Do not place the ETx directly on the skin. Direct skin contact may cause irritation and/or sensitivity. The ETx must be placed overtop a thin layer of clothing at all times.

Painful Stimulation – If the patient experiences painful stimulation, the power on the ETx should be decreased immediately or removed from the body.

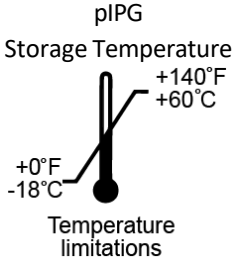
Aircraft Usage – Safety has not been established for use of MiniStim PNS on aircrafts. Use of MiniStim PNS on a commercial aircraft may result in damage to the device or harm to the patient.

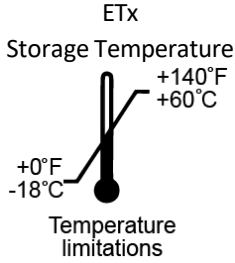
PRECAUTIONS

Physician training – Prescribing clinicians should be experienced in the diagnosis and treatment of peripheral pain and should be familiar with using MiniStim PNS. Implanting clinicians should be experienced and review the procedures described in Instructions for Use.

Keep the ETx dry – The ETx is not waterproof. Keep it dry to avoid damage. Do not use the ETx when engaging in water activities.

Storage temperatures – MiniStim PNS should be kept within the storage temperatures listed on product packaging. Exceeding the storage temperature could cause harm to you or the component. Please contact the manufacturer if a storage temperature is surpassed.





Clean the ETx – Clean the outside of the ETx with a damp cloth when needed to prevent dust and grime. Mild household cleaners will not damage the device.

Handle the ETx with care – The ETx is a sensitive electronic device. Avoid dropping the device. Keep the ETx out of the reach of children and pets.

Medical tests and procedures – Before undergoing medical tests or procedures, contact the clinician to determine if the procedure will cause damage to the patient or to MiniStim PNS.

Physician instructions – Always follow the programs and therapy instructions established by the clinician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Use the ETx as directed – Use the ETx only as discussed in the User Manual. Using the ETx in any other manner could result in harm.

Do not dismantle the ETx – Do not dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, contact the clinician for help.

Flammable or Explosive Environments – Do not use the ETx in flammable or explosive environments. Using the ETx in one of these environments could result in harm.

Use of another patient's ETx - Never use another patient's ETx. Use of another patient's ETx could result in overstimulation.

Activities requiring excessive twisting or stretching – Avoid activities that potentially can put undue stress on the device. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause the pIPG to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Scuba diving or hyperbaric chambers – Do not dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA) . These conditions can damage the device. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with the clinician.

Skydiving, skiing, or hiking in the mountains – High altitude should not affect MiniStim PNS. However, take care to not put undue stress on the pIPG. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the pIPG. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation. Some patients have described this as a jolting or shocking sensation. You should reduce the power to the lowest setting and turn OFF MiniStim PNS before engaging in activities that could become unsafe. Discuss these activities with your clinician.

Adverse Event Summary

Implantation of a peripheral nerve pIPG is similar to any surgical procedure. Risks include the following:

- Allergic or immune system response to implanted material.
- Infection.
- Hemorrhage or hematoma.

Therapeutic use of the MiniStim PNS incurs the following risks:

- Undesired change in stimulation.
- Migration, erosion through the skin, or fracture resulting to loss of therapeutic effect.
- Electromagnetic interference leading to change in System performance.
- Loss of therapeutic effect despite a functioning system.

Adverse events that could occur with the MiniStim PNS:

- Migration, resulting in altered stimulation therapy that may be uncomfortable.
- Device fracture, resulting in loss of stimulation.
- Infection, resulting in tissue sensitivity, redness and swelling.

Adverse effects of stimulation are usually mild and go away when stimulation is turned off. Patients should be instructed to contact their clinician immediately if they experience any problem or if they experience a change in stimulation. Over time there could be changes in the level of pain control.

Safety and Technical Checks

Periodic safety checks or maintenance of the ETx are not required. The ETx contains no user-serviceable parts. If repair or service is needed, contact your clinician for a replacement, or refer to the contact information at the end of this manual.

ETx Disposal

The ETx should be returned to your clinician. Do not dispose of your ETx.

Patient Identification Card

A patient identification card (ID) is mailed to you after MiniStim LLC receives your implant registration form. The patient ID card supplies information about you, your MiniStim PNS, and your doctor. Your identification card may allow you to bypass security devices. Carry this card with you at all times. If you move, change doctors, or lose your card, contact MiniStim LLC for a replacement card. Refer to the MiniStim LLC contacts at the end of this manual.

SPECIFICATIONS

Item	Specification
Amplitude (500Ω)	0 to 16.6 mA
Pulse Width	50 to 500 µs
Frequency (of therapy)	5 to 1,500 Hz
Number of Channels	1
Number of Programs (selectable)	3
Transmit Carrier Frequency	915 MHz
USB Charger Power Source	100-240V 50-60 Hz power line
Operating/storage temperature, relative humidity	-18º C to 60º C (0º F to 140º F) 20% to 90%
Operating/storage atmospheric pressure	70 kPa to 150 kPa (20.7 in Hg to 44.3 in Hg)
Size (approximate)	7.6 cm x 5 cm x 2 cm (3 in x 2 in x 0.8 in)
Weight (approximate)	0.5 kg (1 lb.)
ETx Material	Aluminum

Parameter	Min	Typical	Max	Units
Supply Voltage	100	---	240	$V_{A/C}$
Supply Voltage Frequency	50	---	60	Hz
Output Voltage (DC)	4.5	5	5.5	V
Input Current	---	---	1.0	A
Output Current (each)	---	---	2.4	A
Battery Recharge Time (assuming 3.7V battery)	3	4	5	hours
Modulation	---	CW	---	N/A

WIRELESS INFORMATION

MiniStim PNS uses wireless technology to power the pIPG. Various programs are stored in memory within the ETx, which can be selected as needed.

ETx Wireless Specifications	
FCC ID	2AHXAPDBT2
Transmission Frequency	915 megahertz (MHz)
Bandwidth	149 kilohertz (kHz)
Tissue Depth	Up to 2 cm (0.80 in.)
Quality of Service	ETx should be centered over pIPG within 0.8 inches (2 cm). ETx should be worn in the same position as when it was originally fitted. When the wireless link between the ETx and pIPG is broken, stimulation will cease. The wireless link may not function in the presence of large magnetic or radio fields.
Wireless Security	pIPG will only operate within a short distance of ETx. ETx uses encryption and proprietary data protocols to reduce the likelihood of inadvertent control or malicious "hacking". No identifiable personal data is stored or transmitted by ETx.

TROUBLESHOOTING

NOTE:

- *If a problem is not solved after several attempts, or if a problem is not described here, contact your clinician.*

Problem	Causes and Actions
Uncomfortable stimulation: You are too uncomfortable with the current stimulation to think about how to change it.	Selected parameter settings are not suitable for your activity or posture. ▪ Reduce the power level of the ETx. ▪ Remove the ETx from your body.
Intermittent stimulation: You feel stimulation only some of the time.	ETx may have a poor connection with pIPG. The antenna may not be placed over the pIPG. ▪ Place antenna directly over the pIPG. ▪ If you are not receiving adequate pain relief, contact your clinician.
No stimulation: You do not feel stimulation but you think stimulation should be on.	Stimulation is off. ▪ Turn the power OFF and wait 5 seconds before turning the power back ON. Antenna is not placed over the pIPG. ▪ Place ETx directly over the pIPG. ETx power is set too low to feel stimulation. Increase the power.
ETx is unresponsive: The indicator light does not turn on. The stimulation power buttons do not respond.	ETx has “frozen”. ▪ Turn the power OFF and wait 5 seconds before turning the power back ON. The battery is not charged. Recharge battery by placing ETx on charger.
Dropped ETx: Your ETX falls off a cabinet or table.	ETx is designed to withstand a short drop on a hard surface and still operate normally. Try powering ON the ETx and allow it to transmit for 10 minutes while not worn on the body. If the ETx is functioning properly, try using it.
Fluid on the ETx: Fluid was spilled on ETx or the ETx was dropped into water.	ETx is not waterproof, and water can damage the device. Immediately remove the ETx from the water, then dry the ETx with a towel. Allow the ETx to dry at room temperature for 24-48 hours.

CONTACT INFORMATION

MANUFACTURER
MiniStim LLC
1900 Glades Road, Ste 500,
Boca Raton, Florida 33431,
United States
Telephone: +1.888.691.0585
Fax: +1. 888.691.0585
Internet: www.ministim.com

31-00012-3 Published Nov 2022