INTERX®

1000 PERSONAL DEVICE

OPERATIONS MANUAL & TREATMENT GUIDE

Introduction

The InterX® 1000 is designed to provide personal treatment of painful conditions like arthritis, injuries, and general aches and pains. The InterX® 1000 can be prescribed independently or used in conjunction with other therapies and as a support to treatment with the InterX® professional models.

The InterX® 1000 provides an interactive response to the body's changes during recovery from injury or surgery. When applied to the skin, electrical impulses adjust dynamically as the device encounters changes in the skin. The InterX® 1000 responds to the changes in skin tissue as it makes contact through the electrodes and continues to adjust as the body begins to heal.
This interactive capability not only provides results, but also resists the body's natural tendency to develop a tolerance to static therapies.

Ergonomically designed and completely portable, the InterX® 1000 is a pain management device suitable for clinical, home, or "on the go" use.

Please read this manual completely prior to using the InterX® 1000.

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InterX®1000

Operations Manual

This manual provides information regarding the safety, warnings, cautions, controls, and functions of the InterX® 1000. The InterX® 1000 must be used strictly in accordance with these instructions.

Indications for use

The InterX® 1000 is FDA cleared for:

- symptomatic relief and management of chronic intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain.

InterX® Technologies is ISO 13485 Registered company.

Contact InterX® Technologies for country specific information or additionalregulatory approvals.

Any serious incident that occurs in relation to the device should be reported immediately to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Definitions: Warnings and Cautions

Warning: A WARNING message contains special safety emphasis and must be observed at all times. Failure to observe a WARNING message could result in serious personal injury.

Caution: Failure to observe a CAUTION associated with the use of the device could result in minor injury or product damage. Such problems include device malfunction, device failure, damage to the device, or damage to other property.

Contra-Indications

- Electrode placement over malignant tumors
- Transcerebral and/or carotid sinus electrode placement
- Use over mucous membranes
- Undiagnosed pain (until etiology is established)
- Patients who are prone to seizures (e.g. patients with epilepsy)
- Use over pharyngeal or laryngeal muscles. The electrical impulses generated may cause muscle spasm resulting in difficulty in breathing
- Patients that have a demand-type cardiac pacemaker

Warnings

Federal (U.S.A.) law restricts this device to sale by, or on the order of, a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Federal (U.S.A.) law requires the InterX® 1000 be used only by a licensed practitioner or under the supervision of a practitioner licensed by law to direct the use of the device. Adequate instructions for use have been created in this manual and online training. The InterX® 1000 must be used only by the person for whom it is prescribed. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

Safe use of the InterX® 1000 is the primary responsibility of the user. The user is responsible for the monitoring of the product. Contact clinical / technical support if the InterX® 1000 appears to be operating incorrectly.

The user must keep this device out of reach of children.

Not for unattended use on children.

The InterX® 1000 is a symptomatic treatment and as such could suppress the sensation of pain which would otherwise serve as a protective mechanism.

The safety of the use of the InterX® 1000 has not been established during pregnancy or childbirth.

Do not operate the InterX® 1000 before verifying that other medical devices will not be adversely affected by the electrical impulses generated (e.g., electrical implants). Turn off spinal cord stimulators before using the InterX®.

If the patient has a pacemaker that is not demand-type, do not treat directly over the pacemaker or directly around the pacemaker with the electrodes.

Warnings (cont.)

Stimulus delivered by this device may cause electrocution. Electrical current of this magnitude must not flow through the thorax or carotid sinus nerves because it may cause cardiac arrhythmia or interfere with cardiac function.

If the Preset LEDs become blank or inoperative, discontinue use.

Extreme heat or cold may affect the operation of the InterX® 1000.

Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the InterX® device is in use.

Do not use on patients that are undergoing dialysis or are being treated in an MRI, X-ray, or with other diagnostic equipment that may be impacted by the electrical impulses. Remove all jewelry before treatment.

The InterX® 1000 is not to be used in the presence of anesthetic or otherflammable gases.

The InterX® 1000 has no curative value.

Avoid placing the device on the skin when turning on to avoid electrical signal.

Treatments with the InterX® 1000 should not exceed 1 hour in any specific area of the body. There should be a minimum of 2 hours between treatment sessions to avoid isolated cases of skin irritation.

Skin irritation, bruising, electrode burns, dizziness, nausea, and headaches are potential adverse reactions. Check your skin after 10 or 20 minutes of continuous stimulation with the flex arrays or electrodes to assess for irritation.

Use caution in applying the InterX® 1000 over areas which are swollen, infected, or inflamed as this may result in a worsening of symptoms.

This device should not be used within the vicinity of the heart.

Cautions

The InterX® 1000 should be used only with manufacturer approved electrodes and accessories. Built-in device electrodes and external electrodes should not be used in combination transcerebrally.

The InterX® 1000 device should never be used in the shower, immersed in water, or with visible condensation on the device.

Avoid spilling fluids on the device. If the InterX® 1000 is immersed in any liquid it must be replaced with a new device.

Do not sterilize the InterX® 1000.

Do not expose any part of the InterX® 1000 to chemical solvents or harsh cleaning fluids. Follow cleaning instructions described further in this manual.

Effectiveness of the InterX® 1000 is highly dependent upon training. See training online at Interx.com and this manual's guide.

The InterX® 1000 should not be used while driving, operating machinery, or during any activity which may put the user at undue risk of injury.

Do not open the InterX® 1000 case. Opening or removing the housing may expose you to dangerous voltages or other hazards and can damage the internal circuitry. Opening the case will void the manufacturer's warranty. If the device should need repair or service, contact InterX® Technologies, your InterX® 1000 distributor, or an authorized InterX® service representative.

Turn device OFF before replacing batteries to avoid unexpected electrical stimulations. Only the battery cover may be removed when changing batteries. Do not attempt to connect the InterX® 1000 to any other power source.

Do not use any damaged stainless steel electrodes.

Use caution in applying the InterX® 1000 to patients suspected of having heart disease.

Use caution when making contact with the InterX® 1000 electrodes on wet skin. Natural bodily fluids, including perspiration, are acceptable.

Use caution when treating at high levels over areas of sensitive skin.

Caution should be taken when electrodes are placed over areas associated with phlebitis, thrombophlebitis and varicose veins as these conditions present an increased risk of forming blood clots which could become dislodged during stimulation.

Authorities and Symbols

MD

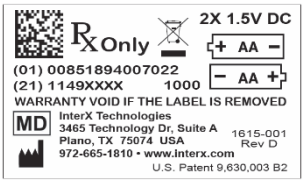
This MD symbol signifies that this product is a medical device.

The "NRTL/C" indicator adjacent to the CSA (Canadian Standards Association) mark signifies the product has met the applicable ANSI/UL and CSA standards for use in the U.S. and Canada. NRTL (Nationally Recognized Testing Laboratory) is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

This stimulator is internally powered only. This symbol indicates the device was manufactured according to the degree of protection against electrical shock for this type BF protection class equipment.

DO NOT use the InterX® 1000 without reading this manual.

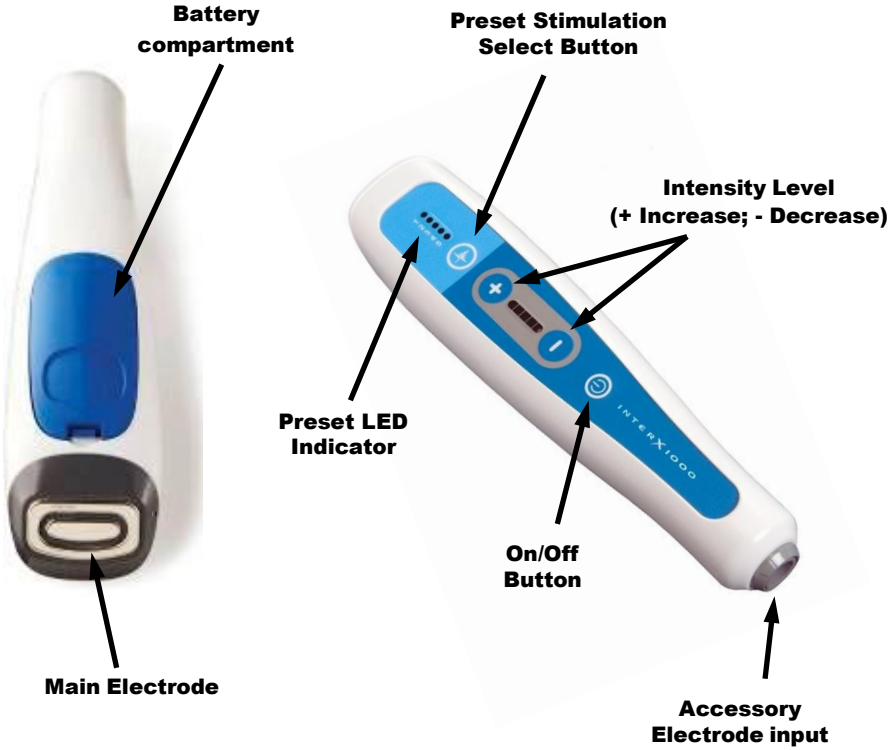
This symbol indicates the medical device manufacturer.



The Serial Number (SN) and the manufacturing information are located on the label inside the battery compartment.

The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.

Overview of Controls and Functions



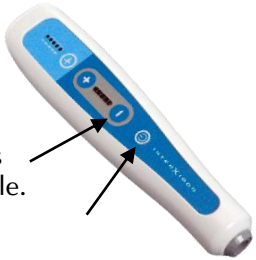
Turning the InterX® 1000 ON/OFF

To begin InterX® therapy, turn the device ON by pressing the ON/OFF button for a brief moment. Any Electrodes (either the built-in Electrode or an attached external electrode) should be free of skin contact.

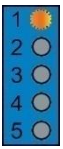
ON/OFF Button

Silencing all Sounds During Use:

To mute all audible buzzers, alerts, clicks, or other sounds, press and hold the ON button and the DOWN (-) button, holding these both until the LED start-up display sequences are completed. All audio is muted until the next power cycle.



Upon start-up, the InterX® 1000 goes through a short self-test and then a short audible beep will be heard. The amber LED for Preset 1 will illuminate to show the device is turned on. Wait 5 seconds before placing the device on the skin.



To turn the InterX® 1000 OFF, press and hold the ON/OFF button until an audible beep is heard.

The InterX® 1000 may not perform correctly if:

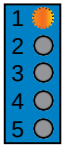
1. The battery is dead.
2. An incompatible electrode is plugged in.
3. There is a device failure.
4. The electrode heads are dirty with skin residue or oils.

The InterX® 1000 will automatically turn off after two (2) minutes of inactivity. Skin contact is considered a working activity.

Selecting a Preset Stimulation Pattern

There are five preset stimulation patterns on the InterX® 1000. Press the PRESET button until you have reached the desired stimulation setting. An amber LED will light to show the preset stimulation pattern that is active. Your physician or therapist may provide you with the most appropriate preset stimulation pattern for your condition.

PRESET button 

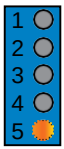


Preset 1 : 15 – 60 PPS (Pulses Per Second)
Low to moderate stimulation setting. This variable impulse is recommended for conditions that are very chronic or for hypersensitive skin or young children.

Preset 2 : 60 PPS
This preset is appropriate for ongoing pain and persistent conditions.

Preset 3 : 30 – 120 PPS
Moderate to high stimulation setting. This variable impulse is recommended for new or chronic pain resulting from an injury or recent surgery.

Preset 4 : 240 PPS
High stimulation setting. This preset is recommended for higher pain levels and when a new painful condition has recently occurred.

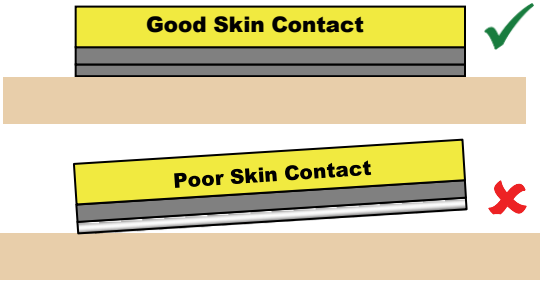


Preset 5 : 480 PPS
The highest stimulation setting. This preset is recommended for the immediate treatment of an injury and is a strong stimulation. Maximum stimulation time is 10 minutes.

How to Set Stimulation Intensity

Place Electrode on the Skin

Ensure the InterX® 1000 electrodes are in full contact with the skin on or near the area to be treated before increasing intensity. The sensation from the InterX® 1000 will vary from place to place and day to day so it is VERY important to only increase intensity when the device is on the skin.

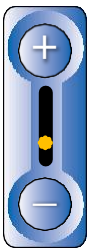


NOTE: It is recommended that the skin remain in a "natural" condition. Creams and lotions should not be used, and excess perspiration should be wiped away.

Set Stimulation Intensity

Press + to increase the intensity to a comfortable tingling sensation.

Press − to decrease the intensity if the stimulation is uncomfortable.



Intensity Display

NOTE: While changing the intensity, the preset LED will flash.

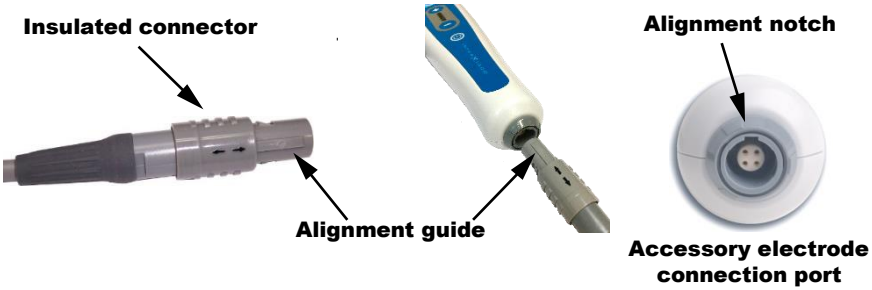
The intensity level should be started at a minimum level and gradually increased until you feel a comfortable tingling sensation. It is not necessary to use a high level of stimulation.

The amber LED displays the level of intensity as it is changed. This will only be displayed while you are changing the level of intensity.

Description of Accessory Electrodes

There is a range of accessory electrodes available for use with the InterX® 1000. The accessory electrodes plug into the accessory port of the InterX® 1000 located at the end of the device (opposite end to the main built-in electrode). Use care when plugging in the connector noting the alignment guide for connection. Do not twist the connector while pushing it into the port. Align first, then push the connector in. To remove, hold the insulated connector and gently pull apart.

NOTE: Jerking or twisting the lead wire instead of holding its insulated connector may cause damage.



Do not attempt to plug other devices or accessories into the accessory port of the InterX® 1000. Only manufacturer approved electrodes may be used with the InterX® 1000. The electrode package contains instructions for care and replacement of accessory electrodes.

When an accessory electrode is plugged or unplugged, the device will default to preset 1 and minimum stimulation intensity.

The main electrode will be inactive when an accessory is plugged in. Adjust the Mode and Intensity of the accessory electrode in the same way as the main built-in electrode.

NOTE: Some accessory electrodes will provide different stimulation patterns based on intended use.

All instructions in this manual apply to user placement of both built-in and external electrodes.

Accessory Electrodes for use with the InterX® 1000

The **Dome Electrode** – designed specifically to cover a larger area of skin tissue.

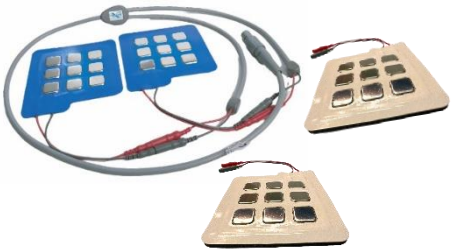
The **Soft-Tissue Electrode** – designed for use on muscles, myofascial release, or massage tool.

The **Comb Electrode** – electrode is designed for use on areas of skin where hair is thicker and on the scalp. Stimulation is continuous regardless of skin contact.

The **Flexible Array™** – designed to provide unattended treatment options once treatment parameters have been set. It comes in two sizes: 3x3 dual pads and a 4x4 single pad.

The **Cosmetic Electrode** – primarily used as a facial treatment.

The **Classic Electrode** – for use on smaller areas, such as the face, neck, hands, and feet.



The **Personal Flexible Array & Comfort Flex III Array** – designed to be thin and more flexible around bony points, providing good skin contact.

Explanation of Electrode Use

Built-in Main Electrodes and the Dome, Classic, Comb, Cosmetic, and Soft Tissue External Electrodes:

The built-in main electrode will operate like the Dome, Classic, and Soft Tissue electrodes. All the external electrodes operate on the settings described on page 10. When using either the built-in electrodes or when an external electrode is plugged into the Interx® 1000 device, the electrodes will operate for 20 minutes of stimulation on preset settings 1-4 before going into a 5 minute pause mode. A single tone will be heard at the 30 second timer mark and every minute thereafter and a double tone will be heard at the 60 second timer mark and every minute thereafter. With the **Built-in electrodes or the Dome, Classic, Cosmetic, and Soft Tissue external electrodes**, the device will turn off if no skin contact is detected in 2 consecutive minutes after startup. When using preset settings 1-4, pressing the plus (+), minus (-), or preset selection button during pause mode will restart the stimulation for another 20 minutes at the preset setting and intensity that was previously set with a 2 second ramp up. If no button is pressed during pause mode, the device will time-out and turn off.

Notes: During the pause mode, a tone will be heard every 10 seconds to remind you that the device has paused the stimulation. Pause mode is not implemented for Preset setting 5 (480 PPS). Preset setting 5 will only operate for 10 minutes of stimulation before turning off.

The **Cosmetic electrode** comes with its own instruction manual when purchased with the Interx® 1000 device for cosmetic use. Two unique features of the Cosmetic electrode are:

- Maximum intensity level is 32% for any Preset setting
- Preset setting 1 is set to 15 PPS (Pulses Per Second)

The **Comb electrode** is unique in that it will produce a continuous stimulation regardless of skin contact.

Explanation of Electrode Use (cont.)

Flexible Array Electrodes (dual 3x3 and 4x4 pads):

The use of these external electrodes is explained on page 30. When plugged into the InterX® 1000 device, the pads will operate for 20 minutes of stimulation on all 5 preset settings before going into a 5 minute pause mode. A single tone will be heard at the 30 second timer mark and every minute thereafter and a double tone will be heard at the 60 second timer mark and every minute thereafter. During the pause mode, a tone will be heard every 10 seconds to remind you that the device has paused the stimulation. Pressing the plus (+), minus (-), or preset selection button will restart the stimulation for another 20 minutes at the preset setting and intensity that was previously set with a 2 second ramp up. If no button is pressed during pause mode, the device will time-out and turn off.

Personal "Blue" Flexible Array Electrode:

The use of these external electrodes is explained on page 31. When plugged into the InterX® 1000 device, the pads will operate for 20 minutes of stimulation on preset settings 1-4 before going into a 5 minute pause mode. A single tone will be heard at the 30 second timer mark and every minute thereafter and a double tone will be heard at the 60 second timer mark and every minute thereafter. During the pause mode, a tone will be heard every 10 seconds to remind you that the device has paused the stimulation. When using preset settings 1-4, pressing the plus (+), minus (-), or preset selection button will restart the stimulation for another 20 minutes at the preset setting and intensity that was previously set with a 2 second ramp up. If no button is pressed during pause mode, the device will time-out and turn off. It is recommended that preset setting 5 only be used for one cycle of 10 minutes in one location with these pads. **If a longer timeframe is desired in the same location, please check the skin for irritation before turning the device back on and restarting setting 5.**

Note: Pause mode is not implemented for Preset setting 5 (480 PPS). Preset setting 5 will only operate for 10 minutes of stimulation before turning off.

General Device Care

Battery Replacement

The InterX® 1000 operates by battery power only. Use new, high quality AA alkaline batteries for longer life and optimum performance of the device. Rechargeable batteries may be used but are not recommended. Ensure that these are fully charged before use. The InterX® 1000 is rated for continuous operation.

Battery life is highly dependent on how often the device is used and the specific settings that are used for treatments. However, under normal use (approximately 1-2 hours per day at varying degrees of power) battery life of the device is approximately 4 weeks.

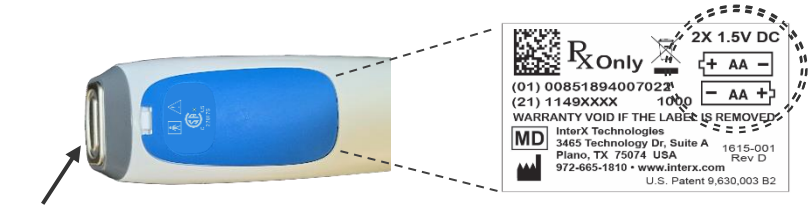
Low Battery Condition

When the battery is low, a tone will sound and the LED will flash. If this happens, the batteries should be replaced in order to continue uninterrupted use. The device will continue providing stimulation, but will periodically make a descending tone to warn of a low battery condition until the batteries are changed.

If the battery becomes completely depleted the device will emit the low battery tone and then turn off automatically and will not restart. You MUST replace the batteries to continue use.

Removing and Replacing Batteries

To remove the batteries, open the battery case and take out the old batteries. Properly dispose of the old batteries and replace with fresh, new AA alkaline batteries as indicated below. Securely replace the battery cover back on the device by pushing until it snaps in place. The device will not function if the batteries are placed in the compartment incorrectly.



Main Electrode

Battery compartment

Storage and Cleaning

Remove the batteries when storing the InterX® 1000 for more than one month. Always transport the InterX® 1000 with care. When not in use, store the InterX® in dry conditions.

Clean the InterX® 1000 and accessory electrodes with the main power OFF. The InterX® 1000 is a non-critical contact device indicated only for contact between the electrodes and intact skin. Between treatments, thoroughly clean the main electrode, accessory electrodes, and surrounding device area with 70% isopropyl alcohol wipes. Be sure to remove all debris on the electrode so it performs properly. Use of other cleaning solutions may damage the housing. Never spray cleaners directly on the device.

CAUTION: Do not use cleaning products that contain ethyl alcohol and/or ammonium chloride. These chemicals may cause cracking of the plastic. The only approved cleaning agent is isopropyl alcohol that is less than or equal to 80% by volume.

Using unapproved cleaning agents will void the manufacturer's warranty.

Service and One-Year Limited Warranty

The InterX® 1000 is not user serviceable. Never attempt to open the housing as this device contains high voltages during operation. All warnings, cautions, and instructions contained in this manual must be followed to ensure full warranty coverage.

To obtain service, contact InterX® Customer Service at (1) 972-665-1810, for a Return Authorization (RA) number. Send the entire unit, with all accessories (if applicable), packed in the original carrying case, freight and insurance prepaid to the address provided to you by InterX®. Include in the package a copy of your original invoice and a note describing the problem. Be sure to include your return address, phone number, fax number and/or an email address, if available.

InterX® Technologies will not be responsible for damage due to improper packaging or shipment.

InterX® Technologies warrants to the original purchaser that each new InterX® 1000 is free of defects in workmanship and materials under normal use for a period of one year from original purchase date, except for the battery and carrying case.

During the warranty period, our sole obligation shall be, at InterX® Technologies' option, to repair or replace the InterX® 1000 without charge. If the InterX®1000 is outside the warranty coverage period, any requested repairs or replacement charges will be invoiced to the customer.

If InterX® Technologies determines there is a defect covered by this warranty, the repaired or replaced product will be shipped back, freight and insurance prepaid. If InterX® determines, in its judgment, that the product does not contain defective workmanship or materials, InterX® Technologies will return the product and invoice the customer for the repairs, return freight, and insurance charges.

The warranty is voided immediately if the product has been subjected to abuse, accidental damage, damage in transit, negligence, acts of nature, damage resulting from failure to follow operating instructions, or alteration/disassembly by anyone other than InterX®. Opening of the InterX® 1000 case will void the warranty.

InterX® shall not be liable for any direct, indirect, special, incidental, or consequential damages, lost profits, or medical expenses caused by any defect, failure, malfunction, or otherwise of the product, regardless of the form in which any legal or equitable action may be brought against InterX® Technologies (such as contract, negligence, or otherwise). In no event shall InterX® Technologies liability under any cause of action relating to the product exceed the purchase price of the product. Repair or replacement of the device under this warranty will not extend the original warranty time period.

Batteries and carrying cases are excluded from the warranty and are sold as is.

Treatment Guide

Treatment Guidelines

Treatment should be focused on the point or area where the pain is felt. Begin stimulation at the site of the injury and/or pain. If this is not possible, start on the opposite side.

The skin and tissue around the injury/pain site is often impacted by the damage, therefore stimulation to the surrounding skin is also recommended.

Treatment can be expanded to other areas if the pain does not resolve; see treatment instructions for ongoing pain (pg. 28).

If necessary, wipe away any excess perspiration.

The InterX® 1000 is unlike other electrical stimulation products:

- Do not exceed the recommended treatment time.
- The treatment Intensity level will vary from treatment to treatment or within one treatment session. DO NOT allow the stimulation to be uncomfortable or painful.
- Certain conditions and injuries may require professional treatment and appropriate advice and information should always be sought in these circumstances.

Stages of Condition and Pain

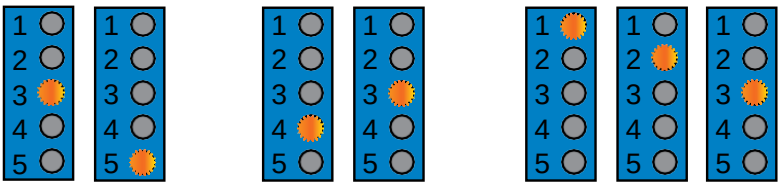
Treatment of pain in different stages

Different preset stimulation patterns are available to treat different conditions and pain stages. The illustration below is a guide to the preset selections and general time periods for treatment. For any stage of injury, if the person is very sensitive, start on setting 1.

New
Pain resulting from an injury (sprain, strain, bruise) or recent surgery.

Recovery/Rehab
Pain associated with return to normal activities or increasing function.

Ongoing
Pain or injury that has persisted for 3 months or longer.



Recommended Presets

Treating with the InterX® 1000

The InterX® 1000 can be used to relieve or manage pain to increase function and return to activity. Treatment may begin by placing the electrodes of the device on the skin at and around the site of pain. Appropriate pressure should be applied to the InterX® 1000 device or the accessory electrode to ensure good contact with the electrodes and the skin.

How often should you treat and for what duration:

Recommended – 10-30 minutes per treatment

New (Injuries & Post Surgery):

Maximum – 20 minutes per treatment, up to 5 times per day
Minimum – Once per day in early injury stage or as pain and discomfort indicate.

Ongoing conditions:

Maximum – 30 minutes per treatment, up to 2 times per day
Minimum – As pain and discomfort indicate

NOTE: Do not exceed 2 hours of total treatment time per day

Several treatment approaches are outlined in this manual based upon the area and type of pain. If normal activities are not restored within the recovery period prescribed, please contact your physician or therapist for further guidance.

Some conditions may require professional treatment. Please consult your therapist or physician for additional information regarding appropriate treatment for your specific condition.

How to Treat a Point of Pain

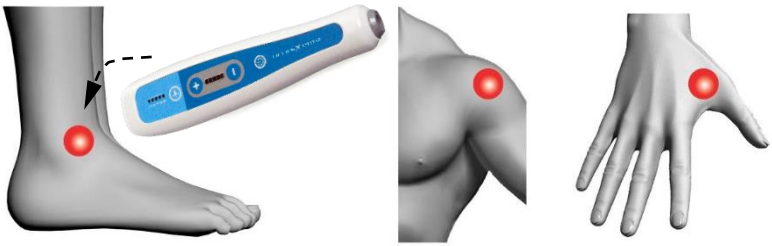
When: Pain due to a recent injury or condition
Where: Very specific pain site
How Often: Up to 5 times per day
Duration: Approximately 12 minutes

STEP 1: Select Preset based upon Condition or Pain Stage

Stages:	New	Recovery	Ongoing
Presets:	5	4	2

STEP 2: Place device on skin

Place the electrode onto the most sensitive point of pain.

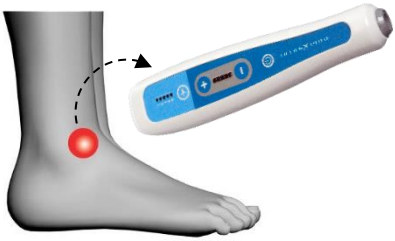


STEP 3: Set Intensity

Set Stimulation intensity to a comfortable tingling sensation. Adjust intensity to maintain comfortable stimulation.

STEP 4: Hold Device on skin

Maintain full contact with the skin and hold the InterX® 1000 still with the electrodes on the pain site.



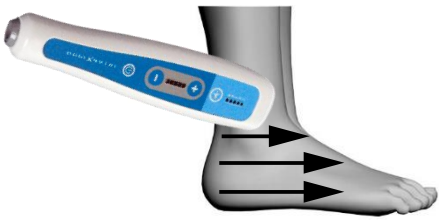
Remove the electrodes from the skin after the device beeps. The device will beep every 30 seconds.

STEP 5: Repeat up to eight times

STEP 6: Change Preset

Stages:	New	Recovery	Ongoing
Presets:	3	3	1 or 2

Slide the device firmly and very slowly over and around the painful area for about **5 minutes**. Adjust intensity so that the sensation is a comfortable tingling. The sensation will vary slightly in presets 1 and 3 and the intensity may need to be adjusted to maintain a comfortable level.



How to Treat an Area of Pain

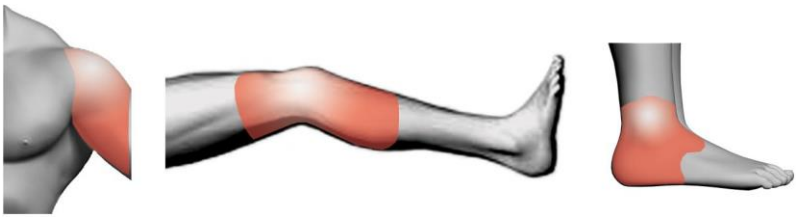
When:	During all pain conditions and stages when the pain is not focused on a single point of pain
Where:	The general area of pain (knee, shoulder, low back, neck)
How Often:	Up to 2 – 3 times per day
Duration:	20 to 30 minutes

STEP 1: Select Preset based upon Condition or Pain Stage

Stages:	New	Recovery	Ongoing
Presets:	5	4	2

STEP 2: Place device on skin

Place the electrode onto the skin near the area of pain.

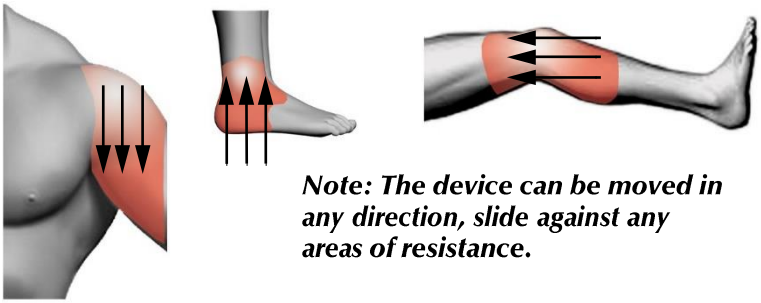


STEP 3: Set Intensity

Set stimulation intensity to a comfortable tingling sensation. Adjust intensity to maintain comfortable stimulation.

STEP 4: Slide device slowly

Slide the electrode firmly and very slowly over and around the area of pain for **10 minutes.** The sensation from the device may vary. DECREASE intensity if the device becomes uncomfortable.



Note: The device can be moved in any direction, slide against any areas of resistance.

STEP 5: Hold Device on "Hot Spots"

If the sensation feels stronger or the electrodes resist or drag on any specific points, hold the device still on those points for 1 minute each. DECREASE intensity if the device becomes uncomfortable. The skin may turn red at these points in response to stimulation. This is a normal reaction.

STEP 6: Change Preset

Stages:	New	Recovery	Ongoing
Presets:	3	3	1 or 3

Slide the device firmly and very slowly over and around the painful area for a further **10 minutes**. Adjust intensity so that the sensation is a comfortable tingling. The sensation will vary slightly in presets 1 and 3 and intensity may need to be adjusted to maintain a comfortable level.

Expanded Treatment
Increase Function and Activity

When: After treating an area or point of pain; if movement does not cause further injury

Where: On the point that is painful during movement

How often: Up to 5 times per day

Duration: 30 to 60 seconds per point of pain

STEP 1: Select Preset based upon Condition or Pain Stage

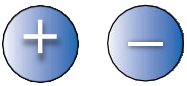
Stages:	New	Recovery	Ongoing
Presets:	5	4	2

STEP 2: Place device on skin

Place the electrode onto the skin near the area of pain.

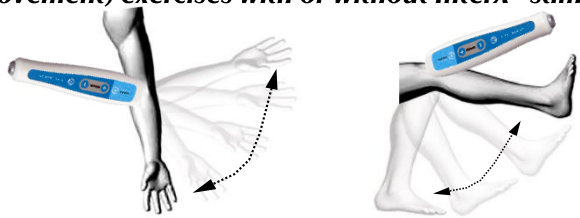
STEP 3: Set Intensity

Set Stimulation intensity to a comfortable tingling sensation. Adjust intensity to maintain strong but comfortable stimulation.



STEP 4: Hold device on skin

Hold electrode still for 30 seconds on the point while in the painful position. Perform small movements. If appropriate, hold for an additional 30 seconds and perform the motion that creates the pain or discomfort. ***NOTE: You may want to check with your therapist before performing dynamic function (movement) exercises with or without InterX® stimulation.***



STEP 5: Repeat
Search for other pain sites while assuming a painful position or performing a painful motion for a total treatment time of 5 to 10 minutes. It is common for the pain site to move around the area and treatment should follow the pain as it moves.

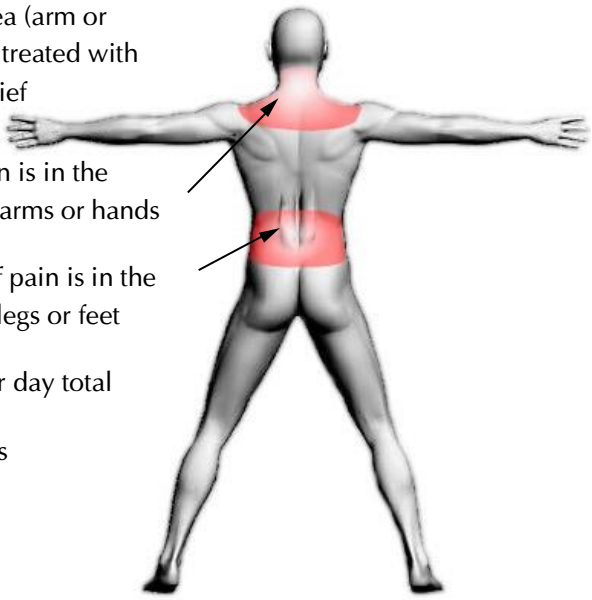
NOTE: Use caution when applying this technique, ensure pain does not increase. If in doubt, ask your healthcare practitioner.

NOTE: The following treatments (pg. 28-30) are focused on the back and may require assistance from another person in order to carry out the treatment effectively. The Flexible Array can also be used (pg. 34).

Expanded Treatment
For Ongoing Pain

When:

1. Pain directly in the neck or back as indicated
2. Expanded treatment if pain in another area (arm or leg) has been treated with little or no relief



Where: Neck area if pain is in the neck, shoulders arms or hands

Low back area if pain is in the low back, hips, legs or feet

How Often: Up to 1 hour per day total

Duration: 20 to 30 minutes

STEP 1: Select Preset based upon Condition or Pain Stage

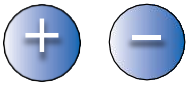
Stages:	New	Recovery	Ongoing
Presets:	2 or 4	4	2

STEP 2: Place device on skin

Place the electrode onto the skin near the area of pain.

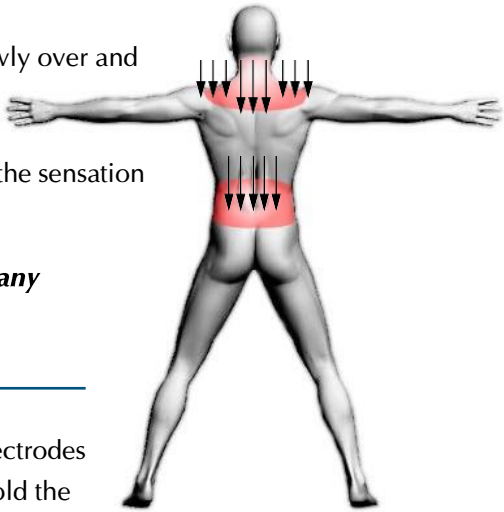
STEP 3: Set Intensity

Set stimulation intensity to comfortable tingling sensation. Adjust intensity to maintain comfortable stimulation.



STEP 4: Slide device slowly

Slide the electrode firmly and very slowly over and around the area to be treated for **10 minutes**. The sensation from the device may vary. Decrease intensity if the sensation becomes uncomfortable.



NOTE: The device can be moved in any direction. Slide against any areas of resistance.

STEP 5: Hold device on "Hot Spots"

If the sensation feels stronger or the electrodes resist or drag on any specific points, hold the device still on those points for 1 minute each. DECREASE intensity if the device becomes uncomfortable. The skin may turn red at these points in response to stimulation. This is a normal reaction.

STEP 6: Change Preset

Slide the device firmly and very slowly over and around the painful area for a further **10 minutes**. Adjust intensity so that the sensation is a comfortable tingling. The sensation will vary slightly in presets 1 and 3 and intensity may need to be adjusted to maintain a comfortable level.

Stages:	New	Recovery	Ongoing
Presets:	2 or 4	3	1

Flexible Array™ Electrode
Selecting a Preset Stimulation Pattern

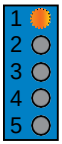
Plug the flexible array into the accessory port of the device. Press the Preset select button until you have reached the desired stimulation setting. As you select a Preset, an amber LED will light to show the Preset that is active. Maximum stimulation is 20 minutes.

Stimulation is delivered through the Flexible Array in one of three types of settings:

Cycle – this is a series of Presets in sequence which repeat to complete a 20-minute treatment.

Variable – stimulation is delivered through one Preset and will vary in frequency (PPS)

Constant – stimulation is delivered through the 5th preset at a constant PPS, it will not cycle or be variable.

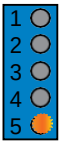


Preset 1: 15 – 60 PPS Low to moderate stimulation setting. This variable impulse is recommended for low to moderate pain and/or ongoing pain conditions.

Preset 2: Low Cycle Recommended for low to moderate pain and/or ongoing pain conditions. The Presets in the cycle are 30–120 PPS; 15–60 PPS; 15 PPS

Preset 3: 30 – 120 PPS. Moderate stimulation setting. This is recommended for moderate to high pain levels and/or when the injury has recently occurred.

Preset 4: High Cycle
The Presets in this cycle are 90-360 PPS; 30-120 PPS; 240 PPS; 3:1 modulation.



Preset 5: 360 PPS
This preset is for acute or chronic pain, is a constant stimulation, good for dynamic treatment.

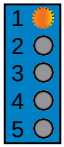
NOTE: The sensation of stimulation will vary depending on the preset you have chosen. Always ensure that the intensity is set to a COMFORTABLE level.

Comfort Flex III Array™ Electrode

Selecting a Preset Stimulation Pattern

Plug the Comfort Flex III Array into the accessory port of the device. Press the Preset select button until you have reached the desired stimulation setting. As you select a Preset the amber LED will light to show the Preset that is active. Settings 1-4 have a maximum stimulation time of 20 minutes. Preset 5 maximum stimulation is 10 minutes.

PRESET button 

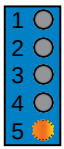


Preset 1: 15 - 60 PPS (Pulses per Second)
Low to moderate stimulation setting. This variable impulse is recommended for conditions that are very chronic or for hypersensitive skin or young children.

Preset 2: 60 PPS
This preset is appropriate for ongoing pain and persistent conditions.

Preset 3: 30 – 120 PPS
Moderate to high stimulation setting. This variable impulse is recommended for new or chronic pain resulting from an injury or recent surgery.

Preset 4: 240 PPS
High stimulation setting. This preset is recommended for higher pain levels and when a new painful condition has recently occurred.



Preset 5: 480 PPS
The highest stimulation setting. This preset is recommended for the immediate treatment of an injury and is a strong stimulation. Maximum stimulation time is 10 minutes. It is recommended to only use this preset for 10 minutes in one location.

Flexible Array™ Electrode
How to Treat an AREA of Pain

When: During all injury and pain stages

Where: The general area of pain (knee, shoulder, low back, neck)

How Often: Up to 2 hours per day total.

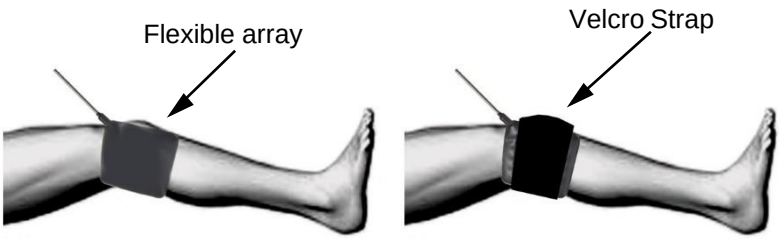
Duration: Up to 2 hours

STEP 1: Attach the Flexible Array
Plug the Flexible Array into the electrode port at the narrow end of the InterX 1000.

STEP 2: Select Preset based upon Condition or Pain Stage
If the person is very sensitive start on setting 1.

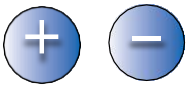
Stages:	New	Recovery	Ongoing
Presets:	3 or 5	3 or 4	1 or 2

STEP 3: Place the Flexible Array onto the skin over the area of pain. The stainless steel square electrodes should be on the skin. Either hold the Flexible Array firmly onto the skin or attach it using a strap as shown. If the area of pain is too sensitive or bandaged, place the flexible array above the pain area OR on the opposite extremity mirror image of the pain site.



STEP 4: Set intensity

Set stimulation intensity to a comfortable tingling sensation. The stimulation may vary so continue to monitor that the intensity is comfortable and make adjustments as necessary.

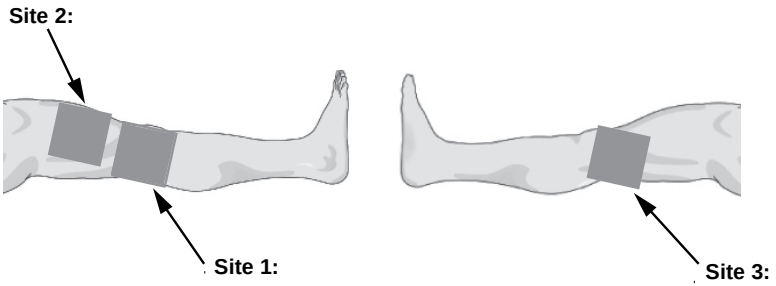


STEP 5: Provide Treatment

The InterX 1000 will stimulate for 20 continuous minutes in one place. After 20 minutes the device will sound an audible beep and then go into pause mode for 5 minutes. while in pause mode the LED lights will cascade through the intensity windows and beep every 10 seconds unless audio is disabled. To restart the stimulation, just press the + or - or Preset button and the stimulation will start again where it was previously set. If no button is pushed during the 5-minute pause time, the device will turn off at the end of the 5 minute pause cycle. (Please note that if the sound is turned off no sound will be heard during the pause mode)

STEP 6: Repeat steps 3-5

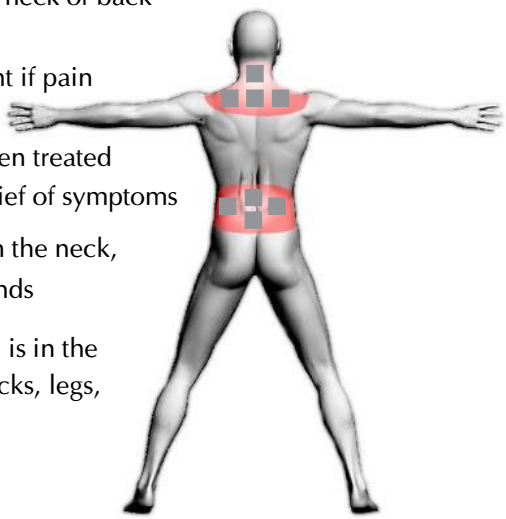
Turn the device back on and repeat steps 3 – 5 on another area of pain or around the original area of pain for a maximum of 40 minutes / two treatments.



NOTE: If the pain still remains at the original point, treat above or below the area of pain or treat the opposite joint at the mirror image. Dynamic treatment also would be recommended if done safely.

Flexible Array™ Electrode
Expanded Treatment for Ongoing Pain

When:
1. Pain directly in the neck or back as indicated
2. Expanded treatment if pain in another area (leg or arm) has been treated with little or no relief of symptoms



Where: Neck area if pain is in the neck, shoulders arms or hands

Low back area if pain is in the low back, hips, buttocks, legs, or feet

How Often: Up to 1 hour per day
Duration: 20 to 40 minutes

STEP 1: Attach the Flexible Array
Plug the Flexible Array into the electrode port at the narrow end of the 1000 device.

STEP 2: Select Preset based upon Condition or Pain Stage

Stages:	New	Recovery	Ongoing
Presets:	4 or 5	3 or 4	1 or 2

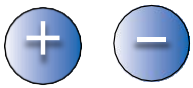
STEP 3: Place the Flexible Array onto the skin

Place the Flexible Array onto the skin over the area of pain. The stainless-steel square electrodes should be on the skin. Either hold the Flexible Array firmly onto the skin or attach it using a strap as shown.

NOTE: Always ensure good contact with the electrodes and the skin. To treat the back either lie on or sit against the Flexible Array throughout treatment or use the back strap.

STEP 4: Set intensity

Set stimulation intensity to a comfortable tingling sensation. The stimulation may vary so continue to monitor that the intensity is comfortable and adjust as necessary.

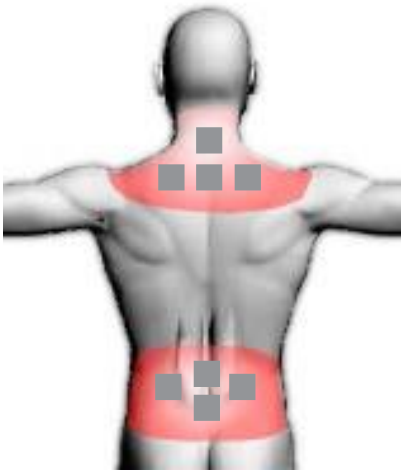


STEP 5: Provide Treatment

The InterX 1000 will stimulate for 20 continuous minutes in one place. After 20 minutes, the device will go into pause mode for 5 minutes. Press the plus (+), minus (-), or a Preset button to start the stimulation at the previous setting. If no button is pressed, the device will turn off after the 5 minute pause.

STEP 6: Repeat steps 3-5

Turn the device back on and repeat steps 3 – 5 on another area of pain or around the original area of pain for a maximum of 40 minutes.



Flexible Array™ Electrode

Expanded Treatment for Ongoing Pain
The Spine Area

When: Treating the same on-going pain area has not relieved symptoms
The pain area is larger than the upper or lower back (e.g. general back pain)

Where: Along the spinal column (middle) and on either side (left & right) between hairline and the base of the spine

How Often: Once per week
Duration: 20 to 30 minutes

STEP 1: Attach the Flexible Array
Plug the Flexible Array into the electrode port at the narrow end of the InterX 1000 device.

STEP 2: Select Preset based upon Condition or Pain Stage

Stages:	New	Recovery	Ongoing
Presets:	N/A	3 or 5	1 or 2

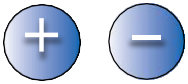
STEP 3: Place the Flexible Array onto the skin

Place the Flexible Array onto the skin over the area of pain. The stainless steel square electrodes should be on the skin. Either hold the Flexible Array firmly onto the skin or attach it using one of the provided straps.

NOTE: Always ensure good contact with the electrodes and the skin. To treat the back either lie on or sit against the Flexible Array throughout treatment or use the back strap.

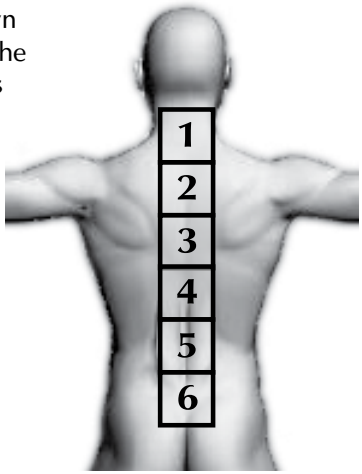
STEP 4: Set intensity

Set stimulation intensity to a comfortable tingling sensation. The stimulation may vary so continue to monitor that the intensity is comfortable and make adjustments as necessary.



STEP 5: Provide Treatment

Place the Flexible Array on the skin down the middle column from the hairline to the base of the spine as shown for 5 minutes per area.



Explanation of Device Tones

KEYBOARD TONE: Single tone heard with any acceptable press of either the plus (+), minus (-) or preset buttons.

STIM LIMIT REACHED: Single tone heard when the plus (+) key is pressed after the maximum power setting has been reached or when the minus (-) key is pressed after the minimum power setting has been reached.

30 SECOND TIMER TONE: Single tone heard starting at 30 seconds after power-on and every minute thereafter during normal operation (not pause mode).

60 SECOND TIMER TONE: Double tone heard starting at 60 seconds after power-on and every minute thereafter during normal operation (not pause mode).

PAUSE MODE TONE: Single tone that repeats every 10 seconds for 5 minutes during pause modes.

LOW BATTERY WARNING: Three tones heard when the battery voltage is first detected to be at or below Low Battery Warning Level; session continues after these tones are heard.

LOW BATTERY SHUTDOWN: Three tones heard when the battery voltage falls below Low Battery Shutdown Level; session terminates after these tones are heard.

POWER ON: Single, short tone heard when the user presses the Power button to turn the unit on.

POWER OFF: Single, long tone heard when the user presses the Power button to turn the unit off.

ELECTRODE CHANGE: Single tone heard when a valid electrode is inserted into or removed from the external electrode connector port.

ELECTRODE ERROR: Double tone heard when an unapproved electrode type is detected at the external electrode connector port. When this tone is generated, the session is terminated and device will power off.

POWER BUTTON HELD: Triple tone heard when the unit is off and the power button is pressed and continues to be held down. This alert is generated every 10 seconds until the power button is released or until 45 seconds has elapsed. If the power button is released within 45 seconds, the unit continues normal operation. If not, the unit will automatically be turned off.

STUCK KEY: Six tones heard when the plus (+), minus (-), or Preset button is held down for longer than 60 seconds and the unit will automatically be turned off.

OVERCURRENT: Five tones heard when an overcurrent (stimulation current) condition has been detected; the session will be terminated and the device will power off.

Glossary / Definitions

Area of Pain – Treatment of an area over and around the point of pain (pg. 24).

Hot Spots – Points where the sensation and stimulation intensity of the device suddenly feels stronger.

Expanded Treatment to:

Increase Function and Activity – Treatment of a painful site using gentle movement to elicit pain (pg. 26 for general treatment).

Ongoing Pain – Treatment of an older condition that lingers; often knee pain, tennis elbow, osteoarthritis, which has not responded to local treatment (pg. 28 for general treatment or pg. 34 using the Flexible Array).

Intensity – Strength of the electrical impulse which can vary from a minimum of 2% to a maximum of 100% (pg. 11).

NOTE – Highlights information throughout the manual that acts as a reminder or helps explain a concept or procedure.

Point of Pain – Treatment of a known specific point of pain often due to a recent injury (pg. 22).

Preset stimulation patterns – Specific settings that allow a range of different treatment patterns for various conditions (pg. 10 for general use or pg. 30 for the Flexible Array or pg. 31 for the Personal "Blue" Flexible Array). Preset might also be referred to as Mode.

Sliding - The motion used to move the device over the skin to detect and treat injured areas. Always move electrodes slowly to ensure maximum results.

Troubleshooting Problems

IF	THEN
The treatment area is covered (bandaged)	Treat the same area of the opposite limb instead of where the pain is felt or experienced, treat the back. (see expanded treatment, pg. 28)
You feel the device is uncomfortable or painful	Turn the Intensity down. Do NOT use the InterX 1000 at an uncomfortable Intensity level.
An incision/wound is too fresh or tender	Work parallel to the incision/wound – to protect the healing. Do not slide away from or over the wound.
The area of intended treatment is large	Use the Dome or Flexible Array electrodes.
You cannot change any settings on the device	Switch the device off and then on again.
The device shuts down on its own	Press the ON/OFF button to re-start. No skin contact within 2 full minutes will shut down the device. The battery may be dead. Replace if necessary.
No response to treatment	Try a different treatment technique or contact your health care practitioner.

Product Specifications

Size	215mm X 52mm X 43mm
Weight	Approx. 185 grams (6.5 ounces)
Operating Temperature	15 deg C to 40 deg C
Operating Humidity	5% - 85% relative humidity (non-condensing)
Storage Temperature	-40 deg C to 60 deg C
Storage Humidity	5% - 85% relative humidity (non-condensing)
Power Source	2 AA DC Alkaline batteries
Pulse Duration	10 – 500 micro-seconds
Pulse Frequency in burst mode	120 – 480 pulses per second
Typical Skin Resistance	3000 Ohms
Typical Peak Voltage Output (on skin)*	135 V
Typical Peak Current Output (on skin)*	45 mA
Typical Average Voltage (on skin)*	17 V
Typical Average Current (on skin)*	6 mA
Electrodes	Stainless steel
Waveform	Pulsed, damped, bi-phasic sinusoidal
Degree of protection in water	IPXO ordinary rating

Tested for 510(k) requirements, the peak output voltage of the InterX 1000 is 640V into an open circuit load. The peak voltage is 48V and the peak current is 95 mA into a 500 Ohm resistive load. Tested for IEC – 60601 requirements, the peak negative output voltage is 640V. The peak positive output voltage is 460V (1.1kV peak to peak) for an open circuit load. The peak positive output current is 160 mA; the peak negative output current is 25 mA (185 mA peak to peak) for a short circuited output.

Non-Invasive Neuro Stimulation System
US Patent No. 9,630,003 B2

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