INTERX®

1000 PERSONAL DEVICE

OPERATIONS MANUAL & TREATMENT GUIDE

Patent Pending

Introduction

The InterX 1000 is designed to provide personal treatment of painful conditions, like arthritis and also 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.

Conveniently designed and completely portable, the InterX 1000 is a pain management device suitable for individuals everywhere.

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

Table of Contents

InterX 1000

Operations Manual

This manual provides information regarding the 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 indicated for:

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

The InterX 1000 carries the European CE mark for pain relief.

Neuro Resource Group, Inc. is an ISO 13485 Registered company.

Contact NRG for country specific information or additional regulatory approvals.

Definition – 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.

Definition – Caution: Failure to observe a CAUTION associated with use 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 trained healthcare practitioner or under the continued supervision of a licensed healthcare practitioner. 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.

The InterX 1000 is not effective for pain of central origin including headaches.

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).

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.

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

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

If the display becomes blank or inoperative, discontinue use.

Do not make contact with the InterX 1000 electrodes on wet skin. Natural bodily fluids, including perspiration, are acceptable.

Extreme heat or cold may effect the operation of the InterX 1000.

Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when stimulation 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 other flammable gases.

The InterX 1000 has no curative value.

Avoid placing the device on the skin when turning on or returning from pause to avoid electrical signal.

Treatments with the InterX 1000 should not exceed 1 hour in any specific area of the body and 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.

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.

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 in this manual.

Effectiveness of the InterX 1000 is highly dependent upon patient selection by a person qualified in the management of pain.

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 voltage or other hazards and can damage operating circuits. Opening the case will void the manufacturer's warranty. If the device should need repair or service contact the Neuro Resource Group, your InterX 1000 distributor or an authorized NRG service representative.

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

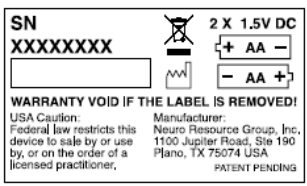
Definitions and Symbols

This CE symbol certifies that the product complies with the essential requirements of the Medical Device Directive.

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.

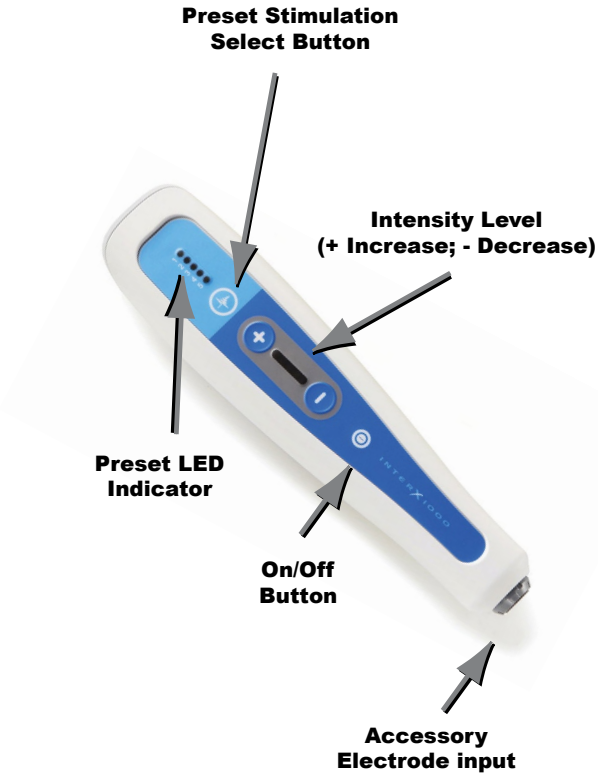
This stimulator is internally powered only. The symbol indicates the device was manufactured according to the degree of protection against electrical shock for this type BF protection class equipment.

DO NOT use the InterX 1000 without reading this manual.



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

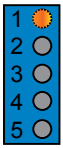
Overview of Controls and Functions



Turning the InterX Personal Sport ON/OFF

ON/OFF Button

To begin InterX therapy, turn the device on by pushing the ON/OFF button, with the device off the skin.



Upon start-up the instrument goes through a short self-test and then a short audible beep will be heard. The amber LED for Preset 1 will glow to show the device is turned on. To turn the InterX 1000 off, press and hold the ON/OFF button until an audible beep is heard. Wait 5 seconds before placing the device on the skin.

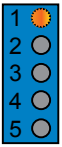
The InterX 1000 may not perform correctly if:

1. The battery is dead.
2. An incompatible electrode is plugged in.
3. There is a device failure.

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 

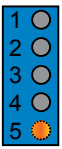


Preset 1 : 60 PPS (pulses per second)
This preset is appropriate for ongoing pain and persistent conditions.

Preset 2 : 15 – 60 PPS
Low to moderate stimulation setting. This variable impulse is recommended for conditions that are moving towards recovery and ongoing pain conditions.

Preset 3 : 30 – 120 PPS
Moderate to high stimulation setting. This variable impulse is recommended for new 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.

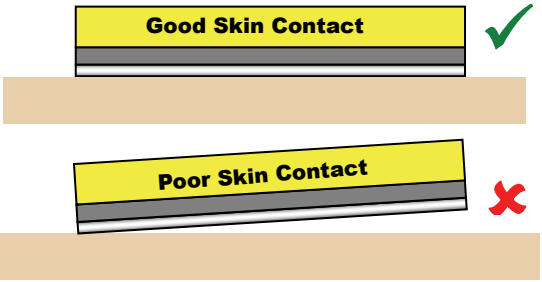


Preset 5 : 480 PPS in bursts
The highest stimulation setting. This preset is recommended for the immediate treatment of an injury, and is a strong stimulation.

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.

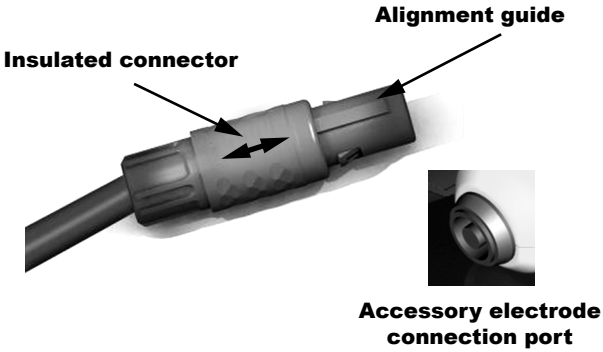
The intensity level should be started at a minimum level and gradually increased until you feel a comfortable tingling sensation. It is not necessary to use a high level of stimulation.

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 and for three seconds afterwards.

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 lead wire noting the alignment guide for connection. To remove, hold the insulated connector and gently pull apart.

NOTE: Jerking 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. Use the accessory electrode in the same way as the main built- in electrode is used.

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 Available

For use with the InterX 1000

The Dome Electrode – designed specifically to cover larger areas of skin tissue. Use it on thighs, shoulders and legs.

The Comb Electrode – designed for use on the scalp and for areas where hair might interfere with electrode contact.

The Flexible Array™ – designed to provide 10 minute treatment cycles to hard to reach areas, such as the back.

Velcro Straps – there are a range of straps designed for use with the Flexible Array™. The straps can be used on the ankles, back, shoulders, knees and limbs.

General Device Care

Battery Replacement

The InterX 1000 operates by battery power only. Use new, quality AA alkaline batteries for longer life and optimum performance of the device. Rechargeable batteries may be used. 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.

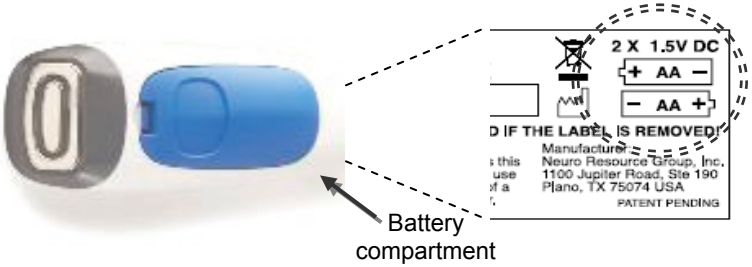
Low Battery Condition

When the battery is low, a tone will sound and the LED will flash. If this happens, the batteries should be replaced to continue 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.



Storage and Cleaning

Remove the battery when storing the InterX 1000 for more than one month. Always transport the InterX1000 with care. When not in use, store the InterX in dry conditions.

Clean the InterX 1000 periodically 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 electrodes and surrounding device area with 70% isopropryl alcohol wipes. 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 90% 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 NRG Customer Service at (1) 972-665-1810, for a Returned Goods Authorization (RGA) 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 NRG. 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.

NRG will not be responsible for damage due to improper packaging or shipment.

NRG 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, NRG's sole obligation shall be, at NRG's 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 NRG determines there is a defect covered by this warranty, the repaired or replaced product will be shipped back, freight and insurance prepaid. If NRG determines, in its judgment, that the product does not contain defective workmanship or materials, NRG will return the product and invoice the customer for the reparis, 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, or damage resulting from failure to follow operating instructions, or alteration/disassembly by anyone other than NRG. Opening of the InterX 1000 case will void the warranty.

NRG 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 NRG (such as contract, negligence, or otherwise). In no event shall NRG's 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.

InterX 1000

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.

The skin and tissue around the injury/pain site is often impacted by the damage, therefore stimulation to 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. 26).

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

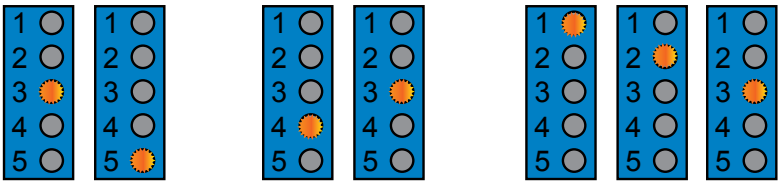
Treatment of pain in different stages

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.

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 is carried out by placing the electrodes of the device on the skin at and around the site of pain.

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.

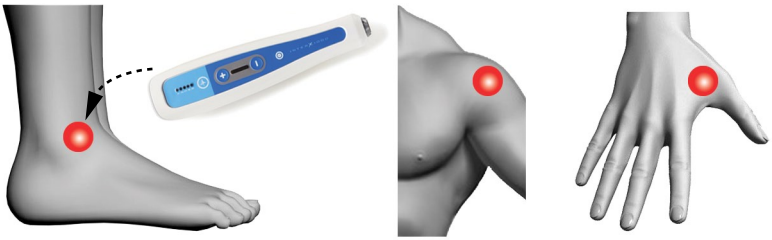
How to Treat a Point of Pain

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	1

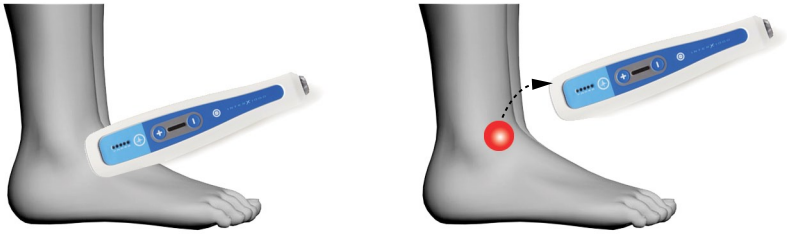
STEP 2: Place device on skin
Place the electrode onto the most sensitive point of pain.



STEP 3: Set Intensity
Set Stimulation intensity to 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.

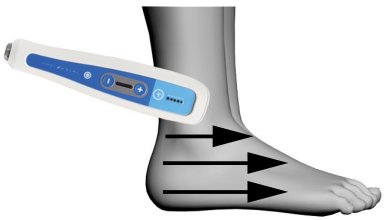
STEP 5: Repeat eight times

Repeat STEP 4 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 2 and 4 and the intensity may need to be adjusted to maintain a comfortable level.



How to Treat an Area of Pain

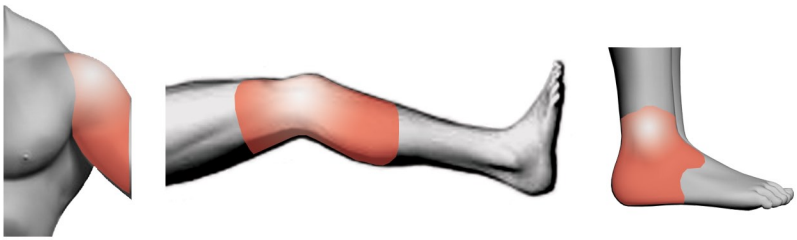
When:	During all pain conditions and stages when the pain is not focused on a single point of pain
Where:	The general area of pain (knee, shoulder, low back, neck)
How Often:	Up to 2 – 3 times per day
Duration:	20 to 30 minutes

STEP 1: Select Preset based upon Condition or Pain Stage

Stages:	New	Recovery	Ongoing
Presets:	5	4	1

STEP 2: Place device on skin

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

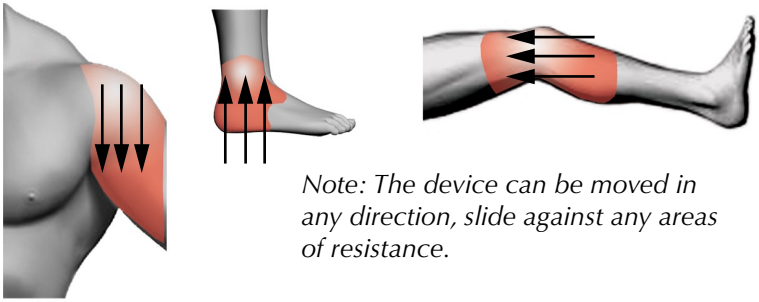


STEP 3: Set Intensity

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	2 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 2 and 4 and intensity may need to be adjusted to maintain a comfortable level.

Expanded Treatment
Increase Function and Activity

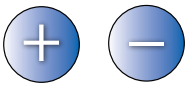
When:	After treating an area or point of pain; if movement does not cause further injury
Where:	On the point that is painful during movement
How often:	Up to 5 times per day
Duration:	30 seconds per point of pain

STEP 1: Select Preset based upon Condition or Pain Stage

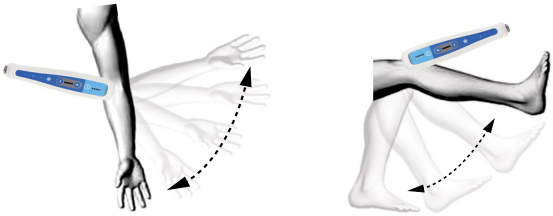
Stages:	New	Recovery	Ongoing
Presets:	5	4	1

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: Hold device on skin
Hold electrode still for 30 seconds on the point while in the painful position. 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.

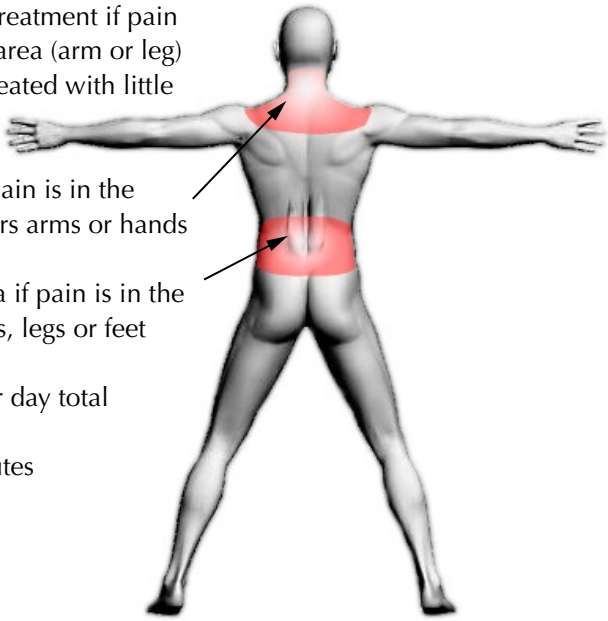
NOTE: The following treatments (pg. 26-28) are focused on the back and may require assistance from another person in order to carry out the treatment effectively. The Flexible Array can also be used (pg. 31).

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 hr per day total

Duration: 20 to 30 minutes

STEP 1: Select Preset based upon Condition or Pain Stage

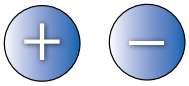
Stages:	New	Recovery	Ongoing
Presets:	N/A	4	1

STEP 2: Place device on skin

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

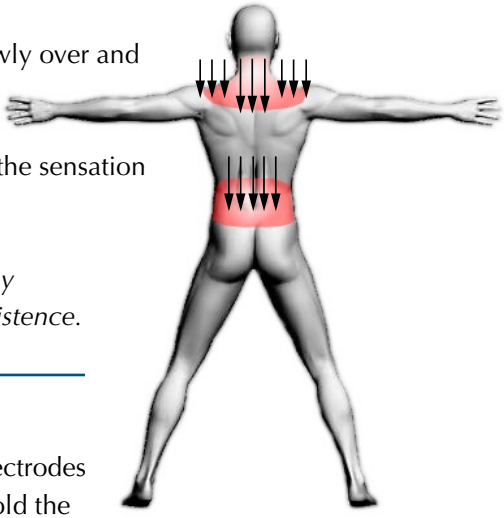
STEP 3: Set Intensity

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 to be treated for **10 minutes**. The sensation from the device may vary. Decrease intensity if the sensation becomes uncomforatble.



NOTE: The device can be moved in any direction, slide against any areas of resistence.

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 2 and 3 and intensity may need to be adjusted to maintain a comfortable level.

Stages:	New	Recovery	Ongoing
Presets:	N/A	3	2

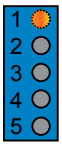
Flexible Array™ Electrode
Selecting a Preset Stimulation Pattern

There are four presets on the InterX 1000 that are active when the Flexible Array is plugged in. 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.

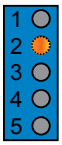
Stimulation is delivered through the Flexible Array in one of two types of settings:

Cycle – this is a series of Presets in sequence which repeat to complete a 10 minute treatment.

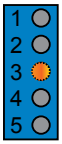
Variable – stimulation is delivered through one Preset and will vary in frequency (PPS)



Preset 1 : Low Cycle
Recommended for low to moderate pain and/or ongoing pain conditions. The Presets in the cycle are 30-120PPS; 15-60PPS; 15PPS.

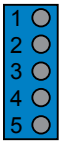


Preset 2 : 15 – 60PPS.
Low to moderate stimulation setting. This variable impulse is recommended for low to moderate pain and/or ongoing pain conditions.



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 90-360PPS; 30-120PPS; 240PPS; 3:1 modulation.



Preset 5 : is not active when the Flexible Array electrode in plugged in.

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.

Flexible Array™ Electrode
How to Treat an AREA of Pain

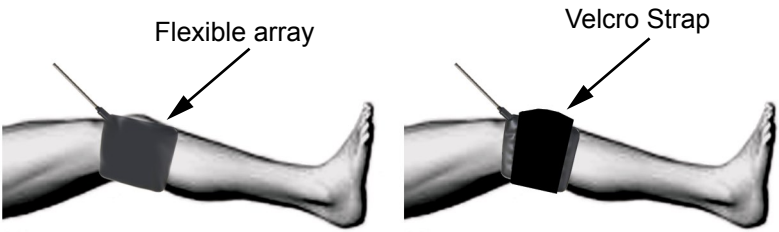
When: During all injury and pain stages
Where: The general area of pain (knee, shoulder, low back, neck)
How Often: Up to Up to 2 hrs per day total.
Duration: 10 to 30 minutes.

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

STEP 2: Select Preset based upon Condition or Pain Stage

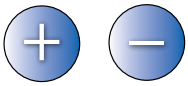
Stages:	New	Recovery	Ongoing
Presets:	3 or 4	3 or 4	1 or 2

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.



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.



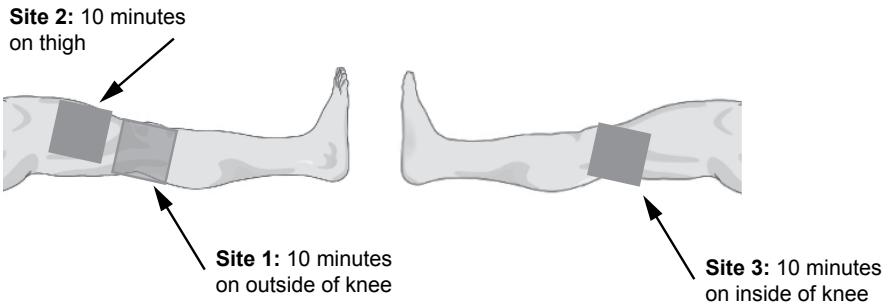
STEP 5: Provide Treatment

The InterX 1000 will stimulate for 10 continuous minutes in one place. After 10 minutes the device will sound an audible beep and then turn off.

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 30 minutes / three treatments.

E.g. Typical 30 minute treatment for knee pain.

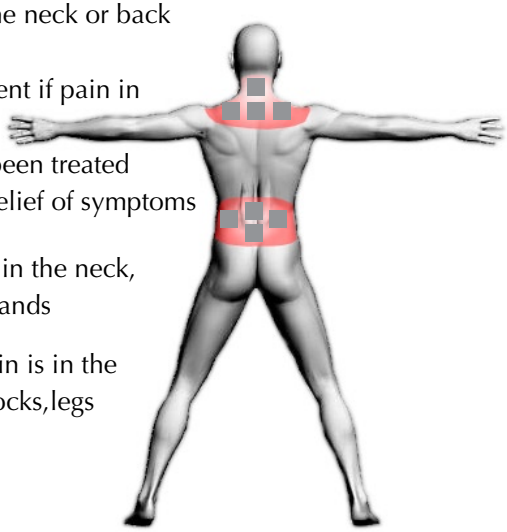


NOTE: If the pain still remains at the original point, you can repeat the stimulation for a maximum total treatment time of 20 minutes at any one point.

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 hr 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:	N/A	3 or 4	1 or 2

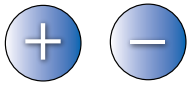
STEP 3: Place the Flexible Array onto the skin

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 make adjustments as necessary.

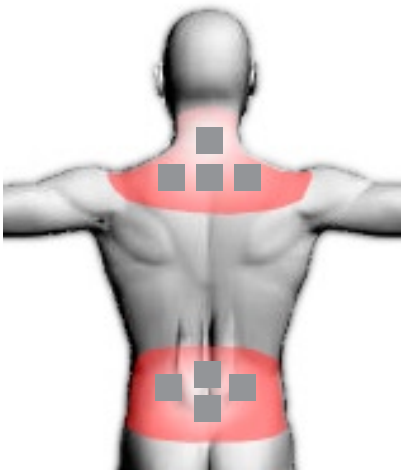


STEP 5: Provide Treatment

The InterX 1000 will stimulate for 10 continuous minutes in one place. After 10 minutes the device will sound an audible beep and then turn off.

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 30 minutes / three treatments.



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 4	1 or 2

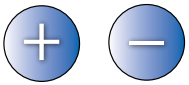
STEP 3: Place the Flexible Array onto the skin

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.

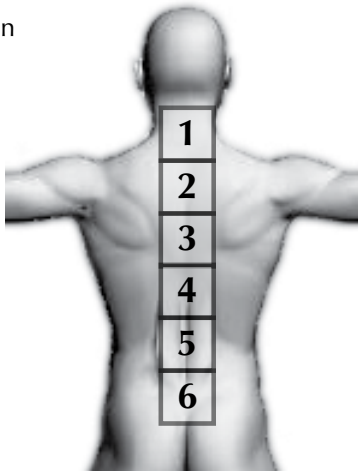
STEP 4: Set intensity

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



Glossary/Definitions

Area of Pain – Treatment of an area over and around the point of pain (pg.22).

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. 24 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.26 for general treatment or pg. 31 using the Flexible Array).

Intensity – Strength of the electrical impulse which can vary from a minimum of one 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.20).

Preset sitmulation patterns – Specific settings that allow a range of different treatment patterns for various conditions (pg.10 for general use or pg. 28 for the Flexible Array).

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, or treat the back. (see expanded treatment, pg 26)
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, connecting to the device as described on page 12.
You cannot change any settings on the device	Switch the device off and then on again.
The Device switches off on its own	Press the ON/OFF button to re-start. 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
Single Pulse Frequency	15 – 350 pulses per second
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 95mA 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.*

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