INTERX®

5002 PROFESSIONAL DEVICE

OPERATIONS MANUAL

US Patent No. 9,630,003 B2 and Patents Pending

Introduction

The **InterX® 5002** is designed specifically for medical professionals, combining interactive technology with a new user interface that provides access to stimulation patterns to treat a range of conditions from traumatic injury to post-surgical rehabilitation to chronic degenerative conditions.

InterX® Therapy is effective in the treatment of both acute and chronic pain caused by inflammatory or degenerative processes; it is also proven in cases of neuropathic pain. InterX® treatment provides very effective, non-invasive, non-drug pain relief and has proven to be an excellent addition to any rehabilitation program.

The therapeutic effect of the InterX® 5002 is based on Interactive Neurostimulation. Unlike conventional neurostimulation products, the InterX® 5002 provides an interactive response to impedance changes in the tissue. When applied to the skin, its electrical impulses adjust dynamically as the device encounters changes in the tissue contacting its electrodes. The InterX® 5002 responds to the condition of the tissue it is touching and continues to adjust as the body responds and reflects its changes through the skin. The interactive capability not only provides results, but also resists the body's natural tendency to develop a tolerance to static therapies.

Please read the manual completely prior to using the InterX® 5002.

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InterX 5002 Operations Manual

This manual provides information regarding the controls and functions of the InterX 5002. The InterX 5002 must be used strictly in accordance with these instructions. Further training is required to fully use the device and obtain optimal patient treatment outcomes.

Indications for use

The InterX 5002 is indicated for:

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

InterX Technologies is an ISO 13485 Registered company.

Contact InterX Technologies for country specific information or additional regulatory 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.

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 5002 be used only by a trained healthcare practitioner or under the continued supervision of a licensed healthcare practitioner. The InterX 5002 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 5002 is the primary responsibility of the user. The user is responsible for the monitoring of the product. Contact clinical/technical support if the InterX 5002 appears to be operating incorrectly.

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

Not for unattended use on children.

The InterX 5002 is not effective for pain of central origin including headaches.

The InterX 5002 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 5002 has not been established during pregnancy or childbirth.

Do not operate the InterX 5002 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 5002 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 5002 to patients suspected of having heart disease. This device should not be used within the vicinity of the heart.

If the display becomes blank or inoperative discontinue use.

Do not make contact with the InterX 5002 electrodes on wet skin. Natural bodily fluids, including sweat, are acceptable.

Extreme heat or cold may effect the operation of the InterX 5002.

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 5002 is not to be used in the presence of anesthetic or other flammable gases.

The InterX 5002 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 5002 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 5002 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® 5002 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 5002 is immersed in any liquid, it must be replaced with a new device.

Do not sterilize the InterX 5002.

Do not expose any part of the InterX 5002 to chemical solvents or harsh cleaning fluids. Follow cleaning instructions in this manual.

Effectiveness of the InterX 5002 is highly dependent upon patient selection by a person qualified in the management of pain.

The InterX 5002 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 5002 case. Opening or removing the device 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 InterX Technologies, your InterX 5002 distributor or an authorized InterX 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 5002 to any other power source.

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

Do not use any damaged stainless steel electrodes.

Definitions and Symbols

MD

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

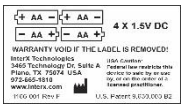
The “NRTL/C” indicator adjacent to the CSA (Canadian Standards Association) mark signifies the product has met the applicable ANSI/UL and CSA standards for use in the U.S. and Canada. NRTL (Nationally Recognized Testing Laboratory) is a designation granted by the U.S. Occupational Safety and Health Administration (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 this device without adequate training in its function and purpose. This manual provides information regarding the controls and functions of the InterX 5002. Additional training is required.

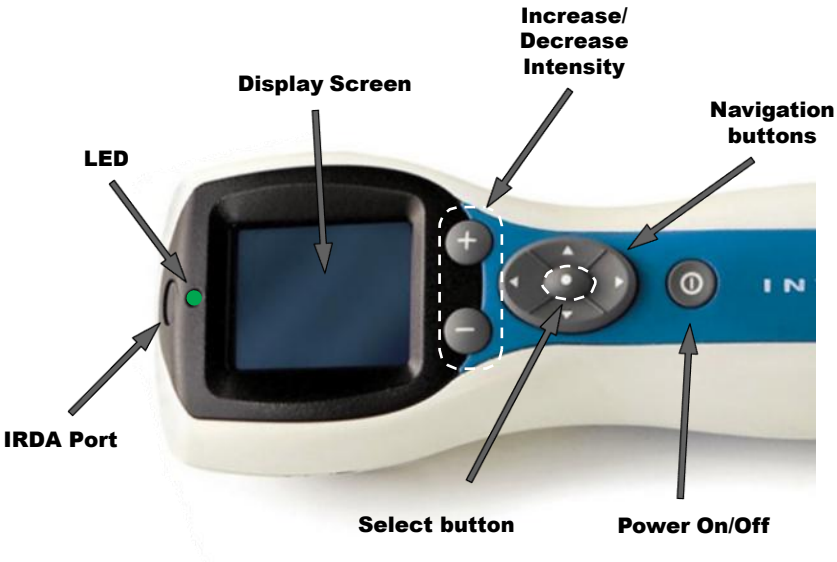
The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.

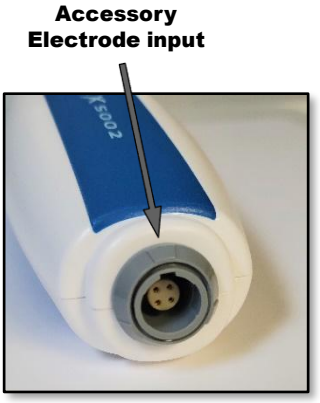
This symbol indicates the medical device manufacturer.

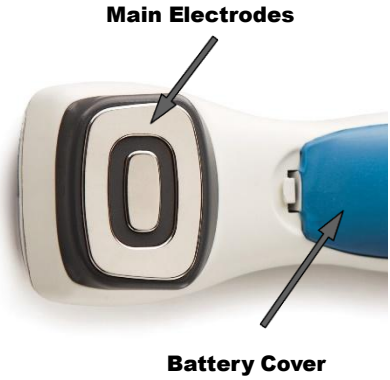


The Serial Number and the manufacturer labels are located inside the battery compartment. To view, remove the battery cover and batteries. The serial number is also available on the unit test screen which will appear when you turn the device on. It is also visible in the setup menu on the device.

Controls and Functions





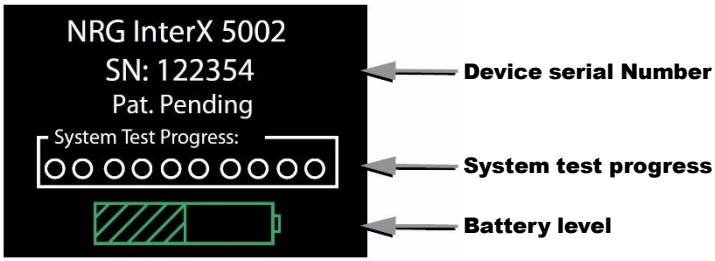


Instructions for Use

1. Turning the InterX 5002 ON

Once the patient has been examined, InterX therapy can begin. Turn the device on by pushing the ON/OFF button.

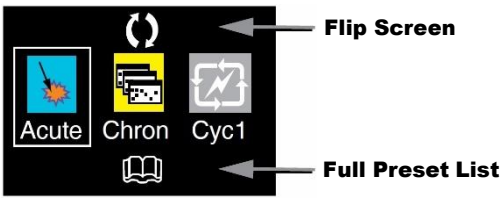
Upon startup the user should verify a short audible beep, the LED will then briefly flash red and then green and the device will perform a brief system test (see below). Once complete, the Main Screen will appear on the display.



NOTE: To turn the device off, press and hold the ON/OFF button for a few seconds. This feature prevents accidental loss of stimulation.

2. The Main Screen

The main screen provides a guide to select stimulation patterns based upon the patient's condition.



SELECT Acute, Chronic, or Cycle to access the recommended list of preset stimulation patterns for that application.

The Flip screen icon allows a user to flip the screen orientation for left handed use. Highlight the icon and press SELECT to activate. To return to the right handed screen, highlight and SELECT the icon again.

3. Select a Preset Stimulation Pattern

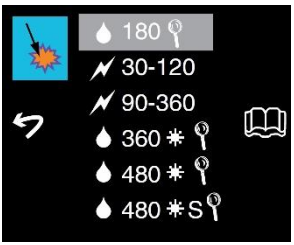
In the chosen screen, highlight and SELECT a preset stimulation pattern from the list provided. Selecting a preset stimulation pattern will activate stimulation to begin treatment.

Each preset is displayed as the number of pulses per second (PPS). ie. 480* has 480pps.

ACUTE
Pain due to trauma or surgery

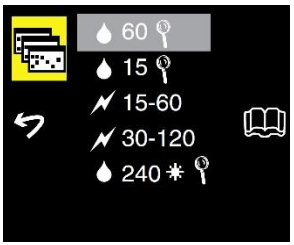
Stimulation patterns for use in post-surgical rehabilitation or in exacerbation of symptoms in chronic conditions

Default recommendation 180



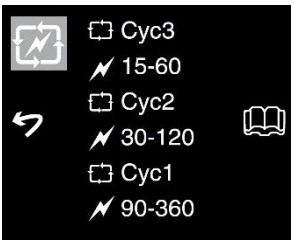
CHRONIC
Chronic intractable pain

Stimulation patterns for use in conditions due to degeneration, inflammation or those that persist past expected recovery time
Default recommendation 60
Hypersensitive patients: 15, 15-60



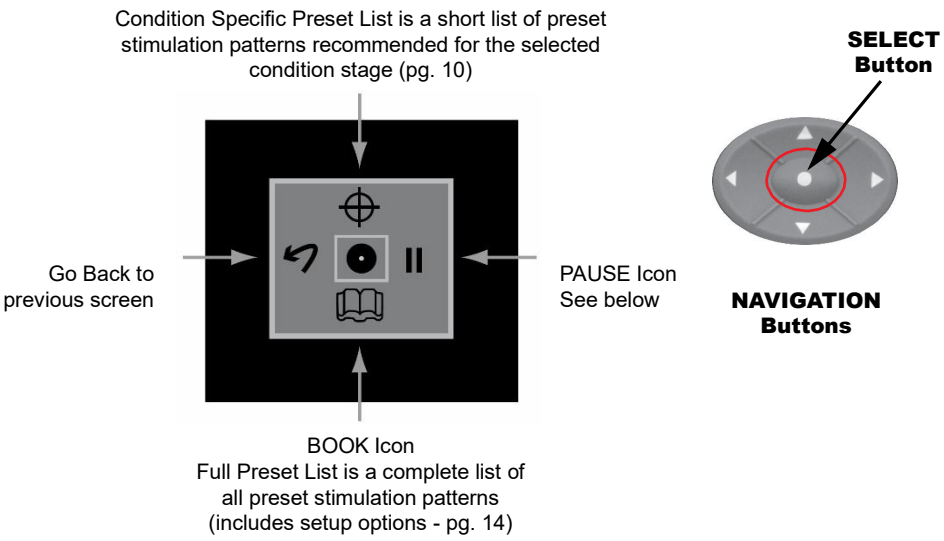
CYCLES AND VARIABLES
Preset stimulation patterns with varying frequencies often used for longer treatment periods.

Acute : Cyc2, 30-120, Cyc1, 90-360
Acute/Chronic: Cyc2, 30-120
Chronic : Cyc3, 15-60, Cyc2, 30-120



4. Stimulation Screen Navigation Options

While in an active stim screen, press any NAVIGATION button to display navigation options.



Pause

To pause the operation of the InterX 5002 press any NAVIGATION button to bring up the navigation screen. Using the right NAVIGATION button highlight the PAUSE icon and press the SELECT button. The screen will go blank and stimulation will cease. The green LED will flash to indicate that the device is in pause mode.

In pause, the most recent stimulation preset used as well as the stimulation intensity will be saved in memory. To restart the device, press the SELECT button again.

During active stimulation, if the device does not detect skin contact for one minute, it will automatically enter pause mode. If you are not in active stimulation, the device will automatically pause after two minutes if no buttons are pushed.

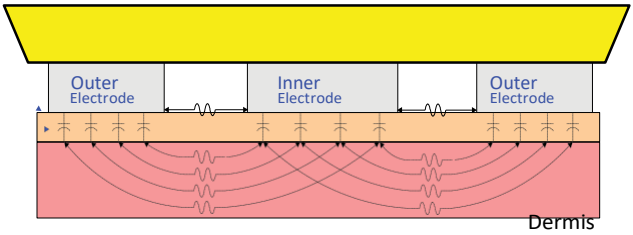
NOTE: If the InterX 5002 is not restarted within 60 minutes after being paused, the device will turn off completely to save battery power. The LED will stop flashing and it will be necessary to use the ON/OFF button to turn the device back on.

4. Establishing Electrode Contact

Electrode placement is determined by multiple factors, including patient complaint, practitioner experience, tissue response and InterX 5002 readings.

When beginning treatment with the InterX 5002, ensure that the device is in a preset stimulation screen and the intensity is at the initial default setting of 2.0%. Identify the area of electrode placement as directed in InterX training.

Place the two fixed electrodes firmly on clean dry skin.



Ensure that the inner and outer electrodes have good contact with the skin when using the InterX 5002. Appropriate pressure should be applied to the InterX® 5002 device or the accessory electrode to ensure good contact with the electrodes and the skin. If the shape of the area being treated causes poor electrode contact (e.g. fingers, ankles, elbow) use a smaller accessory electrode with your device to ensure good contact.

NOTE: The most desirable electrode placements are those that provide the best relief of symptoms while maintaining a comfortable sensation.


Indicates poor skin contact


Indicates good skin contact in burst or continuous frequency preset stimulation patterns


Indicates good skin contact in variable preset stimulation patterns


Indicates good skin contact in cycle preset stimulation


Indicates continuous stimulation regardless of skin contact in burst or continuous frequency stimulation patterns. Active only when the comb electrode is plugged into the device.

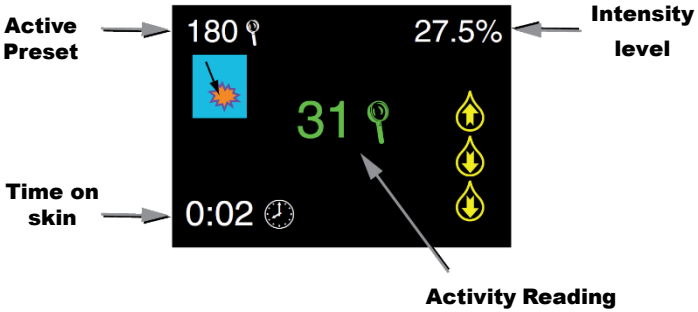
The InterX 5002 is designed not to allow more than 10 minutes of continuous skin contact. The device will pause if the time on skin reaches 10 continuous minutes without a break.

NOTE: It is recommended that the skin remain in a "natural" condition. The patient should not use creams or lotions for at least 2 hours before treatment. Any excess perspiration should be wiped away before using the InterX 5002.

5. Set Stimulation Intensity

The Intensity is the strength of stimulation. The patient should experience a comfortable tingling and vibration at the correct level of stimulation intensity.

Place the device onto the skin and press the + button until a comfortable stimulation is felt. In any stimulation screen, pressing the + / − button sets the intensity of stimulation from a minimum of 2% to a maximum of 100%. The device will emit a buzzing sound that becomes louder as the stimulation intensity increases.



If the intensity is increased to a level that makes the patient uncomfortable, reduce the intensity until the patient is more comfortable with the sensation.

NOTE: The treatment intensity level will vary from patient to patient based upon individual sensitivity to the electrical impulse and skin impedance. The sensation may also vary from location to location on the skin of a patient.

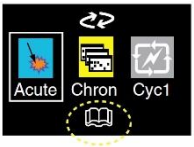
Activity Reading

The icon indicates that the Activity Reading feature is active. The InterX waveform is sensitive to changes in skin impedance and can be used to provide a relative measure of tissue impedance between different points on the skin.

Activity Reading (AR) is an objective measurement of the effect that skin impedance has on the waveform. This feature of the InterX 5002 can be used as a guide to identify target treatment areas. See page 20 for further instructions on use of this feature.

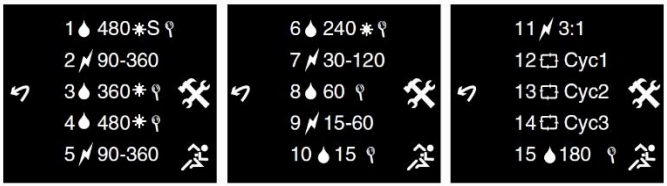
Full Preset List and Descriptions

The book icon takes you to the full preset stimulation pattern list and the setup options. To access the book icon, turn the device on and use the NAVIGATION button to highlight and select the book icon in the bottom center portion of the screen.



From a preset stimulation pattern screen, press any of the NAVIGATION buttons to bring up the navigation screen and select the book icon (pg. 11).

To change from one preset to another, simply use the UP and DOWN NAVIGATION buttons to highlight the desired preset and then press the SELECT button to activate it.



Preset stimulation patterns are displayed by a number that represents pulses per second (e.g., 480* has 480 PPS). Stimulation is delivered in burst, variable, or continuous stim patterns.

All presets are numbered and listed in order based upon the Condition stage in which they appear.

Access to InterX Setup options (pg. 24).

Activate Sport Mode (pg. 25).

Activity Reading is active in presets with this icon (pg. 13).

Note: Activity Reading is not available when the comb electrode is plugged into this device.

Preset Stimulation patterns

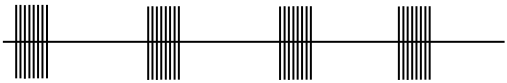
Below is an approximate illustration of the stimulation pattern for each preset.

BURST Stim Patterns

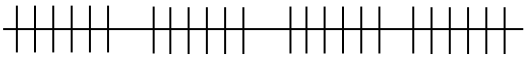
Presets 1, 3, 4, 6

*Burst preset patterns are indicated by an asterisk (*).*

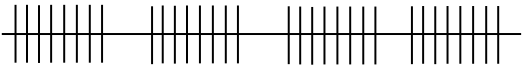
Preset 1: 480*s PPS - 8 impulses per burst; 60 bursts per second. The delay between impulses within the burst is short making this a very aggressive preset.



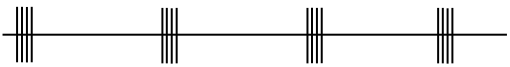
Preset 3: 360* PPS - 6 impulses per burst; 60 bursts per second.



Preset 4: 480* PPS - 8 impulses per burst; 60 bursts per second. The delay between impulses is longer than 480*s making this a less aggressive preset.



Preset 6: 240* PPS - 4 impulses per burst; 60 bursts per second.



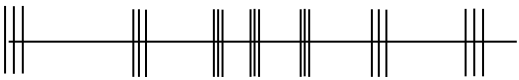
VARIABLE Stim Patterns

Presets 2, 5, 7, 9

Patterns with a range between two frequencies. This is shown by the highest and lowest PPS in the range.

Note: Stimulation may continue for up to 7 seconds after removing electrodes from skin as the variable pattern is completed.

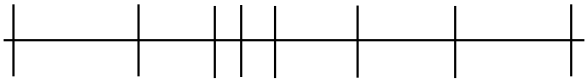
Preset 2: 90-360 PPS - 3 pulses per burst; variable between 30 and 120 bursts per second.



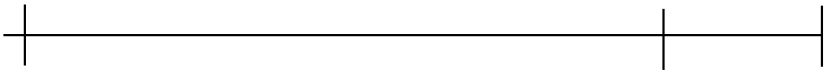
VARIABLE Stim Patterns (cont.) **Presets 2, 5, 7, 9**

Preset 5: 90-360 PPS - Same as Preset 2.

Preset 7: 30-120 PPS - Variable frequency between 30 and 120 PPS.



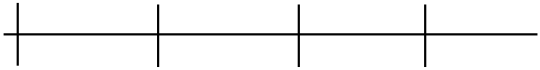
Preset 9: 15-60 PPS - Variable frequency between 15 and 60 PPS.



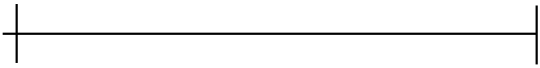
CONTINUOUS Stim Patterns **Presets 8, 10, 11, 15**

Consistent frequency pulsed waveform

Preset 8: 60 PPS

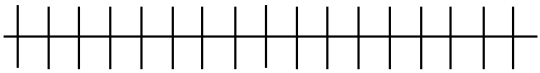


Preset 10: 15 PPS



Preset 11: 3:1 Modulation - 120 PPS; modulates 3 seconds on, 1 second off.

Preset 15: 180 PPS



CYCLE Patterns **Presets 12, 13, 14**

Stimulation pattern using a series of preset patterns over a 5 minute period. The cycle will repeat until the maximum treatment time of 10 minutes has been reached the device will then enter the pause mode.

This icon will briefly appear when one preset setting in the cycle has completed and a new preset setting is set to begin.

This icon will briefly appear on the screen when the InterX 5002 has completed delivering each 5 minute segment of the cycle.

Preset 12 Cyc 1 - Presets: 5, 7

Preset 5 - 2 minutes 90 – 360 PPS
Preset 7 - 2 minutes 30 – 120 PPS
Preset 5 - 1 minute 90 – 360 PPS

Preset 13 Cyc 2 - Presets: 5, 6, 7, 11

Preset 5 - 1 minute 90 – 360 PPS
Preset 6 - 1 minute 240* PPS
Preset 7 - 2 minutes 30 – 120 PPS
Preset 11 - 1 minute 3:1 with 120 PPS

Preset 14 Cyc 3 - Presets: 7, 9, 10

Preset 7 - 2 minutes 30 – 120 PPS
Preset 9 - 2 minutes 15 – 60 PPS
Preset 10 - 1 minute 15 PPS

Accessory Electrodes

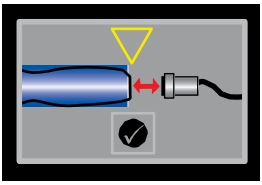
Accessory electrodes plug into the accessory port located at the opposite end of the device to the main electrodes. Use care when plugging in the lead wire noting the alignment guide for connection. To remove, hold the insulated connector and gently pull apart.

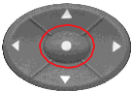
NOTE: Do not jerk the lead wire upon removal as this may cause damage.

Insulated connector

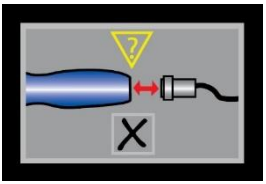
Accessory electrodes should be connected when there is no active stimulation, for example, while the InterX 5002 is in the Main screen.

If an electrode is plugged in during active stimulation, this caution screen appears. Press the SELECT button to accept the accessory electrode and return to the Main Screen. Reset the appropriate preset stimulation pattern for the treatment you are providing and reset the stimulation intensity. For safety reasons, certain accessory electrodes are compatible with limited preset options.





Do not attempt to plug other devices or accessories into the InterX 5002. Only manufacturer approved electrodes may be used. The individual accessory electrode packaging contains instructions for care and replacement of accessory electrodes. Use of all accessory electrodes should be consistent with the instructions provided in this manual unless differences are stated in the instructions provided with the electrode.



If an invalid electrode is detected this caution screen will appear and the device will become unresponsive until the electrode in question is removed. Remove the electrode and the InterX 5002 will return to the Main Screen. Reconnect the electrode to determine the cause of the invalid electrode caution screen. If the device accepts the electrode, resume using the device. If the caution screen reappears, please contact your InterX 5002 distributor for advice and assistance.

Accessory Electrodes for use with the InterX 5002

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

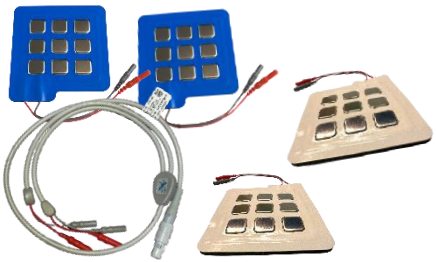
The **Soft-Tissue Electrode** – designed for use on muscles, myofascial release, or massage tool.

The **Comb Electrode** – electrode is designed for use on areas of skin where hair is thicker and on the scalp. The Point-stim and Activity Reading (AR) features are not active when this electrode is in use. Stimulation is continuous regardless of skin contact.

The **Flexible Array**™ – designed to provide 10-minute treatment options and can be used unattended once treatment parameters have been set. It comes in two sizes: 3x3 dual pads and 4x4 single pad.

The **Small Soft-Tissue Electrode** – for use on very small areas, for specific stimulation.

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 contact. Numeric readout of impedance is available on the InterX 5002.

NOTE: The following instructions (pages 20 – 23) are for descriptive purposes and not intended as training or treatment guidelines. Full training is recommended to use Point-stim and Multi-stim. Please refer to the relevant training materials and manual.

Activity Reading:
Objective Indication of Skin Impedance

The InterX waveform is sensitive to changes in skin impedance and can be used to provide a relative measure of impedance between different points on the skin. The optimal treatment area is identified by the comparison of AR(s), there are no 'good' or 'bad' readings.

The icon indicates that the Activity Reading capability is active. When placed on the skin, the device will display an Activity Reading (AR) on the screen. The higher the number, the higher the activity or body response to injury. Higher numbers relate to lower impedance of the tissue. AR is a measurement of the effect that skin impedance has on the waveform.

---

1. Select a preset

Select a preset stimulation pattern that displays the icon. Preset stimulation patterns with active Activity Reading are available in the Acute and Chronic setting list. This feature is not available in the Cycle settings.

---

2. Set stimulation intensity (pg. 12-13)

The stimulation should be a comfortable tingling sensation.

---

3. Place the device on the skin

Place the device onto the skin. After one second of skin contact, the Activity Reading (AR) will appear on screen. It is the green number in the middle of the screen. It will appear for 3 seconds. If the device is held on the skin, the InterX will automatically start to calculate a Point-stim. If the device is removed from the skin, the Activity Reading will disappear immediately.

Activity Readings are useful to identify the target for treatment; the higher Activity Reading will typically indicate where Point-stim should be applied.

Point-stim

Point-stim is the targeted treatment of a specific area of pain and/or low impedance. A Point-stim may take only a few seconds or it may take up to a minute. The Point-stim function is active in all continuous or burst preset patterns. These preset patterns are labeled with a ♦ icon in the preset list. Pressing a button or removing the device from the skin during a Point-stim will cancel the process automatically. Upon completion, a tone will sound indicating that the body is responding to the stimulation and the InterX 5002 has recorded a change in the tissue impedance.

1. Select a preset stimulation pattern

Either from the Main Screen or from the full preset list.

---

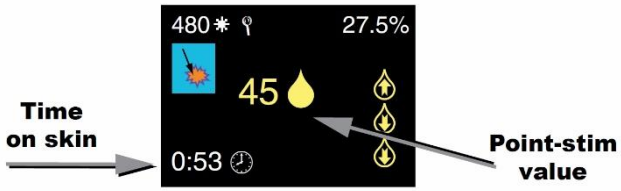
2. Set stimulation intensity (pg. 12-13)

The stimulation should be a comfortable tingling sensation.

---

3. Apply a Point-stim

Place the device onto the skin and hold it still until the Point-stim value appears on the screen and audible tone is heard. This indicates that the Point-stim is complete.



Point-stim value – An audible tone will be heard, the green LED will flash once and the numeric value will appear next to the stimulation icon.

Time on skin – This timer indicates how long the device has been in contact with the patient's skin. A single Point-stim usually takes between 20 and 60 seconds. When the time on skin reaches 9 minutes 59 seconds the device will enter the pause mode.

Multi-stim

Multi-stim is a series of Point-stims delivered to one point of treatment. To activate Multi-stim, briefly remove the device from the skin after the first Point-stim tone is heard and immediately replace in the exact same location.

The aim is to achieve a peak in the Point-stim values followed by two successively lower values or up to eight Point-stims (whichever is occurs first). During Multi-stim the peak value is saved in the top position on the right side of the screen and any subsequently lower Point-stim values are saved below this peak value. The Multi-stim function is an extension of the Point-stim and is active in all continuous or burst preset stimulation patterns.

These presets are labeled with a ♦ icon in the preset stimulation list.

1. Select a preset

Either from the Main Screen or from the full preset stimulation list.

---

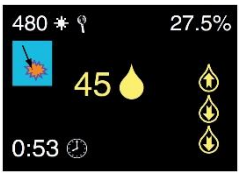
2. Set Stimulation Intensity (pg. 12-13)

The stimulation should be a comfortable tingling sensation.

---

3. Apply a Point-stim

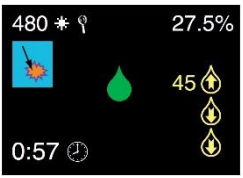
Place the device onto the skin and hold it still until the Point-stim value appears on the screen, the green LED flashes and a tone rings. This indicates that the Point-stim is complete.



---

4. Activate Multi-stim

Once the initial Point-stim is completed, remove the device from the skin and replace onto exactly the same point within 3 seconds to retain the value and activate Multi-stim. The Point-stim value is then saved on the right side of the screen. As Multi-stim continues, the peak Point-stim value is saved in the top row and any subsequently lower Point-stim values are saved below it.



NOTE: Removing the device from the skin during any individual Point-stim or pressing any button will automatically cancel Multi-stim.

5. Complete Multi-stim

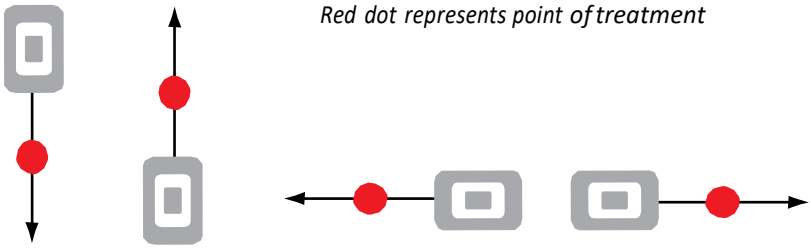
Continue to remove and replace the device from the skin after each Point-stim to continue Multi-stim. Repeat this process until Multi-stim is complete.

Multi-stim is complete either when the sequence of Point-stim values peaks and then falls twice consecutively or when 8 Point-stims have been completed (whichever occurs first). When Multi-stim is complete a check mark will appear in the middle of the screen, a tone will sound and the green LED will flash.

---

6. Slide to Finish

To finish the treatment, slide the device in 4 directions over the treated areas (indicated by the red dot) as shown below.



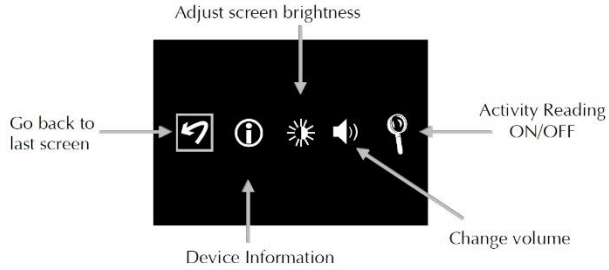
Red dot represents point of treatment

InterX Setup Options

To enter the setup option menu while in a preset stimulation pattern screen bring up the navigation screen by pressing any button.

Highlight and select the book icon (pg. 14) and select the setup icon on the right hand side of the full preset stimulation list.

Highlight and select 🛠 on the right hand side of the screen to enter setup.



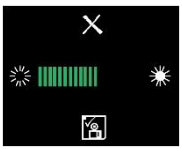
Save changes

Reject changes

NOTE: Failure to select the SAVE CHANGES icon result in selected changes being discarded.

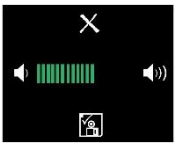
Screen Brightness

Press the RIGHT or LEFT navigation buttons to change the brightness of the screen on the InterX 5002.



Volume

Press the RIGHT or LEFT navigation buttons to change the volume of the ring tones on the InterX 5002.

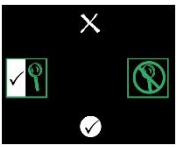


InterX 5002 Device Information

Serial Number (SN), Display Processor version (Dp-v), Software version (Sp-v), Stim hours (cumulative hours on skin) and battery power level.
NOTE: This screen is informational only.

Activity Reading

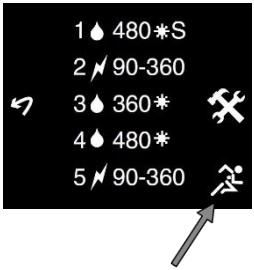
Press the RIGHT or LEFT navigation buttons to highlight and select Activity Reading ON or OFF.



Select ✔ to accept the changes. If the device is powered OFF, this selection will not be saved.

Sport Mode

The Sport mode of the InterX 5002 can be accessed by selecting the Sport icon from the full preset list.



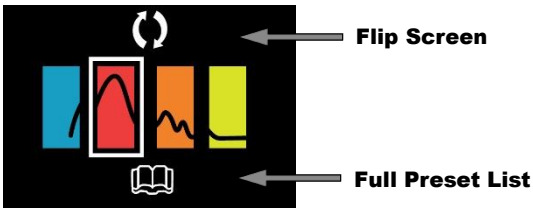
The Sport mode provides the same preset stimulation patterns as the 5002 mode but the method of selection is through the Injury Curve. The Injury Curve is a graphical representation of the stages of recovery from injury. It serves as a guide to select stimulation patterns based upon the stage of injury, from initial occurrence beyond repair to chronic.

Sport icon

To return to the 5002 mode select the 5002 icon that is on the right side of the full preset list.

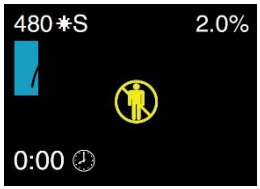
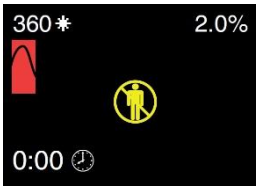
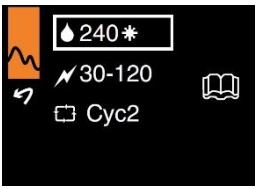
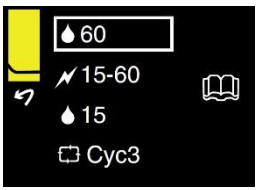
5002 icon

The Injury Curve main screen of the Sport Mode



Selecting one of the icons of the injury curve will immediately activate the default preset stimulation pattern for that stage.

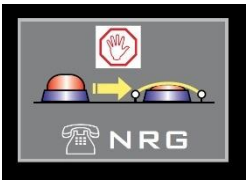
NOTE: Activity Reading is OFF when using the Sport Mode. Go to InterX setup options (pg. 24) to turn Activity Reading ON while in Sport Mode.

Default Stimulation Screen	Injury Stage	Injury Curve Preset List
	**ACUTE ONSET** Initial occurrence as symptoms develop Default = 480*s PPS Intensity = 2.0%	
	**ACUTE INFLAMED** Peak of injury symptoms Default = 360* PPS Intensity = 2.0%	
	**REPAIR** Injury begins to improve Default = 240* PPS Intensity = 2.0%	
	**CHRONIC** Conditions that persist beyond expected recovery time Default = 60 PPS Intensity = 2.0%	

Battery Operation and Device Warnings

Button Fault

If a button fault is detected during the self-test at start-up, then this screen will appear and the device will turn off automatically. Turn the device on again, if the problem has been fixed the device will start as normal. If the failure occurs again, call InterX Technologies or your InterX distributor for assistance.



Device Malfunction

This icon signifies that the InterX 5002 has malfunctioned and will not operate. It is necessary to call InterX Technologies or your InterX 5002 distributor for advice and assistance.

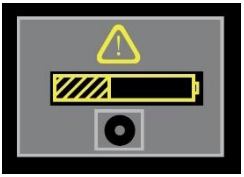
The InterX 5002 operates by battery power only. Use new, quality AA alkaline batteries for longer life and optimum performance of the device. Rechargeable batteries may be used. The effective usage time of rechargeable batteries may differ from that of new AA alkaline batteries. Always ensure that rechargeable batteries are fully charged before use. The InterX 5002 is rated for continuous operation.

NOTE: *The battery warning operation and battery power indicator may give incorrect readings when rechargeable batteries are used.*

Battery life is highly dependent upon how often the device is used and the specific settings that are utilized for treatments. Under normal professional use (approximately 5 hours per day) battery life of the device is estimated to be 1 – 2 weeks.

Low Battery Condition

When the battery is low, the yellow low battery warning will appear on screen. Press select to continue using the device after this warning. The InterX 5002 will continue to stim for approximately one additional hour.

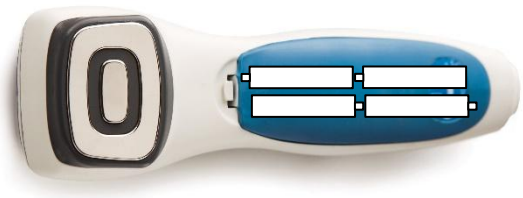


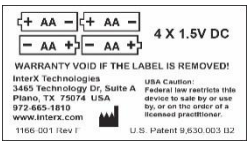
Battery Dead Condition

When the battery is dead, the red dead battery warning icon will appear on the screen. The device will immediately turn off. Change batteries to continue use. Once you have replaced the batteries, reset the appropriate treatment settings and intensity to continue treatment.

Removing and Replacing Batteries

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





General Care Instructions

NOTE: Do not disassemble the InterX 5002. Dangerous voltages could be present. The InterX 5002 does not contain any user-serviceable components. If the device needs repair or service, contact InterX Technologies, your InterX distributor or an authorized service representative.

Do not expose any part of the InterX 5002 to chemical solvents or harsh cleaning fluids. Do not sterilize or immerse the InterX 5002 in any fluid.

Storage and Cleaning

Remove the batteries when storing the InterX 5002 for more than one month. Storage in extreme heat or cold will deplete battery life.

For protection purposes, use the black holster to transport the InterX 5002. When not in use the InterX 5002 should be turned off.

Clean the device and accessory electrodes with the main power off. Between patient treatments, thoroughly clean the main electrode, accessory electrodes, and surrounding device area with 70% isopropyl alcohol wipes. Never spray cleaners directly on the device.

The InterX 5002 is a non-critical patient contact device indicated only for contact between the electrodes and intact skin.

CAUTION: Do not use cleaning products that contain ethyl alcohol and/or ammonium chlorides. 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.

Glossary

Activity Reading – An objective measure of skin impedance that is used to provide relative measures between different points on the skin.

Burst * – Stimulation presets that deliver multiple pulses per burst are indicated by *.e.g., 480* is 8 pulses per burst, 60 bursts per second.

Condition Screen – The main menu of the InterX 5002 that provides a guide to select stimulation patterns based on the patient's condition.

Cycle – Predefined cycle of preset stimulation patterns most often used with the Flexible Array electrode.

Impedance – Measure of the tissue's combined electrical characteristics which impact its ability to absorb the energy generated by the InterX Sport.

Injury Curve – The cycle of recovery from injury, incorporated into the InterX Sport to guide selection of preset stimulation patterns.

Injury Curve Preset List – Listing of the recommended preset stimulation patterns for a specific stage of injury.

Modulation – The ratio of time that the device is sending stimulation into the skin to the amount of time it is off. The Modulation setting of 3:1 indicates the device is transmitting stimulation for 3 seconds and then sends no stimulation for 1 second.

Multi-stim – A series of Point-stims.

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

Point-stim – A signal to the operator that a certain level of impedance change has been measured by the device.

Preset Stimulation Patterns – A range of settings delivering pulses per second as either continuous, burst, variable or cycles.

Pulses Per Second (PPS) – The number of pulses per second. The preset stimulation patterns are identified by a number that relates to the pulses per second.

Stimulation Intensity – The strength of the impulse on the patient's skin – the higher the intensity the stronger the tingling sensation felt by the patient. It is important that the stimulation intensity is delivered at a comfortable level.

Stimulation Screen – When the device is active and emitting stimulation.

InterX 5002 Screen Symbols

5002 Mode Main Menu – page 9

Main Screen

Flip screen for left-handed orientation

Full Preset List and Setup Options

Sport Mode Main Menu – page 25

Injury Curve

Stimulation Screen Icons

Time on skin

Stimulation intensity 0-100% Preset

pulses per second Continuous

Stimulation icon

Icon to confirm proper skin contact in Burst or Continuous frequency stimulation patterns

Point-stim value (Point-stim complete)

Activity Reading (Objective indication of skin impedance) Saved

Point-stim values during Multi-stim

No skin contact

Multi-stim complete

Slide device in four directions

Icon to confirm skin contact in Cycle preset patterns

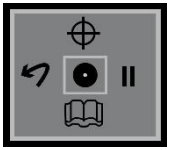
Waiting for next stimulation pattern in Cycle

Cycle complete

Icon to confirm skin contact in variable stimulation preset patterns

InterX 5002 Screen Symbols Cont.

Navigation options – page 11



Go back to previous screen

Condition Specific Preset short list

Full preset list and setup options

Pause

Setup Icons – page 24

InterX 5002 setup

Screen brightness

Ring tone volume

Device software information and battery level

Accept/save setup change

Reject setup change

Activity Reading OFF

Activity Reading ON

Service and One–Year Limited Warranty

The InterX 5002 is not user-serviceable. Never attempt to open the case as this device contains high voltages during operation. To obtain service, first contact InterX Customer Service at 972-665-1810, or your InterX 5002 distributor for a Return Authorization (RA) number. Send the entire unit, with all accessories, 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. Always be sure to include the RA number you were assigned with your returned device.

InterX will not be responsible for damage due to improper packaging or shipment. InterX warrants to the original purchaser that each new InterX 5002 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's option, to repair or replace the InterX 5002 without charge. If the InterX 5002 is outside the warranty coverage period any requested repairs or replacement charges will be invoiced to the customer.

If InterX 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, we will confirm repair costs with the customer, obtain authorization to repair the device and return the product and invoice the customer for the return freight and insurance charges. All repair charges under this condition will be invoiced to the customer.

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 InterX. Opening of the InterX 5002 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 (such as contract, negligence, or otherwise). In no event shall InterX 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.

Product Specifications

Size	220mm X 63mm X 45mm
Weight	Approx 330g
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	4 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 USA FDA regulatory requirements, the peak output voltage of the InterX 5002 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.*

INTERX Technologies

www.interx.com

Manufactured by:
InterX Technologies
3465 Technology Dr, Suite A
Plano, TX 75074 USA
Tel: +1 (972) 665-1810 Fax: +1 (972) 665-1814