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### About the IF8100

Interferential stimulation is used for a wide range of applications, generally with the purpose of either pain relief and/or muscle stimulation. Interferential stimulation differs from other types of electrical stimulation by its frequency and the principle of "interference". A substantially higher frequency (4,000 Hz) than traditional stimulation (1-150 Hz), allows the applied stimulation to penetrate the skin with less resistance. The skin impedance is approximately 100 times less than with using traditional TENS and NMES devices. The theory is that the more of the stimulation energy reaches the nerve and muscle fibers and hence becomes more "productive".

Applying two channels of 4,000 Hz stimulation in a cross pattern allows the center of the cross to beat with the interferential frequency (f1 minus f2). This is felt below the skin as a beating, pulsating feeling when the interferential frequency is set below 20 Hz. Above 20 Hz the fast beating will just feel like constant stimulation.



"I/F (Interferential) stimulation is a constant stimulation and is indicated for symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain. A NMES (NeuroMuscular Electrical Stimulation) Mode is available for indications such as muscle re-education, relaxation of muscle spasms, prevention or retardation of disuse atrophy, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, increasing local blood circulation, and maintaining or increasing range of motion. In the NMES mode, the stimulation comes on in six seconds intervals, thus allowing the muscle to rest from the contraction every six seconds."

Important:

This device must be ordered or prescribed by a licensed physician.

### Get started with IF8100

Make sure the electrodes are placed properly on the skin (see "Electrodes and Skin Care" for details) and that the lead wires are properly connected.

Turn on the unit by pressing ON for more than 1 second. A green or blinking light indicates that the leads and electrodes are properly connected and that the unit functions properly.

Begin pressing  $\uparrow$  button until a comfortable level is reached, as indicated by your physician or therapist. Stimulation will continue for 20 minutes and automatically shut off unless the treatment timer is changed.

During treatment the display will show remaining time left on upper line and stimulation level on lower line. The green light will be flashing with the set Interferential frequency (f.ex. 1 pulse per second.)

To stop treatment, pressing and hold the  $\downarrow$  button until display turns off. Thereafter, remove the electrodes and place them on the plastic sheet and seal them in the plastic bag.

Interferential stimulation at 4000 Hz consumes more energy than regular stimulation at lower frequency. It is therefore recommended to use the optional A/C adaptor for continued use.

### **Controls and Features**

<u>Turn unit ON and OFF</u>: Press  $\uparrow$  button for 1 second to turn the unit on. The display will light up and the right LED will be flashing or constant green. Press and hold the  $\downarrow$  button to turn the unit off. It takes two additional seconds after reaching 0 mA to turn it off. If no controls have been touched for 60 seconds with the stimulation level at 0 mA or 60 seconds after timeout, the IF8100 will automatically turn off.

**Setting Stimulation Level:** Use  $\uparrow$  and  $\downarrow$  buttons to increase or decrease stimulation level. Do not use the PRG button. After 20 seconds the  $\uparrow$  and  $\downarrow$  buttons are electronically locked as a safety feature to prevent an unintentional increase in stimulation. To decrease, just press  $\downarrow$  button to reduce it by at least 1 mA, which will unlock the safety feature. Thereafter, you have 20 seconds to increase to desired stimulation level, before the lock is activated again. Any change in stimulation level or mode will unlock the control buttons.

### Setting the Mode

Press PROG button once and use  $\uparrow$  or  $\downarrow$  buttons to select the desired mode:

### Low Mode:

- Stimulation is present constantly during the entire treatment time.
- The interferential frequency is sweeping between 1 and 10 Hz over a period of 15 seconds continuously.

### Low-High Mode:

- Stimulation is present constantly during the entire treatment time.
- The interferential frequency is sweeping between 1 and 150 Hz over a period of 15 seconds continuously.

### High Mode:

- Stimulation is present constantly during the entire treatment time.
- The interferential frequency is sweeping between 80 and 150 Hz over a period of 15 seconds continuously.

### Muscle Mode:

- Stimulation is applied for 6 seconds, then paused for 6 seconds. Commonly known as NeuroMuscular Electrical Stimulation (NMES). Upramp is 1 second and down-ramp is 0.5 second, fixed.
- The interferential frequency is fixed at 50 Hz.

### **Combo Mode:**

- See the above modalities:
- 2 minutes in Low, 2 minutes in High, 2 minutes in Muscle, then repeated until the duration of the treatment session.

<u>Setting the Treatment Time</u>: Press PROG two times and use  $\uparrow$  or  $\downarrow$  buttons to select the desired Treatment Time. Keep pressing  $\downarrow$  or  $\uparrow$  button to set a Continuous Treatment Time.

<u>Compliance data</u>: Press PROG three times and use  $\downarrow$  button to display the usage time in minutes and number of times used, when prompted by text in display. Only stimulation levels above 5 mA are recorded as usage time. The compliance meter can be reset by pressing  $\uparrow$  button to show prompt in display and thereafter press  $\downarrow$  button twice to reset both parameters to zero.

### **Electrodes and skincare**

Proper skin care will help make the use of this device more comfortable and trouble-free. Prior to treatment, wash the areas where the electrodes will be placed with mild soap and water, rinse and dry the skin thoroughly. If necessary, remove excess body hair.

The IF8100 is intended to be used with re-usable, self-adhesive electrodes. Extended number of uses can be obtained by adding water to the adhesive surface immediately after each use and placing them on the plastic pad. They will regain their conductivity and adhesiveness as compared to leaving them dry.

Sterile electrodes may be required for some post-op applications.

### **Batteries**

One 9 volt Alkaline battery is used. The battery compartment on the back of the device opens by sliding the cover downwards. Please ensure to dispose of the used batteries properly.

Rechargeable batteries are not recommended as they only have a short usage time and are not charged while in the device.

# **Zynex Medical** Contact Information

### **CUSTOMER SERVICE**

### (866) 940-7030

Supplies:	To order more electrodes or other accessories	
Technical Support:	Questions or problems with using your device	
Device Return:	Order a postage paid return envelope to return your device at no charge	

### MAIN OFFICE

### (800) 495-6670

**Billing Questions:** Questions regarding insurance benefits and covered benefits for durable medical equipment or questions about an Explanation of Benefits form you received in the mail

### FAX NUMBER

### (800) 495-6695

### MAILING ADDRESS

Zynex Medical 9990 Park Meadows Drive Lone Tree, CO 80124

### **EMAIL**

### info@zynexmed.com

**WEBSITE** 

zynexmed.com

# **Post-Operative Knee**

### PAIN RELIEF & EDEMA REDUCTION

### **ELECTRODE PLACEMENT:**

When applying electrodes in the operating room, sterile electrodes must be used and placed away from incisions as shown below. Electrodes applied outside the operating room do not need to be sterile and should be placed around the bandaged area in the pattern shown below.

### **INTENSITY LEVEL:**

Set the amplitude as high as possible without pain or muscle contraction

### TREATMENT TIME & FREQUENCY:

Phase <u>One</u> for 15 minutes followed by Phase <u>Two</u> for 15 minutes (3x/day)

### TREATMENT PHASE ONE



# Muscle Spasm (Back & Neck)

## **Spasm Reduction**

### **ELECTRODE PLACEMENT:**

Place 4 electrodes surrounding the affected area with the black leads opposite of each other as shown below

### **INTENSITY LEVEL:**

Use **button** to set level to a strong, but comfortable strength. The timer will automatically turn off stimulation after user's preset time.

### **TREATMENT TIME & FREQUENCY:**

Push Prog. Button until "Timer" is in display. Use button to set treatment time between 30 - 60 minutes. (3x per day)

### **RECOMMENDED MODE:** MUSCLE MODE

Press Prog. Button then Up Button and Choose MUSCLE

















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# Shoulder Rotator Cuff, AC joint, Bicep Tendonitis

## **PAIN RELIEF**

### **ELECTRODE PLACEMENT:**

Place 4 electrodes as shown with the black leads opposite of each other

### **RECOMMENDED MODE: LOW-HIGH**



Interferential Treatment: Usual treatment time is 20-30 minutes 3x per day; Max is 3 hours of use within a 24 hour period

# **Cervical**/Neck

# PAIN RELIEF

### **ELECTRODE PLACEMENT:**

Place 4 electrodes as shown with the black leads opposite of each other

### **RECOMMENDED MODE: LOW-HIGH**

Press Prog. Dutton then up button and choose LOW-HIGH The IF frequency is sweeping between 1 Hz and 150 Hz over a period of 15 seconds continuously.



### ALTERNATIVE MODE:

**HIGH** - The IF frequency is sweeping between 80 Hz and 150 Hz every 15 seconds continuously

### INTENSITY LEVEL:

Use button to set level to a strong, but comfortable strength. The timer will automatically turn off stimulation after user's preset time.

# **INCREASE CIRCULATION**

### **RECOMMENDED MODE:**

**COMBO** - Combination Low Mode (1-10 Hz), High-Mode (80-150 Hz), and Muscle Mode ( 6 sec. On & 6 Sec. Off)

### **INTENSITY LEVEL:**

Use button to set level to a strong, but comfortable strength. A slight muscle twitch may enhance blood circulation to the area.



**Interferential Treatment:** Usual treatment time is 20-30 minutes 3x per day; Max is 3 hours of use within a 24 hour period

# **Plantar Fascitis**

## PAIN RELIEF

### **ELECTRODE PLACEMENT:**

Place 4 electrodes as shown with the black leads opposite to each other

### **RECOMMENDED MODE: HIGH**



### Indications, contraindications, precautions, safety and warnings.

#### **Safety References**

Zynex Medical (Zynex) is only responsible for the safety, reliability and function of the device when repairs, adjustments and changes have been carried out by persons authorized by Zynex for such work and the device is used according to the user manual. Repairs and technical safety tests shall only be carried out by trained personnel.

#### Indications

This Zynex device has been designed for muscle re-education, prevention of retardation of disuse atrophy, increase local blood circulation, maintain or increase range of motion, relaxation of muscle spasms and edema reduction.

Symptomatic relief of chronic intractable pain, post-traumatic and postsurgical pain. (IF Mode)

Relaxation of muscle spasms. Prevention of retardation of disuse atrophy. Increasing local blood circulation. Muscle re-education. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. Maintaining or increasing range of motion.

This stimulator should only be used under supervision for adjunctive therapy for the treatment of medical diseases and conditions.

#### Contraindications

- This stimulator should <u>not</u> be used on patients with a cardiac demand pacemakers.
- Electrodes should <u>not</u> be placed so that current will be applied to the carotid sinus (neck) region or transcerebally (through the head).
- This stimulator should <u>not</u> be used whenever pain syndromes are undiagnosed, until etiology is established. (In I/F Mode)

### **Warnings**

### In I/F Modes

- The safety of tens devices for use during pregnancy or birth has not been established.
- This device is not effective for pain of central origin. (This includes headache)
- This device should only be used under the continued supervision of a physician.
- This device does not have curative value.
- This device offers symptomatic treatment such as suppressing the sensation of pain which would otherwise serve as a protective mechanism.
- The user must keep the device out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when this device is in use.

### In Muscle Mode:

- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.

### **Precautions**

### For the I/F Modes:

- Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.
- Effectiveness is highly dependent upon patient selection by a person qualified in management of pain patients.

### For the NMES Mode:

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
  - 1. When there is a tendency to hemorrhage following acute trauma or fracture;
  - 2. Following recent surgical procedures when muscle contraction may disrupt the healing process:
  - 3. Over the menstruating or pregnant uterus; and
  - 4. Over the areas of the skin which lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- This device should be kept out of reach of children.
- This device should be used only with the leads and electrodes recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which voluntary muscle contractions may put the user at undue risk of injury.

### **Adverse Reactions:**

Skin irritation and burns beneath the electrodes are potential adverse reactions.

# **Trouble-shooting**

Problem	
Unit stays on – even after treatment ends.	Hold Off button down for 2 seconds to shut unit off – else unit will shut off automatically after 5 minutes of no stimulation. Alternatively you can start a new treatment session now, without having to start from scratch.
Can not increase level from its current setting.	Turn level down 1 mA to unlock this safety feature – then turn it up to the desired level/intensity. Intensity level is always locked after 20 seconds of no change of settings.
Do not feel the traditional I/F beat in the center of the four electrodes.	Check that the lead wires are connected correctly to the electrodes (red opposite to each other, black opposite to each other)
Display shows electrode alarm.	Check your electrodes, they must be fresh and stick well. Then check your electrodes again, possibly change to new electrodes. Then check that all four electrodes are connected to lead wires and that both lead wires are connected to the unit. Eventually put all four metal pins together to short-circuit the outputs – that should make the electrode alarm go away – and thereby prove that the problem IS the elec- trode quality.

# **Technical specifications:**

Carrier frequency:	4000 Hz nominal
Modulation frequency:	Continuous 4001-4150 Hz, freq. Shift modes 4001-4240 Hz
I/F Modes:	Low, Low-High, High.
Muscle Mode:	50 Hz, 6 sec. On, 6 sec. Off. Up-ramp is 1.0 sec. and down-ramp is 0.5 sec.
Treatment timer:	Continuous, 10-100 minutes, in 10 minutes steps. Factory setting is 20 minutes.
Compliance meter:	Records total usage time in minutes and number of times used. Can be reset.
Dimensions:	4.5 x 2.5 x 0.9 in.
Weight:	5 oz. Incl. Battery
Warranty:	3 Years manufacturers warranty on materials and workmanship. Accessories excluded.





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