

IF-4000

INSTRUCTION MANUAL



SPINAL REHAB SOLUTIONS, INC.



CAUTION : In the U.S.A federal law restricts this device to sale by or on the order of a physician so licensed by the state.

INDICATIONS :

- Interferential Stimulator is used for symptomatic relief and management of chronic pain and/or as an adjunctive treatment in the management of postsurgical and posttraumatic acute pain.

CONTRAINDICATIONS :

- Interferential stimulation is contraindicated for patients using cardiac pacemaker. It's use is not recommended for patients with known myocardial arrhythmia without physician evaluation.
- Interferential stimulation is contraindicated for use over the carotid sinus nerves, laryngeal or pharyngeal muscles.
- Do not apply interferential stimulation for undiagnosed syndromes until etiology is established.
- Do not apply interferential stimulation transcerebrally.

WARNINGS :

- For external use only.
- Safety of interferential stimulation during pregnancy or delivery has not yet been established.
- This device should be used only under the continued supervision of a physician.
- Interferential stimulation therapy is ineffective for pain of central origin.
- Interferential stimulation is of no curative value.
- Interferential stimulation is a symptomatic treatment and, as such, suppresses the sensation of pain which would otherwise serve as a protective mechanism on the outcome of the clinical process.
- Do not stimulate the eye area.
- Interferential stimulation may interfere with ECG monitoring, including alarms.
- KEEP OUT OF REACH OF CHILDREN.**
- Avoid abrupt changes of stimulator controls while operating dangerous machinery, such as automobiles.

**PRECAUTIONS :**

- Isolated cases of skin irritation may occur at the sites of electrode placement following long-term application.
- The use-effectiveness of interferential stimulation is directly related to patient selection.

ADVERSE REACTIONS :

- Possible skin irritation or electrode burn under electrode may occur.
- Possible allergic skin reaction to tape or gel.



INSTRUCTION

TO THE PATIENT :

Your physician has prescribed the IF-4000 Interferential Stimulation System to help control your pain. Please read this operating manual carefully before using your IF-4000. The instruction on the following page will show you how to use and care for your IF-4000 in a general manner. You should be particularly familiar with the prescription information and precautions before proceeding.

You should consult with your clinician if you have specific questions or problems regarding the use of your IF-4000, your clinician possesses technical knowledge.

PAIN AND THE USE OF INTERFERENTIAL STIMULATION :

Pain is normally a useful warning device to let us know something is wrong so additional injury can be avoided. However, once that warning is given the continued presence of pain can be counter productive and lead to other problems. The use of interferential stimulation in acute and chronic pain can relieve these pain symptoms. However, it is important to realize that only the pain symptoms are relieved and the underlying condition is not affected or cured. Therefore, interferential stimulation should be used only for those symptoms specifically recommended by your physician or therapist. Any new symptoms or pain areas should be reported to your doctor for appropriate diagnosis and treatment.

HOW INTERFERENTIAL STIMULATION WORKS :

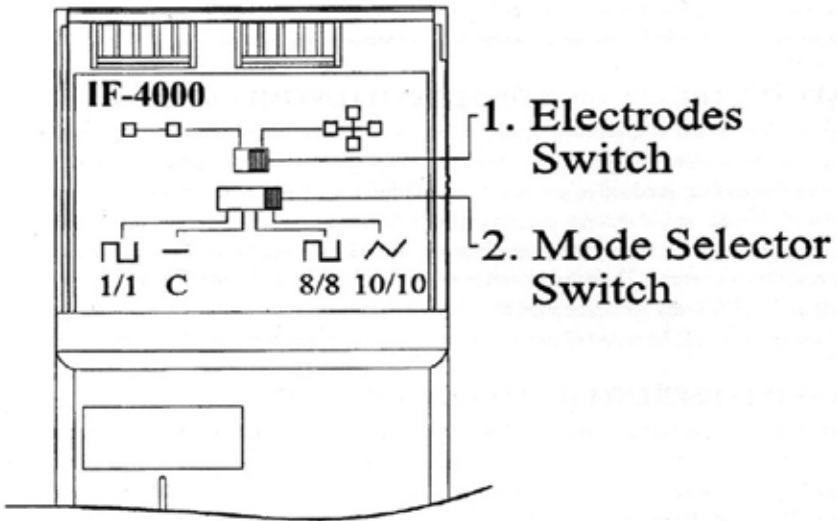
First of all, there is nothing "magic" about interferential stimulation .Your IF-4000 sends small comfortable electrical impulses through your skin into the painful area causing a mild tingling sensation .The sensation works to prevent pain signals from reaching the brain. The IF-4000 has two channels, allowing it to operate on either one or two pairs of electrodes which allows a better focus and deeper tissue stimulation when compared to other types of electrical stimulation.

Though pain relief varies by individual patient and the type of pain, in many cases the stimulation will greatly reduce or eliminate the pain sensation .In many patients the reduction of pain lasts longer than the actuarial period of stimulation. In others, the pain is only modified while the stimulation actually occurs.



IF-4000 INTERFERENTIAL STIMULATOR CONTROLS AND FUNCTIONS

< TOP VIEW >



1. Electrodes Switch:

Slide to the left when applying one pair of electrodes (the "two electrodes" position). Slide the switch to the right when applying two pairs of electrodes (the "four electrodes" position).



2.Mode Selector Switch:

The mode selector switch is used to alter the sequence of stimulation from a regular or continuous waveform to an irregular one. The most important reason for changing the waveform is to provide alternative modes for the most effective patient treatment and comfort.

In the "C"(Continue)mode, there is no change in the pulse rate. When set at other modes, the interference frequency changes over time. For example, when the frequency control was set at 100 Hz, the interference frequency would shift repeatedly from -25% to +55%; that is, from 75 Hz to 155 Hz.

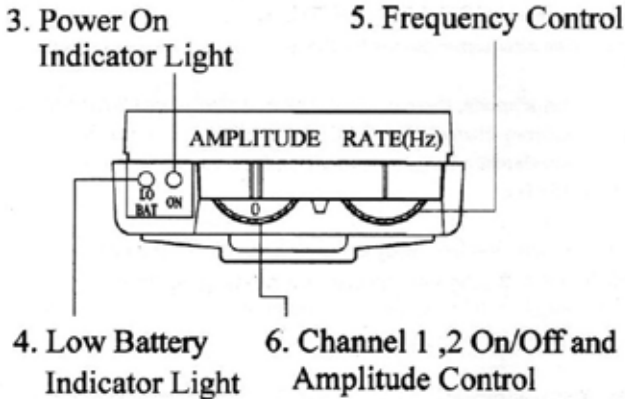
When set at "1/1" with the frequency control set at 100 Hz, the interference frequency would be at 75 Hz for (1 ± 0.5) second. then shift abruptly to 155 Hz for (1 ± 0.5) second. then back to 75 Hz for (1 ± 0.5) second. The pattern will be repeated as long as the mode selector switch is "1/1"mode.

The option "8/8" is identical to "1/1", except that each interference frequency value (75 Hz to 155 Hz in the above example) is held for (8 ± 2) seconds.

The option "10/10" works from the -25% value to the +55% value gradually instead of rapidly. For example, when the frequency control was set at 100, the IF-4000 will sweep gradually from 75 Hz to 155 Hz over a (10 ± 2) second period, then from 155 Hz to 75 Hz during the next (10 ± 2) seconds.



< FRONT VIEW >



3. Power ON Indicator Light :

The power "ON" indicator light is used to indicate the stimulator on or off.

4. Low Battery Indicator Light :

The low battery indicator light remains off when the IF-4000 is in operation and the battery is at sufficient strength for normal operation. The light will glow amber when the battery requires replacement. The light will cease glowing when the battery is completely drained. When the unit is turned on or off, the indicator light may flash between one to three seconds, which is normal and does not indicate a low battery condition.

5. Frequency Control :

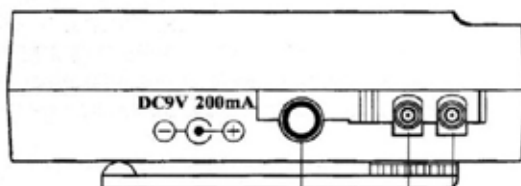
Turn the dial to select the frequency directed by your clinician.

6. Amplitude Control :

It controls the strength of the electrical stimulation delivered through both channels. The "off" position indicates that power to the unit is turned off. No stimulation is delivered at the "off" setting. Slowly turn the amplitude control clockwise until you achieve the amount of stimulation recommended by your clinician. Always set the amplitude control to the "off" position before conducting a treatment, inserting the lead cables and removing or replacing battery.



< SIDE VIEW >



- 7. Adapter Receptacle
- 8. Channel 2 Output Receptacle
- 9. Channel 1 Output Receptacle

7. Adapter Receptacle :

You also can use adapter instead of battery. Insert adapter plug into the adapter receptacle to be used, pushing all the plug in. Whenever you use adapter, the battery power supply will be cut off automatically.

The specifications of adapter

Input : 120 Volts AC , 60Hz. 7W

Output : 9 Volts DC , 200mA



8.9. Output Sockets :

The lead cable plugs are inserted into the output sockets. When applying only one pair of electrodes, use the socket "Channel 2". No stimulation is delivered from socket "Channel 1" when one pair of electrodes is utilized and the electrode switch is set in the "Two electrodes" position. Use both sockets when applying two pairs of electrodes.



HOW TO USE YOUR IF-4000 STIMULATOR

1.Clean the skin thoroughly

Proper skin care will help make your Interferential Stimulation Program more comfortable and trouble-free. Using mild soap and water, wash the skin areas where the electrodes will be placed. Rinse and thoroughly dry the skin. If necessary, remove excess body hair.

2.Check Battery

Be sure you are using a fresh battery.

3.Prepare electrodes

Following the instructions included with the electrode pads you choose.

4.Connect the electrodes to the lead wires

If the electrodes pads you have chosen use lead wires with straight connectors:

- (a) Insert the connector pin into the appropriate hole in the electrode.
- (b) Push the connector pin in all the way. Make certain no metal is exposed.

5.Place electrodes on skin

Apply the electrodes to the exact site indicated by your physician following the instruction included with the electrode system. Make sure that the electrodes are placed firmly to the skin and make good contact between the skin and the electrodes.

6.Connect lead wires to the output sockets

The IF-4000 is supplied with two twin lead wires. When applying only one pair of electrodes, plug the dual connector into the socket " Channel 2" and the electrode switch is set in the

" Two electrodes" position. Use both sockets when applying two pairs of electrodes.

7.Make sure the IF-4000 is in the "off" position before use.

8.Set the frequency dial to the position your health professional has indicated.



9. Turn on the amplitude control

Slowly turn on the IF-4000 by turning the amplitude dial in a clockwise direction. Turn it up to the desired strength that your health professional has indicated to you.

10. Turn off the amplitude control

When your prescribed treatment time is finished, turn the amplitude control to the "off" position. Then disconnect the lead wires from the unit and remove the electrodes from your skin.

WARNING : Always turn the stimulator off before attempting to remove wires or electrodes.



SKIN CARE

1. Apply electrodes on clean, dry and unbroken skin only.
2. Before applying electrodes and after removing-always wash the site with mild soap and water. Then rinse and dry thoroughly.
3. Excess body hair in the electrode placement site should be clipped and not shaved.
4. If clinician recommends skin prep usage-follow instructions as directed.
5. When applying electrodes, do not stretch skin or electrodes.
6. When removing electrodes-always peel back in direction of hair growth, or moisten edges or underside of electrode.
7. Applying unflavored Milk of Magnesia over electrode placement sites after removing electrode helps maintain the natural pH of the skin and reduces irritation problems.
8. If perspiration occurs in the area of the electrodes causing the electrodes to slide out of position, wipe area with unscented antiperspiration pads and allow to dry before reapplying electrodes.
9. If skin irritation arises and persists from the use of interferential stimulator and certain type of electrodes, discontinue usage immediately and consult your clinician.



ELECTRODES CARE

There are many kinds of electrodes. Use the electrodes recommended by your physician and obey the instructions attached to the electrodes.

TO THE PHYSICIANS : PLEASE USE THE DIMENSIONS OF ELECTRODES ABOVE 16cm² AND WHICH HAS FDA 510(K) NUMBER.

1.Reusable Electrodes

After using any of these electrodes, grasp the corner of the electrode and gently remove it from your skin. Do not pull on the electrode snap or wire connection. Reapply the release liner to the adhesive side of the electrode. Store the electrode in a resealable pouch or plastic bag. To prolong the lifespan of electrodes, remoisten them by applying a few drops of tap water when they show signs of drying out or losing their adhesiveness . Apply the water with your finger tip.

After repeated usage, reusable electrodes begin to lose their adhesiveness and therefore delivery less stimulation and shorten battery life. Replace reusable electrodes as needed.

2.Disposable Electrodes

These electrodes use a solid polymer gel and come with a built-in tape patch. They can be worn while showering, but long soaks in hot baths will loosen them. When electrodes are not adhering well or fail to deliver proper stimulation, remove and replace them.

3.Carbon Rubber Electrodes

Clean your carbon electrodes with mild soap and water between uses. Carbon rubber electrodes deliver less stimulation as they age and typically need replacement every six months.



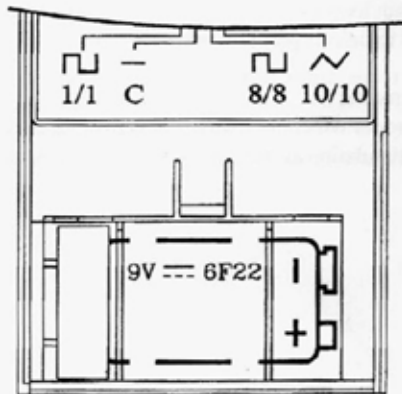
BATTERY REPLACEMENT

The IF-4000 requires one 9 volts square battery. Insert the battery into the battery compartment of IF-4000. Make sure the direction of the battery is correct (see diagram inside battery compartment).

To replace the battery :

1. Turn the amplitude control to the "off" position. Remove the front panel by sliding it completely off. This exposes the battery for removal.
2. Tip the stimulator so the battery pivots outward. Then unsnap the old battery from the connector. Discard the old battery.
3. Snap a new 9 volt alkaline battery into the connector.
4. Slide the front panel into the grooves on the case and push up until the battery and control panel are covered.

< Battery Compartment >





TECHNICAL SPECIFICATIONS

Carrier Frequency : $(4000 \pm 10\%)$ Hz, fixed.

Difference Frequency : $(1 \pm 0.5) \sim (150 \pm 10\%)$ Hz, adjustable.

Output Voltage : (16 ± 2.5) Volts. (500 Ω Loading).

Waveform : Symmetric biphasic square.

Pulse Width : $(125 \pm 10\%)$ microseconds for each phase.

Power Source : 9V alkaline battery or adaptor.

Four Frequency Shift : Continuous, 1/1 abrupt, 8/8 abrupt, 10/10 ramped Options.