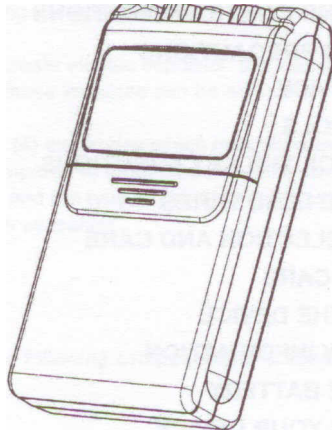


INTRODUCTION TO THE INTERFERENTIAL STIMULATOR (IF)

Model: GM322IF



ULTRA-IF

Sine Wave Technology

FDA 510k

What is pain?

Pain is the body's warning system. Pain is important because it signals an unusual condition in the body and alerts us before additional damage or injury can occur. However, long-lasting persistent pain, often called chronic pain, once diagnosed serves no apparent purpose. The Interferential Stimulator is developed to help relieve many types of chronic and acute pain.

How Does IF work?

The unit is a dual-channel electric stimulator for active treatment application, which is equipped with a Digital Display indicating operation modes and output as well as an 8-bit microcomputer for controlling the system.

The electronics of the unit create electric impulses: the intensity, duration, frequency per second and modulation of these impulses can be adjusted.

The IF stimulator uses four (4) electrodes which may allow better focus and deeper tissue stimulation when compared to other types of electrical stimulation. Pain relief varies by individual patient and the type of pain; in many cases the stimulation may reduce or eliminate the pain sensation.

SYSTEM COMPONENTS

Your device may include the following components or accessories:

- Interferential Stimulator Unit
- Carrying Wires
- Lead Wires
- Electrodes
- Battery (9-volt alkaline, option)
- 9V DC Adaptor
- Operation Manual

Indications

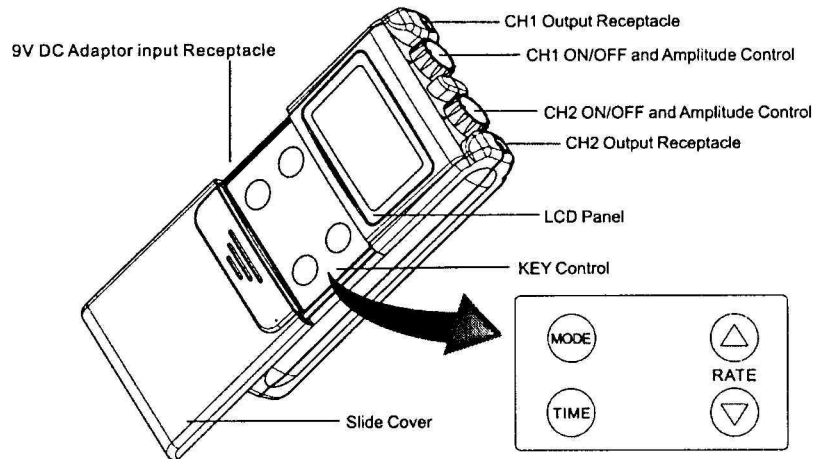
This device may be used with a physician's prescription, for the symptomatic relief and management of chronic (long term) pain and for the treatment of postoperative or posttraumatic pain.

Contraindications

- Patients with implanted electronic devices (for example, a pacemaker) or metallic implants should not undertake IF treatment without first consulting a physician.
- Any electrode placement that applies current to the carotid sinus (neck) region.
- The use whenever pain symptoms are undiagnosed, until etiology is determined.

ABOUT THE DEVICE

Your device offers two controllable output channels. This device creates electrical impulses whose amplitude, duration, and modulation can be altered with the controls or buttons. The device controls are very easy to use and the side cover protects accidental changes in settings.



DEVICE CONTROLS

Panel Cover

A cover conceals the controls for Pulse Rate, Mode Selector, and Time Selector. Press the topside of the cover and pull down in order to open the cover.

Intensity

The intensity knobs located on the top of the unit for the strength adjustment of the stimulation and also function as ON/OFF controls.

Mode

The mode button is used to select or set the type of treatment utilized. The nine modes are one Constant, three Auto Sweep, and five frequency Shift.

Pulse Rate

The Pulse Rate key regulates the number of pulses per second for both channels.

Time Control

Treatment time of the device can be preset with the timer key. There are two fixed durations; 15, and 30 minutes. Press the key until engaged in desired position.

EXPLANATION OF THE KEY FUNCTIONS

MODE (Therapy mode selection / setting)

This key can select the nine preset modes, with each depression of the key you switch to the next mode. The selected mode will be shown on the LCD and will blink.

TIME (Therapy time selection / setting)

After turning your device on, press the TIME key to set the therapy time to 15 or 30 minutes. The next time you operate your device, the treatment time will be automatically stored in memory until you select otherwise.

RATE ▲ ▼ (Pulse rate settings)

This key selects the pulse frequency of the current therapy. By pressing ▲ you can increase the frequency in 4 bps/step increments. By pressing ▼ you can decrease the frequency in 4 bps/steps.

ATTACHING THE LEAD WIRES

The lead wires provided with the device insert into the jack sockets located on the top of the unit. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks. After connecting the wires to the stimulator, attach each wire to an electrode.

Lead wires provided with the device are compliant with mandatory compliance standards set forth by the FDA.

Note: Use carefully when you plug and unplug the wires. Pulling on the lead wire instead of its insulated connector may cause wire breakage.

Caution: Never insert the plug of the lead wire into an AC power supply socket.

ELECTRODE SELECTION AND CARE

Follow application procedures outlined in the electrode packaging to maintain stimulation and to prevent skin irritation. The electrode packaging will provide instruction for care, maintenance and proper storage of your electrodes. Be sure to use the electrodes provided by the manufacturer.

TIPS FOR SKIN CARE

Good skin care is important for comfortable use of your device.

- Always clean the electrode site with mild soap and water solution, rinse well, and blot dry thoroughly prior to any electrode application.
- Any excess hair should be clipped, not shaved, to ensure good electrode contact with the skin.
- You may choose to use a skin treatment or preparation that is recommended by your physician. Apply, let dry, and position the electrodes as instructed. This will reduce the chance of skin irritation and extend the life of your electrodes.

- Avoid excessive stretching of the skin when applying electrodes. This is best accomplished by applying the electrode and smoothly pressing it in place from the center outward.
- When removing electrodes, always remove by pulling in the direction of the hair growth.
- It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.

CONNECTING THE DEVICE

1. Prepare the skin

Prepare the skin as previously discussed and according to instructions provided with your electrodes. Before attaching the electrodes, identify the area in which your physician/practitioner has recommended for electrode placement.

2. Connect lead wires to the electrodes

Connect the lead wires to the electrodes before applying the electrodes to the skin. **Note: Be sure both intensity controls for Channel 1 and 2 are turned to the “OFF” position.**

3. Place Electrodes on Skin

Place the electrodes on the skin as recommended by your clinician.

4. Insert Lead Wire Connector to device

Plug end of lead wire into the channel output receptacle to be used, pushing plug in as far as it will go.

5. Select Treatment Settings

Check and be sure your unit is still set to the proper settings recommended by your physician/practitioner.

6. Adjusting Channel Intensity Control

Locate the intensity control knob at the top of the unit. Slowly turn the intensity control knob for Channel 1 clockwise until you reach the intensity recommended by your medical professional. Always start with the lowest step and increase slowly. Repeat the same process for Channel 2.

If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level or cease stimulation and contact your physician/practitioner if problems persist.

POWER SUPPLY INFORMATION

9-Volt DC Adaptor

Because the current consumption is large for the IF unit, it is recommended to use the 9V DC adaptor. Plug the DC plug into the DC jack of the unit, and plug the adaptor into your 110V wall outlet. Please be sure you are using the correct polarity of DC plug.

Battery

A 9-volt disposable battery (optional) may be provided with your unit. When the low battery mark light on the LCD appears, the battery has become too weak to power the unit and it is time to change the battery. At this point, the unit will shut off until a fresh battery is inserted.

Note: Due to the high output of this device, the 9V alkaline battery will run out of power quickly; therefore the 9-Volt DC adapter is the recommended power source.

CHANGING THE BATTERY

When the low battery mark light is on the LCD panel, the battery should be replaced with a fresh battery.

1. Remove the Panel Cover by pressing the top and sliding down until it is completely removed from the unit. This will reveal the battery compartment.
2. Remove the discharged battery from the device.
3. Place the new battery into the compartment. Note the proper polarity alignment indicated on the battery and the compartment.

CLEANING FOR YOUR DEVICE

Your device may be cleaned by wiping gently with a damp cloth moistened with mild soap and water. Never immerse the device in water or other liquids.

Wipe lead wires with a damp cloth as above if they become soiled.

To properly store the device for an extended period of time, remove the battery from the unit. Put the unit and accessories in the carrying case and store in a cool, dry location.

TROUBLESHOOTING

If the device does not function properly:

1. Make sure the battery is properly installed or replace the battery. Be sure to observe proper polarity markings when replacing the battery. If the low battery mark light is on the LCD panel when the unit is turned on, replace the battery and check again.
2. If the intensity has been adjusted and there is no stimulation, check that the lead wires are properly connected and the electrodes are in place. If the unit appears to

be functioning and there is no stimulation, the lead wires or electrodes may need to be replaced.

3. If the battery appears to be charged and the unit is not functioning, turn both the intensity control knobs to the OFF position (counter clockwise) for about 5 seconds. After doing this, gradually turn the intensity control knob clockwise until stimulation is felt. If the device is still not working, turn the unit off and contact your physician.

TECHNICAL SPECIFICATIONS

Channel:	Dual, isolated between channels
Pulse Intensity:	Adjustable 0-60mA peak into 500 ohm load each channel, constant current
Carrier Frequency:	4000Hz fixed (CH1)
Modulating Frequency:	4004-4160Hz Adjustable (CH2)
IF Frequency Mode:	Constant Mode: 4-160 bps, Adjustable Auto Sweep: 80 -145 bps, 4 – 45 bps, 4 – Set bps Frequency Shift: 1/1 abruptly shift, 6/6 abruptly shift, 6/6 ramped, 10/10 abruptly shift, 10/10 ramped
Sweep Time:	15 seconds
Frequency Shift Percent:	Frequency shifts from 30% below set frequency to 60% above and return to 30% below set.
Output Configuration:	Quad polar (4 electrodes)
Wave form:	Symmetrical balanced Sine wave
Interference Pulse Freq:	4 – 160 bps, Adjustable 4 bps/step
Pulse Duration:	125 μ s maximum
Patient Compliance Meter:	Shows the treatment times
Patient Lock:	Prevents the patient from changing any of the set parameters by the physician/practitioner.
Timer:	15, 30 minute selectable
LCD:	Shows modes, bps rate, abrupt/ramp, timer and channels
Max Charge Per Pulse:	15 Micro-coulombs Maximum
Power Source:	9 Volt DC adapter, 500mA or Alkaline 9 Volt battery
Tolerance:	+/- 10%



Output Parameters

There are nine modes: Five modes with frequency shift. Three modes with Auto Sweep, and one mode fully adjustable.

Constant Mode

Maintains set pulse frequency. (SET: bps can be adjusted)

Auto Sweep

It will modulate frequency between the range that is selected. For example, select 80-145bps auto sweep model. The modulation range of pulse frequency is from 80 bps to 145 bps. The sweep-time is 15 seconds and repeat.

There are three modes of Auto Sweep:

1. 80 – 145 bps
2. 4 – 45 bps
3. 4 – SET bps

Frequency Shift

There are five modes in Frequency Shift

1. **1/1 abruptly shift:** The pulse frequency varies from -30% to +60% of the set pulse frequency. One second at the lower frequency, and one second at the higher frequency. The transition is abrupt (square wave function).
2. **6/6 abruptly shift:** The pulse frequency varies from -30% to +60% of the set pulse frequency. Six seconds at the lower frequency, and six seconds at the higher frequency. The transition is abrupt (square wave function).
3. **6/6 ramped shift:** The pulse frequency varies from -30% to +60% of the set pulse frequency. Six seconds from the lower frequency modulate to the high frequency, and six seconds from the higher frequency modulate to the lower frequency. The transition is ramping (triangular wave function).
4. **10/10 abruptly shift:** The pulse frequency varies from -30% to +60% of the set pulse frequency. Ten seconds at the lower frequency, and ten seconds at the higher frequency. The transition is abrupt (square wave function).
5. **10/10 ramped shift:** The pulse frequency sweeps from -30% to +60% of the pulse frequency. Ten seconds from the lower frequency modulate to the high frequency, and ten seconds from the higher frequency modulate to the lower frequency. The transition is ramping (triangular wave function).