

FastStart® IF



Patient Operating Manual

VQ Wholesale is not liable for any misuse or misunderstanding of the FastStart® IF product or patient manual. Please call your local representative if any additional assistance is required regarding this product and its patient instructions.



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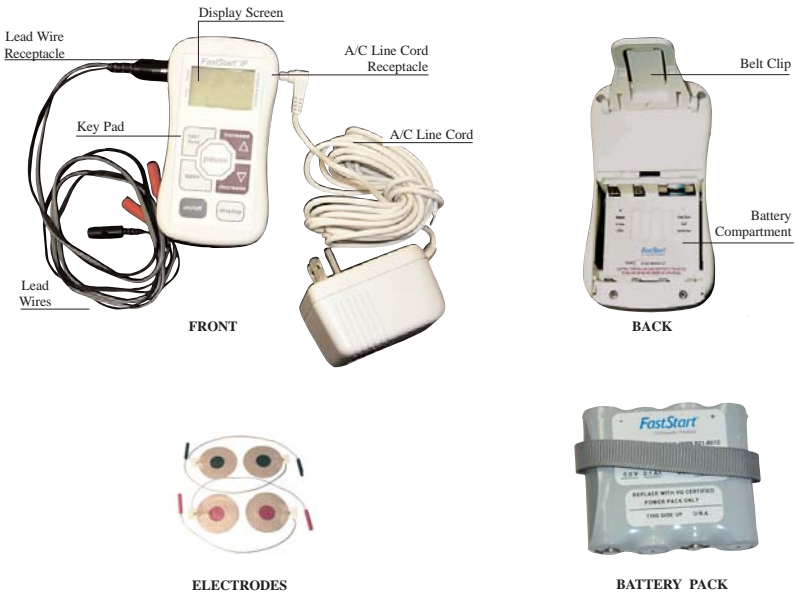
System Components

The FastStart® IF stimulation system is operated with:

- One (1) FastStart IF stimulator
- One (1) package of electrodes
- One (1) lead wire (4 lead)
- Four (4) AA alkaline batteries, or one (1) battery pack

In addition your system comes with:

- One (1) carrying case
- One (1) operating manual
- One (1) AC Adapter



Letter to the Patient

Your physician has selected the FastStart® IF device because it is the most applicable to your specific need.

Your FastStart IF is a portable stimulator that generates small pulses of electrical current that are delivered through lead cables and the electrodes you place on your skin. These electrical pulses pass through your skin and activate underlying nerves. At lower levels of stimulation, the FastStart IF stimulates sensory nerves, producing a tingling sensation. Higher levels of stimulation activate motor nerves, resulting in muscle contractions.

It is important to realize that the FastStart IF is not a substitute for proper medical evaluation and treatment. You should always consult your physician or therapist if you have specific questions or problems regarding the use of your stimulator. Your physician or therapist possesses technical knowledge about the FastStart IF and is familiar with your specific condition and requirements. In addition, always follow the instructions of your physician or therapist to gain the most benefit from your FastStart IF.

Your physician or therapist will instruct you on the correct degree of stimulation and provide you with direction on the proper mode of operation for your condition.

Please read the following sections carefully before using your FastStart IF.

- Precautions and Prescription Information
- Controls and Features
- Treatment Sessions
- Care and Maintenance

Precautions and Prescription Information

NOTE: Please read the following prescription information carefully before using your FastStart® IF. If you have any questions on this information, consult with your physician of therapist before proceeding.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a practitioner licensed by law of the State in which he/she practices to use or order the use of the device.

Indications

- Symptomatic relief and management of postsurgical, acute, or chronic pain.
- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Muscle re-education.
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

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

Contraindication

- Should not be used on patients with cardiac demand pacemakers.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a 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 or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to cancerous lesions.

Precautions

- Safety 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:
 - When there is a tendency to hemorrhage following acute trauma or fracture;
 - Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - Over the menstruating or pregnant uterus; and
 - Over 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.
- Keep out of the reach of children.
- Should be used only with the leads and electrodes recommended for use by the manufacturer.
- Portable stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions

- Skin irritation and burns beneath the electrodes have been reported with the use of stimulators.

Controls and Features

The FastStart® IF can be operated on a tabletop by folding out the belt clip and setting on top of the table. You can also attach the unit to your belt by folding the clip against the unit and fastening the clip over the top of a belt or pants.

ON/OFF Button

Press the On/Off button when you are ready to begin your therapy session. The FastStart IF always turns on with 0 intensity. Pressing the On/Off button at any time during the therapy session will immediately stop stimulation and turn the device off. If you press and hold the On/Off button you will see your serial # displayed on the screen.

Tab/Field Button

Press this button to highlight preset number or intensity to make changes.

Display Button

Press this button to display each of the parameters for the preset. There are four screens of information for each preset.

Save Button

Used by your clinician to set up the unit.

Increase Button

Pressing and releasing or pressing and holding this button increases the intensity of the stimulation. The display will show you in milliamps how high your intensity is set. The range is from 0 to 50 milliamps in 0.5 milliamp increments.

Decrease Button

Pressing and releasing, or pressing and holding this button decreases the intensity of the stimulation. Usually when your treatment is over the unit will turn off automatically. It is not necessary to decrease the intensity to turn the unit off.

Pause Button

Press and release this button to instantly stop stimulation. The device remains on and the timers are paused. Press and release the button a second time to return to the same point in the therapy program. Always pause your treatment before connecting or disconnecting your AC adapter. **If your unit is running press the PAUSE button to pause your treatment before connecting or disconnecting your AC adapter. Press the PAUSE button again to resume your treatment.**

LCD Display

The LCD display will keep you informed about your treatment showing you the following items.

- Left corner will indicate the preset you are using.
- Upper right corner will indicate the time remaining in your treatment.
- Lower left corner will indicate the rate.

- Lower right is your output voltage.
- In between the rows there are flashing bars to indicate the current is flowing.
- Low battery indicator to the left of the preset display.
- Pause indicator to the right of the remaining time display.

Low Battery Indicator

This will flash on when the batteries are nearly depleted, indicating you have approximately 5-30 minutes of battery life left, depending on your parameter settings. Try to replace them as soon as possible. When the batteries are sufficiently depleted, the device automatically shuts itself off.

Belt Clip

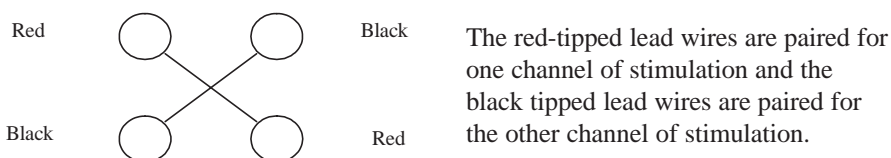
The belt clip is used to attach the FastStart® IF to a belt loop for mobility during a therapy session. By rotating the belt clip to the upper position the FastStart IF can be used as a tabletop device.

Lead Wire Socket

The electrode lead wire is plugged into this socket. There is an index mark on the unit that will align with the index mark on the lead wire.

Lead Wire

The lead wire colors indicate the two channels of stimulation that are commonly crossed in interferential stimulation.



The red-tipped lead wires are paired for one channel of stimulation and the black tipped lead wires are paired for the other channel of stimulation.

Power Supply

For your convenience, the FastStart IF can be operated with an AC adapter. Before connecting or disconnecting the AC Adapter, press the pause button. Then, either connect or disconnect the AC Adapter and press the pause button again to resume treatment. **THE AC ADAPTER WILL NOT CHARGE THE BATTERIES THAT ARE IN THIS UNIT, THESE ARE NOT RECHARGEABLE BATTERIES.** You do not have to remove the batteries to run the unit using the AC adapter. Use of other products' AC adapters, could possibly cause damage to your FastStart IF, use only the AC adapter provided. **If your unit is running press the PAUSE button to pause your treatment before connecting or disconnecting your AC adapter. Press the PAUSE button again to resume your treatment.**

Battery Pack

These packs are designed to make it easier to use your unit with battery power. They must be inserted with the removal ribbon up so you can remove them when they have depleted. These are not rechargeable; please discard when they are completely depleted. These are alkaline batteries and can be discarded in normal waste systems.

Proper Skin Care

CAUTION: DO NOT apply lotion, oils or any other ointments to skin prior to the application of electrodes, unless directed to by your clinician or your dealer representative. Topical agents may increase your risk of skin irritation.

DO NOT clean skin with anything other than soap and water.

DO NOT clean skin with alcohol, alcohol-based cleaners or Iodine-based antiseptic. This may interfere with proper conduction and increase the risk of skin irritation.

By properly caring for skin covered by electrodes, you will:

- Allow more stimulation to reach targeted nerves.
- Prolong the life of your electrodes.
- Reduce the chance that any skin irritation will develop.

To reduce the risk of skin irritation, observe the following instructions for proper skin care before each treatment. However, if skin irritation develops, remove the electrodes, discontinue using your FastStart® IF and consult your physician or therapist.

- Wash all electrode sites with mild soap and water before applying electrodes. **Do not clean with alcohol.**
- Dry your skin thoroughly before electrode application.
- Trim excess body hair from electrode sites with scissors, being careful not to cut (or break) the skin. **Never shave the area you are about to treat!**

Electrodes

- Electrodes should always be placed at least 1 inch apart.
- If your electrodes dry out, you can place a few drops of water on them to remoisten them for continued use.
- After repeated usage, reusable electrodes begin to lose their adhesion, deliver less stimulation and shorten battery life. When this happens and remoistening them does not work, you should replace the electrodes.

Treatment Sessions

1. Insert (4) AA batteries or (1) battery pack into the FastStart® IF as shown in the battery compartment and then replace the battery door. If desired, use the AC adapter that came with your FastStart IF instead of batteries.
2. Prepare the skin: Wash the electrode application sites with mild soap and water then dry skin thoroughly. Remove any excess body hair with a pair of scissors, being careful not to cut your skin.
3. Connect the lead cables to the electrodes. Do not use unnecessary force in connecting the electrodes to the lead wires. If they do not fit, use a different set of electrodes, and return the unusable electrodes to your physician or therapist or whoever supplied you with your unit.
4. Place the electrodes on the sites prescribed by your physician or therapist and press them firmly onto the skin.
5. Insert the end of the lead wire into the FastStart IF.
6. Turn the FastStart IF on by pressing and releasing the On/Off button.
7. To select your preset, press the tab/field button until the preset number is flashing. Then, press increase or decrease to select the preset you want to use. Press tab/field again to set the intensity and begin your treatment.
8. Increase the stimulation intensity level by repeatedly pressing and releasing the Increase button or pressing and holding the Increase button. Continue increasing the stimulation level to the amount prescribed by your physician or therapist.
9. At the end of the prescribed treatment time, the FastStart IF will automatically turn itself off.

When your therapy session is completed

- Grasp the corner of the electrode and gently remove it from your skin; then return it to the plastic storage sheet.
- Replace the electrodes in the plastic storage sheet in the resealable pouch provided.

Care and Maintenance

CAUTION: DO NOT immerse the FastStart® IF stimulator, AC adapter, or batteries in water.

Cleaning

Maintenance, care and cleaning of your FastStart IF are quick and easy procedures when these instructions are followed.

Clean the outside of the FastStart IF casing as needed with a damp cloth and mild soap. Never immerse your stimulator or batteries in water, alcohol or other fluids since this could seriously damage the internal electronics. Avoid using cleaning fluids or solvents to remove stains and dirt because such liquids may damage the casing.

Storage

When not in use, store your FastStart IF in its carrying case to prevent inadvertent damage. During periods of prolonged storage, remove all batteries to prevent possible damage caused by battery leakage or corrosion.

Battery Information

Safety considerations: Only use battery packs provided by VQ Wholesale. Do not mix rechargeable battery packs with alkaline battery packs. Never attempt to recharge alkaline battery packs as an explosion may occur.

CAUTION: Always use the battery packs that are provided with your FastStart IF. For your safety, never attempt to recharge an alkaline battery, as this may result in an explosion. Never mix alkaline with nickel-cadmium batteries.

Technical Data and Specifications

Physical

Power Source: One (1) FastStart battery pack
or FastStart AC Adapter
Size: 5.25" x 2.8" x 1.75" (including belt clip)
Weight: 10.8 oz. with batteries

Electrode

Use with any electrode approved for use with electrical stimulators

Electrical

Tolerances: All electrical specifications are $\pm 10\%$ into a 500 Ohm load impedance for each channel and using the AC Adapter, unless stated otherwise.

Treatment Timer: 5 min - 8:00 hours in 5 min increments or continuous

Compliance Timer: 0-999 hrs, 59 min (41.66 days) in 1 min intervals
Not changeable by patient.

Number of Preset Programs:

Preprogrammed: 5
Available presets: 20

User Interface

Custom LCD Display - 2 rows of 8 characters

Indicators for Low Battery & Pause

Flashing indicator to show current flow

Output Type

IF Interferential

NM Neuromuscular Interferential (Same as IF but uses a six second on/off cycle)

There is a 2 second ramp-up time for each cycle of stimulation.

Pulse Intensity

0-50 mA peak in .5 mA increments

Technical Data and Specifications (cont.)

Pulse Shape

Standard (4 electrode) 2 channels each having square wave outputs
Premodulated (2 electrode) One channel with rectangular waves
Output is only in channel 2 (black leads)

Carrier Frequency

4000 Hz

Pulse Duration

Standard Fixed at 125mSec
Premodulated 5-125mSec

Beat Frequency

0-150 bps in 1 bps increments

Sweep Modes

	<u>Rate</u>	<u>Speed (seconds up/down)</u>
S1	1-20	15
S2	1-150	15
S3	80-150	15
S4	1-20	30
S5	1-150	30
S6	80-150	30

Pulse Coordination Modes

Number of Modes

5

Modes

C Continuous
1|1 60% of set frequency for 1 second
then 160% for 1 second
6|6 60% of set frequency for 6 seconds
then 160% for 6 seconds
6/6 60% of set frequency then ramps
to 160% of set frequency in six
seconds. The next six seconds it
ramps from 160% to 60%. This
cycle repeats every six seconds
NM 6 seconds ON time; 6 seconds OFF
time. 2 seconds ramp up.

Automatic Switching to Next Preset

Preset 1-20 or OFF

Waveform

Output of Carrier Frequency

Figure 1

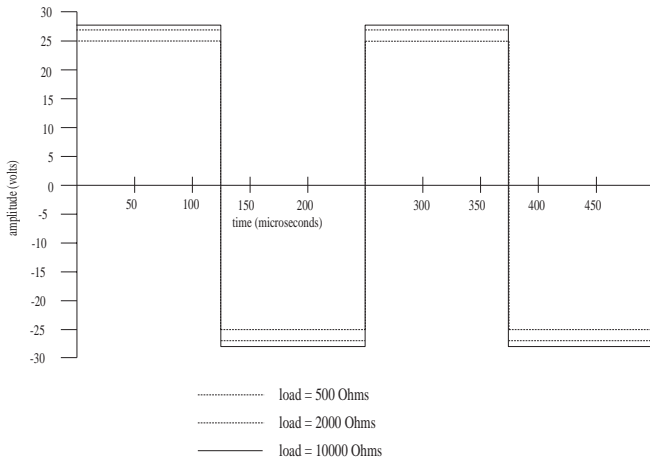


Figure 1: Electric output of carrier frequency with various loads with Amplitude Control set at 50% of maximum.

IF Mode

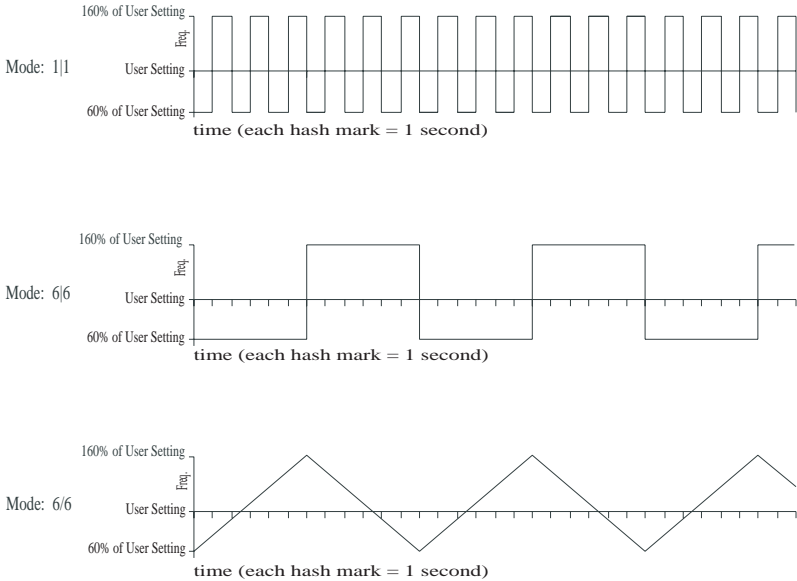


Figure 2: Electric output of carrier frequency on 1000 ohm resistive load with Amplitude Control set at 50% of maximum. Note constancy of voltage relative to Figure 1.

NMES Mode

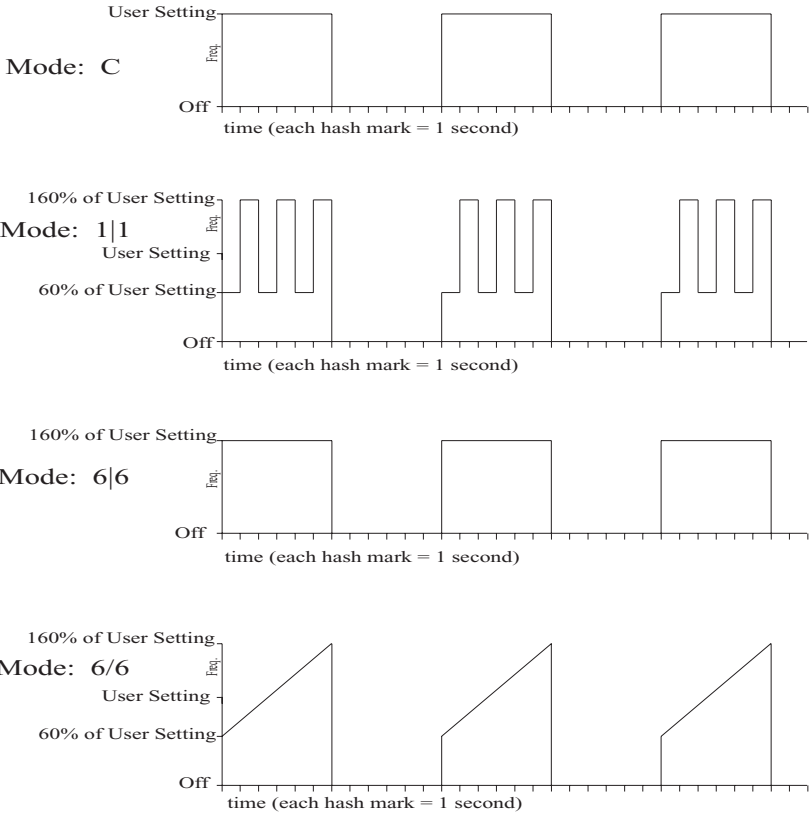


Figure 3: Voltage (top) and current (bottom) outputs of carrier frequency on 1K AAMI load (mimicking skin impedance).

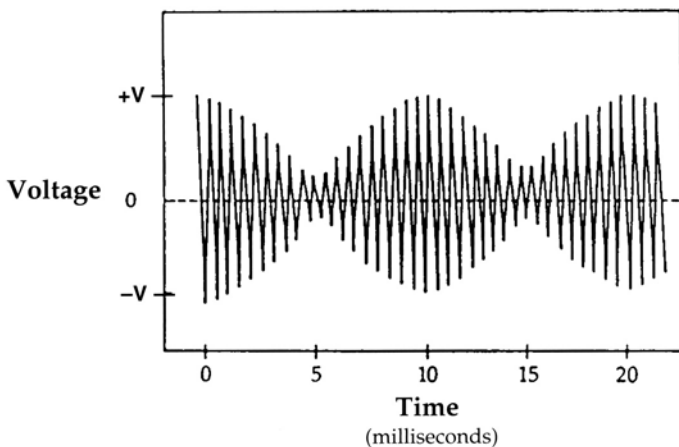


Figure 4: Electrical output during bipolar (2-electrode) stimulation measured across the capacitive element of the AAMI load. This shows the interaction of the carrier frequency and adjustable frequency which takes place internal to the stimulator. The interference frequency is evident as an “envelope” of stimulation occurring at 100 Hz. This figure is provided to illustrate interferential stimulation, but does not correspond exactly to the output which an oscilloscope would record with a skin load.

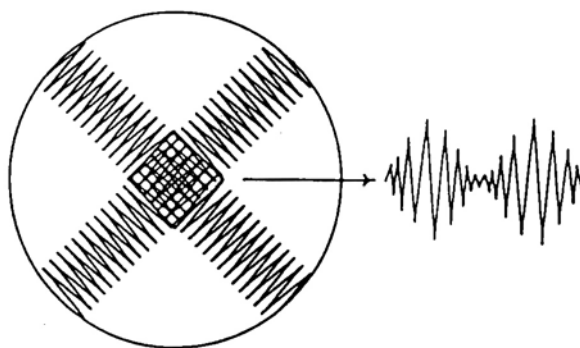


Figure 5: A conceptual diagram of quadrapolar (4-electrode) stimulation with interference taking place within the tissue.

Warranty

VQ Wholesale warrants the FastStart® IF to be free from electrical circuit defects in workmanship and materials for a period of three (3) years upon shipment. The casing and belt clip are warranted to be free from defects in workmanship and materials for one (1) year upon shipment. VQ Wholesale will repair or replace, at its facilities, any units found to have become defective within the warranty period.

This warranty does not apply to accessories, specifically lead wires, electrodes, batteries, tapes, gel, carrying case, AC adapter or other accessories, nor does it apply to stimulators which have been damaged due to misuse, or repaired or altered other than by VQ Wholesale at its facilities.

This warranty is in lieu of any other warranties expressed or implied. No person or entity is authorized to bind VQ Wholesale to any representation of warranty other than those specifically set forth herein.

