

FastStart® HVPC



Patient Operating Manual

VQ Wholesale is not liable for any misuse or misunderstanding of the FastStart® HVPC 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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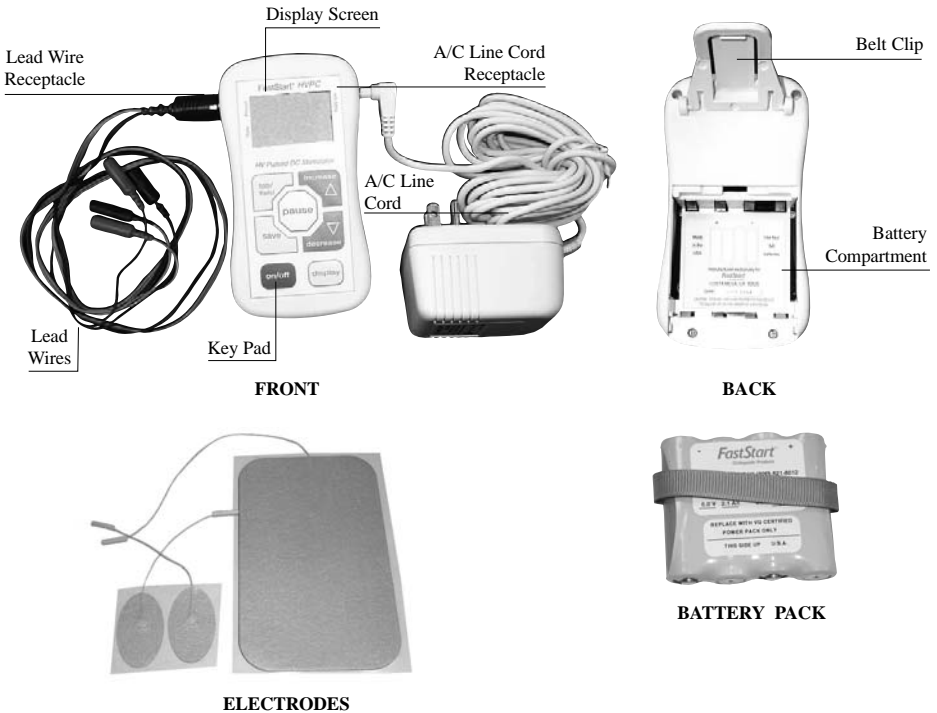
System Components

The FastStart® HVPC stimulation system is operated with:

- One (1) FastStart HVPC stimulator
- One (1) package of electrodes
- One (1) lead wire
- 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® HVPC device because it is the most applicable to your specific need.

Your FastStart HVPC 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 HVPC 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 HVPC 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 HVPC 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 HVPC.

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 HVPC.

- 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® HVPC. If you have any questions on this information, consult with your physician or 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

- 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

ON/OFF Button

Press the **on/off** button when you are ready to begin your therapy session. The stimulator 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.

Preset Selection

Your clinician has set at least one preset in your unit. If you have more than one preset you can access the various presets by pressing the **tab/field** button until the preset number is flashing then press the **increase** or **decrease** buttons to select presets. When you get to the preset you want to use then press the **tab/field** button again until the “0V” number is flashing.

Your clinician may set your device for a preset selection that includes a “sleep” mode. In this preset, the device will run through a stimulation session following by a period of rest or “sleep” where there will be no stimulation for a set period of time. The screen will display the countdown of time in “sleep” mode as indicated below. When finished, your device will run a stimulation preset again and may repeat several times as prescribed by your clinician.

2	*0:01
20	SLEEP

Tab/Field Button

Used to view preset and preset settings.

Increase Button

Pressing and releasing the **increase** button increases the intensity of the stimulation. The display will show you in volts how high your intensity is set. The range is from 0 to 330 volts in 5 volt increments.

Decrease Button:

Pressing and releasing, or pressing and holding the **decrease** 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 the **pause** 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.

Save Button

The **save** button is used by your clinician to setup the unit.

LCD Display

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

- Upper 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 frequency of stimulation.
- Lower right will indicate output voltage.
- In between the rows there are flashing bars to indicate that the current is flowing.
- An asterisk * may be illuminated to indicate that another preset will follow.
- Low battery indicator is to the left of the preset display.
- Pause indicator is to the right of the remaining time display.

Low Battery Indicator

This will flash when the batteries are nearly depleted. This will indicate you have anywhere from 30 minutes to 2 hours 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 stimulator to a belt loop for mobility during a therapy session. By rotating the belt clip to the upper position the stimulator can be used as a table top device.

Controls and Features (cont.)

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.

Power Supply

For your convenience, the stimulator 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. BATTERIES ARE NOT RECHARGEABLE.** 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 stimulator. Use only the AC adapter provided.

Battery Pack

These packs are designed to make it easier to use your units on battery power. They must be inserted with the removal ribbon up so you can remove them when they have depleted. These batteries 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

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 of skin irritation

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 stimulator 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, be careful to not cut (or break) the skin. **Never shave the area you are about to treat!**

Electrodes

- If your electrodes dry out, you can place a few drops of water on each electrode and gently rub the water in to remoisten.
- After repeated usage, reusable electrodes begin to lose their adhesion, deliver less stimulation and shorten battery life. When this happens and remoistening does not work, you should replace the electrodes.

Treatment Sessions

1. Insert (four) AA batteries or (one) battery pack into the stimulator as shown in the battery compartment, then replace the battery door.
If desired, use the AC adapter that came with your stimulator instead of batteries
2. Prepare the skin: Wash the electrode application sites with mild soap and water, then dry your 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 stimulator.
6. Turn the stimulator on by pressing and releasing the **on/off** button.
7. If you have more than one preset you can access the various presets by pressing the **tab/field** button until the preset number is flashing then press the **increase** or **decrease** buttons to select presets. When you get to the preset you want to use, press the **tab/field** button again until the “0V” number is flashing.
8. Increase the stimulation intensity level by repeatedly pressing and releasing 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 stimulator 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 re-sealable pouch provided.

Care and Maintenance

CAUTION: Do not immerse the FastStart® HVPC stimulator, cables, AC adapter, or batteries in water.

Cleaning

Clean the outside of the stimulator 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 stimulator 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 stimulator. Do not use rechargeable nickel-cadmium batteries. They will not provide proper performance from your stimulator. For your safety, never attempt to recharge an alkaline battery, as this may result in an explosion. Never mix alkaline with nickel-cadmium batteries.

Note for your safety: It is not possible to change batteries and to run the stimulator at the same time.

Technical Data and Specifications

Physical

Power Source: One (1) battery pack or AC adapter
Size: 5.2" x 2.8" x 1.75" (including belt clip)
Weight: 9.3 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: 1 min – 8:00 hours or continuous

Total Hour Timer: 0-999hrs, 59min (41.66 days) in 1 min intervals

Number of Preset Programs

Therapist Accessible: 20
Patient Accessible: 1-20 programmable

User Interface

Custom LCD display – 2 rows of 8 characters
Indicators for low battery and pause
Flashing indicator to show current flow

Pulse Intensity

0-330 Volts peak in 5 V increments

Pulse Shape

Exponential spikes delivered in pairs

Pulse Duration

5 μ sec per pulse @ 50% of pulse amplitude

Pulse Frequency

0-150 Hz in 1 Hz increments

Frequency Modulation

- S-1 Modulates 1-150 over 40 seconds
- S-2 Modulates 10-20 over 40 seconds
- S-3 Modulates 80-150 over 40 seconds

Simultaneous or Alternating Modes

7 second alternate with 2 second ramp up

Selectable Polarity

Positive or negative out of the active lead (red lead)

Automatic Switching to Next Preset

1-20 Presets or OFF

Waveform

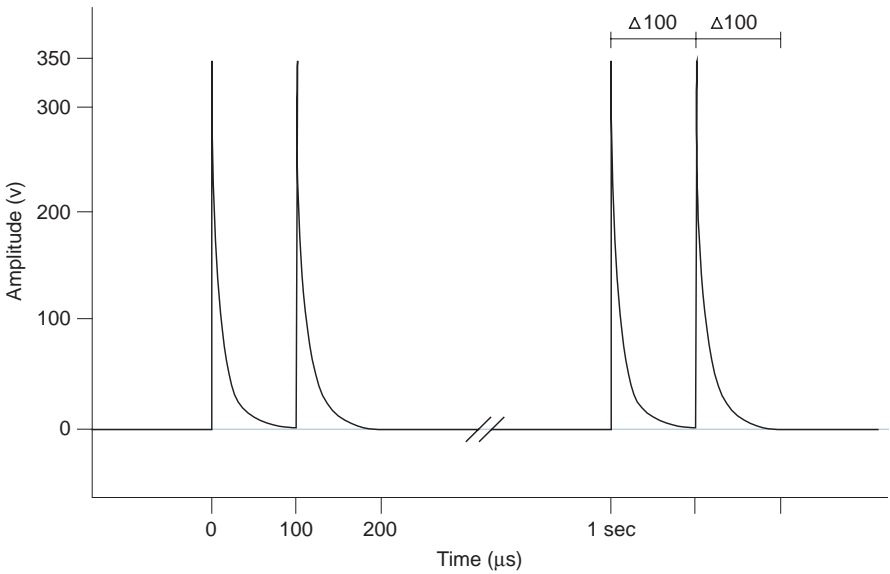


Figure 1 - HVPC Stimulation

This drawing shows the output waveform in the HVPC stimulation mode at maximum amplitude (330V). The waveform is shown with a purely resistive load of 500 Ohms. The stimulation on each channel looks the same. The signal repeats at a period of time equal to the reciprocal of the rate. The rate for this waveform is 1 Hz.

Notes:

Notes:

Warranty

VQ Wholesale warrants the FastStart® HVPC to be free from electrical circuit defects in workmanship and materials for a period of three (3) years upon shipment. The casing, knobs 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 damaged due to misuse, 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.

