

- ACCESSORIES:**
- 2 Red leadwire cables for Active Channels
 - 1 Black leadwire cable for Dispersive Channel
 - 4 AA Batteries/optional wall adaptor
 - 4 Active Electrodes
 - 1 Dispersive Electrode

- SPECIFICATIONS:**
- Size:** 2.75" x 4.5" x 1.5"
(6.9 cm x 11cm x 3.8cm)
- Weight:** 8.1 oz. (229 grams)
- Channels:** 2 active outputs; 1 dispersive return
- Waveform:** Pulsed Galvanic twin peak monophasic delivered in pairs.
- Pulse Rate:** 1-100 Hz
- Pulse Width:** Interpulse intervals of 100 microseconds. 5 Microseconds at 50% of peak voltage
- ON Time:** Continuous mode or 5 seconds fixed on alternating mode
- OFF Time:** 5 seconds fixed on alternating mode and continuous on continuous mode.
- Output Voltage:** 0-350 volts adjustable

- Output Current:** Adjustable 0-700 mA peak
- Polarity Switch:** Positive and negative of active electrodes.
- Stimulation:** Continuous alternating: On for 5 seconds and Off for 5 seconds.
- Timer:** 15, 30, 60 min
- Indicator Light:** Two, one for each active output
- Power Source:** 4 AA or optional wall adaptor
- Electrodes:** 1 dispersive pad, 2 pair 2" oval (5 cm oval)

- Lead Wires:** 1 dispersive 72" (1.8m), 2 pair 72" (1.8m)
- Tolerances:** +- 10%

Graphic Symbol Definitions

Refer to operating instructions

An IEC 601-1 safety standard (type BF)

We herewith declare that the above mentioned product meets the provisions of the Medical Device Directive

Patient Safety Information

Please read the following prescription information carefully before using the GV 350®. If you have any questions about this information, consult with your clinician before proceeding.

Caution: Federal law (USA) restricts the sale by, or on the order of, a physician so licensed by the State. Keep out of reach of children.

Adverse Reactions: Improper use of stimulation may result in skin irritation and burns beneath the electrodes.

Indications: High Voltage Pulsed Current (HVPC) devices should only be used under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.

HVPC Applications: Maintain or increase range of motion. Prevent or retard disuse atrophy. Reeducate muscles. Relax muscle spasms. Increase local blood circulation. Prevent venous thrombosis by immediate post-surgical stimulation in selective muscles

Contraindications: Cardiac Pacemakers: HVPC should not be used on patients with demand-type cardiac pacemakers. Cancer Patients: Do not use HVPC on cancer patients.

Warnings:

Heart Patients: Adequate precautionary measures should be taken prior to using HVPC on patients suspected of having heart disease. Transthoracic Stimulation: Use caution in transthoracic application of HVPC as introduction of electrical current may Transcerebral Stimulation: do not apply HVPC transcranially. Epilepsy: Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy. Children: HVPC devices should be kept out of reach of children. Carotid Sinus: Do not use HVPC over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex. Neck Stimulation: Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are placed across the neck or the mouth. This may be strong enough to close off the airway or cause difficulty in breathing. Machinery Operation: Patients should never operate potentially dangerous machinery such as power saws, automobiles, etc. during HVPC stimulation. Pregnancy: The safety of HVPC stimulation during pregnancy, labor or delivery has not been established for either mother or fetus. Skin and Vascular Problems: Do not use HVPC over swollen, infected or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis or varicose veins. Long-Term Effects: The long-term effects of chronic use of HVPC are unknown. Skin Irritation: Some patients may experience skin irritation hypersensitivity due to electrical stimulation or the electrical conductive medium used. Should this occur, remove the electrodes, discontinue stimulation and consult your clinician to determine the cause of irritation. Irritation may be reduced by alternate conductive medium or alternate electrode placement.

Precautions: Skin irritation may occur under electrodes in isolated cases following long-term application. Consult physician if skin irritation develops. The effectiveness of HVPC Stimulation directly depends upon patient selection. Do not immerse in water or other liquids. EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

Adverse Effects: Skin irritation or electrode burns have been reported with the use of electrical muscle stimulators.

Additional Precautions: Do not immerse unit in water or other liquids. Turn unit off when applying or removing electrodes. Do not use the stimulator on any muscles or for any purpose other than that for which it was prescribed. Do not use the device on any individuals other than those for whom the device has been prescribed. Stimulation over areas where bone is near the skin can be painful in some patients. Be sure to adjust amplitude slowly. If HVPC treatment is ineffective or unpleasant, discontinue therapy and consult your physician or therapist. For external use only. Do not use over the eyelids.

The Controls

The amplitude (voltage) and pulse rate mode selectors operate independently of each other, but interact to achieve a stimulation pattern which is unique to HVPC Stimulation. As individual syndromes differ, the controls are adjusted to a setting which gives optimal relief. There is no benefit to painful stimulation.

(1) Amplitude (Voltage) Control
Slide the button forward on the left side of the GV 350® case to raise the Amplitude dial. This controls the strength of the electrical stimulation delivered through both Active electrode outlets. The numeric values on the control dial correspond to output stimulation in volts. Slowly turn the Amplitude (voltage) control dial clockwise until you achieve the amount of stimulation prescribed by your health professional. After adjustment, push dial back into unit.

(2) Rate Control
Slide the button forward on the right side of the GV 350® case to raise the Rate dial. This controls the number of pulses delivered each second through both Active electrode outlets. The numeric values on the control dial indicate the number of pulses delivered per second. Set the dial to the position your health professional has indicated. After adjustment, push dial back into unit. The Active (red) and Dispersive (black) lead wires are plugged into the appropriate Active or Dispersive outlet (red lead wire into red outlet, black lead wire into black outlet).

(3) Active Electrode Outlets
The GV 350® can be used with one, two, three or four active electrodes. If your clinician has prescribed using only one active electrode, the red lead wire can be plugged into either red Active electrode outlet (A1 or A2). To form a complete circuit that delivers stimulation, one dispersive electrode must be used.

(4) Dispersive Electrode Outlet
One black lead wire is plugged into the Dispersive electrode outlet (DIS.). One dispersive electrode must be used with either one, two, three or four active electrodes to form a complete circuit that delivers stimulation.

(5) Active Electrode Indicator Lights
An indicator light is located near each of the two Active electrode outlets. When the GV 350®'s Amplitude is turned "On," each light will glow when stimulation is being delivered through its respective outlet. With the C/A switch set at the Continuous position, both lights will glow green, indicating that stimulation is being delivered continuously through both outlets. With the C/A switch set at the Alternating position, the two lights will glow green alternately in a 5-second "On," 5-second "Off" cycle.

(6) Low Battery Indicator Light
The Low Battery indicator light will glow amber when there is insufficient power to run the GV 350® (replace

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with new AA batteries). When the GV 350® is turned on or off, the light may flash for a few seconds. A slide-on panel covers the Polarity switch, Continuous/Alternating switch, Timer and Battery compartment. Your health professional may wish to set these controls for you and may request that you leave the cover in place, except to change the batteries or to set the timer. To remove the cover, simply press cover slightly and slide down. To place batteries in the battery compartment, slide panel down to expose compartment. Insert 4 AA batteries*. Be sure to observe the polarity directions imprinted in the battery compartment. Although it is not recommended, if you choose to use rechargeable Ni-Cad batteries, insert all AA Ni-Cads into an AA charger unit. Plug charger into standard 110 volt electrical outlet. Fully charging will take 14 - 16 hours. Never attempt to recharge an alkaline or standard battery. To maximize the peak efficiency of the Ni-Cad batteries, allow them to run all the way down before recharging.

(8) Positive/Negative Switch

The Positive/Negative (+/-) switch determines the polarity of the Active electrodes. When the switch is set in the Positive position (+), the Active electrodes will be positive; when set in the Negative position (-), the Active electrodes will be negative. Your health professional will tell you which setting to use. *Optional wall adaptor with 12' cord negates the necessity of using batteries.

(9) Continuous/Alternating Switch

The Continuous/Alternating (C/A) switch determines whether the two Active electrode outlets provide stimulation Continuously or in an Alternating mode. Your health professional will tell you which setting to use. In the Continuous mode (C), stimulation is delivered continuously. In Alternating mode (A), each active electrode is "On" for five seconds and "Off" for five seconds. If only one active electrode is used, the Alternating mode produces a 5-second "On"/ 5-second "Off" stimulation pattern.

(10) Timer Switch

The Timer switch determines the length of your treatment. Move switch to the time your health professional prescribed.

(11) Belt Clip

The Belt Clip permits you to wear the GV 350® by fastening it to your belt or another piece of apparel. Electrodes Follow the instructions on the package of electrodes that are provided with the GV 350®. Use only BioMedical Life Systems, Inc. approved accessories. Non-approved accessories may damage your device. Improper use of electrodes may cause burns. Care should be exercised to use only electrodes specified by BioMedical Life Systems, Inc. Always apply electrodes to the skin area as prescribed by your Health Professional. Do not use old electrodes that do not adhere or fail to provide proper stimulation.

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Patient and Clinician Guidelines

Step 1

Slide the Battery cover (7) down to expose Control switches and Battery compartment.

- A. Insert batteries as indicated.
- B. Set Polarity switch (8) as recommended by your health professional.
- C. Set the Continuous/Alternating switch (9) as recommended by your health professional.
- D. Set the Timer switch (10) to the desired treatment time.
- E. Close Battery cover (7).

Step 2

Attach lead wires to electrodes, and place electrodes firmly to your body as you were shown by your health professional.

Step 3

Slide the switch on the side of the device to raise the Amplitude (voltage) dial (1). Make sure the Amplitude is in the "0" (Off) position.

Step 4

Slide the switch on the side of the device to raise the Pulse rate dial (2). Set the dial to the position your health professional has indicated. After adjustment, push dial back into device.

Step 5

Insert Active lead wires (red) into red Active outlet (3). Insert Dispersive lead wire (black) into black outlet (4).

Step 6

Slowly turn on the GV 350® by turning the Amplitude dial (1) in a clockwise direction. Turn up to the desired strength your health professional has indicated to you.

Step 7

The GV 350® is equipped with a Belt clip (11) that can be attached to a belt or waistband.

Step 8

At the end of treatment

- A. Turn off device.
- B. Unplug lead wires.
- C. Disconnect electrodes from lead wires.
- D. Store electrodes according to the instructions on the electrode package.

Maintenance and Care

Alcohol is suitable for cleaning the device.
NOTE: Do not smoke or work with open lights (for example, candles, etc.) when working with flammable liquids!
Stubborn stains and spots can be removed with a cleaning agent.
Do not submerge this device in any liquid or use excessive cleaning liquid when cleaning the surface area.
If the device is not to be used for a long period of time, remove the battery from the battery compart-

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ment unless there is no risk of a SAFETY HAZARD arising (acid can leak from old and used batteries and damage the device). Batteries should be disposed of in the proper manner.

Please Note: Use only BioMedical Life Systems, Inc. approved accessories. Non-approved accessories may damage your device.

Caution: Improper use of electrodes may cause burns. Caution should be exercised to use only electrodes specified by BioMedical Life Systems, Inc.

Warranty

LIMITED THREE-YEAR WARRANTY (U.S. Only)*

BioMedical Life Systems, Inc. promises to the original consumer-purchaser to repair or, at the option of BioMedical Life Systems, Inc., to replace any neuro-stimulator which malfunctions or proves defective in materials or workmanship under normal use for a period of three years from the date of purchase. During the three years, BioMedical Life Systems, Inc. will provide all labor and parts necessary to correct such defects or malfunctions free of charge. It is the duty of the consumer-purchaser to deliver the unit to a service facility of the factory as described under service.

EXCLUSIONS

This warranty shall not apply to damage resulting from failure to follow the operating instructions in the user manual, accident, abuse, alteration, or disassembly by unauthorized personnel. This warranty does not extend to accessory items such as rechargeable batteries, electrodes, electrode leads, and conductive gel which are not an integral part of the stimulator. These items can be provided by your service representative, but costs for repair or replacement will be the responsibility of the consumer-purchaser. BioMedical Life Systems, Inc. shall not be liable for incidental or consequential damages resulting from the sale or use of the unit. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.


WARNING

Only use accessories, electrodes, lead wires and batteries approved by BioMedical Life Systems, Inc.

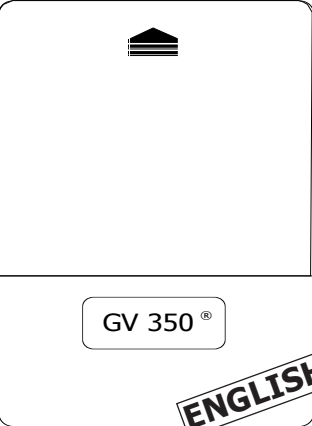
NO OTHER WARRANTIES

This limited warranty is the only express warranty given by BioMedical Life Systems, Inc. Implied warranties, including, but not limited to, warranties of merchantability and fitness for a particular purpose are limited to the warranty period set forth above. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have rights which vary from state to state.

*For more detailed information on limited three-year warranty, please contact our *Customer Service Department. Outside USA, please contact your distributor.


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BioMedical Life Systems, Inc.
Galvanic Stimulator
GV 350®



Instructions

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GV350. ENGLISH 08/25/2006 REV.A