

Galvanic Vestibular Oscillating Stimulator

Model 0809



Operator's Manual

Version 1
December 2015

NOTICE

THE FOLLOWING MATERIAL IN THIS MANUAL IS EXCLUSIVELY FOR INFORMATIONAL PURPOSES. THE CONTENT AND THE PRODUCT IT DESCRIBES ARE SUBJECT TO CHANGE WITHOUT NOTICE. IN NO EVENT WILL **SOTERIX MEDICAL INC.**, BE LIABLE FOR THE DAMAGES ARISING FROM OR RELATED TO THE USE OF THIS MANUAL OR THE PRODUCT IT DESCRIBES.

CAUTION

As an ultimate user of this apparatus, you have the responsibility to understand its proper function and operational characteristics. This operator's manual should be thoroughly read and all operators given adequate training before attempting to place this unit in service.

Awareness of the stated cautions and warnings and compliance with recommended operating parameters – together with maintenance requirements – are important for safe and satisfactory operation. The unit should be used for its intended application. Recommended accessories should be used while using this system.

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Contents

Page Title Page

- iii. Notice
- iv. Caution
- vi. Contents

Introduction

- 2. Intended Use
- 4. Getting to Know the Product
- 5. Use of This Manual

Health and Safety

- 7. Precautions and Warnings
- 10. Regulatory Statements

Product Description

- 12. Items Supplied
- 13. Front Panel
- 14. Back Panel
- 15. Control Keys

Device Operation

- 18. Inserting and Replacing the Batteries
- 20. Description of Special Features
- 22. Pre-Stimulation Setup
- 26. Stimulation Procedure

Specifications and Warranty

- 30. Specifications
- 30. Electrical and Operating Characteristics
- 30. Storage and Operating Conditions
- 31. Warranty
- 32. Maintenance and Disposal
- 33. Definition of Symbols Used

Further Information

- 36. Bibliography
- 41. Contact Information

Introduction

Intended Use - 2

Getting to Know the Product - 4

Use of this Manual - 5

This chapter introduces you to the basics required to use this manual fully as well as operate the **Soterix Medical** Galvanic Vestibular Stimulation (GVS) device.

Overview:

This section gives a description of the process of Galvanic Vestibular Oscillating Stimulation.

Getting to Know the Product:

Read this section to learn what sets the **Soterix Medical** GVS apart from the rest.

Use of this Manual:

Refer to this section for information on how this manual is organized as well as an explanation of the symbols used throughout the manual.

Intended Use

Galvanic Vestibular Stimulation (GVS) is a non-invasive procedure in which a device sends a small current across the mastoid to modulate the vestibular system. The modulation of function depends on the modality of the application, which can be direct (Direct Current Stimulation, DCS), pulsed (Pulsed Current Stimulation, PCS), or oscillating direct (Oscillating Direct Current Stimulation, ODCS). For DCS, when the extremely low level current passes from the anode to the cathode, it may alter the firing pattern of the canal afferents leading to changes in human balance control. For biphasic PCS, electrode polarity is not an issue as current reverses its direction at regular intervals.

The most common GVS mode is the *bilateral bipolar* mode in which the anode is placed on the mastoid process behind one ear and the cathode behind the other ear. The direct current signal (DCS) originating from the semicircular canals during bilateral bipolar GVS evoke a large roll and small yaw toward the cathodal side. This may cause subjects to sway toward the anodal side likely due to the appropriate balance response. Another mode called *bilateral monopolar* uses electrodes of the same polarity on the mastoid process with a distant reference electrode. This GVS mode with DCS is shown to produce a semicircular canal signal of a small backward pitch with no roll component causing subjects to sway backward with anodal GVS on both sides and subjects swaying forward with cathodal GVS on both sides. Yet another mode called *unilateral* comprises of stimulating electrode in one mastoid while the non-stimulating electrode is placed at a distant region such as arm or the forehead. This mode of GVS with DCS has been shown to evoke sway responses with an oblique trajectory. The lateral component of the oblique sway produced by unilateral GVS mode is either towards the anodal electrode or away from a cathodal electrode.

GVS dose can be defined as: 1) The size and position of the electrodes on the body and 2) For DCS, the main determinants are intensity, duration, and electrode polarity. For ODCS, the main determinants are intensity, duration, electrode polarity, and frequency. While for PCS, the main determinants are intensity, duration, and frequency. **Soterix Medical** engineers and scientists can work with you to determine the best configuration for your application. **Note:** GVS is an investigational technique

and it is the responsibility of the operator to determine the appropriate GVS dose for a particular application.

GVS safety is supported by medical literature to have common side effects limited to mild and reversible skin itching and tingling, when using standard GVS protocols and guidelines. **Soterix Medical** GVS stimulators and electrodes are uniquely designed to minimize skin irritation – for example, the exclusive SMARTscan-ES™ feature provides a simple indicator to the operator of the contact conditions before, during, and after stimulation.

GVS comfort can be controlled by the operator by using devices, such as the **Soterix Medical** GVS Stimulator, which are specifically designed for clinical GVS. For example, the unique RELAX feature available on all **Soterix Medical** GVS models is designed to accommodate subject feedback without stopping stimulation.

GVS protocol, clinical results, and safety data can be better understood by consulting the papers found in the bibliography at the end of this manual.

Getting to Know the Product

Thank you for purchasing a **Soterix Medical** Galvanic Vestibular Oscillating Stimulator. Unlike other stimulators, the **Soterix Medical** stimulators are simple to use and designed especially for GVS.

The **Soterix Medical** GVS stimulator is designed to generate low levels of current between the electrodes placed on the body. For direct current (DCS) and oscillating direct current (ODCS), the anode is the positive electrode from which current from the device enters the body, while the cathode is the negative electrode from which current exits the body and returns to the device. For bipolar pulsed current (PCS) application, electrode polarity is not an issue as current reverses its direction at regular intervals.

Provided **Soterix Medical** GVS accessories allow for simple and comfortable positioning of the electrodes on the body. The operator must set the waveform desired (DCS or PCS), frequency of stimulation (for DCS, 0 Hz is set automatically), duration of stimulation (in seconds or minutes), intensity of current (in units of mA), active or sham setting, and finally waveform polarity (unipolar setting generates oscillating direct current wave) before initiating the stimulation. For duration and intensity selection, there are four settings. For waveform, there are two settings, while for frequency, desired value can be freely selected.

Clinicians and researchers choose the **Soterix Medical** GVS devices to:

- 1) Ensure reproducible and precise GVS operation across subjects and time.
- 2) Provide for simple and comfortable GVS set-up and stimulation.
- 3) Conduct clinical studies with state-of-the-art control and safety features.

The **Soterix Medical** GVS stimulators includes several proprietary features to enhance GVS safety and subject comfort including TRUE CURRENT™, SMARTscan-ES™, and RELAX. By reading this manual and understanding these unique features, operators of the **Soterix Medical** GVS stimulator can enhance the efficacy and comfort of GVS.

Use of This Manual

This manual contains details of installation, setup, and operation of the **Soterix Medical** GVS unit and its accessories. This manual must be read in its entirety before commencing any stimulation with the **Soterix Medical** GVS unit. If the instructions in this manual are not precisely followed, the performance of this product and/or the safety of the user and/or patient may be compromised. If you have any questions, comments, or concerns, please contact **Soterix Medical** before starting use of the device.

The consequences that could result from failure to observe the precautions listed in this section are indicated by the following symbol:



This icon marks warnings, information that should be read before using this **Soterix Medical** product to prevent possible injury.

Health and Safety

Precautions and
Warnings - 7

Regulatory
Statements - 10

This chapter dictates the required precautions for both you and your patient's safety.

Precautions and Warnings:

Read this section for the important list of precautionary measures required to operate this device.

Regulatory Statements:

This is where you will find the regulatory statements for certain countries, which determines how you may use this device under federal law.

Precautions and Warnings

To prevent damage to your **Soterix Medical** product or injury to yourself or to others, read the following safety precautions in their entirety before using this equipment. Keep these safety instructions where all those who use the product can easily access them.

- Environment and Moisture
 - Do not immerse the **Soterix Medical** GVS Stimulator in water or any other fluids.
 - The **Soterix Medical** GVS Stimulator should not be used in a moist environment or if any parts of the stimulator are damp or wet.
 - The **Soterix Medical** GVS Stimulator is not certified for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. The consequences of using the **Soterix Medical** GVS Stimulator near flammable atmosphere are unknown.
 - The **Soterix Medical** GVS Stimulator is not certified for use in an environment with strong magnetic fields (including, but not limited to, MRI). The consequences of using the **Soterix Medical** GVS Stimulator in a strong magnetic environment are unknown.
 - Do not use any electronic device such as communication or entertainment devices (i.e. GSM/CDMA cellular phones or cordless phones, MP3 players) while the **Soterix Medical** GVS Stimulator is being used. The consequences of potential interference from communication and entertainment devices on the **Soterix Medical** GVS Stimulator are unknown.
 - Do not use the **Soterix Medical** GVS Stimulator if it was transported or stored at temperatures outside of the specific range indicated in this manual. The consequences of using the **Soterix Medical** GVS Stimulator after it is been transported or stored at temperatures outside of the specific range are unknown.
- External Damage
 - Do not drop the device.

- The **Soterix Medical** GVS Stimulator should not be used if there are any signs of external damage.
- Carefully inspect the device on arrival and prior to each use.
- If any controls or displays are not working as indicated in this manual, do not use the **Soterix Medical** GVS Stimulator. Immediately return the device to **Soterix Medical Inc.** for repair.
- Cables
 - When connecting cables to the output jacks, use only the cables provided or sold by **Soterix Medical Inc.** to maintain compliance with product regulations.
 - Make sure all cables are fully inserted in the correct receivers before operating the **Soterix Medical** GVS Stimulator.
- Irritation
 - Use only approved **Soterix Medical Inc.** Galvanic electrodes and head strap indicated for use with the **Soterix Medical** GVS Stimulator. Do not modify the electrodes or strap.
 - The **Soterix Medical** GVS Stimulator may cause minor and transient irritation, discomfort and redness at the electrode sites. If irritation persists, consult your clinician.
 - Do not place the **Soterix Medical** GVS electrodes over previously irritated, burnt, or damaged skin.
 - Since electrode current density (injected current) has been shown to be an indicator of skin irritation, it is recommended to use specific Galvanic electrodes for >2 mA current application. Contact **Soterix Medical** for more information. There is no single “safe” current density for all applications. It is the responsibility of the operator to ensure the chosen current density is appropriate for a given application prior to stimulation.
- Internal Parts
 - Do not disassemble. Touching the product's internal parts could result in injury. In the event of a malfunction, only a qualified technician should repair the product from **Soterix Medical**.

Should the product break open as the result of a fall or other accident, remove the batteries and return the product to **Soterix Medical** for repairs.

- No modification of the **Soterix Medical** GVS Stimulator is allowed.

- Batteries
 - Observe proper precautions when handling batteries. Be sure the product is off before replacing batteries.
 - Use only batteries approved for use in this equipment. Do not attempt to insert batteries upside down or backwards.

- Electronic Monitoring
 - Electronic monitoring equipment (such as ECG monitors, ECG alarms) may not operate properly when GVS stimulation is in use.

- Technique
 - The **Soterix Medical** GVS Stimulator must only be used with appropriate supervision and by a trained operator. Even experienced operators must carefully read and fully follow all the following instructions and guidelines.
 - Presence of pacemaker and metal implant are usually considered contraindications.
 - All operators must ensure that **Soterix Medical** GVS Stimulator is applied within local and federal or country guidelines as relevant.
 - The **Soterix Medical** GVS Stimulator should not be used in combination with any other implanted or external electrical stimulation device.

Regulatory Statements

Galvanic Vestibular Stimulation (GVS) is an investigational technique. It is limited by Federal law to investigational use under appropriate Institutional Review Board guidelines.

USA:

CAUTION: The Soterix Medical Galvanic Vestibular Oscillating Stimulator is an investigational device. Federal (or United States) law limits device to investigational use.

Product Description

Items Supplied - 12

Front Panel - 13

Back Panel - 14

Control Keys - 15

This chapter is comprised of the following sections:

Items Supplied:

This section gives a checklist of the items that are found in every package sent out with the GVS Stimulator as well as any items that could be sent out additionally to the standard package.

Front Panel:

This section contains an illustration of the front panel with every button labeled numerically.

Back Panel:

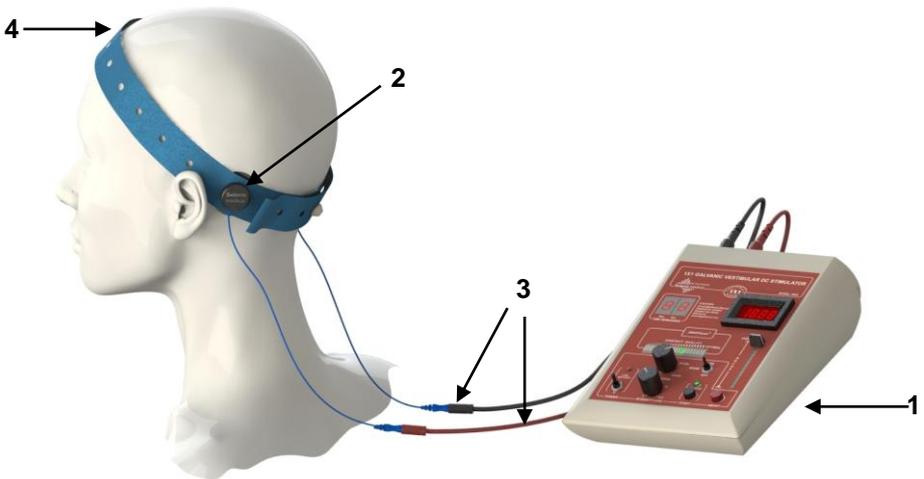
This section contains an illustration of the rear panel with every button labeled numerically.

Control Keys:

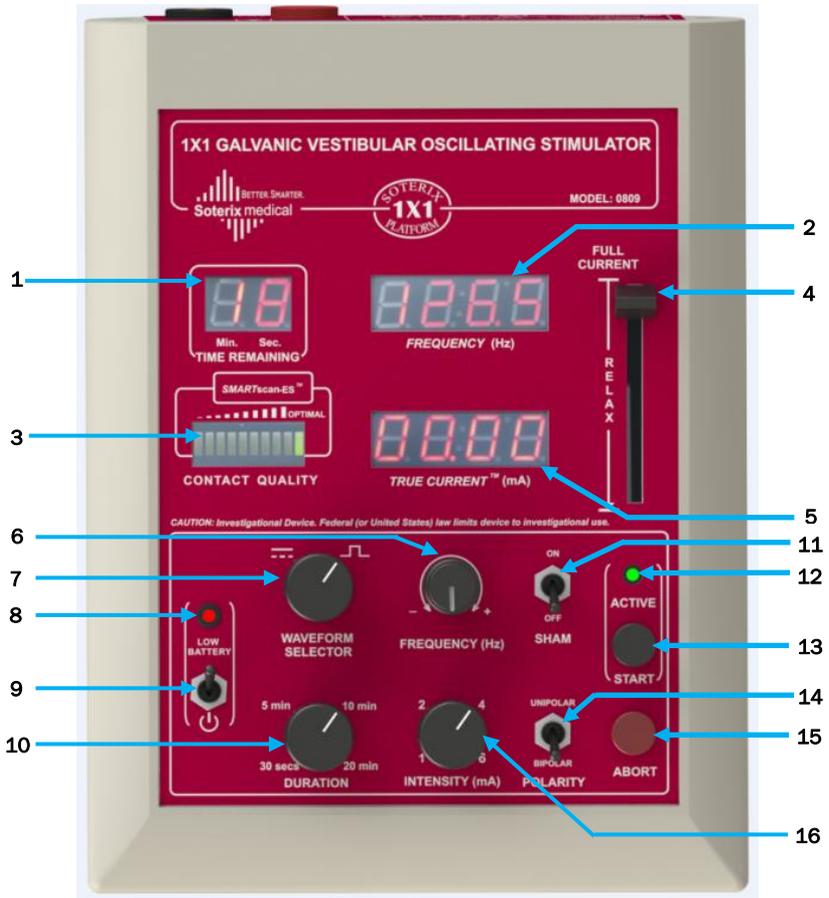
Basic description of all the controls and display functions indicated in the previous two sections.

Items Supplied

1. One **Soterix Medical** Galvanic Vestibular Oscillating Stimulator
2. Ten Galvanic electrodes with Four Galvanic electrode holders
3. Connecting cables: One Red anode cable and One Black cathode cable
4. One Galvanic HEADstrap



Front Panel



Back Panel



Control Keys

- 1.** A display, which indicates the amount of time remaining in the stimulation.
- 2.** A display, which indicates the frequency of the waveform.
- 3.** A display which indicates how “good” the contact quality of the leads are.
- 4.** Modulates the current value produced by the device.
- 5.** A display that indicates the amount of current produced by the device.
- 6.** Adjusts the frequency of waveform (0-200 Hz) prior to the start of stimulation.
- 7.** Adjusts the desired waveform (DCS or PCS) prior to the start of stimulation.
- 8.** Indicates if there is low battery by illuminating red.
- 9.** Turns on or off the device.
- 10.** Adjusts the duration of the stimulation (30 seconds, 5, 10, or 20 minutes) prior to the start of stimulation.
- 11.** Activates or deactivates SHAM.
- 12.** Indicates current ramp (up or down) by flashing green. Indicates steady phase by steady green.
- 13.** Starts the stimulation.
- 14.** Allows setting waveform polarity (unipolar, bipolar) prior to the start of session.
- 15.** Stops the stimulation.

- 16.** Adjusts the current (1, 2, 4, 6 mA) prior to the start of stimulation.
- 17.** The connector for the anode cable.
- 18.** The connector for the cathode cable.

Device Operation

Inserting and Replacing
the Batteries - 18

Description of Special
Features - 20

Pre-Stimulation
Setup - 22

Stimulation
Procedure - 26

This chapter outlines the steps needed to operate your **Soterix Medical** GVS Stimulator

Inserting and Replacing the Batteries:

This section explains how you must insert the batteries into the device. It also explains how to replace them and when it is required.

Description of Special Features:

This section gives an in-depth description of all the special features that come with your purchase of this **Soterix Medical** GVS Stimulator device.

Pre-Stimulation Setup

Here is provided information about the first steps you must take to prepare the device and subject prior to stimulation.

Stimulation Procedure

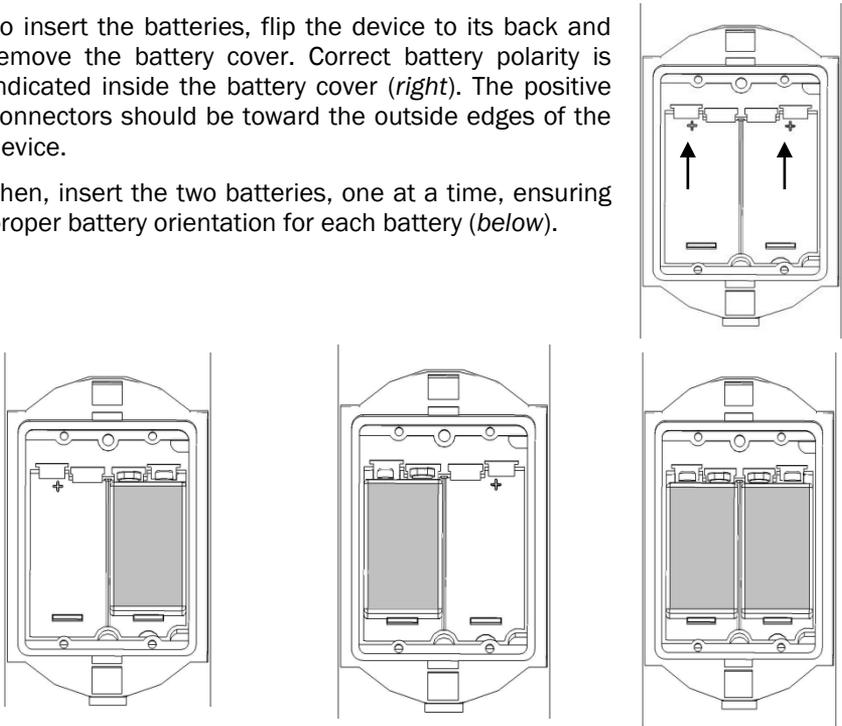
This section contains the procedure for the GVS. Additionally it gives a list of what the operator must do and provides information about what the device does during stimulation.

Inserting and Replacing the Batteries

The GVS Oscillating Stimulator operates on two 9V alkaline batteries. **Duracell brand batteries are recommended for use.**

To insert the batteries, flip the device to its back and remove the battery cover. Correct battery polarity is indicated inside the battery cover (*right*). The positive connectors should be toward the outside edges of the device.

Then, insert the two batteries, one at a time, ensuring proper battery orientation for each battery (*below*).



After the batteries are in place, replace the battery compartment lid by sliding the lid back into its place and pressing it down until it “snaps” into place. Immediately after battery insertion, power up the GVS Stimulator to ensure correct battery placement. If the GVS Stimulator does not power up, check that the batteries are good and inserted correctly.

Note: Batteries should be removed from the GVS Oscillating Stimulator if it is not likely to be used for an extended period of time.



Please observe the proper direction of the battery's polarity as indicated by the stickers inside of the battery compartment. When facing the back of the device, *both* the positive connectors must be toward the outside of the device and *both* the negative connectors toward the inside.

Batteries should be replaced every 3 hours of use or when the low battery indicator is illuminated. Do not use abrasive cleaners on the battery contacts.

To replace the batteries, first remove the old batteries by removing the bottom of the battery first. Take out the batteries one-at-a-time. Then insert the new batteries.



Dispose of depleted batteries in accordance with local regulations.

Note: When the device is not in use, turn the power off to save battery life.

Description of Special Features

TRUE CURRENT™: The TRUE CURRENT™ display is active whenever the device is on. TRUE CURRENT™ always indicates the actual value of current (in mA) being supplied by the device to the electrodes – regardless of device settings. TRUE CURRENT™ thus functions as a fully independent and redundant safety feature when monitored by the operator.

Note: It is recommended the TRUE CURRENT™ be monitored for the entire duration of stimulation.

SMARTscan-ES™: The SMARTscan-ES™ feature provides a constant display of electrode contact quality before, during, and after stimulation. There is no “best” SMARTscan-ES™ level that applies to every GVS configuration. With experience, operators can determine ideal, tolerable, and cautionary levels. The SMARTscan-ES™ indication is provided by a 10 bar LED display (1 to 10 from left to right). LED 1 denotes short condition and LED 2 denotes open-circuit condition. Do not stimulate if either LED 1 or LED 2 is lit.



SMARTscan-ES™ is a feature intended to assist in the set-up and operation of GVS. It is not intended to substitute or replace operator judgment and protocol. Each set-up and operation should be independently monitored and verified by a trained operator following best GVS protocols. Any issues or concerns identified by the operator should be addressed regardless of the SMARTscan-ES™ reading.

Stimulation ABORT: At any point during stimulation, the operator may terminate the stimulation by pressing the ABORT button. The operator is responsible for determining when aborting the stimulation is appropriate. It is recommended to hit ABORT if TRUE CURRENT deviates from expected output current and/or TIME REMAINING deviates from expected duration setting.

Note: Pressing ABORT will ramp down the current to zero and terminate the entire stimulation run.

RELAX: At any point during stimulation, the operator may use the RELAX slider to decrease the set level of current from the maximum (FULL CURRENT) value. TRUE CURRENT™ will indicate the reduced current value.

Adjusting the RELAX amount will have no effect on the duration of stimulation. The operator is responsible for determining when to use the RELAX feature, for example, based on a subject's discomfort level. **It is important that the RELAX amount is decreased and increased slowly, to avoid any sudden current changes.**



RELAX feature is disengaged. Full set current supplied



RELAX feature is engaged. Set current is reduced as slider is lowered



With RELAX slider fully lowered, minimal current is supplied.



Rapid changes in current level, either decreasing or increasing, should be minimized. When using the RELAX feature, always monitor the TRUE CURRENT™ display and adjust slider gradually.

Pre-Stimulation Setup

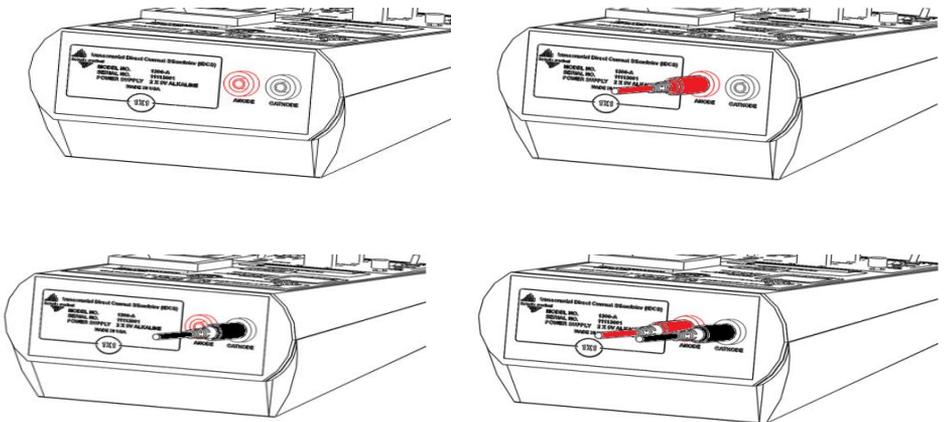
1) Turn the POWER switch **ON**. The TRUE CURRENT™ display will illuminate and indicate 00.00 mA. The SMARTscan-ES™ display will illuminate indicating a low quality. The FREQUENCY display will either indicate 000.0 Hz or 050.0 Hz depending on the WAVEFORM SELECTOR setting selected on device (50 Hz is the default setting for PCS waveform)



When the subject is connected to the device, turning the power on or off is not recommended.

2) If LOW BATTERY is illuminated, do not proceed with stimulation. Replace both batteries with new batteries. Make sure both batteries are inserted in the correct polarity, as indicated inside the battery compartment.

3) Connect the provided cables to the device using the banana plugs on the back of the device. To attach the cables, take the long plastic end and insert it into the similarly colored receiver. The red wire must be inserted into the red receiver labeled “anode” and the black wire inserted into the grey receiver labeled “cathode” (*below*).



4) Clean the surface of the skin at the intended stimulation sites to remove any signs of lotion, dirt, etc. and allow it to dry. Inspect the electrodes, holders, and strap for wear. If there is any evidence of deterioration, throw out the dirty components and use a new electrode.

5) Insert the electrode holders through the slits on the HEADstrap corresponding to the intended stimulation sites. Position the HEADstrap on the subject. Adjust the HEADstrap as needed to ensure that the electrode holders coincide with the stimulation site. Insert electrode gel (HD-GEL) into the electrode holder and then position the Galvanic High-Definition (HD) electrodes inside the holder. Add additional gel as necessary to ensure that the gel contacts the scalp and the Galvanic HD electrode contacts the gel. Use the electrode holder cap to lock the Galvanic HD electrodes into place.



Consult the HD Electrode Holder manual available separately for additional information on loading the Galvanic HD electrodes

6) The SMARTscan-ES™ contact quality meter will now indicate the quality of the electrode contact. There is no single “best” reading for all applications; however, generally a higher quality reading indicates a “better” electrode-skin contact (the right most bar on the 10 bar LED display indicates the best display). It is the responsibility of the operator to ensure that the SMARTscan-ES™ quality reading is appropriate for a given application prior to stimulation. If the quality reading is not in the desired range, adjust one or both of the electrode contacts. The SMARTscan-ES™ will constantly update showing the current electrode quality during adjustments.

7) Once the SMARTscan-ES™ reading is in the desired range, set the WAVEFORM SELECTOR to the desired waveform, set FREQUENCY to the desired frequency value (in Hz) if applicable, set the CURRENT INTENSITY to the desired current value (in mA) and set DURATION to the desired duration value (in either seconds or minutes). The FREQUENCY display will constantly update showing the chosen frequency value during adjustments.

For ODCS, set the POLARITY switch to unipolar. A unipolar wave causes the continuously changing bipolar PCS wave to be DC offset, shifting it into the positive territory.

It is the responsibility of the operator to ensure that the current and duration values are appropriate and safe for the application.

Note: The duration value does not include an approximately 30 second ramp up time at the start of stimulation and an approximately 30 second ramp down time at the end of stimulation. Active GVS (or SHAM OFF) waveform is shown below.

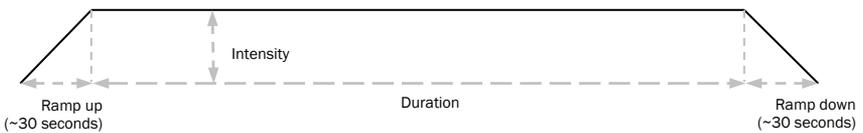


Figure 1: Active DCS waveform

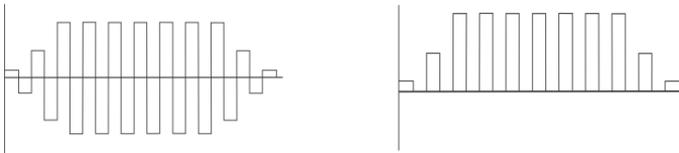


Figure 2: Active bipolar PCS waveform (left). Active unipolar PCS waveform or ODCS waveform (right).

For any of the waveforms selected, current ramps up in 30 seconds, stimulates for the duration selected via the DURATION knob and ramps-down in 30 seconds.

8) Select either SHAM ON or OFF using the switch. (SHAM ON waveform shown below for DCS)



Figure 3: Sham DCS waveform

Similarly for other waveforms (PCS, ODCS), current ramps up to set intensity in 30 seconds and ramps down in 30 seconds at the beginning of session. There is no stimulation in the interim and current ramp up and ramp down is repeated at end of session. *Note: For 30 second duration setting, there are no ramps at the end of session. This is to ensure same total duration of stimulation in both the active and sham arms.*

9) Ensure the RELAX slider is set to FULL CURRENT (*right*).



Stimulation Procedure

1) Confirm that the WAVEFORM, FREQUENCY, INTENSITY and DURATION are set to the desired values, SHAM is set to its desired setting, and the RELAX slider is set to full current.

2) Start the stimulation by pressing the START button (*right*)

Note: Once the START button is pressed and GVS begins, changing the waveform, frequency, duration, intensity and polarity controls will have no effect on the ongoing stimulation. These controls are to be set before the start of the stimulation to allow for proper GVS.



3) The stimulation ACTIVE light will first flash for a period of approximately 30 seconds while the current is ramping up. The TRUE CURRENT™ display will show the current ramping up to the set INTENSITY value. For waveforms with frequency content (PCS, ODCS), TRUE CURRENT™ indicates the maximum value the waveform is able to reach.

4) Once the ramp up is complete, the stimulation ACTIVE light will stop flashing and remain illuminated. The TIME REMAINING display will now indicate the time remaining in the stimulation session. The value will start at the time selected in DURATION and count down. The value will initially show the amount of minutes remaining.

5) The TRUE CURRENT™ display constantly shows the current delivered to the subject. The operator should monitor this display. If there is any deviation from the expected current, as set by the operator and described in this manual, stimulation should be aborted.

6) The SMARTscan™ feature indicates contact quality during stimulation. The operator should monitor this display during stimulation. It is typical for electrode quality to improve during stimulation, while a decrease may indicate a problem with the electrodes. The stimulator will *not* automatically shut down during stimulation. It is the responsibility of the operator to ensure that the SMARTscan™ quality reading is appropriate for a given application during stimulation.



During GVS, tampering with the placement of the electrodes is not recommended.

7) The RELAX feature can be used at any point during the stimulation. It can be used to accommodate individual subject's scalp sensation by moving the RELAX slider down, away from FULL CURRENT. When moving the slider, the current supplied by the device will change and will be reflected by the value shown in the TRUE CURRENT™ DISPLAY.

8) When there is 1 minute remaining in the stimulation, the TIME REMAINING display will switch to seconds. It will count down the final 60 seconds. This is not applicable for the 30 seconds DURATION setting, where the device will naturally only count down in seconds.

9) When the TIME REMAINING reaches zero, the display will turn off and the current will ramp down for approximately 30 seconds. During the ramp down, the stimulation ACTIVE light will flash.

10) Once the ramp down is complete, the stimulation ACTIVE light will turn off.

11) GVS is now complete.

12) Disconnect the electrodes from the subject.

13) Turn the POWER switch OFF.

Note: If during the course of stimulation, it is desired to stop the stimulation manually, it is recommended that the ABORT feature be used instead of the power being switched off.



When the subject is connected to the device, turning the power on or off is not recommended.



Please use **Soterix Medical** GVS Oscillating Stimulator only as directed by this document. Failure to do so might result in an unexpected outcome. Do not modify the equipment without prior authorization of the manufacturer.



If equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

Specifications -- 30

Warranty -- 31

Maintenance and
Disposal -- 32

Definition of Symbols
Used --33

Specifications and Warranty

This chapter is comprised of the following sections:

Specifications:

This section contains a list of the details of the device specification.

Warranty:

Here is the Limited Warranty. It dictates under what circumstances your Galvanic Vestibular Oscillating Stimulator is repaired free of charge. It also explains how to obtain your warranty service.

Maintenance and Disposal:

This sections lists instructions for continued safe-use and disposal

Definition of Symbols Used:

This section defines the symbols used on the device and the packaging.

Specifications

Electrical and Operating Characteristics

Power source: 2, 9V Alkaline batteries

Battery life (with fresh batteries): 3 hrs. *

3 standard modes: DC (DCS and ODCS) and non-DC (PCS)

Adjustable frequencies up to 200 Hz with 0.5 Hz resolution

Adjustable duration up to 20 minutes

Adjustable current intensity up to $\pm 6,000 \mu\text{A}$

Length: 7.91 in.

Width: 5.9 in.

Height: 2.83 in.

Connector type: shielded banana

Maximum Output Voltage: $40\text{V} \pm 2\text{V}$

Storage and Operating Conditions

Parameter	Storage	Operating
Minimum temperature	50° F (10° C)	50° F (10° C)
Maximum temperature	110° F (43° C)	110° F (43° C)
Minimum humidity	20%	20%
Maximum humidity	90%	90%
Minimum atmospheric pressure	20.7 in. Hg (700 hPa)	20.7 in. Hg (700 hPa)
Maximum atmospheric pressure	31.3 in. Hg (1060 hPa)	31.3 in. Hg (1060 hPa)

*All measurements are approximated

** Test perform with 2x9V Alkaline Duracell Battery

Warranty

Soterix Medical Limited Warranty

- A.** This Limited Warranty provides the following assurance to the first purchaser of the **Soterix Medical Inc.** GVS Oscillating Stimulator Model 0809, hereafter referred to as "Equipment":
- (1) Should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the delivery of the Equipment to the purchaser, **Soterix Medical** will at its option: (a) repair or replace any part or parts of the Equipment; (b) issue a credit to the purchaser equal to the Purchase Price against the purchase of the replacement Equipment or (c) provide a functionally comparable replacement Equipment at no charge. The Equipment must be returned to **Soterix Medical Inc.**, carriage paid and insured, in the most appropriate method as determined by **Soterix Medical Inc.**
 - (2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement Equipment.
- B.** To qualify for Limited Warranty set forth in Section A(1), the following conditions must be met:
- (1) The Equipment must be returned to **Soterix Medical** within thirty (30) days after discovery of the defect, (**Soterix Medical** may, at its option, repair the Equipment on site).
 - (2) The Equipment must not have been repaired or altered outside of **Soterix Medical's** factory in any way, which, in the judgment of **Soterix Medical**, affects its stability and reliability. The Equipment must not have been subjected to misuse, abuse, or accident. This warranty does not apply to any exterior appearance item of the Equipment which has been damaged or defaced, which has been subject to misuse and abuse, abnormal service or handling, or which has been altered or modified in design or construction.
 - (3) This warranty does not apply to any interconnection cables supplied with the Equipment.
- C.** This Limited Warranty is limited to its expressed terms. In particular:
- (1) Except as expressly provided by this Limited Warranty, **SOTERIX MEDICAL IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT FAILURE OR MALFUNCTION OF THE EQUIPMENT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.**

- (2) This Limited Warranty is made only to the purchaser of the Equipment. AS TO ALL OTHERS, **SOTERIX MEDICAL INC.** MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE, THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.
- (3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights, which vary within specific regions.
- (4) No person has any authority to bind **Soterix Medical Inc.** to any representation, condition, or warranty except this Limited Warranty.

Obtaining Warranty Service

Warranty service of this Equipment can be obtained by returning the Equipment, carriage paid and insured, to **Soterix Medical**. Prior authorization before shipping the product is advised for the most expedient service.

Maintenance and Disposal

For continued safe use and disposal of **Soterix Medical** Galvanic Vestibular Oscillating Stimulator, read the following instructions.

- The **Soterix Medical** GVS Stimulator must be stored away from fluids and heat sources.

- To clean the **Soterix Medical** GVS Stimulator, use a dry cloth to wipe dust from the external surface when necessary. Do not spray liquid cleaners directly on the **Soterix Medical** GVS Stimulator, as this will void your warranty.
- Do not disinfect the **Soterix Medical** GVS Stimulator
- Return the device to Soterix Medical for disposal when the device is no longer required.
- Do not throw the **Soterix Medical** GVS Stimulator in generic waste.
- Discharged batteries must be disposed appropriately in accordance with national regulations in force.
- Output cables, Galvanic electrodes, and Galvanic HEADstrap can be disposed in generic waste when no longer required.

Definition of Symbols Used

	<p>Type BF protection against electric shock. Isolated (floating) applied part suitable for intentional application to the subject, excluding direct cardiac application</p>
	<p>Refer to instruction manual/booklet</p>
	<p>Fragile. Handle with care</p>

 KEEP AWAY FROM WATER	Keep Dry. Protect from Water.
	Device runs on DC current.
	Operate between 50°F – 110°F (10°C – 43°C)
	Serial Number
	Address of manufacturer

Bibliography – 36

Contact Information –
41

Further Information

In this chapter, you can find:

Bibliography:

Here is a selection of peer-reviewed articles that **Soterix Medical** has found to be relevant to GVS practices.

Contact Information:

This section houses a list of all the ways **Soterix Medical** can be contacted.

Bibliography

The following bibliography includes a selection of peer-reviewed publications. This is not a comprehensive list of all GVS studies, but includes a representative list as of the date of the publication of this manual. The inclusion of these reports in this bibliography does not in any way imply an endorsement of the protocol or results reported in these studies by **Soterix Medical**. It remains the responsibility of the device user to remain informed of all current, relevant GVS practices. **Note:** GVS is an investigational medical technique and has not been cleared by the FDA and therefore can only be used for research under appropriate Institutional Review Board guidelines.

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