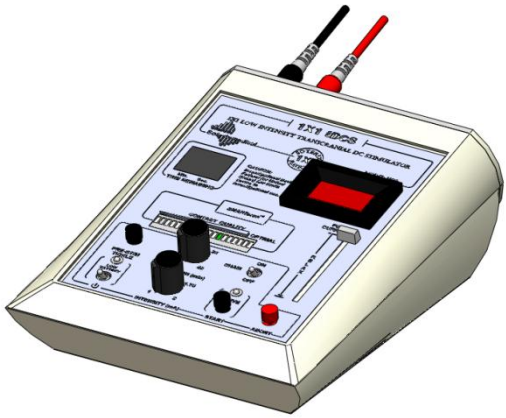
1x1 Transcranial Direct Current (tDCS) Low-Intensity Stimulator

Model 1300A



Operator's Manual

Version 8.2

June 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

Introduction

This chapter introduces you to the basics required to use this manual fully as well as operate the **Soterix Medical** 1x1 tDCS line of stimulators.

Overview:
This section gives a description of the process of transcranial Direct Current Stimulation.

Getting to Know the Product:
Read this section to learn what sets the **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator 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

Transcranial Direct Current Stimulation (tDCS) is a non-invasive procedure in which a device sends a small Direct Current (DC) across the scalp to modulate brain function. The **Soterix Medical** 1x1 line tDCS Low-Intensity Stimulator sends a low-level current from the positive electrode, anode, to the negative electrode, cathode. When the extremely low level current passes from the anode to the cathode, it may simultaneously increase the activity of the brain by the anode and decrease the activity of the brain near the cathode. Emerging evidence indicates that it is can be used to treat different neurological and psychiatric disorders. In particular, tDCS has been shown to be effective in treating Depression and reducing Pain. tDCS increases spontaneous brain activity and metabolism in areas found to be hypoactive in patients suffering from major depressive disorder. Per application for pain, primary motor cortex tDCS interferes with perceptual processing of pain while prefrontal cortex stimulation modulates the affective reaction to painful experiences.

tDCS mechanisms are considered to result from the ability of very weak DC currents to safely induce reversible changes in cortical plasticity. The induction of lasting changes in cortical excitability can, under some conditions, reversibly modify behavior and interact with normal learning. Such findings have driven a large number of studies examining whether tDCS might induce functionally significant changes in patients with a large variety of neurological and psychiatric disorders.

tDCS dose can be defined as: 1) The size and position of the electrodes on the body and 2) The duration (in minutes) and intensity (in mA) of current passed across the electrodes. **Soterix Medical** tDCS systems allow precise reproduction of tDCS doses commonly used in medical literature. **Soterix Medical** engineers and scientists can work with you to determine the best configuration for your application. **Note:** tDCS is an investigational technique and it is the responsibility of the operator to determine the appropriate tDCS dose for a particular application.

tDCS safety is supported by medical literature to have common side effects limited to mild and reversible skin irritation, when using standard tDCS protocols and guidelines. **Soterix Medical** tDCS stimulators and electrodes are uniquely designed to minimize skin irritation – for example,

the exclusive SMARTscan™ feature provides a simple indicator to the operator of the contact conditions before, during, and after stimulation. **Note:** tDCS is an investigational technique and it is the responsibility of the operator to identify and follow the most appropriate safety protocols.

tDCS comfort can be controlled by the operator by using devices, such as the **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator, which are specifically designed for clinical tDCS. For example, the unique PRE-STIM TICKLE and RELAX features available on all **Soterix Medical** 1x1 models are designed to condition the skin prior to stimulation and allow the operator to accommodate subject feedback without stopping stimulation.

tDCS 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** 1x1 Transcranial Direct Current Low-Intensity Stimulator. Unlike other stimulators, the **Soterix Medical** 1x1 line of stimulators is simple to use and designed especially for tDCS.

The **Soterix Medical** 1x1 line of low-intensity tDCS stimulators is designed to generate low levels of DC current between one anode and one cathode placed on the body. 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. It is recommended to not use the device across the chest as it may cause interference with the heart rhythm.

Provided **Soterix Medical** tDCS accessories allow for simple and comfortable positioning of the electrodes on the body. The operator must set the intensity of current (in units of mA) and duration of stimulation (in minutes) before initiating the stimulation. For both duration and intensity, there are four settings.

Clinicians and researchers choose the **Soterix Medical** 1x1 to:

1) Ensure reproducible and precise tDCS operation across subjects and time.

2) Provide for simple and comfortable tDCS set-up and stimulation.

3) Conduct clinical studies with state-of-the-art control and safety features.

The **Soterix Medical** 1x1 tDCS line of stimulators includes several proprietary features to enhance tDCS safety and subject comfort including TRUE CURRENT™, *SMART*scan™, RELAX, and PRE-STIM TICKLE. By reading this manual and understanding these unique features, operators of the **Soterix Medical** 1x1 can enhance the efficacy and comfort of tDCS.

Use of This Manual

This manual contains details of installation, setup, and operation of the **Soterix Medical** 1x1 unit and its accessories. This manual must be read in its entirety before commencing any stimulation with the **Soterix Medical** 1x1 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.

Classifications

In accordance with IEC 60601-1

- Internally powered equipment
-Type BF equipment.
-Continuous operation according to the mode of the operation.
-Portable equipment.

In accordance with EU Medical Device Directive

- Class IIa

Health and Safety

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.

Contraindications:
Read this section to learn about contraindications related to 1x1 tDCS Low-Intensity Stimulator

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** 1x1 tDCS Low-Intensity Stimulator in water or any other fluids.
    - The **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator should not be used in a moist environment or if any parts of the stimulator are damp or wet.
    - The **Soterix Medical** 1x1 tDCS Low-Intensity 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** 1x1 tDCS Low-Intensity Stimulator near flammable atmosphere are unknown.
    - The **Soterix Medical** 1x1 tDCS Low-Intensity 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** 1x1 tDCS Low-Intensity 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** 1x1 tDCS Low-Intensity Stimulator is being used. The consequences of potential interference from communication and entertainment devices on the **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator are unknown.
    - Do not use the **Soterix Medical** 1x1 tDCS Low-Intensity 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** 1x1 tDCS Low-Intensity 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** 1x1 tDCS Low-Intensity 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** 1x1 tDCS Low-Intensity 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** 1x1 tDCS Low-Intensity Stimulator.
- Irritation
    - Use only approved **Soterix Medical Inc.** *EASYpads*™ indicated for use with the **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator. Do not modify the *EASYpads*™. Do not reuse *EASYpads*™ that are indicated only for single use.
    - The **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator may cause minor irritation, discomfort and redness at the electrode sites. If irritation occurs, consult your clinician.
    - Do not place the **Soterix Medical** 1x1 tDCS electrodes or sponges over previously irritated, burnt, or damaged skin.
    - Since sponge current density (injected current / sponge area) has been shown to be an indicator of skin irritation, it is recommended to use *EASYpads*™ of size 5x5 cm and greater for 2 mA current application. 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 Inc**. Should the product break open as the result of a fall or other accident, remove the batteries and return the product to **Soterix Medical Inc.** for repairs.
    - No modification of the **Soterix Medical** 1x1 tDCS Low-Intensity 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 tDCS stimulation is in use.
- Technique
    - The **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator must only be used with appropriate supervision and by a trained operator at either a clinical laboratory or a healthcare facility. The **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator is not intended to be used for home use. Even experienced operators must carefully read and fully follow all the following instructions and guidelines.
    - 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. Pressing ABORT will

ramp down the current to zero and terminate the entire stimulation run.

- All operators must ensure that **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator is applied within local and federal or country guidelines as relevant.
- The **Soterix Medical** 1x1 Low-Intensity Stimulator should not be used in combination with any other implanted or external electrical stimulation device.

Contraindications

- Presence of pacemaker and metal implant are usually considered contraindications.
- History of seizure, Traumatic Brain Injury, history of stroke, are usually not strict contraindications and might be inclusion criteria in some trials.
- To-date there have been no published studies in pregnant women. The safety of electrical stimulation during pregnancy has not been established.

Regulatory Statements

Transcranial Direct Current Stimulation (tDCS) is an investigational technique. It is limited by Federal law to investigational use under appropriate Institutional Review Board guidelines.

USA:

CAUTION: The Soterix Medical 1x1 Low Intensity DC Stimulator is an investigational device. Federal (or United States) law limits device to investigational use.

Product Description

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 1x1 tDCS Low-Intensity 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 **Soterix Medical** 1x1 Transcranial Direct Current Low-Intensity Stimulator

☐ 5 pairs **Soterix Medical** *EASYpads*™ sponges(2x carbon rubber electrode insets). EASYpads sponges are rated for one-time use only.

☐ 1 Red anode cable

☐ 1 Black cathode cable

☐ Elastic fasteners (one long, one short) with plastic joints (2x)

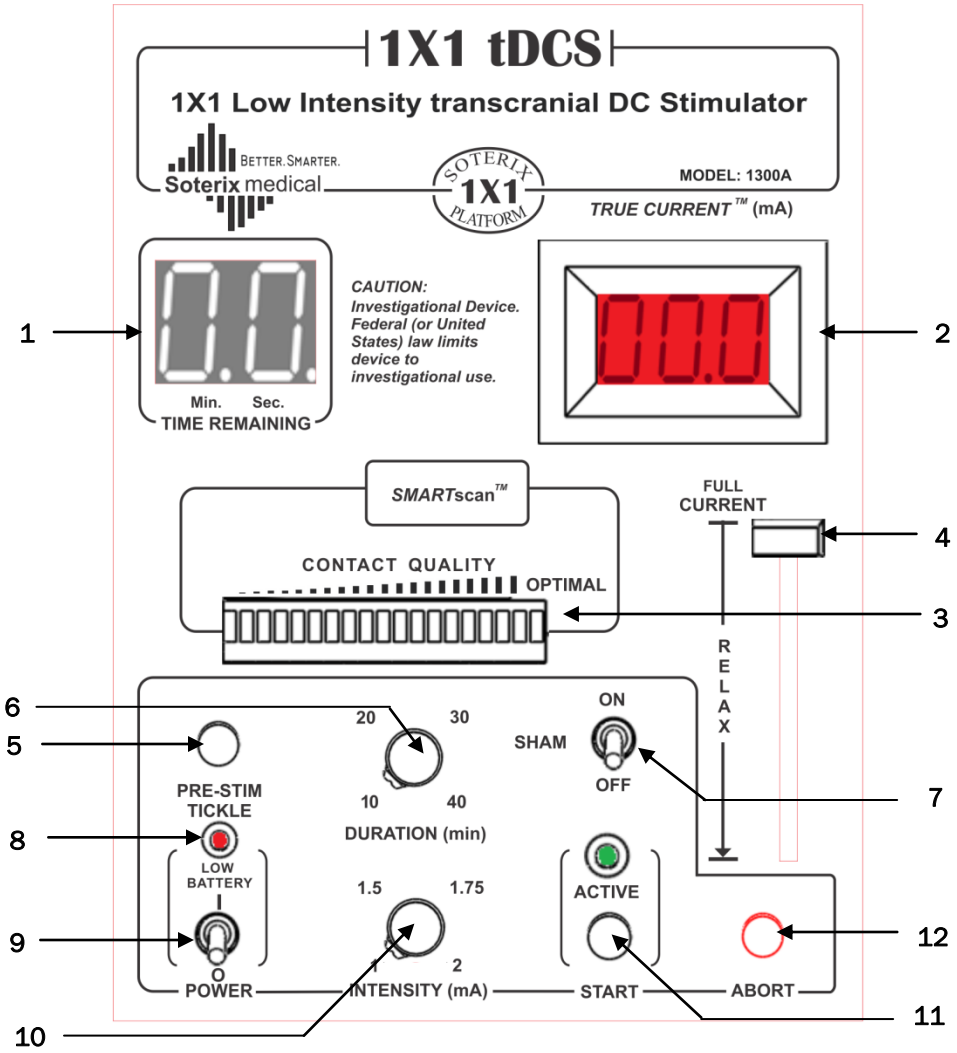
Items Supplied Separately

☐ 100 Replacement **Soterix Medical** *EASYpads*™

Standard *EASYpads*™ sizes **3x5cm, 5x5cm, 5x7cm, 5x10cm.**

(*Customizable EASYpads*™ *sizes available upon customer request*)

Front Panel



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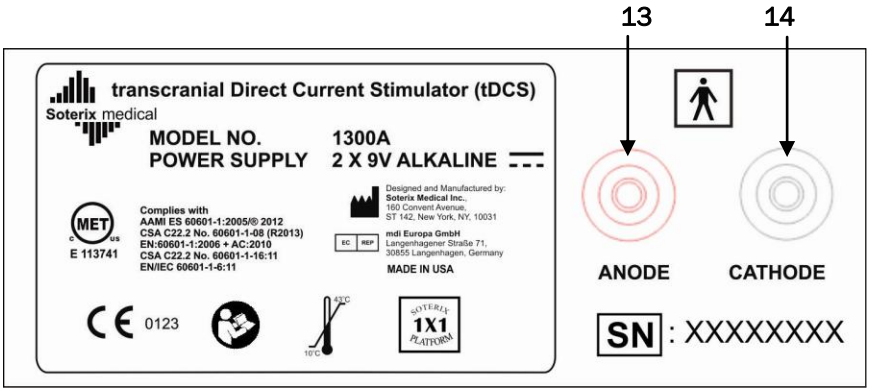


Control Keys

1. A display, which indicates the amount of time remaining in the stimulation.
2. A display that indicates the amount of current being produced by the device.
3. A display which indicates how "good" the contact quality of the leads are.
4. Modulates the current value being produced by the device.
5. Starts the PRE-STIM TICKLE.
6. Adjusts the duration of the stimulation (10, 20, 30, or 40 minutes) prior to the start of stimulation.
7. Activates or deactivates SHAM.
8. Indicates if there is low battery by illuminating red.
9. Turns on or off the device.
10. Adjusts the current (1, 1.5, 1.75, 2 mA) prior to the start of stimulation.
11. Starts the stimulation.
12. Stops the stimulation.
13. The connector for the anode cable.
14. The connector for the cathode cable.

Device Operation

This chapter outlines the steps needed to operate your **Soterix Medical** 1x1 tDCS Low-Intensity 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** 1x1 tDCS Stimulator device.

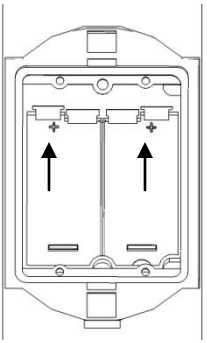
Pre-Stimulation Setup
Here you are provided with information about the first steps you must take to prepare the device and subject prior to stimulation.

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

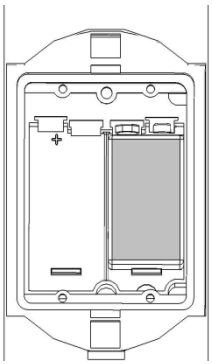
Inserting and Replacing the Batteries

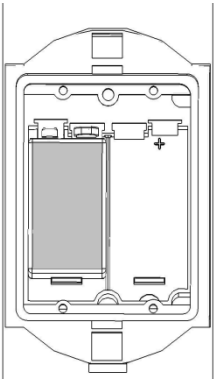
The 1x1 tDCS Low-Intensity Stimulator operates on two 9V alkaline batteries. **Duracell is recommended for use.**

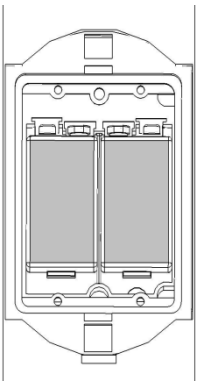
To insert the batteries, flip the device to its back and remove the battery cover. Correct battery polarity is indicated inside the battery cover (right). The positive connectors should be toward the outside edges of the device.



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 1x1 tDCS Low-Intensity Stimulator to ensure correct battery placement. If the 1x1 tDCS Low-Intensity Stimulator does not power up, check that the batteries are good and inserted correctly.

Note: Batteries should be removed from the 1x1 tDCS Low-Intensity 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™: The *SMARTscan™* feature provides a constant display of electrode contact quality before, during, and after stimulation. There is no "best" *SMARTscan™* level that applies to every tDCS configuration. With experience, operators can determine ideal, tolerable, and cautionary levels. The *SMARTscan* indication is provided by a 20 bar LED display (1 to 20 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™ is a feature intended to assist in the set-up and operation of tDCS. 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 tDCS protocols. Any issues or concerns identified by the operator should be addressed regardless of the *SMARTscan™* reading.

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. **Note:** The current does not reduce to zero.

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-STIM TICKLE: When the device is turned on and after the electrodes are placed on the subject, but before stimulation is initiated, the PRE-STIM TICKLE button may be pressed to activate an approximately 30 second, 1 mA current. During PRE-STIM TICKLE, the TIME REMAINING display will indicate "Pr" and the TRUE CURRENT™ display will indicate the current. The operator is responsible for determining when it is appropriate to use PRE-STIM TICKLE, for example, to condition the electrodes, skin, or the subject. Pressing the PRE-STIM TICKLE button during stimulation will have no effect.

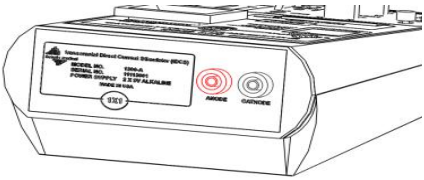
Pre-Stimulation Setup

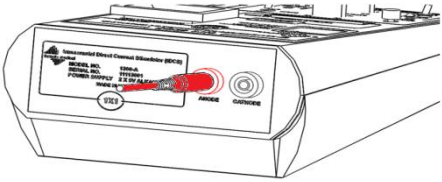
1) Turn the POWER switch **ON**. The TRUE CURRENT™ display will illuminate and indicate "**00.0"**. The *SMART*scan™ display will illuminate indicating a low quality.

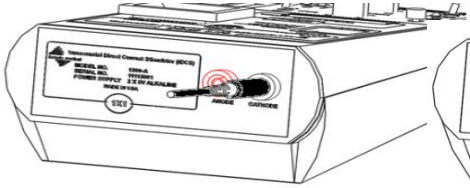
When the subject is connected to the device, turning the power on or off is not recommended.

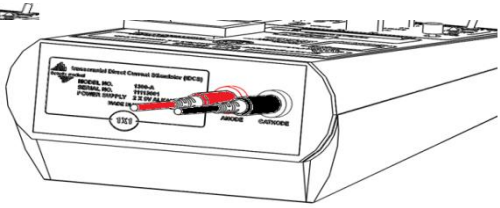
2) If LOW BATTERY is illuminated, do not proceed with stimulation. Replace both batteries with new batteries. Make sure both batteries are inserted in the correct polarity, as indicated inside the battery compartment.

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).

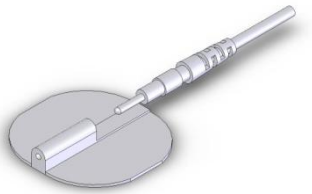








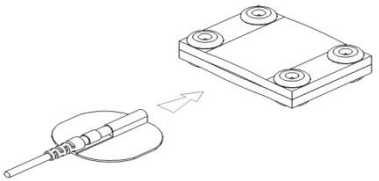
4) Clean the surface of the skin to remove any signs of lotion, dirt, etc. and allow it to dry. Inspect the rubber insets and sponges for wear. If there is any evidence of deterioration, throw out the dirty components and use a new electrode.

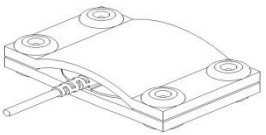


5) Insert the connector cord pin securely into the opening of the receptacle on the rubber inset. (right)

6) Each side of the sponge should be soaked with saline solution. For a 35 cm^2 sponge, approximately 6 mL of saline (total of 12 mL per sponge) may suffice. **Be careful not to over soak the sponge**. Avoid fluid leaking across the subject.

7) Then slide the rubber inset fully into the sponge EASYpads™ (5x7 cm EASYpads™ shown below).



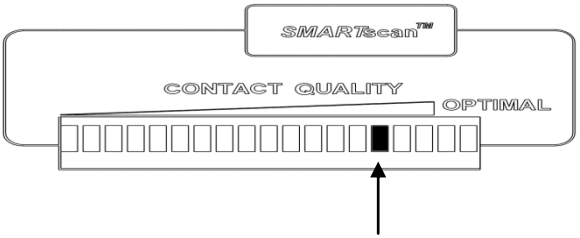


8) **Use only appropriate accessories to fix the sponge to the subject** including **Soterix Medical** elastic fasteners. Apply the electrodes to the treatment site by firmly pressing down the center of the pad and then smoothing down towards the electrode edges. **Verify there is a smooth and even contact with the skin and ensure that the rubber insert does not contact the skin.**

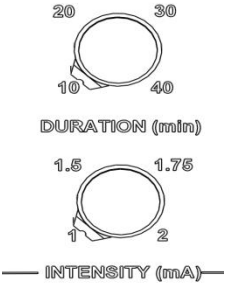
Note: Both sponges must remain evenly moist across the entire surface for the duration of the procedure.

Electrode sponges should remain moist across the entire surface for the duration of stimulation. If the sponges are dry, do not start stimulation. If any irritation or discomfort occurs, discontinue use and consult a clinician

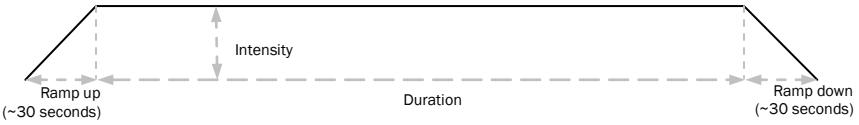
9) The *SMART*scan™ contact quality meter will now indicate the quality of the electrode contact. There is no single "best" reading for all applications; however; generally a higher quality reading indicates a "better" electrode-skin contact. It is the responsibility of the operator to ensure the *SMART*scan™ 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 *SMART*scan™ will constantly update showing the current electrode quality during adjustments.



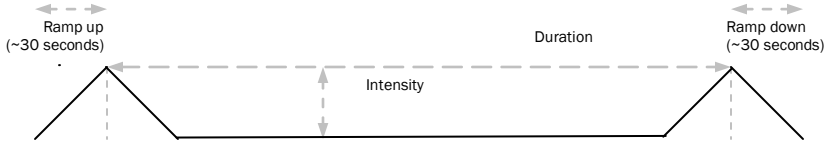
10) Once the *SMART*scan™ reading is in the desired range, set the CURRENT INTENSITY to the desired current value (in mA) and set DURATION to the desired duration value (in minutes). It is the responsibility of the operator to ensure that the current and duration values are appropriate and safe for the application (right).



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 tDCS (or SHAM OFF) waveform is shown below.



11) Select either SHAM ON or OFF using the switch (right). (SHAM ON waveform shown below)



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

13) Now would be the time to activate the PRE-STIM TICKLE if desired. To do so, press the PRE-STIM TICKLE button (below). It is the responsibility of the operator to determine if it is appropriate to use the PRE-STIM TICKLE.

Stimulation Procedure

1) Confirm that both the 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 tDCS begins, changing the duration and intensity knobs will have no effect on the ongoing stimulation. These knobs are to be set before the start of the stimulation to allow for proper tDCS.

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.

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 *SMART*scan™ feature indicates contact quality during stimulation. The operator should monitor this display during stimulation. It is typical for electrode quality to decrease during stimulation, while an increase 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 *SMART*scan™ quality reading is appropriate for a given application during stimulation.

During tDCS, tampering with the placement of the sponges is not recommended.

7) The RELAX feature can be used at any point during the stimulation, generally, the RELAX feature is used to accommodate individual subjects by moving the RELAX slider down, away from FULL CURRENT, the current supplied by the device will decrease to 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 will be indicated by the illumination of the light adjacent to "Sec" below the TIME REMAINING display.

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) tDCS 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** 1x1 tDCS Low-Intensity 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 continued to ensure continued safe use of equipment.

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 1x1 Transcranial Direct Current Low-Intensity 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

Specifications

Electrical and Operating Characteristics

Power source: 2, 9V Alkaline batteries
Battery life (with fresh batteries): 3 hrs**
Maximum Output Current: 2000 µA DC ± 1%
Length: 7.91 in.
Width: 5.9 in.
Height: 2.83 in.
Connector type: shielded banana
Maximum Output Voltage: 40V ± 5%

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.** 1x1 tDCS Low-Intensity Stimulator Model 1300, 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

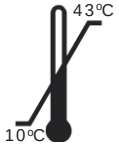
For continued safe use and disposal of **Soterix Medical** 1x1 Low-Intensity Stimulator, read the following instructions.

- The **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator must be stored away from fluids and heat sources.

- To clean the **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator, use a dry cloth to wipe dust from the external surface when necessary. Do not spray liquid cleaners directly on the **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator, as this will void your warranty.
- Do not disinfect the **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator
- Return the device to Soterix Medical for disposal when the device is no longer required.
- Do not throw the **Soterix Medical** 1x1 tDCS Low-Intensity Stimulator in generic waste.
- Discharged batteries must be disposed appropriately in accordance with national regulations in force.
- Output cables, carbon-rubber insets, and elastic fasteners can be disposed in generic waste when no longer required.
- EASYpads sponges are rated for one-time use only and can be disposed in generic waste after use.

Definition of Symbols Used

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

	Keep Dry. Protect from Water.
	Device runs on DC current.
	Certified MET Mark product safety for United States and Canada
	Operate between 10°C – 43°C (50°F – 110°F)
	Serial Number
	Collect separately for electrical and electronic equipment
	Address of manufacturer

	Do not re-use
	Authorized Representative in the European Community

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 tDCS 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 tDCS 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 tDCS practices. **Note:** tDCS 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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