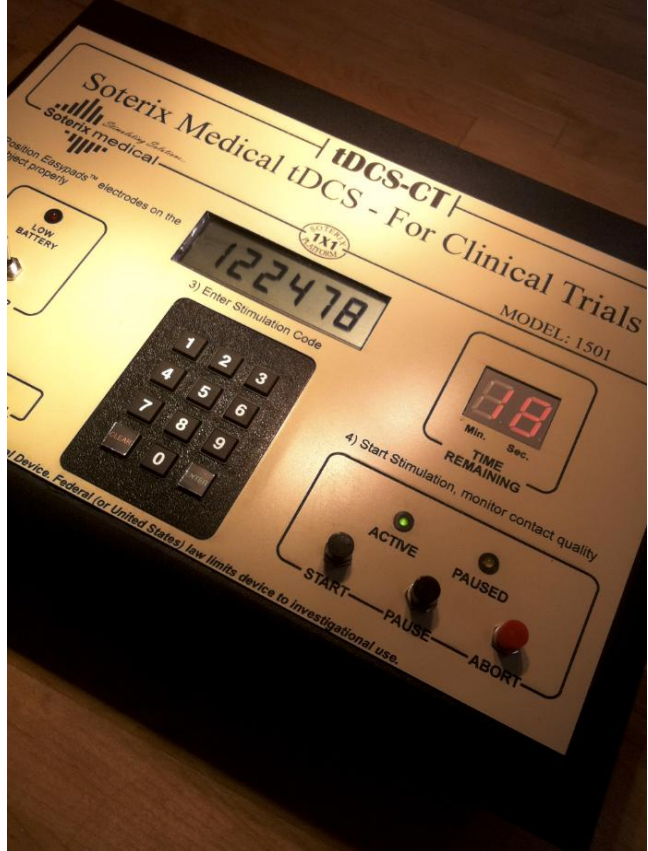


Transcranial Direct Current Stimulator Clinical Trials(tDCS-CT)

Model 1500



CUSTOM OPERATOR'S MANUAL

Version 2
January 2013

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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Introduction

Intended Use - 1

Getting to Know the Product - 3

Use of this Manual - 4

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.

Intended Use:

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-Clinical Trials (CT) 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 tDCS-Clinical Trials 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.

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.

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

this manual.

The Soterix Transcranial Direct Current Stimulator Clinical Trials (tDCS-CT) system is the most advanced and customizable stimulation for true double-blind control trials. Each 1x1 tDCS-CT unit is shipped configured to a specific trial or set of trials, including custom accessories, and relevant features to ensure the highest standards of reproducibility and safety, all without breaking subject's or operator's blind. In addition, you can count on Soterix Medical engineers and scientists to provide continuous design and trial support.

Getting to Know the Product

Thank you for purchasing a **Soterix Medical** 1x1 Transcranial Direct Current Stimulator Clinical Trials Unit. Unlike other stimulators, the **Soterix Medical** 1x1 tDCS 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.

The provided **Soterix Medical** tDCS accessories allow for simple and comfortable positioning of the electrodes on the body.

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 on selected units: TRUE CURRENT™, SMARTscan™, SMARTscan-PLUS™, SET-UP CONTACT QUALITY, STIM CONTACT QUALITY, RELAX, and PRE-STIM TICKLE. By reading this manual and understanding these unique features, operators of the **Soterix Medical** 1x1 CT units 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 CT** unit and its accessories. This manual must be read in its entirety before commencing any stimulation with the **Soterix Medical 1x1 CT** 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 symbols:



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 - 6

Regulatory
Statements - 9

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 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-CT Stimulator in water or any other fluids.
 - The **Soterix Medical** 1x1 tDCS-CT 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-CT 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-CT Stimulator near flammable atmosphere are unknown.
 - The **Soterix Medical** 1x1 tDCS-CT 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-CT 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-CT Stimulator is being used. The consequences of potential interference from communication and entertainment devices on the **Soterix Medical** 1x1 tDCS-CT Stimulator are unknown.
 - Do not use the **Soterix Medical** tDCS-CT 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-CT 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-CT 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-CT 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-CT Stimulator.
- Irritation
 - Use only approved **Soterix Medical Inc.** *EASYpads*[™] indicated for use with the **Soterix Medical** 1x1 tDCS-CT Stimulator. Do not modify the *EASYpads*[™]. Do not reuse *EASYpads*[™] that are indicated only for single use.
 - The **Soterix Medical** 1x1 tDCS-CT 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-CT Stimulator 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- CT 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-CT 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. 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.
 - All operators must ensure that **Soterix Medical 1x1 tDCS-CT** is applied within local and federal or country guidelines as relevant.

- The **Soterix Medical 1x1 tDCS-CT Stimulator** should not be used in combination with any other implanted or external electrical stimulation device.

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 tDCS-CT Stimulator is an investigational device. Federal (or United States) law limits device to investigational use.

Product Description

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Front Panel - 12

Back Panel - 13

Control Keys - 14

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-CT 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**

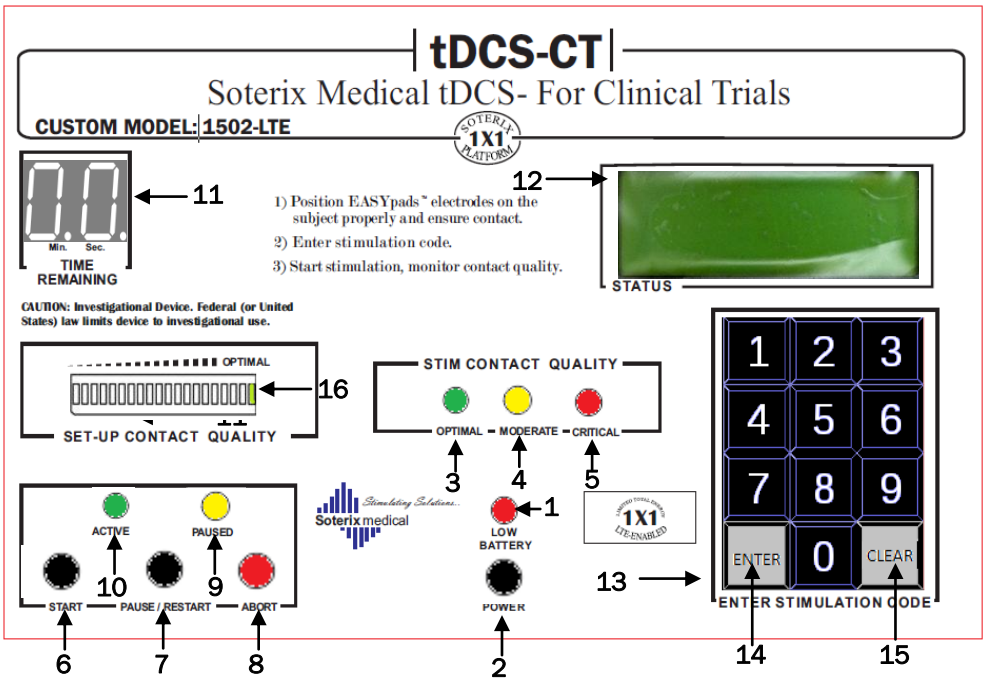


- 5 pairs **Soterix Medical EASYpads™** (2x carbon rubber electrode insets)
- 1 Red anode cable
- 1 Black cathode cable
- Elastic fasteners (one long, one short) with plastic joints (2x)

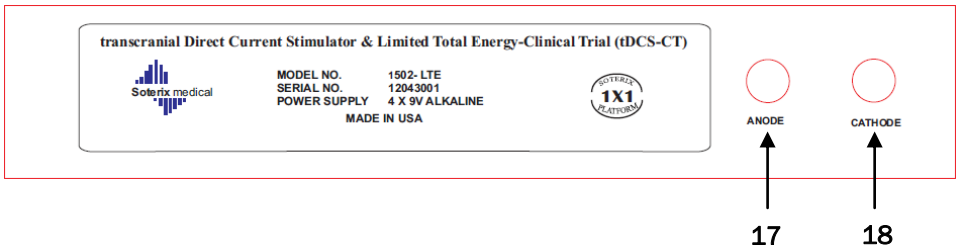
Items Supplied Separately

- 100 Replacement **Soterix Medical EASYpads™**
Standard *EASYpads™* sizes are **3x5 cm, 5x5 cm, 5x7 cm, 5x10 cm.**
(Customizable EASYpads™ sizes available upon customer request)

Front Panel



Back Panel



Control Keys

1. LOW BATTERY indicator indicates the battery charge is low.
 2. POWER switch, turns ON or OFF the device.
 3. CRITICAL™ (Red LED) indicates the STIM CONTACT QUALITY™ is OUTSIDE the desired range and stimulation will only continue for a short time. (**Device Beeps ONCE** whenever it enters CRITICAL mode).
 4. MODERATE™ (Yellow LED) indicates the STIM CONTACT QUALITY™ is NOT within the desired range. However, stimulation will continue.
 5. OPTIMAL™ (Green LED) indicates the STIM CONTACT QUALITY™ is WITHIN the desired range.
 6. START button, which activates the stimulation.
 7. PAUSE/RESTART™ button, activates the PAUSE/RESTART feature. (**Device BEEPS THRICE** whenever it enters PAUSE mode).
 8. ABORT button, stops the stimulation.
 9. PAUSE™ (Yellow LED) indicates the stimulation is PAUSED.
 10. PAUSE™ (Green LED) indicates the stimulation is ACTIVE.
 11. The TIME REMAINING™ display indicates the amount of time remaining in the stimulation. The display reads in minutes and in seconds (for the last minute).
 12. STATUS LCD™ displays welcome screen, indicates code entered, and displays status messages during the course of the session.
 13. KEYPAD (NUMERIC 0-9), enter code.
 14. KEYPAD (ENTER), after code entry hit enter.
 15. KEYPAD (CLEAR), if wrong code entered, hit clear.
 16. SET-UP CONTACT QUALITY™, indicates how “good” the contact quality of the sponge-scalp interface is.
 17. The connector for the anode cable.
 18. The connector for the cathode cable.
-

Device Operation

Inserting and Replacing
the Batteries - 16

Description of Special
Features - 18

Pre-Stimulation
Setup - 20

Stimulation
Procedure - 24

This chapter outlines the steps needed to operate your **Soterix Medical 1x1 tDCS-CT 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 the **Soterix Medical 1x1 tDCS-CT 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.

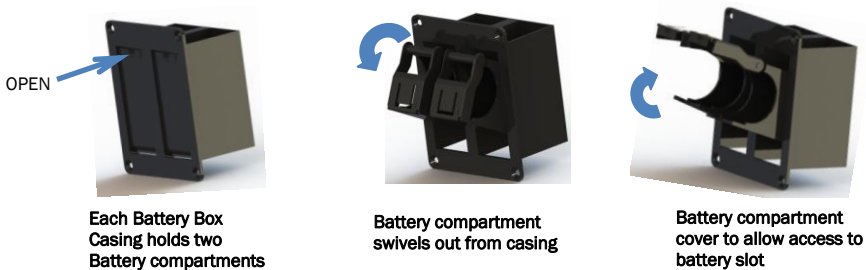
Stimulation Procedure

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.

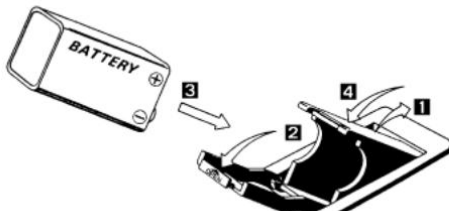
Inserting and Replacing the Batteries

The 1x1 tDCS-CT Stimulator operates on four 9V alkaline batteries. **Duracell is recommended for use.**

To insert the batteries, flip the device to its back and follow the four-step process detailed below. The device houses batteries in two battery box casings with each casing holding two battery compartments. **Step 1:** Slide your finger at the end marked 'OPEN' to lift the individual battery compartment. Note that the battery compartment swivels out from the battery box casing until its almost 90 degrees to the casing. **Step 2:** Lift the battery compartment cover by pressing at end marked 'OPEN' to get access to the battery slot. Correct battery polarity is indicated on the battery compartment cover. The battery compartment cover will not close if batteries are inserted in the wrong orientation. **Step 3:** Insert battery. **Step 4:** Close



the battery compartment cover until it “snaps” into place. Push the battery compartment down into battery box casing



Four-step battery insertion process

Immediately after battery insertion, power up the 1x1 tDCS-CT Stimulator to ensure correct battery placement. If the 1x1 tDCS-CT Stimulator does not power up, check that the batteries are good.

Note: Batteries should be removed from the 1x1 tDCS-CT Unit 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 on the battery compartment cover.

Batteries should be replaced every 5 hours of use or when the low battery indicator is illuminated. Do not use abrasive cleaners on the battery contacts.



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

Each 1x1 tDCS-CT unit is customized to a clinical trial. Features available on each unit will vary but may include:

SET-UP CONTACT QUALITY™: The *SET-UP CONTACT QUALITY™* feature provides a constant display of electrode contact quality during setup or when stimulation has stopped (PAUSE). There is no “best” *SET-UP CONTACT QUALITY™* level that applies to every tDCS configuration. With experience, operators can determine ideal, tolerable, and cautionary levels. The quality level 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.



SET-UP CONTACT QUALITY™ 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 setup 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 *SET-UP CONTACT QUALITY™* reading.

STIM CONTACT QUALITY™: The *STIM CONTACT QUALITY™* monitor provides a constant display of electrode contact quality during stimulation. The appropriate impedance profile will depend on the trial specific electrode size, position, target factors. Each 1x1 shipped customized trial or set of clinical *STIM CONTACT QUALITY™* waveform, and other tDCS-CT unit is for a specific clinical trials.



CRITICAL™ (Red LED) indicates that the contact quality is outside the desired range and stimulation will only continue for the short time and PAUSE (see below).

MODERATE™ (Yellow LED) indicates that the contact quality is not within the desired range. However, stimulation will still proceed.

OPTIMAL™ (Green LED) indicates the contact quality is within the desired starting range.

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.

PAUSE/RESTART™: At any point during stimulation, the operator may PAUSE™ the stimulation by pressing the PAUSE™ button. The operator is responsible for determining when PAUSEing the stimulation is appropriate. Further, if the contact quality is outside the desired range, stimulation will only continue for the short time and automatically PAUSE™. PAUSE™ will not terminate the session. Session can be resumed by hitting PAUSE/RESTART™ again.



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

Pre-Stimulation Setup

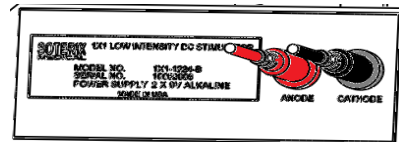
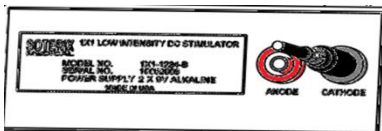
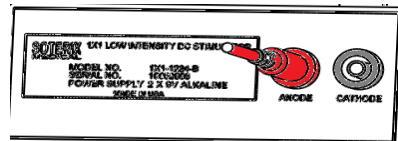
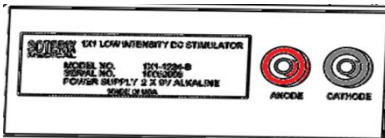
1) Turn the POWER switch **ON**. The STATUS LCD™ will illuminate.



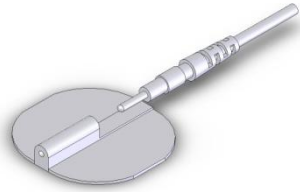
When the subject is connected to the device, turning the power on or off is not recommended.

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) Unless otherwise indicated for your clinical trial, 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).



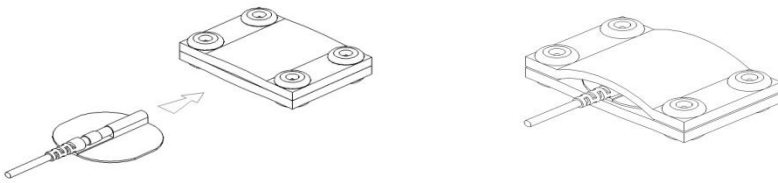
4) Clean the surface of the skin to remove any signs of lotion, dirt, etc. and allow it to dry. Inspect the rubber electrode insets and sponges for wear. If there is any evidence of deterioration, throw out the dirty components and use a new electrode.



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

6) Each side of a 35 cm² sponge should be soaked with approximately 6 mL of saline solution (total of 12 mL per sponge). **Be careful not to over soak the sponge.** Avoid fluid leaking across the subject.

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



For your clinical trial, different EASYpad™ electrodes may be indicated. Ensure the appropriate amount of fluid for each EASYpad™ side is used.

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 electrode inset 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.



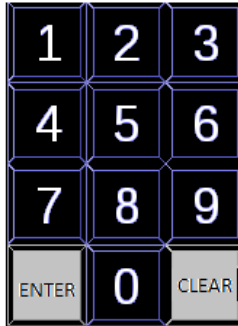
For your clinical trial, special (EASYstrap™) or customized headgear may be indicated.

9) The *SET-UP CONTACT QUALITY™* 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 *SET-UP CONTACT QUALITY™* 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 *SET-UP CONTACT QUALITY™* will constantly update showing the current electrode quality during adjustments.



If the *SET-UP CONTACT QUALITY™* reading is not in the desired range, adjust one or both of the electrode contacts. The *SET-UP CONTACT QUALITY™* will constantly update showing the current electrode quality during adjustments.

10) Once the *SET-UP CONTACT QUALITY™* reading is in the desired range, enter the subject code of the study in the keypad (below), followed by the ENTER button. STATUS LCD™ display, will show ‘correct’ when correct code is entered.



An incorrect code will not be accepted and the code display will re-set. Please re-check and re-enter the code carefully. Hit CLEAR to clear display.

Stimulation will not initiate immediately when you enter the code. The START™ button must be pressed. **See next section.**

Stimulation Procedure

- 1) Confirm that the *SET-UP CONTACT QUALITY™* reading is acceptable.
- 2) Start the stimulation by pressing the *START™* button

*Note: Once the *START™* button is pressed and tDCS begins, the keypad is disabled. The correct subject code must be entered before starting stimulation.*

- 3) The stimulation *ACTIVE™* light will go on.
- 4) The *TIME REMAINING™* display will now indicate the time remaining in the stimulation session. The value will initially show the amount of minutes remaining.
- 5) The *STIM CONTACT QUALITY™* 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. If the quality *STIM CONTACT QUALITY™* changes to *YELLOW (MODERATE)*, the stimulator will *not* automatically *PAUSE* during stimulation. If the *STIM CONTACT QUALITY™* goes into *CRITICAL* mode (Red LED) and stays in *CRITICAL™* mode (Red LED) for duration of 30 seconds in total during a session the stimulator will automatically *PAUSE™* (see step 6), the *PAUSE™* light will illuminate, and the countdown clock will stop.



During tDCS, excessive tampering with the placement of the sponges is not recommended. Special care must be taken during adjustment of stimulation fluid level while stimulation is active (when the *ACTIVE* light is illuminated)



During operation, additional audio or display information may be provided for your clinical trial. These trial specific features may include a single 'beep' when the stimulation enters the CRITICAL™ mode and three 'beeps' when the sessions enters the PAUSE™ mode.

6) The PAUSE/RESTART™ feature can be used at any point during the stimulation; generally, the PAUSE/RESTART™ feature is used to accommodate individual subjects' sensation and/or to adjust the electrode set-up. When the PAUSE™ is pressed, the countdown clock will stop, and stimulation will ramp down to zero until the PAUSE/RESTART™ is pressed again.



When the PAUSE/RESTART™ is pressed, wait till the PAUSED LED stops flashing. As needed, you may now adjust the electrode set-up. SET-UP CONTACT QUALITY™ will continue to indicate the electrode quality as you make adjustments. Stimulation will not start again until the PAUSE/RESTART™ button is pressed again. When stimulation re-starts countdown clock will re-activate.

7) 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.

8) tDCS is now complete. STATUS LCD displays end of stimulation and the session code entered. Press '0' to display number of critical events and the time it stayed in the CRITICAL™ mode.

9) Disconnect the electrodes from the subject.

10) 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. Unlike the PAUSE feature, when ABORT is pressed, stimulation cannot be restarted.

After tDCS is complete, additional stimulation report information may be provided through the device displays. These trial specific messages may include a summary 'code' that should be recorded by the operator.



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



Please use **Soterix Medical** 1x1 tDCS Clinical Trials Stimulator only as directed by this document. Failure to do so might result in an unexpected outcome.

Specifications, Warranty, Maintenance and Disposal, and Definition of Symbols

Specifications – 28

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Maintenance and Disposal – 30

Definition of Symbols Used – 31

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 Stimulation Clinical Trials 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 provides an explanation of the symbols used for marking on the equipment and packaging.

Specifications

Electrical and Operating Characteristics*

Power source: 4, 9V Alkaline batteries
 Battery life (with fresh batteries): 5 hrs**
 Length: 11 in.
 Width: 8 in.
 Height: 3.5 in.
 Connector type: Shielded Banana

Storage and Operating Conditions

Parameter	Storage	Operating
<i>Minimum temperature</i>	50 °F	50 °F
<i>Maximum temperature</i>	110 °F	110 °F
<i>Minimum humidity</i>	20%	20%
<i>Maximum humidity</i>	90%	90%
<i>Minimum atmospheric pressure</i>	20.7 in. Hg (700 hPa)	20.7 in. Hg (700 hPa)
<i>Maximum atmospheric pressure</i>	31.3 in. Hg (1060 hPa)	31.3 in. Hg (1060 hPa)

*All measurements are approximated

** Test performed with 4x9V 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 Clinical Trial Unit Model 1500, 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 tDCS-Clinical Trials Stimulator**, read the following instructions.

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

- To clean the **Soterix Medical** 1x1 tDCS CT 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 CT Stimulator, as this will void your warranty.
- Do not disinfect the **Soterix Medical** 1x1 tDCS CT Stimulator
- Return the device to Soterix Medical for disposal when the device is no longer required.
- Do not throw the **Soterix Medical** 1x1 tDCS CT 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 AWAY FROM WATER	Keep Dry. Protect from Water.
	Device runs on DC current.
	Operate between 10°C – 43°C (50°F – 110°F)
	Serial Number
	Address of manufacturer
	Do not re-use

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Contact Information –
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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 and 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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