

1x1 Animal Transcranial Direct Current (tDCS) Stimulator

Model 2100



Operator's Manual

Version 2
June 2016

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.

Contents

Page Title Page

- iii. Notice
- iv. Caution
- v. Contents

Introduction

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

Health and Safety

- 6. Precautions and Warnings
- 8. Regulatory Statements

Product Description

- 10. Items Supplied
- 11. Front Panel
- 12. Back Panel
- 13. Control Keys

Device Operation

- 15. Inserting and Replacing the Battery
- 16. Description of Special Features
- 17. Pre-Stimulation Setup
- 21. Stimulation Procedure

Specifications and Warranty

- 24. Specifications
- 24. Electrical and Operating Characteristics
- 24. Storage and Operating Conditions
- 25. Warranty
- 26. Maintenance and Disposal
- 27. Definition of Symbols Used

Further Information

- 30. Bibliography
- 32. Contact Information

Introduction

Intended Use - 2

Getting to Know the Product - 2

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 Animal tDCS** stimulator.

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 makes the **Soterix Medical 1x1 Animal tDCS Stimulator** one of a kind for animal research.

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 Animal tDCS 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. The 1x1 Animal tDCS device is indicated to be used only on animals and not on human subjects.

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. The **Soterix Medical Animal tDCS** system allows precise reproduction of tDCS doses commonly used in rat and mice studies to-date. **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 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

Unlike other stimulators, the **Soterix Medical 1x1 Animal tDCS stimulator** is simple to use and designed especially for rodent experiments using rats and mice.

Provided **Soterix Medical Animal tDCS accessories** allow for simple and reliable positioning of the electrodes. The operator must set the intensity of current (in units of mA) and duration of stimulation (in minutes) before initiating the stimulation.

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

- 1) Ensure reproducible and precise tDCS operation
- 2) Provide for simple tDCS set-up and stimulation.
- 3) Conduct animal research with state-of-the-art control and safety features.

The **Soterix Medical** 1x1 Animal tDCS stimulator includes proprietary features to ensure robust tDCS application including TRUE CURRENT™ and SMARTscan™. By reading this manual and understanding these unique features, operators of the device can enhance the efficacy and administration of tDCS.



Use of This Manual

This manual contains details of installation, setup, and operation of the **Soterix Medical** 1x1 Animal unit and its accessories. This manual must be read in its entirety before commencing any stimulation. If the instructions in this manual are not precisely followed, the performance of this product and/or the safety of the animal 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 unreliable operation and possible injury.

Precautions and
Warnings - 6

Regulatory
Statements - 8

Health and Safety

This chapter dictates the required precautions and regulations for safe operation of the device.

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 and ensure reliable operation, 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 Animal tDCS Stimulator in water or any other fluids.
 - The **Soterix Medical** 1x1 Animal tDCS Stimulator should not be used in a moist environment or if any parts of the stimulator are damp or wet.
 - The **Soterix Medical** 1x1 Animal tDCS 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 Animal tDCS Low-Intensity Stimulator near flammable atmosphere are unknown.
 - The **Soterix Medical** 1x1 Animal tDCS 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 Animal tDCS 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 Animal tDCS Stimulator is being used. The consequences of potential interference from communication and entertainment devices on the **Soterix Medical** 1x1 Animal tDCS Stimulator are unknown.
 - Do not use the **Soterix Medical** 1x1 Animal tDCS 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 Animal tDCS Stimulator after it has been transported or stored at temperatures outside of the specific range are unknown.

- External Damage
 - Do not drop the device.
 - The **Soterix Medical** 1x1 Animal tDCS 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 Animal tDCS Stimulator. Immediately return the device to **Soterix Medical Inc.** for repair.
- Cables
 - When connecting cables to the output jacks, use only the cables provided 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 Animal tDCS Stimulator.
- 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 Animal tDCS Stimulator is allowed.
- Battery
 - Observe proper precautions when handling battery. Be sure the product is off before replacing battery.
 - Use only battery approved for use in this equipment. Observe instructions stated in this manual when inserting battery.
- Technique

- The **Soterix Medical** 1x1 Animal tDCS Stimulator must only be used by a trained operator at a clinical laboratory. 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 DURATION 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 Animal tDCS Stimulator is applied within local and federal or country guidelines as relevant.

Regulatory Statements

Transcranial Direct Current Stimulation (tDCS) is an investigational technique. It is limited by Federal law to investigational use under appropriate Institutional Animal Care and Use Committee (IACUC).

USA:

CAUTION: The **Soterix Medical 1x1 Animal tDCS Stimulator** is an investigational device. Federal (or United States) law limits device to investigational use in laboratory or other tests that do not involve human subjects.

Product Description

Items Supplied - 10

Front Panel - 11

Back Panel - 12

Control Keys - 13

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 Animal tDCS 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 Animal Transcranial Direct Current Stimulator
- 1 Red anode cable
- 1 Black cathode cable

Items Supplied Separately

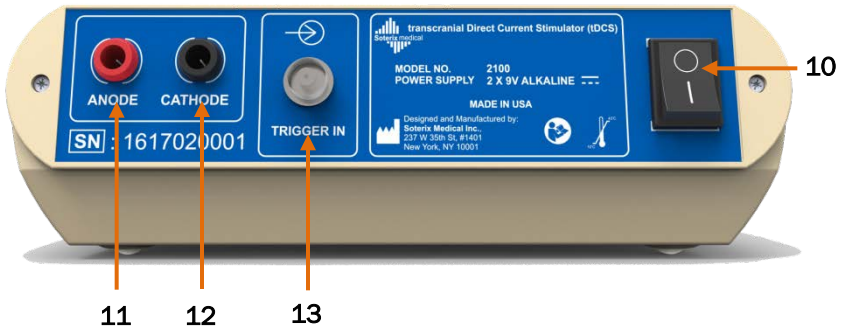
- **Soterix Medical** Epicranial electrode implant
- Surface stimulation electrode
- Conductive adhesive paste
- Animal jacket

(Customizable accessories available upon request)

Front Panel



Back Panel



Control Keys

- 1.** A display, which indicates the amount of time remaining and the programmed intensity of the session. It also displays stimulation status messages.
- 2.** A display which indicates how “good” the contact quality of the leads are.
- 3.** Adjusts the INTENSITY of current to be delivered prior to the start of stimulation.
- 4.** Adjusts the DURATION of the session prior to the start of stimulation.
- 5.** Indicates if there is low battery by illuminating red.
- 6.** A display that indicates the amount of current being produced by the device.
- 7.** Stops the stimulation.
- 8.** Starts the stimulation.
- 9.** Activates or deactivates SHAM.
- 10.** Turns on or off the device.
- 11.** The connector for the anode cable.
- 12.** The connector for the cathode cable.
- 13.** The trigger input port.

Device Operation

Inserting and Replacing
the Battery - 15

Description of Special
Features - 16

Pre-Stimulation
Setup - 17

Stimulation
Procedure - 20

This chapter outlines the steps needed to operate your **Soterix Medical 1x1 Animal tDCS Stimulator**

Inserting and Replacing the Battery:

This section explains how you must insert the battery into the device. It also explains how to replace it 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 Animal tDCS Stimulator** device.

Pre-Stimulation Setup

Here you are provided with information about the first steps you must take to prepare the device and animal 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 Battery

The 1x1 Animal tDCS 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 compartment. Insert the batteries, one at a time, ensuring proper battery orientation. After the batteries are in place, replace the battery cover by sliding it back into its place and pressing it down until it “snaps” into place.

Immediately after battery insertion, power up the 1x1 Animal tDCS. If the device does not power up, check that the batteries are good and inserted correctly.



Note: Batteries should be removed from the 1x1 Animal tDCS Stimulator if it is not likely to be used for an extended period of time.

Batteries should be replaced every 6 hours of use or when the low battery indicator is illuminated. Do not use abrasive cleaners on the battery contacts.

To replace the batteries, repeat instructions above. 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 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™ 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 the operator following best tDCS protocols. Any issues or concerns identified by the operator should be addressed regardless of the SMARTscan™ reading.

Pre-Stimulation Setup

1) Turn the POWER switch **ON**. The TRUE CURRENT™ display will illuminate and indicate “**0.01**” mA. The LCD display will turn on displaying an introductory message and then default to **Duration: 05 min** and **Intensity: 0.02 mA**. The SMARTscan™ display will illuminate with LED 2 lit indicating an open-circuit condition.

The TRUE CURRENT reading of 0.01 mA indicates the device standby current or test current. The standby current is the minimal current that is required to be generated by the device to robustly determine the contact quality of the electrodes. The default duration and intensity values indicate the minimum duration and the minimum intensity values that can be generated by the device.



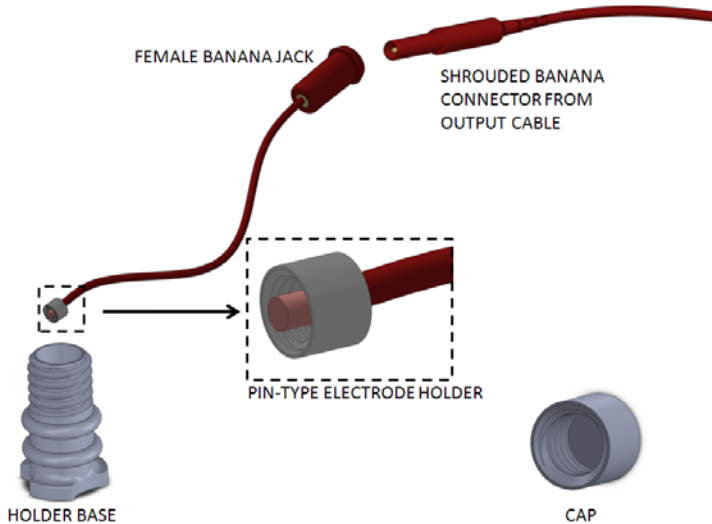
When the animal is connected to the device, turning the power on or off is not recommended.

2) If LOW BATTERY is illuminated, do not proceed with stimulation. Replace the existing battery with a new one. Make sure the battery is inserted correctly as per instructions above.

3) Connect the provided cables to the back of the device using the shrouded banana plug ends. To attach the cables, insert the shrouded end 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”.

4) Electrodes on the rats and mice are typically placed either epicranially or directly on the body. For direct body application, go to section on *Positioning surface electrodes* below.

Soterix Medical Epicranial implant comprises of three parts: 1) a cylindrical holder base, 2) cap, and 3) a pin-type electrode holder. The pin-type electrode holder holds a pellet Ag/AgCl stimulation electrode. The holder base has an inner diameter of 3.5 mm and is fixed directly on the skull with dental cement (see figure below).



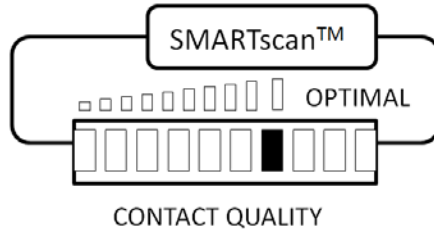
Inspect the epicranial implant base and the pin-type electrode holder for wear. If there is any evidence of deterioration, replace the corresponding part with a new replacement.



The stimulation electrode will provide a limited number of total applications due to charge imbalance from DC application. Contact Soterix Medical for further information.

- 5) Insert the shrouded banana connector end of the output cable securely into the female banana jack of the pin-type electrode holder.
- 6) The epicranial implant base fixed to the skull is first filled with conductive gel. The pin-type electrode holder is then mounted on the base by screwing onto it. **Ensure to completely fill the implant base.** The pin-type electrode holder can be unscrewed from the base and replaced with a cap when not in use.
- 7) As soon as both the anode and cathode are connected to the animal, the SMARTscan™ contact quality meter will 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 SMARTscan™ 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™ will constantly update showing the current electrode quality during adjustments.

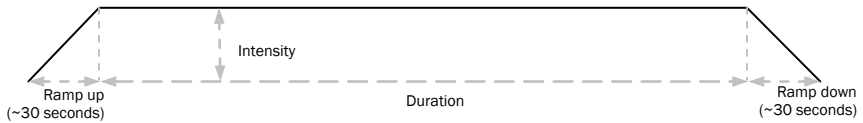


8) Once the SMARTscan™ reading is in the desired range, set the INTENSITY to the desired current value (in mA) from the minimum value of 0.02 mA (20 uA) by rotating knob clockwise. Note that the knob rotates in both directions such that one can start at the highest available setting (1.00 mA) and dial down by rotating knob counter-clockwise. Then set DURATION to the desired duration value (in minutes) from a minimum value of 05 min by rotating knob clockwise. Note that the DURATION knob also rotates in both directions such that one can start at the highest available setting (60 min) and dial down by rotating knob counter-clockwise.

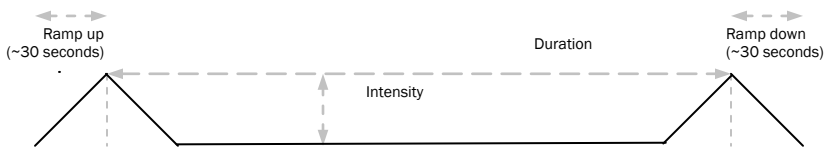


It is the responsibility of the operator to ensure that the current and duration values are appropriate and safe for the application.

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



9) Select either SHAM ON or OFF by pressing the SHAM switch on the front panel. When pressed from the SHAM OFF position, the switch glows green (SHAM ON condition). SHAM ON waveform is shown below.



Positioning surface electrodes

Most studies have used a carbon rubber electrode held inside a saline soaked sponge as used typically in clinical experiments. The sponge electrode is held onto the thoracic area or the abdominal area of the animal using a jacket. Some studies have directly positioned ECG electrodes using a conductive adhesive paste or hydrogel. In this case, the body may be shaved for better adherence.

Contact Soterix Medical for selecting the right accessories for your experiment.

Stimulation Procedure

1) Confirm that both the INTENSITY and DURATION are set to the desired values. SHAM is set to its desired setting and CONTACT QUALITY displays a value other than LED 1 or LED 2.

2) Start the stimulation by pressing the START button.

Note: Once the START button is pressed and tDCS begins, changing the duration, intensity, and condition (sham on or off) settings will have no effect on the ongoing stimulation. These settings are to be set prior to the start of the stimulation.

Note the stimulator can also be triggered to start by a TTL trigger pulse input via the BNC socket on the rear panel.

3) The LCD display changes from the default display to “**Ramping Up. . .**” indicating the ramp-up period of 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, LCD will change to show **Duration: XX M : YY s**. This indicates that XX minutes and YY seconds remain in the stimulation session. The LCD will also indicate “**Stimulating. . .**” throughout, indicating an on-going session. The duration display value will start at the time selected in DURATION and count down.

5) The TRUE CURRENT™ display constantly shows the current delivered to the animal. 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 continuously during stimulation. The operator should monitor this display during stimulation. It is typical for electrode quality to improve during stimulation, while a deteriorating quality may indicate a problem with the electrode contacts. 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 tDCS, tampering with the placement of the electrodes is not recommended.

7) When time remaining reaches zero as indicated by the **Duration** readout, the LCD will display "**Ramping down. . .**" indicating beginning of the ramp down period. The current will now ramp down for approximately 30 seconds.

10) Once the ramp down is complete, the LCD will indicate the default setting of Duration 05 min and Intensity of 0.02 mA. The TRUE CURRENT™ will display 0.01 mA.

11) tDCS is now complete.

12) Disconnect the electrodes from the animal.

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



Please use **Soterix Medical** 1x1 Animal tDCS 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 – 23

Warranty – 24

Maintenance and
Disposal – 25

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 Animal tDCS 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): 6 hrs**

Standby Current: 0.01 mA (10 μ A)

Adjustable Output Current: 20 μ A - 1000 μ A DC with 10 μ A resolution

Adjustable duration: 5 min - 60 min with 1 min resolution

Length: 6.89 in.

Width: 4.89 in.

Height (front): 1.52 in.

Height (back): 2.45 in.

Connector type: shrouded banana

Maximum Output Voltage: 40V \pm 5%

Trigger:

Electrical via BNC socket on rear panel

Triggers at +5V on positive edge TTL

Maximum input: +15 V

Minimum pulse duration: 100 microsecond

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 1x9V 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 Animal tDCS Stimulator Model 2100, 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 Animal tDCS Stimulator, read the following instructions.

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

- To clean the **Soterix Medical 1x1 Animal tDCS 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 Animal tDCS Stimulator**, as this will void your warranty.
- Do not disinfect the **Soterix Medical 1x1 Animal tDCS Stimulator**
- Return the device to Soterix Medical for disposal when the device is no longer required.
- Do not throw the **Soterix Medical 1x1 Animal tDCS Stimulator** in generic waste.
- Discharged battery must be disposed appropriately in accordance with national regulations in force.
- Output cables, epicranial implants, and surface electrodes can be disposed in generic waste when no longer required.

Definition of Symbols Used

	Refer to instruction manual/booklet
	Device runs on DC current.
43°C 10°C	Operate between 10°C – 43°C (50°F – 110°F)
	Serial Number



Address of manufacturer

Bibliography – 29

Contact Information –
31

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 animal tDCS research.

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 animal 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.

- 1) Anticonvulsant effects of transcranial direct-current stimulation (tDCS) in the rat cortical ramp model of focal epilepsy. Liebetanz D, Klinker F, Hering D, Koch R, Nitsche MA, Potschka H, Löscher W, Paulus W, Tergau F. *Epilepsia*. 2006 Jul;47(7):1216-24.
- 2) After-effects transcranial direct current stimulation (tDCS) on cortical spreading depression. Liebetanz D, Fregni F, Monte-Silva KK, Oliveira MB, Amâncio-dos-Santos A, Nitsche MA, Guedes RC. *Neurosci Lett*. 2006 May 1;398(1-2):85-90.
- 3) Effects of transcranial direct current stimulation coupled with repetitive electrical stimulation on cortical spreading depression. Fregni F, Liebetanz D, Monte-Silva KK, Oliveira MB, Santos AA, Nitsche MA, Pascual-Leone A, Guedes RC. *Exp Neurol*. 2007 Mar;204(1):462-6.
- 4) Brain transcranial direct current stimulation modulates motor excitability in mice. Cambiaghi M, Velikova S, Gonzalez-Rosa JJ, Cursi M, Comi G, Leocani L. *Eur J Neurosci*. 2010 Feb;31(4):704-9
- 5) Flash visual evoked potentials in mice can be modulated by transcranial direct current stimulation. Cambiaghi M, Teneud L, Velikova S, Gonzalez-Rosa JJ, Cursi M, Comi G, Leocani L. *Neuroscience*. 2011 Jun 30;185:161-5
- 6) Safety limits of cathodal transcranial direct current stimulation in rats. Liebetanz D, Koch R, Mayenfels S, König F, Paulus W, Nitsche MA. *Clin Neurophysiol*. 2009 Jun;120(6):1161-7
- 7) Transcranial direct current stimulation induces polarity-specific changes of cortical blood perfusion in the rat. Wachter D, Wrede A, Schulz-Schaeffer W, Taghizadeh-Waghefi A, Nitsche MA, Kutschenko A, Rohde V, Liebetanz D. *Exp Neurol*. 2011 Feb;227(2):322-7

- 8) Cumulative benefits of frontal transcranial direct current stimulation on visuospatial working memory training and skill learning in rats. Dockery CA, Liebetanz D, Birbaumer N, Malinowska M, Wesienska MJ. *Neurobiol Learn Mem.* 2011 Oct;96(3):452-60.
- 9) A rat model for measuring the effectiveness of transcranial direct current stimulation using fMRI. Takano Y, Yokawa T, Masuda A, Niimi J, Tanaka S, Hironaka N. *Neurosci Lett.* 2011 Mar 10;491(1):40-3.
- 10) After-effects of consecutive sessions of transcranial direct current stimulation (tDCS) in a rat model of chronic inflammation. Laste G, Caumo W, Adachi LN, Rozisky JR, de Macedo IC, Filho PR, Partata WA, Fregni F, Torres IL. *Exp Brain Res.* 2012 Aug;221(1):75-83.
- 11) Reversal of chronic stress-induced pain by transcranial direct current stimulation (tDCS) in an animal model. Spezia Adachi LN, Caumo W, Laste G, Fernandes Medeiros L, Ripoll Rozisky J, de Souza A, Fregni F, Torres IL. *Brain Res.* 2012 Dec 13;1489:17-26
- 12) Cathodal transcranial direct current stimulation induces regional, long-lasting reductions of cortical blood flow in rats. Mielke D, Wrede A, Schulz-Schaeffer W, Taghizadeh-Waghefi A, Nitsche MA, Rohde V, Liebetanz D. *Neurol Res.* 2013 Dec;35(10):1029-37
- 13) Transcranial direct-current stimulation increases extracellular dopamine levels in the rat striatum. Tanaka T, Takano Y, Tanaka S, Hironaka N, Kobayashi K, Hanakawa T, Watanabe K, Honda M. *Front Syst Neurosci.* 2013
- 14) Reversal of chronic stress-induced pain by transcranial direct current stimulation (tDCS) in an animal model. Spezia Adachi LN, Caumo W, Laste G, Fernandes Medeiros L, Ripoll Rozisky J, de Souza A, Fregni F, Torres IL. *Brain Res.* 2012 Dec 13;1489:17-26

Contact Information

Soterix Medical Inc.
237 W 35 ST, 1401
New York, NY 10001
Tel: 888-990-8327
Fax: 212-315-3232
Email: contact@soterixmedical.com
Internet: www.SoterixMedical.com

Thank you for purchasing a **Soterix Medical 1x1 Animal Transcranial Direct Current Model 2100 Stimulator**.



If you arrive at a problem, or have any questions, comments, or concerns, please feel free to contact us at SoterixMedical.com

Manufacturer

Soterix Medical, Inc.
237 W 35 ST, 1401
New York, NY 10001
Tel: 888-990-TDCS
Fax: 212-315-3232
ISO 13485:2012 certified
ISO 13485:2003 certified

