4X1 High Definition - transcranial Direct Current Stimulation Multichannel Stimulation Interface Model 4X1-C3A

Operator's Manual

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December 2015

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CAUTION

As an ultimate user of this apparatus, you have the responsibility to understand its proper function and operational characteristics. This operational 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

This chapter introduces you to the basics required to read this manual and operate the **Soterix Medical** HD-tDCS Multichannel Stimulation Interface.

Getting to Know the Product:
Read this section to learn the basics of what the 4X1 Multichannel Stimulation Interface is.

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

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Intended Use

The 4X1 Multi Channel Stimulation Interface is an accessory to an isolated 2-channel tDCS stimulator and does not function as a stand-alone electrical stimulator or generator. tDCS is a non-invasive procedure in which a device sends a small Direct Current (DC) across the scalp to modulate brain function.

The 4X1 device is designed to be used as an interface device between an isolated 2-channel current controlled tDCS stimulator and 5 stimulation leads; where 4 leads are connected to one output of the tDCS stimulator while the remaining 5th lead is connected to the other output of the tDCS stimulator. The output leads connect to smaller high-definition (HD) electrodes, instead of the larger sponge electrodes using in conventional 2-channel tDCS.

The device operates in two modes: SCAN and PASS mode. In PASS MODE, the 4X1 does not modulate the waveform of the tDCS stimulator, and acts only as a passive current divider (Figure 1).

The 4X1 can only be operated by qualified and trained medical personnel who fully understand both the tDCS stimulator and the 4X1 HD-tDCS device functionality.

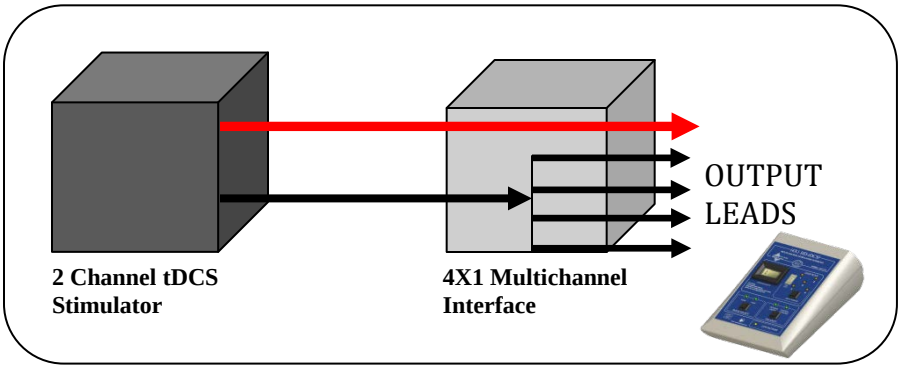

Figure 1: The schematic illustrates that in PASS MODE, the 4X1-C3 acts as a passive current divider

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*This device is protected by US patent numbers **8,494,627** and **8,718,778** and numerous other international patents issued and pending.*

Use of This Manual

This manual contains full details of installation, setup, and operation of the **Soterix Medical** 4X1 unit and its accessories. 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.

Please use **Soterix Medical** 4X1 Multi Channel Stimulation Interface only as directed by this document. Failure to do so might result in unexpected outcome.

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Health and Safety

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This chapter dictates the information required for both your and your patient's safety:

Safety Features and Modes:
Read this section for the important list of precautionary measures for each mode of the device.

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

Regulatory Statements
Read this section for regulatory information pertaining to the 4X1 Multichannel device.

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Safety Feature and Modes

When in SCAN MODE, the 4X1 device provides functionality for accessing lead quality. Albeit this function is intended to facilitate multichannel High Definition-transcranial Direct Current Stimulation (HD-tDCS), in PASS MODE, this functionality is disengaged, leaving only passive current division.

When set to PASS MODE, the 4X1 device is designed *not* to augment or modulate the 2-channel tDCS stimulator output, beyond the passive dividing of one stimulation channel into 4 output leads. The combined output of the 4 black output leads (as depicted in Figure 1) is thus equivalent to the single black colored input. In PASS MODE, if the tDCS stimulator is disconnected or is not generating an output, then the output of the 4X1 device leads is therefore zero.

When set to SCAN MODE, the 4X1 Multi Channel Stimulation Interface device functions as a low-current lead resistance meter, which can provide the operator with information about lead quality and potential faults. In this mode, the 4X1 Multi Channel Stimulation Interface device disconnects the 4X1 device 2-channel input from the 5-channel output.

When the 4X1 Multi Channel Stimulation Interface is powered OFF, the 4X1 device 2-channel input is disconnected from the 5-channel output. When turned OFF, the output of the 4X1 is zero.

The described features are incorporated to increase stimulation efficacy and safety <u>only where appropriate</u>. It should be apparent that the use of the 4X1 Multi Channel Stimulation Interface device does not reduce or replace the responsibility of the operator to understand both the tDCS stimulator and 4X1 device functionality fully.

It is recommended to use only use approved High-definition (HD) electrodes, HD electrode holders, and HD stimulation gel (HD-GEL) which have been specifically tested for safety and tolerability of HD-tDCS.

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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 will read them.

- Environment and Moisture
  - Do not immerse the 4X1 Multi Channel Stimulation Interface in water or any other fluids.
  - The 4X1 Multi Channel Stimulation Interface should not be used in a moist environment or if any of the parts are damp or wet
  - The **Soterix Medical** 4X1 Multi Channel Stimulation Interface 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** 4X1 Multi Channel Stimulation Interface near flammable atmosphere are unknown.
  - The **Soterix Medical** 4X1 Multi Channel Stimulation Interface 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** 4X1 Multi Channel Stimulation Interface in a magnetic environment are unknown.
  - Do not use the **Soterix Medical** 4X1 Multi Channel Stimulation Interface if it was transported or stored at temperatures outside of the specific range mandated by **Soterix Medical**. Allow the equipment to stabilize to a temperature within the specific range before use.

- External Damage
  - Do not drop the device
  - The 4X1 Multi Channel Stimulation Interface 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 4X1 Multi Channel Stimulation Interface. Immediately return the device to **Soterix Medical** for repair.

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- Cables and Accessories
  - When connecting cables to the input or output jacks, use only the cables provided or sold by **Soterix Medical** for the purpose, to maintain compliance with product regulations.
  - Make sure all cables are fully inserted in the correct receiver before operating the 4X1 Multi Channel Stimulation Interface.
  - Use only approved High-Definition (HD) electrodes, HD electrode holders, and electrically conductive HD stimulation gel (HD-GEL). Note that the HD electrodes provide a limited number of total applications. Contact Soterix Medical for further information.

- Internal Parts
  - Do not disassemble. Touching the product's internal parts could result in injury. In the event of a malfunction, only a qualified technician should repair the product from **Soterix Medical**. Should the product break open as the result of a fall or other accident, remove the battery and return the product to **Soterix Medical** for repairs.

- 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 is in use.

- Technique
  - The **Soterix Medical** 4X1 Multi Channel Stimulation HD Interface must only be used with appropriate supervision, accessories, and by trained medical personnel. Even experienced operators must carefully read and fully follow all the following instructions and guidelines.

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- All contraindications for tDCS are also applicable for HD-tDCS. 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 much ensure the tDCS is applied within local and federal or country guidelines as relevant.

Regulatory Statements

Transcranial Direct Current Stimulation (tDCS) and High Definition-transcranial Direct Current Stimulation (HD-tDCS) are investigational techniques. It is limited by Federal (or United States) law to investigational use under appropriate Institutional Review Board (IRB) guidelines. In countries outside United States, local Ethics Committee or appropriate local body's approval is required.

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Product Description

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Control Keys –19

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 for the 4X1 Multichannel Stimulation Interface Device as well as any items that could be sent out additionally to the standard package.

Front Panel:
This section contains a large picture of the front panel with every button labeled with a number.

Back Panel:
This section contains a large picture of the rear panel with every button labeled with a number.

Control Keys:
Here is a basic description of what each button activates, deactivates, or controls. Further sections will give further details on the function of each button.

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Items Supplied

Carefully remove all components from the shipping container. One of each should be included:

- ☐ 1 4X1 Multichannel Stimulation Interface Device
- ☐ 1 CSIN-X2 Input Cable
- ☐ 1 CSOP-D5A Output Cable

Figure 2: 4X1 Multichannel Stimulation Interface

Figure 3: CSIN-X2 Input Cable

Figure 4: CSOP-D5A Output Cable

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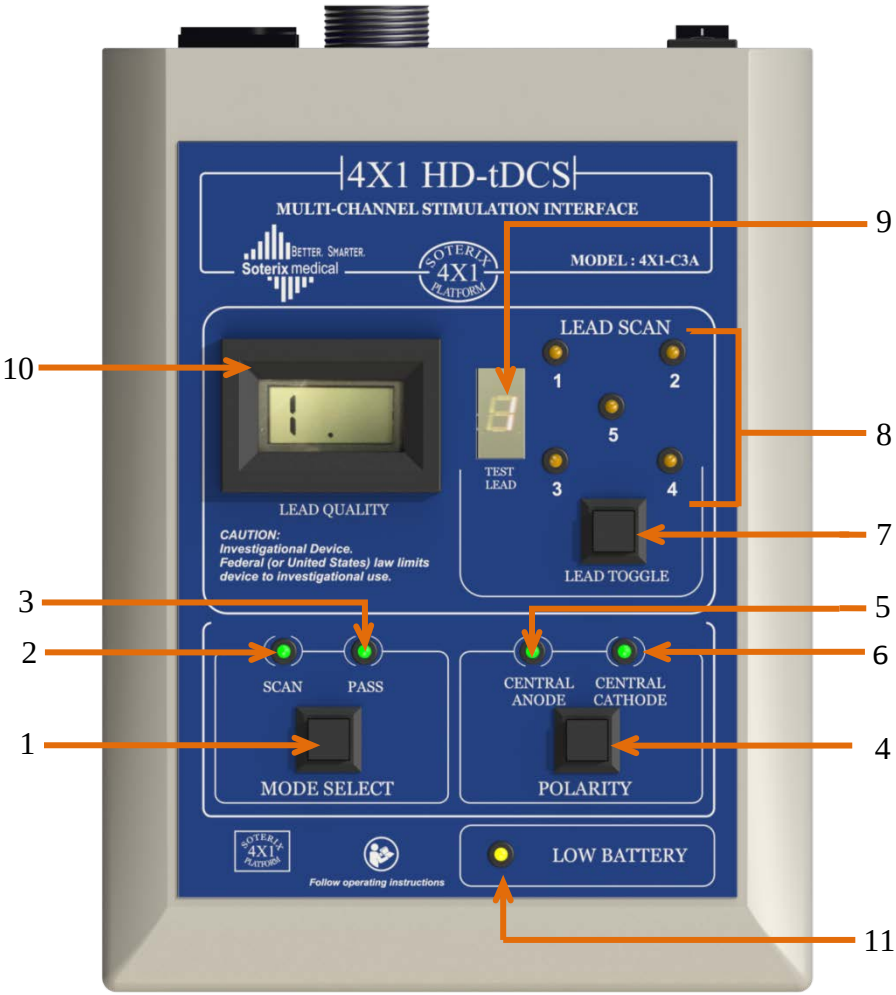
Front Panel


4X1 HD-tDCS
MULTI-CHANNEL STIMULATION INTERFACE
BETTER. SMARTER.
Soterix medical
SOTERIX 4X1 PLATFORM
MODEL : 4X1-C3A
LEAD SCAN
1
2
5
3
4
TEST LEAD
LEAD QUALITY
CAUTION:
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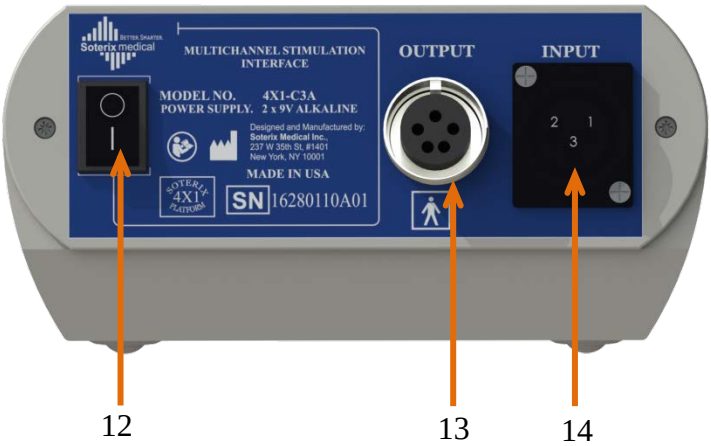
LEAD TOGGLE
SCAN
PASS
MODE SELECT
CENTRAL ANODE
CENTRAL CATHODE
POLARITY
Follow operating instructions
LOW BATTERY
1
2
3
4
5
6
7
8
9
10
11

Back Panel


Soterix medical
MULTICHANNEL STIMULATION INTERFACE
MODEL NO. 4X1-C3A
POWER SUPPLY. 2 x 9V ALKALINE
Designed and Manufactured by:
Soterix Medical Inc.,
237 W 35th St, #1401
New York, NY 10001
MADE IN USA
SN 16280110A01
OUTPUT
INPUT
2
1
3
12
13
14

Control Keys

1) Switch to select the two possible modes- SCAN or PASS MODE.
2) A light which indicates if SCAN MODE is activated by illuminating.
3) A light which indicates is PASS MODE is activated by illuminating.
4) Switch to select the two possible polarity options for the central electrode- CENTRAL ANODE or CENTRAL CATHODE.
5) A light which indicates if CENTRAL ANODE is activated by illuminating.
6) A light which indicates if CENTRAL CATHODE is activated by illuminating.
7) A switch when pressed once, toggles through the 5 leads. Pressing the switch second time, locks the display on a selected lead. Pressing switch again causes the device to toggle through the 5 leads.
8) A grouping of lights which indicates the specific lead that is in use by illuminating the corresponding light.
9) Numerical display of the specific lead in use.
10) A display which shows the quality of the lead. The value varies from a minimum of 0.00 to a maximum of 19.99 quality units.
11) Indicates if there is a low battery supply by illuminating.
12) Turns ON or OFF the device.
13) The receiver for the output cable
14) The receiver for the input cable

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Device Operation

Inserting and Replacing Batteries – 21
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Troubleshooting – 32

This chapter gives a systematic process for everything you must know and do to operate your **Soterix** 4X1 HD-tDCS Multichannel Interface Device.

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.

Pre-Stimulation Setup
Here you will find the first things you must do to prepare the device for stimulation

Stimulation Procedure
Here is the procedure for 4X1 HD stimulation. It gives a list of everything the operator must do and the device does during stimulation.

Troubleshooting
This section gives a list of common errors as well as their potential causes and solutions.

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Inserting and Replacing the Batteries

The 4X1 Multichannel Stimulation Interface 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. Insert the two batteries, one at a time, with the connectors facing the top of the device.

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 4X1 Multichannel Stimulation Interface to ensure correct battery placement. If the 4X1 device does not power up, check that the batteries are good and inserted correctly.

Note: Batteries should be removed from the 4X1 Multi Channel Stimulation Interface if it is not likely to be used for an extended period of time.

Please observe the proper direction of the battery's polarity before inserting the battery 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 the negative connectors toward the inside.

Batteries should be replaced 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.

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Pre-Stimulation Setup

Connecting the 2-Channel tDCS Stimulator to the 4X1 Interface

The CSIN-X2 Input cable is intended to connect a 2-channel isolated current-controlled tDCS stimulator with the 4X1 HD-tDCS Device.

The CSIN-X2 Input cable can be connected to the tDCS stimulator by connecting the red and black banana cables of the input cable to the similarly colored red and black colored output receivers of the tDCS stimulator. The red banana cable must be inserted into the red receiver labeled "anode" and the black banana cable inserted into the black colored receiver labeled "cathode" (Figure 5).

Connect the 3-pin black cone plug of the CSIN-X2 Input cable to the "INPUT" port on the back panel of the 4X1 device (Figure 6).

Do not power ON the tDCS Stimulator at this time.

It is the responsibility of the device operator to understand both the tDCS stimulator and the 4X1 HD-tDCS device function fully and to guarantee that both the input and output cables are connected properly.

Do not connect or disconnect the output connector, the input connector, or any leads while the tDCS stimulator is generating an output.

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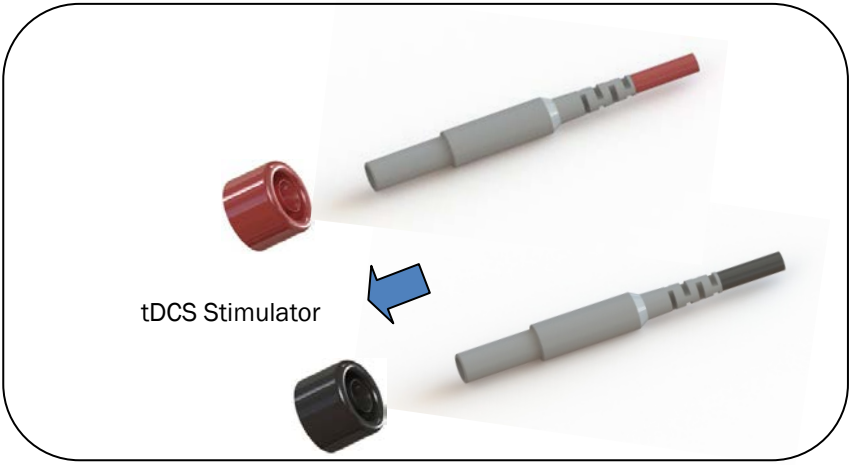

Figure 5: Method of connecting the CSIN-X2 Input Cables to the tDCS Stimulator

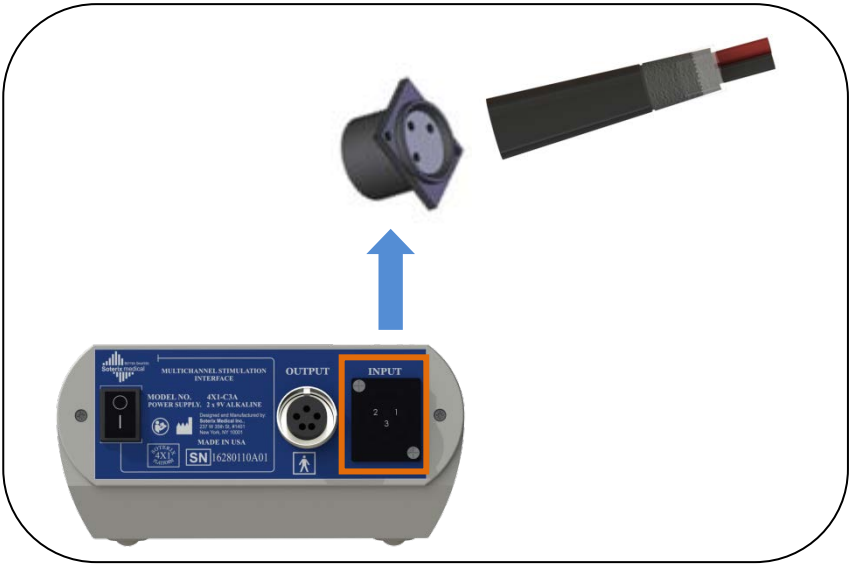

Figure 6: Method of connecting the CSIN-X2 Input cable to the 4X1 Interface

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Connecting the CSOP-D5A Output Cable to the 4X1 Interface

Connect the 5-pin cylindrical plug of the CSOP-D5A connector to the "OUTPUT" port on the back panel of the 4X1 Interface Device (Figure 7).

- Always use the supplied cables to connect the 4X1 device with the stimulator
- Ensure all cables and leads are fully inserted in the receptor sockets before operating the 4X1 device.

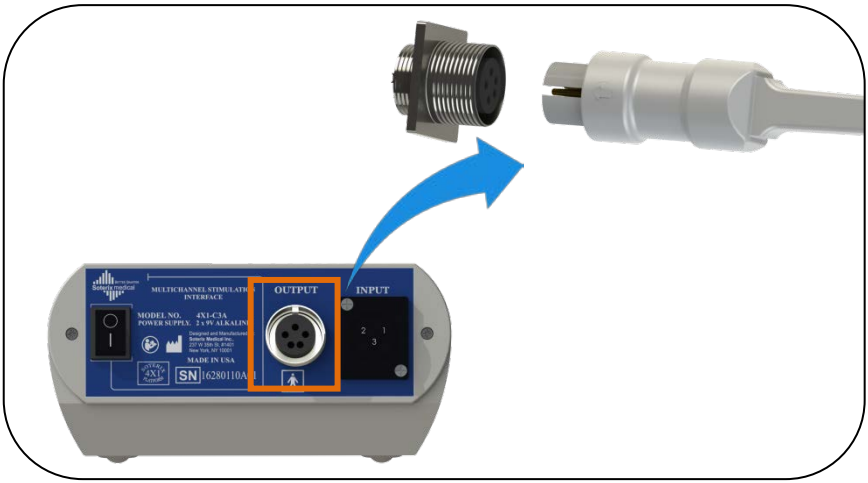

Figure 7: Connecting the CSOP-D5A Output cable to the 4X1 Interface

Connecting the 5 Stimulation Electrodes to the CSOP-D5A Output Cable

Stimulation electrode plugs can be connected on the flat-connector end of the CSOP-D5A Output Cable. The 5 output receiver plugs on the Output Cable are number coded 1 - 5 (see Figure 8). Note that the stimulation electrode connected to receiver plug 5 is treated as the "Center" of 4X1 HD stimulation and is therefore labeled as such on the Front Panel (Lead 5). This HD stimulation electrode defines the DC polarity delivered from the central electrode as either anodal or cathodal. Polarity of Lead 5 is simply

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selected by using the POLARITY switch (defined below).

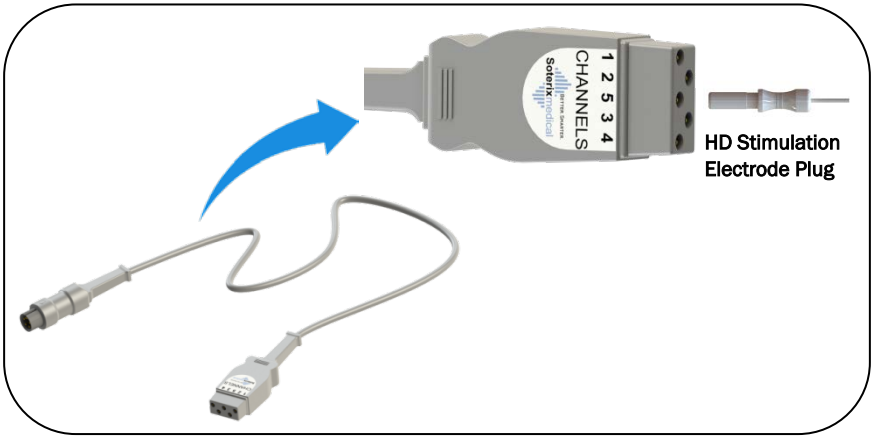

Figure 8: Inserting the Leads into the CSOP-D5A Output cable

Make sure to connect the central electrode for 4X1 HD stimulation to the center receiver plug (labeled 5). Then, connect the remaining electrodes into the surrounding receiver plugs. It should be noted that the arrangement of the remaining four electrodes (labeled 1, 2, 3, and 4) is not critical, as they will be all of the same polarity. Make sure all 5 HD stimulation electrode plugs are fully inserted into the receiver plugs of the CSOP-D5A Output Cable.

The HD electrodes fit the base of the HD electrode-holders. The HD electrode-holder and electrode are attached to the HD Cap and fitted on the subject's head. Electrode gel forms the interface between the electrode and the subject.

It is the responsibility of the device operator to understand both the tDCS Stimulator and the 4X1 HD-tDCS Device function fully and to guarantee that the CSOP-D5A cable is properly connected to the 5 output leads.

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Turning the 4X1 Interface System On

The Power switch is located in the back panel of the device (Figure 9).

After turning the Power on, if the low-battery light is on, you must change the batteries. Do not try to operate the 4X1 Interface device when the low-battery light is on. Turn the power off and follow the battery change instructions.

Do not turn the 4X1 Multichannel Stimulation Interface ON if the tDCS stimulator is already generating an output.

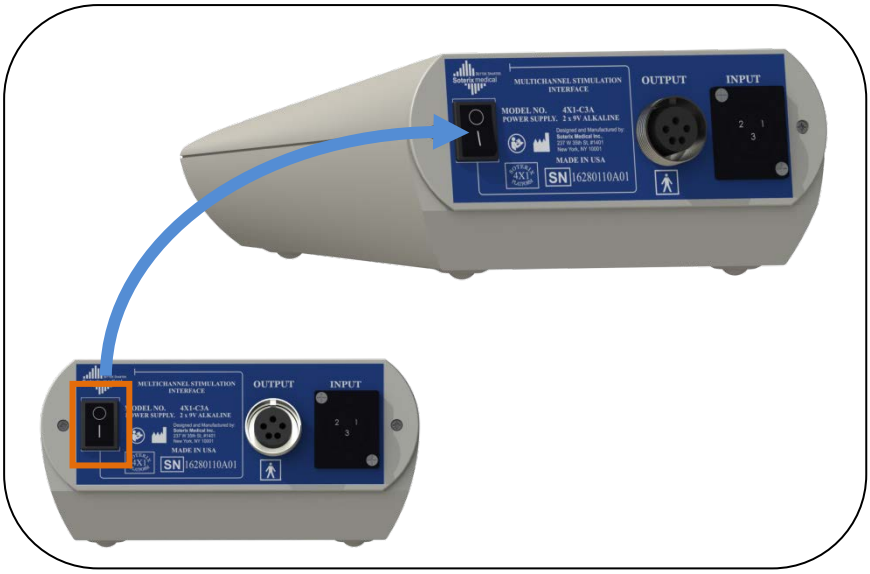

Figure 9: Turning the 4X1 Multichannel Interface on

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Changing Between SCAN MODE and PASS MODE

After turning the 4X1 system ON, select the mode by pressing the "MODE SELECT" switch located on the front panel (Figure 10). Each press of the MODE SELECT switch lets you alternate between the two modes. The corresponding LED indicator will turn on for SCAN or PASS MODE.

When the tDCS stimulator is generating an output in PASS MODE, do not change to SCAN MODE.

Figure 10: Switching between SCAN MODE and PASS MODE

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Toggling between Leads in SCAN MODE

"LEAD TOGGLE" switch is used to toggle between the 5 leads or stimulation electrodes. Press once to scan the leads while monitoring the corresponding "LEAD QUALITY" readings. The corresponding lead LED indicator will turn on indicating the selected lead and the selected lead number will be indicated in the "TEST LEAD" display. The LEAD TOGGLE button can be pressed again to lock the display on an individual selected lead for an extended examination of electrode impedance. LEAD QUALITY display will give a value representing the quality for the selected lead or electrode (Figure 11). LEAD TOGGLE can be pressed again to resume automatic scanning of leads.

- Wait at least 5 seconds for the system to give a stable LEAD QUALITY value
- In PASS MODE, the LEAD TOGGLE has no function

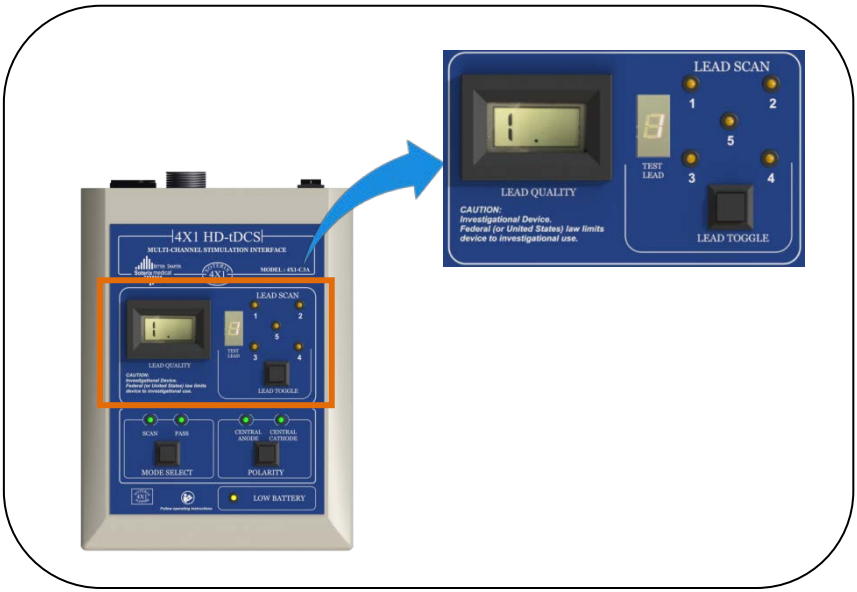

Figure 11: Toggling between leads in SCAN mode

Selecting Central Electrode's Polarity

The "POLARITY" switch is used to toggle between the two polarity options for Lead 5 or the "Center" of 4X1 HD stimulation: CENTRAL ANODE and CENTRAL CATHODE. Each press of the POLARITY switch lets you alternate between the two polarity options. The corresponding LED indicator will turn on for CENTRAL ANODE or CENTRAL CATHODE. In tDCS and HD-tDCS, "anode" refers to the relatively positive terminal where positive current flows into the body. On the other hand, the "cathode" is the relative negative terminal where positive current then exits the body.

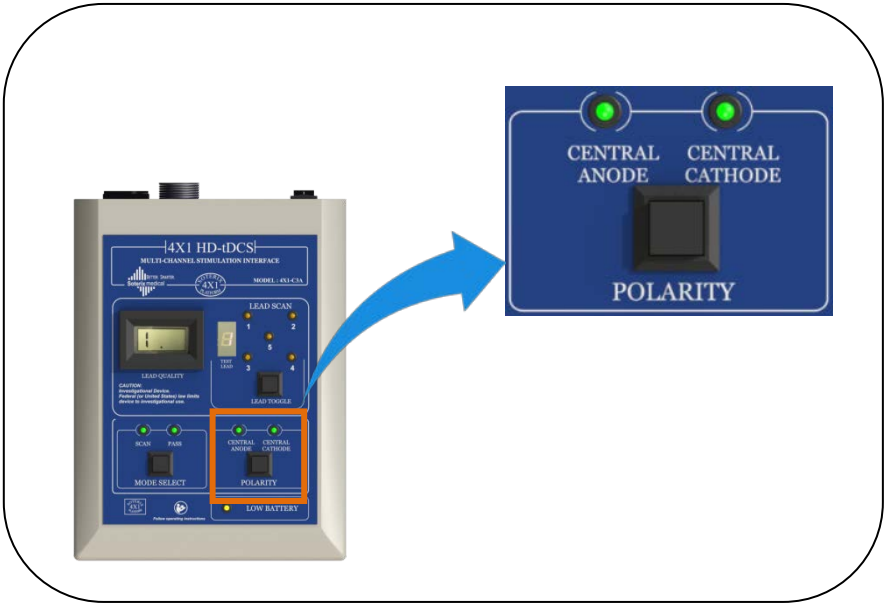

Figure 12: Polarity selection

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Stimulation Procedure

1) Make sure connections are ready. Ensure that the impedance values are within an adequate range by selecting the SCAN mode via pressing the MODE SELECT switch on the 4x1 Multichannel Interface. Do not power ON the 2 channel tDCS Stimulator while the 4x1 Interface is in SCAN mode, as stimulation will not be delivered to the subject.

2) If impedance values are beyond desired limits, follow standard EEG procedures (adjust hair and electrode, insert more gel, etc) to obtain optimal impedance. Check impedance again and repeat procedure for other electrodes as needed. Optimal quality indication may vary from subject to subject, but a quality indication higher in one electrode may indicate poor contact in that electrode.

3) Once the impedance quality for all electrodes is confirmed to be within the desired range, press the MODE SELECT switch to enter the PASS mode. This setting allows the current to pass from the 2 channel tDCS Stimulator to the 5 electrodes via the 4x1 Multichannel Interface.

4) Operator can now power ON the 2-channel tDCS Stimulator and initiate stimulation. 4X1 HD stimulation is applied using the settings on the 2-channel tDCS Stimulator (Intensity, Duration, Sham, etc).

5) The TRUE CURRENT display on the 2-channel tDCS Stimulator constantly shows the current delivered to the subject. The operator should monitor the display. If there is any deviation from the expected current, as set by the operator, stimulation should be aborted. The RELAX feature on the 2-channel tDCS Stimulator can be used at any point during stimulation to decrease the output current to accommodate individual subject's sensation levels.

6) After the session is complete, impedance across the 5 channels can be measured again if desired.

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7) HD-tDCS is now complete. Remove the HD electrodes from the subject. Turn the power switch on the tDCS stimulator OFF. Turn the power switch on the 4X1 Multichannel Stimulation Interface device OFF.

Please use **Soterix Medical** 4X1 Multichannel Stimulation Interface only as directed by this document. Failure to do so might result in an unexpected outcome.

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Troubleshooting

Problems	Possible Reason(s)	Possible Solutions
System not turning on	o Batteries are running low	o Replace batteries o Contact Soterix Medical
Display too dim	o Batteries are running low	o Replace batteries
Lead quality value unstable	o System is still measuring o Cable contact is loose o Lead contact is bad	o Wait at least 5 seconds o Properly connect input and output cables o Improve lead contact integrity
No LEAD QUALTIY display	o System is not off o System in PASS MODE o Batteries are running low	o Turn on device o Change to SCAN MODE, if needed o Replace batteries
No lead output	o System in SCAN MODE o Cables are not connected o 2-Channel Stimulator is not activated	o Change to PASS MODE o Connect input and output cables o Activate stimulator, if needed
Lead toggle switch not working	o Switch is not pressed properly o Switch needs replacement	o Depress toggle switch completely o Reset system by turning power off then on

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

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Maintenance and Disposal -- 37
Definition of Symbols Used -- 38

This chapter is comprised of the following sections:

Specifications:
Here you can find a list of the details of the device specification.

Warranty:
Here is the Limited Warranty. It dictates under what circumstances your 4X1 Multichannel Interface is repaired free of charge. It also explains how to obtain your warranty service.

Maintenance and Disposal
This section 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.

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Specifications

Electrical and Operating Characteristics

Length: 7.91 in.
Width: 2.83 in.
Height: 5.9 in.
Weight (without batteries): 2.8 lb

Safety Features

Touch proof safety connectors
ABS plastic encasing
Number coded connectors for safe and quick connections
Low battery indicator
User friendly operation
Bench top "easy read" design for simple operation

Scan Mode

Output Current (to measure total voltage drop across each channel): nominally <40 μA ± 2 μA
Number of channels: 5

Range of measurement: Min: 0.00 units. Max: 19.99 units. Tolerance: 0.05%
'1 .' is indicative of open-circuit condition.
Values less than '0.10' is usually indicative of short-circuit condition.

Power Source

Batteries: 2 Duracell alkaline 9.0V batteries
Run time: ~ 10 hrs depending on use

Cables

Input Cable: Shielded 2 channel
Connectors: Split Banana to 3 pin XLR type
Output Cable: Shielded 5 channel
Connectors: Circular 5 Pin Standard Din to Din-5 leads

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Storage and Operating Conditions

Parameter	Storage	Operating
Minimum temperature	50° F	50° F
Maximum temperature	110° F	110° F
Maximum humidity	70% non-condensing	70% non-condensing
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)

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Warranty

Soterix Medical Limited Warranty

A. This Limited Warranty provides the following assurance to the first purchaser of the **Soterix** 4X1 Multichannel Stimulation Interface Model 4X1-C3A, 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**, carriage paid and insured, in the most appropriate method as determined by **Soterix Medical**.

(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.

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(2) This Limited Warranty is made only to the purchaser of the Equipment. AS TO ALL OTHERS, **SOTERIX** 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 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** 4X1 Multichannel Stimulation Interface device, read the following instructions.

- The **Soterix Medical** 4X1 Multichannel Stimulation Interface device must be stored away from fluids and heat sources.
- To clean the **Soterix Medical** 4X1 Multichannel Stimulation Interface device, use a dry cloth to wipe dust from the external surface. Do not spray liquid cleaners directly on the **Soterix**

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Medical 4X1 Multichannel Stimulation Interface device, as this will void your warranty.

- Do not disinfect the **Soterix Medical** 4X1 Multichannel Stimulation Interface device.
- Return the device to Soterix Medical for disposal when the device is no longer required.
- Do not throw the **Soterix Medical** 4X1 Multichannel Stimulation Interface device in generic waste
- Discharged batteries must be disposed appropriately in accordance with national regulations in force.

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
	Warning notice for users.
	Serial Number
	Address of manufacturer

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Further Information

Bibliography — 40

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In this chapter, you can find:

Bibliography:
Here is a selection of peer-reviewed articles that Soterix has found to be relevant to tDCS and HD-tDCS practices.

Contact Information:
This section houses a list of all the ways Soterix can be contacted.

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The following bibliography includes a selection of peer-reviewed publications. This is not a comprehensive list of all tDCS and HD-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**. It remains the responsibility of the device user to remain informed of all current, relevant tDCS practices. tDCS and HD-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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Thank you for purchasing a **Soterix Medical** 4X1 Multichannel Stimulation Interface.

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

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