

4X1-C2 Multichannel Stimulation Interface



Operator's Manual

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 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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Contents

Notice.....2

Caution.....3

Contents.....5

Introduction

 Getting to Know the Product.....8

 Use of This Manual.....9

Health and Safety

 Safety Feature and Modes.....11

 Precautions and Warnings.....12

Product Description

 Items Supplied.....16

 Front Panel.....17

 Back Panel.....18

 Control Keys.....19

Device Operation

 Inserting and Replacing the Batteries.....21

 Pre-Stimulation Setup.....22

 Connecting the 2-Channel tDCS Stimulator to the 4X1-C2 Interface...22

 Connecting the CSOP-D5 Output Cable to the 4X1-C2 Interface.....24

 Connecting the 5 Stimulation Leads to the CSOP-D5 Output Cable...25

 Turning the 4X1-C2 System On.....26

 Stimulation Procedure.....27

Changing Between SCAN MODE and PASS MODE.....27

Activating PRESTIM TICKLE in SCAN MODE.....28

Toggling between Leads in SCAN MODE.....29

Engaging/Disengaging BUFFER MODE.....30

Troubleshooting.....31

Specifications and Warranty

Specifications.....33

 Electrical and Operating Characteristics.....33

 Storage and Operating Conditions.....34

Warranty.....35

 Soterix Limited Warranty.....35

 Obtaining Warranty Service.....36

Further Information

Bibliography.....38

Contact Information.....46

Introduction

Getting to Know the Product – 8

Use of this Manual –9

This chapter introduces you to the basics required to read this manual and operate the **Soterix** line of tDCS adaptors.

Getting to Know the Product:

Read this section to learn the basics of what the 4X1-C2 Stimulator 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.

Getting to Know the Product

The 4X1-C2 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.

The 4X1-C2 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 (colored) are connected to one output of the tDCS stimulator and the remaining lead (white) is connected to the other output of the tDCS stimulator.

In PASS MODE, the 4X1-C2 does not modulate the waveform of the tDCS stimulator, and acts only as a passive current divider (Figure 1).

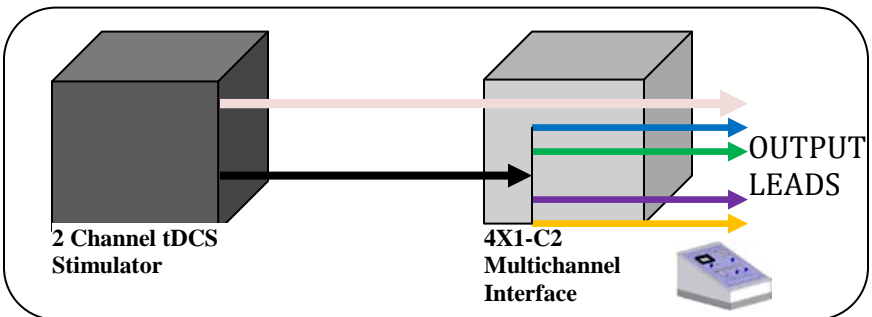


Figure 1: The schematic illustrates that in PASS MODE, the 4X1-C2 acts as a passive current divider

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.

Health and Safety

Safety Features and Modes – 11

Precautions and Warnings – 12

This chapter dictates the information required precautions 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.

Safety Feature and Modes

When not in PASS MODE, the 4X1-C2 provides functionality for accessing lead quality and buffering system output. Albeit these functions are intended to facilitate multi channel stimulation, in PASS MODE this functionality is disengaged, leaving only passive current division.

When set to PASS MODE, the 4X1-C2 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 colored output leads is thus equivalent to the single colored input. In PASS MODE, if the tDCS stimulator is disconnected or is not generating an output, than the output of the 4X1-C2 device leads is therefore zero.

When set to BUFFER MODE the 4X1-C2 Multi Channel Stimulation Interface device disconnects the 4X1-C2 device 2-channel input from the 5-channel output. In BUFFER MODE the 4X1-C2 device output is zero. BUFFER MODE is an optional feature available to operators.

When set to SCAN MODE the 4X1-C2 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 SCAN MODE, the maximum output is nominally 7 μA . In SCAN MODE, a TICKLE features activates a transient $<100 \mu\text{A}$ pulse, intended to “regulate” lead resistance. When set to SCAN MODE the 4X1-C2 Multi Channel Stimulation Interface device disconnects the 4X1-C2 device 2-channel input from the 5-channel output. SCAN MODE is an optional feature available to operators.

When the 4X1-C2 Multi Channel Stimulation Interface is powered OFF the 4X1-C2 device 2-channel input is disconnected from the 5-channel output. When turned OFF, the output of the 4X1-C2 is zero.

The described features are incorporated to increase stimulation efficacy and safety only where appropriate. It should be apparent that the use of the 4X1-C2 Multi Channel Stimulation Interface device does not reduce or replace the responsibility of the operator to understand both the tDCS stimulator and 4X1-C2 device functionality fully.

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 4X1-C2 Multi Channel Stimulation Interface in water or any other fluids.
 - The 4X1-C2 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-C2 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-C2 Multi Channel Stimulation Interface near flammable atmosphere are unknown.
 - The **Soterix Medical** 4X1-C2 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-C2 Multi Channel Stimulation Interface in a magnetic environment are unknown.
 - Do not use the **Soterix Medical** 4X1-C2 Multi Channel Stimulation Interface if it was transported or stored at temperatures outside of the specific range mandated by **Soterix Medical Inc.** Allow the equipment to stabilize to a temperature within the specific range before use.
- External Damage
 - Do not drop the device
 - The 4X1-C2 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 **Soterix Medical** 4X1-C2 Multi Channel

Stimulation Interface. Immediately return the device to **Soterix Medical Inc.** for repair.

- Cables
 - When connecting cables to the input or 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 4X1-C2 Multi Channel Stimulation Interface.
- 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.
- 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 CES stimulation is in use.
- Technique
 - Transcranial Direct Current (tDCS) is an investigational technique. It is limited by Federal law to investigational use. The **Soterix Medical** 4X1-C2 Multi Channel Stimulation Interface 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.
 - All operators must ensure the tDCS is applied within local and federal or country guidelines as relevant.

- Disposal
 - Return the device to **Soterix Medical Inc.** for disposal when the device is no longer functional.

Product Description

Items Supplied -16

Front Panel -17

Back Panel -18

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-C2 Multichannel Stimulation 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.

Items Supplied

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

- 1 4X1-C2 multichannel Stimulation Interface
- 1 CSIN-X2 Input Cable
- 1 CSOP-D5 Output Cable

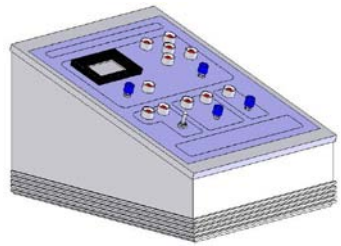


Figure 2: 4X1-C2 Multichannel Stimulation Interface

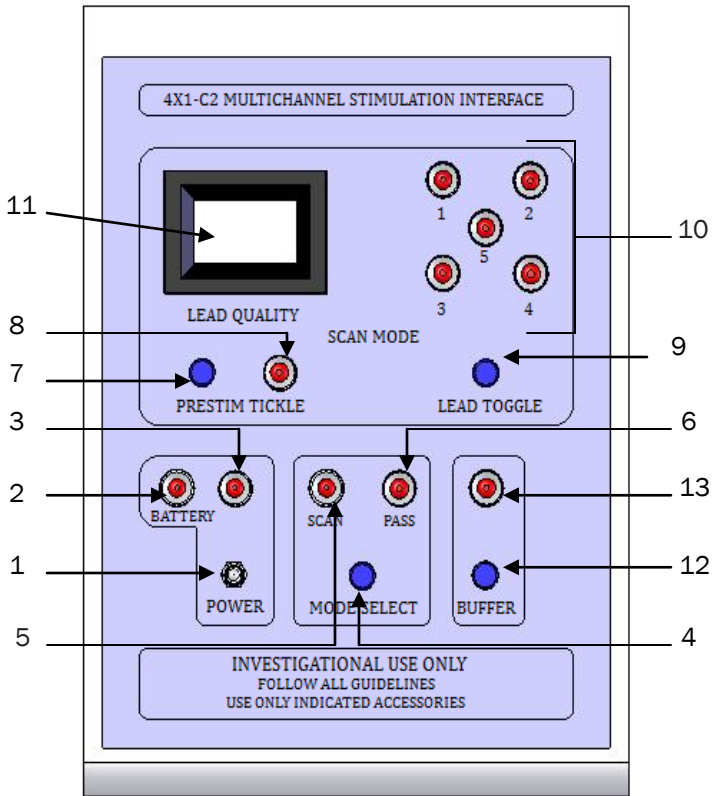


Figure 3: CSIN-X2 Input Cable

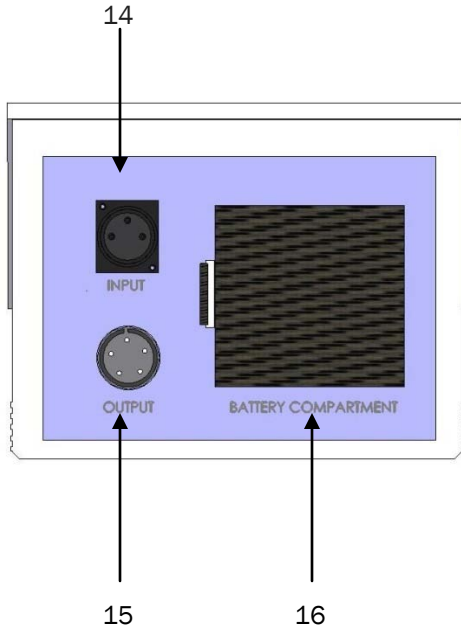


Figure 4: CSOP-D5 Output Cable

Front Panel



Back Panel



Control Keys

- 1) Turns on or off the device
- 2) Indicates if there is a low battery supply by illuminating
- 3) Power light (on or off)
- 4) Toggles through the possible modes
- 5) A light which indicates if SCAN MODE is activated by illuminating
- 6) A light which indicates is PASS MODE is activated by illuminating
- 7) Switches on or off the PRESTIM TICKLE
- 8) A light which indicates if PRESTIM TICKLE is activated by illuminating
- 9) A switch which toggles through the leads
- 10) A grouping of lights which indicate the lead that is in use by illuminating the corresponding light
- 11) A display which shows the quality of the lead
- 12) A switch which activates BUFFER MODE
- 13) A light which indicates if BUFFER MODE is active
- 14) The receiver for the input cable
- 15) The receiver for the output cable
- 16) The compartment for the batteries

Device Operation

Pre-Stimulation Setup – 22

Stimulation Procedure – 27

Troubleshooting – 31

This chapter gives a systematic process for everything you must know and do to operate your **Soterix Medical 4X1-C2 Multichannel Interface Device**.

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 the tDCS. 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.

Inserting and Replacing the Batteries

The 4x1-C2 Multichannel Interface Device operates on two 9V alkaline batteries. Duracell is recommended, but any battery will work.

To insert the batteries, flip the device to its back and remove the battery cover. Correct battery polarity is indicated inside the battery cover. Then 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-C2 Multichannel Interface Device to ensure correct battery placement. If the 4x1-C2 Multichannel Interface Device does not power up, check that the batteries are good and inserted correctly.

Note: Batteries should be removed from the 4x1-C2 Multichannel Interface Device 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 after every 8 hours of use or when the low battery indicator is illuminated. Do not use abrasive cleaners on the battery contacts.

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



Dispose of depleted batteries in accordance with local regulations.

Pre-Stimulation Setup

Connecting the 2-Channel tDCS Stimulator to the 4X1-C2 Interface

The CSIN-X2 cable is intended to connect a 2-channel isolated current-controlled tDCS stimulator with the 4X1-C2 Device.

The CSIN-X2 can be connected to the tDCS stimulator in one of two polarities:

- 1) The white connector may be connected to the positive (anode) output of the 2-channel tDCS stimulator and the colored connector is connected to the negative (cathode) output of the 2-channel tDCS stimulator (Figure 7 on following page).
- 2) The colored connector may be connected to the positive (anode) output of the 2-channel tDCS stimulator and the white connector is connected to the negative (cathode) output of the 2-channel tDCS stimulator (Figure 8 on following page).

The selected CSIN-X2 connection option will determine the polarity of the device output leads

In PASS MODE, the 4 colored output leads are connected to the colored CSIN-XA connector, and the white output lead is connected to the CSIN-XA connector.

Warning: It is the responsibility of the device operator to understand both the tDCS stimulator and the 4X1-C2 device function fully and to guarantee that the CSIN-X2 cable is connected to the tDCS stimulator in the correct polarity.

Connect the CSIN-X2 cable to the "Input" port on the back panel of the 4X1-C2 (Figure 9).



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

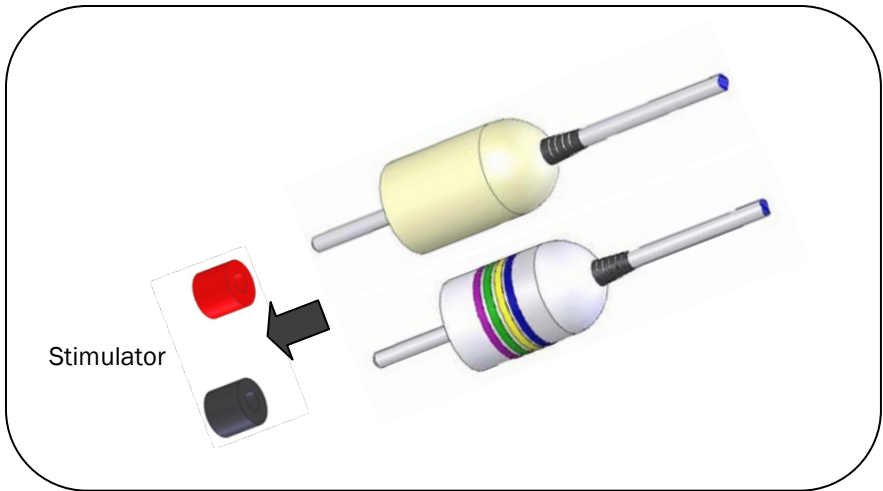


Figure 7: Method 1 of connecting the CSIN-X2 cables

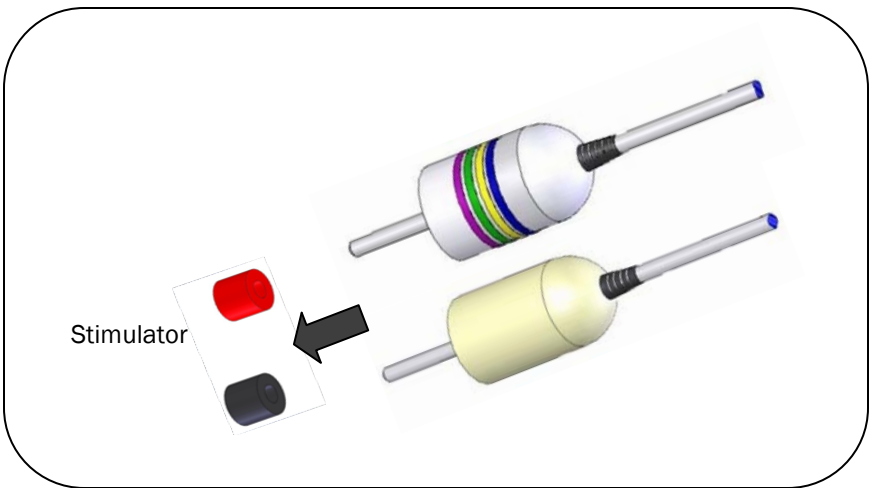


Figure 8: Method 2 of connecting the CSIN-X2 cables

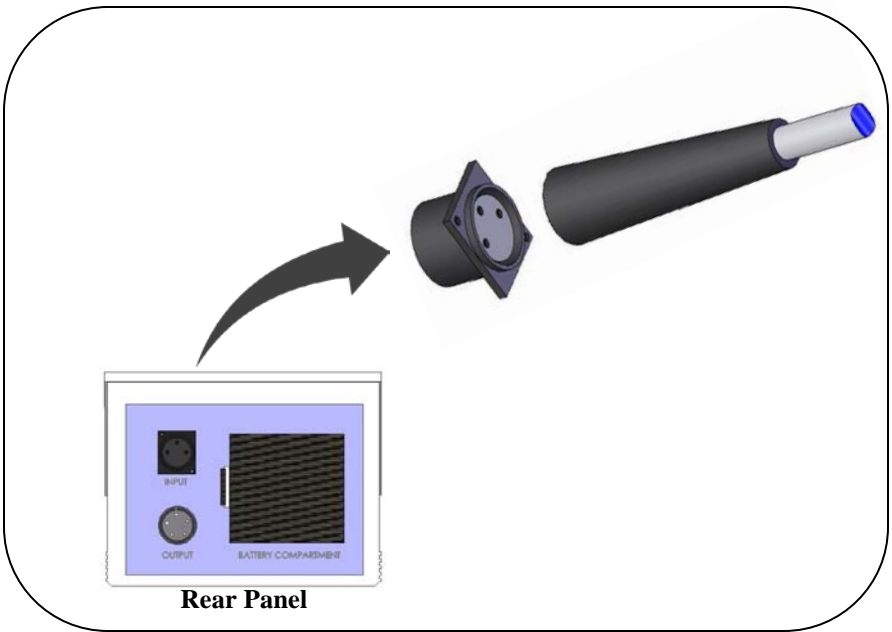


Figure 9: Connecting the CSIN-X2 cable

Connecting the CSOP-D5 Output Cable to the 4X1-C2 Interface

Connect the CSOP-D5 connector to the OUTPUT port on the back panel of the 4X1-C2 Interface Device (Figure 10).

- Always use the supplied cables to connect the 4X1-C2 device with the stimulator
- Ensure all cables and leads are fully inserted in the receptor sockets before operating the 4X1-C2.

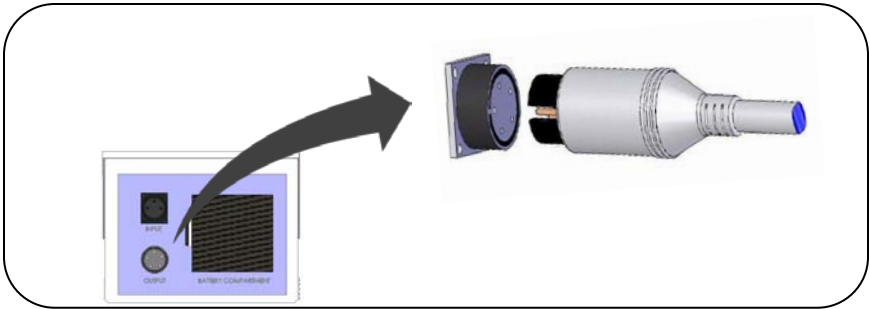


Figure 10: Connecting the SCOP-D5 Output cable

Connecting the 5 Stimulation Leads to the CSOP-D5 Output Cable

Leads can be connected on the flat-connector end of the CSOP-D5 Output Cable. The 5 output ports are color coded (Figure 11).



It is the responsibility of the device operator to understand both the tDCS Stimulator and the 4X1-C2 Device function fully and to guarantee that the CSOP-D5 cable is properly connected to the 5 output leads.

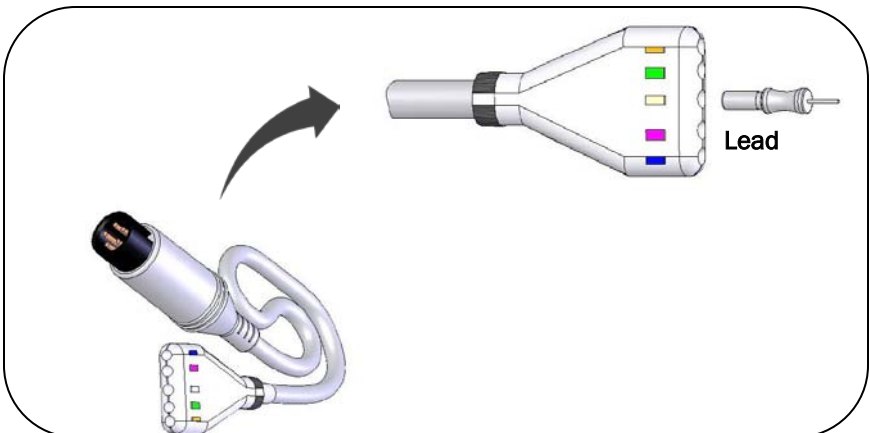


Figure 11: Inserting the Leads into the CSOP-D5 Output cable

Turning the 4X1-C2 System On

The Power switch is located near the lower left portion of the control panel (Figure 12).

After turning the Power on, if the battery light is on, you must change the batteries. Do not try to operate the 4X1-C2 when the battery light is on. Turn the power off and follow the battery change instructions.



Do not turn the 4X1-C2 Multichannel Stimulation Interface ON if the tDCS stimulator is already generating an output.

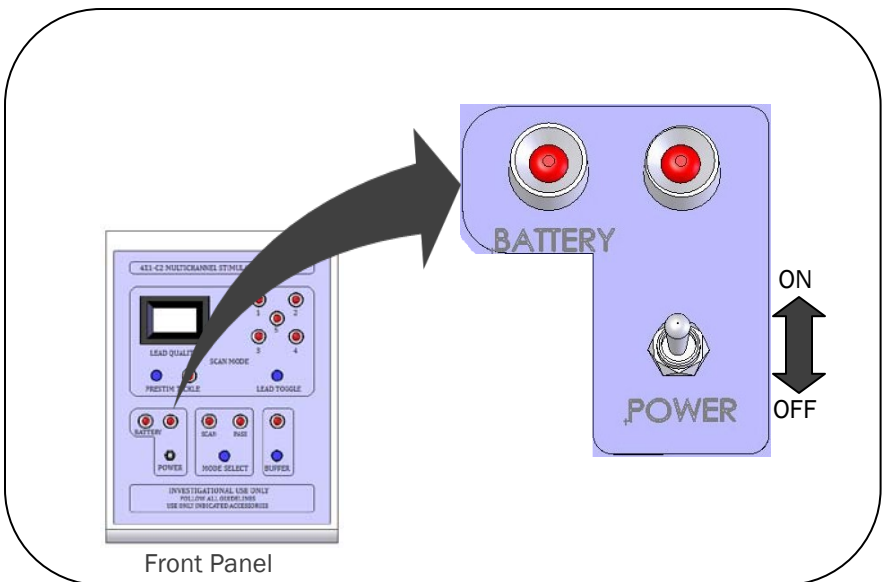


Figure 12: Turning the device on

Stimulation Procedure

Changing Between SCAN MODE and PASS MODE

After turning the 4X1-C2 system ON, select the mode by using the MODE SELECT switch located next to the power switch (Figure 13). The corresponding indicator will turn on for SCAN or PASS MODE.



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

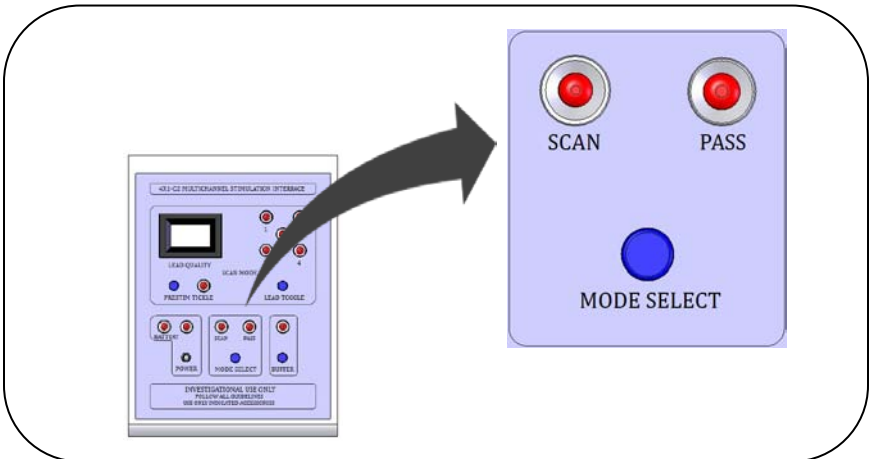


Figure 13: Switching between SCAN MODE and PASS MODE

Activating PRESTIM TICKLE in SCAN MODE

When in SCAN MODE, pressing the PRESTIM TICKLE button once will activate a single electrical conditioning pulse (Figure 14).



Do not activate the PRESTIM TICKLE without full understanding the 4X1-C2 operation and all safety factors related to lead outputs.

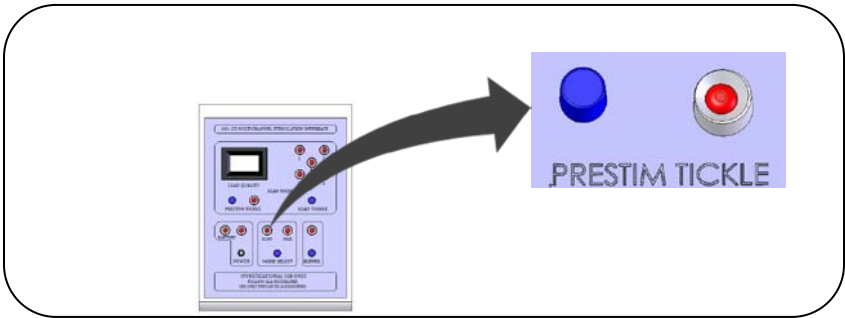


Figure 14: Controls to active PRESTIM TICKLE

Toggleing between Leads in SCAN MODE

LEAD TOGGLE is used to toggle between leads. Press once to select the next lead. The corresponding lead indicator will turn on indicating the selected lead; the selected lead number and color will be indicated. The LEAD QUALITY display will give a value represented the quality for the selected lead (Figure 15).

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

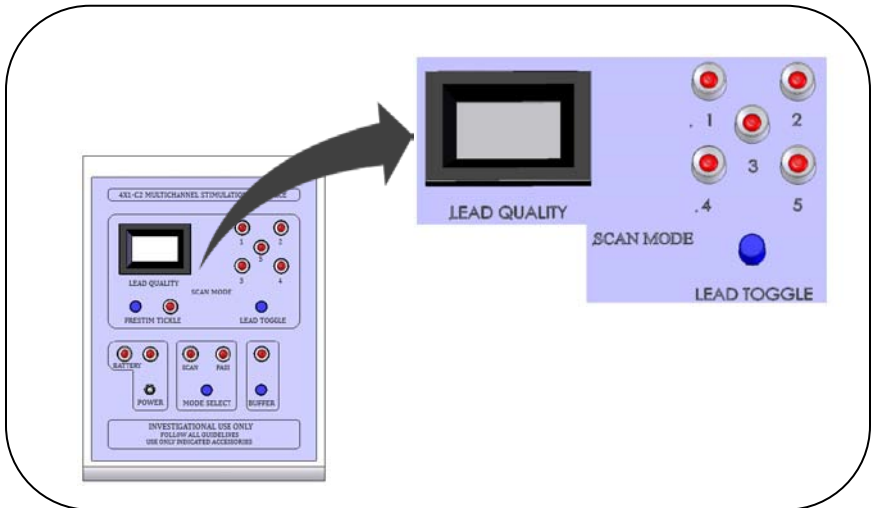


Figure 15: Toggleing between leads

Engaging/Disengaging BUFFER MODE

Pressing the BUFFER MODE button will engage or disengage the buffer mode. The BUFFER MODE light will turn on. The BUFFER MODE will activate regardless of if the device was previously in PASS MODE or SCAN MODE.



Pressing BUFFER MODE while the tDCS stimulator is on will disengage the output leads from the tDCS stimulator. It is the responsibility of the device operator to understand both the tDCS stimulator and the 4X1-C2 device function fully.

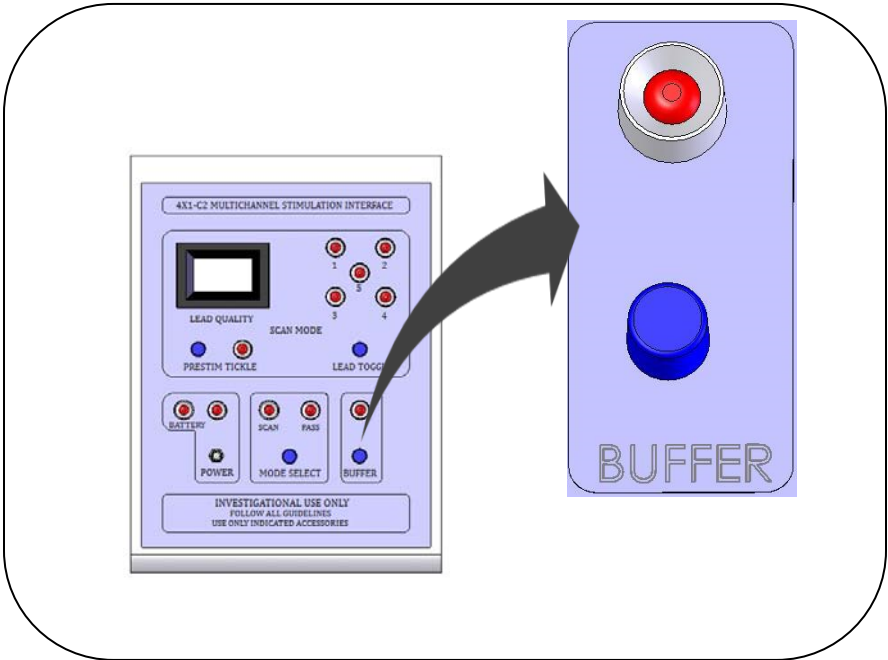


Figure 16: BUFFER MODE activator/deactivator

Troubleshooting

Problems	Possible Reason(s)	Possible Solutions
System not turning on	<ul style="list-style-type: none"> ○ Batteries are running low 	<ul style="list-style-type: none"> ○ Replace batteries ○ Contact dealer
Display too dim	<ul style="list-style-type: none"> ○ Batteries are running low 	<ul style="list-style-type: none"> ○ Replace batteries
Lead quality value unstable	<ul style="list-style-type: none"> ○ System is still measuring ○ Cable contact is loose ○ Lead contact is bad 	<ul style="list-style-type: none"> ○ Wait at least 5 seconds ○ Properly connect input and output cables ○ Improve lead contact integrity
No LEAD QUALITY display	<ul style="list-style-type: none"> ○ System is not off ○ System in PASS MODE ○ Batteries are running low 	<ul style="list-style-type: none"> ○ Turn on device ○ Change to SCAN MODE, if needed ○ Replace batteries
No lead output	<ul style="list-style-type: none"> ○ System in SCAN MODE ○ Cables are not connected ○ 2-Channel Stimulator is not activated ○ System is in BUFFER MODE 	<ul style="list-style-type: none"> ○ Change to PASS MODE ○ Connect input and output cables ○ Activate stimulator, if needed ○ Disengage BUFFER MODE

Lead toggle switch not working	<ul style="list-style-type: none"> ○ Switch is not pressed properly ○ Switch needs replacement 	<ul style="list-style-type: none"> ○ Depress toggle switch completely ○ Reset system by turning power off then on
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Specifications – 33

Warranty – 35

Specifications and Warranty

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-C2 Multichannel Interface Device is repaired free of charge. It also explains how to obtain your warranty service.

Specifications

Electrical and Operating Characteristics

Power source: 2 9V Alkaline batteries
 Battery life (with fresh batteries): 8 hours
 Length: 197 mm
 Width: 155 mm
 Height: 121 mm
 Weight (without batteries): 2.8 lb
 Case material:

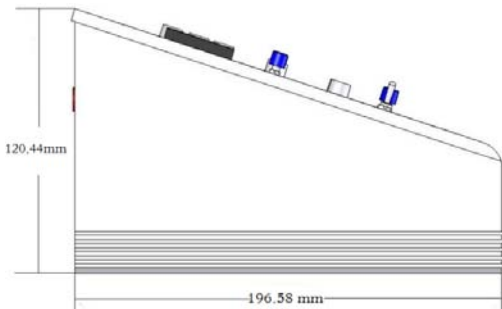


Figure 6: Side view

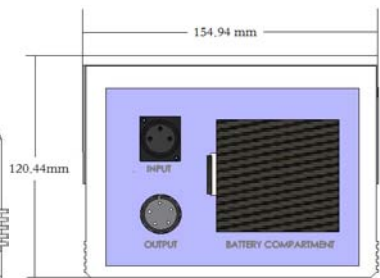


Figure 5: Rear view

Safety Features

- Touch proof safety connectors
- BUFFER MODE for secondary isolation of input from output
- ABS plastic encasing
- Color coded connectors for safe and quick connections
- Low battery indicator and low battery disconnect
- User friendly operation
- Bench top “easy read” design for simple operation

Scan Mode

Output Current (to measure total voltage drop across each channel):

nominally $<7\mu\text{A}$

Tickle current: $<100\mu\text{A}$

Number of channels: 5

Range of measurement: 0-2V

Power Source

Batteries: 2 alkaline 9.0V batteries

Run time: ~ 8hrs depending on use

Low Battery Indicator: At 75% of max voltage

Display: Datel 4 digit LCD

Cables

Input Cable: Shielded 2 channel

Connectors: Split Banana to 3 pin XLR type

Length: 4 Feet

Weight: 0.6 lb.

Output Cable: Shielded 5 channel

Connectors: Circular 5 Pin Standard Din to Din-5 leads

Length: 5 feet

Weight: 0.8 lb

Switches

Mechanical: Push type

Digital: Electronic IC

Emergency stop: Buffer Switch

Storage and Operating Conditions

Parameter	Storage	Operating
<i>Minimum temperature</i>	50° F	55° F
<i>Maximum temperature</i>	80° F	85° F
<i>Maximum humidity</i>	70% non-condensing	70% non-condensing
<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)

Warranty

Soterix Medical Limited Warranty

- A.** This Limited Warranty provides the following assurance to the first purchaser of the **Soterix Medical Inc.** 4X1-C2 Multichannel Stimulation Interface, 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.

Bibliography – 38

Contact Information –
46

Further Information

In this chapter, you can find:

Bibliography:

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

Contact Information:

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

Bibliography

The following bibliography includes a selection of peer-reviewed publications. This is not a comprehensive list of all tDCS studies, but includes a representative list as of the date of the publication of this manual. The inclusion of these reports in this bibliography does not in any way imply an endorsement of the protocol or results reported in these studies by **Soterix Medical**. It remains the responsibility of the device user to remain informed of all current, relevant tDCS practices. 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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Contact Information

Soterix Medical Inc.
Room ST-142
160 Convent Ave
New York, NY 11238
www.SoterixMedical.com
contact@soterixmedical.com

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