MXN-9 High Definition-Transcranial Electrical Current (HD-tES) Stimulator

Model 9002A

OPERATOR’S MANUAL

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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 operator’s manual should be thoroughly read and all operators given adequate training before attempting to place this unit in service.

Awareness of the stated cautions and warnings and compliance with recommended operating parameters – together with maintenance requirements – are important for safe and satisfactory operation. The unit should be used for its intended application. Recommended accessories should be used while using this system.
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Introduction

This chapter introduces you to the basics required to use this manual fully as well as to operate the Soterix Medical MXN High Definition- transcranial Electrical Stimulation (HD-tES) stimulator.

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

Getting to know the Product:
Read this section to learn the basics of MXN High-Definition Stimulator.

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.
Overview

Transcranial Electrical Stimulation (tES) is a non-invasive procedure in which a device sends a small current across the scalp to modulate brain function. These currents generate an electrical field in the brain that modulates brain function according to the modality of the application, which can be direct (transcranial Direct Current Stimulation, tDCS), sine (transcranial Alternating Current Stimulation, tACS), pulsed (transcranial Pulsed Current Stimulation, tPCS), random noise (transcranial Random Noise Stimulation, tRNS), or oscillating direct (transcranial Oscillating Direct Current Stimulation, tODCS). For tDCS, when this small current passes from the positive electrode, anode to the negative electrode, cathode, it may simultaneously increase the activity of the brain by the anode and decrease the activity of the brain near the cathode. For tPCS, tACS, tRNS, electrode polarity is not an issue as current reverses its direction at regular intervals. tPCS, tACS and tRNS may interfere with ongoing neuronal oscillations and may produce neuromodulatory effects similar to tDCS.

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

**tES dose** can be defined as: 1) The size and position of the electrodes on the body and 2) For tDCS, the main determinants are intensity, duration, and electrode polarity. For tODCS, the main determinants are intensity, duration, electrode polarity, and frequency. While for tPCS, tACS, and tRNS, the main determinants are intensity, duration, and frequency.

**tES efficacy** can be meaningfully increased by injecting currents using multiple small contact area stimulation electrodes. See section on **Getting to Know the Product** below.

**tES safety** is supported by medical literature to have common side effects limited to mild and reversible skin irritation, when using standard tES protocols and guidelines. **Soterix Medical** HD-tES stimulators and electrodes are uniquely designed to minimize skin irritation – for example, the
resistance indication feature provides a simple indicator to the operator of the contact conditions before, during, and after stimulation.

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

**Soterix Medical** tES systems allow precise reproduction of tES doses commonly used in medical literature. **Soterix Medical** engineers and scientists can work with you to determine the best configuration for your application.

### Getting to Know the Product

Thank you for purchasing a **Soterix Medical** MXN High-Definition Transcranial Electrical Stimulator (HD-tES).

High-Definition stimulation is the application of weak currents by conductive-gel based small contact area scalp electrodes. This technique was introduced by **Soterix Medical** to deliver currents to the brain in an optimal and application-specific manner. For instance, multiple electrodes can be arranged in an “array-like” fashion to selectively target desired brain targets while sparing current delivery to remaining brain regions.

The **Soterix Medical** MXN HD-tES Stimulator is a multi-channel stimulator that sends a weak current from one or more positive electrodes, anodes to one or more negative electrodes, cathodes. The stimulator comprises of multiple, independent, and isolated channels with one common (or reference channel). Each channel can either deliver positive or negative current while the common reference channel balances the residual current to ensure total current sourced equals total current sunk (current in = current out) for constant-current stimulation. The MXN HD-tES Stimulator therefore allows combining anodes and cathodes in any combination. The “M” and “N” in the MXN indicate variables. For instance, a 5X3 montage denotes 5 cathodes and 3 anodes, while a 2X2 montage denotes 2 cathodes and 2 anodes.

The MXN HD-tES Stimulator ensures the maximum current delivered by each channel is limited while the net current delivered using any combination of channels is also limited. The maximum voltage available for each channel is
limited while the net voltage using any combination of channels is also limited.

The MXN montage and the individual currents that need to be injected from each electrode may be determined by Soterix Medical Neurotargeting Softwares: HD-Targets and HD-Explore. HD-Targets software lets you determine the optimal montage based on user defined optimization constraints (desired brain target, available electrodes, etc). HD-Explore software allows user to explore brain current flow using their own planned montages and pick the one that best suits their requirements.

This device is protected by patents, design patents, patents pending, or design patents pending.

Use of This Manual

This manual contains details of installation, setup, and operation of the Soterix Medical MxN HD unit and its accessories. This manual must be read in its entirety before commencing any stimulation with the Soterix Medical MxN unit. If the instructions in this manual are not precisely followed, the performance of this product and/or the safety of the user and/or patient may be compromised. If you have any questions, comments, or concerns, please contact Soterix Medical before starting use of the device.

The consequences that could result from failure to observe the precautions listed in this section are indicated by the following symbols:

This icon marks warnings, information that should be read before using this Soterix Medical product to prevent possible injury.
Health and Safety

This chapter dictates the required precautions for both you and your patient’s safety.

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

**Regulatory Statements:**
This is where you will find the regulatory statements countries, which determines how you may use this device under federal law.
Precautions and Warnings

To prevent damage to your Soterix Medical product or injury to yourself or to others, read the following safety precautions in their entirety before using this equipment. Keep these safety instructions where all those who use the product can easily access them.

- Environment and Moisture
  - Do not immerse the Soterix Medical MxN HD-tES Stimulator in water or any other fluids.
  - The Soterix Medical MxN HD-tES Stimulator should not be used in a moist environment or if any parts of the stimulator are damp or wet.
  - The Soterix Medical MxN HD-tES 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 MxN HD-tES Stimulator near flammable atmosphere are unknown.
  - The Soterix Medical MxN HD-tES 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 MxN HD-tES Stimulator in a strong magnetic environment are unknown.
  - Do not use the Soterix Medical MxN HD-tES 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 MxN HD-tES Stimulator after it is been transported or stored at temperatures outside of the specific range are unknown.

- External Damage
  - Do not drop the device.
  - The Soterix Medical MxN HD-tES 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 MxN HD-tES Stimulator. Immediately return the device to Soterix Medical Inc. for repair.

- **Cables**
  - When connecting cables to the output jacks, use only the cables provided or sold by Soterix Medical Inc. to maintain compliance with product regulations.
  - Make sure all cables are fully inserted in the correct receivers before operating the Soterix Medical MxN HD-tES Stimulator.

- **Irritation**
  - Use only approved Soterix Medical Inc. High-Definition accessories indicated for use with the Soterix Medical MxN HD-tES Stimulator.
  - The Soterix Medical MxN HD-tES Stimulator may cause minor irritation, discomfort and redness at the electrode sites. If irritation occurs, consult your clinician.
  - Do not place the Soterix Medical MxN HD-tES Stimulator electrodes or sponges over previously irritated, burnt, or damaged skin.

- **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**
  - The device consists of re-chargeable internal batteries. Observe proper instructions while charging the batteries.

- **Electronic Monitoring**
Electronic monitoring equipment (such as ECG monitors, ECG alarms) may not operate properly when tES stimulation is in use.

- **Technique**
  - The **Soterix Medical** MxN HD-tES Stimulator must only be used with appropriate supervision and by a trained operator. Even experienced operators must carefully read and fully follow all the following instructions and guidelines.
  - All operators must ensure that **Soterix Medical** MxN HD-tES is applied within local and federal or country guidelines as relevant.
  - The **Soterix Medical** MxN HD-tES Stimulator should not be used in combination with any other implanted or external electrical stimulation device.

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

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

USA:
CAUTION: The Soterix Medical MXN HD-tES Stimulator is an investigational device. Federal (or United States) law limits device to investigational use.
Product Description

This chapter is comprised of the following sections:

**Items Supplied**
This section gives a checklist of the items that found in every package sent out with the MxN HD-tES Stimulator

**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 top panel and a basic description.

**Control Keys**
Basic description of all the controls and display functions indicated in the previous two sections.
**Items Supplied**
Carefully remove all components from the shipping container. One of each should be included:

1) MXN-9 HD-tES Stimulator
2) Tenergy Ni-MH charger with rechargeable D cell batteries
3) CSOP-D5 Output Cable A
4) CSOP-D5 Output Cable A

![Figure 1: MXN-9 HD-tES Stimulator](image1.png)
![Figure 2: Tenergy Ni-MH charger](image2.png)
![Figure 3: CSOP-D5 Output Cable A](image3.png)
![Figure 4: CSOP-D5 Output Cable B](image4.png)
Front Panel
Back Panel
**Control Keys**

1. **INT 1 Knob**: Sets the desired intensity of Channel 1. The value set is indicated in the corresponding LCD entry in the CHANNEL INTENSITY Display section. INT knobs are also used to set corresponding channel polarity.

2. **CHANNEL INTENSITY Display**: Section of the LCD that displays individual channel intensity and polarity (Channels 1-8). Individual channel intensity and polarity is set by the corresponding INT knobs (INT 1- INT 8).

3. **CURRENT STATUS Display**: Displays “DEVICE READY” during set-up when net intensity shown via NET INTENSITY display is less than total allowable current limit (2.50 mA). Displays “WARNING” when limit is exceeded. Display is blank when output current delivered is lower than the total allowable limit.

4. **DEVICE OPERATION Display**: Displays “Set STIMULATION DOSE” prompting operator to set the desired INTENSITY, DURATION, WAVEFORM, FREQUENCY, WAVEFORM POLARITY, and CONDITION during set-up. Displays “OPERATION STARTED: Hit ABORT to STOP” during stimulation session. Displays “OVERCURRENT: Reduce INTENSITY” when net current delivered exceeds allowable limit.

5. **CHANNEL QUALITY Display**: Indicates the contact quality by showing the resistance value for each channel (Channels 1-8). Value is also displayed by a color-coded progress bar with GREEN denoting OPTIMAL, YELLOW denoting MODERATE, and RED denoting POOR
quality. CHANNEL QUALITY is displayed under the corresponding CHANNEL INTENSITY.

6. WAVEFORM Display: Indicates the waveform selected for the session via the WAVEFORM knob. Display will show DC, B-SINE, U-SINE, B-PULSE, U-PULSE, B-RAND, and U-RAND.

7. NET INTENSITY Display: Displays the net intensity of stimulation. Value is determined by value set by the individual INT Knobs (INT 1-INT 8).

8. CONDITION Display: Displays “ACTIVE STIM” for real stimulation. Displays “SHAM STIM” for sham stimulation.

9. FREQUENCY Display: Indicates the frequency selected for the session via the FREQUENCY knob.

10. DURATION Display: Displays the duration set for stimulation during set-up. Value is set by the DURATION Knob. The duration selected starts counting down when stimulation is initiated indicating the amount of time remaining in stimulation. The display reads in minutes and in seconds.

11. BATTERY Display: Indicates the battery level.

12. DURATION Knob: Sets the desired duration of stimulation. The value set is indicated in the DURATION Display section of LCD during set-up.

13. WAVEFORM Knob: Sets the desired waveform of stimulation (DC corresponding to tDCS; SINE corresponding to tACS; PULSE corresponding to tPCS and RAND corresponding to tRNS) prior to the start of stimulation. In combination with the WAVEFORM
POLARITY switch (see 15), unipolar (“U”) or bipolar (“B”) polarities can be selected.

14. FREQUENCY Knob: Sets the desired frequency of stimulation prior to the start of stimulation.

15. WAVEFORM POLARITY Switch: Sets the desired waveform polarity (unipolar or bipolar) prior to the start of stimulation.

16. SHAM Switch: Allows user to set SHAM option for stimulation session. Switch is illuminated by green light when SHAM switch is pressed. CONDITION Display shows SHAM STIM when SHAM is on.

17. START Button: Initiates the stimulation.

18. ACTIVE LED: Flashing green light indicates current ramp (up or down). Steady green light indicates steady current.


20. TRIGGER START: Allows external trigger signal to initiate stimulation.

21. TRIGGER ABORT: Allows external trigger to abort stimulation.

22. Receiver port A: receiver for CSOP-D5 Output Cable A.

23. Receiver port B: receiver for CSOP-D5 Output Cable B.

24. BATTERY COMPARTMENT: Device is powered by 4 Ni-MH rechargeable batteries. Remove batteries for recharging as needed.

25. POWER Switch: Turns ON or OFF the device.
Device Operation

This chapter outlines the steps needed to operate your Soterix Medical MxN HD-tES Stimulator.

Description of Special Features
This section gives an in-depth description of all the special features that come with your purchase of the Soterix Medical MxN HD-tES Stimulator device.

Inserting and Replacing Batteries
This section provides instruction on inserting and replacing batteries.

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

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

Battery Charging
This section provides instruction on how to charge the rechargeable batteries.
Description of Special Features

**TRUE CURRENT™**: During a session, the CHANNEL INTENSITY display indicates the TRUE CURRENT™ or the actual value of current (in mA) being supplied by the device to the electrodes – regardless of the respective individual channel settings. The TRUE CURRENT™ feature thus provides a fully independent and redundant safety feature when monitored by the operator.

*Note: It is recommended that the CHANNEL INTENSITY display be monitored for the entire duration of the stimulation.*

**CHANNEL QUALITY™**: The CHANNEL QUALITY™ display provides a constant display of the individual channel resistance (range: 0 K – 999 K) prior, during, and at end of stimulation. Quality is also displayed by a color-coded progress bar with GREEN denoting OPTIMAL, YELLOW denoting MODERATE, and RED denoting POOR quality. Un-used channels display either OFF within a fully filled WHITE progress bar or 999.0 K within a fully filled RED progress bar (see below for more information). If high (or bad) contact quality is encountered, use standard corrective steps as used in electroencephalography (EEG) to improve resistance while monitoring the display. Stimulation can be initiated even if quality is POOR (RED).

CHANNEL QUALITY™ is a feature intended to assist in the set-up and operation of HD-tES. It is not intended to substitute or replace operator judgment and protocol. Each setup should be independently monitored and verified by a trained operator following best HD-tES protocols. Any issues or concerns identified by the operator should be addressed regardless of the CHANNEL QUALITY™ reading.

**Stimulation ABORT**: At any point during stimulation, the operator may terminate the stimulation by pressing the ABORT button. The operator is responsible for determining when aborting the stimulation is appropriate.
Inserting and Replacing the Batteries

The MxN HD-tES Stimulator operates on four D cell rechargeable batteries. Only provided Tenergy Ni-MH batteries can be used. See section on Battery charging for more information.

To insert the batteries, remove the individual battery compartment covers on the back panel of the device. Correct battery polarity is indicated on the battery compartment cover. Insert the batteries, one at a time, ensuring proper battery orientation for each battery.

After the batteries are in place, replace the individual battery compartment covers by pressing it down fully on the individual battery. Rotate clockwise until the cover “locks” into place. The cover should rotate smoothly if the cover has been pressed down properly. If the cover does not rotate smoothly, stop. Ensure the cover has been pressed down fully before rotating it.

Immediately after all batteries have been inserted, power up the MxN HD-tES Stimulator to ensure correct battery placement. If the MxN HD-tES Stimulator does not power up, check that the batteries are good and inserted correctly.

**Note:** Batteries should be removed from the MxN HD-tES Stimulator if it is not likely to be used for an extended period of time.

Please observe the proper direction of the battery’s polarity as indicated by the battery compartment cover.

Batteries should be replaced every ~12 hours of use or when the low battery indicator is illuminated. Do not use abrasive cleaners on the battery contacts.

To replace the batteries, remove the battery compartment cover by rotating counter-clockwise as instructed above. Take out the batteries one-at-a-time. Then insert the new batteries.
Dispose of batteries that have exhausted their lifetime charging times in accordance with local regulations.

Note: When the device is not in use, turn the power off to save battery life.
Pre-Stimulation Setup

1) Turn the POWER switch ON. Each of the individual CHANNEL INTENSITIES (1-8) would display the last used setting. The NET INTENSITY display shows the maximum of summed positive or summed negative current. If the channels are set to output more than the allowed net intensity of 2.50 mA, the CURRENT STATUS display indicates "WARNING". The CURRENT STATUS display of "DEVICE READY" indicates that the intensity (net) is within the overcurrent limit.

The CHANNEL QUALITY is indicated by colored progress bars in addition to the actual impedance number in ohms. A GREEN colored progress bar indicates OPTIMAL quality while the extent of the fill indicates the impedance magnitude. YELLOW colored progress bar indicates MODERATE channel quality and caution is warranted. RED denotes POOR or outside of defined range. For un-used or un-connected channels (open-circuit condition), the CHANNEL QUALITY indicates a fully filled RED progress bar indicating 999.0K.

Note: When stimulation begins, the CHANNEL QUALITY of the un-used channels will display a fully filled WHITE progress bar indicating OFF, as long as the INTENSITY setting of the un-used channel is set to 0.00 mA prior to stimulation start. Otherwise, the CHANNEL QUALITY of the un-used channel will display a fully filled RED progress bar indicating 999.0K with the CHANNEL INTENSITY reflecting pseudo test current. The test current is a small current device injects into tissue to determine contact quality. The information displayed by the un-used channels has no bearing on device operation as the channels are not being used.

The DURATION display defaults to lowest duration setting of 5 minutes. The WAVEFORM display defaults to DC while the FREQUENCY display defaults to 0 Hz. The CONDITION display indicates ACTIVE or SHAM STIM corresponding to the position of the SHAM switch.

The battery charge level of the internal rechargeable batteries is indicated by the color of the battery symbol on the BATTERY display. A green battery symbol indicates that the batteries have enough charge to run at-least a
session of 40 min duration. A red battery symbol indicates that the batteries have low charge.

Note: If the battery symbol in BATTERY display is red, do not proceed with stimulation. Replace batteries with charged batteries. Make sure batteries are inserted in correct polarity (refer to the Inserting and Replacing batteries section).

Note: The BATTERY display will show red battery symbol momentarily, when powering ON device (for a second).

2) Connecting the CSOP-D5 Output Cables to the MxN HD-tES Stimulator:
Each MxN HD-tES stimulator ships with two CSOP-D5 cables, consisting of 5 output receiver plugs each. The center plug on each receiver plug is connected to the “Common” and the remaining plugs are labeled as Channel 1 through 4 on the Output Cable A, and Channel 5 through 8 on Output Cable B. Connect the 5-pin cylindrical plug of the CSOP-D5 Output Cable A to the receiver port A on the back panel of the MxN HD-tES stimulator. Connect the 5-pin cylindrical plug of the CSOP-D5 Output Cable B to the receiver port B on the back panel of the MxN HD-tES stimulator (Figure 5).

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

Figure 5: Connecting CSOP-D5 Output Cables to the MXN Stimulator
3) Connecting the required stimulation electrodes to both CSOP-D5 Output cables:
The HD stimulation electrode plugs can be connected to the flat connector end of each of the CSOP-D5 Output Cables. Make sure all electrode plugs are fully inserted into the receiver plugs of the output cables. Connect only desired number of electrodes as per HD-tES dose (see Section 6 below for more information).

![Figure 6: Inserting the Leads into the CSOP-D5 Output Cables](image)

4) Connecting electrode leads to the subject:
Load the HD electrode-holders provided onto the corresponding electrode positions on the HD cap. Fit the HD cap onto the subject’s head. The HD electrodes fit the base of the HD electrode-holders. Electrode gel (HD-GEL) forms the interface between the electrode and subject.
5) Monitoring CHANNEL QUALITY:
The resistances are monitored via the individual CHANNEL QUALITY displays. The resistance of an individual channel is the resistance of the entire path from the individual channel to the common channel. Thus, the common channel should always remain connected during resistance measurements. Resistance monitoring provides an indication if the electrodes are properly interfaced with subject before starting stimulation. Ensure appropriate amount of HD-GEL is used for each electrode contact. It is the responsibility of the operator to ensure that the CHANNEL QUALITY™ reading is appropriate for a given application prior to stimulation. If the quality reading is not in the desired range, adjust the corresponding electrode contact. The CHANNEL QUALITY™ will constantly update showing the quality during adjustments.

Common (or reference) channel should always remain connected during measurements.

6) Setting INTENSITY and POLARITY of desired channels:
The INTENSITY rotary knobs (INT 1- INT 8) can be adjusted on each of the individual 8 channels to set the desired intensity and polarity for your HD-tES session. Each knob can be set to a “center position” indicated by corresponding CHANNEL INTENSITY displaying +0.00 mA. Rotating the knob clockwise from this center setting, will allow you to set +current and rotating counter-clockwise will allow setting –current (Figure 7). The corresponding INTENSITY and POLARITY are constantly updated showing you the adjustments. Dial each channel (in mA) clockwise or counter-clockwise as required by HD-tES dose. No current is being passed to the subject yet.

Note: Since the current value indicated by the CHANNEL INTENSITY displays is obtained by continuously sampling the output current delivered, the value displayed will fluctuate (X± delta). The INTENSITY value registered by the device via the INTENSITY knob is the X value.
It is the responsibility of the operator to ensure that the INTENSITY and POLARITY value is appropriate for a given application prior to stimulation.

Soterix Medical Neurotargeting softwares: **HD-Targets** and **HD-Explore** can be used to pre-determine optimal electrode position based on identified brain targets and subject-specific anatomy (Figure 8). The “dose” parameters can be programmed into the MxN Stimulator using the INTENSITY, POLARITY, and DURATION settings.
7) Timing the DURATION of stimulation:

The DURATION knob can be rotated clockwise or counter-clockwise to set the desired duration dosage. The DURATION display is constantly updated showing you the adjustment. It is the responsibility of the operator.
to ensure that the DURATION value is appropriate for a given application prior to stimulation.

8) Set the WAVEFORM and corresponding FREQUENCY of stimulation:

![Figure 10: Setting WAVEFORM and FREQUENCY](image)

The WAVEFORM knob can be rotated to select the desired waveform (DC, SINE, PULSE, or RAND). These selections correspond to tDCS, tACS, tPCS, and tRNS modalities. Depending on the position of the WAVEFORM POLARITY switch (see below), one can obtain unipolar or bipolar versions of the waveforms. For instance, “B-SINE” denotes bipolar-sine while ‘U-SINE” denotes unipolar-sine. The unipolar option allows one to select tODCS waveforms.

The FREQUENCY knob can be rotated to set the desired frequency (in Hz). The WAVEFORM and FREQUENCY displays will constantly update showing the chosen waveform and frequency during adjustments.
9) Set the WAVEFORM POLARITY of stimulation:

The WAVEFORM POLARITY switch can be toggled to select either UNIPOLAR or BIPOLAR versions of the wave selected via the WAVEFORM switch. The position of the switch has no significance for DC wave.

10) Set the CONDITION (SHAM ON or SHAM OFF) of stimulation:
The SHAM switch on the front panel can be pressed to set sham stimulation. When pressed, the switch glows green (SHAM ON condition). Figures 13-15

Figure 11: Setting WAVEFORM POLARITY

Figure 12: Setting CONDITION
below depict the ACTIVE and SHAM time profiles for the different waveforms. The SHAM waveform for tACS, tPCS, trNS, and tODCS follows the same time course as the SHAM waveform for tDCS.

*Note: The DURATION value includes the entire duration of the session including the ramp times.*

![Diagram](image)

**Figure 13:** ACTIVE (SHAM OFF) and SHAM waveforms for tDCS

**Figure 14:** ACTIVE tACS (SINE) waveform on left. ACTIVE tPCS (PULSE) waveform in middle. ACTIVE tRNS (RAND) waveform on right.

**Figure 15:** ACTIVE tODCS waveforms. tODCS is generated from unipolar versions of figure 14: Sine (left), Pulse (middle), and Random Noise (right).
Stimulation Procedure

1) Confirm that the INTENSITY, POLARITY, DURATION, WAVEFORM, FREQUENCY, and WAVEFORM POLARITY are set to desired values. These parameters can be determined from Soterix Medical Neurotargeting softwares: HD-Targets and HD-Explore. Set CONDITION (SHAM OFF or SHAM ON) to desired value.

2) Confirm that only the desired channels are enabled. All un-used channels are automatically disabled. Confirm that the green color battery symbol is shown in BATTERY display.

3) Ensure that the “common” or the reference channel is always used. The common channel is needed for individual channel resistance measurement and guarantees current balance during multi-channel stimulation. Since the center plug of both CSOP-D5 output cables are internally connected to the common or the reference channel, either one of the two center HD stimulation electrodes can be used as the reference channel.

4) Press the START button located at the lower right portion of the front panel. The ACTIVE LED turns ON indicating session has been initiated. Current starts from zero value and ramps up and reaches to the set amount of current over 30 seconds.

The stimulator can also be triggered to START or ABORT by a TTL trigger pulse input via the corresponding BNC socket on the back panel.

**Note:** Once the START button is pressed or device is triggered to start and HD-tES begins, changing the device controls (intensity, duration, waveform, frequency, waveform polarity, and condition) will have no effect on the ongoing stimulation. These controls have to be set before the start of stimulation.
5) The individual TRUE CURRENT™ CHANNEL INTENSITY displays will show the current ramping up to the set INTENSITY value. The individual CHANNEL QUALITY displays will show the corresponding resistance values. The CHANNEL QUALITY displays of the un-used channels will display either 999.0 K or OFF. When the CHANNEL QUALITY of the un-used channel displays 999.0 K, pseudo test current is also displayed.

6) The DURATION display indicates the time remaining in the stimulation session. The value starts at the time selected by the DURATION knob and counts down.

7) The WAVEFORM display indicates the waveform selected for the session while the FREQUENCY display indicates the frequency selected.

8) The CURRENT STATUS displays either blank or WARNING depending on whether the net current being delivered to the electrodes is below or above the allowable limit.

9) The TRUE CURRENT™ displays on each channel shows the current being delivered to the subject. The operator should monitor this display. If there is any deviation from the expected values as set by the operator prior to stimulation, stimulation should be ABORTED. Stimulation ABORT can be initiated by pressing the ABORT button triggering a 30 second ramp-down period, where current values are lowered to zero over 30 seconds. The DURATION display starts counting down from 30 seconds over this period. During a SHAM ON session, actual current ramp-down is not applicable. However, similar to SHAM OFF condition, the DURATION display starts counting down from 30 seconds.

10) HD-tES is now complete. The ACTIVE LED should be OFF.

11) Disconnect the electrodes from the electrode holders. Remove the HD cap.

12) POWER OFF the device.

During HD-tES, excessive tampering with the placement of the HD electrodes is not recommended.
Battery Charging

The MxN-9 device operates using Tenergy Ni-MH rechargeable D batteries. The device ships with a Tenergy TN190 Advanced Universal Charger and four rechargeable batteries (10,000 mAh each). The batteries are rated to be recharged 500 times. The battery charger is equipped with the following safety features: safety timer control for overcharge protection, short-circuit protection, non-rechargeable/bad cell detection and reverse polarity protection.

Operating Instructions

1) Insert 1 to 4 pieces of D cell Ni-MH batteries into the battery charger (Figure 16)

![Figure 16: Parts Location](image)

2) Observe polarity by matching (+) and (-) on the batteries to (+) and (-) on the battery compartment in the charger (Figure 17).
3) Plug charger into standard 100-240V/50-60 Hz AC outlet.

4) The charger will automatically begin charging the batteries. The LCD will display “CHARGE” and indicate the capacity for each battery (Figure 18).

![Diagram of battery capacity indicator]

Figure 18: LCD Display of Charger indicates battery status and battery capacity.

During the charging function, if a battery is detected as damaged, faulty or expired, the LCD will display “BAD” and the status indicator will flash. Replace the faulty battery with a fresh battery.
5) When the batteries are fully charged, the LCD will display “FULL”.

6) The batteries are now ready for use. Remove the batteries and unplug the charger when not in use.

7) A charging time of ~8 hours is indicated for D batteries of capacity of 10,000 mAh. This charging time can vary depending on temperature and battery status.
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 MXN HD-tES is repaired free of charge. It also explains how to obtain your warranty service.

Definition of Symbols Used:
This section defines all the symbols used.
Specifications
Electrical and Operating Characteristics

8 isolated programmable current controlled sources with common ground to ensure current conservation at all times.
Adjustable current intensity per channel: +/- 2.50 mA
Total net allowable output current: +/- 2.50 mA
Adjustable duration: 5 to 40 minutes with 5 min resolution
Waveform: DC (tDCS and t0DCS) and non-DC (tACS, tPCS, and tRNS)
Adjustable frequencies: Up to 200 Hz with 0.5 Hz resolution. From 200-600 Hz with 5 Hz resolution.
Resolution: 12 bit D/A conversion
Precision: 1% over full current range.
Individual channel compliance voltage: ~30V
Power source: 4, Rechargeable D 1.2 V Ni-MH batteries (10,000 mAh). Battery Life (with fully charged internal batteries): ~12 hrs
Dimensions: 13.6 inch, 10.2 inch, 6 inch (W,D,H)
Weight: 7 lbs

Trigger:
Electrical via BNC socket on real panel
Trigger at +5V on positive edge TTL
Maximum input: +15V
Minimum pulse duration: 100 microsecond

Storage and Operating Conditions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Storage</th>
<th>Operating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum temperature</td>
<td>50°F (10°C)</td>
<td>50°F (10°C)</td>
</tr>
<tr>
<td>Maximum temperature</td>
<td>110°F (43°C)</td>
<td>110°F (43°C)</td>
</tr>
<tr>
<td>Minimum humidity</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Maximum humidity</td>
<td>90%</td>
<td>90%</td>
</tr>
<tr>
<td>Minimum atmospheric pressure</td>
<td>20.7 in. Hg (700 hPa)</td>
<td>20.7 in. Hg (700 hPa)</td>
</tr>
<tr>
<td>Maximum atmospheric pressure</td>
<td>31.3 in. Hg (1060 hPa)</td>
<td>31.3 in. Hg (1060 hPa)</td>
</tr>
</tbody>
</table>

*All measurements are approximated
Warranty

Soterix Medical Limited Warranty

A. This Limited Warranty provides the following assurance to the first purchaser of the Soterix Medical Inc. MXN HD-tES (Model #9002A), 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.

Definition of Symbols Used
<table>
<thead>
<tr>
<th>Icon</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person</td>
<td>Type BF protection against electric shock. Isolated (floating) applied part suitable for intentional application to the subject, excluding direct cardiac application</td>
</tr>
<tr>
<td>Document</td>
<td>Refer to instruction manual/booklet</td>
</tr>
<tr>
<td>Fragile</td>
<td>Fragile. Handle with care</td>
</tr>
<tr>
<td>Keep Dry</td>
<td>Keep Dry. Protect from Water.</td>
</tr>
<tr>
<td>Temperature</td>
<td>Operate between 10°C – 43°C (50°F – 110°F)</td>
</tr>
<tr>
<td>Serial Number</td>
<td>Serial Number</td>
</tr>
<tr>
<td>Address of manufacturer</td>
<td>Address of manufacturer</td>
</tr>
</tbody>
</table>
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 tES 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 tES studies, but includes a representative list. 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 tES practices. Note: tES 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.

7. Arul-Anandam AP, Loo CK, Martin D, Mitchell PB. Chronic neuropathic pain alleviation after transcranial direct current stimulation to the dorsolateral prefrontal cortex; Brain Stimulation (2009) 2, 149–51


88. Peña-Gómez C, Vidal-Piñeiro D, Clemente IC, Pascual-Leone A, Bartrés-Faz D. Down-regulation of negative emotional processing by transcranial direct current stimulation: effects of personality characteristics. 2011;6(7)


106. Tanaka S, Sandrini M, Cohen LG. Modulation of motor learning and memory formation by non-invasive cortical stimulation of the


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Thank you for purchasing a Soterix Medical MXN-9 High-Definition trancranial Electrical Current (HD-tES) Stimulator.

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