

tDCS Stimulator (1ch)

MANUAL

TCT Research

NOTICE

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CAUTION

As a user of this device you have the responsibility to understand its proper function and operational characteristics. This manual should be thoroughly read before attempting to use or placing this device into service. This device should only be used for its intended application.

WARNING

Do not use this device if you have any metal implants in the head, or implanted devices such as cochlea implants or cardiac pacemakers.

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Unit 1010 Miramar Tower

132 Nathan Road

TST Kowloon

Hong Kong

Use of This Manual

This manual contains details of use of the TCT Research tDCS 1ch stimulator and its accessories. This manual must be read entirely before performing any stimulation with this tDCS device. If the instructions in this manual are not precisely followed, the performance of the product and/or the safety of the user and/or patient may be compromised. If you have any questions, comments, or concerns, please contact a licensed health care professional familiar with this device or TCT Research before starting to use the device.

Important

The information you read in this manual cannot replace the relationship that you have with your health care professional. None of the the information in this manual should be considered medical advice. You should always talk to your health care professional for diagnosis and treatment.

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1 Introduction

General Introduction to tDCS

Transcranial Direct Current Stimulation (tDCS) is a non-invasive procedure in which a device sends a small Direct Current (DC) across electrodes on the scalp to modulate brain function. These electrodes are placed at a region of interest, where the current induces an intra cerebral current flow. This current flow then either increases or decreases the neuronal excitability in the specific area being stimulated, based on which type of stimulation is being used. When the current passes from the anode to the cathode, it may increase the activity of the brain at the anode site and decrease the activity of the brain near the cathode site. This change of neuronal excitability leads to alteration of brain function, which can be used in various therapies as well as to provide more information about the functioning of the human brain. [1]

Transcranial direct current stimulation (tDCS) of different cortical areas has shown, in various studies, to result in modifications of perceptual, cognitive, and behavioral functions. Other applications include disorders of the brain.

One of the most important aspects of tDCS is its ability to achieve cortical changes even after the stimulation is ended. The duration of this change depends on the length of stimulation as well as the intensity of stimulation. The effects of stimulation increase as the duration of stimulation increases or the strength of the current increases. [2]

The way in which stimulation changes brain function is either by causing the neuron's resting membrane potential to depolarize or hyperpolarize. When positive (anodal) stimulation is delivered, the current causes a depolarization of the resting membrane potential, which increases neuronal excitability and allows for more spontaneous cell firing. When negative (cathodal) stimulation is delivered, the current causes a hyper polarization of the resting membrane potential. This decreases neuron excitability due to the decreased spontaneous cell firing. [1][3]

The way that transcranial direct current stimulation functions is assumed to be due to long term potentiation (LTP) and long term depression (LTD) of plasticity. Long term potentiation is the strengthening between two neurons while long term depression is the weakening between two neurons. These effects are achieved mainly through an alteration of synaptic transmission ability. tDCS stimulation involves the alteration of synaptic transmission ability through modifications of intracellular cAMP and calcium levels. Also, both LTP, LTD, and the effects of tDCS are protein synthesis dependent. It is for these reasons that LTP and LTD are proposed mechanisms of the function of tDCS. [1][3]

Product features

tDCS is known to have limited and reversible skin irritation as a common side effect. Your tDCS stimulator is designed to minimize the risks of irritation and discomfort during the stimulation. In addition, the delivered current and electrode resistance is continuously monitored to ensure safe and comfortable stimulation.

- ◆ Current settings from 0.5 to 2mA in 0.1mA increments
- ◆ Duration up to 30 minutes with countdown clock display
- ◆ Continuous monitoring and display of actual current
- ◆ Continuous monitoring and display of electrode quality
- ◆ Slow ramp up for skin conditioning and comfort
- ◆ Automatic abort on excessive resistance to prevent skin irritation

Packing list

- ◆ 1 Transcranial Direct Current 1ch Stimulator
- ◆ 1 5x5cm electrode set (1x rubber electrode, 1x sponge)
- ◆ 1 5x7cm electrode set (1x rubber electrode, 1x sponge)
- ◆ 1 7x10cm electrode set (1x rubber electrode, 1x sponge)
- ◆ 1 Dual wire electrode cable (with red marked positive terminal, the anode)
- ◆ 1 Neoprene head harness with 2 straps and velcro pads
- ◆ 1 Documentation CD-ROM
- ◆ 1 Calibration certificate

Not included, but necessary items are 2x 9V batteries and normal saline solution.

Resources

Please inform yourself about tDCS protocols, safety data and clinical results by consulting the papers mentioned in references section of this manual and the ones that can be found in the research section of our website:

www.trans-cranial.com/research

2 Risks, Health and Safety

Risks

Transcranial Direct Current Stimulation or tDCS is a safe technique. But there are some small risks and possible adverse effects, which are described below. These risks and adverse effects are based on a review^[4] of 567 tDCS sessions and from questionnaire responses from 102 participants:

1. **Tingling:** The most common report - by 70% of participants - is that of a tingling sensation under the electrodes. This is present during and shortly after the period of stimulation, and has no adverse effects or risks. A small proportion of participants report this sensation as burning (22%) or painful (18%), although they scored the burning or painful sensation as quite mild (under 2 on a 5-point scale from none to intense).
 2. **Fatigue:** The next common report - by 35% of participants - was of tiredness during the stimulation, and 25% reported this continued afterwards. The authors of the study suggest this may be due to the prolonged and uninteresting tasks the participants were doing.
 3. **Headache:** Less than 10% of participants reported a headache after the stimulation. Such headaches are usually mild and can be treated with normal over-the-counter painkillers, if required. There is no evidence that tDCS leads to any change in frequency or severity of headaches.
 4. **Seizures:** tDCS has the potential to excite the brain and induce brief seizures. These seizures are related to epileptic seizures but are short-lasting localised fits rather than grand mal epileptic seizures. They can be confused with syncope - a temporary faint or swoon - induced by anxiety.
- The risk of a seizure is very low, there have been no reported incidences according to the authors (0%). Some people, especially those with a history of epilepsy, may be prone to have a seizure related to an epileptic fit. It is therefore important that you, or if you or anyone in your immediate family has ever had a seizure, do this under strict medical guidance.
5. **Mood changes:** People with bipolar or other psychiatric disorders should do this under strict medical guidance. Cases of hypomanic episodes after tDCS were documented. ^[5]
 6. **Nausea:** Certain electrode positions, specifically those close to the mastoid process, can influence the vestibular system and cause nausea and vertigo.
 7. **Metal devices and implants:** As tDCS uses an electric current it is very important that you do not use this therapy if you have any metal devices such as cochlea implants or cardiac pacemakers. Metal implants in the head (excluding standard orthodontic braces, fillings etc) would also exclude you from tDCS therapy.
 8. **Children:** Due to the absence of studies, very little is known about the long term effects of tDCS on developing brains.

Precautions

To prevent damage to your tDCS Stimulator or injury to yourself or to others, read the following safety precautions before using this device. Keep these safety instructions where all those who use the device can easily access them.

1. Environment and Moisture

Do not immerse the tDCS Stimulator in water or any other fluids.

The tDCS Stimulator should not be used in a moist environment or if any parts of the stimulator are damp or wet.

The tDCS Stimulator is not suitable for use in an environment with strong magnetic fields (including, but not limited to, MRI). The consequences of using the tDCS Stimulator in a strong magnetic environment are unknown.

The tDCS Stimulator is not suitable for use in the presence of a flammable anesthetic mixtures with air or other gasses. The consequences of using the tDCS Stimulator in a flammable atmosphere or near flammable conditions are unknown.

Do not use the tDCS Stimulator at temperatures outside of the specific range indicated in this manual. The consequences of using the tDCS Stimulator outside of the specific temperature range are unknown and may affect the calibration of the device.

2. External Damage

Do not drop the device.

The device should not be used if there are any signs of external damage.

If any buttons or the display are not working as indicated in this manual, do not use the tDCS Stimulator. Return the device for repair.

3. Internal Parts

Do not disassemble. Touching the product's internal parts could result in injury. Should the product break open as the result of a fall or other accident, remove the batteries and return the product to TCT Research for repairs.

4. Batteries

Be sure the product is switched off before replacing batteries.

Use only batteries indicated for use in this device.

Do not attempt to insert batteries upside down or backwards.

5. Cables

Make sure all cables are fully inserted in the correct receivers before initiating the tDCS stimulation.

6. Electrodes and Irritation

Only use sponge electrodes with rubber insets.

Only use indicated safe electrode positions.

The tDCS Stimulator may cause minor irritation, discomfort, and redness at the electrode sites. If irritation occurs, discontinue the stimulation.

Do not place electrodes or sponges over previously irritated, burnt, or damaged skin. This may create current hot spots and result in injury.

8. Electronic Monitoring

Electronic monitoring equipment (such as ECG monitors, ECG alarms, EEG) may not operate properly when tDCS stimulation is performed.

Warning

Do not use this device if you have any metal implants in the head, or implanted devices such as cochlea implants or cardiac pacemakers.

No vehicles or machinery should be operated while undergoing tDCS stimulation.

Regulatory Information

Transcranial Direct Current Stimulation or tDCS is an investigational technique in many countries and may not be legal in your country.

3 Electrodes

Safe Electrode Positions

Safe electrode positions are the head (including forehead, face and chin), neck, upper shoulders and arms.

Reference electrodes (ie. the non stimulating electrode), can be placed on the chin, neck, upper shoulders or arms to avoid unwanted reduction in cortical plasticity at the reference electrode or to have a more suitable current path for the application.

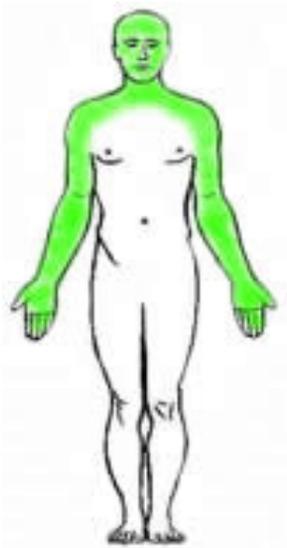


Fig 1. Safe electrode positions

NEVER place electrodes across the chest!

Safe Current Densities

In most published studies, current densities delivered varied between 0.029 and 0.080 mA/cm². [1]

With the supplied electrodes, a maximum current density of 0.080 mA/cm² can be achieved.

Electrode Size (cm)	Electrode Surface (cm ²)	Current Density (mA/cm ²)
5 x 5	25	0.080
5 x 7	35	0.057
7 x 10	70	0.028

Table 1. Electrode current densities

Research has shown that cathodal stimulation, with current densities above 14.290 mA/cm², and with charge densities of 52400 C/m², caused overt brain damage in animal subjects. [7][8][9]

It is recommended to increase stimulation duration and/or the frequency of stimulation and not current density, if a prolonged effect of tDCS for an extended time is wanted.

NEVER exceed the maximum current density of 0.080 mA/cm² by using electrode sizes smaller than 5x5 cm or 25 cm² at the maximum output of 2 mA!

Choosing a Stimulation Site

To achieve the intended electrical stimulation effects, an area of interest needs to be selected, in function of the orientation of the electrical field, which is defined by the electrode positions and polarity. The stimulation area is called the site of the active electrode. The other electrode, the reference electrode, is usually placed on the opposite side of the body. The anode is defined as the positive charged electrode, the cathode is the negative charged electrode. About 50% of the current will reach the brain tissue, the rest will be shunted across the scalp. The induced currents in the brain will be depending on (and be distorted by) tissue density and conductivity. To ensure an optimal current path, electrodes should be spaced apart a minimum distance of 7 cm.

Electrode sites are usually defined as 10/20 EEG electrode positions. The 10/20 EEG positioning protocol and references to various commonly used electrode positions can be found on our website:

www.trans-cranial.com

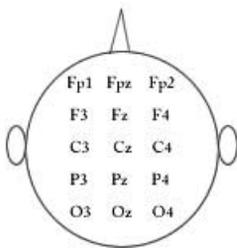


Fig 2. 10/20 EEG electrode positions

tDCS not only stimulates the intended cortical areas, but also adjacent areas. This can specifically be an issue when a cephalic reference electrode is used. The focus of the electrical field can be limited by using

larger electrodes. This lessens the effects of stimulation at the reference site. There is also the possibility of using an extra cephalic reference electrode, positioned on the chin, neck, upper shoulders or arm.

Ensuring Proper Electrode Contact

Hair and skin should be free from contaminants, such as residues of hair products. Unwanted ionic compounds from these products can be transported across the skin. Skin preparation by simple cleaning (with normal saline and/or isopropyl alcohol) also reduces resistance and improves the homogeneity of the electrical field under the electrodes. The use of nonmetallic electrodes (such as the supplied silicon rubber electrodes) avoids electrochemical polarization effects.

Do not place electrodes on skin lesions or irritated skin, this may create current hot spots and cause additional injury. The condition of the skin under the electrodes should be inspected before and after stimulation. A mild redness under the electrodes is not a sign of skin damage, but most likely the result of neurally driven vasodilation.

Electrode sponges should be soaked with normal saline and be sufficiently wet, but not wet enough to drip across the scalp.

If normal saline is not available, it can be made by dissolving 9 grams of table salt (NaCl) in water, to a total volume of 1000 ml. This results in a concentration of 0.154 mole per liter.

4 Device Operation

Control Keys and Display

The front of your tDCS device has a dimmable back lit LCD screen, a power button and 4 cursor buttons (left, right, up, down).



Fig 3. tDCS stimulator front

To switch the device on or off, press the power button. (batteries need to be present)

Assignment of functions to the 4 cursor buttons can change, according to the menu position or screen.

In general, the following conventions are followed:

- ▶ Next, Accept, Enter
- ◀ Back, Cancel, Exit
- ▲ Move cursor up, Increase value
- ▼ Move cursor down, Decrease value

General Description of the User Interface

When powering on the device by pressing the power button, and after a successful self check, the 'Main menu' will be shown on the display:

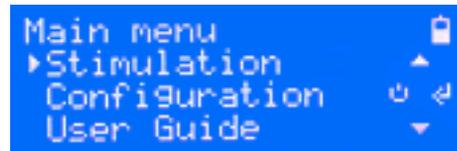


Fig 4. Stimulator main menu

The up (▲) and down (▼) buttons can be used to move the cursor. The right (▶) button selects the item at the cursor position.

Stimulation

Selecting 'Stimulation', will make a new screen appear where stimulation parameters can be set. Stimulation parameters are further explained on page 11.

Configuration

Selecting 'Configuration', will make a new screen appear. Configuration options are detailed on page 10.

User guide

Selecting 'User guide', will direct the user to the manuals section of our website:
www.trans-cranial.com

Low Battery Warnings

Battery performance is continuously monitored: when switching on the device, when no specific action is ongoing, during and after stimulation.

If after powering on the battery check fails, the following message will appear on the display:

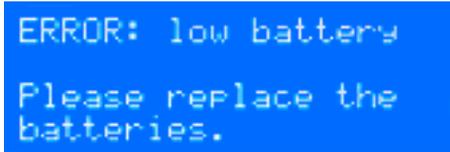


Fig 5. Battery failed message

When showing the failed battery check message, the device will be frozen in this state and will not proceed to the main menu to prevent unstable operation during a stimulation session.

When no specific action is ongoing, or if a low battery condition occurs before stimulation, the message as displayed above in figure 5 will be displayed. The device will be frozen in this state until the batteries are replaced.

If during stimulation a low battery condition occurs, the tDCS stimulator will continue with the stimulation and dim the display back light. If the quality of the battery deteriorates further, to the point where a stable operation of the device can no longer be maintained, the stimulation current will be ramped down to 0 mA over a period of 5 seconds. A beeping sound will alert the user of the error. The elapsed stimulation time will be shown on the screen, along with the message 'Battery check failed!'

If a low battery condition occurred during stimulation but the stimulation was not interrupted, after the stimulation the message displayed above in figure 5 will be shown on the screen. The device will be frozen in this state until batteries are replaced.

Configuration Menu

The configuration menu allows various device parameters to be set.

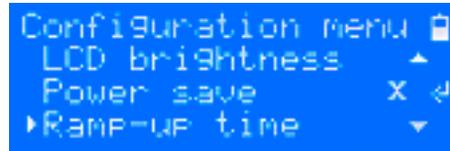


Fig 6. Stimulator configuration menu page 1

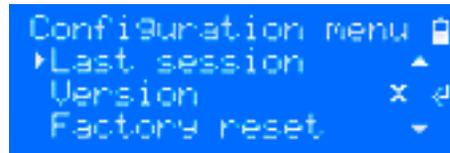


Fig 7. Stimulator configuration menu page 2

Use the up (▲) and down (▼) buttons to move the cursor to the desired item and press the right (▶) button enter the item settings.

To exit the configuration menu and return to the main screen, press the left (◀) button.

LCD brightness

Selecting 'Brightness', will make a new screen appear where you can set the display brightness. Use the up (▲) and down (▼) buttons to change the display brightness and press the right (▶) button to accept the new brightness level.

Power save

Selecting 'Power save', will bring up a new screen. Here you can change the time for shutting down the stimulator automatically when not in use. This is to prolong battery life.

Ramp-up time

Selecting 'Ramp-up', will allow you to change the current ramp-up time. Making the time longer will allow you to adjust better to the current levels during stimulation. The default value for ramp-up is 30 seconds.

Last session

Selecting 'Last session', will bring up a new screen, showing the end status of the last stimulation.

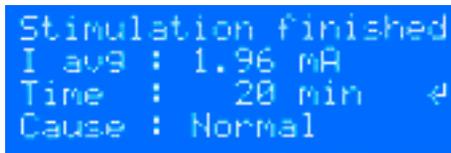


Fig 8. Last session screen

It shows the average current at the end of the stimulation session, the duration of the session and why the session ended.

Press any button to exit this screen.

Version

Selecting 'Version', will display the firmware version, device type and the production data.

Press any cursor button to return to the 'Configuration' menu.

Factory reset

Selecting 'Factory reset', will make a new screen appear. To reset your device to the default values, press the right (▶) button.

All data will be restored to initial default values, including the last session data.

Three Phases of Stimulation

The stimulator automatically switches between these phases when appropriate.

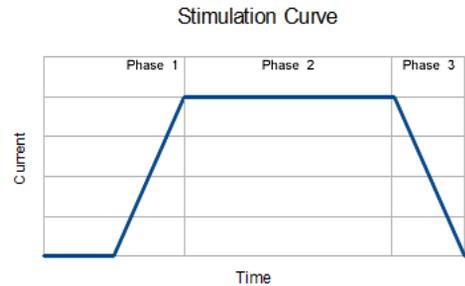


Fig 9. Stimulation current ramp

Phase 1 - Ramp-up

During this phase, the current is slowly ramped up to the desired level. This is necessary to accommodate to the required level of current.

Phase 2 - Normal stimulation

The stimulator keeps the stimulation current constant at the desired level.

Phase 3 - Ramp-down

To prevent an electric shock and phosphene (visual flash), during the last two seconds of the stimulation, the current is ramped down.

Stimulation Procedure

1. Skin preparation

Clean the skin at the electrode sites with normal saline solution and/or isopropyl alcohol. This is very important. Most problems with electrode resistance are due to bad skin preparation.

2. Place electrodes

Moisten the electrodes with normal saline and place the electrodes at the appropriate locations. Electrodes should not be dripping across the scalp. Do not place electrodes on damaged or irritated skin.

3. Switch on the tDCS stimulator

Before making a connection with the electrodes, switch on the stimulator by pressing the power button.

4. Select 'Stimulation'

Select 'Stimulation' from the 'Main menu', by pressing the right (▶) button.

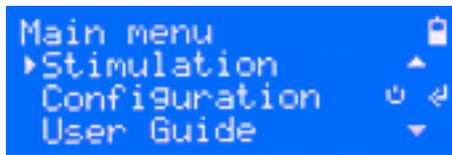


Fig 10. Stimulator main menu

5. Set parameters and press 'Start'

Set the appropriate parameters for current and duration. When done, select 'Start' by placing the cursor at the first item and press the right (▶) button.

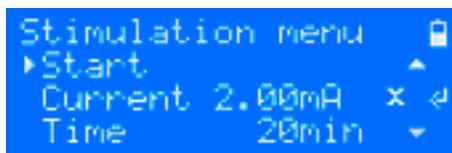


Fig 11. Stimulator parameters menu

6. Connect the electrodes to the tDCS stimulator

Connect the electrode cable to the receiver socket located at the right side of the stimulator. Press any cursor button to start the stimulation.



Fig 12. Connect the electrodes screen

7. Ramp-up

The ramp-up phase is initiated. If the skin resistance is within normal limits, the stimulation will continue normally. If the resistance is too high, the stimulation will be ramped down and terminated with a warning.



Fig 13. Ramping-up screen

8. Stimulation

During the second phase of stimulation, to follow screen will be shown.

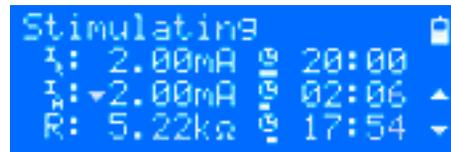


Fig 14. Stimulating screen

At this point, you are allowed to change the target current. This could be necessary when the level of current is too uncomfortable to be tolerated. If you repeatedly experience problems with tolerating the current, try making the Ramp-up time longer.

9. Changing the target current

During the stimulation, the target current can be lowered by using the down (▼) button. It can later be increased to the original target current by pressing the up (▲) button. A cursor down will be shown next to 'It' to indicate that the target current has been lowered.

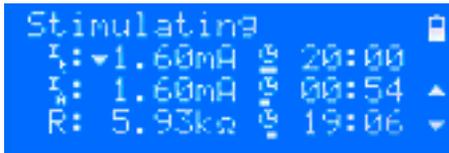


Fig 15. Changed target current

7. Ramp-down

Two seconds before the end of the stimulation session, the stimulator transitions into the ramp-down phase.



Fig 16. Ramping-down screen

9. Stimulation end

An alert sound will indicate the end of the stimulation. The average current will be shown on the screen, along with the elapsed time and status.

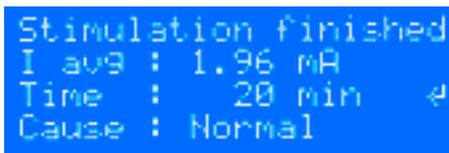


Fig 17. Stimulation finished screen

Press any key to continue.

10. Removing the electrodes

You can now disconnect the electrodes and power off the stimulator by pressing the left cursor button (◀). Pressing the right button (▶) will take you back to the Stimulation menu.

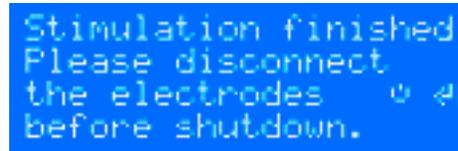


Fig 18. Disconnect electrodes screen

Please make sure to disconnect the electrodes before shutting down. Failing to do this may cause a phosphene (visual flash) and a mild electric shock.

Ending the stimulation manually

If you would like to terminate the stimulation, please do this by pressing the right (▶) or left (◀) buttons.

Removing the electrodes, switching off the device or unplugging the electrodes while the stimulation is ongoing is not recommended. It can cause phosphenes (visual flashes) and/or electric shocks.

Important note

Research has indicated that neuronal activity can diminish the effects of tDCS. To make the most of your stimulation session, it is recommended that you do not engage in any mental or physical activities and place yourself in a noise free and calm environment.

Do not operate any equipment that may cause interference with your tDCS device, such as cordless phones, mobile phones, computers or devices emitting strong EM fields.

Stimulation Display Values

The stimulation display is updated once every second. Internally the stimulator works at a much higher speed, it performs 22 measurements and current corrections per second.

The following values are shown on the display:



Phase of the stimulation

I_t - Target current

I_a - Actual current

R - Skin resistance

Total time

Elapsed time

Remaining time

I_t ▼ The target current has been lowered

I_a * The direction of the current correction

Electrode Resistance

Electrode resistance is constantly monitored. If the electrode resistance is too high, this can cause irritation and possibly injury. If this happens, to protect you, an alert will sound and the stimulation will be terminated if needed.

The ideal electrode resistance is around 4 to 6 k Ω for conductive rubber electrodes. It is perfectly ok to start at 15k Ω , the resistance will lower over time. Just make sure to check that it drops fast enough when the normal stimulation phase begins.



Fig 19. Resistance too high during ramp-up



Fig 20. Stimulation terminated because of high resistance

During the normal phase of the stimulation, the resistance should be going down. If the resistance increases, this could indicate drying of the electrode pads. A warning signal will sound, and the following message will be shown on the display every 30 seconds.

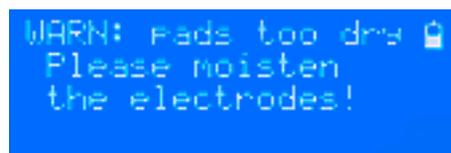


Fig 21. Increased resistance during stimulation

5 Specifications and Warranty

Specifications

Power source: 2x 9V alkaline batteries

Battery life (with fresh batteries, non backlit display): 8 hrs continuous operation.

Length: 14,0cm Width: 11,5cm Height: 3,5cm

Weight: 350 gr (batteries included)

Connector type: 3.5mm jack : Tip: anode (+) Ring: cathode (-)

Electrical specifications	Min	Max
Current	0,50mA	2,00mA
Output current protection	-	5,00mA
DAC	-	8bit
Samples	-	22/sec
Current correction time	-	45ms
Precision	-	±0.004mA
Display resolution	-	0,01mA
Output voltage	-	28V
Ripple (RMS)	-	25mV

Operating limits	Min	Max
Temperature	14 °C	28 °C
Humidity (non-condensing)	-	70%
Atmospheric pressure	700hPa	1060hPa

Storage limits	Min	Max
Temperature	0 °C	60 °C
Humidity (non-condensing)	-	70%
Atmospheric pressure	700hPa	1060hPa

Warranty

TCT Research Limited Warranty Summary

A. This Limited Warranty provides the following assurance to the first purchaser of the TCT Research 1 CH tDCS stimulator Model 101, 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, TCT Research Limited 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 TCT Research Limited, carriage paid and insured, in the most appropriate method as determined by TCT Research Limited.

(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 TCT Research Limited within thirty (30) days after discovery of the defect.

(2) The Equipment must not have been repaired or altered outside of TCT Research Limited’s factory in any way. 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 or accessories 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, TCT Research Limited Ltd 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.

6 References

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The following references list includes a selection of peer-reviewed publications consulted for this manual.

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