ActivaDose tDCS

Read Before Use

Contents

Activadose tDCS Device at a glance

Warnings and Precautions

A. **Never attempt to reuse single-use electrodes. If you are using electrodes designed for single-use, discard after use.**

B. **tDCS can cause skin irritation and burns. Users should be advised of this potential. It is important to note the following:**

1. Continuous direct current used in tDCS can cause transient (uniform or mottled) erythema under either electrode which will generally resolve within a few hours to a few days.
2. Advise user to report any undue burning or pain during stimulation at once. Pause stimulation, inspect area under the electrodes and make any necessary corrective actions before resuming the tDCS session.
3. Users should remove any jewelry that may come in contact with either electrode. Failure to do so many cause burns.
4. Do not exceed maximum levels of current or dose (total delivered charge):
   Maximum current: 2.0 or 4.0 milliamps (mA), depending on version.
   Maximum dose: Please refer to "LOTES-2017" paper by Dr. Marom Bikson—
   https://www.neuralengr.org/wp-content/uploads/2017/11/Limited-output-transcranial-electrical-stimulation-LOTES-2017.pdf.
5. Failure to observe the following precautions may result in excessive skin irritation or burns.
   Do not use electrodes that have been altered or appear damaged.
   Do not apply electrodes over damaged skin.
   Do not reuse single-use electrodes.
6. Do not use the ActivaDose tDCS Unit and electrodes on individuals with electrically sensitive support systems (e.g., pacemakers). Doing so may cause the support system to malfunction.
7. Exercise caution in handling the ActivaDose tDCS Unit. Do not allow it to be dropped or immersed in fluids. Do not connect unit to external devices. Doing so may cause a malfunction or user injury.
8. Users with known sensitivity to electrical current should be stimulated with lower current settings than those recommended for general use. If transcranial stimulation results in prolonged skin irritation or burns, consult a physician and do not attempt additional uses.
9. The "REJECT" safety feature of the ActivaDose tDCS Unit terminates the delivery of the electric current to the electrodes whenever an interruption in the electrical circuit occurs. This is indicated by the flashing "REJ" light, beeps and a flashing "ELECTRODE REJECT" on the display. A mild shocking sensation may be experienced by the user whenever an electrode reject occurs. Do not disconnect the lead wires from the electrodes, or the electrodes from the user while the current is ON since this will cause the reject feature to function. The user should avoid unnecessary movement during transcranial stimulation to ensure that an inadvertent disconnection of an electrode or lead wire does not occur.

C. **Do not allow children to handle the Activadose tDCS without adult supervision.**

Contraindications

When performing studies on subjects, the contraindications issued by the Institutional Review Board (IRB) for tDCS are the following: The Activadose tDCS Unit is contraindicated for use on patients with electrically sensitive support systems (e.g., pacemakers). On subjects with metal implants in the head. On subjects that are pregnant. It is also contraindicated for use over damaged or denuded skin or other recent scar tissue

Indications for Use

tDCS is classified as investigational technology by the US Food and Drug Administration (FDA), therefore tDCS does not have any medical indications for treatment of any kind.

Activadose tDCS Unit Safety and Convenience Features

A. **Description**: The ActivaDose tDCS Unit is a solid state, microprocessor controlled device utilized to deliver direct current for tDCS use. The microprocessor performs several safety tests continually from the time of power on and other safety tests depending upon the mode of operation.
B. **Display Help**: During normal operation the display provides guidance. Various prompts help in performing the next step. In only a few seconds, the dose and current can be set and tDCS can be started.
C. **Turning the Dose Controller ON and OFF**: The dose controller can be turned ON by depressing the On/Dose/Start knob **OR** turning it clockwise. The unit can be turned OFF by depressing the On/Dose/Start knob. Note: If stimulation is being performed and the unit is turned off, it will automatically ramp down prior to shut-off.
D. **Pause Feature**: If a pause in a tDCS session is desired, pressing the CURRENT knob will automatically ramp down the current and place the unit in pause mode. The current can also be turned down manually to activate pause mode. To restart the tDCS session, set the current to the desired level and turn the On/Dose/Start knob clockwise. The unit will automatically recalculate the stimulation time, ramp up and continue tDCS.
E. **Automatic Time Calculation**: Only the desired dose and current need to be entered for a tDCS. All time calculations are performed automatically, even if dose and current settings are changed or the unit is paused.
F. **Automatic Current Ramp Up**: After selecting the desired dose and setting the current, stimulation can be started. The unit automatically ramps up the current output at a rate comfortable for most users. The current may be adjusted for user comfort any time during tDCS session, including during current ramp up.
G. **Automatic or Manual Current Ramp Down**: After the preset dose is reached, the current automatically ramps down to 0.0 mA and the unit beeps, terminating the tDCS session. Also, automatic current ramp down takes place if a "**LOW BATTERY REJECT**" occurs during stimulation. Current may be turned off manually any time, including during ramp up, to terminate tDCS session.
H. **Resistance Limit**: Occasionally, when treating high resistance skin areas, the unit may beep and flash "**LIMIT**" on the display. However, the unit will continue stimulation if possible. As resistance drops during tDCS session, the unit will automatically ramp up

the current to the desired level, or as high as possible if the desired level cannot be reached.

I. **Dose and Current Limit**: The unit will beep and the dose display will flash "**LIMIT**" if an attempt is made to turn the dose knob beyond the upper limit of the device, 80 mA x min. Also, the unit will beep and the current display will flash "LIMIT" if an attempt is made to turn the current knob beyond the maximum of 4.0 mA (or 2.0 mA depending on version). Refer to directions for use supplied with electrodes for maximum recommended dose and current.

J. **Electrode Reject**: Circuit problems (e.g., loose electrodes, dry skin, improperly connected electrodes, etc.) can cause an "**ELECTRODE REJECT**." The unit beeps, the "**REJ**" light flashes and the display shows "**ELECTRODE REJECT**." The current output is turned off automatically. See "**Troubleshooting**" section, to correct the problem.

Setting Up the Activadose tDCS Unit

A. Install 9V Battery: Do not use rechargeable type batteries.

1. Prior to a stimulation, if battery power is too weak for proper circuit operation, the current output of the unit will remain disabled and the "**BAT**" indicator will light. If a tDCS session is attempted, the alarm will sound and the display will flash "**LOW BATTERY**."
2. The battery compartment is at the rear of the unit. To open, gently press the door inward and slide it open. Polarity symbols (+) and (-) are marked on the inside of the compartment. If the battery is installed incorrectly, with the polarity reversed, the unit will not operate. Be sure the door is fully closed after installing the battery.
   NOTE: always insert battery FLAT into the battery compartment. Use battery strap to remove. DO NOT remove or insert battery at an angle or attempt to pry battery from the compartment, as this will damage battery contacts.

B. **Twin Lead Connectors**: Connect the appropriate twin lead connector to the ActivaDose tDCS Unit (see Figure 1).

Preparing Electrodes and User for tDCS Session

A. Examine the skin sites for both electrodes. The skin must be free of damage, i.e., avoid broken skin, skin with ingrown hairs, acne, razor nicks, wounds that have not healed, recent scar tissue, etc.

B. Apply 0.9% saline to sponge electrodes according to instructions found in the "**Saline application"** section.

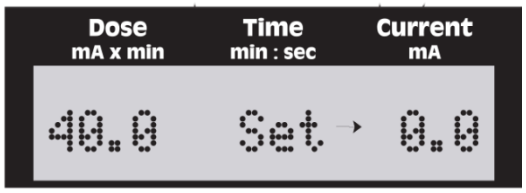
C. Remove any jewelry that may come in contact with either electrode.
D. Attach the twin lead connectors to the electrodes. Refer to specific electrode montage of interest for specific guidelines concerning polarity.
    a. Note: Red Anode (+) Black Cathode (-)
E. Apply tDCS sponge electrodes to user at the intended positions according to the specific electrode montage selected using the Caputron Universal Strap.

Operating the Activadose tDCS Unit

Normally, a typical tDCS session requires only three steps:

1. Select Dose (Timer for tDCS)
2. Set Current
3. Start tDCS session.

A. Select Dose: Depress the ON / DOSE / START knob or turn clockwise to turn on the unit. The unit performs a "System Check." The unit is preset at 40.0 mA-min (milliamps-minutes) dose. If desired, dose can be changed.
EXAMPLE: For a 40 mA-minute dose, the display shows:

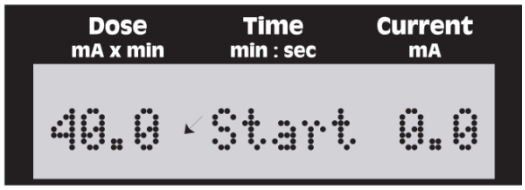


NOTES:
1. Dose is the timer
    a. 4 mA x 10 min = 40 mA-min (dose)
    b. 2 mA x 20 min = 40 mA-min (dose)
    c. 2 mA x 40 min = 80 mA-min (dose)
2. After a two-second delay, current can be set.

B. Set Current: Read electrode instructions for recommended current. Turn the CURRENT knob clockwise to set the current. Maximum possible current is 2.0 mA or 4.0 mA.
EXAMPLE: To deliver 4.0 mA of current, the display shows:

C. Start session: Turn on the ON / DOSE / START knob clockwise one "click" to start stimulation. Current automatically ramps up gradually to desired set point and display shows:

NOTES:
1. "DOSE" shows dose delivered as mA-minutes accumulate.
2. "TIME" shows time remaining in minutes and seconds until tDCS session is complete. Time calculation is automatic.
3. "CURRENT" shows actual current being delivered in mA-minutes.
4. Automatic current ramp includes built in "comfort pauses."



IMPORTANT:
If a user experiences significant discomfort at a current setting of 4.0 mA, the current may be decreased anytime during the tDCS session by turning the CURRENT knob counterclockwise. Stimulation time is automatically increased to achieve the preset dose. For example, if the current is reduced from 4.0 mA to 2.0 mA, the stimulation time will automatically double to deliver the preset dose.
TIP: For manual ramp up: Set dose, then set current below the maximum desired. Example: Set current at 0.1 mA. Start tDCS session. Gradually increase current to desired level, according to user comfort, by turning CURRENT knob clockwise. Each "click" increases current 0.1 mA.

D. Pause or Stop stimulation Manually: During stimulation or current ramp up, turn the CURRENT knob counterclockwise to reduce current output to 0.0 mA, or press the CURRENT knob for automatic ramp down. The display will flash "PAUSE", and the dose delivered prior to the pause is retained in memory.
EXAMPLE: After decreasing current to 0.0 mA display shows:

NOTES:
1. During a pause, electrodes may be disconnected, replaced or removed. Dose and/or current may also be adjusted.
2. To restart the tDCS session, turn the CURRENT knob clockwise to the desired current level.
3. Turn the ON/DOSE/START knob clockwise to start. The unit will automatically recalculate the stimulation time, ramp up and continue stimulation.

E. Stop Stimulation Automatically: After the preset dose is reached, the current automatically ramps down to 0.0 mA. After a 40 mA-minute tDCS session is complete the unit beeps and the display shows:

NOTES:
1. After Automatic current ramps down, turn the current knob to silence the beep, or depress the ON/DOSE/START knob to turn OFF.
2. Turn CURRENT knob counterclockwise to 0.0 mA anytime to stop stimulation, or depress the ON/DOSE/START knob.

F. After tDCS Session:
Remove electrodes: Disconnect the lead wires and remove the electrodes from the user. Discard the sponge electrode after 3-4 uses. They should not be reused past this. They will have non-uniform current distribution.

Electrode Placements

As tDCS is still investigational (As of October 2018), Caputron is not permitted to provide medical use instruction on electrode placement for various electrode montages.

However we do provide a list of third party resources on our website that allows you access to a thorough archive of current, up-to-date tDCS electrode montages with their corresponding intended effects. *Caputron is not liable for the information provided on these websites and the user should always refer to the actual publication for the most up-to-date and accurate information.

Saline Application

An application of ~7 ml of 0.9% saline to the 2x2 electrode sponge insert or ~15 ml of 0.9% saline to the 3x3 electrode sponge insert is recommended for optimal stimulation configuration. **Saline application should be performed after dry electrode sponge has been inserted into electrode holder.**

Sponge and Electrode Maintenance

It is important to properly maintain sponge electrode shells and electrode sponge inserts in order to obtain consistent and uniform current distribution throughout the tDCS electrode, this minimizes the chance of current “hotspots” where current may tend to concentrate at certain areas of the electrode sponge surface due to the constant wear and subsequent degradation of the sponge material through usage—this results in inconsistencies in current density distributions. As a result, sponges should be discarded after 3-4 uses.

It is advised that you replace your electrode sponge inserts every 3-4 uses, and replace your sponge electrode shells every 2 months. Make sure to position the connector portion of the conductive carbon rubber with the bump facing away from the electrode sponge insert—this ensures proper surface contact between the conductive rubber and the electrode sponge.

Activadose tDCS Unit Maintenance

Keep device clean and ensure dust does not enter battery compartment and all other openings. Clean your Activadose tDCS unit with a damp cloth when necessary.

Troubleshooting

Display Shows	Possible cause	Corrective Action
"**ELECTRODE REJECT**" and "**REJ**" indicator lights	• Loose electrical connections at one or both electrodes. • One or both electrodes have pulled away from the skin. • Electrode not properly hydrated.	• Turn CURRENT knob counterclockwise to "PAUSE" stimulation and silence beep. • Correct problem. • Turn CURRENT knob to reset current. Restart stimulation.
Dose "**LIMIT**"	• Maximum dose of 80.0 mA-min has been reached.	• Refer to electrode directions for dosage recommendations
Current "**LIMIT**"	• Maximum current of 4.0 mA has been reached (2.0 mA for respective version).	• Adjust current
"**RESISTANCE LIMIT**"	• Skin resistance at an electrode site is too high for preset current level.	• None. The unit automatically ramps current up to preset level, or as high as possible, and adjusts time to delivered desired dose.
"**PAUSE**"	• Stimulation has been paused by decreasing current to 0.0 mA, or by depressing the CURRENT knob.	• During a pause, electrodes may be disconnected, moved or replaced. • Correct situation that caused stimulation to be paused. • Turn CURENT knob to reset current. Restart stimulation.
BAT indicator lights during tDCS session.	• Battery voltage is decreasing during stimulation but stimulation may continue.	• After stimulation is finished, replace battery.
"**LOW BATTERY**" and "**BAT**" indicator lights when unit is turned on.	• Battery voltage is too low for proper operation. • If battery voltage is very low only BAT indicator lights. • Unit will not allow stimulation to begin.	• Replace battery.

"**LOW BATT REJECT**" and during stimulation "**BAT**" indicator lights.	• Battery voltage is too low for stimulation to continue. • Unit will not allow stimulation to be restarted. • Unit ramps down current before preset dose is complete.	• Replace battery.

Specifications

Electrical Shock	 Type BF Applied Part.
Environmental Conditions	Transport and store 50°F to 131°F (10°C to 55°C). Operate 41°F to 104°F (5°C to 40°C). Humidity less than 90%. Atmospheric pressure from sea level to 9,842 feet (3,000m)
Ingress of Water	Not protected against ingress of water
Flammability	Do not use around flammable gases, liquids or materials.
Mode of operation	Continuous.
Dimensions	6.1" x 3.5" x 1.9" (15.5 x 8.9 x 4.8cm)
Weight	.4 lbs. (.18kg)
Cleaning	Clean the case and lead clip wires as needed with an alcohol moistened cloth. Do not immerse in fluids.
Disposal	Dispose of according to local, state and federal regulations. Remove battery before disposal.
Controls	Two (dose and current)
Dose Range	0 to 80 mA-min.
Maximum Voltage	80V DC (or 29V DC)
Maximum Current	4.0 mA (or 2.0 mA)
Current Ramp Up	Automatic (0 to 4.0 mA)Built-in option for manual override
Current Ramp Down	Automatic at end of tDCS session; paused or turned off by depressing knob. Built-in option for manual override
Battery	Use only 9V DC Alkaline. Ensure battery door is in place before starting tDCS session. Remove battery from unit when not in use.
Display	Dose, Time Remaining, and Current(displayed simultaneously with interactive set-up)

Pause Feature	YES (w/recalculation when restarted)
Visual indicators	Low battery and open circuit
Audible Alerts	Low battery, open circuit, and end-of stimulation
Auto Shut-Off	Will automatically shut off after one (1) minute, if not in use.

Warranty

A. Caputron represents and warrants to the Purchaser that the Product (excluding accessories such as batteries, electrodes, cables and the component parts thereof), will be free of defects in materials and workmanship for a period of one (1) year, the “Warranty Period” from the date of purchase.

B. Accessories, including, but not limited to, cables, batteries or electrodes assemblies are excluded from this warranty since they are designed to be used over a short period of time

CAPUTRON

tDCS -TMS - CES - EEG

215 West 125th St
New York NY, 10027
(646) 926-3646
contact@caputron.com
www.Caputron.com