

Nuraleve[™] SmartStim[™] Model 200 tDCS Device

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Using This Manual

Document Conventions

The following table lists the typographical conventions used throughout the Nuraleve documentation.

Convention	Description
	Notes – Alerts users about potential unexpected results.
<u>^</u>	Caution – Instructions following this symbol indicate warnings or precautions associated with the device.

About this Manual

This manual covers the basic information that you need to operate the Nuraleve SmartStim Model 200 device, best practices associated with the device as well as troubleshooting information for common problems. This manual is not a replacement for proper training and practice in the use of the Nuraleve SmartStim system.

Users of the Nuraleve SmartStim system should become familiar with the material in this manual in its entirety as part of their training and background on delivering tDCS with the SmartStim Model 200.



Overview

This section contains important safety information that you should read before connecting or operating the SmartStim system.

Caution: The safety precautions listed here are meant to complement your organization's current safety guidelines. If there is any inconsistency between a particular safety instruction listed below and your organization's current practices and procedures, ensure that you clarify with a qualified person before continuing.

Pharmacological Contraindications

Clients taking the following medications should not undergo tDCS sessions, unless authorized by a physician. Interactions between tDCS and medications are not all known or fully studied. Thus, this is not an exhaustive list of tDCS/drug interactions. Care must be exercised when combining tDCS with medications.

Substance	Effect
L-dopa	Plasticity may be prevented by low and high dosages. Medium dosage may prolong inhibitory effects and convert facilitatory plasticity. Side effects: Nausea/vomiting reported in some cases.
Ropinirole	Plasticity may be prevented by low-dosage ropinirole, re- established by medium dosage. High dosage ropinirole reduces facilitatory plasticity and converts inhibitory plasticity. Side effects: Nausea/vomiting reported in some cases.
Citalopram	Facilitatory plasticity enhanced and inhibitory plasticity converted into facilitation.

Table 1: Pharmacological contraindications noted in recent tDCS studies¹

¹ Noted from review article by M. A. Nitsche and W. Paulus, "Transcranial direct current stimulation - update 2011," Restorative neurology and neuroscience, vol. 29, no. 6, pp. 463-492, Nov. 2011.

Safety Precautions

When using this equipment, please follow these basic safety precautions to reduce the risk of fire, electrical shock, or personal injury:



Caution: Before connecting or disconnecting the electrodes, stop the stimulus via the PC.

Note: Expected reactions to tDCS with SmartStim include nausea, tingling, mild headache, discomfort due to headband, seeing a flash of light during session start or stop, slight itching lasting up to 30 seconds, transient aching/burning sensation, skin irritation or redness under electrodes, dizziness and sleepiness.²



Caution: Only use the electrode lead wires provided with the system.



Caution: Do not use a cable with a damaged connector as this may prevent the stimulus from being effective.



Caution: Do not mix old batteries with new batteries. Mixing old and new batteries may result in batteries leaking.



Caution: Do not mix different battery chemistries. Example: Do not mix alkaline batteries and NiMH batteries. Mixing battery chemistries may result in batteries leaking.



Caution: Do not mix batteries with very different levels of charge. For example, do not mix mostly empty batteries with mostly charged batteries. This may result in batteries leaking.



Caution: The use of accessories and cables other than those provided and sold by Nuraleve may result in unexpected consequences.

² Refer to review article by M. A. Nitsche and W. Paulus, "Transcranial direct current stimulation - update 2011.," Restorative neurology and neuroscience, vol. 29, no. 6, pp. 463-492, Nov. 2011.





Caution: Electrode leads must never come into contact with the mains power line.



Caution: All flexible wiring to lights, heaters, dryers, etc. in the clinic must have the insulation periodically inspected by the maintenance staff. Bare or frayed wiring connecting to any electrical device must be immediately disconnected from the electrical system and replaced.



Caution: Product is intended for indoor-use only.



Caution: Do not apply electrodes near metal objects such as glasses, facial piercings or metal implants in the head on a client.



Caution: Electrodes should not be in direct contact with each other.

Disposal

Battery and device disposal

Do not dispose batteries as household waste and dispose according to local regulations. For device disposal, return the device to Nuraleve for disposal when the device is no longer functional. Do not dispose the unit with general wastes.

The SmartStim System

Introduction

Transcranial Direct Current Stimulation is a tool for modulating cortical excitability in a selected region of the brain. TDCS was developed as a mean to change stimulus-induced behavior/modify cue-provoked smoking craving/craving behavior in the 1960s when studies proved that mild brain stimulation could modulate brain functions by changing cortical excitability.

Cutting edge science is revealing the power of tDCS as a tool for exciting or depressing specific brain regions.

"Non-invasive brain stimulation promises innovative experimental possibilities for psychology and neuroscience as well as new therapeutic and palliative measures in medicine. Because of its good risk-benefit ratio, non-invasiveness and reversibility as well as its low effort and cost, it has good chances of becoming a widespread tool in science, medicine and even in lay use."³

"Prefrontal tDCS reduces food, alcohol, marijuana and cigarette craving acutely, if it is applied in a single session."⁴

"tDCS has been shown to modulate activity in both the motor and visual cortices, and more recently has been shown to directly influence excitability of the spinal cord."⁵

The Nuraleve[™] SmartStim[™] Model 200 device and accompanying software represent the very latest in tDCS technology.

INTENDED USE OF THE SMARTSTIM MODEL 200

The SmartStim Model 200 device is intended to apply established standard transcranial direct current stimulation protocols, with the device being operated by a trained professional. TDCS is a non-invasive neuromodulatory technique that delivers low-intensity, direct current to cortical areas facilitating or inhibiting spontaneous neuronal activity.

Stimulation with the SmartStim Model 200 contains several layers of client protection. The SmartStim Model 200 has safety systems built into the hardware and software, and ensures that the output current does not exceed 4 milliamps.

³ *The promises and perils of non-invasive brain stimulation*, Jan-Hendrik Heinrichs, International Journal of Law and Psychiatry, 2012.

⁴ Journal of Restorative Neurology and Neuroscience, *Transcranial direct current stimulation - update 2011* by Nitsche MA, Paulus W.

⁵ Reidler, S., Zaghi, S., & Fregni, F. (2011). Neurophysiological Effects of Transcranial Direct Current Stimulation. Neurofeedback and Neuromodulation Techniques and Applications (pp. 319-350). Elsevier Inc. doi:10.1016/B978-0-12-382235-2.00012-3.



The software can be used to control several SmartStim devices at once wirelessly, a feature ideal for tDCS during group sessions. All data exported from the devices are stored on an encrypted and redundant cloud computing solution enabling easy integration of data across institutions and clinical sites.

The SmartStim Model 200 has been designed to be light-weight, simple to operate, and easy to handle in a clinical setting. The portability and ergonomics designed into the device allow for a range of settings and electrode placement montages. In order to enhance client comfort, sessions can be paused and resumed, and the quality of electrode connection is monitored continuously.



The SmartStim Model 200

Overview

The SmartStim Model 200 tDCS system consists of two parts:

- The SmartStim Model 200 hardware components.
- Nuraleve SmartStim software components.

Below is an overview of the SmartStim system as it is used in the clinical setting:



Overview of the SmartStim System

SmartStim Model 200 Hardware

The SmartStim Model 200 from Nuraleve represents the latest technological advancement in Transcranial Direct Current Stimulation. It is

- Safe Includes many safeguards so that clients and operators are protected at all times.
- Small Unintrusive, and easy to handle.
- Easy to maintain Modular and requires little or no maintenance other than batteries and external electrodes and sponges.



 Runs under the direction of the Nuraleve software on the PC. The SmartStim Model 200 and the PC transmit commands and data via standard Bluetooth®⁶, wireless communication.



Components of the SmartStim Model 200

Note: Three-lead electrode cable shown. Some systems are supplied with two-lead electrode cable, depending on user requirements.

The SmartStim Model 200 unit is powered by a set of four "AA" batteries. Two sets of rechargeable "AA" batteries have been included with the system, as well as a compatible battery charger. Other commercial "AA" batteries may be used if desired. High quality batteries of NiMH chemistry are recommended for best battery life.

⁶ The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Nuraleve Inc. is under license. Other trademarks and trade names are those of their respective owners.

SmartStim Software

Nuraleve provides a complete package for the operator administering *Transcranial Direct Current Stimulation* with the SmartStim Model 200, including the following features:

- Integration with a standard PC running Microsoft Windows Vista/7 (x86/x64).
- An easy-to-use application for administering stimulation and logging session data.
- Secure integration with an online client database.
- Alerts and notifications before, during and after sessions.
- Simultaneous operation of one or more SmartStim devices.



Nuraleve SmartStim software interface on the PC

Instructions for installing and using the SmartStim software are provided later in this manual.



Internet Connection & Remote Database

The SmartStim system uses the internet to store data and to collect data from multiple clinical sites. One PC running the SmartStim software can operate and monitor the SmartStim devices in its clinic. Use of the SmartStim Model 200 requires an internet connection for proper functionality.

The SmartStim system obtains authentication details, assigned device list, and the stimulation parameters such as current and stimulation time from Nuraleve secure database system. The system also uses this online database to store session information to improve the user experience in the future. Thus, internet connection for the PC running SmartStim software is mandatory.

Getting Familiar with the Model 200 Device

Below are the basic features of the Model 200 unit that you should be familiar with and that will be referred to throughout this manual.

⊕ ○ POWER (A)	
► O BATTERY LOW (B)	
-√-○ STIMULATING (C)	
₿ ○ BLUETOOTH (D)	
∧ ° error (E)	
NORDOCS TECHNOLOGIES INC Ottawa, ON	
Transcranial Direct Current Stimulation Model 200	
1	

- (A) POWER Indicator: Illuminates GREEN to indicate that the device is ON.
- (B) BATTERY LOW Indicator: Blinks RED when the batteries are becoming low, and will hold RED when the batteries are critically low.
- (C) STIMULATING Indicator: Rapidly flashes YELLOW while a tDCS session (or a sham session) is being delivered.
- (D) BLUETOOTH Indicator: Blinks BLUE to indicate that the device is searching for a wireless Bluetooth connection and holds BLUE to indicate that the Bluetooth is connected.
- (E) ERROR Indicator: Blinks RED a number of times corresponding to the error being indicated. The indicator will hold RED if a critical error renders the device inoperable.
- (F) Electrode Connector: This connector accepts the electrode lead cable supplied with the device.
- (G) Power Switch: Turns the device ON and OFF.
- (H) Battery Compartment: Located on the bottom of the device, four 'AA' batteries are inserted here.







SmartStim Package

The following is a list of accessories that are part of the SmartStim M200 system. Please note that depending on the package ordered, not all of the accessories might



be present. Please contact Nuraleve to request additional accessories you may need from the list.

Part Number	Name & Description	
ND-1-101	SmartStim Model 200 tDCS device	
ND-1-183	4 AA battery NiMH rechargeable	
ND-1-417	IFU - Printed, bound M200 User Manual	
ND-1-186	Electrode lead cable	
ND-1-187	Electrode - Conductive carbon, 4cmx6cm	
ND-1-188	Electrode - Conductive carbon, 8cmx12cm	
ND-1-192	Sponge Pocket for 4cmx6cm electrode	
ND-1-408	Sponge Pocket for 8cmx12cm electrode	
ND-1-401	Bluetooth Dongle - USB	
ND-1-184	Battery charger	
ND-1-420	Headband	
ND-1-405	Skin Marker - purple ink, single use	
ND-1-404	Saline Solution - Sterile, 0.9%, 1000mL bottle	
ND-1-402	Measuring Tape	
ND-1-403	Alcohol Swab	
ND-1-406	Syringe	

Getting Started

Overview

It is easy to get started with the Nuraleve SmartStim tDCS system. The steps are:

- 1. Set up the SmartStim Model 200 device(s).
- 2. Run the SmartStim software on your PC.
- 3. Connect your PC to the device via wireless Bluetooth.



Caution: If the red "ERROR" indicator is turned on or is flashing, do not attempt to use the device until the issue is resolved.

These setup steps are discussed in detail on the following pages. Once you have completed this setup and become familiar with using the device, you will be ready to use the SmartStim system in sessions with clients.

Handling and Storage Conditions

Before using the SmartStim Model 200, please be aware of the following handling, storage and operating considerations to ensure continued functioning of the device:

- Operating Temperature: 0 to 40 °C.
- Storage Temperature: -30 to 70 °C.
- Operating Humidity: 20% to 90% non-condensing.
- Storage Humidity: 0% to 90% non-condensing.
- Observe temperature considerations for the batteries you are using.
- Do not drop device or expose device to mechanical shock.
- Device is rated for indoor use only.
- Device is **not** rated as water resistant.
- Do not disassemble device in any way.



Caution: Failure to observe proper handling and storage conditions may result in damage to the device.



Setting up the SmartStim Model 200

Unpacking

Remove the SmartStim Model 200 from its package.

Battery Installation

To install the batteries, open the battery compartment located at the underside of the unit by lightly pressing on the battery door where it is marked OPEN. Slide the door to open it.





Caution: Please refer to the battery charger manual for information on using it safely.

Place four AA batteries into the battery compartment according to the positive (+) and negative (-) polarity indications on the inside of the compartment.



Battery Placement



Caution: Do not reverse the polarity of the batteries from those indicated or the device will not power up and there is a risk of damaging the batteries. Close the battery compartment door by gently sliding it back into place in the direction shown in the figure below. Ensure that the door snaps tight to prevent batteries from being dislodged.



Closing the Battery Compartment

Assembly

Connect the **electrode lead cable** to the SmartStim device as shown below. Use only light pressure to insert the connector. The connector can only be inserted in one orientation - should the connector not easily slip into place, gently rotate it very slightly clockwise and counter-clockwise until it connects.



Caution: Do not use force to attach the connector as it may bend or break the connector pins. Do not use a connector with damaged pins.





Inserting the electrode lead connector into the SmartStim Model 200

Connect the **electrodes** to the leads as shown below. Depending on your selected protocol, you may have been provided with an electrode lead with either two or three electrode connections. It is critical to observe which electrode performs which function. The electrode connections are colour-coded as follows:

Two electrode system:

- 1. **Red** connector: Anode (positive/stimulating)
- 2. **Blue** connector: Cathode (ground return)

Three electrode system:

- 1. **Red** connector: Anode (positive/stimulating)
- 2. Blue connector: Cathode (ground return) intended for head
- 3. **Black** connector: Cathode (ground return) intended as arm reference

The size and placement of each electrode will depend on your desired protocol. It is very important to understand where each electrode needs to be placed for your session. Due to the wide variety of possible electrode combinations, this information is not covered by this manual. The protocol for a given application must be specified by a qualified physician.



Caution: Correct polarity of anode and cathode and use of correct electrode sizes for the session is critical to the success of tDCS. Incorrect connectivity of electrodes may be detrimental to the SmartStim success and may have other unintended effects.



Caution: When connecting and disconnecting the leads and electrodes, care should be taken to hold the solid part of the connector and to avoid pulling by the wires.



Connecting a lead to an electrode The size/shape of your electrodes may vary.

Insert the electrodes into the **sponges** as shown below. As with the electrodes, the correct sizing of the sponge is important to the success of SmartStim. Because the sponge is the material that makes electrical contact with the client's skin, the size of the sponge is a key factor in the current density that is applied to the client. The correct sponges to use must be a part of the protocol designed by a qualified physician.

Please refer to the sanitary procedures section of this manual for details on cleaning and sanitizing the electrodes.



Caution: Correct sponge sizing determines current density and is important to the success of SmartStim. Always use the sponges specified in a protocol designed by a qualified physician.



Inserting an Electrode into a Sponge The size/shape of your electrodes and sponges may vary.



Running SmartStim Software on Your Computer

System Requirements:

The following specifications are suggested for the computer used to control the SmartStim device. Configurations not meeting this list may work in some instances but are not supported. In some cases, Nuraleve may provide an appropriate PC for use with the SmartStim system.

- Operating System: Windows 7/Vista/XP (32 or 64 bit).
- Available USB 2.0 port.
- Disk Space: At least 500MB free for the software and log files.
- RAM: 1GB or greater for Windows 7/Vista.
- Active internet connection.
- Keyboard, mouse & monitor with 1024x768 or greater resolution.
- Latest Java (Available for download at: <u>http://www.java.com</u>).

Verifying Java Installation

To verify the latest version of Java is installed and running, please visit the Java website at http://www.java.com/en/download/testjava.jsp. A confirmation screen will appear ensuring the latest Java installation:



Java Installation Confirmation

Running the SmartStim Software

Access the link provided by Nuraleve to access the SmartStim Software. If no link was provided, please contact Nuraleve. You should be presented with the user interface as shown below. Use the credentials provided to you by Nuraleve.



SmartStim Software User Interface



Caution: Proper training is required to use the Nuraleve SmartStim Desktop Edition Software. Please consult Nuraleve to request training prior to using this software

Installing the Bluetooth Dongle

Bluetooth is a wireless technology that allows your PC to communicate with your SmartStim device(s). A Bluetooth dongle is included in your tDCS package. Nuraleve cannot provide technical support for other Bluetooth devices.

To install the Bluetooth dongle onto your PC, simply insert the dongle into a USB port on your PC. The drivers will install automatically.



Bluetooth Dongle provided with SmartStim system



The dongles provided may vary.



Note: The Bluetooth dongle must be connected to your PC in order to communicate with the SmartStim Model 200.

Verify Setup

Your Nuraleve SmartStim Model 200 tDCS device hardware and software should now be ready to use. Operators must familiarize themselves with the device, software and their functions before applying them clinically.

Getting Started with SmartStim Software

The SmartStim Model 200 is a Bluetooth-enabled wireless device. The first thing you should do after opening the Nuraleve SmartStim software on your PC is to wirelessly connect the PC to the Model 200 device. Instructions on making this connection are below:

1. Make sure that the SmartStim Model 200 is switched on, using the power switch on the right side of the device. Ensure that the green POWER indicator is illuminated. If the power indicator does not come on, refer to the Troubleshooting section of this manual.



The On-Off Switch

2. *Select Device* in the SmartStim software Bluetooth selection screen. Under this tab, you can search for and connect to SmartStim devices that are within Bluetooth wireless range.



Connecting to a Model 200 device in the SmartStim software

- 3. Any SmartStim Model 200 devices within wireless range in the area will light up in the list. The device name in this list corresponds to the unique serial number printed on the back of the device. Click the name of the device to connect to it. If your device does not appear in the list of devices or does not light up, consult the Troubleshooting section of this manual.
- 4. In case the software finds more than one SmartStim device, always ensure that you are connecting to the intended device.





Location of the device serial number on the label on the back of the device

5. There is a status bar located at the top of the program window. The software will indicate when you are connected to the device using the device name.



Caution: If you have multiple SmartStim devices nearby, always be sure you are connecting to the intended device by matching the serial number shown in the program window to the serial number on the bottom of the intended device. Mismatching devices could result in confusion and incorrect stimulation being delivered.

Getting Ready for a Session

Sanitary Procedures

In order to prepare for a tDCS session, the following sanitary procedures must be observed. Standard sanitary practices for your institution also apply even if not listed here. In case of any discrepancy between these procedures and your institution's procedures, clarify with a qualified person before continuing.

Cleaning of the apparatus

Switch off the apparatus and disconnect any attached cables. The apparatus can be cleaned with a damp cloth. Use lukewarm water and a non-abrasive liquid neutral detergent (non-abrasive, non-alcohol content solution).

Cleaning of sponge pads and electrodes

The rubber electrodes should be cleaned with lukewarm water and disconnected from the lead wire. For stubborn stains or dirt, cleaning and disinfection of the rubber electrodes can be done using a 70% alcohol solution. During this process, the black colouration of the rubber electrodes may be stained. This does not affect the operation of the electrodes.



Caution: Wash and rinse sponge pads well before first use and after each use and let them dry.

The sponge pads must be washed before first use and after each use in warm water with a neutral detergent. Then they must be rinsed with water, drained thoroughly and then dried, after they have been placed like roofing tiles. Damaged sponge pads must be replaced.

When the electrodes are not being used, the sponge pads should be removed. This increases the operational life of the rubber electrodes. We advise that you should keep extra sets of sponge pads in stock.

Inspecting leadwires

Check the cable regularly for damages and/or bad electrical contact. We also advise that you keep a few extra sets of leadwire cables in stock.



Testing the Model 200

Before applying stimulation, you should test that your SmartStim Model 200 is functioning properly. Below are instructions for testing the SmartStim device.

This self test will send electrical current through the lead wires and verify that all of the system elements (device, sponges, electrodes and lead wires) are functional and intact.



Caution: A self-test should be performed at regular intervals for continued assurance that the stimulation is done correctly. Nuraleve recommends running the self-test procedure at least once each day that the device is being used.

To run the self test:

1. Turn on your SmartStim Model 200 via the On-Off switch located on the side of the device. All indicator lights will flash during device startup. Ensure the green power indicator is on, and the Bluetooth indicator is flashing. Connect to the Model 200 device via the SmartStim software on your PC.



The On-Off Switch



The lead wire connected to the SmartStim Model 200

- 2. If not already connected, connect the lead wire to the SmartStim Model 200. The lead wire does not need to be disconnected between sessions or during storage.
- 3. Connect the electrodes to the lead wire according to the prescribed protocol. Verify that the electrode sponges are damp by adding saline.
- 4. Stack the electrodes on top of each other or hold them together.
- 5. Run the SmartStim software and ensure that the indicated connection quality is 'Good'. This indicates that the device and accessories are achieving a complete circuit and reading correctly.

GOOD
Electrode Connection

Connection quality indicator

- 6. If the indicated connection quality is 'Poor' then try adding saline solution to improve connection quality.
- 7. If you are unable to achieve "Fair" or "Good" connection quality, please see the troubleshooting guide for help in diagnosing the problem.



Overview

The Nuraleve SmartStim software constantly monitors the SmartStim Model 200 device(s) and continuously notifies the operator of the status of the device(s). Data from the SmartStim Model 200 is automatically saved in the Nuraleve database for later review and analysis. This section discusses use of the SmartStim Model 200 in the clinical environment.

Client Preparation

Best Practice

Best practice must be followed at all times to ensure the safety and comfort of the client. This section contains important information on preparing a client for a safe tDCS session with the SmartStim Model 200.



Caution: Correct polarity of anode and cathode and use of correct electrode sizes for the desired stimulation is critical to the success of SmartStim. Incorrect connectivity of electrodes may be detrimental to the SmartStim success and may have other unintended effects.



Caution: The electrodes must be placed in the sponge pads before coming into direct contact with the skin.



Caution: Do not apply stimulation with a dry sponge. This may result in mild electrical burning or skin irritation.



Caution: Do not apply electrodes near metal objects such as glasses, implanted metal, or facial piercings on a client. There is a risk of mild electrical skin/tissue burns or irritation. Applying tDCS to a client wearing metal-framed glasses may decrease its effectiveness.



Caution: This device should not be used when there are wounds or lesions near the electrodes, between the electrodes, or present in the general area of the stimulation. This includes open wounds, bruising, skin abrasion, skin lesions, and rashes.



Caution: This device should not be used on clients suspected of carrying viral or bacterial infectious diseases, or presenting with fever. These clients shall not have tDCS sessions without the authorization of a physician.



Caution: Do not apply tDCS through or near the neck.



Caution: The safety of tDCS has not been established for use on pregnant clients. Do not apply stimulation to a client who is pregnant without authorization of a physician.



Caution: tDCS should not be applied to children without authorization from a physician.



Caution: tDCS should not be applied to clients with pacemakers or similar implanted devices without authorization from a physician.



Note: Skin irritation and itching have sometimes been reported at the site of stimulation.



Note: For better connection, pre-wet hair if necessary by rubbing the sponge in the target location. Then, re-apply saline on the sponge.



Note: Use alcohol swabs to remove marker dots from scalp at end of session.

Skin Preparation

The client's skin, where the electrodes are to be placed, should be examined before each tDCS session.



Caution: Examine the client's skin where the electrodes are to be placed. Should any injuries be noted, it may be necessary to abandon the session.



Placement of the Electrodes

- 1. Insert the electrodes into previously washed and rinsed sponges.
- 2. Dampen the sponges with saline solution using a syringe, eye dropper or similar method.
- 3. Attach the electrodes to the head of the client in the manner indicated by your desired protocol. Some protocols may require an additional reference electrode attached to the arm. The connections at the electrode lead cable are colour-coded as follows:

Two electrode system:

- i. **Red** connector: Anode (positive/stimulating)
- ii. **Blue** connector: Cathode (ground return)

Three electrode system:

- i. **Red** connector: Anode (positive/stimulating)
- ii. **Blue** connector: Cathode (ground return) intended for head
- iii. Black connector: Cathode (ground return) intended as arm reference



Caution: Correct polarity of anode and cathode and use of correct electrode sizes for the session is critical to the success of SmartStim. Incorrect connectivity of electrodes may be detrimental to SmartStim success and may have other unintended effects.

- 4. The electrodes are secured to the client with a headband or armband. Headbands are included with the SmartStim system. Other non-conductive headbands may be substituted. If using metal clips, secure them away from the electrode sites. The method of securing the electrodes with the headband may vary depending on electrode placements.
- 5. Surplus saline solution should be removed with a disposable absorbent paper towel.

Do not allow the headband to be soaked in saline or to contain excess saline. Excess saline on the headband between the electrodes may make the stimulation ineffective by passing most of the current only along the band.



Caution: Do not apply stimulation with a dry sponge. This may result in mild electrical burning or skin irritation.



Caution: Try to maximize the amount of electrode sponge surface making contact with the client. Inadequate electrode contact area causes high current density, which may result in skin irritation and mild electrical burning. Low electrode contact area may also reduce SmartStim effectiveness.



Caution: Make sure that the sponges are not over-saturated and sponges are not spilling liquid on client's face or body. Make sure that the headband does not contain excess saline in the areas between the two head electrodes. Make sure that saline solution is not accumulating excessively between the two electrode sites.



Caution: tDCS should not be applied with electrodes touching each other or with electrodes placed very close together. This will result in an ineffective stimulation.

Session Overview

Beginning a Session

Once you have connected the client to the SmartStim Model 200 device and the device has been switched on, you can initiate a session on the PC.

- 1. Log into the software by entering your user name and password, and then clicking the *Login* button on the *Login* screen.
- 2. Make sure the PC is connected via Bluetooth to the SmartStim device.
- 3. Click on the *Next* tab and ensure you are connected to the SmartStim Model 200 device that you will be using.
- 4. When you are ready to begin the stimulation, press the button and a session will be initiated.



Nuraleve - Delivery Software - ND-M20	00-0010	
Delivery Software Session id: Z56K	Bluetooth ND-M200-0010	N/A Electrode Connection
19 Time	9:57 mine Remaining	n
2.0 mA Current Applied		
RUNNING		
	0% bout Nuraleve	

Stimulation Tab

You can pause the session temporarily by clicking on the substant. You can resume the session by clicking on the button. If you wish to stop the session and reset the timer, click on the button. You also have the ability to change the session time and current by clicking the button and adjusting the values as prescribed.

The Status Bar on the top of the screen keeps you informed of the status of the connection to the device and the connection to the remote database.



Note: If, at any time during the session, the Bluetooth connection is lost, the experiment will automatically be stopped and the session ended, and a request to reconnect to the device will pop up. See Bluetooth Connection below for instructions.



Caution: Always stop the stimulation on the PC before connecting or disconnecting electrodes.

During the Session

Maintain periodic contact with the client to ensure that there is no agitation or discomfort. It may be necessary to apply additional solution to the electrode sponges should they become dry. Should it be necessary to absorb surplus saline leaking from the sponges, or to add additional solution, use the PC to pause the session, absorb the leaking solution or add additional solution, then resume the session with the PC.

During the delivery of the current, a session ID appears on the top-left of the screen. This is a 4 character ID that can be used as reference if there are any issues and support is needed or in case of reporting adverse events.



Note: If the device is unable to provide the desired level of current due to poor electrode connection (indicated on the stimulation tab), stop the stimulation on the PC and add saline solution to the sponge. Resume the stimulation once connection quality has been improved.



Note: If client reports pain as the output current ramps up, try pausing the session and waiting 2 minutes before resuming stimulation. In many cases this will give the skin time to adapt and help to reduce pain.



Note: If the software doesn't show the electrode connection as 'Good' or 'Fair' even after adjusting sponges and adding saline, try leaving the electrodes on the client for 2 minutes. In some cases, this will give the skin time to adapt.



Note: If there's an Internet disconnection during stimulation, a counter will appear in the status bar. This is the number of manual, i.e. without Internet connection, tDCS sessions that can be performed. After that, a connection must be established in order to deliver more sessions.





Session counter during Internet disconnect

After the Session

The tDCS session should stop automatically when the session timer counts down to zero. Once the session is over, you can remove the electrodes and other paraphernalia from the client. Store the electrode sponges as specified by the cleaning protocol.

At this point you may perform any additional recording or logging activities required by your protocol. Observe sanitary procedures before beginning tDCS on another client.

Protocol for smoking craving reduction

This section describes the SmartStim setup to be used for smoking craving reduction. It gives more details on the electrodes and placement of the electrodes.

Electrodes

The protocol uses a two-electrode system. The current flows from the left (anode) to the right (cathode).

- Anode
 - Small electrode (30 cm²)
 - Red connector on the lead wire
- Cathode
 - Large electrode (100 cm^2)
 - Blue connector on the lead wire

Placement of the electrodes

Placement of the electrodes follows the EEG 10-20 Measuring system. For smoking craving reduction, two points are of interest, F3 and F4.



EEG 10-20 Measuring System

In this protocol, the small 30 cm^2 electrode goes onto the F3 point and the large 100 cm^2 electrode is placed onto F4.





F3 and F4 electrode placement

To find these points, the following procedure must be followed (as the measurement is done, it is helpful to mark the points with a skin marker):

- 1. Measure head midline with loose measuring tape intersecting the Nasion and Inion, marking the midpoint.
- 2. Measure head from *LPA* to *RPA* and mark the midpoint (defined in the next section).
- 3. Intersection of both marked points is the vertex Cz.
- 4. C3/C4 is 20% of distance from LPA to RPA through Cz, starting from Cz and going DOWN (this is the M1).
- 5. F3 is 5 cm forward from C3. Measure to the correct location and mark.
- 6. F4 is 5 cm forward from C4. Measure to the correct location and mark.

Pre-auricular points (LPA, RPA)

The preauricular point is a point of the posterior root of the zygomatic arch lying immediately in front of the upper end of the tragus. It is marked with a red dot in the following figure:



Pre-auricular points



Error Messages

Error indicator codes

If before, during or after the session the device's ERROR indicator blinks, please refer to the following table (code is the number of blinks):

Code	Message	Description
3	Bluetooth timeout	Device is not receiving any Bluetooth data. Please refer to the <i>Bluetooth Connectivity</i> paragraph in the <i>Troubleshooting Problems</i> Section.
4	Poor electrode connection	Electrodes may be disconnected or device is unable to reach target current on client.
5,6,7,8	Nuraleve internal hardware error codes	Contact Nuraleve if errors persist after resetting your device.

SmartStim PC Application Error Messages

"No Bluetooth Radio Found"

This error is displayed when there are no active Bluetooth dongles on the computer.

- Ensure that the computer has a Bluetooth dongle provided by Nuraleve plugged into one of its USB ports. If no dongle is found on the computer, install the dongle and wait for the computer to complete installation of the drivers, and restart the PC Software.
- If there is a dongle present, remove the dongle from the USB port, wait 10 seconds, and plug it back in again, and restart the PC Software.
- If no Bluetooth connection is available after repeating the two previous steps, please contact Nuraleve to request a new Bluetooth dongle.

"Bluetooth disconnected."

This error is displayed in the status bar when the stimulation is paused due to lost connection with the SmartStim Model 200.

Possible causes of this error are:

- The device has been accidentally shut off, or the batteries are discharged.
- The device has been moved outside of the Bluetooth range.

The software automatically makes 3 attempts to reconnect to the device and displays 'reconnecting' on the status; failure to connect results in a 'disconnected' status message. You can click on the Bluetooth icon and connect to the same device manually or pick another device to connect to from the list.

"Electrode Connection Lost"

This message will be displayed during a session when there is an electrode disconnection detected.

Possible causes of this error are:

- The electrodes have lost firm contact from the client's skin;
- The electrodes have slipped off or shifted;
- The lead wires have been separated from the device or the electrodes, or the lead wires have been damaged.

The Electrode Issues section below will guide you in troubleshooting this problem.

"Failed to Start"

This message is displayed when the session START button is pressed but the device does not respond with an acknowledgement. Try pressing the START button again and if the problem persists, consult the troubleshooting guide below to ensure the M200 device is properly functioning

"Failed to Stop"

This message is displayed when the STOP button is pressed but the device does not respond with an acknowledgment within 3 seconds. Press the STOP button again after closing the dialog prompt and the session will stop.

For the safety of the client, if the M200 does not maintain communication with the software for more than 5 seconds at anytime during the connection, it will automatically stop any ongoing sessions and disconnect.



Troubleshooting Problems

This section will help you identify and fix common problems that you may encounter while using the SmartStim Model 200 device. If you experience a recurring error that is not in this list, or you are unable to operate your device, please contact Nuraleve immediately.

Device Functionality

Device does not turn on

If the device does not turn on when the power switch is enabled:

- Ensure that the batteries are inserted in the proper order and not reversed.
- Ensure that the batteries are not depleted or have a low charge; if so, replace with fresh batteries.
- Verify that there is no mechanical damage to the device. If the device has been splashed or soaked, dropped, exposed to extreme temperatures or left in direct sunlight, there may be irreversible damage to the device. Please contact Nuraleve for further information.

All device LEDs stay illuminated or LEDs blink continuously

• Device is unable to power up properly, or has encountered an unknown error. Please contact Nuraleve.

All device LEDs stay illuminated and the ERROR LED blinks

• The device failed its Power-On Self-Test. Please contact Nuraleve.

Bluetooth Connectivity

Unable to Find SmartStim Device

If the PC Software is unable to find the SmartStim Model 200:

- Ensure that the device is switched on and that the Bluetooth LED is blinking.
- Ensure that the device is within a 10 meter range of the PC.
- Ensure that your Bluetooth dongle is properly installed and working correctly. To verify that your Bluetooth dongle is working properly, please contact your system administrator.

Unable to Connect to SmartStim Device

If the PC can detect the SmartStim Model 200 but is unable to make a connection:

- Verify that the serial number of the desired SmartStim Model 200 matches the displayed device name.
- Ensure that the device is not presently in use by another station.
- Bring the PC and the SmartStim Model 200 closer together.
- Remove all obstacles between the SmartStim and the PC.
- If possible, having a line of sight between the SmartStim and the PC may allow an increased range.

• Disable all possible interfering devices, such as microwave ovens, cordless phones and other Bluetooth-enabled devices.

Connection Drops Frequently

If you find that, during tDCS sessions, the Bluetooth connection is frequently lost, it is usually an indication that you are beyond the device's Bluetooth range.

- Bring the PC and the SmartStim Model 200 closer together.
- Remove obstacles between the SmartStim and the PC where possible.
- Having a clear line of sight between the SmartStim and the PC may allow an increased range.

Database Connectivity

Proper use of the SmartStim system includes Internet access to the client database. Database connectivity is indicated in the status bar of the Nuraleve tDCS software. If you are unable to connect to the database:

- Ensure that you are connected to the Internet. If you are unable to connect, contact your network administrator.
- Ensure that your name and password are correct. If you are unable to authenticate and start the session, please contact Nuraleve for further assistance.

Electrode Issues

Electrode connection quality remains low

If the connection quality display does not increase:

• Ensure that there is sufficient contact area between the electrodes and the client. Hair, lack of saline, lack of pressure or uneven pressure over the entire electrode may contribute to a low connection quality.

Electrode connection quality remains at zero

If the PC Software does not show any change in the electrode connection quality display:

- Ensure that the lead wires connector is properly inserted in the receptacle on the device.
- Verify that placing the electrodes together brings the connection quality up to 'Good'. If this does not happen, replace lead wires.

Session Controls

Session will not start

If the session does not start:

• Verify that the connection quality 'Good' or 'Fair'. If the connection quality is not 'Good' or 'Fair', please refer to the "Electrode connection quality is low" section above.

Start/Resume Button is disabled

If you are unable to start the session:



- Make sure the software is connected to the device. An indicator listing the name of the device will appear in the status bar of the software. Please ensure the battery level is not low, and that the PC software has connected to the device that you intended.
- Ensure that the connection quality bar displays 'Fair' or 'Good'. If connection quality is insufficient, please consult the Electrode Issues section above for solutions.

If the problem persists, you may need to restart the software and restart the device.

Nuraleve Warranty

The Nuraleve products specified below, to which this certificate relates, have been inspected and tested in accordance with the conditions and requirements of the contract or purchase order; and unless otherwise noted, conform in respect of the relevant specification.

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Nuraleve Inc. warrants the Nuraleve products purchased directly or through an authorized representative, to be free of defects in materials and workmanship for a period of twelve (12) months* from the date of the purchase. If you have a service agreement with Nuraleve then the service agreement provides the terms of your warranty and servicing, and this warranty does not apply to you.

This warranty does not apply to non- Nuraleve branded products even if packaged with Nuraleve product. The warranty also does not apply to the following exclusions:

- a) consumable parts, such as batteries, electrodes, and leads, unless failure has occurred due to a defect in materials or workmanship;
- b) cosmetic damage, including scratches, dents and broken plastic parts;
- loss of, or damage to, the Nuraleve product due to accident, abuse, misuse, improper packaging or shipping, alteration, installation of any software that conflicts with, damages or limits the pre-installed Nuraleve product software or the removal of any Nuraleve software required modules;
- d) damage caused by failure to follow operating, maintenance or environmental instructions prescribed by Nuraleve in the user manual;
- e) damage caused by servicing performed by someone other than a Nuraleve authorized service provider. Without limiting the foregoing, water damage, sand/corrosion damage, battery leakage, dropping the Nuraleve product, will be presumed to have resulted from misuse, abuse or failure to operate the Nuraleve product as set forth in the operating instructions;
- f) use of parts or supplies (other than Nuraleve -branded parts or supplies) that cause damage to the Nuraleve product or cause abnormally frequent service calls or service problems;
- g) damage caused by operation outside of Nuraleve published guidelines;



- h) defects caused by normal wear and tear or otherwise due to the normal aging of the product; and
- i) where the Nuraleve product has had its serial number or dating altered or removed.

To make a claim under this limited warranty, you must ship the product or the component believed to be defective to Nuraleve Inc. in proper packaging, prepaid only after coordinating with the Nuraleve Service Department, as specified below. Nuraleve Inc. assumes no liability for products or components shipped until they are actually in the custody and possession of Nuraleve. Upon inspecting the defective products and/or components and based on the sole discretion of Nuraleve, provided that the damage is not as a result of one of the above listed exclusions, Nuraleve will repair or replace the defective product with new or comparable product containing new or rebuilt parts, or replace the said component with a new or rebuilt component as determined by Nuraleve or an authorized Nuraleve service provider, at their sole discretion.

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Nuraleve does not accept any responsibility for its products or component parts that have been altered outside of the Nuraleve factory.

If the purchaser uses, or allows others to use, in or with the product, parts that have not been made, supplied or authorized by Nuraleve, this warranty shall become null and void.

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Name: _____ Date: _____

* All replaceable batteries are warranted for a period of 6 months.



Technical specifications

Product dimensions

- Height: 40mm
- Width: 100mm
- Length: 196mm
- Weight: 285 grams

Battery life

Typical battery life 12 - 24 hours depending on usage

Output characteristics

Parameter	Min.	Тур.	Max.	Unit
Max output	3.9	4	4.1	mA
current				
Max output	26.5	30	32	V
voltage				
Output	-	±1	±5	%
current				
tolerance				

Product requirements

- Operating System: Windows 8/7/Vista
- Available USB 2.0 port.
- Disk Space: At least 500MB free for the software and log files.
- RAM: 1GB or greater
- Active internet connection.

Electromagnetic emissions

Battery

4.8V DC, 4 x 1.2V AA

Data transfer

Bluetooth v2.1

Symbols and meaning



Type BF applied part

Operating conditions

Temperature	Humidity
0 to +40°C	20% to 90%
	Non-condensing

Storage conditions

Temperature	Humidity
-30 to +70°C	0% to 90%
	Non-condensing
This Class B digital apparatus complies with	

This Class B digital apparatus complies with Canadian ICES-003 (CAN ICES-3(B)/NMB-3(B))

Portable and mobile RF communications equipment can affect SmartStim M200. SmartStim M200 needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided below.

The equipment is intended for use in the electromagnetic environment specified below. The customer or					
the user of the equipment should assure that it is used in such an environment.					
Emissions test	Compliance	Electromagnetic environment – guidance			
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.			
RF emissions CISPR 11	Class B	The equipment is suitable for use in all establishments including domestic			
Harmonic emissions IEC 61000- 3-2	Class A	establishments and those directly connected to the public low voltage power supply			
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	network that supplies buildings used for domestic purposes.			

The equipment is intended for use in the electromagnetic environment specified below. The customer or the						
user of the Equipment should assure that it is used in such an environment.						
Immunity test	IEC 60601 test level	Compliance level	environment – guidance			
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.			
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial/residential or hospital environment			
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial/residential or hospital environment.			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 Vac	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial/residential or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.			
Power frequency (50 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial/residential or hospital environment.			



The equipment is intended for use in the electromagnetic environment specified below. The customer or the						
user of the equipment should assure that it is used in such an environment.						
Immunity test	IEC 60601 test	Compliance level	Electromagnetic environment – guidance			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to th frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{F_1}]\sqrt{P}$ $d = [\frac{3.5}{F_1}]\sqrt{P}$ BO MHz to 800 MHz $d = [\frac{7}{F_1}]\sqrt{P}$ BO MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each			
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	than the compliance level in each frequency range ^b . Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from						
structures, objects and people.						
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur						

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SmartStim M200

The SmartStim M200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SmartStim M200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartStim M200 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter M			
power	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5GHz	
of transmitter W	$d = [\frac{3.5}{V_1}]\sqrt{P}$	$d = [\frac{3.5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$	
0.01	0.12	0.12	0.24	
0.1	0.37	0.37	0.74	
1	1.17	1.17	2.34	
10	3.69	3.69	7.38	