starstim-home NE®

Neuroelectrics Starstim-Home

- Part 1 -

Instructions for Use

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Instructions for Use Update:

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Model Name:
Starstim-Home tES

The manufacturer should be contacted:

- for assistance, if needed, in setting up, using or maintaining the Starstim-Home system;

- to report unexpected operation of events that result from the usage of the device.

Input: 5W, 4.8 - 5,5V

About the Starstim-Home Investigator Instructions for Use

Before the first use of the Starstim system and provide it to the home users, read the present instructions for use (**Part I:** Starstim-Home tES Instructions for Use) and all the instructions for use relevant to this device:

- **Part II:** NIC2 Instructions for Use
- **Accessories:** Electrode Instructions for Use

The PDF version of these Instructions for use can be found under the User Manual section of Neuroelectrics webpage:

https://www.neuroelectrics.com/resources/manuals

Table of Contents

I. Use of Starstim-Home

Starstim-Home is a transcranial electrical stimulation (tES) system with real-time remote supervision.

Starstim-Home offers unique benefits:

- Reliable Remote Management of even Large Home Studies;
- Unparalleled Home-based tES Safety;
- Unique Experience for Home Users;
- State-of-the-Art for Quality of Data Security & Transfer;
- Customer Support over Product Lifetime & Multiple Warranty Options.

I.1

Transcranial Electrical Stimulation (tES)

Transcranial electrical stimulation (tES) is a neurophysiological technique capable of modulating the excitability of the neuronal tissue of the central and peripheral nervous system through the application, for a finite time length, of an electrical field. This electric field is generated by the application of weak electrical currents through the scalp and into the brain.

It has been demonstrated in recent years that the technique is safe and beneficial if used within the known bounds of intensity, density and duration. Nevertheless, its application must be controlled by specialized medical personnel able to guarantee the application of correct stimulation parameters.

Brain stimulation can be performed only under medical prescription or under the supervision of an appropriate Ethics Committee as regulated in each country of intended use.

The tES technique is classified into three types according to the waveform of the stimulation current that is applied: tDCS, tACS and tRNS. Starstim-Home allows as well for self-designed custom waveforms. Additionally, the Sham mode can be used for controlled experiments.

Transcranial Direct Current Stimulation (tDCS)

tDCS is the most popular tES technique, and it is described by stimulation currents that are held constant, like DC current. In general, the current is injected into the brain (anodal stimulation) over a cortical region leading to excitatory effects; and collected from the brain (cathodal stimulation) leading to inhibitory effects. tDCS produces short term effects on neuronal excitability, and long lasting plastic after/effects involving synaptic modification.

Transcranial Alternating Current Stimulation (tACS)

tACS is a form of tES in which the stimulation currents are time dependent with a sinusoidal shape, like AC current. Amplitude, frequency, and relative phases across stimulation electrodes can be defined. tACS provides a powerful way to couple with the oscillatory behaviour of the brain, which is at the present an active research field in basic and clinical Neuroscience.

Transcranial Random Noise Stimulation (tRNS)

tRNS is a type of tES in which the stimulation currents are randomly varied. Unlike tDCS, tRNS has been recently introduced to the Neuroscience community, and there is little experience with it. However, it appears as if its main effect are excitatory. The lower and upper

values of the band frequency of the stimulation signal can be chosen between 0 to 500 Hz.

Custom waveforms

As well the waveforms which, due to their complexity, can not be created using a linear combination of tDCS, tACS and/or tRNS (e.g. rectangular waveform) can be executed as part of home sessions. Refer to the NIC2 Instructions for Use to learn more.

Sham stimulation mode

Sham stimulation is the term used to describe an inactive form of stimulation which is used in research to control the placebo effect.

I.2
Intended Use & Use Environment

Starstim-Home tES is a wireless 8-channel transcranial electrical stimulation investigational device with real-time remote supervision capabilities. It has been designed to be used for research purposes, in a home-healthcare environment, clinical environment, hospital or research center. The qualified professional that programs the treatment is responsible for providing and keeping a record of proper training to the layperson in charge of operating the device. The qualified professional is also responsible for the remote supervision of the use of the device.

Starstim-Home tES can only be used with electrodes and cables commercialized by Neuroelectrics.

Starstim-Home tES is an investigational device.

I.3
Potential Contraindications

Following is a list of recommended exclusion criteria to screen patients entering a tES study. The sponsor/ investigator needs to assess the risk-benefit ratio of including a patient falling under one or more of the criteria:

- Patients with a history of seizures;
- Patients with unexplained episodes of loss of consciousness, since such condition could be related with brain alterations or epilepsy;
- Patients with unstable or non-controlled neuropsychiatric illness;
- Patients having implanted brain medical devices;
- Patients with implanted pacemakers;
- Patients having any electrically, magnetically or mechanically activated implant;
- Patients having cardiac, neural or medication implants;
- Patients having vascular clips or any other electrically sensitive support system in the brain;
- Patients with serious brain injury;
- Patients showing damage of skin at sites of stimulation (the device can only be used in healthy skin without wounds, otherwise the resistance to current can be altered);
- Patients suffering from skin problems, such as dermatitis, psoriasis or eczema;
- Patients suffering from severe or frequent headaches;
- Patients with any serious life-threatening disease such as congestive heart failure, pulmonary obstructive chronic disease or active neoplasia;
- Pregnant women (women of childbearing age should undertake a pregnancy test to confirm eligibility before treatment).

I.4
Potential Adverse Events

Possible side effects include but are not limited to:

- Scalp itching.
- Tingling.
- Headache.
- Burning sensation or discomfort at the site of application of electrodes.
- (For clinicians) skin erythema.
- (For patients) skin irritation or redness.
- Fatigue/sleepiness.

II. Quality and Regulatory Information

II.1
Quality Management System

The Quality Management System of Neuroelectrics Barcelona S.L.U. is ISO13485:2016 certified (ISO13485 ES12/11934 certificate and MDSAP ES20/87347 certificate). Thus, our medical devices are designed, manufactured and distributed in accordance with the applicable requirements of ISO 13484:2016 and Part 820 (Quality System Regulation) of Title 21 of the Code of Federal Regulation.

II.2
Medical Device Regulations

The Devices described in this manual are investigational devices in the US: “CAUTION Investigational devices. Limited by Federal (or United States) law to investigational Use” and in the EU : “exclusively for clinical investigations”.

III. Safety Information

Starstim 8 and Starstim tES have been tested for electrical safety according to the international standard IEC 60601-1 and for electromagnetic compatibility according to the international standard IEC 60601-1-2 using the following limits:

Category	Standard	Compliance Level
Radiated Emissions	EN 55011:2016/A1:2017	Group 1, Class B
Conducted Emissions	EN 55011:2016/A1:2017	Group 1, Class B
Harmonic Emissions	EN 61000-3-2:2014	Class A
Voltage fluctuations/ flicker emissions	EN 61000-3-3:2013	Complies
Electrostatic Discharge (ESD)	EN 61000-4-2:2010	±2 kV, ±4 kV, ±8 kV, ±15kV - Air discharge ±8 kV - Direct contact discharge ±8 kV - Indirect contact discharge
Electrical fast transient/burst Immunity	EN 61000-4-4:2013	±2 kV for ac power ports through direct injection 100 kHz repetition frequency
Surge Immunity	EN 61000-4-5:2015	±0.5kV and ±1kV Input power ports Combination Wave (1.2 μs x 50 μs Voltage, 8 μs x 20 μs Current)
Radiated RF Immunity	EN 61000-4-3:2007 + A1:2008 + A2:2011	10V/m, 80 MHz to 2700 MHz, 80% AM at 1 kHz 1% frequency step
Immunity to conducted disturbances, induced by RF fields	EN 61000-4-6:2014	3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur radio bands

Category	Standard	Compliance Level
Voltage dips, short interruptions and voltage variations on power supply input lines	EN 61000-4-11:2005	Voltage dips at: 0% UT; 0,5 cyle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT; 1 cycle at 0°, 70% UT; 25 (50 Hz)/ 30 (60 Hz) cycles at 0° Voltage interruptions at: 0% UT; 250 (50 Hz)/ 300 (60 Hz) cycles at any sync degree Supply voltage 100 V and 240 V
Power frequency magnetic field immunity	EN 61000-4-8:2011	30 A/m, 50/60 Hz at the enclosure
Proximity fields from RF wireless communications equipment	EN 61000-4-3:2007+ A1:2008 + A2:2011	See Table Below.

Test Frequency (MHz)	Modulation	Immunity Level Applied (V/m)
385	Pulse Modulation: 18 Hz	27
450	FM + 5 Hz deviation: 1 kHz sine Pulse Modulation: 18 Hz	28
710, 745, 780	Pulse Modulation: 217 Hz	9
810, 870, 930	Pulse Modulation: 18 Hz	28
1720, 1845, 1970	Pulse Modulation: 217 Hz	28
2450	Pulse Modulation: 217 Hz	28

III.1
Warnings and Precautions

- The use of the device can be unsafe in case a subject has pacemakers, intracranial electrodes, implanted defibrillators, cranial pathologies (e.g. holes, plaques) or any other prosthesis.
- The use of cables or electrodes other than the ones delivered with the product might produce higher EMC emissions and less EMC immunity.
- The device communicates wirelessly to the home tablet software so it might be affected by other RF signals. In case the communication is dropped, the home tablet software will inform the user accordingly.
- The device cannot be used in environments with atypically high electromagnetic fields such as an MRI room or close to CT, diathermy, RFID and electromagnetic security systems such as metal detectors. In the case that there exist RF emitters (e.g. RFID), which might not be visible, the device can potentially be exposed to fields from these RF emitters without the user's awareness and corrupts the signal acquisition that might lead to session auto-abortion.
- The device is not protected against other high frequency devices such as electrocautery devices. To avoid risks, place the CMS/DRL as far as possible from the electrodes of the high frequency device.
- The device must be charged only with the certified charger provided by the manufacturer.
- If the device is going to be used during the study in combination with another device connected to the subject, please contact Neuroelectrics to check the correct simultaneous use.
- Never use the device or install the electrodes on the head of a subject while connected to the power network.
- The device will not work when the battery is charging.
- The electrodes and wires or any conductive part cannot touch any other conductive part of any other device including the ground.
- To avoid dropping and losing parts, the device and its accessories shall be stored in the provided packaging as soon as they are cleaned and dry after a session.
- Before using or providing to a study subject, please check that the device is undamaged and the packaging has not been affected by transport or storage.
- The device is not provided sterile and should not be sterilized.
- Always follow cleaning instructions after each use of the device and its parts.
- The cap is intended to be on the subject for less than 24 hours.
- Do not use the device or the electrode gel if the provided storage conditions on their labels were not met at any point in time.
- Handing over the Starstim-Home kit to a study subject or their caregiver must be preceded by an assessment of their knowledge on how to operate the device, conducted by a qualified medical personnel.

- Inform subjects and their caregivers that in the case that the home tablet software does not respond during a brain stimulation session, they shall use the push button of the device to safely shut-down the stimulation and the device.
- In case of malfunction, immediately contact the manufacturer or the distributor.
- The device must not be subjected to unreasonable amounts of mechanical force.
- Ensure that only the authorized and trained personnel has access to the treatment session scheduling feature of the NE Portal.
- Verify that every scheduled treatment session matches the approved treatment protocol for the subject. All stimulation sessions have an intended duration of less than two hours.
- Inform study subjects and their caregivers that the device may only be used during preprogrammed protocol sessions and no self-treatment is allowed.
- Inform subjects and their caregivers to keep all the kit components out of reach from children and anyone else who might swallow electrodes or any other component, ingest electrode gel, strangle themselves with the cables, or cause injury to themselves. Inform to seek medical advice if such situation occurs.
- In case the instructions for use are unclear, contact the manufacturer or the distributor and do not use the device.
- The device must never be opened or damaged.
- The modification of the device is not allowed.
- The device does not need installation, maintenance or calibration.
- If the device has not been used during a long period of time, check visually that there is no battery leakage.
- The device shall be charged at least once every 3 months.
- Regularly check the device and the accessories for any potential damage. Inform subjects and caregivers to do so too.
- Only the Ag/AgCl electrodes and gel recommended by the manufacturer or the carbon rubber with sponges soaked with saline solution recommended by the manufacturer shall be used for tES stimulation.
- For the efficacy of the treatment, the set-up shall exactly match the programmed protocol. Inform the subject or caregiver to pay special attention to follow the colour code of the electrodes and the cap according to the instructions of the home tablet software.
- During each session, it is mandatory to use reference electrodes connected to CMS and DRL cables.
- Do not switch the device on or off when it is assembled and placed on the subject's scalp.
- The device can only be used on healthy skin without wounds.
- This device does not contain any user-serviceable parts. The device can only be repaired by the manufacturer.
- The device is not protected against excessive moisture or immersion in liquid. In the case of the device becoming wet or damp, do not use it and immediately contact the manufacturer. Inform subjects and caregivers about this risk.
- Do not operate the device in proximity to flammable materials such as gas or particulate matter. Inform subjects and caregivers about this risk.

IV. The Starstim-Home System

This chapter describes the Starstim-Home system. First, it lists the features and technical specifications of Starstim. Then, the components included in the Starstim-Home tES package are listed and described. For each item, you may find the product code, the product name, a picture and a short description of its function. Lastly, it describes the Neuroelectrics Control Box (Necbox) which is the core and the control unit of Starstim.

For further information regarding the use of the electrodes, please consult the Electrode Instructions for Use. Additionally, to learn how to design protocols and make use of other researcher functionalities, refer to the NIC2 Instructions for Use.

IV.1
Features

Optimized usability for home use

- All components are designed with usability, comfort and easy maintenance in mind

Real remote access control

- The home device is available only during periods scheduled remotely

Real-time remote monitoring

- Real-time home event emails, access to impedance data, and questionnaire records

Bipolar, HD, or multi-channel tES

- Easy-to-use protocol design tools and optimization services allow application of tDCS, tACS and arbitrary waveforms at home – including sham stimulation.

IV.2
Technical Specifications

Stimulation functionality

- Number of channels: (up to) 8 channels
- Sampling rate: 1000 SPS
- Frequency range: 0 to 249 Hz (tACS) and 0 to 500 Hz (tRNS)
- Stimulation types: linear combination of tDCS, tACS and tRNS, custom waveform; and Sham
- Maximum current per channel: ± 2 mA
- Current resolution: 1 μA
- Current accuracy: 10%
- Maximum voltage: ± 15V per electrode (allows 30 V of stimulation potential difference)

Stimulation safety features

- Maximum input current per channel: 2 mA
- Maximum total inject current: 4 mA (by all electrodes, at any time)
- Maximum duration per session: 1 hour
- Stimulation session must be pre-programmed
- Electrode impedance check before and during stimulation
- Abort functionality possible at hand at any instant

Other Technical Specifications

- Battery operating time: 4.5 hours
- Operating System: Microsoft Windows 10
- Memory: 4096 MB
- Storage: 64 GB eMMC Flash

Home Tablet Specifications

- Operating System: Microsoft Windows 10
- Memory: 4096 MB
- Storage: 64 GB eMMC Flash

Wireless Information

Starstim-Home device operates at the 2.4GHz Industrial Medical and Scientific (ISM) band. The device connects through the wireless link to the Home Tablet software. The data is streamed through the wireless link. The standard operating distance is 10 meters. Below are the technical specifications regarding the Wireless connection.

Wireless Specifications

- Wi-Fi: IEEE 802.11g
- Operating frequency band: from 2.412 to 2472 MHz
- Transmitting power: Max. +16dBm
- Qualifications: CE, FCC, IC, Japan and South-Korea
- Data rate: 921600 BPS
- Encryption: WPA2PSK

IV.3
Conditions of Use

Starstim-Home device must be used with normal temperature, humidity, and pressure conditions:

- Temperature Range: +5 to 40 °C
- Humidity: 15 - 93 %
- Atmospheric Pressure: 700 - 1.000 hPa

The device must be stored inside the box between uses, in the following environmental conditions:

- Temperature Range: -25 to +65 °C
- Humidity: 15 - 93 %

This equipment needs to be installed and put into service in accordance to the information provided in this Instructions for Use.

IV.4
Contents of the Starstim-Home Package

The Neuroelectrics® Starstim-Home package contains all the components required to perform a stimulation session, and some additional items that may be useful during your experiments. Please confirm you have all the items listed below that pertain to your bill of materials.

Quantity	Code	Name
1	NE012HWF / NE012HEWF	Starstim-Home Necbox
1	NE055W	Power Adapter
1	NE013a NE013b NE013c NE013d	EU / US / UK / AU Power Supply Plug
1	NE017-H	10 Electrode Cable Color-coded
1	NE019-K-NB1.0M. NH.RU:GV	Neoprene headcap Home M
1	NE029-P.08. MD:GV	Electrode: NG Pistim (bag of 8)
1	NE026a-P.04. MD:GV	Electrode: Sponstim 25 (bag of 4)
1	NE027-P.01. MD:GV	Electrode: Earclip (bag of 1)
1	NE016b	SIGNAGEL ® Electrode Gel (250g)
1	NE033	Saline Solution 100 ml
2	NE014	Curved Syringe
1	UM006M	Patient Leaflet

Quantity	Code	Name
1	NE031b	USB Wi-Fi Dongle
1	NE031C	USB-C to USB to USB 3.0 Adapter
1	NE180G	Home Tablet
Researcher tools (outside of the packaging box)		
1	NE038	Testboard Head
1	NE039	Testboard Cable
1	NE044	Neoprene Punch Tool
1	NE176	Headcap positions coloring kit
1	NE015-SHES	USB Stick with Manuals & Software
1	NE177-A	Portal: Free Institutional Account Credentials
1	NE179 / NE179E	Starstim-Home Cloud Data Storage (5-year license)

In this page we present the electrodes included in the package, but you must read the Electrode Instructions for Use to learn how to use, to assemble and to clean the electrodes. Additionally, in the following three pages, there is a list of the rest of the items of the package and each item is identified with its name and code.

Neuroeletrics Electrodes

Stimulation (tES)

Sponstim 25

NE026a-P.04.MD:GV

EEG & tES

NG Pistim

NE029-P.08.MD:GV

Reference

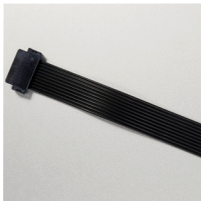
Earclip

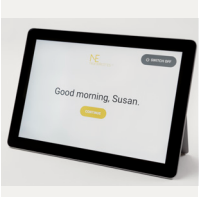
NE027-P.01.MD:GV

Regarding the electrodes, you must use them according to their functionality. They are grouped above as only-tES, hybrid EEG & tES, and Reference electrodes. Bear in mind that electrodes need to be replaced when they reach the end of their lifetime, in order not to compromise the quality of the EEG signal or the efficacy of the stimulation.

Item	Name / Description
	**Starstim-Home Necbox** ▶ The Starstim-Home Neuroelectrics Control Box (Necbox) is the device reponsible for delivering the tES currents. ▶ The Necbox is battery-operated and it is wirelessly paired with the Home Tablet ▶ The Necbox battery cannot be charged when the device is being used.
	**Power Adapter & Power Supply Plug** ▶ The USB power adapter is used to charge the Necbox battery. ▶ The type of the power supply plug (EU/US/UK/AU) included in the kit depends on the country of the customer.
	**Curved Syringe** ▶ The 12 ml curved syringe is used to inject either electrode gel or saline solution in the electrodes. ▶ The syringe is a reusable component and should be washed and cleaned after each use.
	**SIGNAGEL® Electrode Gel (250g)** ▶ Signagel® is a recommended accessory electrolyte, proven to be compatible with our devices. It is a highly conductive and water soluble gel. It must be applied on the contact surface, between the electrode and the scalp, in order to decrease the impedance and improve the signal quality. ▶ The legal manufacturer is Parker Laboratories, Inc.

Item	Name / Description
	**Saline Solution 100 ml** ▶ The saline, or sodium chloride, solution (NaCl 0.9%) is used with the Sponstim electrodes and it should be applied to the yellow exterior face of the sponge that contacts the scalp.
	**10 Electrode Cable Color-Coded** ▶ An Electrode Cable optimized for experienced of users at home. ▶ Its color markers follow setup instructions in the home software providing additional comfort especially while preparing multi-channel montages, consequently reducing training effort.
	**Neoprene Headcap Home M (54 cm)** ▶ The Neuroelectrics® Neoprene Headcap Home is a comfortable, reliable solution allowing researcher for convenient customizations before providing it with Starstim-Home® kit to study participants. ▶ Its positioning grid with 39 clearly annotated positions is based on a subset of the international 10-10 EEG system. Its design enables precise addition of holes matching the required protocol, using Neoprene Punch Tool. ▶ The cap is available in four adult-sized models (XL, L, M, S).

Item	Name / Description
	**USB Wi-Fi Dongle** ▶ The USB Dongle is used to provide a Wi-Fi port for computers that do not have an incorporated port. The wireless communication between the Necbox and the computer is through Wi-Fi. The USB WiFi Dongle must not be used with macOS computers.
	**USB Stick with Manuals & Software** ▶ The USB stick contains the PDF version of the Instructions for Use relevant to your device, and the NIC software. ▶ All the contents can also be found at www.neuroelectrics.com.
	**Testboard Head** ▶ The testboard head alllows you to test the system functionalities and rule out potential problems before the real experiment. ▶ The necbox can be connected to the testboard using either the testboard cable or the 10 electrode cable. When the device is connected to the testboard, it responds as a properly placed system on the subject's scalp, with a very similar electrical environment.
	**Testboard Cable** ▶ The testboard cable is the simplest way to connect the necbox with testboard head. This cable is not needed if you choose to connect the necbox and the testboard head using the electrode cable.

Item	Name / Description
	**Home Tablet** ▶ Home tablet guides home users through the treatment, providing instructions on device preparation and maintenance, matching high accessibility standards. ▶ It allows strict remote access control and detailed remote progress monitoring. ▶ It matches the highest data transfer and storage security standards. ▶ For details on hardware maintenance, see: Surface Go help [https://support.microsoft.com/en-ca/hub/4346532/surface-go-help]

In order to allow Starstim-Home fully suit your application, you can add accessories to your kit.

In our catalog and webpage, you may find:

- Different sizes of the neoprene headcap: XL, L, M, S, Kids
- Kid-sized headcaps are provided with a headcap cover
- Different shapes of the sponge electrodes
  Circular 25 cm^2 o r 8 cm^2, or rectangular 5 cm x 7 cm, you choose the contact area.

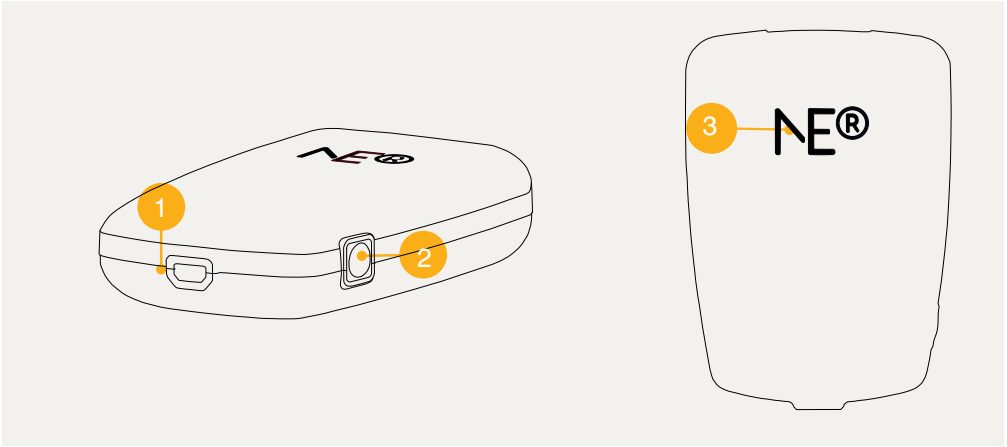
These items are available upon request.
Please contact our sales team if you want your Starstim to be more complete.

V. About System Components & Services

V.1

Starstim-Home Device

The Necbox is the core and the control unit of Starstim-Home. The Necbox is a battery operated device. It weighs 85 g and its dimensions are 87 mm x 61 mm x 24.8 mm. The following diagrams describe the details of the Necbox



1. Charging LED

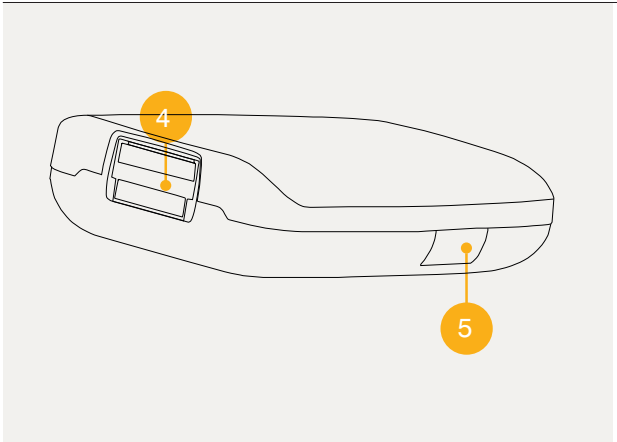
- Off: The charger is not connected.
- Yellow light: The charger is connected and the device is charging
- Green light: The charger is connected and the device is charged.

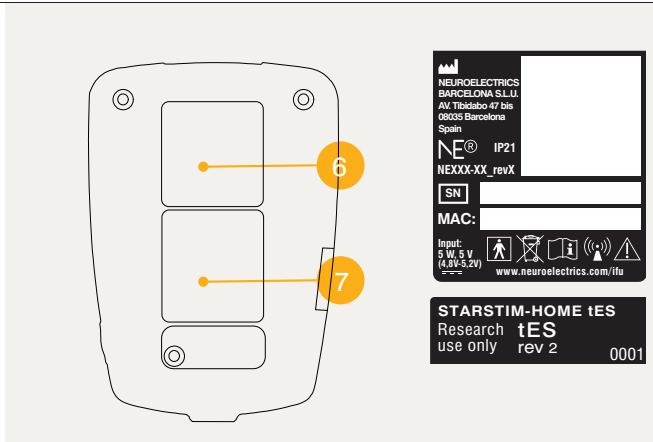
2 ON/OFF Push-Button

- On single push, switches on the device while off.
- On 2s hold, switches off the device while on.

3 Operation LED

- Continuous light: The device is functioning correctly in standard operational mode
- Blinking with 1s period: The device is functioning correctly in “holter” mode
- Blinking with 250ms period: The device lost connection during protocol execution and became nonoperational. To continue, it needs to be switched off and on again.
- Blinking with 200ms period 16 times: The device cannot start in “holter” mode because of a problem with the SD card.





4 Pin connector slots

10-pin slot to connect with the electrode cable.

5 MicroSD card slot

Slot for microSD card (Card not included) for online data storage in the “holter” mode

6 Velcro

To attach the Necbox to the

7 Technical Specifications labels

Serial Number (SN), with the EYYYYMMDD format, where YYYY, MM and DD are the manufacturing year, month and day, respectively.

MAC address of the device.

The bottom label contains (from top-left to bottom-right):
- Product name;
- Regulatory mark;
- Technology (tES if absent);
- Label revision (rev 1 if absent).

V.2

Starstim-Home Device Battery

The battery must not be charged when the device is placed on the subject. The battery charger connects to the Necbox through the micro HDMI connector located at the rear part of the Necbox. The following holds true about the battery and the charging process:

- Only use the charger that came with the device to charge the battery.
- The provided battery charger complies with the Standard EN 60601-1:2006 + A12:2014
- The battery state of charge is measured by NIC when the device is switched on and paired with the computer.
- The battery should not be over discharged when the device is not used for a long time. It should be periodically charged instead.
- Overdischarging may cause loss of cell performance and/or damage to battery function.
- Expected life cycle:
  After 500 cycles > 70% of initial capacity
- The device can be connected to any Class 2 electrical installation.
- Device will not operate when charging.

Operating Temperature

- Charging: 0° C to 45° C
- Discharging: -10° C to 60° C

Storage Temperature (period between charging)

- 3 months at -20 ºC to 45 ºC

V.3
Home Tablet

The Home Tablet is a lightweight and robust software & hardware solution designed for subjects for home studies.

Its graphical interface guides a subject and their caregiver through device setup and maintenance with precise and visual instructions. Additionally, it automatically spots the situations requiring troubleshooting and informs home users about the required steps to solve these issues.

With reliable connection to the device and the institutional database of the investigator, the Home Tablet serves as a telemedical research platform that ensures that both researchers and home users are updated in real-time regarding all relevant events.

V.4
Neuroelectrics Portal

The Neuroelectrics Portal is the secure entry point to cloud services offered as part of Starstim-Home systems.

Its main feature, the Home Study Manager, gives access to real-time remote management of intervention data of Starstim-Home study participants as well as tracking of Starstim-Home kits assignments.

To access Neuroelectrics portal, open one of these browsers and enter https://portal.neuroelectrics.com/. Make sure your institution already has access to the Portal. The account is automatically created and shared with your institution's representative with the institution's first order of the Starstim-Home. See section VI.1 on how to request additional Portal accounts.

The Neuroelectrics Portal is maintained for all modern desktop web browsers. It is validated to work with Apple Safari, Google Chrome, Microsoft Edge, and Mozilla Firefox.

V.5
NIC2

NIC (Neuroelectrics Instruments Controller) 2 is software which allows you to create 8-channel tES protocols needed for the Home Study, from the lab PC or Mac, and visualize the distribution of the tES electric field. If you have a Starstim tES or 8, it will allow you to run the protocols in the lab.

For more information, refer to NIC2 Instructions for Use.

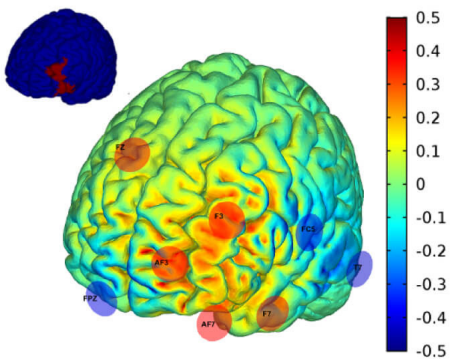
V.7
Neuroelectrics Support

In case of technical questions or issues other than explicitly mentioned in these Instructions for use go to https://www.neuroelectrics.com/support/ and fill in the support query form.

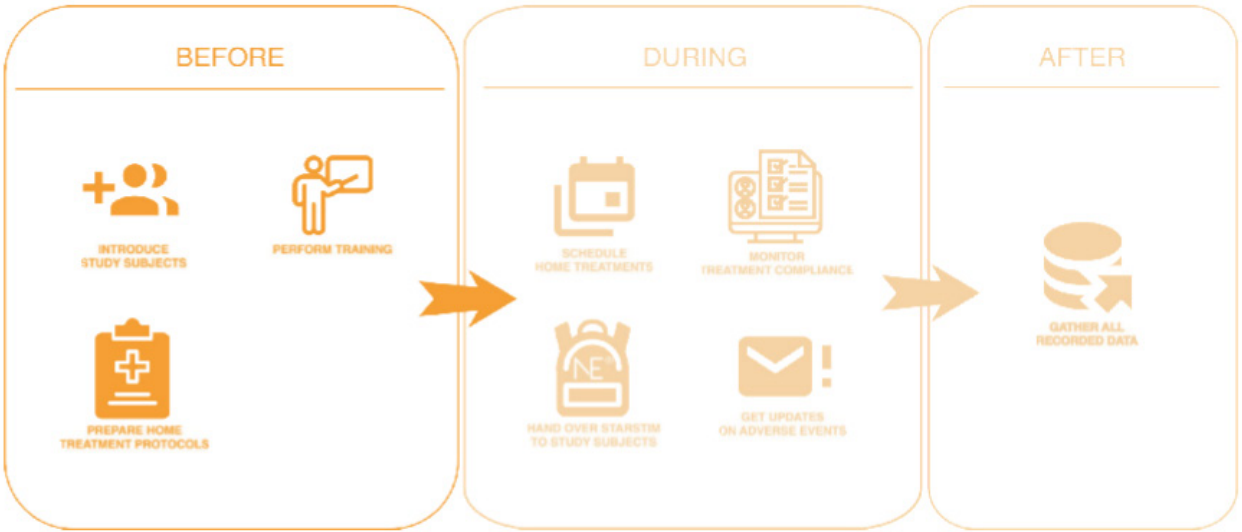
V.6
Modeling Services

For a more efficient stimulation session, you may want to use our modeling services to optimize the electrode montage. With our Stimweaver algorithm, we will determine the ideal montage to target a specific brain region or network in order to achieve the result you want from stimulation. Stimweaver achieves this by creating a computational head model which can be based on a template head or, provided a structural MRI is available, personalized to each subject.

Visit https://www.neuroelectrics.com/solutions/modeling-services for more information.



VI. Instructions for Study Preparation

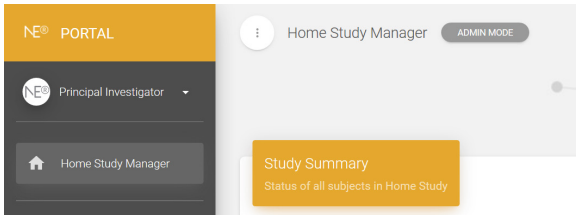


VI.1

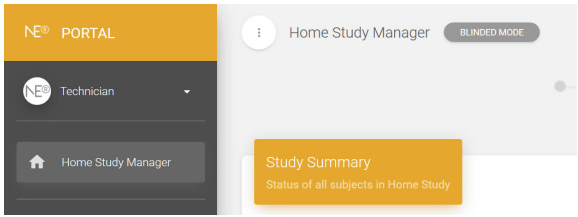
Configuration of Study Team Accounts & Blinding Rules

Together with the delivery of the first Starstim-Home kit, your institution's contact person receives a welcome email with the subject "Your Neuroelectrics Portal account has been created". It contains access details to your institution's first Portal account.

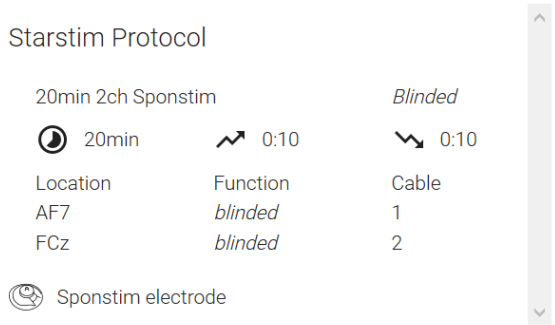
At any time, your study research team can request additional account logins. Each one of them is configurable in blinded or unblinded (admin) mode. Such a setup allows for double-blinded studies.



Admin Mode for unblinded study members



Blinded Mode for blinded study members



Blinded Mode will hide the details of the protocol's tES function. A study admin shall prepare these protocols following Section VI.3 with the names not revealing their function.

To prepare

- List of research team members who require access to the Portal (first name, last name, email);
- Blinding setting for each member.

Steps

1. Send a list of accounts to create to support@neuroelectrics.com.
2. A welcome email containing credentials will be promptly sent to each account.
3. We recommend that as a part of standard procedure, upon first login to the Portal, each study member confirms that the Mode (Admin/Blinded) is correctly defined for their account.

VI.2
Introduction of the Study Subjects in the System

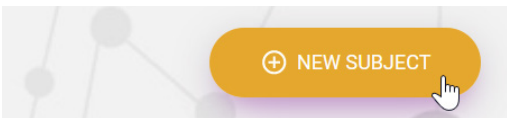
You can add study subjects one-by-one at any point in time before or during the study. The Neuroelectrics portal allows for the definition of the anonymous subject identifiers only, so make sure you have the study subject references stored elsewhere.

To prepare

- List of anonymous identifiers of study subjects.
- Preferred language for each subject (English / German / French).

Steps

1. Using a web browser on your computer, open the Neuroelectrics portal.
2. Use your institutional credentials to sign in.
3. In the left menu, click Home Study Manager.
4. In the top right of the Home Study screen, click New Subject. The New Subject modal window will appear.



5. Specify Subject code. Be cautious, as you will not be able to change it later.
6. Choose language from a drop-down list. This setting will later personalize Starstim-Home tablet. You can update this setting later.
7. Click SAVE.

VI.3
Preparation of Home Treatment Protocols

For the Home Study, you can choose from the whole spectrum of 8-channel tES protocols which NIC2 allows you to define. It may be tDCS, tACS, or tRNS or custom waveforms, with customizable ramp and sham settings.

Follow NIC2 Instructions for Use Section III to learn more on how to design protocols and export them to a file.

Note for optimized tES: You can choose to use optimized tES montages during your study, which Neuroelectrics can provide to you following your target specification and MRI recordings. You can read more about the Neuroelectrics Modelling Services on the Neuroelectrics website. Find more information in Section V.6. Once your optimized tES protocol is created, you will find it in your Neuroelectrics Portal protocols list - you can skip the rest of this section.

Note for double-blind studies: For double-blinded studies, pay attention to the naming convention of the protocols. Users in Blinded Mode will still see names of the protocols while scheduling sessions and monitoring treatment.

Note for personalized studies: For personalized studies, you can facilitate scheduling by paying attention to the naming convention of the protocols. In case a subject name (e.g. SUB01) forms a part of any of the available protocol names (e.g. PROT_SUB01), only these protocols will be presented on the list.

To prepare

- 8-channel tES protocol files exported from NIC2;
- Electrode model – either NG Pistim or Sponstim. Read more about their characteristics in Electrode Instructions for Use;
- Procedure including number of treatment sessions and allowed period of the day during which study subjects will be able to execute the sessions.

Steps

You will use the prepared resources in procedures explained in Section VI.5 and Section VII.1.

VI.4
Headcaps Customization

As a part of your Starstim-Home, you received the tools to customize the headcaps, so they can be used with ease at the study subject's homes. This section outlines how to proceed.

To prepare

- Headcaps you want to customize.
- Punch tool.
- Snap buttons and crimping tool.
- Color-coded electrode cable from one of the Starstim-Home kits.

Steps

1. In NIC2, open the Stimulation Design view of the protocol you want to customize the headcap for (follow NIC2 Instructions for Use Section VI.1 for further details on how to access the view).
2. For each position included in the protocol:
    a. Find position's signature on the headcap.

Note: Standard Neoprene Headcap does not have signatures for all positions available in NIC2.

    b. Make a hole for that position by pressing and rotating the Punch tool in a circle by the position's signature.

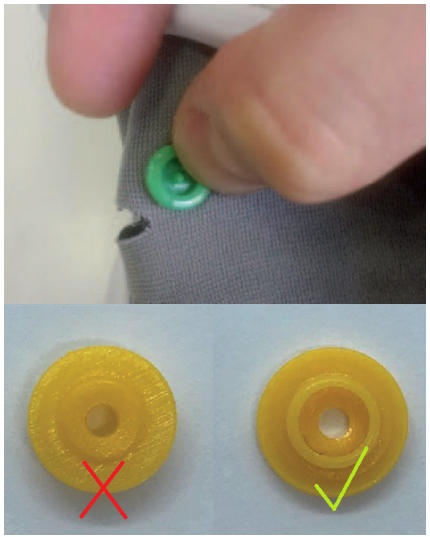
c. Pick a snap button of a color which corresponds to the channel's number.

Note: For colors mapping refer to color-coded electrode cables you have or the graphics on the next page.

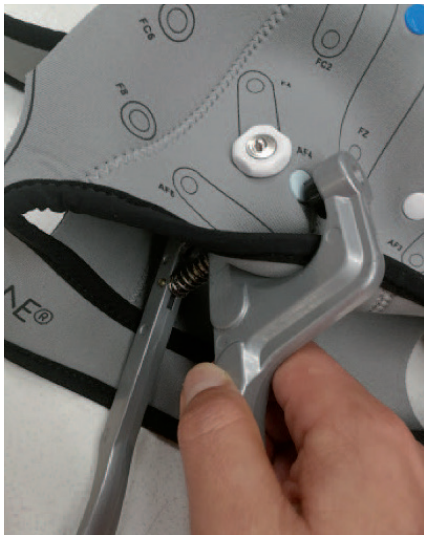
d. Just by the position's signature, stick the snap button tip through the material of the headcap.

e. Pick a crimp tool and the snap button bottom part. On the interior side of the headcap, pair snap button bottom part with its tip. Then, press the snap button with the crimping tool.

Step 2c



Step 2d



Step 2e

Channel Numbers and Colors:

VI.5
Preparation of Training & In-Lab Phase of the Study

Whether you want to train your staff, train your study participants and their spouses/caregivers, or run first phase of your tES-home study in the lab, you can make use of your Starstim-Home devices right away.

Staff Training

For staff training, follow the steps described in Section VI.2 to create a new “training subject”. Then, follow the steps in subsections of the Section VII.

In-Lab Phase of the Home Study

If you want the entire information about your study subject’s treatment to be automatically recorded in one place, follow Section VI.2 to introduce the subject already before the in-lab phase. Then follow Section VII to conduct the study phase with Starstim tES Home.

Use of Testboard

The testboard is used for testing stimulation protocols before conducting experiments. It is recommended to use the testboard before applying tES experiments. It is also a good tool for debugging allowing to test different system functionalities as well as discard problem areas.

The Starstim-Home device connected to a testboard will respond as a system properly placed in a subject, with a very similar electrical environment, that is why we refer to it as an “artificial head”.

Testboard setup. The testboard is connected to Starstim Necbox with a testboard cable:

- Connect the testboard cable from the cable slot of the Necbox to the head shaped section of the testboard.

Impedance toubleshooting. Testboard allows to check the correct setup of the system when having high impedance values. Once you set up the testboard, in NIC, click on check impedances. If the values are correct, it means that the device works fine and the impedance issues are due to another component or the wrong setup. For further details about impedance check, please refer to NIC2 Instructions for Use.

VI.6
Specification of Real-time Email Updates Rules

Any institutional email registered to access the Neuroelectrics portal can receive email updates on specific treatment events. The table below presents the available notification profiles

To prepare

- List of institutional emails registered for the Neuroelectrics portal use.
- Preferred notification profile for each of the emails.

Event	“Warning”	“Information”	“Detail”
Detailed Course of Session	No	No	Yes
Successfully Finished Session	No	Yes	Yes
Session Aborted by Patient	Yes	Yes	Yes
Session Auto-aborted by Starstim	Yes	Yes	Yes
Acute Event Reported	Yes	Yes	Yes

Steps

1. Send an email to support@neuroelectrics.com including the prepared information on preferred settings.

VI.7

Keeping Home Tablets Up to Date

Neuroelectrics regularly releases software updates based on customers feedback to increase the flexibility of treatment design and improve accessibility as well as general patient experience. Check the website to learn about updates to the recent version of the home tablet software before you begin a study.

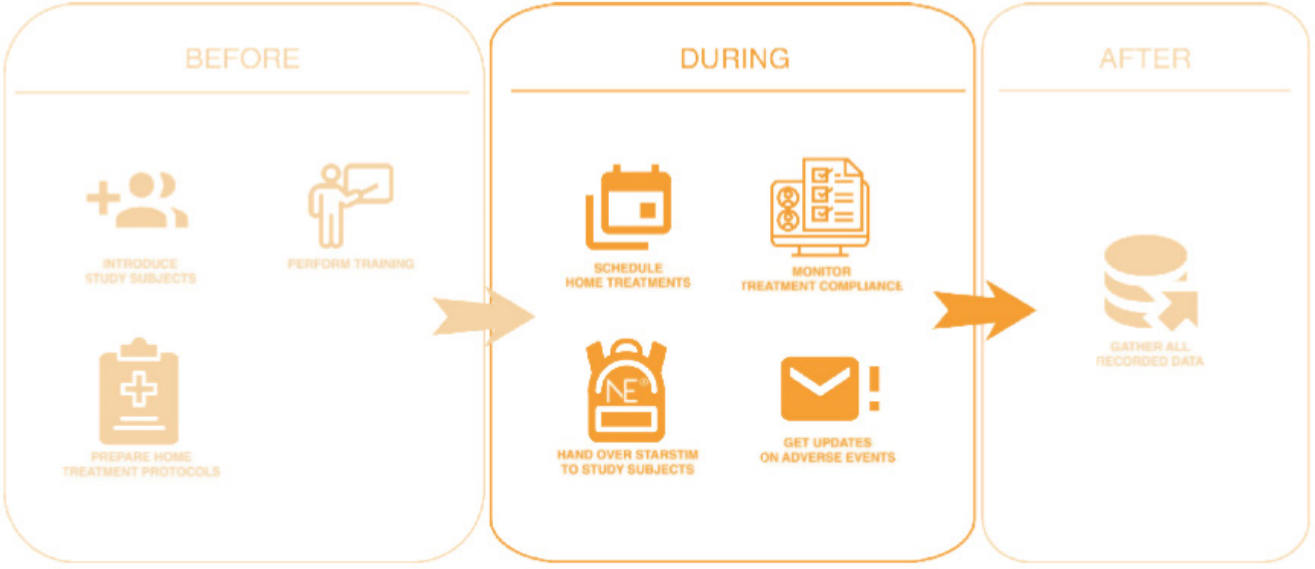
To prepare

- Prepare your home tablet

Steps

1. Switch on home tablet, the welcome screen will appear.
2. Swipe from the right edge of the screen, the Admin panel will appear.
3. Type and confirm a home tablet admin password you have been provided in the welcome email. Protected admin options will appear.
4. In the available App Upgrades section, check if your application is up to date.
5. Click the RESTART & UPGRADE button. You will be requested for the Windows administrator password - it is the same as the password you used to access the admin panel.
6. Follow the instructions of the software update process. The software will be updated to the latest version.

VII. Instructions During the Study



VII.1
Scheduling a Home Study

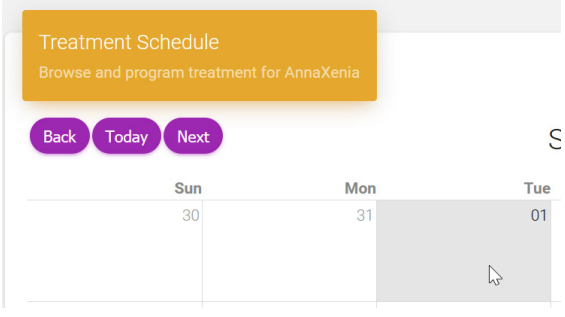
You can schedule treatment sessions for each of your subjects, choosing a period of the day with precision down to one hour.

To prepare

- Dates and periods of the day when a subject is supposed to perform the sessions.
- Protocols for treatment sessions used for this study.

Steps

1. Using a web browser on your computer, open the Neuroelectrics portal
2. Use your institutional credentials to sign in.
3. On the left menu, click Home Study Manager.
4. In the Study Summary table, click on the code of the subject who you want to schedule home treatment for. The subject profile will appear.
5. In the Treatment Schedule calendar, click on the day you want the subject to perform the session. Treatment Scheduler popup window will appear.



6. In the Schedule card of the popup window, choose the daytime period. Click NEXT. Protocol card will appear.
7. On the top left of the popup window, choose the protocol you want the subject to apply.

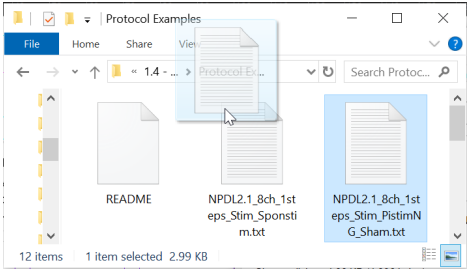
   Note: To facilitate personalized studies, in case any protocol name (e.g. SUB01_PROT) contains the subject's name (e.g. SUB01), other protocols will be filtered out.

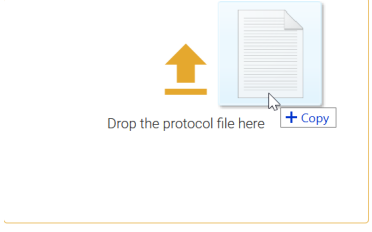
8. In the case the protocol is missing on the list:

   a. Open a folder on your drive where you have the exported NIC2 protocols stored (see: Section VI.3).

   b. Drag-and-drop the required protocol on Upload area in the bottom left of Protocol card (see images on the right).

9. In the right column, verify that all the details of the protocol are as expected.
10. In the bottom of the right column, make sure the protocol's electrode is specified. In case it is not, choose the one you want to be used with the protocol.
11. Click SCHEDULE. If the information you provided is correct, the popup window will close, and the session will automatically appear in the calendar.





VII.2
Study Participants Training and Knowledge Assessment

Study Participant Training

It is the responsibility of the Researcher to assess the competence of the caregiver/user in using the Starstim-Home device before bringing it home.

The home tablet software guides home users throughout the steps of the sessions preparation and execution. For most of them, the instructions are detailed.

There are two important aspects which are not included in the home tablet software:

- Information regarding the safety warnings. Each study subject and/or their caregiver shall be informed about relevant warnings to be found in Section III.1 of these Instructions for Use.
- Detailed cleaning instructions. These are listed in the following point.

Cleaning Instructions

The home tablet software includes only general information on how to clean up the components of the kit before the app is switched off. The following is the correct maintenance of the specific components which each study subject and/or caregiver shall be trained to do.

Necbox & Electrode Cable

The Starstim Necbox should be cleaned using a dry paper towel after each use.

Neoprene Headcap

The Neoprene Headcap should be cleaned and disinfected as it follows:

- Rinse the gel with warm tap water and ivory soap
- Dry the cap conscientiously using paper towel
- Spray the cap with disinfectant and let it sit for 10 minutes, or use disinfectant wet wipes
- Rinse the cap thoroughly
- Hang up the cap to dry

Electrodes

The cleaning instructions for the electrodes can be found in the Electrode Instructions for Use.

Knowledge Assessment Checklist

The caregiver/user shall show competence in the following aspects:

- To switch ON/OFF the tablet;
- To connect the tablet to Home's Wi-Fi network;
- To charge the tablet;
- To recognise when a session is scheduled and available to be done on the tablet software;
- To switch ON/OFF the Starstim-Home device;
- To charge the Starstim-Home device;
- To attach the device to the large velcro of the cap;
- To plug/unplug the electrode cables into/from the StarstimHome device;
- To put the cap on user's head making Cz position in the midline "vertex" top of the head;
- To insert/remove the bottom part of the electrode or sponge electrode into/from the holes of the cap;
- To put the gel into the bottom part of the electrode or saline solution on the sponge electrode;
- To recognise the colours of the electrode cables and their associated positions on the cap;
- To screw the electrode on the bottom part of the electrode;
- To clip/unclip the electrode cable on/from the electrodes on the cap;
- To place the reference earclip electrode with gel on the ear lobe;
- To be aware of the possibility of a tingling sensation during set-up checking and stimulation session;
- To know that the user needs to be resting and still during the stimulation session (unless a concurrent behavioural task is asked to be performed during the session);
- To recognise the indications of the tablet software about problems with the set-up and following instruction on how to handle it;
- To be aware that the stimulation session can be aborted and how to do it through the ABORT SESSION button on the tablet software;
- To know how to report the reason for aborting a session;
- To know how to answer pre/post questionnaires if they existed;
- To know how to make a call to the Researcher using the tablet software (if this option is available);
- To be aware of all the warnings indicated in the Instructions for Use.

VII.3
Handing over Starstim-Home Kits to Study Participants

Right before or during your meeting with a study participant, in the portal, you must mark the device as assigned to that subject. You can take a few additional steps to improve the experience of the study subject.

To prepare

- An available Starstim-Home backpack:
  - Make sure all the components (box, necbox, and home) have the same information on their labels.
  - Make sure all the components (necbox, and home) are fully changed. Connect the necbox to charge and wait for the light to turn green. You can ensure it for the home by switching it on and checking the battery status in the right corner of Windows task bar.

Steps

1. Using a web browser on your computer, open the Neuroelectrics portal.
2. Use your institutional credentials to sign-in.
3. In the left menu, click Home Study Manager.
4. In Study Summary table, click on the code of the subject who you want to hand over the device to.
5. In the top right of the Home Study screen, click Assign Device. The drop-down list will appear.
6. Click on the device of your choice on the list and follow the instructions in order to assign it. The button will change to Device Assigned.
7. On the next switch on, home tablet will automatically synchronize the assigned subject's treatment.

Optional actions

Personalize the home tablet

1. Switch on the home , the welcome screen to appear.
2. Swipe from the right edge of the screen, the admin panel will appear.
3. Type and confirm the home admin password you have been provided in the welcome email. The protected admin options will appear.
4. In the Patient field, type and confirm a name of the study subject. On each start, home will welcome the study subject with their name.

Synchronize treatment information before the hand over

1. Switch on the home .
2. Connect to the wireless network through the Windows task bar.
3. Run the home app again. Click the Continue button.
4. Allow the application to synchronize. If you see the Upcoming Sessions screen right away, it means your scheduled treatment has already been synchronized.

VII.4
Remote Monitoring of Adverse Events

While your study subjects execute the treatment sessions at home, you will be receiving email updates accordingly with the rules explained in Section II.5.

In case you want to receive additional alerts, consult your email software documentation on how to specify rules for emails sent by dont-reply@neuroelectrics.com.

Remote Monitoring of Compliance

	Home interface internet connection continuously present	Home interface internet connection lost during the session
Session successfully finished	With maximum of a few seconds of delay	Whenever home interface is connected to the internet again (subject is unable to run the next treatment session unless reconnected)
Session aborted by subject		
Session auto-aborted on high impedances		
Session auto-aborted because of technical problems		
Session missed	The next day, starting at midnight. Note: This will be the case even if the session was scheduled for a limited daytime period.	

Steps

1. Using a web browser on your computer, open the Neuroelectrics portal.
2. Use your institutional credentials to sign-in.
3. In the left menu, click Home Study Manager.
4. In Study Summary table, take a look at the Treatment Compliance column. For each study subject, it gives a visual summary of every treatment session. The sessions are ordered by the scheduled date.

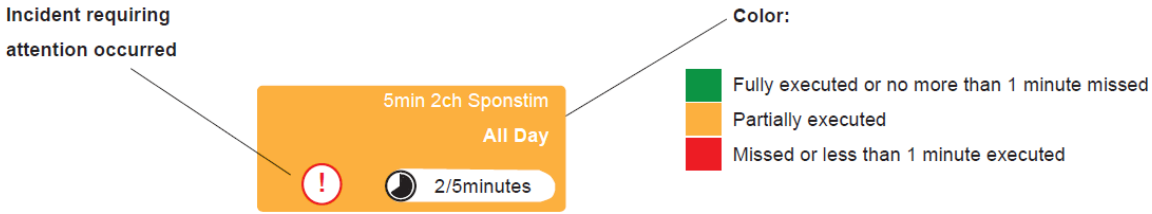
5. Hover the mouse over a chosen session to see the details including protocol name, date and compliance details.

VII.6

Review of the Treatment Session Status

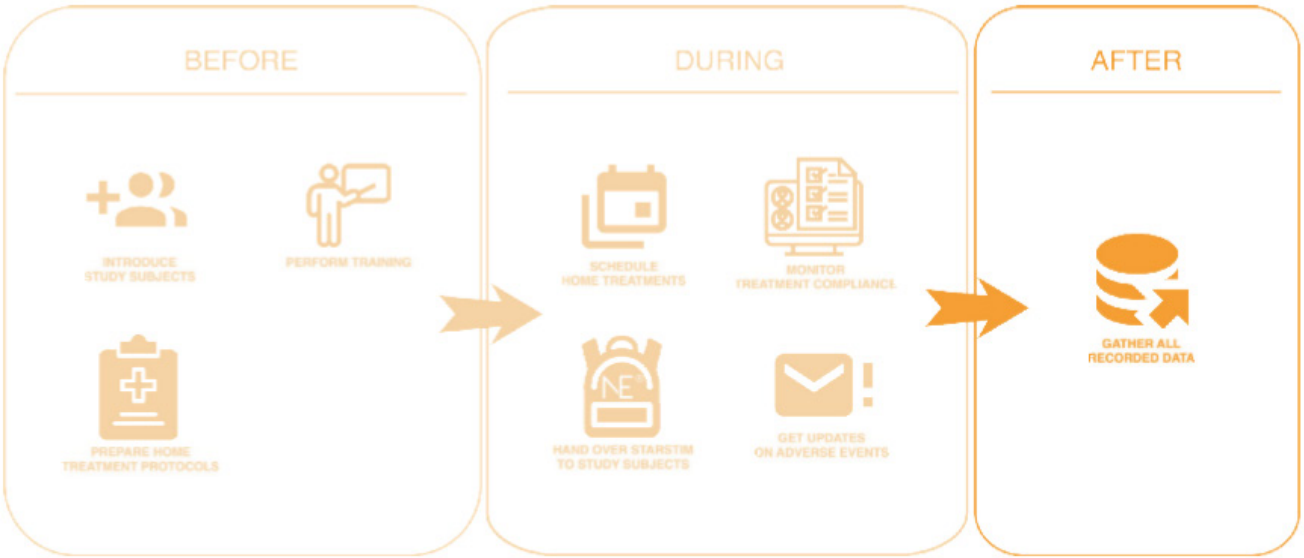
Steps

1. In Study Summary table, click on the code of the chosen subject. The subject profile will appear.
2. In Treatment Schedule panel, review the treatment sessions by choosing one of the views:
   - In Calendar view, choose a month of your interest. Follow the key below to analyze the course of the subject's chosen past sessions.



   - In History view, choose a year of your interest. An overview of all the sessions from that year will appear.
3. To see more details about a chosen past session, go to Calendar view and click on it. The modal will appear.

VIII. Analysis of the Study Data



VIII.1
Access to Session Records

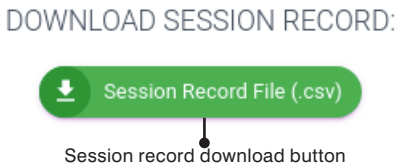
At any time, you can access and store the recording of each session in the CSV format. The information includes a list of time-stamped events and recording of impedance values from the impedance check as well as from 20-second intervals during the session execution.

Note: If your Portal is currently set to the blinded mode, the downloaded file will miss the impedance recordings.

Steps

1. In Study Summary table, click on the code of the chosen subject. The subject profile will appear.
2. In Treatment Schedule panel's Calendar view, click a chosen past session. The popup window will appear. Alternatively, find a session in History view.
3. Click on the green download button.
4. The file in CSV format will download and be stored under the name following the convention:

   SubjectID_SessionDate_UniqueSessionID (blinded flag)
   e.g.: *Subject123_2020-10-15_4200.csv* or *Subject123_2020-10-15_4200 (blinded).csv*



5. View and analyze the file in a chosen CSV reader (e.g. Excel, LibreOffice, or Python):
   - Configure the separator setting to ";".
   - Notice that the first line of the file holds a header with the name for each column.

Note: If your Excel does not open the file correctly by default, use Data > Get & Transform Data > From Text/CSV.

IX. Symbols Used

Symbol	Description
	ISO 7000-1641 Read Instructions for use symbol according to EN ISO 15223-1:2021. The symbol is accompanied by the link to have access to the electronic instructions for use.
	ISO 7000-0434A Caution symbol according to EN ISO 15223-1:2021.
	IEC 60417-5010 Push ON/OFF button EN 60601-1:2006/ A12:2014.
	ISO 7000-2498 Serial Number according to EN ISO 15223-1:2021.
	ISO 7000-3082 Device manufacturer symbol according to EN ISO 15223-1:2021
	ISO 7000-2606 Do not use device if product or packaging have been damaged symbol according to EN ISO 15223-1:2021.
	Do not throw Starstim in generic waste symbol. WARNING! When you want throw away the device, NEVER throw it in the trash, but go to the RECYCLABLE POINT or the nearest waste collection for further treatment, thus contributing to environmental care.
	ISO 60417-5140 Non-Ionizing Electromagnetic radiation.

Symbol	Description
	ISO 7000-0632 Transport and storage temperature conditions according to EN ISO 15223-1:2021.
	ISO 7000-2620 Transport and storage humidity conditions according to EN ISO 15223-1:2021
	ISO 7000-2621 Transport and storage atmospheric pressure conditions according to EN ISO 15223-1:2021
	ISO 7000-0626 Transport package shall be kept away from rain and in dry conditions according to EN ISO 15223-1:2021.
	ISO 7000-0624 Transport package shall not be exposed to sunlight EN ISO 15223-1:2021.
	ISO 7000-5333 BF type applicable part according to EN 60601-1:2006/ A12:2014..
IP 21	This device is protected from objects not greater than 12 mm in diameter and protected from dripping water
	Direct Current symbol