

# starstim-home<sup>NE®</sup>

Neuroelectrics User Manual  
Starstim-Home Investigator Manual

CAUTION: INVESTIGATIONAL DEVICE  
Limited by United States law to investigational use.



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Code: UM010

Version: 1.3

Date: 2020.09.28

Model Name:

Starstim-Home tES

Starstim-Home tES-EEG

### 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, 5V, (4.8-5.2V)



# About the Starstim-Home Investigator Manual

The Starstim-Home Investigator Manual belongs to the Part I of the Neuroelectrics User Manual.

The Neuroelectrics User Manual includes three parts:

- ▶ Part I: Starstim-Home Investigator Manual
- ▶ Part II: Electrode User Manual
- ▶ Part III: NIC User Manual

Before you first use the Starstim-Home system and provide it to the home users, you should read the three parts of the Neuroelectrics User Manual.

Ensure you train your home study participants in accordance with this manual before providing the Starstim-Home kit to them.

The PDF version of all parts of the Neuroelectrics User Manual can be found under the Resources section of the Neuroelectrics website:

[www.neuroelectrics.com/resources/manuals](http://www.neuroelectrics.com/resources/manuals)

# Change of Record

Issue	Date	Changes made
1.0	2019.12.03	First version
1.1	2020.01.10	Updates to Monitoring and Analysis Views in Portal v1.0
1.2	2020.08.10	Portal v1.2 Update: - New section "Configuration of Study Team Accounts & Blinding Rules" - Sections VI.3 & VII.1: Notes on double-blind & personalized studies Sections VI.2, VI.7, VII.1 & VII.7: Added images and/or extended information
1.3	2020.09.28	Portal v1.3 Update: Session Record download Renamed Section VIII to consolidate content on gathering data for analysis.

# Table of Contents

About the Starstim-Home Investigator Manual .....	4	<b>V. About System Components &amp; Services .....</b>	<b>27</b>
Change of Record .....	5	V.1 Starstim-Home Device .....	28
<b>I. Use of Starstim-Home .....</b>	<b>8</b>	V.2 Starstim-Home Device Battery .....	30
I.1 Transcranial Electrical Stimulation (tES) .....	9	V.3 Home Tablet .....	31
I.2 Intended Use .....	10	V.4 Neuroelectrics Portal .....	31
I.3 Conditions of Use .....	11	V.5 NIC2 .....	32
<b>II. Quality and Regulatory Information .....</b>	<b>12</b>	V.6 Modelling Services .....	32
II.1 Quality Management System .....	13	V.7 Neuroelectrics Support .....	32
II.2 Medical Device Regulations .....	13	<b>VI. Instructions for Study Preparation .....</b>	<b>33</b>
II.3 For US Audience only .....	13	VI.1 Configuration of Study Team Accounts & Blinding Rules .....	34
<b>III. Safety Information .....</b>	<b>14</b>	VI.2 Introduction of Study Subjects in the System .....	36
III.1 Safety Warnings .....	15	VI.3 Preparation of Home Treatment Protocols .....	37
<b>IV. The Starstim-Home System .....</b>	<b>18</b>	VI.4 Headcaps Customization .....	39
IV.1 Features .....	19	VI.5 Preparation of Training & In-Lab Phase of the Study .....	42
IV.2 Technical Specifications .....	19	VI.6 Specification of Real-time Email Updates Rules .....	44
IV.3 Contents of the Starstim-Home Package .....	21	VI.7 Keeping Home Tablets Up to Date .....	45

<b>VII. Instructions During the Study</b>	46
VII.1 Scheduling a Home Study	47
VII.2 Study Participants Training and Knowledge Assessment	49
VII.3 Handing Over Starstim-Home Kits to Study Participants	51
VII.4 Remote Monitoring of Adverse Events	53
VII.5 Remote Monitoring of Compliance	54
VII.6 Review of the Treatment Session Status	55
<b>VIII. Analysis of the Study Data</b>	56
VIII.1 Access to Session Records	57
VIII.2 Access to EEG Recordings	58
<b>IX. Symbols Used</b>	59
<b>X. Error Messages</b>	60

# I. Use of Starstim-Home

Starstim-Home is the only transcranial electrical stimulation (tES) and an electroencephalogram (EEG) monitoring 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;
- ▶ Multi-step Multi-channel Programmable tES-EEG;
- ▶ eHealth Standard for Quality of Data Security & Transfer;
- ▶ Convenient & Precise Home EEG Analysis;
- ▶ Integrations for Questionnaires, Telehealth, and Behavioral Treatment Research;
- ▶ Lifetime Customer Support & Multiple Warranty Options.





## I.1

# Transcranial Electrical Stimulation (tES)

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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

## I.2

### Intended Use

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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 NIC User Manual 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.

The Starstim-Home systems are remotely supervised home use neurostimulator devices, intended for users in an environment that meets the requirements listed in the instructions for use including the home-healthcare environment.

The intended use is research and clinical investigation of tES applications in home-healthcare environments. 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 system and for remote supervision of its use.

Remotely-supervised tES serves as an extension of in-clinic/in-lab administered tES sessions. Proper frameworks around staff training, user capability and training, and remote supervision are essential to maintain the same level of safety and tolerability experienced within the clinic/lab setting.

Careful consideration of each of these criteria should be considered in a remotely supervised application.

Starstim-Home systems must be always used according to the brain stimulation applications already described in the literature. In any other case, the supervision of a local Ethics Committee or analogous body must be required for the experimental use of this device.

Starstim-Home devices can only be used with electrodes and cables commercialized by Neuroelectrics to maintain compliance with product regulations.

### I.3

## Conditions of Use

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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 user manual.



## II. Quality and Regulatory Information

## II.1

### Quality Management System

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Neuroelectrics is an ISO 13485 and ISO 9001 certified company. Thus, our medical devices are designed and manufactured following the corresponding ISO quality management systems.

Neuroelectrics complies with Quality System Regulation 21 CFR 820.

## II.2

### Medical Device Regulations

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Starstim-Home tES and Starstim-Home tES-EEG are intended for research use only.

## II.3

### For US Audience only

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CAUTION:

US Federal Law classifies Neuroelectrics® and Starstim-Home tES and Starstim-Home tES-EEG as Investigational Devices.

# III. Safety Information

Starstim-Home conforms to the following standards:

Medical device software life-cycle

- ▶ IEC 62304:2006/A1:2015

Biological evaluation

- ▶ EN ISO 10993-1:2009 + AC:2010

Usability

- ▶ IEC 62366-1:2015/Cor 1:2016

Electrical safety and electromagnetic compatibility

- ▶ IEC 60601-1:2005/COR2:2007
- ▶ IEC 60601-1-11:2010


















Others

- ▶ EN ISO 15223-1:2016
- ▶ EN 1041:2008 + A1:2013
- ▶ EN ISO 14971:2012
- ▶ 2011/65/EU







### III.1

## Safety Warnings








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-  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.


-  The result of the EEG recordings is not displayed in legal units or other units within the meaning of Directive 80/181/ECC. Therefore the device is not considered to have a measuring function.
-  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 pre-programmed 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 shall be used for EEG recording.





-  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 a healthy skin without wounds.
-  This device does not contain any user-servicable 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-EEG and Starstim-Home tES packages 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 User Manual. Additionally, to learn how to design protocols and make use of other researcher functionalities, refer to the NIC User Manual.

## IV.1

### Features

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#### **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

#### **Simultaneous EEG recordings\***

- ▶ A secure storage of EEG recordings from before, during or after the home stimulation

#### **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

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#### **EEG functionality\***

- ▶ Number of channels: (up to) 8 channels
- ▶ Sampling rate: 500 SPS
- ▶ Bandwidth: 0 to 125 Hz (DC coupled)
- ▶ Resolution: 24 bits - 0.05  $\mu$ V
- ▶ Measurement noise: < 1  $\mu$ V RMS
- ▶ Common mode rejection ratio: -115 dB
- ▶ Input impedance: >1 G $\Omega$

#### **Stimulation functionality**

- ▶ Number of channels: (up to) 8 channels
- ▶ Sampling rate: 1000 SPS
- ▶ Frequency range: 0 to 250 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:  $\pm$  2 mA
- ▶ Current resolution: 1  $\mu$ A
- ▶ Current accuracy: 1%
- ▶ Maximum voltage:  $\pm$  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

\*EEG monitoring is only available with Starstim-Home tES-EEG

### **Other Technical Specifications**

- ▶ Battery operating time: 4.5 hours
- ▶ Accelerometer\*: 3-axis
- ▶ EEG Output\*: NEDF (24 bits)

### **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

# Contents of the Starstim-Home Package

The Neuroelectrics® Starstim-Home package contains all the components required to perform an EEG monitoring or 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	USB Power Adapter
1	NE013a NE013b NE013c	EU / US / UK Power Supply Plug
1	NE017-H	10 Electrode Cable Color-coded
1	NE019-M-Home	Neoprene Headcap M (54 cm)
8	NE029	Electrode: NG Pistim
4	NE026a	Electrode: Sponstim 25
1	NE027	Electrode: Earclip
1	NE016a	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	USB Stick with Manuals & NIC
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 User Manual 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.

## Neuroelectric Electrodes

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### Stimulation (tES)

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**Sponstim 25**

NE026a

### EEG & tES

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**NG Pistim**

NE029

### Reference

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**Earclip**

NE027




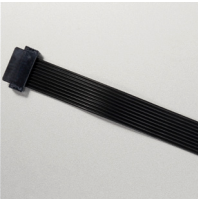
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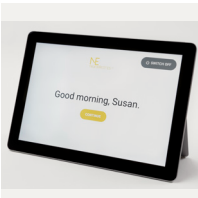
Regarding the electrodes, you must use them according to their functionality. They are grouped above as only-tES, hybrid EEG & tES, and Reference electrodes. Bear in mind that electrodes need to be replaced when they reach the end of their lifetime, in order not to compromise the quality of the EEG signal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

Item	Name / Description	Code
	<p><b>Starstim-Home Necbox</b></p> <ul style="list-style-type: none"> <li>▶ The Starstim-Home Neuroelectrics Control Box (Necbox) is the device responsible for delivering the tES currents and recording EEG.</li> <li>▶ The Necbox is battery-operated and it is wirelessly paired with the Home Tablet</li> <li>▶ The Necbox battery cannot be charged when the device is being used.</li> </ul>	NE012HWF / NE012HEWF
	<p><b>USB Power Adapter &amp; Power Supply Plug</b></p> <ul style="list-style-type: none"> <li>▶ The USB power adapter is used to charge the Necbox battery.</li> <li>▶ The type of the power supply plug (EU/US/UK) included in the kit depends on the country of the customer.</li> </ul>	NE055W & NE013a NE013b NE013c
	<p><b>Curved Syringe</b></p> <ul style="list-style-type: none"> <li>▶ The curved syringe is used to inject either electrode gel or saline solution in the electrodes.</li> <li>▶ Do not use electrode gel and saline solution simultaneously in the syringe. Wash and clean it when changing the liquid to be used.</li> </ul>	NE014
	<p><b>Electrode Gel 250g</b></p> <ul style="list-style-type: none"> <li>▶ The electrode gel is a highly conductive and water soluble gel.</li> <li>▶ 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.</li> <li>▶ It must not be used with sponstim electrodes.</li> </ul>	NE016a

Item	Name / Description	Code
	<p><b>Saline Solution 100 ml</b></p> <ul style="list-style-type: none"> <li>▶ The saline solution (NaCl 0.9%) is required to use the stimulation sponstim electrodes.</li> <li>▶ It should be applied on the yellow exterior face of the sponge that contacts with the scalp.</li> </ul>	NE033
	<p><b>10 Electrode Cable Color-Coded</b></p> <ul style="list-style-type: none"> <li>▶ An Electrode Cable optimized for experienced of users at home.</li> <li>▶ Its color markers follow setup instructions in the home software providing additional comfort especially while preparing multi-channel montages, consequently reducing training effort.</li> </ul>	NE017-H
	<p><b>Neoprene Headcap Home M (54 cm)</b></p> <ul style="list-style-type: none"> <li>▶ 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.</li> <li>▶ 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.</li> <li>▶ The cap is available in four adult-sized models (XL, L, M, S).</li> </ul>	NE019-M-Home



Item	Name / Description	Code
	<b>USB Wi-Fi Dongle</b> <ul style="list-style-type: none"> <li>▶ 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 Mac OS computers.</li> </ul>	NE031b
	<b>USB Stick with Manuals &amp; NIC SW</b> <ul style="list-style-type: none"> <li>▶ The USB stick contains the PDF version of the three parts of the Neuroelectrics User Manual, and the NIC software.</li> <li>▶ All the contents can also be found at <a href="http://www.neuroelectrics.com">www.neuroelectrics.com</a>.</li> </ul>	NE015
	<b>Testboard Head</b> <ul style="list-style-type: none"> <li>▶ The testboard head allows you to test the system functionalities and rule out potential problems before the real experiment.</li> <li>▶ 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.</li> </ul>	NE038
	<b>Testboard Cable</b> <ul style="list-style-type: none"> <li>▶ 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.</li> </ul>	NE039

Item	Name / Description	Code
	<b>Home Tablet</b>	NE180G
	<ul style="list-style-type: none"> <li>▶ Home tablet guides home users through the treatment, providing instructions on device preparation and maintenance, matching high accessibility standards.</li> </ul>	
	<ul style="list-style-type: none"> <li>▶ It allows strict remote access control and detailed remote progress monitoring.</li> </ul>	
	<ul style="list-style-type: none"> <li>▶ It matches the highest data transfer and storage security standards.</li> </ul>	
	<ul style="list-style-type: none"> <li>▶ For details on hardware maintenance, see: Surface Go help [<a href="https://support.microsoft.com/en-ca/hub/4346532/surface-go-help">https://support.microsoft.com/en-ca/hub/4346532/surface-go-help</a>]</li> </ul>	

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:

- |                                                                                                                                                                                                |                                                                                                                                                                                                            |                                                                                                                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>▶ Different sizes of the neoprene headcap: XL, L, M, S, Kids</li> <li>▶ Mouse Headcap Cover provides kids a more engaging tES-EEG experience</li> </ul> | <ul style="list-style-type: none"> <li>▶ Different shapes of the sponge electrodes<br/>Circular 25 cm<sup>2</sup> or 8 cm<sup>2</sup>, or rectangular 5 cm x 7 cm, you choose the contact area.</li> </ul> | <p>These items are available upon request.<br/>Please contact our sales team if you want your Starstim to be more complete.</p> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|



# 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.

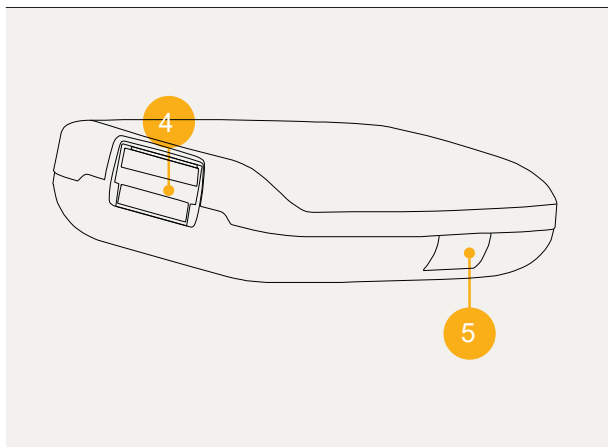
- ▶ On 2s hold, switches off the device while on.

### 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

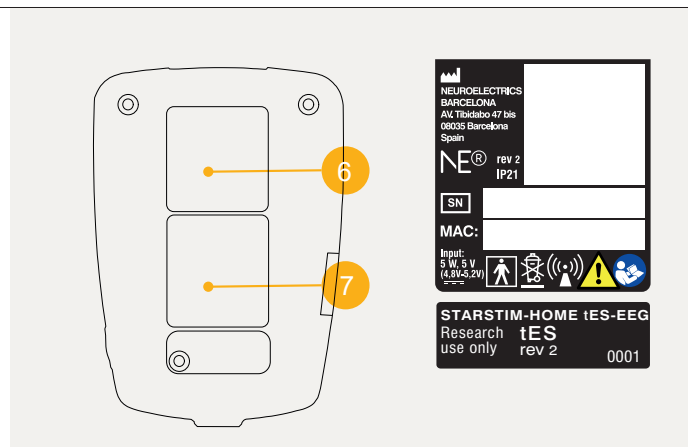
10-pin slot to connect with the electrode cable.

#### 5 MicroSD card slot

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

#### 6 Velcro

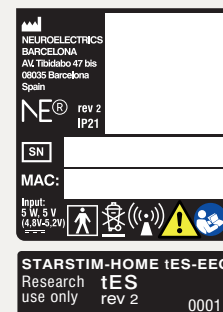
To attach the Necbox to the neoprene cap.



#### 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 °C to 45 °C

## 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 (Neuroelectronics Instruments Controller) 2 is software which allows you to create 8-channel tES-EEG 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 User Manual.

## V.7 Neuroelectronics Support

---

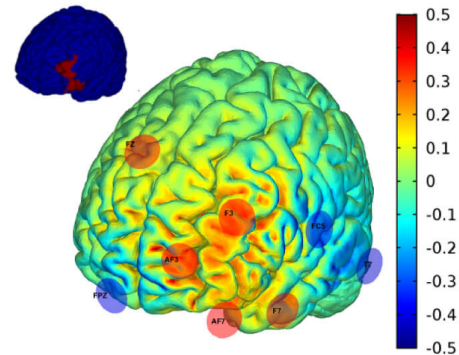
In case of technical questions or issues other than explicitly mentioned in this Manual, go to <https://www.neuroelectronics.com/support/> and fill in the support query form.

## V.6 Modeling Services

---

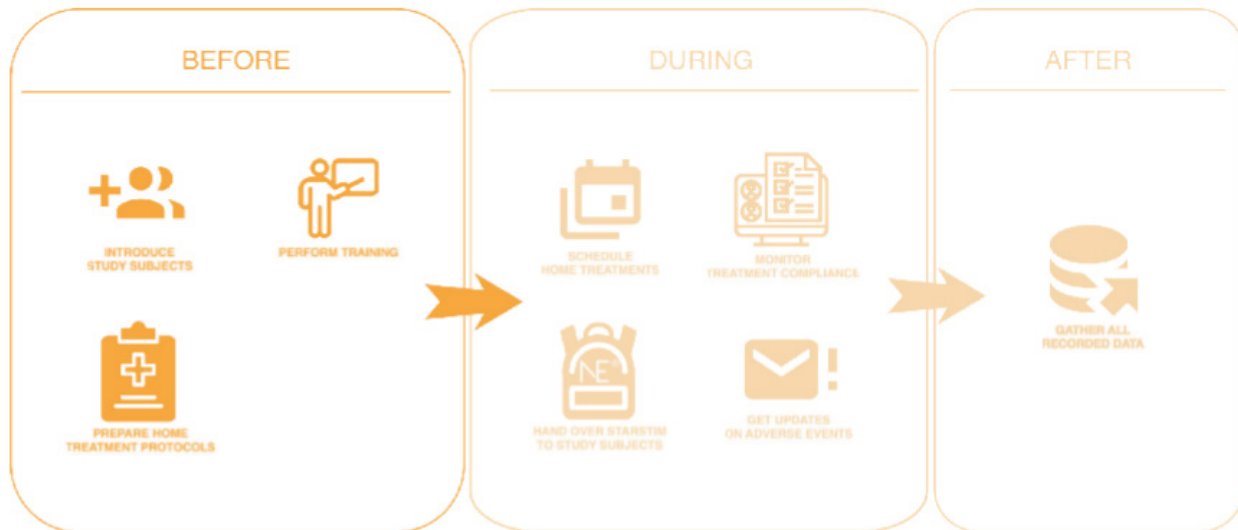
For a more efficient stimulation session, you may want to use our modeling services to optimize the electrode montage. With our Stimweaver algorithm, we will determine the ideal montage to target a specific brain region or network in order to achieve the result you want from stimulation. Stimweaver achieves 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 [Modeling Service webpage](#) for more information.





# VI. Instructions for Study Preparation

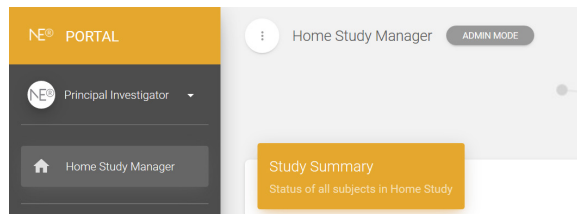


## VI.1

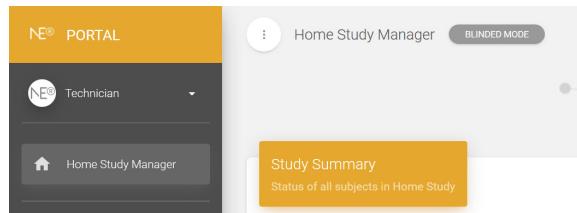
# Configuration of Study Team Accounts & Blinding Rules

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**

## Starstim Protocol

20min 2ch Sponstim

*Blinded*



20min

0:10

0:10

Location

Function

Cable

AF7

*blinded*

1

FCz

*blinded*

2



Sponstim electrode

**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

---

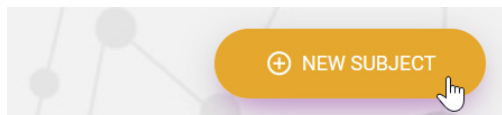
You can add study subjects one-by-one at any point in time before or during the study. The Neuroelectrics portal allows for the definition of the anonymous subject identifiers only, so make sure you have the study subject references stored elsewhere.

#### 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.

**Starstim-Home tES-EEG only:** Additionally, you can apply all the 8-channel multi-step tES-EEG protocols which NIC2 allows you to create.

Follow NIC2 User Manual 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 protocol files exported from NIC2 (tES only for Starstim-Home tES, tES-EEG for Starstim-Home tES-EEG);
- Electrode model – either NG Pistim or Sponstim. Read more about their characteristics in Electrodes User Manual;
- 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 User Manual 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.



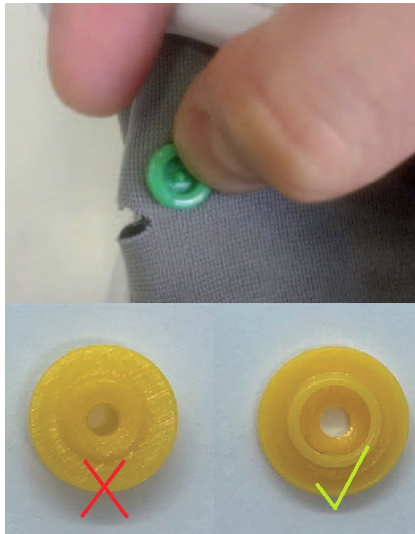
- c. Pick a snap button of a color which corresponds to the channel's number.

**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



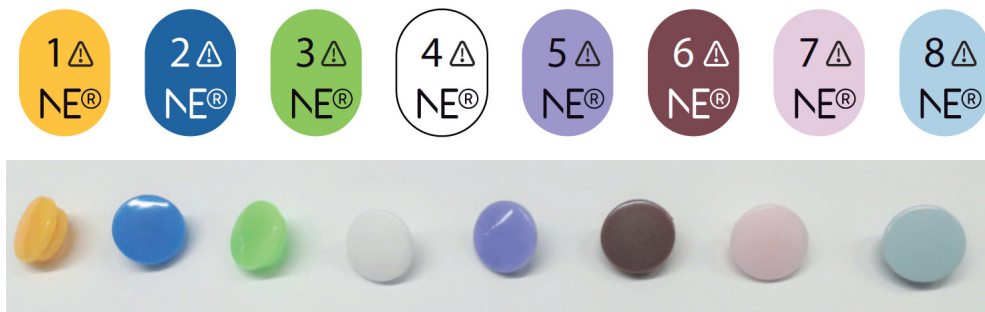
Step 2d



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 troubleshooting.** 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 NIC User Manual.

**EEG quality check.** The testboard can be used to record EEG and testing the quality of the signal. Once you set up the testboard, in NIC, you should observe a small EEG signal with an amplitude of around 10 $\mu$ V. For further details on EEG review in Liveview, please refer to NIC User Manual.

## 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](mailto: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.

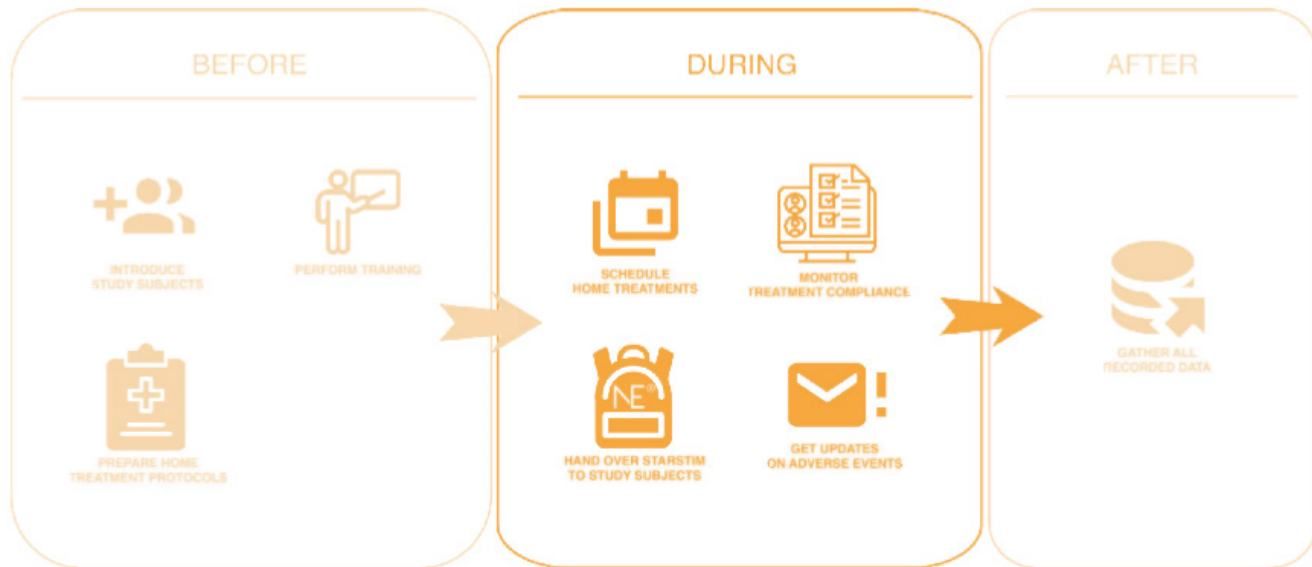
### To prepare

- 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

---

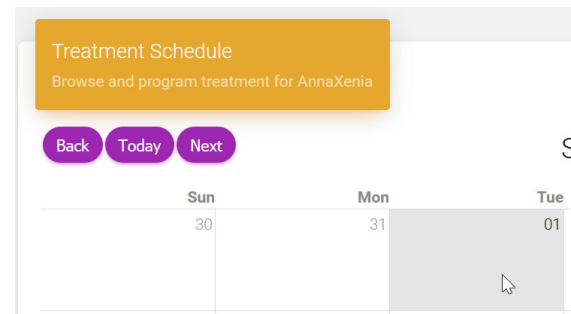
You can schedule treatment sessions for each of your subjects, choosing a period of the day with precision down to one hour.

### 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.

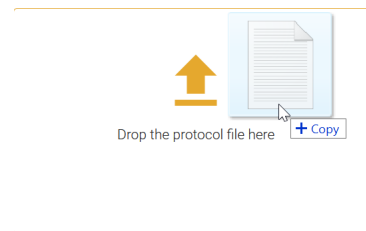
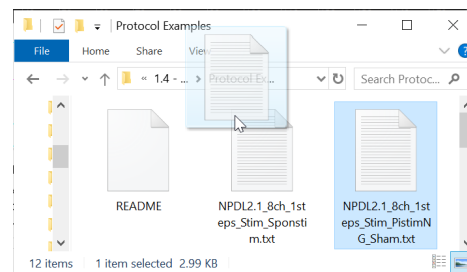


6. In the Schedule card of the popup window, choose the daytime period. Click NEXT. Protocol card will appear.
7. On the top left of the popup window, choose the protocol you want the subject to apply.

**Note:** Apply only a protocol which your device allows. Starstim-Home tES will not allow assignment to the study participants with tES-EEG treatment scheduled.

**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 this Manual.
- ▶ 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 Electrodes User Manual.

## 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 Starstim-Home 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 manual.

## 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 charged. 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 Neuroelectronics 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.

**Note:** Starstim-Home tES will not allow assignment to a study participant with tES-EEG treatment scheduled.

## 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](mailto:dont-reply@neuroelectrics.com).

## VII.5

### 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 Neuroelectronics 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

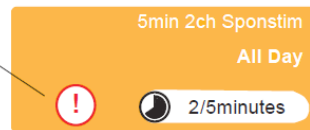
### Review of the Treatment Session Status

---

#### 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.

Incident requiring  
attention occurred

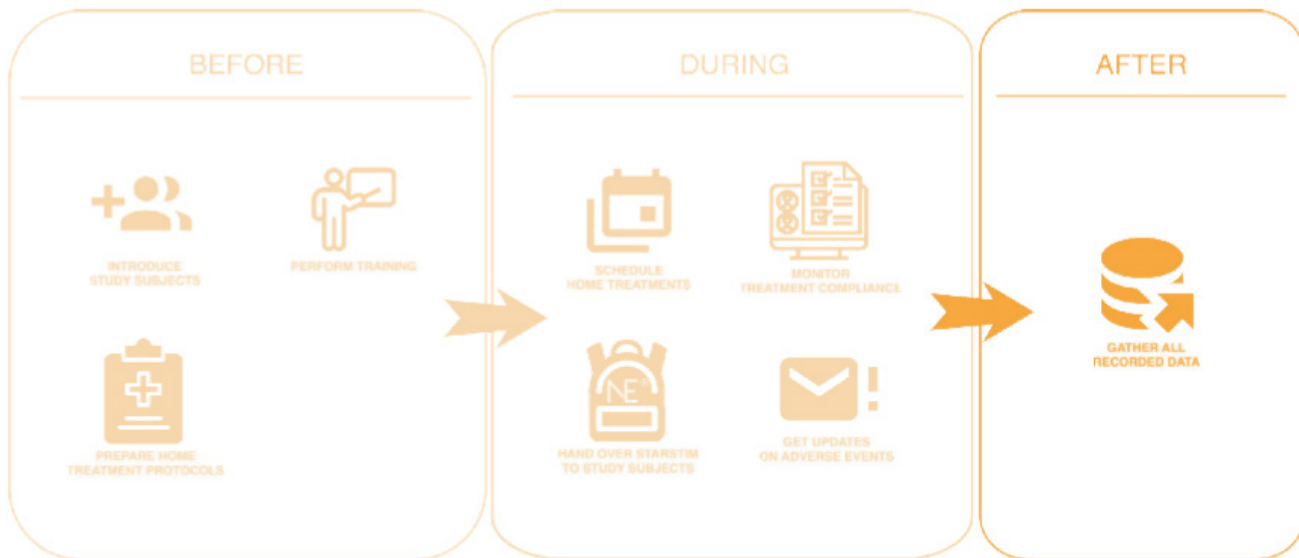


Color:

- Fully executed or no more than 1 minute missed
- Partially executed
- Missed or less than 1 minute executed

- 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.

### DOWNLOAD SESSION RECORD:



Session record download button

## VIII.2

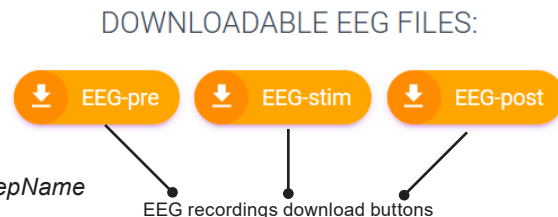
### Access to EEG Recordings

**Note:** This feature is available only with Starstim-Home tES-EEG systems.

#### 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 orange download buttons in order to download pre-, simultaneous-, or post-EEG recording.
4. The file in 24-bit proprietary NEDF format will download and be stored under the name following the convention:

*SubjectID\_UniqueSessionID\_RecordingTimestamp\_ProtocolStepName*  
e.g.: *Subject123\_4200\_20201015142356\_PreEEG.nedf*

















**Note:** You can analyze the downloaded NEDF files:

- In NIC2 Offline Mode. Please, refer to NIC2 User Manual.
- In Python (using NEPy library). See more on our website's Software section.
- In Matlab (using our EEGLab Plugin). See more on our website's Software section.

Refer to NIC2 User Manual if you wish to convert the EEG files into an EDF or ASCII formats.

# IX. Symbols Used

Symbol	Description
	IEC 60417-5333 BF type applicable part according to UNE-EN 60601-1:2008
	IEC 60417-5010 Push ON/OFF button UNE-EN 60601-1=2008
	ISO 7000-2498 Serial Number according to EN 980:2008
	Device manufacturer symbol according to EN 980:2008
	ISO 7000-2606 do not use device if product or packaging have been damaged symbol according to UNE-EN 980
	Do not throw Enobio 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.
	ISO 7000-0632 Transport and storage temperature conditions

Symbol	Description
	ISO 7000-2620 Transport and storage humidity conditions
	ISO 7000-2621 Transport and storage atmospheric pressure conditions
	Transport package shall be kept away from rain and in dry conditions.
	Transport package shall not be exposed to sunlight.
	ISO 7010-W001 General warning sign.
	Refer to the manual/booklet

# X. Error Messages

The following messages might appear during normal operation:

Error message	Cause	Actions
Connection lost	The computer cannot communicate with the device.	Check that the device is switched on, that the device has battery, that the computer Wi-Fi / USB communication is working properly, and the device is close to the computer.
Please switch off the device, and after 5 seconds	The computer has the device paired, but the device is at unknown state.	Restart the device.

