starstim NE®

Neuroelectrics Starstim 8/ Starstim tES

- Part 1 -

Instructions for Use

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Instructions for Use Update:

Code: UM001

Version: 3.0

Date: 2022.10.03

Model Name:
Starstim 8
Starstim tES

The manufacturer should be contacted:

- for assistance, if needed, in setting up, using or maintaining the Starstim 8 system;
- to report unexpected operation of events that result from the usage of the device.

Input: 5W, 4.8 - 5,5V

About the Starstim 8 / Starstim tES Instructions for Use

Before the first use of the Starstim system, read the present instructions for use (**Part I:** Starstim 8/ Starstim 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

Starstim is a transcranial electrical stimulation (tES) and an electroencephalogram (EEG) monitoring device, all in one.

Starstim is a modern neurostimulator:

- It is a wireless operating system
- EEG recording is possible before, during and after stimulation
- Multiple independent stimulation channels improve the spatial distribution of the electric field
- Variety of waveforms for stimulation current: tDCS, tACS, tRNS and Sham mode
- NG Pistim: the hybrid Ag/AgCl electrode that can be used for EEG or tES
- Ease of use despite of the complexity of the technology
- Safety features such as maximal currents and impedance control

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. 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 & Use Environment

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.

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.

Starstim 8 and Starstim tES

Starstim 8 and Starstim tES are wireless 8-channel transcranial electrical stimulation investigational devices with (Starstim 8) or without (Starstim tES) EEG recording function. They have been designed to be used for research purposes in a clinical environment, hospital or research center.

Starstim 8 and Starstim tES can only be used with electrodes and cables commercialized by Neuroelectrics.

Starstim 8 and Starstim tES are investigational devices.

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 ISO 13485:2016 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 device has been tested for EMC emissions and immunity according to UNE-EN 60601-1-2. It is designated for use in professional medical environments. Use in special environments such as military areas, heavy industrial areas, and medical environments with high energy equipment (MRI rooms, CT scanners, etc.) is not permitted.
- The use of cables or electrodes other than the ones delivered with the product or provided by Neuroelectrics may cause higher EMC emissions and less EMC immunity.
- The device must not be used near other electrical equipment connected to the user. If such usage is needed, contact Neuroelectrics.
- The device is not protected against other high frequency devices such as electrocautery machines. Do not use the device with other electronic equipment without consulting Neuroelectrics.
- Never use the device or install the electrodes on the head of the patient while connected to the power network through the charger or any other device.
- The device must be charged only with the certified charger provided by the manufacturer. No cable or device except those provided by Neuroelectrics shall be plugged into the charging port.
- The electrodes and wires or any conductive part must not touch any other conductive part of any other device including the ground.
- During normal operation do not touch the device.
- Always unplug the charger cable from the device prior to connecting electrodes to the subject. The device is prevented from operating while the battery is charging.
- During normal operation do not switch the device on or off while it is assembled and placed on the subject's scalp. Only in the case where the Device Control Software is not responding or does not allow you to stop the stimulation protocol should the device be turned off using the push button. When this is necessary, be sure to wait for the power indicator light on the device to turn off before removing cables or electrodes as a sudden change in current may cause a slight pinching or shock-like sensation.
- The device is not provided sterile and should not be sterilized. For cleaning, follow the instructions in the User's Manual.
- The device is wireless and may be affected by other RF devices.
- If the communication between the Starstim device and the Device Control Software fails, then the Device Control Software will inform the user accordingly.
- During each session, it is mandatory to use reference electrodes connected to CMS and DRL cables. Ensure that they are located correctly and well connected before starting a protocol.
- The device should be charged at least once every 3 months.
- To avoid dropping and/or losing

parts, the device and its accessories shall be stored in the provided packaging as soon as they are clean and dry after a session.

- This device does not contain any user-serviceable parts. The device may only be repaired by the manufacturer.
- The device itself does not need installation, maintenance or calibration.
- In case of malfunction, contact the manufacturer or distributor immediately.
- Do not use the device if the provided storage conditions on their labels were not met at any point in time.
- Brain stimulation must be always applied by indication of a physician.
- Brain stimulation must be applied following stimulation protocols defined and operated by the professionals who own and operate the Starstim Software.
- Before using, please check that the device is undamaged, and the packaging has not been affected by transport or storage.
- Keep all kit components out of the reach of children and anyone else who might swallow electrodes or any other component, ingest electrode gel, be at risk for strangulation with cables, or cause injury to themselves or others. Inform to seek medical attention if such a situation occurs.
- When you want to 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.
- The device must never be disassembled or damaged.
- The battery may only be replaced by authorized personnel.
- Modification of the device is not permitted under any circumstances.
- The device must be used with electrodes provided by Neuroelectrics.
- In case the instructions for use are unclear, contact the manufacturer or the distributor and do not use the device.
- Electrodes shall only be placed over healthy skin without wounds, abrasions, or other skin conditions.
- Do not use the device if the provided storage conditions on their labels were not met at any point in time.
- 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.
- Do not operate the device in proximity to flammable materials such as gas or particulate matter. Inform subjects and caregivers about this risk.
- Before the brain stimulation is applied, confirm the absence of any pacemakers, intracranial electrodes, implanted defibrillators, cranial pathologies (e.g., holes, plaques) or any other impact in the patient. In these cases, the use of the device could become unsafe. Refer to potential contraindications section.
- There is limited information on the use of tES in children.

IV. The Starstim System

This chapter describes the Starstim system. First, it lists the features and technical specifications of Starstim. Then, the components included in the Starstim 8 and Starstim 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 Instructions for Use. Additionally, to learn how to pair your device with the computer, you should read the NIC2 Instructions for Use. The NIC2 Instructions for Use explains the steps needed to correctly conduct a stimulation session, with or without simultaneous EEG monitoring.

IV.1
Features

Wireless, wearable and easy-to-set concept

- Flexible electrode placement based on the 10-10 system
- User-friendly software interface
- Stimulation waveforms: tDCS, tACS and tRNS
- Sham and double-blind modes

EEG monitoring and Stimulation *

- Stimulation compatible with simultaneous EEG monitoring (not in the same site)
- Stimulation and EEG monitoring are possible at the same site with the same electrode (not simultaneously)
- EEG monitoring is possible before, during and after stimulation

IV.2
Technical Specifications

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 μV
- Measurement noise: < 1 μV RMS
- Common mode rejection ratio: -115 dB
- Input impedance: 1 GΩ

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; 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 any instant

*EEG monitoring is only available with Starstim 8.

IV.2
Technical Specifications

Other Technical Specifications

- Battery operating time: 5 hours (combined EEG/tES use)
- Accelerometer: 3-axis
- Communication: NE001WF: Wi-Fi IEEE 802.11 g
- Output: EDF+ (16 bits), ASCII data files or TCP/IP raw data streaming
- OS compatibility: Windows (7 / 8 / 10 / 11) and macOS (≥High Sierra)

Minimum Computer Requirements

- Operating System: Windows 7 or macOS High Sierra
- Processor: 1.3 GHz
- RAM: 2 GB
- Wi-Fi/USB
- NE001WF: Wi-Fi IEEE802.11g

Wireless Information

Starstim is a wireless device operating at the 2.4GHz Industrial Medical and Scientific (ISM) band. The Nexbox connects through the wireless link to the Neuroelectrics Instrument Controller (NIC) software running on a computer. The EEG data is streamed through the wireless link. The standard operating distance is 10 meters. Below are the technical specifications regarding the Wireless connection used by Necbox.

Wireless Specifications

- Wi-Fi: IEEE 802-11 g
- 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
- Security details: Encryption WEB

Battery Operating Times

		All Channels
Wi-Fi	SS 8	5 h 10 min
USB	SS 8	11 h 56 min

IV.3
Contents of the Starstim Package

The Neuroelectrics® Starstim 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	NE012 / NE012WF	Starstim Necbox
1	NE055W	Power Adapter
1	NE013a NE013b NE013c NE013d	EU / US / UK / AU Power Supply Plug
1	NE014	Curved Syringe
1	NE015-SSES NE015-SS08	USB Stick with Manuals & Software
1	NE016b	SIGNAGEL® Electrode Gel (250g)
1	NE017	10 Electrode Cable
1	NE019-K-NB1.0M.WH.MD:GV	Neoprene headcap M (54 cm)
1	NE029-P.08.MD:GV	Electrode: NG Pistim (bag of 8)
1	NE025-P	Electrode: Kendall™ H124SG (bag of 50)

Quantity	Code	Name
1	NE026a-P.04.MD:GV	Electrode: Sponstim 25 (bag of 4)
1	NE026b-P.08.MD:GV	Electrode: Sponstim 8* (bag of 8)
1	NE032-P.08.MD:GV	Electrode: NG Geltrode* (bag of 8)
1	NE027-P.01.MD:GV	Electrode: Earclip (bag of 1)
1	NE031b	USB Wi-Fi Dongle
1	NE033	Saline Solution 100 ml
1	NE038	Testboard Head
1	NE039	Testboard Cable
1	NE164+NE172	USB Isolator & Extension Cable*

*Depending on the kit purchased, items included may vary.

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

Neuroeletrics Electrodes

EEG

NG Geltrode

NE032-P.08.MD:GV

Stimulation (tES)

Sponstim 25

NE026a-P.04.MD:GV

Sponstim 8

NE026b-P.08.MD:GV

EEG & tES

NG Pistim

NE029-P.08.MD:GV

Reference

Kendall™ H124SG

NE025-P

Earclip

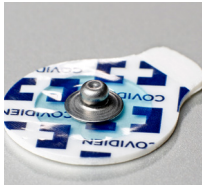
NE027-P.01.MD:GV

Regarding the electrodes, you must use them according to their functionality. They are grouped above as only-EEG, 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.

*Depending on the kit purchased, items included can vary.

Item	Name / Description
	**Starstim Necbox** ▶ The Starstim Neuroelectrics Control Box (Necbox) is the core of the Starstim system. ▶ The necbox is battery operated and it is wirelessly paired with the computer using the Nic software. ▶ The necbox battery should never be charging when the device is being used.
	**Power Adapter & Power Supply Plug** ▶ The 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 12ml 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.
	**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.

Item	Name / Description
	**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 Parker Laboratories, Inc..
	**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** ▶ The 10 electrode cable has 10 electrode medical sockets compatible with the electrodes commercialized by Neuroelectrics. ▶ It contains 8 channels for EEG monitoring or for stimulation, and two reference channels labelled with CMS & DRL.
	**Neoprene Headcap M (54 cm)** ▶ The neoprene cap is a comfortable solution to precisely place the electrodes on the scalp based on the 10-10 system. It provides 39 possible electrode positions, but extra positions can be added using the neoprene punch tool (not included). The cap provided is medium sized, but other sizes are also available.

Item	Name / Description
	**Kendall™ H124SG** ▶ The Kendall™ H124SG is a recommended pre-gelled adhesive electrode, proven to be compatible with our devices. When connected to the CMS & DRL channels, they can be used as reference electrodes. It can be also used to monitor ECG or EOG and does not require the application of electrode gel. ▶ The legal manufacturer is Cardinal Health. Please consult the manufacturer's website to access product's details.
	**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.
	**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
	**USB Cable & Isolator** ▶ The USB Cable & Isolator can be used to transmit EEG and Stimulation data between the device and the computer. This should always be used with the extendor cable. Note that this cable does not charge the device.

In order to make your Starstim experience more complete, you can add accessories to your stimulation kit.

In our catalog and webpage, you may find:

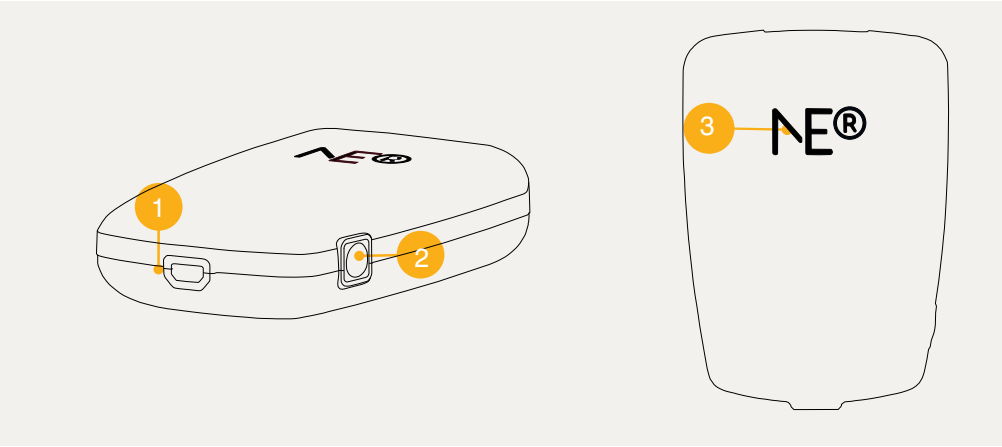
- Different sizes of the neoprene headcap: XL, L, M, S, Kids
- Kid-sized headcaps are provided with a headcap cover
- The neoprene punch tool to customize your own cap.
- Dry electrodes for EEG monitoring for a fast, gel-free experience
- Different shapes of the sponge electrodes
  Cicular 25 cm^2 o r 8 cm^2, or rectangular 5 cm x 7 cm, you choose the contact area.
- MRI kit (Filter & Harness) and MRI compatible electrodes: Take your hybrid EEG/tES system to the MRI room

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

IV.4

Necbox: Neuroelectrics Control Box

The Necbox is the core and the control unit of the Starstim device. 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



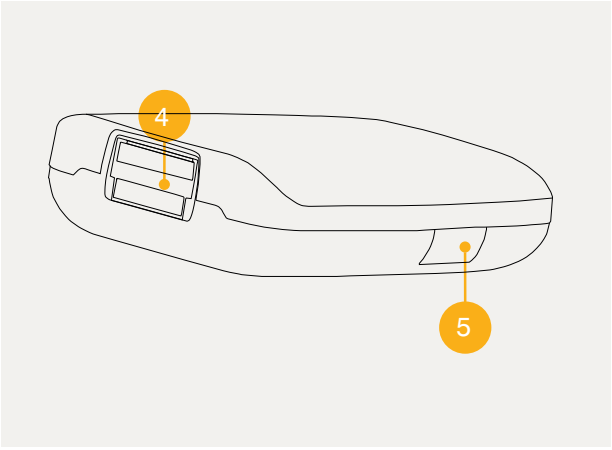
1. Charging LED

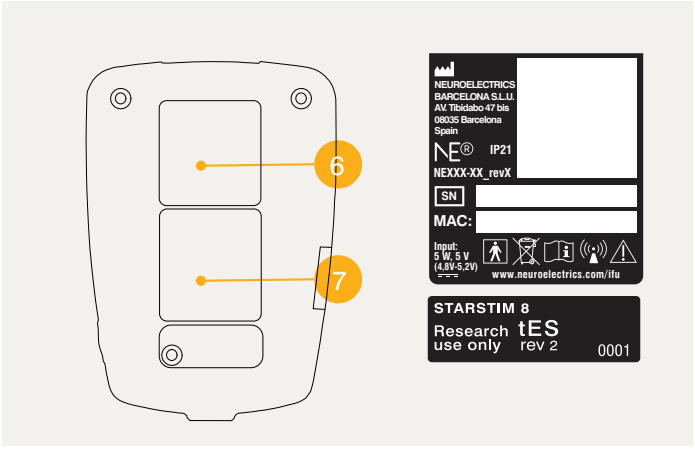
Yellow when charging; green when charged.

2 ON/OFF Push-button

3 Operation LED

The LED behind the logo indicates the normal operation of the device.





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

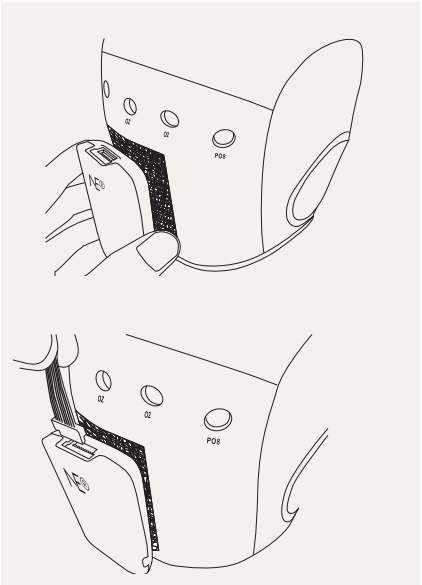
7 Technical Specifications labels

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

IV.5
Assembling the Necbox



The Necbox is attached to the neoprene cap using the velcro, and it is connected to the electrode cable using the 10-pin connector.

IV.6
Necbox battery

The battery can only be charged when the power switch is at the OFF position. The battery charger connects to the Necbox through the microUSB / micro HDMI connector located at the rear part of the Necbox. To charge the battery, the following specifications need to be met:

- Nominal output: 3.7 V (3 V - 4.2 V)
- Current output: 1 A
- Battery charger: must comply according to 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 > 70% of initial capacity
- Charging with higher voltage than specified may damage the cell.
- The usual time to charge a battery from the cut-off voltage to the maximum capacity is around 2 hours, but it depends on each battery (battery life).
- The device can be connected to any Class 2 electrical installation.
- Device will not operate when charging.
- Only use the charger that came with the device to charge the battery.

Operating Temperature

- Charging: 0° C to 45° C
- Discharging: -20° C to 60° C

Storage Temperature

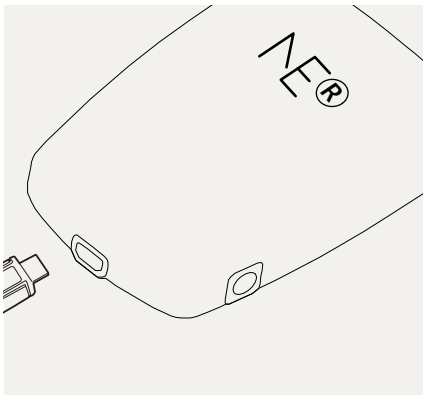
- 1 year at -20 ºC to 65 ºC

Electrical specifications for charging:

- Voltage nominal input: 5 VDC
- Voltage input min/max: 4.8 VDC - 5.5 VDC
- Power input: 5 W

Output current specifications:

- 2 mA per channel with ± 15 V



IV.7 Conditions of Use

Starstim 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.8 Cleaning Instructions

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.

IV.9
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 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.

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 10μV. For further details on EEG review in Liveview, please refer to NIC2 Instructions for Use.

V. 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

VI. 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.