

starstim^{NE®}

Neuroelectrics User Manual
– P1. Starstim 8 / Starstim tcs–

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



Europe Office

Avinguda Tibidabo, 47 bis
08035 Barcelona, Spain
Tel. +34 93 254 03 66
Fax. +34 93 212 64 45

US Office

210 Broadway, Suite 201
Cambridge, MA 02139, USA
Tel. +1 617 682 0770

Email: info@neuroelectrics.com

www.neuroelectrics.com

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Input: 5W, 4.8 - 5,5V



Manufacturer:

Neuroelectrics Barcelona SLU
Avinguda Tibidabo 47, bis
08035 Barcelona

Spain

Telephone: + 34 93 254 03 70



Brand:

Starstim

Models:

Starstim 8

Starstim tcs

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.

About the Starstim User Manual

The **Starstim User Manual** belongs to the **Part I** of the Neuroelectrics User Manual.

The **Neuroelectrics User Manual** includes three parts:

- ▶ **Part I:** Enobio User Manual or Starstim User Manual
- ▶ **Part II:** Electrode User Manual
- ▶ **Part III:** NIC User Manual

Before you first use the Starstim system, you should read the three parts of the Neuroelectrics User Manual. The Starstim User Manual does not discard the need of reading the Electrode and NIC parts.

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

www.neuroelectrics.com/documentation

Change of Record

Issue	Date	Changes made
1.0	2012.02.14	First version
2.0	2016.02.18	Neuroelectrics User Manual divided in three parts: (1) Enobio / Starstim, (2) Electrode and (3) NIC.
2.1	2016.05.10	Starstim tCS info added to Starstim 8 manual
2.2	2017.07.25	Product contents update (Starstim tCS info removed).
2.3	2017.08.23	Regulatory info update
2.4	2018.05.07	Starstim BT and Wi-Fi unified and Starstim tCS info added to Starstim 8 manual

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I. Use of Starstim

Starstim 8 is a transcranial current stimulation (tCS) and an electroencephalogram (EEG) monitoring device, all in one.

Starstim 8 is a modern neurostimulator:

- ▶ It is a wireless battery operated 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
- ▶ Pistim: the new hybrid Ag/AgCl electrode that can be used for EEG or tCS
- ▶ Ease of use despite of the complexity of the technology
- ▶ Safety features such as maximal currents and impedance control



I.1

Transcranial Current Stimulation (tCS)

Transcranial current stimulation (tCS) 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 tCS 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 tCS 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 tCS 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 tCS in which the stimulation currents are randomly varied. Unlike tDCS, tRNS has been recently introduced to the Neuroscience community, and there

1.2

Intended use & use environment

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 tcs are neurostimulator devices. They have been designed for research use only, in a clinical environment, hospital, or research center. Starstim 8 and Starstim tcs 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 8 and Starstim tcs can only be used with electrodes and cables commercialized by Neuroelectronics.

Read the Neuroelectronics User Manual carefully before using Starstim 8 or Starstim tcs.

Starstim 8 and Starstim tcs

Starstim 8 and Starstim tcs are research use only devices.

I.3

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 user manual.



II. Quality and Regulatory Information

II.1 Quality Management System

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

Europe

In Europe, Starstim 8 is intended for research use only.

Canada

In Canada, Starstim 8 is approved as a medical device and it conforms with the Canadian Medical Device Regulations SOR/98-282.

II.3 For US Audience only

CAUTION:

US Federal Law classifies Neuroelectrics® Starstim 8 as an Investigational Device.

III. Safety Information

Starstim 8 conforms to the following standards:

Electrical Safety

- ▶ EN 60601:2006 + Err.:2008 + Corr.:2010 + AC:2013 + A11:2011+ A12:2014
- ▶ EN 60601-1-6:2010
- ▶ EN 60601-1-11:2015
- ▶ EN 60601-2-26:2015

Electromagnetic compatibility

- ▶ EN 60601-1-2:2015
- ▶ EN 55011:2016 + A1:2017
- ▶ EN 61000-3-2:2014
- ▶ EN 61000-3-3:2013
- ▶ EN 61000-4-2:2009
- ▶ EN 61000-4-3:2006 + A1:2008 + A2:2010
- ▶ EN 61000-4-4:2012
- ▶ EN 61000-4-5:2014 + A1:2017
- ▶ EN 61000-4-6:2014
- ▶ EN 61000-4-8:2010
- ▶ EN 61000-4-11:2004 + A1:2017

Medical device software life-cycle

- ▶ EN 62304:2006 + Corr.:2009 + AC:2010

Biological evaluation

- ▶ EN ISO 10993-1:2009 + AC:2010

Usability




















- ▶ EN 62366-1:2015 + AC:2015

Others








- ▶ EN ISO 980:2008
- ▶ EN ISO 15223-1:2016
- ▶ EN 1041:2008 + A1:2013
- ▶ EN 60529:1991 + A1:2000 + A2:2013
- ▶ EN ISO 14971:2012
- ▶ 2011/65/EU


III.1





Safety Warnings


-  Note for clinical use: Brain stimulation must be always used according to medical prescription.
-  Brain stimulation must be used AFTER the prescription of a stimulation protocol made by the specialized and qualified medical personnel who owns and operates the Starstim Software.
-  Before the brain stimulation is prepared, please inform the prescribing clinician or operator of the presence of any pacemakers, intracranial electrodes, implanted defibrillators, cranial pathologies (e.g. holes, plaques) or any other prosthesis. In these cases the use of the device could become unsafe.
-  Before using, please check that the device is undamaged and the packaging has not been affected by transport or storage.
-  In the case of malfunction, immediately contact the manufacturer or the distributor.
-  The device must never be opened or damaged.
-  The battery can only be replaced by authorized personnel.
-  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 touch the device during stimulation or while EEG monitoring is on.
-  Never use the device or install the electrodes on the head of the patient while connected to the power network.
-  Do not switch the device on or off when it is assembled and placed on the subject's scalp.
-  Always unplug the USB power supply from the device prior to connecting electrodes to the subject. The device will not work when the battery is charging.
-  For EEG monitoring, the device must be used with Ag/AgCl electrodes recommended by the manufacturer.
-  For stimulation, Ag/AgCl electrodes or carbon rubber electrodes with sponges soaked with saline solution can be used. The sponges must be bigger than 3 mm² to avoid high density currents.
-  The device is not protected against other high frequency devices. To avoid risks place the CMS/DRL as far as possible from the stimulation and return electrodes of the high frequency device.
-  The device is wireless and might be affected by other RF devices.
-  The device needs special EMC precautions. It needs to be used according to the EMC information at the end of the user manual.
-  The EMC emissions and immunity has been tested using the 10-wire or 12-wire 34 cm cables provided with the system.
-  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 cannot be used beside or piled under other equipment. If such usage is needed, check the normal configuration.
-  The device can only be used in healthy skin without wounds.
-  The device cannot be used in a MRI room.
-  The device is not provided sterile and should not be sterilized.
-  The device does not need installation, maintenance or calibration.
-  The device and the accessories should be regularly checked by the user.
-  If the user wants to use the device in combination to another device connected to the patient, the user should contact Neuroelectrics to check the correct simultaneous use.

 Starstim should not be used in 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. If NIC detects that the signal is very noisy, it will interference with a higher Signal Quality Index.

-  The modification of the device is not allowed.
-  If the device has not been used during a long period of time, the user should check visually that there is no battery leakage.
-  The electrodes and wires or any conductive part cannot touch any other conductive part of any other device including the ground.
-  The cap is intended to be on the patient for less than 24 hours.

 Keep out of reach from children and anyone else who might swallow electrodes, otherwise they may cause injury to themselves.

-  Keep out of reach from children and anyone else who might strangle with the cables of the devices.
-  The result of the recordings must be analysed by a doctor or specialist. No self medication should be done based on this results.
-  The result of the 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.
-  If the system encounters the communication between Starstim and the PC is failed, then the NIC software will inform the user accordingly. Additionally, Starstim incorporates an internal buffer that safeguards the information sent from the device to the PC. So, even if there's a problem of the communication

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 and Starstim tCS 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 Neuroelectronics 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 pair your device with the computer, you should read the NIC User Manual. The NIC User Manual 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
- ▶ Conduct mobile studies away from the clinic or lab
- ▶ 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 μ V
- ▶ Measurement noise: < 1 μ V RMS
- ▶ Common mode rejection ratio: -115 dB
- ▶ Input impedance: 1 G Ω

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: \pm 2 mA
- ▶ Current resolution: 1 μ 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 any instant

*EEG monitoring is not available with Starstim tcs.

IV.2

Technical Specifications

Other Technical Specifications

- ▶ Battery operating time:
8 hours (combined EEG/tCS use)
- ▶ Accelerometer: 3-axis
- ▶ Communication:
NE001: Bluetooth® 3.0 and 2.1
NE001WF: Wi-Fi IEEE 802.11 b/g/n
- ▶ Output: EDF+ (16 bits), ASCII data files or TCP/IP raw data streaming
- ▶ OS compatibility: Windows (Vista / 7 / 8 /10) and MAC OS X

Minimum Computer Requirements

- ▶ Operating System: Windows Vista or MAC OS X Snow Leopard
- ▶ Processor: 1.3 GHz
- ▶ RAM: 2 GB
- ▶ Bluetooth®: 2.1/Wi-Fi/USB
- ▶ NE001: Bluetooth® 2.1 EDR
- ▶ 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.

NE001 - Wireless Specifications

- ▶ Bluetooth 3.0 and 2.1 Class 2
- ▶ Operating frequency band:
from 2.400 to 2483.5 MHz
- ▶ Transmitting power: Max. +3dBm
- ▶ Qualifications: CE, FCC, IC,
Japan and South-Korea
- ▶ Data rate: 921600 BPS

NE001WF- Wireless Specifications

- ▶ Wi-Fi: IEEE 802-11 b/g/n
- ▶ 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

IV.3

Contents of the Starstim 8 package

The Neuroelectrics® Starstim 8 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. Once you have opened

the box, please confirm you have all the items listed below as well as the right quantity of each electrode model. Depending on the communication of your device, items included can vary.

Quantity	Code	Name
1	NE012 / NE012WF	Starstim Necbox
1	NE013 / NE055	USB Power Adapter
1	NE013a NE013b NE013c	EU / US / UK Power Supply Plug
1	NE014	Curved Syringe
1	NE015	USB Stick with Manuals & NIC
1	NE016a	Electrode Gel 60cl
1	NE017	10 Electrode Cable
1	NE019-M	Neoprene Headcap M (54 cm)
8	NE022	Electrode: Geltrode
8	NE024	Electrode: Pistim

Quantity	Code	Name
50	NE025	Electrode: Sticktrode
4	NE026a	Electrode: Sponstim 25
4	NE026b	Electrode: Sponstim 8
1	NE027	Electrode: Earclip
1	NE031 / NE031b	USB Bluetooth Dongle / USB Wi-Fi Dongle
1	NE033	Saline Solution 100 ml
1	NE038	Testboard Head
1	NE039	Testboard Cable
1	NE043	USB Charging Cable (Bluetooth devices)
1	NE0164	USB Cable & Isolator (Wi-Fi / USB devices)



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.

Neuroelectrics Electrodes

EEG



Geltrode

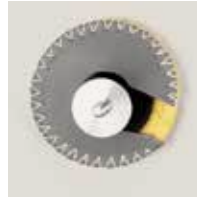
NE022

Stimulation (tCS)



Sponstim 25

NE026a



Sponstim 8

NE026b

EEG & tCS



Pistim

NE024

Reference



Sticktrode





NE025











Earclip


NE027

Regarding the electrodes, you must use them according to their functionality. They are grouped above as only-EEG, only-tCS, hybrid EEG & tCS, 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>Starstim Necbox</p> <ul style="list-style-type: none"> ▶ The StarStim Neuroelectronics 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 charged when the device is being used. 	NE012 / NE012WF
	<p>USB Power Adapter & Power Supply Plug</p> <ul style="list-style-type: none"> ▶ The USB power adapter is used to charge the Necbox battery. ▶ The type of the power supply plug (EU/US/UK) included in the kit depends on the country of the customer. 	NE055 / NE033 & NE013a NE013b NE013c
	<p>Curved Syringe</p> <ul style="list-style-type: none"> ▶ The curved syringe is used to inject either electrode gel or saline solution in the electrodes. ▶ Do not use electrode gel and saline solution simultaneously in the syringe. Wash and clean it when changing the liquid to be used. 	NE014
	<p>USB Stick with Manuals & NIC SW</p> <ul style="list-style-type: none"> ▶ The USB stick contains the PDF version of the three parts of the Neuroelectronics User Manual, and the NIC software. ▶ Both items can be also found at www.neuroelectronics.com. 	NE015

Item	Name / Description	Code
	<p>Electrode Gel 60 cl</p> <ul style="list-style-type: none"> ▶ The electrode gel 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. It must not be used with sponstim electrodes. 	NE016a
	<p>Saline Solution 100 ml</p> <ul style="list-style-type: none"> ▶ The saline solution (NaCl 0.9%) is required to use the stimulation sponstim electrodes. ▶ It should be applied on the yellow exterior face of the sponge that contacts with the scalp. 	NE033
	<p>10 Electrode Cable</p> <ul style="list-style-type: none"> ▶ The 10 electrode cable has 10 electrode medical sockets compatible with the electrodes commercialized by Neuroelectronics. ▶ It contains 8 channels for EEG monitoring or for stimulation, and two reference channels labelled with CMS & DRL. 	NE017
	<p>Neoprene Headcap M (54 cm)</p> <ul style="list-style-type: none"> ▶ 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. 	NE019-M

Item	Name / Description	Code
	<p>USB Bluetooth Dongle</p> <ul style="list-style-type: none"> ▶ The USB Bluetooth Dongle is used to provide a Bluetooth® port for computers that do not have an incorporated Bluetooth® port. The wireless communication between the Necbox and the computer is through Bluetooth®. The USB Bluetooth Dongle must not be used with Mac OS computers. 	NE031/ NE031b
	<p>Testboard Head</p> <ul style="list-style-type: none"> ▶ The testboard head allows 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. 	NE038
	<p>Testboard Cable</p> <ul style="list-style-type: none"> ▶ 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. 	NE039
	<p>USB Charging Cable (only included in Starstim 8 system)</p> <ul style="list-style-type: none"> ▶ The USB charging cable is an alternative to the USB power adapter & power supply plug. ▶ It allows the necbox to be charged by connecting it to the computer. 	NE043

Item	Name / Description	Code
	<p data-bbox="336 232 568 250">USB Cable & Isolator</p> <ul style="list-style-type: none"> <li data-bbox="336 266 1059 340">▶ The USB Cable & Isolator can be used to transmit EEG and Stimulation data between the device and the computer. As we have already seen in the validation. This should always be used with the extendor cable. <li data-bbox="336 356 855 374">▶ Read p. 29 to learn how to use the Isolator Cable. 	NE164

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

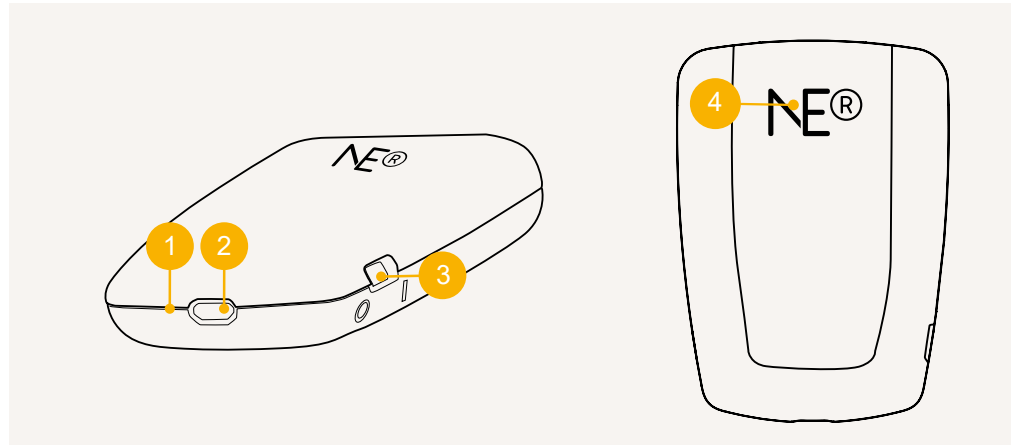
In our catalog and webpage, you may find:

- ▶ Different sizes of the neoprene headcap: XL, L, M, S, Kids
 - ▶ The neoprene punch tool to customize your own cap.
 - ▶ Mouse Headcap Cover provides kids a fun EEG experience
 - ▶ Dry electrodes for EEG monitoring for a fast, gel-free experience
 - ▶ Different shapes of the sponge electrodes
Circular 25 cm² or 8 cm², or rectangular 5 cm x 7 cm, you choose the contact area.
 - ▶ MRI kit (Filter & Harness) and MRI compatible electrodes:
Take your hybrid EEG/tCS 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.5

Necbox: Neuroelectrics Control Box

The Necbox is the core and the control unit of Starstim. The Necbox is a battery operated device. It weighs 65 g and its dimensions are 60 mm x 85 mm x 20 mm. The following diagrams describe the details of the Necbox



1. Charging LED

Yellow when charging; green when charged.

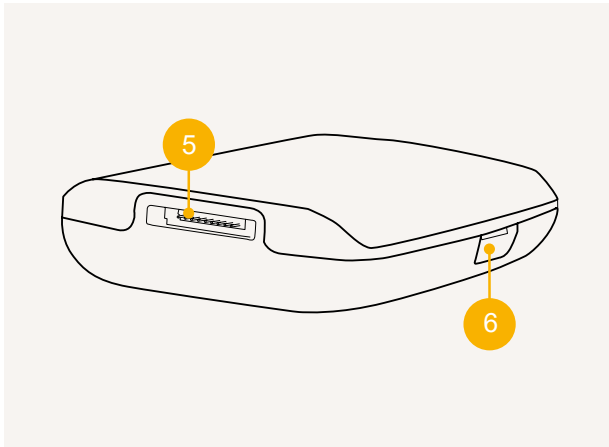
2 USB connector

To charge the Necbox battery either using the power adapter or the USB charging cable.

3 ON/OFF Power switch

4 Operation LED

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

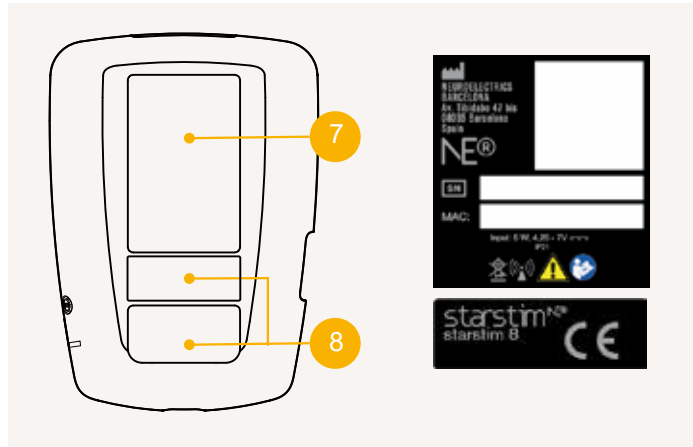


5 Pin connector slots

10-pin slot to connect with the electrode cable.

6 MicroSD card slot

Slot for microSD card (card not included) for offline data storage.



7 Velcro

To attach the Necbox to the neoprene cap.

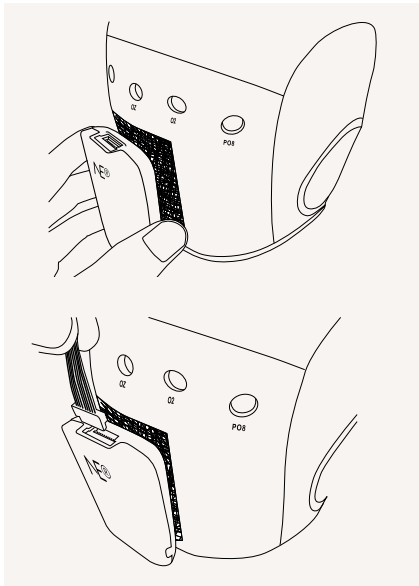
8 Technical Specifications labels

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.

IV.6

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.7

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.

Operating Temperature

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

Storage Temperature

- ▶ 1 year at -20° C to 65° C

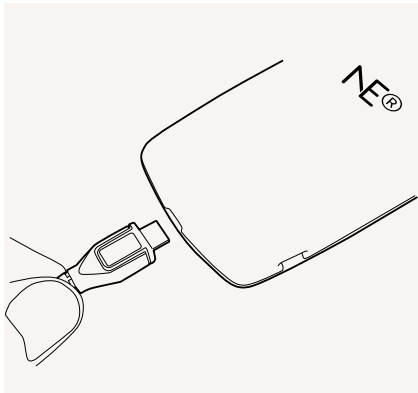
IV.8 Cleaning Instructions

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



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.

V. Symbols Used

Symbol	Description
	ISO 7010-W001 Warning signal according to UNE-EN 60601-1=2008 Parts marked with this symbol are not protected against defibrillator.
	IEC 60417-5008 Switch OFF according to EN 60601-1:2006
	IEC 60417-5007 Switch ON according to EN 60601-1:2006
	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.
	CE marked device certified according to the European Community.
	ISO 60417-5140 Non-Ionizing Electromagnetic radiation.

Symbol	Description
	ISO 7000-0632 Transport and storage temperature conditions
	ISO 7000-2620 Transport and storage humidity conditions
	ISO 7000-2621 Transport and storage atmospheric pressure conditions
IP 21	This medical device is protected from objects not greater than 12 mm in diameter and protected from dripping water.
	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

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 Bluetooth h/ 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.

VII. Electromagnetic Compatibility (EMC) Information

For Professional Use

The Starstim is suitable for use in the specified electromagnetic environment. The customer and/or user of the Starstim should ensure that is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11:2015 + A1:2016	Group 1	The Starstim uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11:2015 + A1:2016	Class B	The Starstim is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions EN 61000-3-2:2014	Class A	
Voltage fluctuations/flicker emissions EN 61000-3-3:2013	Complies	

The Starstim image intensifier is suitable for use in the specified electromagnetic environment. The customer and/or the user of Starstim image intensifier should ensure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Electrostatic discharge (ESD) EN 61000-4-2:2009	+8 kV contact	+8 kV
	+15 kV air	+15 kV
Radiated RF EN 61000-4-3:2006 + A1:2008 + A2:2010	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 1 GHz
Electrical fast transient/burst EN 61000-4-4:2012	2 kV for power supply lines	2 kV for power supply lines
	1 kV for input/output lines	N/A
Surge EN 61000-4-5:2014 + A1:2017	1 kV differential mode	1 kV differential mode
	2 kV common mode	N/A
Conducted RF EN 61000-4-6:2014	3 Vrms 0.15 MHz - 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 Vrms
Power frequency (50/60 Hz) magnetic field EN 61000-4-8:2010	30 A/m	30 A/m

Note: U is the A/C main's voltage prior to application of the test level.

The Starstim is suitable for use in a professional healthcare facility environment except near HF surgical equipment and the RF shielded room for magnetic resonance imaging.

The essential performance of the Starstim is the measure of the EEG and the transcranial stimulation. In case of EM disturbances, the operator can experience lost of communication between the Starstim and the PC.

The only part replaceable of the Starstim are the patient cables (NE017).

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11:2004 + A1:2017	0% U; 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% U; 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
	0% U; 1 cycle	0% U; 1 cycle
	70% U; 25 cycles single phase at 0°	70% U; 25 cycles single phase at 0°
	0% U; 250 cycles	0% U; 250 cycles

WARNING: Use of this equipment adjacent or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provisioned by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Starstim, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

