starstim NE®

Neuroelectrics User Manual

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

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Manufacturer:

Neuroelectrics Barcelona SLU
Avinguda Tibidabo 47, bis
08035 Barcelona
Spain
Telephone: + 34 93 254 03 66

Brand:

Starstim

Models:

Starstim R20
Starstim R32

Manual Update:

Version: 2.4
Date: 2019.06.27

The manufacturer should be contacted:

- For assistance in setting up, using or maintaining the Starstim system or to report an unexpected operation of events that result from the usage of the device.

Input: 5W, 4.25 - 5 V

About the Starstim User Manual

The Starstim User Manual corresponds to the Part I of the Neuroelectrics User Manual

The Neuroelectrics User Manual includes three parts:

- Part I: Starstim User Manual
- Part II: Electrode User Manual
- Part III: NIC User Manual

Read the three parts of the Neuroelectrics User Manual carfeully before the first use of the device. The Electrode and NIC User Manuals must be read as well as the Starstim User Manual before use.

The PDF version of the three parts of the Neuroelectrics User Manual can be found in the Manual Section of Neuroelectrics' webpage: www.neuroelectrics.com/documentation

Change of Record

Issue	Date	Changes made
1.0	2017.02.28	First version
1.1	2017.03.27	Starstim R update
2.1	2018.04.25	Added electromagnetic compatibility information
2.2	2018.06.15	Updated safety and battery information Updated labelling
2.3	2019.05.27	Added section on channel mapping for user-defined montages Extended information on Necbox and cap assembly
2.4	2019.06.27	Updated component images

Table of Contents

I. Use of Starstim

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

Starstim 20/32 is a modern Brain Stimulation and EEG device:

- It allows for cable and wireless data transmission options
- 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
- Custom waveforms can be used in stimulation protocols
- It features hybrid electrodes that can be used for EEG and 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 [1]. 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 safety of the technique has been stablished in the last few years when used within the stablished bounds of intensity, density and duration[1]. Nevertheles, its application must always be controlled and monitored by specialized medical professionals.

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

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 in DC current. In general, current injected into the brain (anodal stimulation) over a cortical region leads to excitatory effects; and collecting current from the brain (cathodal stimulation) leads to inhibitory effects. tDCS produces short term effects on neuronal excitability, and long lasting plastic after/effects involving synaptical modifications [1].

Transcranial Alternating Current Stimulation (tACS)

tACS is a form of tCS in which the stimulation currents are time dependent with a sinusoidal shape, like in 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 [1].

I.2
Intended Use

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 is little experience with it. However, it appears as if its main effect are excitatory. The lower and upper values of the band [1] frequency of the stimulation signal can be chosen between 0 and 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 is a neurostimulator device also capable of recording EEG. Starstim 20 and Starstim 32 have been designed for research use only.

Starstim 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 Commitee, IRB or analogous Body must be required for the experimental use of this device.

(1) Evidence-based guidelines on the therapeutic use of transcranial direct current stimulation (tDCS). Jean-Pascal Lefaucheur et al. Clinical Neurophysiology 128 (2017) 56–92

I.3
Conditions of Use

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

- Temperature Range: +5 to 60 °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: -20 to +65 °C
- Humidity: 15 - 93 %

The equipment does not require installation.

II. Quality and Regulatory Information

II.1
Quality Management System

Neuroelectrics is an ISO 13485 :2016 + AC:2017 certified company. Thus, our medical devices are designed and manufactured following the corresponding ISO quality management system.

Neuroelectrics complies with Quality System Regulation 21 CFR 820.

II.2
Medical Device Regulations

In Europe and Canada, both Starstim R20 and Starstim R32 are research use only devices.

II.3
For US Audience only

US Federal Law classifies Starstim as an Investigational Device.

III. Safety Information

Starstim R20 and R32:

Electrical Safety

- UNE-EN 60601-1:2008 + Err.:2008 + Corr.:2010
- UNE-EN 60601-2-26:2015
- UNE-EN 60601-1-11:2015
- UNE-EN 60601-1-6:2010 + A1:2015
- UNE-EN 60601-1-11:2015
- UNE-EN60601-1-2:2015
- IEC 60601-1:2005 + Corr.1:2006 + Corr.2:2007

Electromagnetic Compatibility

- UNE-EN 60601-1-2:2008 + Corr.:2010
- EN 60601-1-2:2007/AC:2010
- IEC 60601-1-2:2007

Emission

- UNE-EN 55011:2016 + A1:2017

Conducted Emission
Radiated Emission
Immunity

- UNE-EN 61000-4-2:2010
- UNE-EN 61000-4-3:2007+A1:2008+A2:2011
- UNE-EN 61000-4-8:2011
- UNE-EN 61000-4-4:20138
- UNE-EN 61000-4-5:2015 + A1:2018
- UNE-EN 61000-4-6:2014
- UNE-EN 61000-4-11:2005 + A1:2017

Medical device software life-cycle

- UNE-EN 62304:2007 + A1:2016

Biological evaluation:

- UNE-EN ISO 10993-1:2010
- EN ISO 10993-1:2009/AC:2010
- ISO 10993-1:2009

Usability

- UNE-EN 62366-1:2015/AC: 2015

Other

- UNE-EN 980:2008
- UNE-EN 1041: 2009
- UNE-ENE ISO 14971:2012
- 2011/65/EU

III.1
Safety Warnings

- Brain stimulation must be used AFTER the prescription of a stimulation protocol made by specialized and qualified medical research personnel who own and operate the Starstim software.
- Before 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 not damaged 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, manipulated or damaged.
- The battery can only be replaced by authorized personnel after contacting the manufacturer.
- The device is splash-proof but not water-proof or water-resistant. In the event that the device becomes wet or damp, avoid using it and contact the manufacturer immediately.
- 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. In case of a loss of communication with NIC or a software or system crash, always dissconnect the electrode cables before switching off the device.
- Always unplug the HDMI 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 mm^2 to avoid high current densities.
- During each session, it is mandatory to use reference electrodes connected to CMS and DLR cables.
- 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.
- EMC emissions and immunity have 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 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 exists 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 corrupt the signal acquisition. If NIC detects that the signal is very noisy, it will inform the user of this interference with a higher Signal Quality Index.
- Modification of the device is not allowed.
- If the device has not been used during a long period of time, the user must 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 could accidentally strangle themself in the cables of the device.
- The result of the recordings must be analysed by a doctor or specialist. No self assesment or decission to self-medicate should be made based on the data recorded.
- 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 fails, 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 is a communication problem at some point, the device will save the data in the internal buffer to ensure that no EEG samples are lost.
- Do not use in emergency rooms or other hospital-like environments where there are police, firefighters or any personnel with radio transmitters.

IV. The Starstim System

In this chapter, the components that make the Starstim system are described with a focus on the Neuroelectrics Control Box (Necbox) which is the control unit of the system. 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 lab
- User-friendly software interface
- Stimulation waveforms: tDCS, tACS, tRNS or customized
- 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 20 (NE012S 20) or 32 (NE012S 32) 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) 20 or 32 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: 1%
- Maximum voltage: ± 15V per electrode (allows 30 V of stimulation potential difference)

Stimulation safety features

- Maximum input current per channel: 2 mA
- Maximum total injected 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

IV.2
Technical Specifications

Other Technical Specifications

- Battery operating time:
  4 hours using Wi-Fi (combined EEG/tCS use)
  4 hours using USB
  (combined EEG/tCS use)
- Accelerometer: 3-axis
- Communication: Wi-Fi/USB
- 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 Compatibility:
  Windows Vista, 7, 8, 10, or
  MAC OS X Snow Leopard
- Processor: 1.6 GHz
- RAM: 2 GB
- Wi-Fi or USB port

Wireless Information

Starstim is a wireless device. The Necbox connects via Wi-Fi or USB to the Neuroelectrics Instrument Controller (NIC) software running on a computer. The EEG data is streamed through the standard Wi-Fi band, and the standard Wi-Fi operating distance range is 10 meters. Starstim complies with Part 15 of the FCC Rules and it is in conformity with the essential requirements and other relevant requirements of the R&TTE Directive (1999/5/EC).

On the list below, you may find the technical specifications regarding the wireless connection used by Necbox.

- Operating frequency range:
  (2412 ~ 2472) MHz
- Transmission power:
  Min: +14 ~ +15.6 dBm
  Max: +16 ~ +17.6 dBm
- Protocol: Wi-Fi TCP
- Security details: Wi-Fi standard

IV.3

Contents of the Starstim package

The 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. 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.

Quantity	Code	Name
1	NE012S 20/32	Starstim R20/32 Necbox
1	NE055	Power Adapter & Plug
1	NE014	Curved Syringe
1	NE015	USB Stick with Manuals & SW
1	NE016b	Electrode Gel 250g
1	NE017_R20/32	Electrode Cable Set R20/32
1	NE031b	USB WiFi Dongle
1	NE033	Saline Solution 100ml
1	NE038SS32	Testboard Head Starstim 32
4	NE039	Testboard Cable

Quantity	Code	Name
1	NE056M	Headcap R (M)
1	NE164	USB Cable & Isolator
50	NE025a	Electrode: Sticktrode
4	NE026a	Electrode: Sponstim 25
8	NE026b	Electrode: Sponstim 8
20 / 32	NE032	Electrode: NG Geltrode
20 / 32	NE029	Electrode: NG Pistim
1	NE027	Electrode: Earclip

The electrodes included with the kit are shown on this page. The Electrode User Manual must be read for instructions on how to use, assemble and clean the electrodes. The rest of the items contained in the package are listed and described in the next few pages.

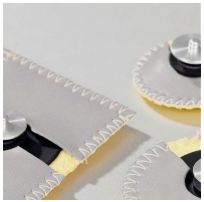
Neuroeletrics Electrodes

EEG

NG Geltrode

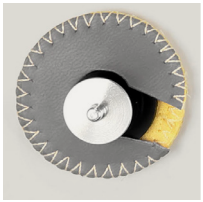
NE032

Stimulation (tCS)



Sponstim 25

NE026a



Sponstim 8

NE026b

EEG & tCS

NG Pistim

NE029

Reference

Sticktrode

NE025a

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
	**Starstim 20/32 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 charged when the device is being used.	NE012S 20/32
	**Power Adapter & Power Supply Plug** ▶ The power adapter is used to charge the Necbox battery. ▶ The power supply plug type (EU/US/UK) will be provided to be compatible in the country of intended use.	NE055 NE013a NE013b NE013c
	**Curved Syringe** ▶ The curved syringe is used to inject either electrode gel or saline solution into electrodes. ▶ Do not use electrode gel and saline solution simultaneously in the syringe. Wash and clean it when switching the fluid to be used.	NE014
	**USB Stick with Manuals & NIC SW** ▶ The USB stick contains the PDF version of the three parts of the Neuroelectrics User Manual, and the NIC software installation files. ▶ Both items can be also found at www.neuroelectrics.com.	NE015

Item	Name / Description	Code
	**Electrode Gel 250 g** ▶ The electrode gel is a highly conductive and water soluble gel. It must be applied on 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.	NE016b
	**Set of Cables Starstim 20/32** ▶ Starstim 20/32 works with four subsets of electrode cables. Each subset has several industry standard sockets compatible with the electrodes commercialized by Neuroelectrics. ▶ The channels can be connected to any electrode for EEG monitoring or for stimulation, and two reference electrodes should be assigned to CMS & DRL channels.	NE017-R20/32
	**USB WiFi Dongle** ▶ The USB Wi-Fi Dongle is used to provide a Wi-Fi port for computers that do not have an incorporated Wi-Fi port. The wireless communication between the Necbox and the computer is Wi-Fi based. The USB Wi-Fi Dongle is not compatible with Mac OS computers.	NE031b
	**Saline Solution 100 ml** ▶ The saline solution (NaCl 0.9%) is required to be used with the stimulation Sponstim electrodes. ▶ It should be applied on the yellow external face of the sponge in contact with the scalp.	NE033

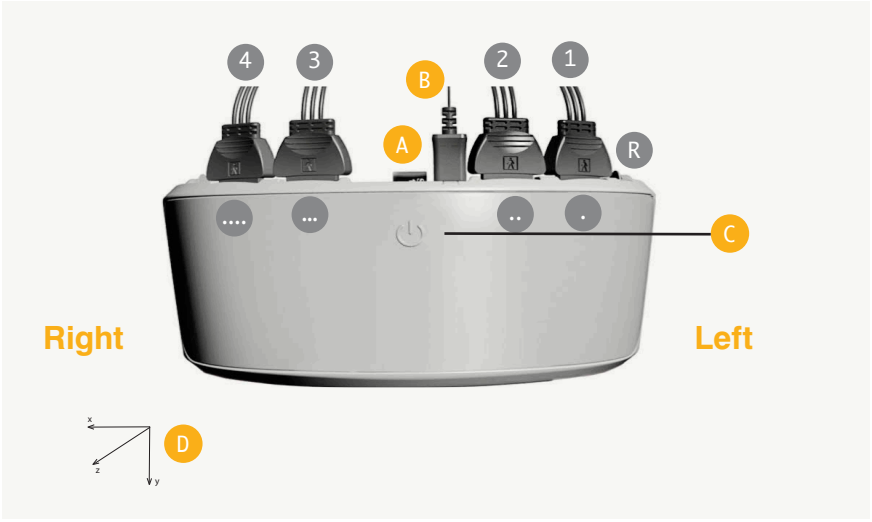
Item	Name / Description	Code
	**Headcap R (M-54 cm)** ▶ The headcap is a comfortable solution to precisely place the electrodes on the scalp based on the 10-10 system. It provides 39 possible electrode positions. The cap provided is medium sized, but other sizes are also available.	NE056-M
	**Testboard Head & Cables** ▶ The testboard alllows you to test the system functionalities and rule out potential problems before the real experiment. The Necbox is connected to the testboard using four testboard cables. 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. ▶ Read p. 28 to learn how to use the testboard.	NE038/39
	**USB Isolator & Extension Cable** ▶ The USB Isolator & Extension Cable can be used to transmit EEG and Stimulation data between the device and the computer. Always use the USB isolator together with the extension cable! ▶ See Section IV.10 to learn how to use the isolator cable.	NE164/172

IV.4
Necbox: Neuroelectrics Control Box

The Necbox is the core and the control unit of Starstim. Attached to the necbox, you can find the technical specifications label. The Necbox is a battery operated device. The following diagrams describe the interfaces of the Necbox.

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.
A microSD Card slot. Starstim 20/32 can be used in holter mode for offline data storage by using a microSD card.

B microHDMI connection. The microHDMI connection is used (1) to connect the power adapter to charge the device, and (2) to connect the isolator cable for non-wireless data transmission. The charging led yellow when charging; green when charged.

IV.5
Assembling the Necbox and cables

C Power button. By pressing the power button, the device is switched on/off.

D Accelerometer axes. The tri-dimensional axes (x, y, z) of the accelerometer embedded in Starstim 20/32 are pre-defined according to the directions shown.

The electrode cable sets (see Connectors 1, 2, 3, 4 on Page 24) and the reference cable (see Connector R on Page 24) should be connected to the correct slot of the Necbox, following the electrode positioning order:

Cable 4
Starstim 20: P3, C3, F3, F7, T7, P7
Starstim 32: P3,C3, F3, F7, FC5, CP5, T7, P7

Cable 3
Starstim 20: Pz, Oz, O2, O1
Starstim 32: PO3, O1, Oz, O2,PO4, Pz, CP1,FC1

Cable 2
Starstim 20: Fp2, Fp1, Fz, Cz
Starstim 32: AF4, Fp2, Fp1, AF3, Fz, FC2, Cz, CP2

Cable 1
Starstim 20: P8, T8, F8, F4, C4, P4
Starstim 32: P8, T8, CP6, FC6, F8, F4, C4, P4

Cable R
Starstim 20 / 32: CMS, DRL

Warning: The use of the reference cable is mandatory during every session.

IV.6
Channel Mapping for User-Defined Montages

Starstim 20

Cable Number / Necbox Slot	Label Position Name	NIC2 Channel
1 / .	P8 (left)	1
	T8	2
	F8	3
	F4	4
	C4	5
	P4 (right)	6
2 / ..	Fp2 (left)	7
	Fp1	8
	Fz	9
	Cz (right)	10
3 / ...	O1 (left)	11
	Oz	12
	O2	13
	Pz (right)	14
4 /	P3 (left)	15
	C3	16
	F3	17
	F7	18
	T7	19
	P7 (right)	20

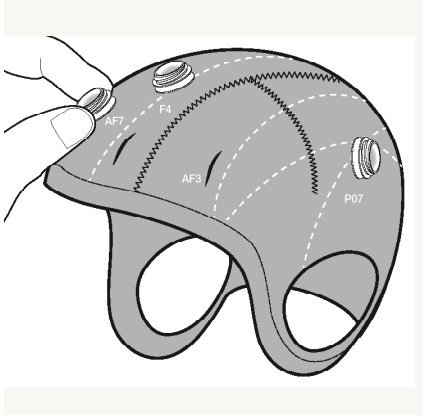
Starstim 32

Cable Number / Necbox Slot	Label Position Name	NIC2 Channel
1 / .	P8 (left)	1
	T8	2
	CP6	3
	FC6	4
	F8	5
	F4	6
	C4	7
	P4 (right)	8
2 / ..	AF4 (left)	9
	Fp2	10
	Fp1	11
	AF3	12
	Fz	13
	FC2	14
	Cz	15
	CP2 (right)	16
3 / ...	PO3 (left)	17
	O1	18
	Oz	19
	O2	20
	PO4	21
	Pz	22
	CP1	23
	FC1 (right)	24
4 /	P3 (left)	25
	C3	26
	F3	27
	F7	28
	FC5	29
	CP5	30
	T7	31
	P7 (right)	32

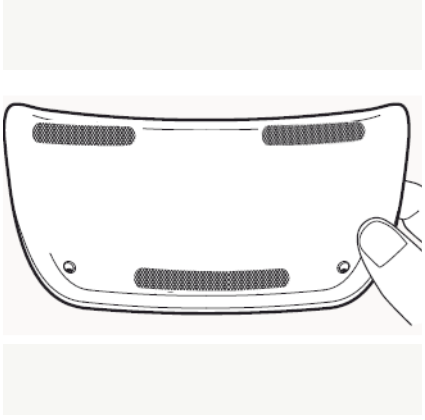
IV.7

Assembling Necbox and Cap

Headcap R should be meticulously assembled:



- Insert the electrodes in the desired positions of the cap.



- Align velcro bands in the Necbox to the velcro bands on the back of the cap.

- Place Necbox on the hindhead of the subject.

IV.8

Necbox battery

The battery can only be charged when the power switch is in the OFF position. To charge the battery, the following specifications need to be met:

- Nominal output: 3.7 V (3 V - 4.2 V)
- Battery charger: must comply according to Standard EN 60601-1:2008 + A1:2010
- 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.
- 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 life and memory is a function of time).
- 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 60° C

Electrical specifications for charging:

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

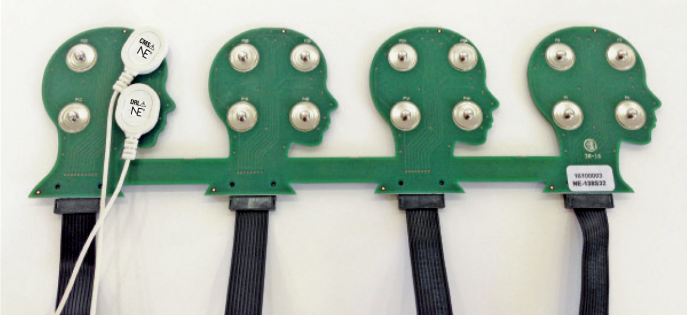
IV.9
Testboard

The testboard is used for testing stimulation protocols before conducting experiments. It is recommended to use the testboard before applying tCS 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 20/32 Necbox with 4 testboard cables, and the 2-channel reference cable:

- Connect the testboard cables from the four cable slots (see Connectors 1, 2, 3, and 4 – p. 24) of the Necbox to the four head shaped sections of the testboard.

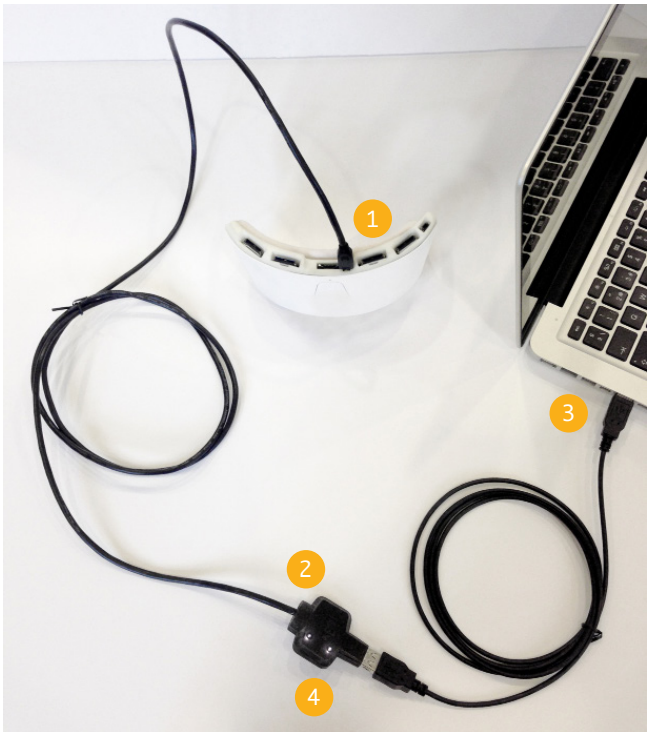


- Use the reference CMS&DRL cable to connect the reference (see Connector R – p. 24) to the testboard. The pair of channels should be connected to the section of the testboard connected to slot 1.

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 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 10µV. For further details on EEG review in Liveview, please refer to NIC User Manual.

IV.10
Cable Connection



Starstim R20/32 can be used in both wireless and wired modes. When the wired connection is chosen, it is important to make sure that the system is well assembled, for safety and efficacy purposes. Proceed as follows:

1 Connect the isolator cable to the microHDMI connection of the Necbox.

2 Connect the isolator to the female port of the USB cable.

3 Connect the USB cable to the USB port of the computer.

4 Verify that a pair of leds lights up in the isolator module.

IV.11

Cleaning Instructions of the Starstim Kit

Necbox & Electrode Cable

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

Headcap R

The Headcap R 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 UNE-EN 60601-1=2008
	IEC 60417-5007 Switch ON according to UNE-EN 60601-1=2008
	ISO 7000-2498 Serial Number according to UNE-EN 980
	Device manufacturer symbol according to UNE-EN 980
	ISO 7000-2606 do not use device if product or packaging have been damaged symbol according to UNE-EN 980
	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.
	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
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.
	General warning sign
	Refer to the manual/booklet

VI. Error Messages

The following messages might appear during normal operation:

Error message	Cause	Actions
WiFi connection lost	The computer cannot communicate with the device.	Check that the device is switched on, that the device has battery, that the computer WiFi is working properly, and the device is close to the computer.
Please switch off the device, and restart/turn on 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 UNE-EN 61000-3-2:2014	Class A	
Voltage fluctuations/flicker emissions UNE-EN 61000-3-2:2013	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) UNE-EN 61000-4-2:2010	+- 8 kV contact	+- 8 kV contact
	+- 15 kV air	+- 15 kV air
Electrical fast transient/burst UNE-EN 61000-4-4:2013	2 kV for power supply lines	2 kV for power supply lines
	1 kV for input/output lines	N/A
Surge UNE-EN 61000-4-5:2015	1 kV differential mode	1 kV differential mode
	2 kV common mode	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines UNE-EN 61000-4-11:2005	0% U; 0.5 cycles at 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º	0% U; 0.5 cycles at 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
	0% U; 1 cycle	0% U; 1 cycle
	70% U; 25 cycles single phase at 0º	70% U; 25 cycles single phase at 0º
	0% U; 250 cycles	0% U; 250 cycles
Power frequency (50/60 Hz) magnetic field UNE-EN 61000-4-8:2011	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 active 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.

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”

The only part replaceable of the Starstim are the patient cables (NE017-R20/R32).

WARNING: Use of accesories, 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.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Conducted RF UNE-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 0.15 MHz - 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF UNE-EN 61000-4-3:2007 + A1:2008 + A2:2011	UNE-EN 61000-4-3:2007 + A1:2008 + A2:2011	UNE-EN 61000-4-3:2007 + A1:2008 + A2:2011