

enobio^{NE®}

Neuroelectrics User Manual
– P1. Enobio –



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Manual Update:

Version: 2.4

Date: 2018.07.16

Brand:

Enobio

Models:

Enobio 8

Enobio 20

Enobio 32

The manufacturer should be contacted:

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



Input: 5W, 4.25 - 7 V

About the Enobio User Manual

The Enobio User Manual belongs to Part I of the Neuroelectronics User Manual.

The Neuroelectronics 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 your first use of the Enobio system, read the three parts of the Neuroelectronics User Manual. The Enobio User Manual does not discard the need of reading the Electrode and NIC parts.

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

www.neuroelectronics.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 into three parts: (1) Enobio / Starstim, (2) Electrode and (3) NIC.
2.1	2017.03.10	SGS Update
2.2	2017.07.25	Product content update
2.3	2017.08.07	CE 0120 & symbols update
2.4	2018.16.07	Product content update & safety symbols update

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I. Use of Enobio

Enobio is a wireless and portable electrophysiology sensor system for the recording of the electroencephalogram (EEG).

Enobio is a modern EEG device:

- ▶ Available with 8, 20 or 32 channels
- ▶ Wireless battery operated system
- ▶ Ideal for out-of-the-lab applications
- ▶ Offline data storage possible with microSD card
- ▶ Comfortable and precise headcap, with different head sizes available
- ▶ Flexible electrode placement with 39 possible positions based on the 10-10 system
- ▶ Capable of monitoring EOG, ECG and EMG
- ▶ Ease of use despite of the complexity of the technology



Enobio 8



Enobio 20



Enobio 32

I.1

Electroencephalography (EEG)

Electroencephalography is a non-invasive neuroimaging technique that records the electrical activity of the brain. Voltage fluctuations, that result from the ionic current within the brain neurons, are detected by electrodes placed on the scalp. The 10-20 international system defines 21 scalp positions to place the EEG electrodes. Additionally, the 10-10 system is obtained by adding electrodes in the intermediate positions. Both locations and nomenclature of the electrodes are standardized by the American Electroencephalographic Society. The EEG measurements can be either bipolar or unipolar. The former method measures the potential difference between pairs of electrodes, while the latter measures the electrode potential compared to a reference. The reference might be either the signal from one electrode or the average of the measurement from two or more electrodes.

The EEG measurements are frequently analyzed with spectral methods to define frequency bands, also known as brain waves. The five most common bands are delta (0 - 4 Hz), theta (4 - 8 Hz), alpha (8 - 13 Hz), beta (13 - 30 Hz), and gamma (30 - 50 Hz). These waveforms provide crucial information regarding brain function which is widely used to diagnose Epilepsy, sleep disorders, Coma or cerebral death. The EEG differs from other neuroimaging techniques due to its high temporal resolution. However, it is often combined with magnetic resonance imaging (MRI) or computed tomography (CT) for the diagnosis of tumors, stroke and other brain disorders whose diagnosis also requires high-spatial resolution. EEG is also used for event-related potentials (ERP's) studies, which analyze the EEG response to visual, somatosensory or auditory stimuli.

I.2

Intended Use

Enobio was created to record EEG, but it can also be used for monitoring EOG, ECG or EMG. It has been designed for use in a clinical environment, hospital, research center or home healthcare environment. Enobio use must be controlled by specialized medical personnel able to guarantee the correct recording. Enobio complies with the European legislation for medical devices. Read the Neuroelectrics User Manual carefully before using Enobio.

I.3

Applications

Brain Computer Interface (BCI)

In order to build real world BCI applications, it is essential that the subject be comfortable and behaving naturally in his typical environment. Enobio was designed with these constraints in mind, thus it may be used as a platform for the development of BCI applications away from the lab. Possible BCI paradigms include Motor Imagery ERD, SSVEP and P300 among others. Currently, Enobio is being used by many researchers and it is compatible with BCI software systems such as BCI2000, OpenVibe, PureData and Processing.

Basic electrophysiological research

Enobio offers an advantage in any scenario in which electrophysiological data is difficult to obtain in a natural way. Spontaneous EEG or ERP's on the go are possible with Enobio due to the absence of long wires.

Medical application development

Enobio is the ideal platform for when large amounts of data need to be collected from several subjects in natural environments in order to develop medical applications. It may be used anywhere, by anyone, and as often as necessary, to quickly and reliably, acquire medical data. Data integrity, versatility and ease of use are the keys to the development of medical applications. NIC software and the Nube Cloud Service provide the means to achieve them efficiently. Clinical applications include sleep monitoring and Epilepsy.

I.3 Applications

Neuromodulation

EEG neuromodulation is the process of modifying brain state via feedback-based training. By visualizing the brain activity, the user can learn to modify it. Recent work provides evidence for the use of neuromodulatory therapy in the treatment of a variety of disorders. This can be achieved by combining Enobio with the Neurosurfer - the Neuroelectrics neurofeedback software tool. Neurosurfer integrates EEG data, brain stimulation, and an immersive virtual reality game, all into one platform.

User affective state

User emotional state can be derived from physiological signals like EEG and ECG. Enobio provides a platform for research and development in affective computing and smart systems.

Biometry

Enobio can be used as a physiological biometry platform to authenticate users based on EEG and ECG signatures. Physiological biometric techniques are naturally robust against spoofing attacks and can provide user state information while authentication takes place.

I.4 Conditions of Use

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

- ▶ Temperature Range: +5 to 45 °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.

II.2 Medical Device Regulations

Neuroelectrics Enobio is a class IIa device according to the classification in the Council Directive 93/42/CEE for medical devices.

Enobio conforms to the following Standards and Directives:

USA

Certified for FDA, regulation 21 CFR 820

Europe

Directive 93/42/CEE for medical devices

Canada

Canadian Medical Device Regulations
SOR/98-282

III. Safety Information

Enobio conforms to the following standards:

- ▶ EN 60601-1:2006/A1:2013
- ▶ UNE-EN 60601-1-2:2008
- ▶ UNE-EN 60601-2-26:2004
- ▶ IEC 60601-1-11:2010
- ▶ EN 980:2008
- ▶ EN 1041:2008
- ▶ EN ISO 14971:2012
- ▶ IEC 60601-1-6:2010

III.1

Safety Warnings

- ⚠ The result of the recordings must be analyzed by a doctor or a specialist. No self medication should be done based on the results.
- ⚠ The device must never be opened or damaged.
- ⚠ The battery can only be replaced by authorized personnel.
- ⚠ Before using, please check that the device is not damaged and the packaging has not been affected by transport or storage.
- ⚠ Before using the device, please inform the prescribing clinician or operator of the presence of any pacemakers, intracranial electrodes, implanted defibrillators, cranial pathologies (e.g. holes, plaques), implantable neurostimulators, deep brain stimulators, or any other prosthesis'. In these cases, the use of the device could become unsafe.
- ⚠ In the case of malfunction, immediately contact the manufacturer or the distributor.
- ⚠ 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 while EEG monitoring is on.
- ⚠ 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.
- ⚠ 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.
- ⚠ The device must be used only with Ag/AgCl electrodes recommended by the manufacturer.
- ⚠ The device is not protected against other high frequency devices. To avoid risks place the CMS/DRL as far as possible from the electrodes of the high frequency device.
- ⚠ The device is wireless and can 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 have been tested using the 10-wire and 12-wire 34 cm cables provided with the system.
- ⚠ The device can only be used on healthy skin without wounds.

-
- ⚠ 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 in the 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 with another device connected to the patient, the user should contact Neuroelectrics to check the correct simultaneous use.
 - ⚠ 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 device cannot be used beside or put under other equipment. If such usage is needed, check the normal configuration.
- ⚠ 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.
- ⚠ Enobio should not be used in an MRI room or close to CT, diathermy, RFID and electromagnetic security systems such as metal detectors. Some of these RF emitters (e.g. RFID) may not be visible and the device can potentially be exposed to fields from these RF emitters without the user's awareness. If any electromagnetic interference is encountered,

the user will be informed by the software with the "Packet Loss" alarm, and will indicate the user to stop the recording and move to a place without interference. In any case, the electromagnetic interference does not involve any risks to the patient, as Enobio is a non-invasive recording device that does not modify or interact with the person's brain.

- ⚠ Keep out of reach from children and anyone else who might swallow electrodes, or cause injury to themselves.
- ⚠ Keep out of reach from children and anyone else who might strangle themselves with the cables of the devices.
- ⚠ 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.

IV. The Enobio System

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

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, read the NIC User Manual. The NIC User Manual explains the steps needed to correctly perform an EEG monitoring session.

IV.1

Technical Specifications

EEG functionality

- ▶ Number of channels: 8, 20 or 32
- ▶ 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

Other Technical Specifications

- ▶ Accelerometer: 3-axis
- ▶ Communication: Bluetooth®, Wi-Fi or 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 Snow Leopard

▶ Battery operating time:

		All Channels EEG
Wi-Fi	Enobio 32	5 h 15 min
	Enobio 20	5 h 20 min
	Enobio 8	6 h 23 min
USB	Enobio 32	19 h 0 min
	Enobio 20	19 h 0 min
	Enobio 8	23 h 35 min
Bluetooth	Enobio 32	11 h 15 min
	Enobio 20	11 h 55 min
	Enobio 8	13 h 55 min

*SD card recording will reduce slightly these values

Minimum Computer Requirements

- ▶ Operating System: Windows Vista or MAC OS X Snow Leopard
- ▶ Processor: 1.6 GHz
- ▶ RAM: 2 GB
- ▶ Bluetooth®, Wi-Fi, or USB

Wireless Information

Enobio is a wireless device. The Necbox connects through Bluetooth® or Wi-Fi to the Neuroelectronics Instrument Controller (NIC) software running on a computer. The EEG data is streamed through Wi-Fi or the standard Bluetooth® ISM band, which has an operating distance range of 10 meters. On the list below, you will find the technical specifications regarding the wireless bluetooth connection used by Necbox.

- ▶ Operating frequency range: (2400 ~ 2483.5) MHz
- ▶ Transmission power:
Min: -11 ~ -9 dBm
Max: +1 ~ +3 dBm
- ▶ RF frequency scheme: 2402 MHz ~ 2480 MHz;
 $f = 2402 + k$, $k = 0.78$
- ▶ Modulation:GFSK (1 Mbps)
P/4 DQPSK (2Mbps)
- ▶ Data Rate: 12 - 48 KBps

IV.2





Contents of the Enobio package





The Enobio package contains all the components required to perform an EEG monitoring session, and some additional items that may be useful during your experiments. In the following pages, you may find a description for each item. Please note that the necbox code, the number of electrodes, and the electrode





cables vary among the three models: Enobio 8 (EN8), Enobio 20 (EN20), and Enobio 32 (EN32).





Quantity	Code	Name
1	NE010/ NE010WF NE002/ NE002WF NE009/ NE 009WF	Enobio 8/20/32 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
0 / 1 / 1	NE018a	10 Electrode Cable EN 20/EN32
0 / 1 / 1	NE018b	12 Electrode Cable EN20/EN32
0 / 0 / 1	NE018c	12 Electrode Cable EN32

Quantity	Code	Name
1	NE019-M	Neoprene Headcap M (54cm)
8 / 25 / 40	NE022	Electrode: Geltrode
50 / 50 / 50	NE025	Electrode: Sticktrode
1	NE027	Electrode: Earclip
1	NE031a	USB Bluetooth Dongle
1	NE043	USB Charging Cable
1	NE164	USB Isolator Cable
1	NE172	USB Extension Cable
1	NE031b	USB Wi-Fi Dongle

Item	Name / Description	Code
	<p>Enobio Necbox (8ch/20ch/32ch)</p> <ul style="list-style-type: none"> ▶ The Enobio Neuroelectrics Control Box (Necbox) is the core of the Enobio 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 during a stimulation session or an EEG recording. 	<p>NE010 NE010WF NE002 NE002WF NE009 NE009WF</p>
	<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. 	<p>NE013 NE013a NE013b NE013c NE055</p>
	<p>Curved Syringe</p> <ul style="list-style-type: none"> ▶ The curved syringe is used to inject electrode gel in the electrodes. ▶ Wash and clean it after each use. 	<p>NE014</p>
	<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 Neuroelectrics User Manual, and the NIC software. ▶ Both items can be also found at www.neuroelectrics.com. 	<p>NE015</p>

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. 	NE016a
	<p>10 Electrode Cable</p> <ul style="list-style-type: none"> ▶ The 10 electrode cable contains 8 channels, numbered from 1 to 8, for EEG monitoring, and two reference channels labelled with CMS & DRL. It is included with Enobio 8, Enobio 20 and Enobio 32. It allows the channels to be freely assigned to any position of the headcap. 	NE017
	<p>10 Electrode Cable EN20/EN32</p> <ul style="list-style-type: none"> ▶ This cable is included with Enobio 20 and Enobio 32, and is used together with NE018b. ▶ Its 10 cable connections are labelled with the positions: ▶ P7, P4, Cz, Pz, P3, P8, O1, O2, CMS & DRL 	NE018a
	<p>12 Electrode Cable EN20/EN32</p> <ul style="list-style-type: none"> ▶ This cable is included with Enobio 20 and Enobio 32, and is used together with NE018a. ▶ Its 12 cable connections are labelled with the positions: ▶ F7, T7, Fp1, F3, C3, Fz, Fp2, F4, C4, F8, T8, and EXT (EN20) or Oz (EN32). 	NE018b

Item	Name / Description	Code
	<p>12 Electrode Cable EN32</p> <ul style="list-style-type: none"> ▶ This cable is included only with Enobio 32, and it is used together with NE018a and NEO18b. ▶ Its 12 cable connections are labelled with the positions: ▶ PO3, AF3, FC5, FC1, CP5, CP1, CP2, CP6, AF4, FC2, FC6, PO4 	NE018c
	<p>Neoprene Headcap M (54cm)</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
	<p>Geltrode</p> <ul style="list-style-type: none"> ▶ The Geltrode is the traditional EEG electrode that can be used in areas with or without hair. It requires the application of electrode gel. <p>Read the Electrode User Manual before using the Geltrode.</p>	NE022
	<p>Sticktrode</p> <ul style="list-style-type: none"> ▶ The sticktrode is a pre-gelled adhesive electrode used for the CMS & DRL reference channels. It can be also used to monitor ECG or EOG. It does not require the application of electrode gel. <p>Read the Electrode User Manual before using the sticktrode.</p>	NE025

Item	Name / Description	Code
	<p>Earclip</p> <ul style="list-style-type: none"> ▶ The Earclip is an easy-to-use alternative to the sticktrode. It is a dual reference electrode because it is used to connect the two reference channels, CMS and DRL, to the same earlobe. The application of electrode gel is highly recommended. <p>Read the Electrode User Manual before using the earclip.</p>	NE027
	<p>USB Bluetooth Dongle or USB Wi-Fi 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>USB Charging Cable</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
	<p>USB Isolator and Extension Cable</p> <ul style="list-style-type: none"> ▶ The USB Isolator and Extension Cable can be used to transmit EEG and stimulation data between the device and computer. 	NE043 NE164

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

In our catalog and on our webpage, you will find:

- ▶ Different sizes of the neoprene headcap:
XL, L, M, S, Kids (K) and Kids Small (KS)
- ▶ The neoprene punch tool:
Customize your own neoprene cap!
- ▶ “Mickey Mouse” Headcap Cover:
Provide kids a funny EEG experience
- ▶ Dry electrodes for EEG monitoring:
For fast and gel-free EEG experiments

These items are available upon request.
Please contact our sales team to learn more.

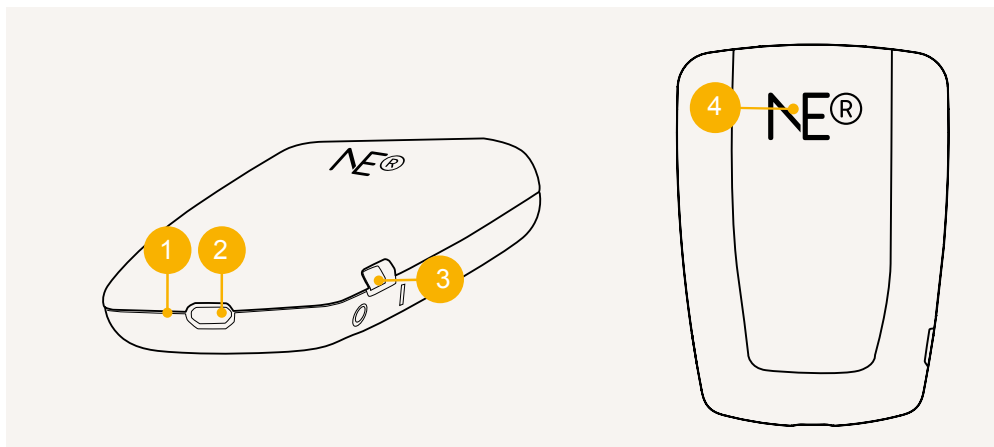


Mouse Headcap Cover

IV.3

Necbox: Neuroelectrics Control Box

The Necbox is the core and the control unit of Enobio. 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

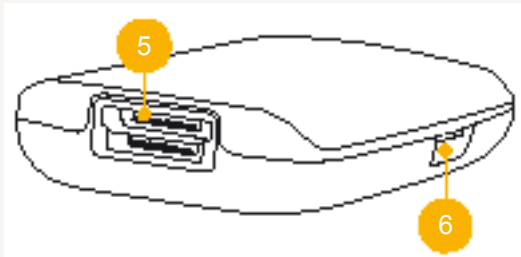
To charge the Necbox battery either using the power adapter or the USB charging cable. The USB charging cable is an alternative to the usb power adapter & power supply plug. It allows the necbox to be charged by connecting it to the computer.

3. ON/OFF Power Switch

O indicates OFF position and allows battery charging;
I indicates ON position (no charging possible).

4. Operation LED

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

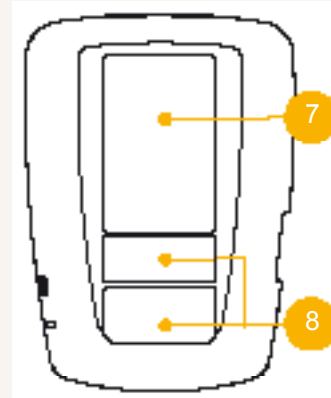


5 Pin connector slots

The number of slots depends on the number of the channels of the Enobio (see next page).

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.4

Assembling the Necbox and the electrode cables

First, the Necbox is attached to the neoprene cap using the velcro. Secondly, the Necbox should be connected to the electrode cable(s). The cables are inserted in the pin connector slots of the Necbox as described in the diagram below:

▶ **Enobio 8**

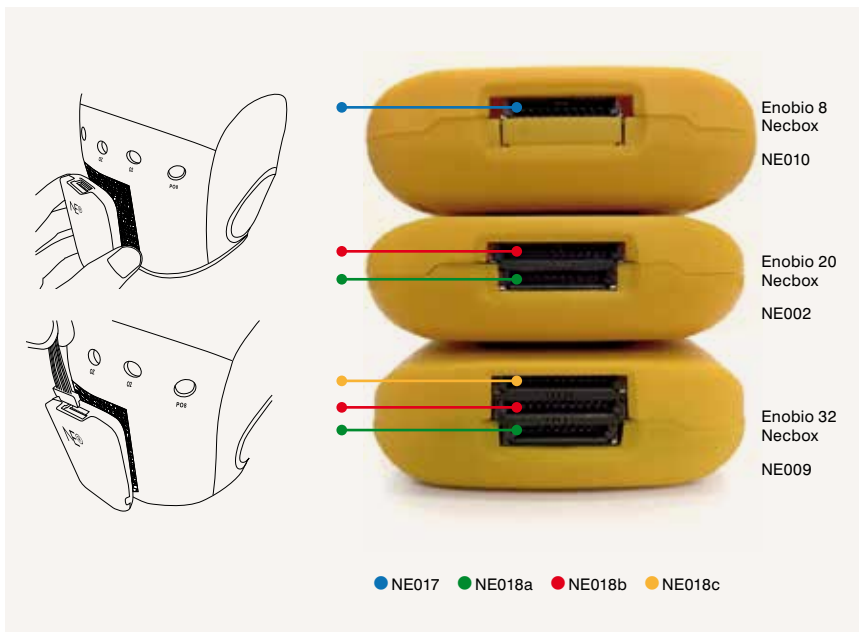
Only electrode cable ● NE017, should be connected to the Necbox using the only available slot (blue).

▶ **Enobio 20**

The pair of cables ● NE018a and ● NE018b that must be connected to the green and red slots, respectively.

▶ **Enobio 32**

Similarly to Enobio 20, but the cable ● NE018c is added and connected to the orange slot.



Enobio 20 and Enobio 32 may be alternatively used as an Enobio 8. In this case, the cable ● NE017 is the only cable that should be used, and it must be connected to the green slot while the remaining slots must be left empty.

IV.5

Necbox battery

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

- ▶ Nominal output: 5V (4.25V - 7V)
- ▶ Current output: 1A
- ▶ Battery charger:
must comply according to Standard IEC-EN 60601-1
- ▶ The battery state of charge is measured by NIC when the device is powered 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:
> 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

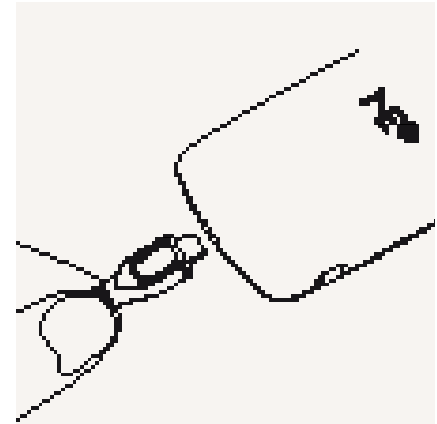
- ▶ Charging: 0°C to 45°C
- ▶ Discharging: -20°C to 60°C

Storage Temperature

- ▶ 1 year at -20°C to 35°C

Electrical Specifications for charging:

- ▶ Voltage nominal input: 5 V DC
- ▶ Voltage input min/max: 4.25 V - 7 V
- ▶ Power input: 5 W



IV.6

Cleaning Instructions of the Enobio Kit

Necbox & Electrode Cable

The Enobio 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 off the gel with warm tap water and ivory soap
- ▶ Dry the cap carefully using a 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	Symbol	Description
	Refer to the manual/booklet		ISO 7000-0632 Transport and storage temperature conditions
	General warning sign		ISO 7000-2620 Transport and storage humidity conditions
	IEC 60417-5008 Switch OFF according to UNE-EN 60601-1=2008		ISO 7000-2621 Transport and storage atmospheric pressure conditions
	IEC 60417-5007 Switch ON according to UNE-EN 60601-1=2008		This medical device is protected from objects not greater than 12 mm in diameter and protected from dripping water.
	ISO 7000-2498 Serial Number according to UNE-EN 980		Transport package shall be kept away from rain and in dry condition.
	Device manufacturer symbol according to UNE-EN 980		Transport package shall not be exposed to sunlight.
	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..		
	CE marked device certified by the Notified Body n. 0120 of the European Community.		
	ISO 60417-5140 Non-Ionizing Electromagnetic radiation.		

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 is communicating properly, and the device is close to the computer.
Please switch off the device, and 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 Enobio is suitable for use in the specified electromagnetic environment. The customer and/or user of the Enobio should ensure that is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The Enobio 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	Class B	The Enobio 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 IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

The Enobio image intensifier is suitable for use in the specified electromagnetic environment. The customer and/or the user of Enobio 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	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact	6 kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	8 kV air	8 kV air	
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines	2 kV for power supply lines	Main power quality should be that of a typical commercial and/or hospital environment.
	1 kV for input/output lines	N/A	
Surge IEC 61000-4-5	1 kV differential mode	1 kV differential mode	Main power quality should be that of a typical commercial and/or hospital environment.
	2 kV common mode	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U (>95% dip in U) for 0,5 cycle	< 5 % U (>95% dip in U) for 0,5 cycle	Main power quality should be that of a typical commercial and/or hospital environment. If the user of the Enobio requires continued operation during power main interruptions, it is recommended that the Enobio image intensifier be powered from an uninterruptible power supply or a battery.
	40% U (60% dip in U) for 5 cycles	40% U (60% dip in U) for 5 cycles	
	70% U (30% dip in U) for 25 cycles	70% U (30% dip in U) for 25 cycles	
	< 5 % U (>95% dip in U) for 5 sec	< 5 % U (>95% dip in U) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position the Enobio image intensifier further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.

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

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

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 50 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Enobio, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter</p> <p>Recommended Separation Distance $d=1,2\sqrt{P}$ $d=1,2\sqrt{P}$ 80 MHz to 800 MHz $d=2,3\sqrt{P}$ 800 MHz to 2,5 GHz</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 1 GHz	<p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the Enobio is used exceeds the applicable RF compliance level above, the

Enobio should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Enobio. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and

The Enobio is intended to be used in a controlled radiated RF environment. The user of the Enobio can help to prevent electromagnetic interferences keeping a minimum distance between the portable RF device (transmitter) and the Enobio as recommended below, according to the maximum output power of the communications device.

Rated Maximum Output Power of Transmitter watts	Separation distance metres		
	150 kHz to 80 MHz $d=1,2\sqrt{P}$	150 kHz to 800 MHz $d=1,2\sqrt{P}$	800 MHz to 2,5 GHz $d=2,3\sqrt{P}$
0.01	0,12	0,12	0,23
0.1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.