enobio NE®

Neuroelectrics® Enobio

Instructions for use

CE 1639

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About Enobio Instructions for Use

Before your first use of the Enobio system, read the present instructions for use and the Electrode instructions for use. The PDF version of both documents can be found under the User Manual section of Neuroelectrics webpage: https://www.neuroelectrics.com/resources/manuals.

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NE neuroelectrics®

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1. Use of the device

1.1 Intended Purpose and Indications for Use

Enobio are wireless, battery-operated and portable electrophysiology sensor systems for the recording of the electroencephalogram (EEG).

Enobio are EEG portable monitoring devices of 8, 20, and 32 channels intended for the diagnosis and monitoring of brain diseases in both adult and children patients.

Enobio has been designed for use in a clinical environment, hospitals or research centers. The devices are intended to be used by trained healthcare personnel able to guarantee the correct recording.

1.2 Contraindications

Enobio should not be used on patients with pacemakers, intracranial electrodes, implanted defibrillators, cranial pathologies (e.g. holes, plaques), implantable neurostimulators, deep brain stimulators, or any other prosthesis.

1.3 Potential Side-Effects

There are no known side-effects derived from the use of this product.

1.4 Warning and Precautions

› Enobio should not be used in a Magnetic Resonance Imaging (MRI) room or close to Computed Tomography (CT), diathermy, Radio Frequency Identification Device (RFID), and electromagnetic security Systems such as metal detectors. Some of these Radio Frequency (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.

› The use of cables or electrodes other than the ones delivered with the product might produce higher EMC emissions and less EMC immunity.

› The result of the recordings must be analyzed by a doctor or a specialist. No self-medications 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 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 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 to 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 piled 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.

› 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 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.

› 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 must be used only with Ag/AgCI electrodes recommended by the manufacturer.

› 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 have been tested using the 10-wire or 12-wire 34 cm cables provided with the System.

› The device can only be used on healthy skin without wounds.

› Do not touch the device while EEG monitoring is on.

› Always unplug the 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 assembled and placed on the subject's scalp.

› 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.

2. Safety Information

Enobio has been tested for electrical safety according to the international standard IEC 60601-1 and for electromagnetic compatibility according to the international standard IEC 60601-1-2 using the following limits:

Category	Standard	Compliance Level
Radiated Emissions	EN 55011:2016/A1:2017	Group 1, Class B
Harmonic Emissions	EN 61000-3-2:2014	Class A
Voltage fluctuations/ flicker emissions	EN 61000-3-3:2013	Complies
Electrostatic Discharge (ESD)	EN 61000-4-2:2010	± 8 kV contact ± 15 kV air
Electrical fast transient/burst Immunity	EN 61000-4-4:2013	2 kV for power supply lines.
Surge Immunity	EN 61000-4-5:2015	1 kV Differential mode. 2 kV Common mode.
Radiated RF Immunity	EN 61000-4-3:2007 + A1:2008 + A2:2011	3V/m 80 MHZ - 2.7 GHz
Immunity to conducted disturbances, induced by RF fields	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

Category	Standard	Compliance Level
Voltage dips, short interruptions and voltage variations on power supply input lines	EN 61000-4-11:2005	0% U; 0.5 cycles at 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315 0% U; 1 cycle 70% U; 25 and 30 cycles single phase at 0º 0% U; 250 cycles
Proximity fields from RF wireless communications equipment	EN 61000-4-3:2007+ A1:2008 + A2:2011	See Table Below.
Power frequency magnetic field immunity	EN 61000-4-8:2011	30 A/m, 50/60 Hz at the enclosure.

Test Frequency (MHz)	Immunity Level Applied (V/m)
380 MHz - 390 MHz	27
430 MHz - 479 MHz	28
705 MHZ - 787 MHz	9
800 MHz - 960 MHz	28
1700 MHz - 1990 MHz	28
2400 MHz - 2570 MHz	28
5100 MHz - 5800 MHz	9

3. Device description

The Enobio kit contains all the components required to perform an EEG monitoring session, and some additional items that may be useful during the use of the device.

In the following pages, you may find a description for each item.

Please note that the number of electrodes and the type and number of electrode cables vary among the three models:

- **Enobio 8** (EN8)
- **Enobio 20** (EN20)
- **Enobio 32** (EN32)

3.1 Components of Enobio device

Quantity	Name	Device
1	Enobio 8/20/32 Necbox	Enobio 8/20/32
1	Power Adapter	Enobio 8/20/32
1	EU / US / UK / AU Power Supply Plug	Enobio 8/20/32
1	Curved Syringe	Enobio 8/20/32
1	NIC Software (provided on a USB Stick)	Enobio 8/20/32
1	SIGNAGEL® Electrode Gel (250g)	Enobio 8/20/32
1	10 Electrode Cable	Enobio 8/20/32
1	10 Electrode Cable EN 20/EN32	Enobio 20/32
1	12 Electrode Cable EN20/EN32	Enobio 20/32
1	12 Electrode Cable EN32	Enobio 32
1	Neoprene Headcap M (54cm)	Enobio 8/20/32
1 / **3** / **4**	Electrode: NG Geltrode (Bag of 8)	Enobio 8/20/32
1	Electrode: Kendall™ H124SG (Bag of 50)	Enobio 8/20/32
1	Electrode: Earclip (Bag of 1)	Enobio 8/20/32
1	USB Isolator	Enobio 8/20/32
1	USB Extension Cable	Enobio 8/20/32
1	USB Wi-Fi Dongle	Enobio 8/20/32

The table above lists the components of the Enobio kit. Ensure that all of them are present upon the device reception.

Enobio Necbox (8ch/20ch/32ch)

- The core of the Enobio system.
- Operated by a rechargeable battery.
- Wirelessly paired with the computer using the NIC software.

NIC Software:
(provided on a USB Stick)

- The Neuroelectrics Instrument Controller (NIC) is the software interface of the medical device
- Before use, NIC shall be installed on a computer.

10 Electrode Cable EN8

- Pluggable on the top part of the Necbox.
- Has 10 electrode medical sockets compatible with the electrodes commercialized by Neuroelectrics.
- Contains 8 channels, numbered from 1 to 8, for EEG monitoring, and two reference channels labeled with CMS & DRL.
- It allows the channels to be freely assigned to any position of the headcap.

10 Electrode Cable EN20 / EN32

- Pluggable on the top part of the Necbox.
- Optimized in length for default Enobio 20 and 32 montages.
- Has 10 electrode medical sockets compatible with the electrodes commercialized by Neuroelectrics.
- Each electrode clip has an annotation of the EEG 10-10 system position in the Enobio 20 default montage, and a small annotation of the channel number to support custom montages: Channels 1-8 (P7, P4, Cz, Pz, P3, P8, O1, O2) & reference (CMS, DRL).

12 Electrode Cable EN20 / EN32

- Pluggable on the top part of the Necbox.
- Optimized in length for default Enobio 20 and 32 montages.
- Has 12 electrode medical sockets compatible with the electrodes commercialized by Neuroelectrics.
- Each electrode clip has an annotation of the EEG 10-10 system position in the Enobio 20 default montage, and a small annotation of the channel number to support custom montages: Channels 9-19 (T8, F8, C4, F4, Fp2, Fz, C3, F3, Fp1, T7, F7) & EXT (EN20) or Oz (EN32).

12 Electrode Cable EN32

- Pluggable on the top part of the Necbox.
- Optimized in length for default Enobio 32 montages.
- Has 12 electrode medical sockets compatible with the electrodes commercialized by Neuroelectrics.
- Each electrode clip has a vivid annotation of the EEG 10-10 system position in the Enobio 20 default montage, and a small annotation of the channel number to support custom montages: Channels 21-32 (PO4, FC6, FC2, AF4, CP6, CP2, CP1, CP5, FC1, FC5, AF3, PO3).

USB Wi-Fi Dongle

- A plug-and-play USB 2.0 802.11b/g/n Wi-Fi Network Adapter.
- Allows continuous connection to your local internet or network connection by providing a dedicated Wi-Fi adapter for your Enobio device, when there is no ethernet connectivity available.

Power adapter & Power supply Plug

- Used to charge the Necbox battery.
- The type of the power supply plug (eu/uk/us/au) included in the kit depends on the country of the customer.

3.2 Accessories manufactured by Neuroelectrics®

Other models of electrodes and electrode positioners (headcaps) compatible with Enobio are available **(see Section 3.8)**.

Neoprene headcap M (54cm)

An electrode positioner system to precisely place the electrodes on the scalp.

39-position grid based on the 10-10 system.

Also available in S, L, and XL sizes.

NG Geltrode

Provides a 1.6 cm^2 circular contact area.

Based on a sintered Ag/AgCl pellet of 4 mm diameter.

Read the Electrode Instructions for Use before using the NG Geltrode.

Earclip

Dual reference electrode.

Mounted on the earlobe.

The Earclip is an easy-to-use alternative to the Kendall™ H124SG. 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.

Read the Electrode Instructions for Use before using the earclip.

USB Isolator

The USB Isolator can be used to transmit EEG data between the device and the computer.

The USB isolator should always be used with the extension cable.

Note that this cable does not charge the device.

3.3 Recommended off-the-shelf accessories

USB Extension Cable

It connects directly the USB Isolator to the standard computer's USB input

Kendall™ H124SG

The Kendall™ H124SG is a recommended pre-gelled adhesive electrode, proven to be compatible with our devices. When connected to the CMS & DRL channels, they can be used as reference electrodes. It can be also used to monitor ECG or EOG and does not require the application of electrode gel. The legal manufacturer is Cardinal Health 200, LLC.

Please consult the manufacturer's website to access the product's details.

Signagel® electrode gel (250g)

Signagel® is a recommended accessory electrolyte, proven to be compatible with our devices. It is a highly conductive and water-soluble gel. It must be applied on the contact surface, between the electrode and the scalp, in order to decrease the impedance and improve the signal quality.

The legal manufacturer is Parker Laboratories, Inc.

Curved Syringe

The 12 ml curved syringe is used to inject electrode gel in the electrodes.

The syringe is a reusable component and should be washed and cleaned after each use.

3.4 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 μV
- Measurement noise: $<$ 1 μV RMS

Other Technical Specifications

- Accelerometer: 3-axis
- Communication: Wi-Fi iEEE 802.11 g or USB (Only available for use with USB Isolator accessory cable)
- Output: EDF+ (16 bits), ASCII data files or TCP/IP raw data streaming
- Battery operating time:

Connection type	Device Model	All Channels EEG
WiFi	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

*SD card recording will increase these values slightly

Battery specifications

- Nominal output: 4.2V
- Expected life cycle: After 500 cycles $>$ 60% of initial capacity
- Operating Temperature
  - Charging: 0 °C to 40 °C
  - Discharging: 0 °C to 40 °C

Battery charger specifications

- Complies with EN 60601-1:2006 + A12:2014

Wireless Information

Enobio is a wireless device. The Necbox connects through Wi-Fi to the Neuroelectrics Instrument Controller (NIC) software running on a computer. The EEG data is streamed through the Wi-Fi band, which has an operating distance range of 10 meters or less.

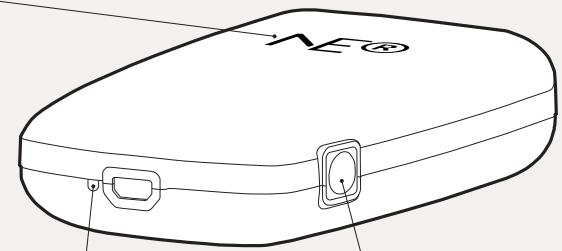
Wireless Specifications

- Wi-Fi iEEE 802.11 g
- Operating frequency band: 2412 ~ 2472 MHz
- Transmitting power Max. 16 ~+17.6 dBm
- Qualifications: CE, FCC, IC, Japan and South Korea
- Data rate: 921 kbps

3.5 Necbox detailed description

Operation LED

- **Off**: The device is off.
- **Continuous light**: The device is functioning correctly in standard operational mode.
- **Blinking with 250ms period**: The device lost connection during protocol execution and became nonoperational. To continue, it needs to be switched off and on again.



Charging LED

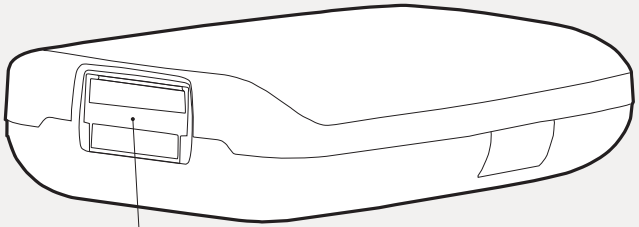
- **Off**: The charger is not connected.
- **Yellow light**: The charger is connected and the device is charging
- **Green light**: The charger is connected and the device is fully charged.

ON/OFF Push-button

- **On single push**, switches on the device while off.
- **On 2s hold**, switches off the device while on.

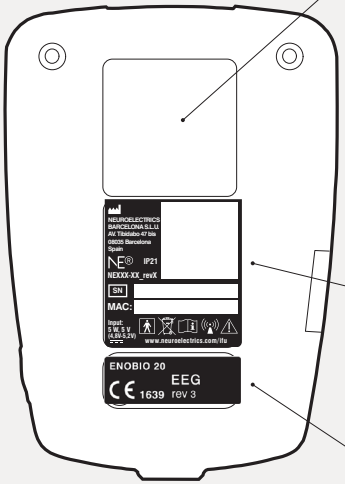
The Neuroelectrics Control Box (Necbox) is the core and the control unit of Enobio.

The Necbox is a battery operated device. It weighs 85 g and its dimensions are 87 x 61 x 24.8 mm. The following diagrams describe the details of the Necbox.



Pin connector slots

10-pin slot to connect with the electrode cable.



Velcro

To attach the Necbox to the neoprene cap.

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.

- Product name
- Regulatory mark
- Use (EEG)
- Label revision

3.6 Use and storage conditions

Use Conditions

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

- Temperature Range: +10 to 40 °C
- Humidity: 20 - 90 %
- Atmospheric Pressure: 70 - 100 kPa

Storage Conditions

The device must be stored inside the box between uses, in the following environmental conditions:

- Temperature Range: +10 to 40 °C
- Humidity: 20 - 90 %
- Atmospheric Pressure: 70 - 100 kPa

* While the device may experience the range of temperatures listed above, e.g. for short periods during shipping, battery life may be reduced when stored for more than 3 months in a temperature above +45 °C.

Lifetime

The device lifetime is 5 years.

3.7 Software description

NIC (Neuroelectrics Instruments Controller) is the software interface of the medical device. NIC is prepared for both wired and wireless connections to control the devices.

NIC2* is the second generation of the NIC software. It provides a unique graphical user interface (GUI) that simplifies the interaction with the advanced technology embedded in Enobio devices.

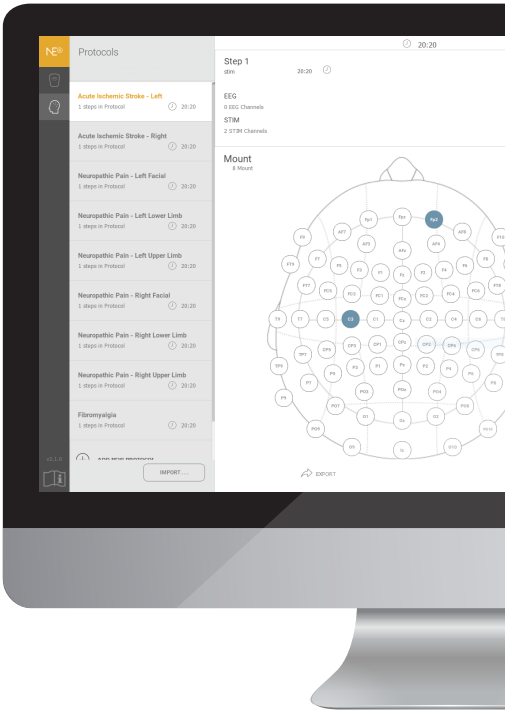
NIC2 allows EEG data to be streamed and analyzed in real-time. NIC2 is a powerful platform that is equipped with basic and advanced modes to design and monitor any experiment involving EEG

Before use, NIC2 shall be installed on the computer. For the installation guidance, see Section 4.1 Software Installation and Access.

Computer Requirements

Operating System	Windows 7/8/10/11
	MAC OS X (≥ High Sierra)
Processor	1.6 GHz
RAM	2 GB
WiFi	IEEE802.11g
USB	USB 2.0 compatible port
Screen resolution	1280 x 768
Admin account credentials	YES

Minimal computer requirements.



* Former Enobio devices (shipped until October 2014; with firmware < 1251) are not compatible with NIC2. Contact our sales team if you would like to benefit from NIC2 features.

3.8 Accessories

A number of accessories are necessary in order to set up an EEG experiment.

While Section 3.2 describes the accessories included in the Enobio kit, this section lists other types and models of accessories compatible with Enobio device and offered by Neuroelectrics®.

Electrodes

Drytrode

Ag/AgCl coated electrode.

Provides a 10-point contact surface.

It does not require the application of any type of gel between the electrode and the scalp.

Foretrode

Based on a sintered Ag/AgCl pellet of 4 mm diameter.

Provide a 0.1 cm^2 circular contact area.

Electrode positioners

Neoprene headcap Pro

Available in S, M, L, and XL sizes.

64-position grid of 10-10 EEG system positions.

Kid neoprene headcap with cover

Available in K (46cm) and KS (42cm) sizes.

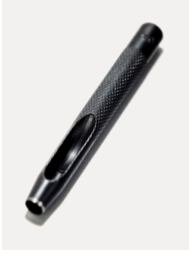
39-position grid based on the 10-10 system.

Provided with a headcap cover.

Neoprene Headband

7-position grid based on the 10-10 system.

Adjustable to different head sizes.



Neoprene punch tool

8 mm punch diameter

Allows for the creation of additional custom positions in the Neuroelectrics® Headcaps and Headband.


FC5
CP6
T8
P8
PO8
F8
AF8

4. First-time use

4.1 Software installation and access

In order to operate the device, first, you need to install and run NIC2.

For minimal computer requirements, see Section 3.7 Software description.

Obtaining NIC2 Installer

1. Connect USB Drive to your computer.
2. Go to your computer's file explorer. In USB Drive directory go to Software folder.
3. **MacOS**: Copy file *Setup_NIC2.X.X.X.dmg* and paste it to a folder on your drive.
   Windows: Copy file *Setup_NIC2.X.X.X.exe* and paste it to a folder on your drive.

Alternatively,

1. Go to https://www.neuroelectrics.com/resources/software/
2. **MacOS**: Click on the icon NIC2.X.X.X macOS
   Windows: Click on the icon NIC2.X.X.X Windows
3. Accept the terms and conditions.
4. NIC2 installer will be stored in the downloads folder set in your browser.

Installing and running NIC2

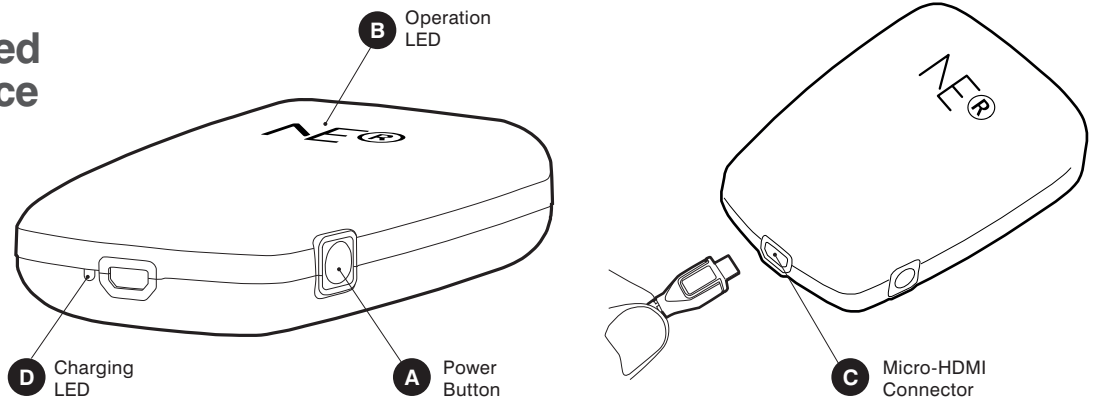
1. Double-click on the previously stored NIC2 installers:

   MacOS: A window will open containing a *Setup_NIC2.X.X.X.app* file. Double-click on it to launch the NIC installer and follow the instructions of the installation process.
   Windows: Follow the instructions of the installation process.
2. On the installer's final screen, agree to execute the software. NIC2 will open.

For Mac users

The user might need to first allow the computer to install programs from unidentified developers. For that, go to System Preferences / Security & Privacy and choose Anywhere in the Allow apps downloaded from. Administrator credentials are required to modify these settings.

4.2 Getting started with the device



Switching on the device

1. Push the power button (**A**) on the device.
2. Ensure the operation LED (**B**) in front of the device goes on.

What if the device does not switch on?

A usual reason of the device not switching on is the discharged battery. Follow these steps to charge it.

1. Take out the power adapter from the kit's packaging box and plug it to the power outlet.
2. Connect the power adapter to the micro-HDMI connector (**C**) on the device.
3. Ensure that the charging LED (**D**) goes on with the yellow light.
4. Wait until the charging LED (**D**) color goes green. You will be able to proceed with switching on the device.

Connecting to the device

Preliminary Step

If planning on using the USB cable connection option, a few steps are needed to install the USB drivers in Windows, before using NIC2. After installing NIC2, follow the instructions below:

In Windows 7, with the device switched on and connected via cable, go to the **Control Panel definitions** and select **Device Manager**. Right-click on **CDC Virtual COM** and choose **Update Driver Software**. Select the driver location as: **C:\Program Files\NeuroElectrics\ NIC2\usbdriver**. After this, you may proceed with **Step 1**.

In Windows 8, with the device switched on and connected via cable, go to **C:\Program Files\ NeuroElectrics\ NIC2\ usbdriverwin8**. Execute and install the driver **driver-atmel-bundle-7.0.888**. After this, you may proceed with **Step 1**.

In Windows 10 there is no need to install any drivers. You may immediately proceed with **Step 1**.

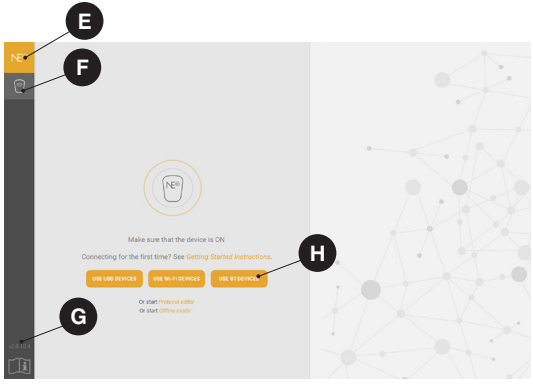
Step 1

Launch NIC2.

When launched, NIC2 displays the ***Home*** pane when launched.

In NIC2 window, the left sidebar is always visible and it contains the Neuroelectrics® icon, the unlocked NIC2 panes, and the version of NIC2 installed.

- By clicking and dragging the Neuroelectrics® icon **E**, NIC2 window can be moved.
- The Pane bar **F** shows all the active panes.
- The installed version of NIC2 is indicated in the Pane bar below the active panes **G**. Make sure you have the latest version installed to get the best of your device. The latest NIC2 version is available on the download section of Neuroelectrics website: https://www.neuroelectrics.com/resources/software

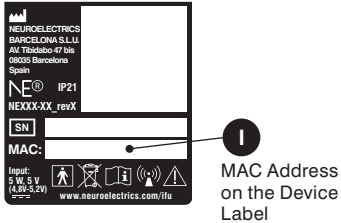


Step 2

Ensure the device is switched on by following the steps presented in Section 3.2.

Step 3

On the label placed on the back of your device, verify its unique MAC address (I).



Step 4

Choose connection type.

The first thing to do after launching NIC2 is to choose the type of connection to interact with the device. NIC2 is prepared to interact with Neuroelectrics® devices that use WiFi, USB and/or Bluetooth (BT). Select the type of connection compatible with your device (H), **(see picture in Step 1)**.

After selecting the type of connection, ***My Devices*** pane will open.

Step 5

Wait a moment until your device MAC appears on the list.

Step 6

If the device MAC did not appear, click **SCAN FOR DEVICES** (R). Repeat the scan for up to a minute until the device appears.

Step 7

Choose your device from the list (L). The ***Settings*** pane will open. Here, the general settings can be defined before pairing the device with NIC2.

› You may lock/unlock TCP connections to and from NIC2 **(see section 5.4, EEG Analysis)**, activate double blind mode, enable the synchronizer, or invert the polarity of the EEG signal for visualization (M).

Note: The synchronizer should be enabled during experiments when the timing synchronization of the device with the computer and/or other external devices is required (e.g. event-related potentials – ERPs). When enabled, the application will perform two synchronisation processes: the first is very short and is carried out before a protocol is loaded. The second is performed afterward, while the EEG is received. It prevents starting a recording until synchronisation accuracy between the Necbox and NIC2 is accurate

enough. This procedure may take a few minutes (1 -3 min).

- You may activate the line noise filter to remove main line artifacts from the EEG data (N). Choose the 50 Hz option in Europe, and the 60 Hz filter for North America. Both options affect the data visualization. If the Enable at recording button is active, the filtering is also applied to the recorded data.
- You may choose the frequencies of the visualization filter, to be applied only for EEG visualization (O).

Step 8

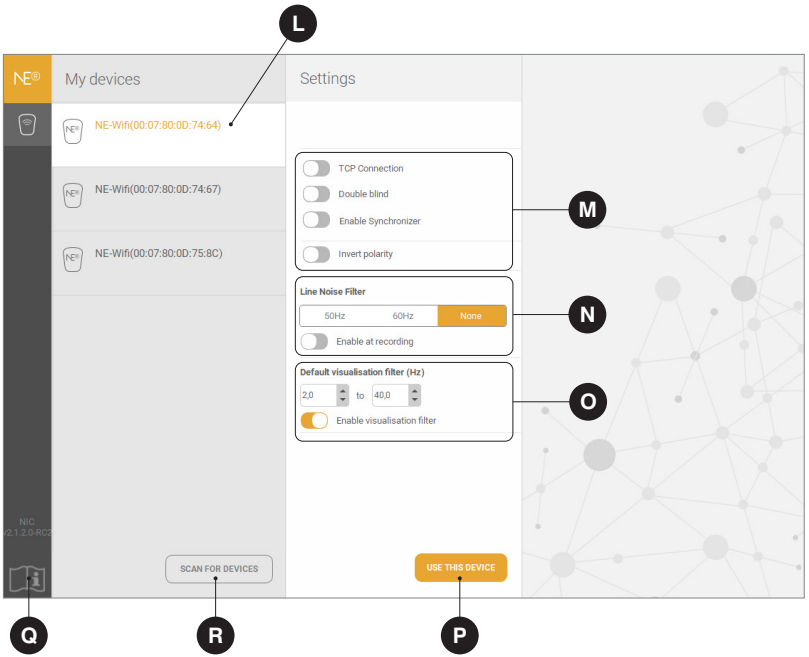
At the bottom of ***Settings*** pane, click **USE THIS DEVICE** (P). The software will establish connection with the device When paired, the button will be replaced by the **DISCONNECT** button.

When a device is successfully connected, the type of device, the firmware version, and the battery level become visible. A successful connection also lights up the LED of the device icon on the lateral pane bar. Each color of the LED has a different meaning related to the battery level:

- grey ●: device not connected
- red ●: [0 - 33] %
- orange ●: [33 - 66] %
- green ●: [66 - 100] %

Accessing the full instructions for use

On the bottom of NIC2 left menu, click the **INSTRUCTIONS FOR USE** button (Q). You will find all relevant instructions to continue your work with the device.

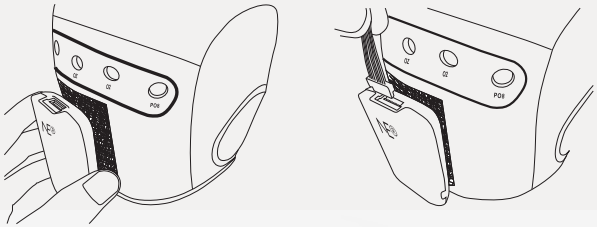


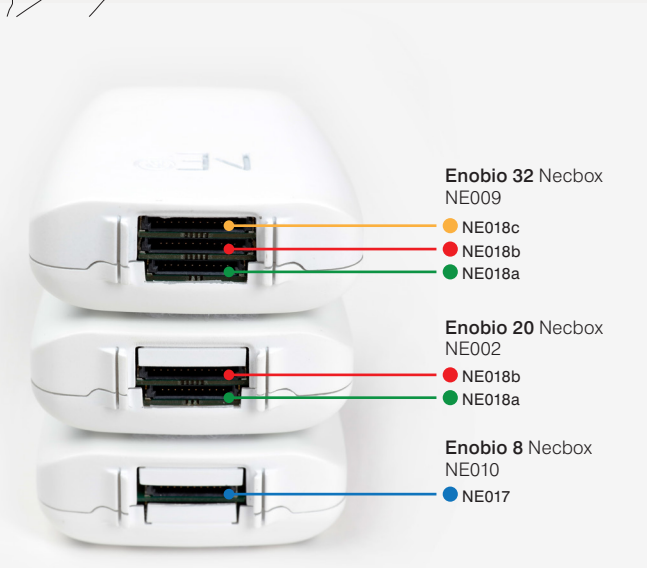
5. Use procedure

5.1 Assembling the Necbox

The Necbox is attached to the neoprene headcap accessory using headcap's velcro. It is then 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.

5.2 Specifying a protocol

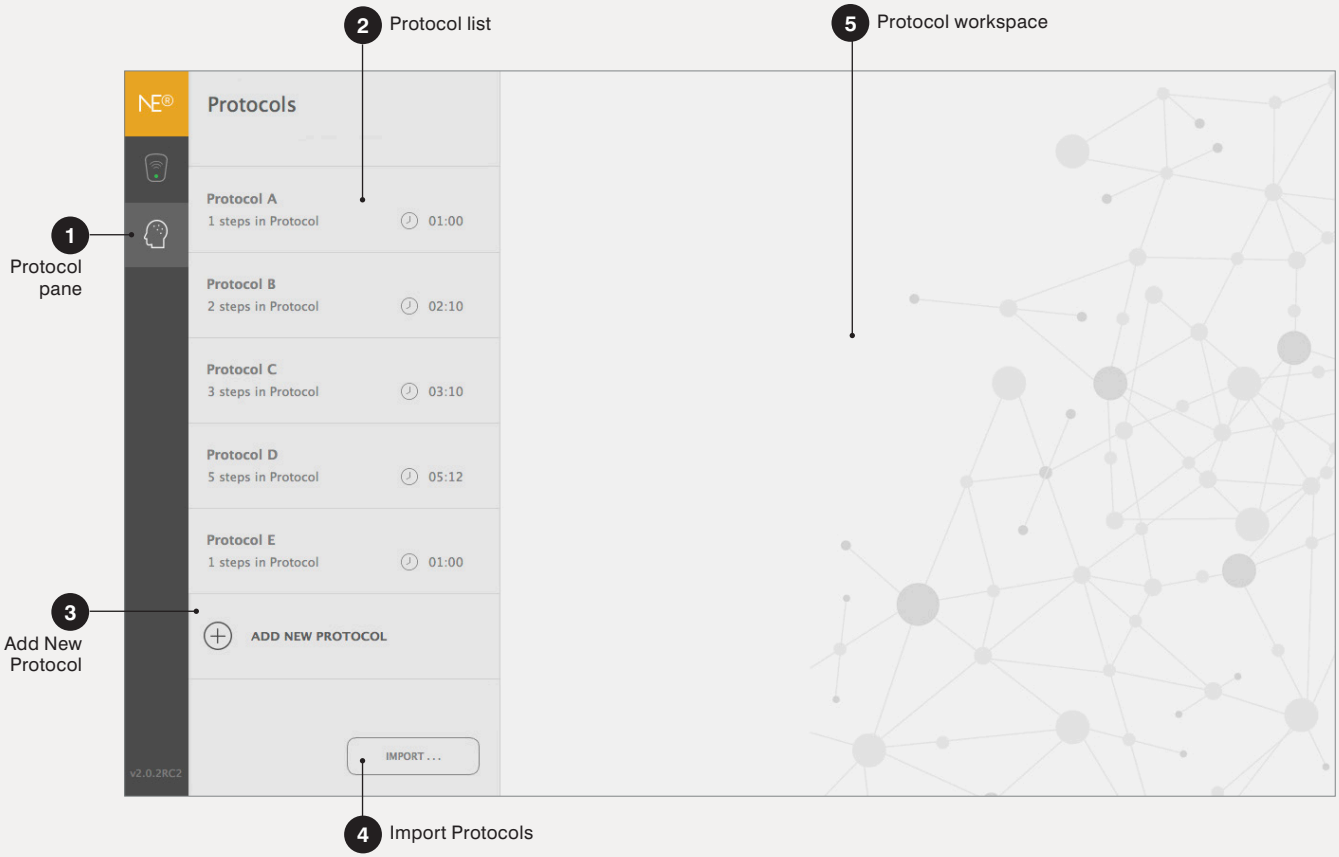
With NIC2, all the experiments are managed with the protocol structure. Each protocol corresponds to one EEG monitoring experiment, and each experiment may contain one or more steps.

The ***Protocol pane*** **(see P1. Protocol)** in NIC2 allows to manage all EEG protocols. It is a available as a second option in the software's left menu **(see P1.1)**.

The ***Protocol pane*** consists of four sections:

1. **Protocol List** **(see P1.2)**. When NIC2 is launched for the first time, there are no protocols listed. If NIC2 has been used before, it may contain previous protocols that were saved. By clicking on a specific protocol, NIC2 displays the protocol summary in ***Protocol Workspace*** on the right side of the page.
2. **Add New Protocol** **(see P1.3)**. To create a new protocol, click on the **ADD NEW PROTOCOL** button. Consult the *Protocol Design* subchapter **(see Section 5.2.1)** to read the protocol creation instructions.
3. **Import Protocols** **(see P1.4)**. NIC2 allows protocols to be imported. If a protocol is imported, any protocol with the same name will be overwritten. NIC2 is not compatible with protocols/ templates created with former NIC.
4. **Protocol Workspace** **(see P1.5)**. The Protocol Workspace is used for:
   - Protocol Design **(see Section 5.2.1)**
   - Protocol Summary **(see Section 5.2.2)**

P1. Protocols



5.2.1 Protocol design

An EEG protocol is typically a one-step protocol. Preparing the EEG protocol is a simple process. Follow the next steps to create a new protocol from scratch:

Protocol Name (see P2.1)

Start by defining the protocol name, the name should be unique. This is a case sensitive field.

Step List (optional).

Define the name **(see P2.2)** and the duration **(see P2.3)** of each step of the protocol. Note that wireless Enobio systems have a limited battery duration. Make sure the battery is charged before loading long protocols.

Multi-step protocols can be created, but the mount must be the same for all the steps of the same protocol, regardless of the function set to each channel. Steps can be copied and re-ordered using the dedicated buttons.

To introduce resting steps between steps of the same protocol, add a new step, with name and duration defined, and set no channels for EEG.

Design.

The design area allows the user to build the electrode montage.

› Define the protocol template **(see P2.4)**. With 8-channel devices, the template option is set to User defined. For 20-/32-channel devices, choose between User defined and Standard mount. The former option allows any of the 76 scalp map positions (or EOG1, EOG2, ECG and EXT) to be assigned to the channels of the device; whilst the latter locks the positions to the predefined mount of the system.

› Define the protocol mount. The ***Head Diagram*** **(see P2.5)** shows a subset of the 10-10 EEG coordinate system. The color code identifies the channels and their function/status:

- green ●: positions available with the current template/mount.
- purple ●: channels assigned to EEG during the current step.
- circled green ○: available positions that are assigned to EEG in other steps of the same protocol.
- white ○: positions unavailable in the standard mount templates.

Place the cursor above the available positions (green ●) and drag them from the ***Head Diagram*** to the ***EEG workspace*** on the right **(see P2.6)**. Alternatively, double-click on the desired position.

Make sure the selected positions become purple ●.

EOG Correction (optional, see P2.7)**.**

Enable **EOG CORRECTION** and define the ***EOG Training settings*** (i.e. EOG channels and EOG Training duration).

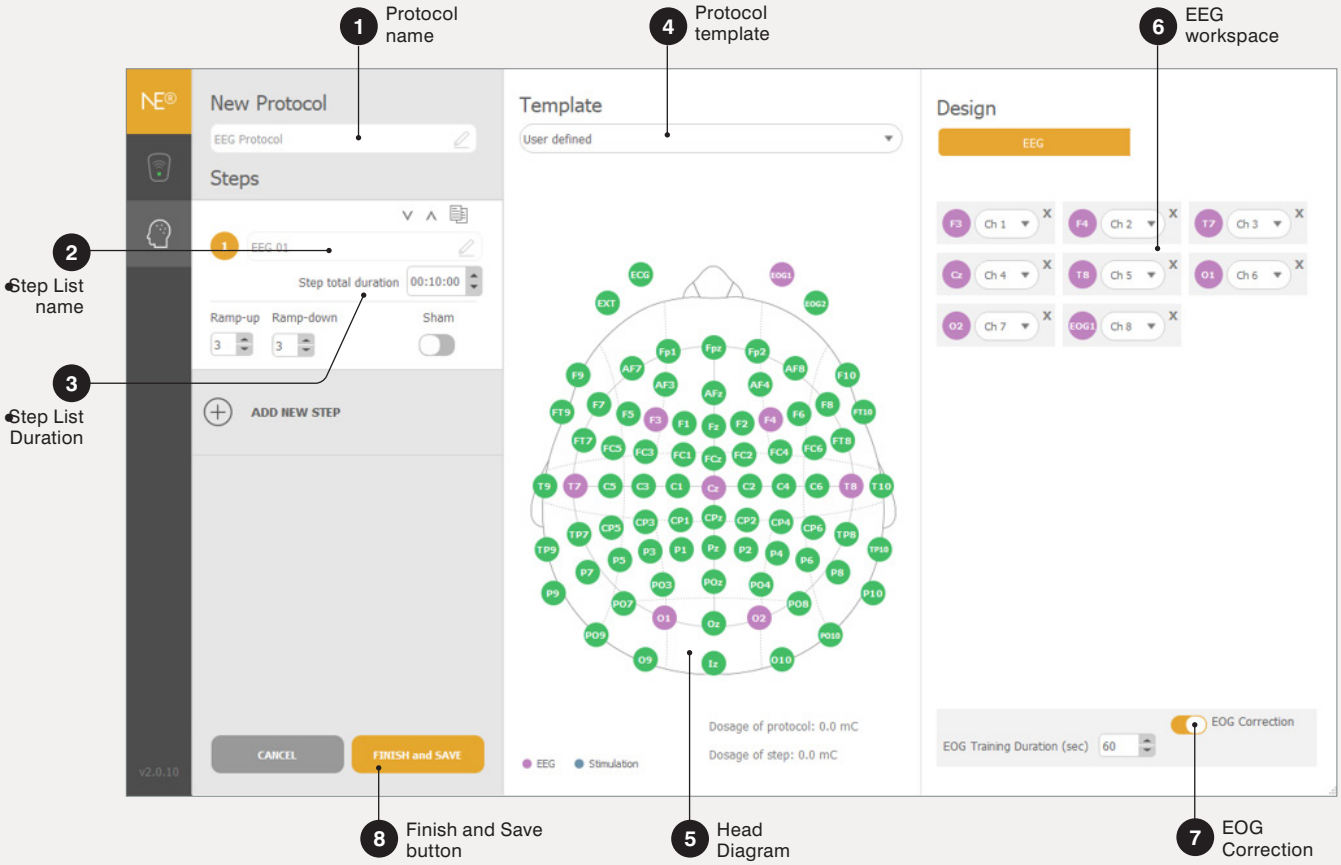
The EOG correction feature allows artifacts, associated to eye movement, to be removed from the EEG signal. The EOG correction requires one

or two channels to be assigned to the EOG function. Those channels should be associated with adhesive electrodes placed near the eye to better detect the ocular movements. To activate the EOG correction, first assign one or two channels of the mount to the EOG labels shown on the Head Diagram. Select the duration of the EOG training which corresponds to the time period during which the EOG channels learn the signals associated with the movement of the eyes. When the EEG protocol starts, the EOG training will start and, when finished, the EEG recording begins. EOG correction will be applied only during visualization.

Cancel, Finish & Save

Once all the parameters are specified as intended, click **FINISH AND SAVE** button **(see P2.8)**. Alternatively, choose **CANCEL** to leave without applying the last changes

P2. Protocol Design



5.2.2 Protocol summary

The ***Protocol*** pane gives access to the general information about each available protocol.

Protocol List

For each protocol on the list, the number of steps and total duration is presented **(see P3.1)**. Once the protocol of interest is selected, on the right side of the window, the ***Protocol Workspace*** will display its summary. Also, the copy icon becomes visible on the ***Protocol List***. By clicking on it, a new protocol is added to the list, identical to the original protocol and with "**_Copy**" appended to the name.

Protocol Sequence (see P3.2).

This section summarizes the selected protocol and briefly describes each of its steps. The top bar displays the duration of the entire protocol, and the table below contains basic data of each step: name, duration, and number of EEG channels. The setup guide diagram below refers to the step selected.

Montage Information (see P3.3).

This section contains a ***Head Map*** on the right side and ***Setup Guide*** box on the upper left side.

Head Map identifies the 10-10 position coordinate of the EEG channels used for the pre-selected step of the protocol.

To facilitate the assembly of the headset, the ***Setup Guide*** box visualizes the channel-headcap position mapping. Browse through mapping one by one using buttons available in the box. Alternatively, click on a chosen position of the ***Head Map*** in order to verify which cable shall be connected to it.

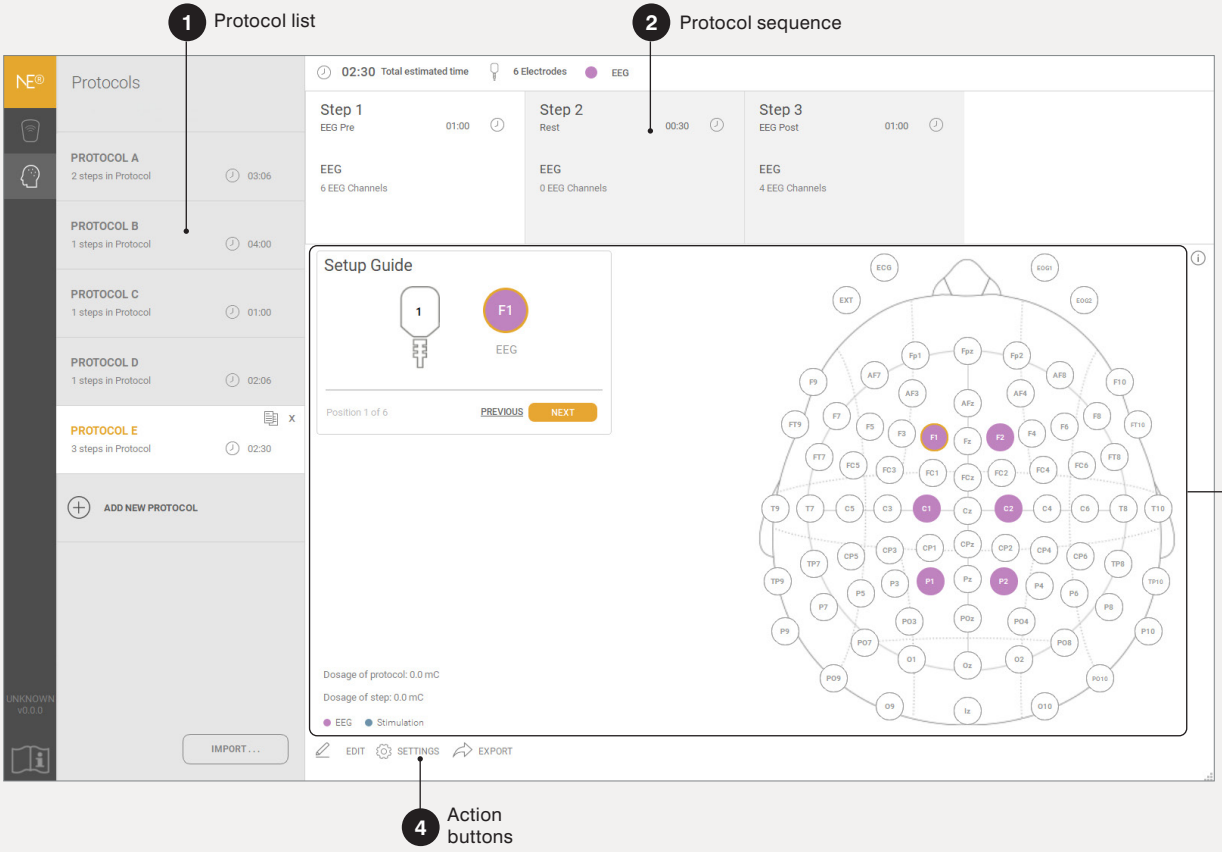
Note: In the case of multi-step protocols, if no step is selected, the head diagram will show in purple ● the positions used in the first step of the protocol. A circled white color ○ code will identify channel positions employed in other steps of the protocol.

Action Buttons (see P3.4)

Three actions can be performed regarding the selected protocol:

- Edit: redirects the user to the ***Protocol Design*** **(see Section 5.2.1)** so the protocol can be modified.
- Settings: general settings regarding the file format, markers and data streaming can be defined **(see Section 5.2.3)**.
- Export: the user may export the protocol data to a ***.txt** file.
- Load Protocol **(see Section 5.3)**.

P3. Protocol summary



5.2.3
Protocol settings

The *protocol settings* are defined for all protocols and they are applied to all their steps.

File formats & Directory (see P4.1)

NIC2 allows five types of file to be saved:

- ***.nedf**: binary file with an ***.xml** header.
- ***.easy**: ASCII file saved during EEG recording.
- ***.edf**: The EDF extension stands for the European Data Format (EDF). The EDF+ is the standard binary file format for EEG data.
- ***.sdeeg**: binary EEG file stored in the SD card during offline recording.

The user may choose which file types to be recorded. More information about the NIC files can be found in **Section 5.6**. Then they should specify the path in the directory where those files should be saved.

Note: The ***.nedf** file format has 24-bit resolution, while the ***.edf** format has 16-bit resolution. The DC component is filtered when ***.edf** files are created.

Markers (see P4.2)

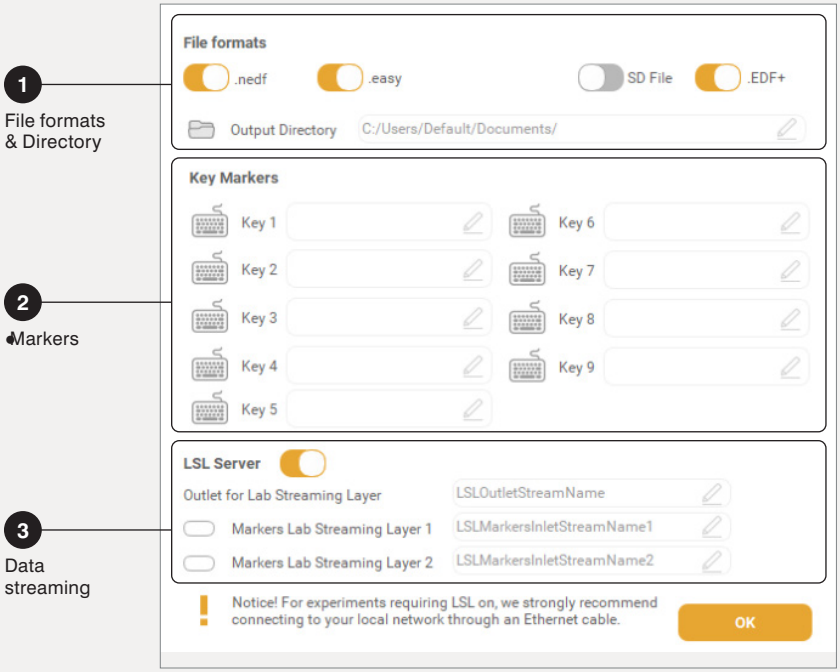
Up to 9 markers can be assigned to the keys 1 to 9 of the keyboard. When those keys are pressed during the experiment, the marker number is added to the corresponding sample.

Data streaming (see P4.3)

NIC2 allows data to be streamed and receive markers from third party software applications running on the same network by using Lab Streaming Layer (LSL) connections.

Warning: Since version 2.1, connectivity using the LSL protocol is disabled by default. Once enabled, LSL functionality will remain active unless manually disabled in protocol settings. LSL is a data intensive streaming service. When requiring LSL, to prevent it from interfering with the device connectivity, we strongly recommend connecting to your local network through an Ethernet cable.

P4. Protocol settings



5.3 Running a session

Once you have assembled the Necbox and all of the accessories of the headset, the ***Liveview*** pane **(see P5. Liveview)** allows proceeding with the protocol execution. It can be accessed by clicking **LOAD PROTOCOL** button in the ***Protocol*** pane **(see P3. Protocol Summary).**

5.3.1 Liveview pane features

When a protocol is loaded, the ***Liveview*** panes are unlocked. The following sections are available in the ***Liveview*** pane:

Liveview Home (see P5.1)

The **Liveview Home** is the NIC2 pane that must be used to control EEG experiments. This pane cannot be customized.

Monitoring bar (see P5.2)

The top monitoring bar contains the basic commands:

- Protocol name and the total number of steps.
- Timing information and **PLAY/PAUSE/ QUIT** button
  - Click on the **PLAY/PAUSE** button to start or stop the EEG protocol anytime.
  - Click the **PLAY/PAUSE** button to pause the protocol
  - Click and hold the **PLAY/PAUSE** button for 3 seconds to stop and re-start the protocol from 0
- Set ID of the saved files.
- Progress bar with step identification.
- Channel bar with signal quality **(see Section 5.3.6)** values.
- Configuration bar – choose the reference channel for visualization and adjust the voltage (μV) and time (s) scales. The voltage scale can be set to Auto so it adjusts to the amplitude of the signals.

Main EEG Plot (see P5.3)

The multi-channel signal is plotted for all the positions defined in the mount template in the ***Protocol Design*** pane. To add/remove channels to/ from the Main EEG Plot, click on the circle label on the Channel Bar.

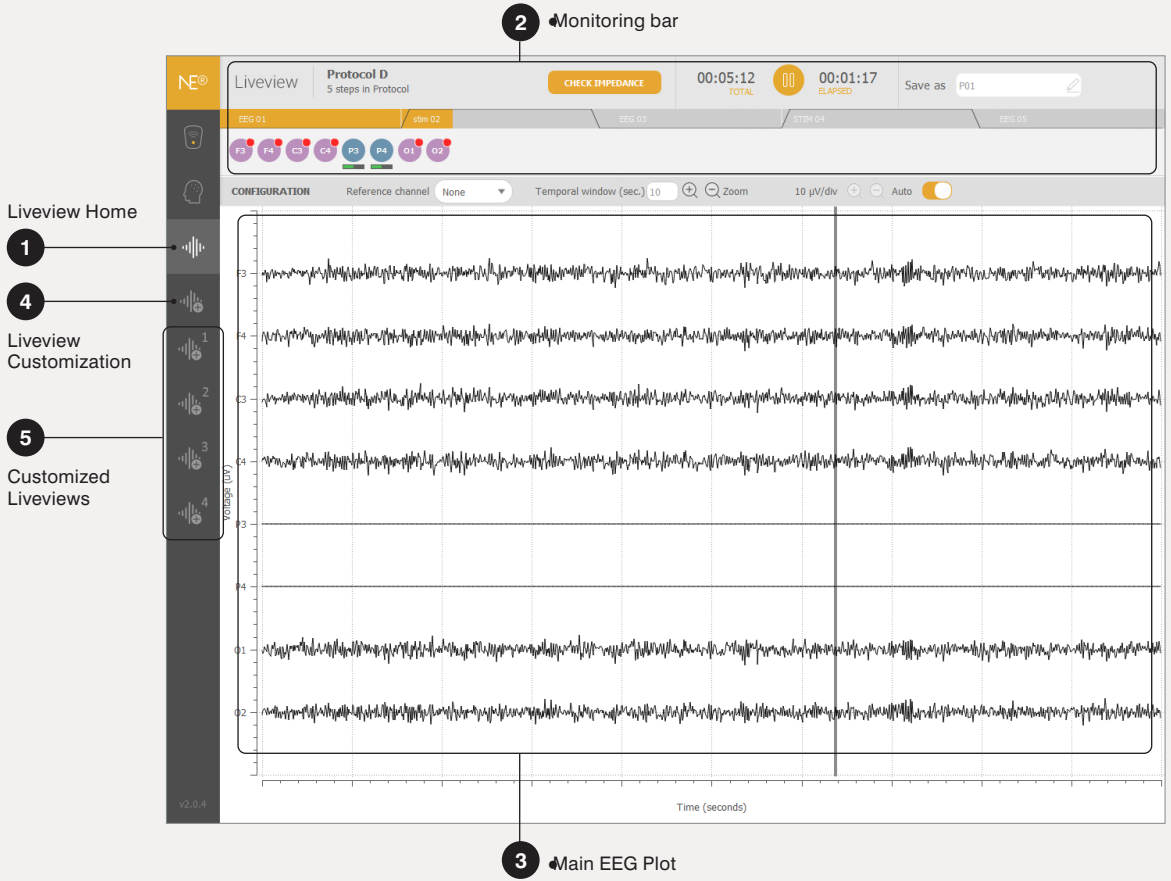
Liveview Customization (see P5.4)

NIC2 allows users to create ***Liveview*** panes according to their preferences. The ***Liveview Customization*** pane is the NIC2 section where the user can select and combine different tools to analyze EEG data in real-time.

Customized Liveviews (see P5.5)

After creating a customized ***Liveview***, the user can load it. The user can load up to 4 customized Liveviews simultaneously. The loaded customized Liveviews are added to the ***Pane bar*** on the left of the NIC2 window. At any time, the user can remove (i.e. unload) a customized Liveview. Click on the cross on the superior right corner of the ***Liveview*** icon to close it.

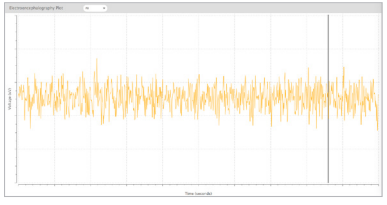
P5. Liveview


2
Monitoring bar
Liveview Home
1
4
Liveview Customization
5
Customized Liveviews
Liveview
Protocol D
5 steps in Protocol
CHECK IMPEDANCE
00:05:12
TOTAL
00:01:17
ELAPSED
Save as
P01
EEG 01
stim 02
EEG 03
STIM 04
EEG 05
F3
F4
C3
C4
P3
P4
O1
O2
CONFIGURATION
Reference channel
None
Temporal window (sec.)
10
Zoom
10 µV/div
Auto
Voltage (uV)
Time (seconds)
v2.0.4
3
Main EEG Plot

5.3.2 Liveview plots

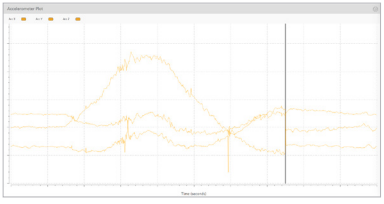
The customizable ***Liveview*** panes allow the user to combine different types of EEG analysis plots. There are seven **Liveview plots** in NIC2 that can be used for real-time EEG monitoring. Below, you may find a description of each plot type.

EEG Plot



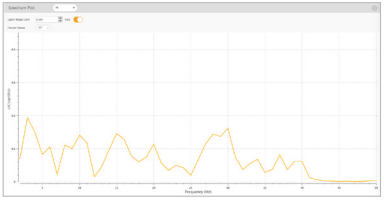
Choose one EEG channel to be plotted. Any channel can be selected from the list of channels selected for EEG in the protocol in use.

Accelerometer



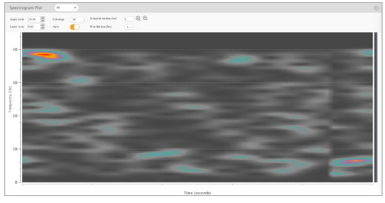
The 3-axis accelerometric data can be displayed in real-time. By clicking on the gear symbol (upper right corner), it is possible to choose which accelerometric components (x, y, z) to be visualized.

Spectrum



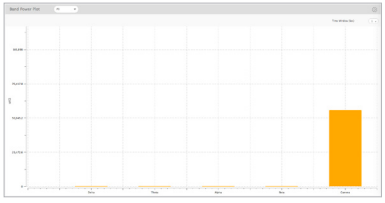
This window displays the Fast Fourier Transform (FFT) or the Power Spectrum Density (PSD) of the selected channel. The upper range limit (vertical scale) can be set to auto or defined by the user. Click on the gear symbol on the top-right corner to modify such parameters.

Spectrogram



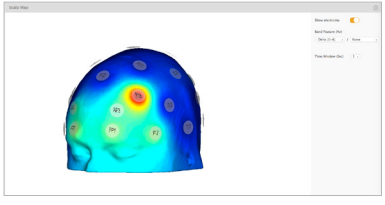
The power spectrogram displays the online frequency contents of the signal of a specific EEG channel over time. The temporal window (horizontal scale), time window (used to compute the signal spectrum to be plotted), the colormap, and the spectrum limits may be adjusted. Click on the gear symbol in the top-right corner to modify such parameters.

Band power



The power of the different EEG bands (Delta, Theta, Alpha, Beta, Gamma) can be computed in real-time for any specific channel. It is possible to adjust the time window (1, 2 or 4 seconds) used to compute band power values. Click on the gear symbol in the top-right corner to modify such parameters.

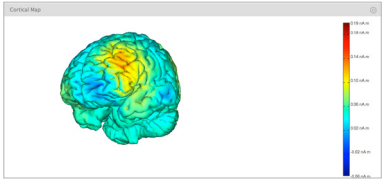
Scalp map



The scalp map displays a color code to spatially represent the power distribution $\mu V2$ for the band, or band ratio, selected.

The electrodes can be made visible or not. Male or female brain model can be selected. Click on the gear symbol in the top-right corner to modify such parameters.

Cortical map



The cortical map uses backward problem solving to compute the density of electric dipoles (nA m) on the brain surface. This source localization tool allows active brain areas to be identified, on both white and grey matter surfaces, based on the electric potential values measured by the scalp sensors. This is only available for devices with 20 and 32 channels using the standard mount.

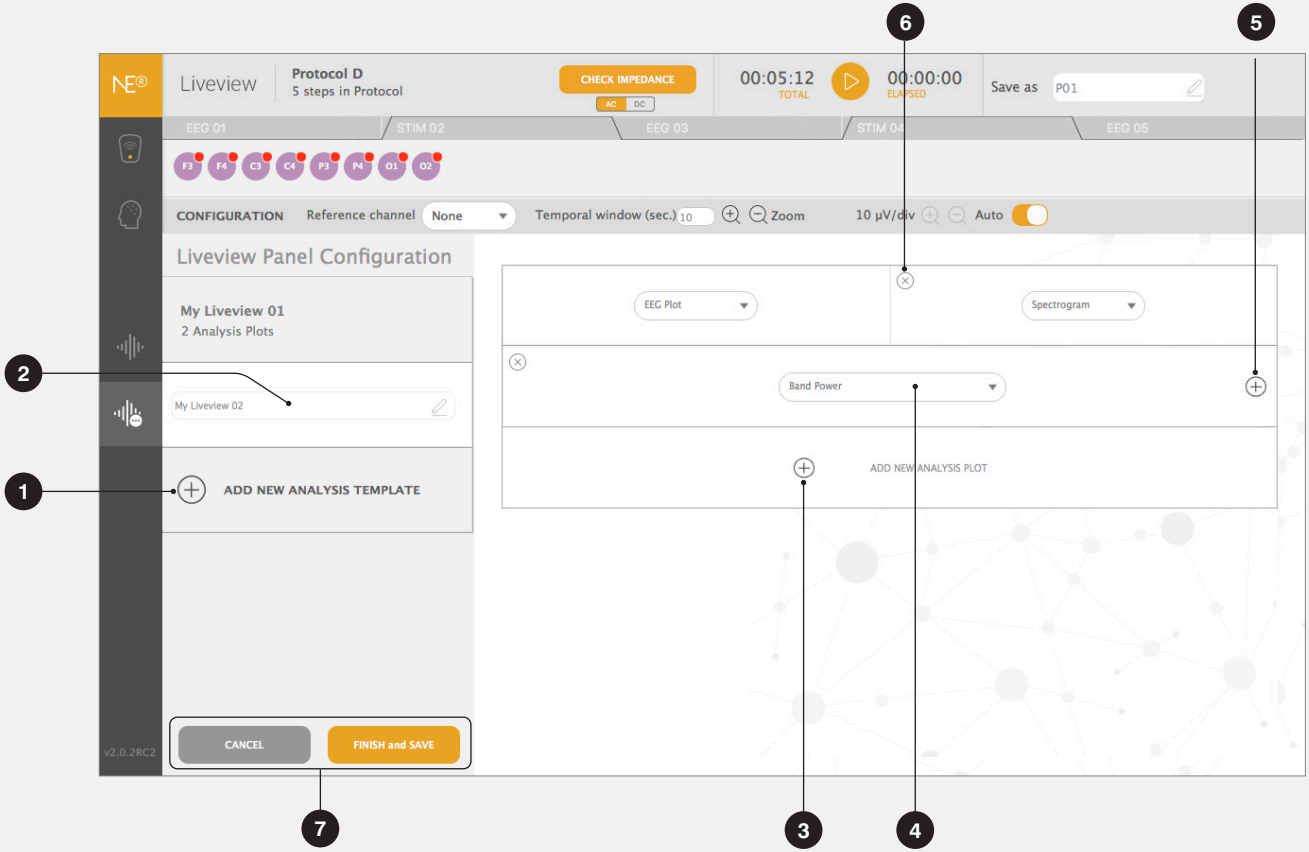
5.3.3 Liveview design

The customizable ***Liveview*** panes are organized in grids, and NIC2 allows groups up to 5 rows and 2 columns – a total of 10 plots. To create a new Liveview, follow the steps **(see P6. Liveview Design).**

- **P6.1** Click on the **ADD NEW ANALYSIS TEMPLATE** button.
- **P6.2** Define the name of your new Liveview. The name should be unique.
- **P6.3** Click on **ADD NEW ANALYSIS PLOT**.
- **P6.4** Choose, from the drop-down list, the type of EEG Analysis Plot to add to the view:
  - EEG Plot
  - Accelerometer (Acc) Plot
  - Spectrum
  - Spectrogram
  - Band Power
  - Scalp Map
  - Cortical Map
- **P6.5** Click on the plus sign to add a second column in the corresponding row. The plus sign is located on the right side of the plot slot. A second drop-down menu will appear Repeat steps 3-5 to add more rows to the customized Liveview.
- **P6.6** To remove any plot from the grid, click on the cross sign located on the top left corner of each slot.
- **P6.7** Click on the **FINISH & SAVE** button when the new Liveview is complete. Alternatively, you may proceed without saving the changes applied to the Liveview by clicking on the **CANCEL** button.

When the Liveview is saved, it is automatically loaded. When returning to the Liveview Design, the edit option allows the user to modify the Liveview grid structure and plots of the customized Liveviews. The **LOAD** button directs the user to the ***Customized Liveview*** pane. NIC2 is capable of loading up to 4 customized Liveviews simultaneously.

P6. Liveview design

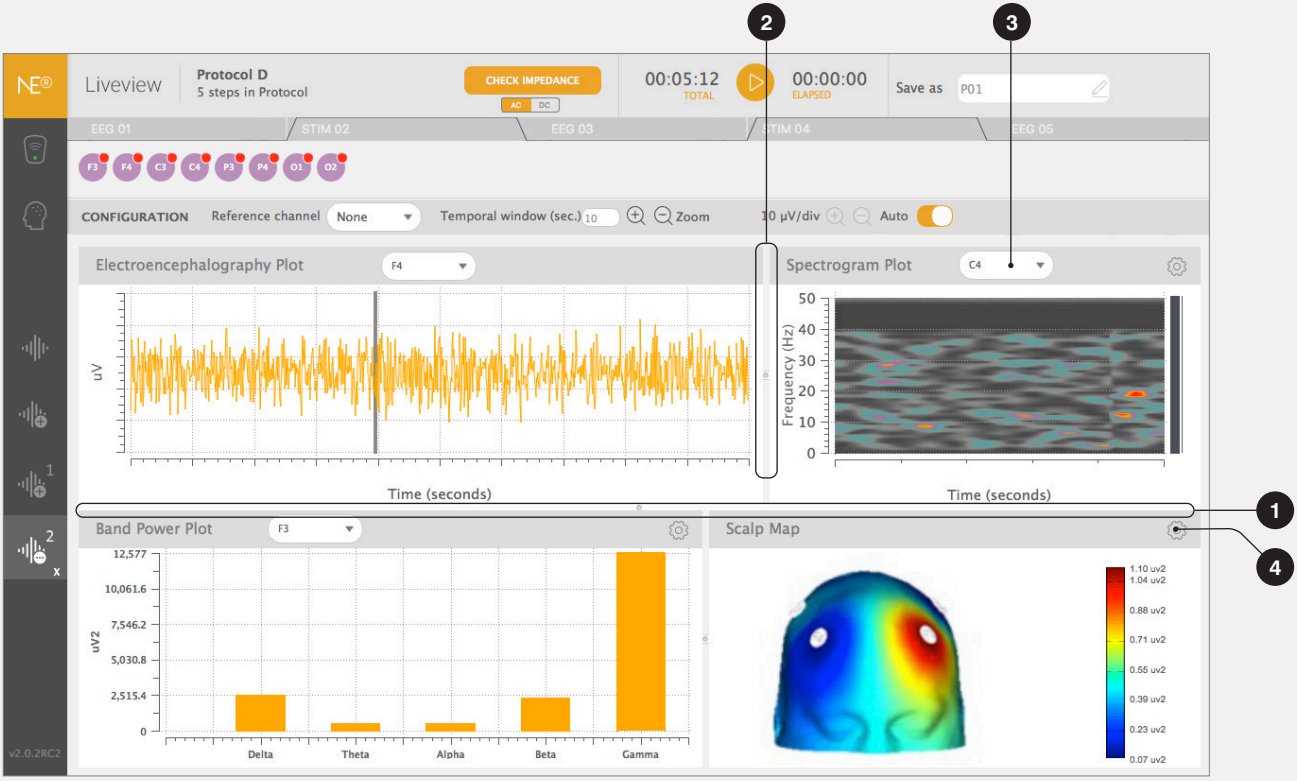


5.3.4
Custom Liveview

When a new Liveview is loaded, all the plots are generated and plotted in NIC2 window. The ***P7. Customized Liveview*** example corresponds to a Liveview created with the following grid structure (2 x 2). The Liveview plots can be further adjusted:

- **P7.1** To modify the height of the rows, drag vertically the horizontal border between them.
- **P7.2** To adjust the column width of slots of the same row, drag the vertical border between both columns.
- **P7.3** For the EEG, Spectrum, Spectrogram, and Band Power plots, the user can choose the channel, from the used mount, to reference the EEG data being plotted. The reference for the Cortical Map plot is Cz and cannot be modified.
- **P7.4** Each plot allows the user to define specific configurations. For instance, the Scalp Map plot allows the option to show/hide the electrodes from the model, and also to plot a band ratio instead of a standard brainwave band. It is up to the user to set those parameters.

P7. Customized Liveview



5.3.5 EEG monitoring

When an EEG protocol is loaded and the **PLAY** button is pressed, the recording starts. If EOG training is activated, the EOG training window will pop-up before the recording starts. During the EEG monitoring, pay attention to the filters, the reference system, and the plot scales. Make use of the Liveview panes **(see Section 5.1.1)** for real-time EEG analysis and visualization.

Data filtering

NIC2 allows EEG data to be filtered. The 50 Hz (Europe) and the 60 Hz (US) filters can be enabled/disabled in the ***My Devices*** pane **(see Section 4.2)**. Both line noise filters are applied for the visualization and they can be optionally applied for the recorded data.

Additionally, the user may define a visualization filter **(see Section 4.2)**. These filters are applied to the EEG plots in NIC2, but they do not affect the data recorded. A possible band-pass filter can be 2 Hz - 40 Hz, since it removes the offset of the channels and line noise.

EEG reference

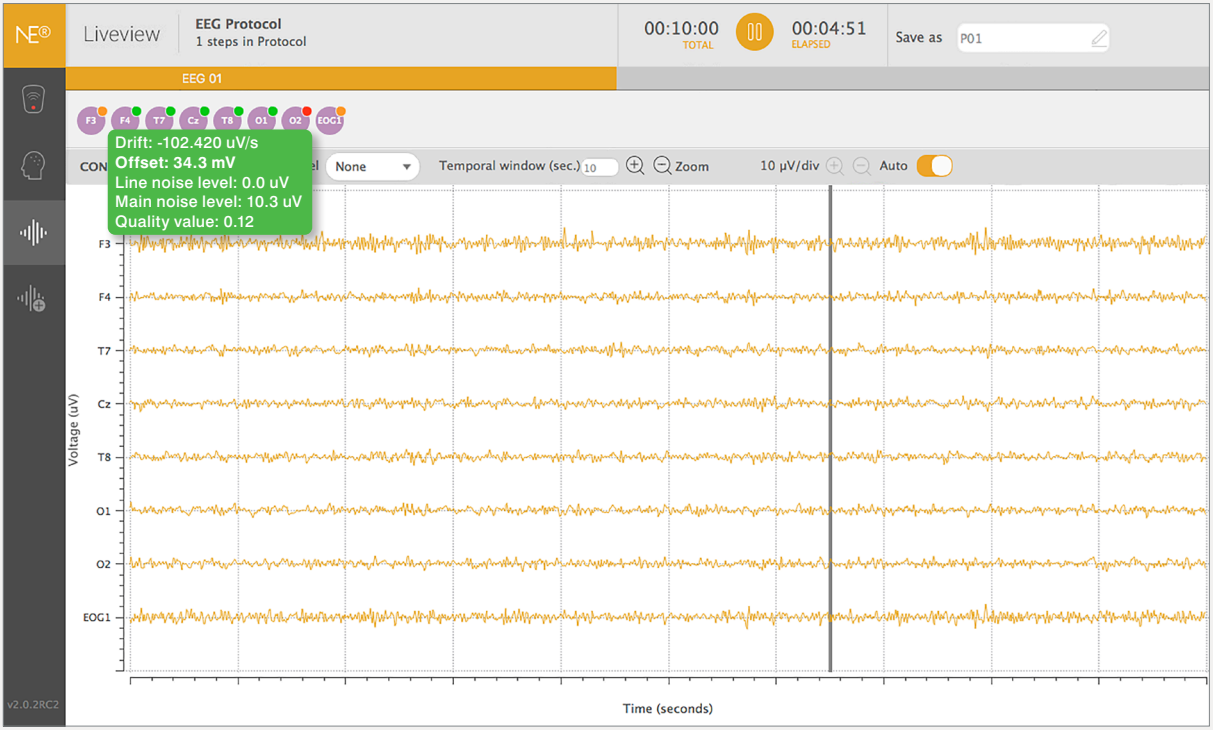
During the monitoring, the operator may select the reference channel. By default, all channels are plotted in reference to the CMS channel. Optionally, the signals can be also referenced to the average of all EEG channels. Bipolar and banana referencing options are available for 20-/32-channel systems using the standard mount template.

Note: the chosen reference is only for visualization purposes. All the recorded EEG data is referenced to the CMS channel.

Time & Voltage scales

Both time and voltage scales can be adjusted. The standard time scale is set to 10 seconds, whilst the voltage scale is initially set to Auto. Use a vertical scale $< 100\,\mu V$, to be able to properly visualize the EEG signals and their quality.

P8. EEG monitoring



5.3.6 EEG signal quality

In NIC2, the quality of the EEG signals is assessed via the quality index (QI). The QI is computed every 2 seconds, and it depends on four parameters as described by ***Equation 1***:

- **Line Noise:** power (μV^2) of the signal in the standard line noise frequency band (EU: 50±1 Hz; US: 60±1 Hz).
- **Main noise:** signal power of the standard EEG band (1–40Hz)
- **Offset:** mean value of the waveform
- **Drift:** the drift is measured but not included in the QI computation because it has a high inter-subject variability. A high drift does not imply bad signal.

During EEG monitoring, place the cursor above the superscripted quality circles, to see the values of drift, offset, main noise, line noise and QI. The parameter in bold is the one affecting the signal the most.

The quality indicator is meant to be used as guidance, it does not need to be taken very strictly; visual inspection of the EEG signal is equally important. If the signal looks good and the quality indicator are orange/green, you may proceed with the experiment. If the indicator becomes red at some point, there is no need to immediately stop recording. Each EEG channel displays a color code based on its QI:

- green ● (QI: 0.0 - 0.5)
- orange ● (QI: 0.5 - 0.8)
- red ● (QI: 0.8 - 1.0)

First visually inspect the signal and wait until it becomes orange or green again. Read the Electrode Instructions for Use to learn how to improve the signal quality. The signal quality depends on the type of EEG electrode and on the CMS reference channel. If that does not happen, several reasons may explain that.

Equation 1:

$$QI(t) = \tanh\left(\sqrt{\left(\frac{Offset(t)}{WeightOffset}\right)^2 + \left(\frac{MainNoise(t)}{WeightMainNoise}\right)^2 + \left(\frac{LineNoise(t)}{WeightLineNoise}\right)^2}\right)$$

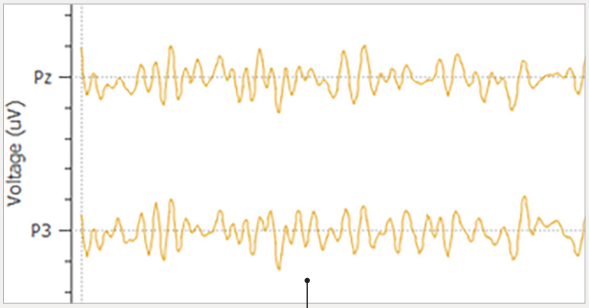
- WeightOffset = 280 mV
- WeightLineNoise = 100 μV
- WeightMainNoise = 250 μV

Warning: The quality index (QI) is not an Impedance Check measurement.

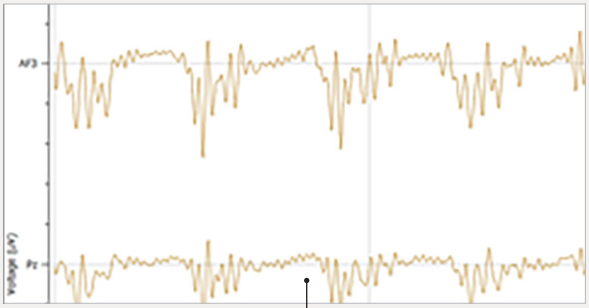
P9. contains examples of EEG signals:

- **P9.1** Normal EEG signal.
- **P9.2** Signal with artifacts derived from repetitive chewing movements.
- **P9.3** Multichannel EEG with one signal with high drift.

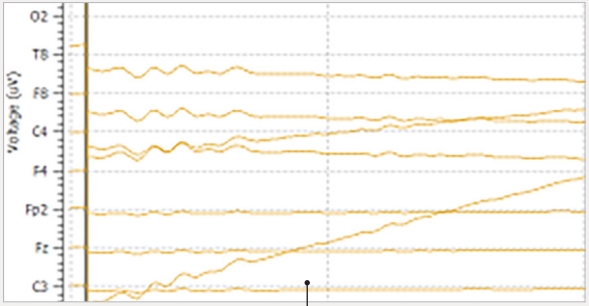
P9. Examples of EEG signals



1



2



3

5.4 EEG analysis

NIC2 allows real-time data analysis via ***Liveview*** panes **(see Section 5.3)**. Nevertheless, the processed data is not stored, only displayed. In order to post-process data, Neuroelectrics® provides TCP/LSL streams. This option makes EEG data available for advanced processing with third-party applications.

Neuroelectrics® also provides a plugin to allow EEG data from NIC2 to be imported into the EEGLAB MATLAB (MathWorks®) toolbox (www.sccn.ucsd.edu/eeglab/).

Data streaming

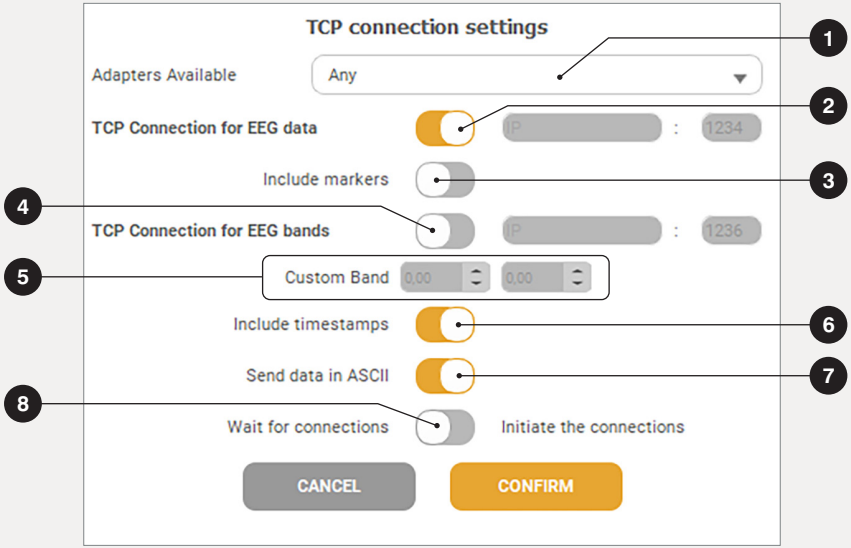
EEG data can be read and processed with third-party software, such as MathWorks® MATLAB. Both Lab Streaming Layer (LSL) and Transmission Control Protocol (TCP) options are available in NIC2. To activate the LSL and/or TCP streams, go to the ***Protocol Settings*** **(see Section 5.2.3)**.

To activate the LSL go to the Protocol Settings and provide a name for the LSL Outlet. NIC2 will use this name to provide 4 different outlets: **provided_name-EEG**, **provided_name-Accelerometer**, **provided_name-Quality**, **provided_ name-Markers**. A third-party application can connect to them to receive information regarding EEG streaming, accelerometer, quality, and markers data respectively.

To activate the connection through TCP go to the ***My Device Settings*** **(see Section 4.2)** and activate the TCP Server option. Click on the gear symbol to modify parameters such as:

- **P10.1** The network adapter where the server will be listening
- **P10.2** Activate/deactivate server for raw EEG data
- **P10.3** Inclusion of received marker on the raw EEG data server
- **P10.4** Activate/deactivate server for EEG power in bands data
- **P10.5** Definition of a custom band to be sent on the EEG power in bands server
- **P10.6** Inclusion of timestamps
- **P10.7** Option to send the information in ASCII format rather than binary
- **P10.8** Option to make NIC2 wait for incoming connections (default) or to actively initiate a connection to the provided IP addresses to send data.

P10. TCP connection settings

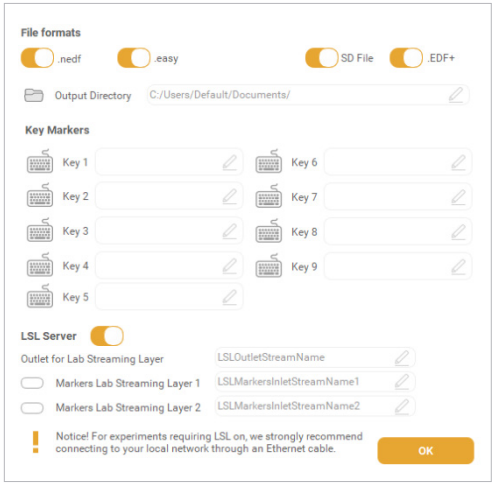


5.5 Holter mode

NIC allows Enobio devices to enter in **Holter Mode**. The data will be stored in the SD card inserted into the Enobio amplifier so the EEG system is completely wireless and wearable. Check your firmware version to make sure it is supported for this function.

How to enter **Holter Mode**:

1. Insert the SD card in the SD card slot (Enobio lateral side) and configure the desired protocol with the total duration the recording shall last.
2. Enable the SD Card file **(Go to Protocol Settings described in Section 5.2.3)**
3. Load the protocol and press the **START** button for EEG acquisition. Note that message with the exact amount of free space in the SD card that is needed to carry out the recording will appear. If there is no such free space, the device will rapidly blink for a few seconds indicating that the recording could not be started on the SD card. The same behavior occurs when the SD card is not present.
4. Once the recording has started, close NIC2. Here, NIC2 asks for permission to enter in Holter Mode so press **YES**.
5. The data recorded is stored for the time the protocol has been configured in NIC2. Note that the device will blink while the recording in the SD card is happening and that will get back to the idle state when it stops recording.



Technical Specifications:

For optimal performance, fast micro SDHC (Micro Secure Digital High-Capacity) cards are recommended (UHS-I or higher, Class 10.) As a recommendation, the SD card should not be protected against writing. The battery level is read every 5 minutes and it records data to SD Card every 10 minutes.

5.6 NIC file formats

NIC2 works with files with distinct file formats.

During EEG recording, if the ***.easy** option is enabled in the ***Protocol Settings*** **(see Section 5.1.3)**, two ASCII files are created with the ***.info** and ***.easy** file extensions. The former corresponds to a text file that contains the metadata of the corresponding recording. Information, like the EEG sampling rate, the percentage of packet loss, and the channel-position list, are written on this file.

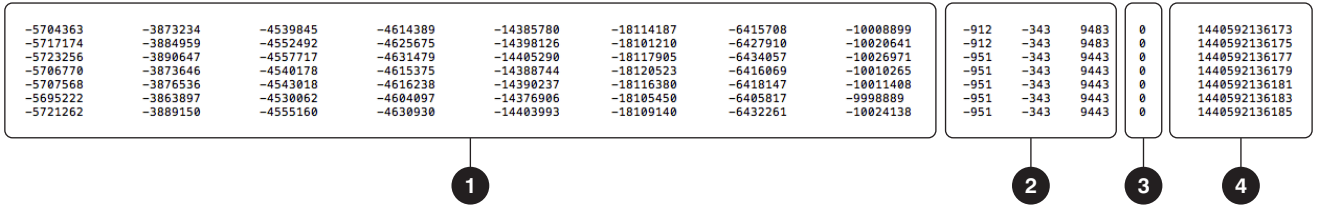
The latter is also a text file containing the data itself which is organized as follows:

1. The first 8 (20 or 32) columns correspond to the voltage signal, in nanoVolts (nV), of the EEG channels.
2. The three following columns will display the acceleration (ax ,ay ,az) in millimeters per second squared (mm/s^2).
3. The next column corresponds to the markers column and it displays mostly zeros. The numbered flags (0 to 9) are registered when the corresponding keys are pressed. The number 255 identifies the samples when data loss occurred.
4. The last column contains the Unix Time Stamp, in milliseconds (ms), for each sample. This time unit refers to the number of milliseconds since January 1, 1970.

The ASCII files (***.info**, and ***.easy**) can be opened with, for instance, Notepad (Windows) or TextEdit (MAC OS).

Additionally, NIC2 also works with binary files: ***.edf**, ***.nedf** and ***.sdeeg**.

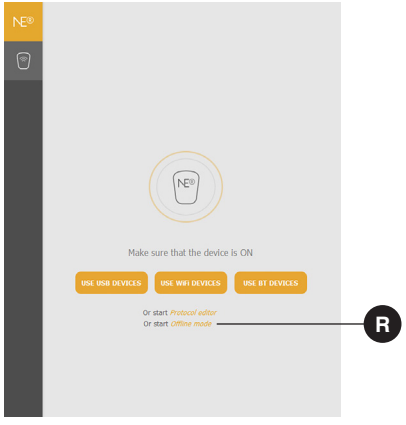
The ***.edf** extension stands for the European Data Format (EDF) which is a binary file format commonly used to exchange and store multichannel data from physiological signals. NIC2 produces the EDF+ files (extension of EDF) which is the standard binary file format for EEG data. The binary ***.nedf** files are proprietary NIC files with an XML header, while the binary ***.sdeeg** file format is used when offline recording is used in an SD memory card.



5.7 Offline mode

NIC2 can read files with distinct formats to inspect their EEG signals.

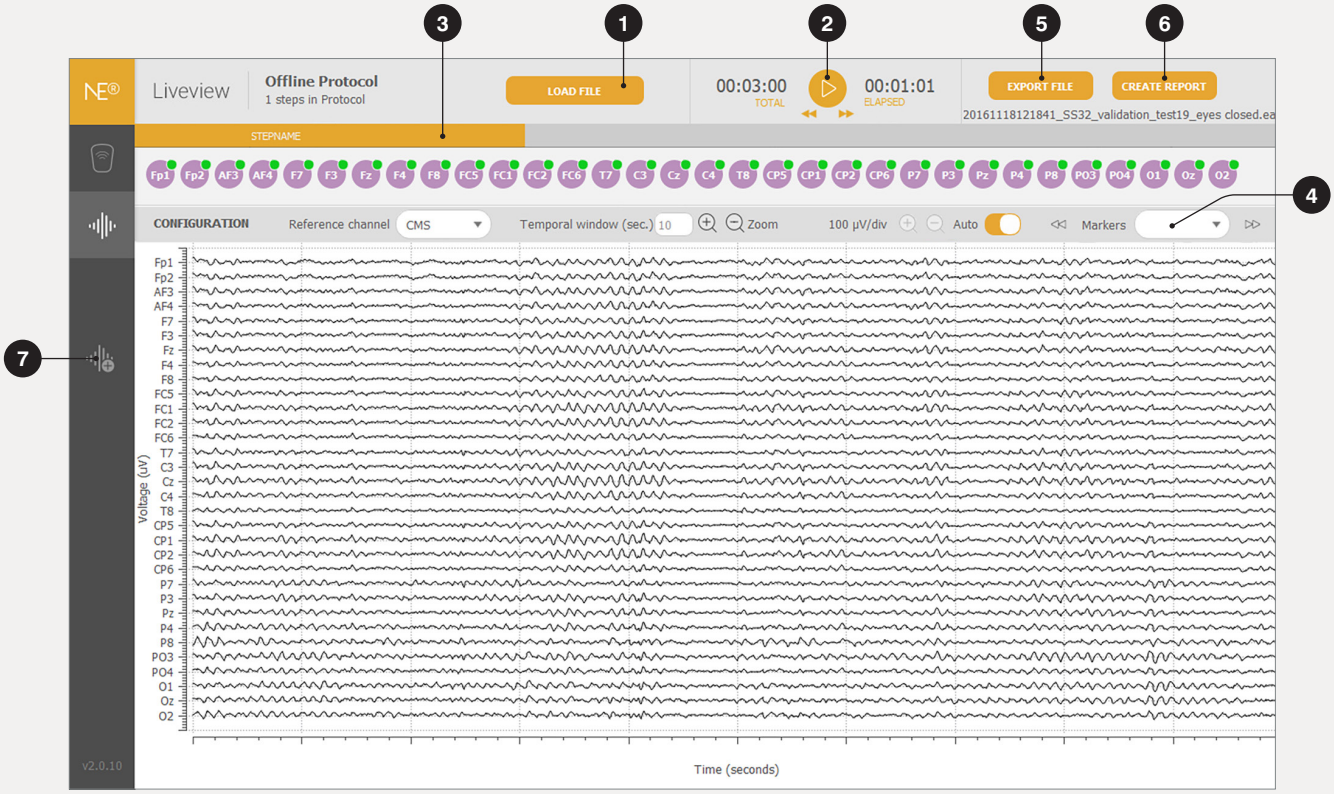
The **Offline Mode** can be accessed from the Home Pane by clicking on the OFFLINE MODE COMMAND (R).



Files with ***.easy**, ***.nedf**, ***info** and ***.sdeeg** formats can be loaded. Once the file is fully read by NIC2 the EEG signals are presented in the *Liveview Home* pane. In Offline mode this pane is slightly changed **(see P11. Offline Mode)**.

- **P11.1** Click on the **OFFLINE MODE** button. A box will appear to load a new file. Make sure to select a file from your Directory.
- **P11.2** Use **PLAY/PAUSE** and **FORWARD/BACKWARD** button to inspect the EEG signals.
- **P11.3** Drag and drop the timeline bars to rapidly move to an exact time in the file.
- **P11.4** When the file contains markers, it is possible to select any type and navigate to where they are with the **DOUBLE-ARROW** buttons.
- **P11.5** Click on the **EXPORT FILE** button to convert the current loaded file to a different format (***.easy**, ***.nedf**, ***.edf**) by clicking on the **EXPORT FILE** button.
- **P11.6** By clicking on the **CREATE REPORT** button, it is possible to generate a post-processing report on the current loaded data. A dialog will be open where the postprocessing parameters can be adjusted as well as the data starting and finishing time.
- **P11.7** Access to ***Custom views*** **(see Section 5.3.4)** is also available in Offline mode.

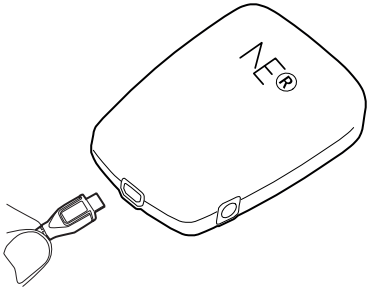
P11. Offline mode



5.8 Cleaning instructions

Proper handling and storage of the Enobio device according to the information provided in these Instructions for Use will be sufficient to maintain the required level of cleanliness of the device during its lifetime. No other cleaning, disinfection, or sterilization methods are necessary.

5.9 Charging instructions



- Only use the charger that came with the device to charge the battery.
- Plugging in the charger cable will automatically power the device off. Therefore, the device will not operate while charging.
- The device can be connected to any Class 2 electrical installation.
- The battery charger connects to the Necbox through the micro-HDMI connector located at the rear part of the Necbox.
- In order to preserve battery capacity, it is highly recommended to fully charge the device at least once per 3 months. Inability to do this may result in decreased operation time for a single charge.
- Whenever possible, avoiding full discharge of the battery by consistent charging after each use will help preserve its capacity over time.
- The expected time to fully charge the device from a fully discharged state is about 2 hours. This time may vary over the lifetime of the device.
- The battery status is provided by the Necbox **(see Section 3.4)** and by NIC2 when the device is switched on and paired with the computer.

Electrical specifications for charging:

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

6. Troubleshooting

Troubleshooting

For troubleshooting of common issues, such as wifi, please refer to the following link:

https://www.neuroelectrics.com/wiki/index.php/Troubleshooting_/_Problem_Solving

7. Symbols used

Symbol	Description
	ISO 7000-1641 Read Instructions for use symbol according to EN ISO 15223-1:2021. The symbol is accompanied by the link to have access to the electronic instructions for use.
	ISO 7000-0434A Caution symbol according to EN ISO 15223-1:2021.
	IEC 60417-5010 Push ON/OFF button UNE-EN 60601-1=2008/ A12:2015.
	ISO 7000-2498 Serial Number according to EN ISO 15223-1:2021.
	Device manufacturer symbol according to EN ISO 15223-1:2021.
	ISO 7000-2606 Do not use device if product or packaging have been damaged symbol according to UNE-EN ISO 15223-1:2017.

Symbol	Description
	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 by the Notified Body n. 1639 of the European Community.
	ISO 60417-5140 Non-Ionizing Electromagnetic radiation.
	ISO 7000-0632 Transport and storage temperature conditions.
	ISO 7000-2620 Transport and storage humidity conditions according to EN ISO 15223-1:2021.
	ISO 7000-2621 Transport and storage atmospheric pressure conditions.

Symbol	Description
	ISO 7000-2621 Transport and storage atmospheric pressure conditions according to EN ISO 15223-1:2021.
	ISO 7000-0624 Transport package shall not be exposed to sunlight according to EN ISO 15223-1:2021.
	IEC 60417-5333 BF type applicable part according to UNE-EN 60601-1:2008/ A12:2015.
	ISO 7000-2493 Catalogue number, to identify the manufacturer's catalogue number of the medical device according to EN ISO 15223-1:2021.
	Medical device is protected from objects not greater than 12 mm in diameter and protected from dripping water.
	Direct Current symbol.

8. A notice to the user

Notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the authority having jurisdiction in your locale.

9. Regulatory statements

Enobio 8, Enobio 20 and Enobio 32 are certified (CE marked) class IIa medical devices under the Council Directive 93/42/EEC concerning medical devices (EC Certificate ES19/86968), and licenced class 2 medical devices in accordance with the Canadian Medical Device Regulations, SOR 98/282, (License number: 90344).

The devices described in this manual are investigational devices in the US: “CAUTION Investigational devices. Limited by Federal (or United States) law to investigational Use”

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