

getting started^{NE®}

Neuroelectrics User Manual
- Part 0. Getting Started -

Manufacturer:



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The manufacturer should be contacted:

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



Labelling of the covered products



Applies to:

Enobio 8

Enobio 20

Enobio 32

These devices comply with the essential requirements of the applicable EU Directives (93/42/CEE), to demonstrate safety and efficacy of the device.

The mark specifies the requirements for the Quality Management System of the Medical Devices manufacturer and aims to demonstrate that the Medical Devices and related services are complying with the legal requirements and the final customer needs



Applies to:

Enobio Research 8

Enobio Research 20

Enobio Research 32

These devices are not medical, only for INDUSTRIAL purpose.

The mark specifies that the products sold in the European Economic Area (EEA) have been assessed to meet high safety, health, and environmental protection requirements. It demonstrates the safety of the device.

Investigational Medical Device

Applies to:

Starstim 8

Starstim tCS

Starstim 20

Starstim 32

These devices are the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device following the regulations in the investigation in each country. They are labelled as Research Use Only.















The mark covers the same assessments for high safety, health, and environmental protection as the Industrial CE Mark.

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




I.1

General Safety Warnings

-  **Before applying the device, connect to NIC and follow the steps in the instructions for use including the full list of the safety warnings detailed.**
-  The device cannot be turned on while it is connected to the main power supply through the power adapter. The isolation of the main power supply is achieved by disconnecting the power adapter.
-  The device must never be opened or damaged.
-  Before using, please check that the device is not damaged and the packaging has not been affected by transport or storage.
-  In the case of malfunction, immediately contact the manufacturer or the distributor.
-  The device 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.
-  The device shall be connected to the power adapter in a way that makes it easy to disconnect.
-  The EEG feature of the device will not function 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 modification of the device is not allowed.
-  If the device has not been used during a long period of time, check visually that there is no battery leakage.
-  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.

I.2 Symbols Used

Symbol	Description
	Refer to the manual/booklet
	General warning sign
	IEC 60417-5010 Push ON/OFF button UNE-EN 60601-1=2008
	ISO 7000-2498 Serial Number according to UNE-EN 980
	Device manufacturer 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.
	CE marked device certified according to the European Community
	ISO 60417-5140 Non-Ionizing Electromagnetic radiation.
	ISO 7000-0632 Transport and storage temperature conditions

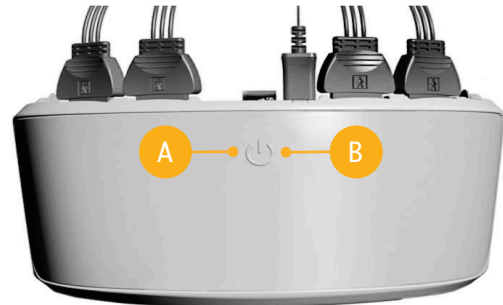
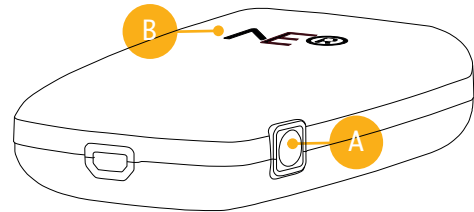
Symbol	Description
	ISO 7000-2620 Transport and storage humidity conditions
	ISO 7000-2621 Transport and storage atmospheric pressure conditions
	Transport package shall be kept away from rain and in dry condition.
	Transport package shall not be exposed to sunlight.
	IEC 60417-5333 BF Type applicable part according to UNE-EN 6061
	Direct Current symbol

II.1

How do I switch 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.



Key:

A Power Button

B Operation LED

II.2

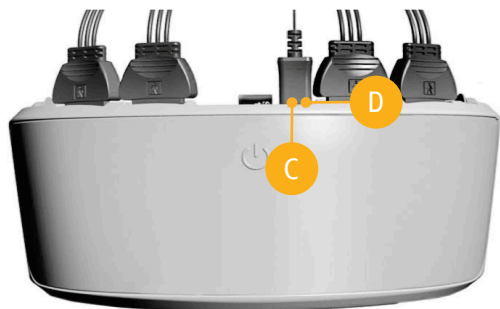
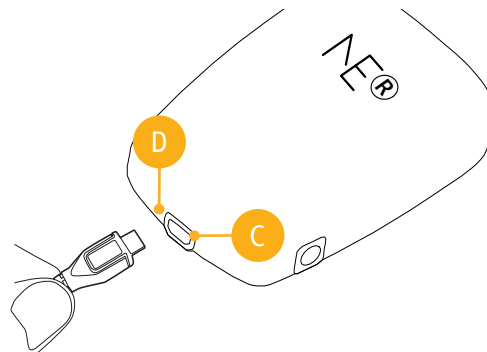
What if the device does not switch on?

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



Key:

C Micro-HDMI Connector

D Charging LED

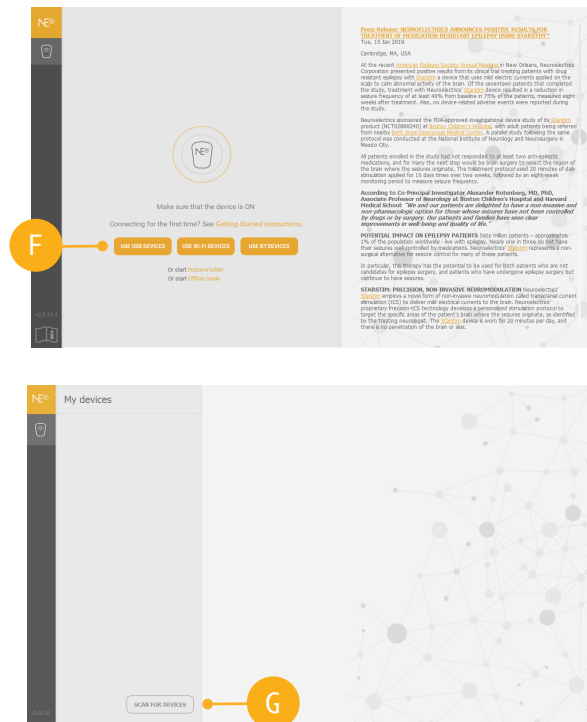
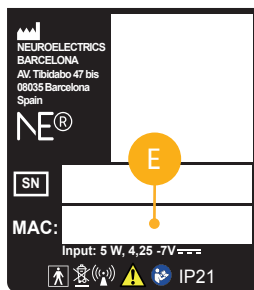
II.3

How do I connect to the device?

- 1 Ensure the device is switched on following the steps in Section II.1.
- 2 On the label placed on the back of your device, verify its unique MAC address (E).
- 3 In NIC2 Home pane, select the type of the device connection (F). My Devices pane will open.
- 4 Wait a moment until your device MAC appears on the list.
- 5 If the device MAC did not appear, click *Scan for Devices* (G). Repeat the scan for up to a minute until the device appears.

Key:

- E MAC Address on the Device Label
- F Connection Selection in Home Pane
- G *Scan for Devices* Button

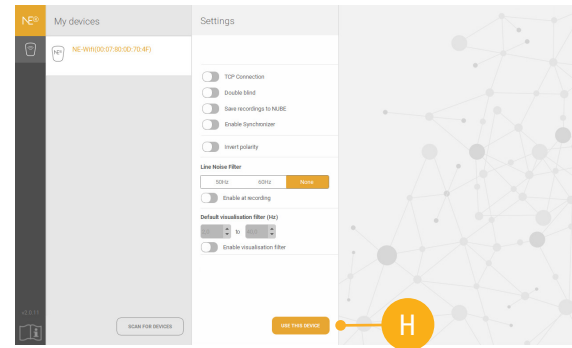


II.3

How do I connect to the device?

6 Choose your device from the list.
Settings pane will open.

7 At the bottom of Settings pane,
click *Use this Device* (H). The software
will establish connection with the
device.



Key:

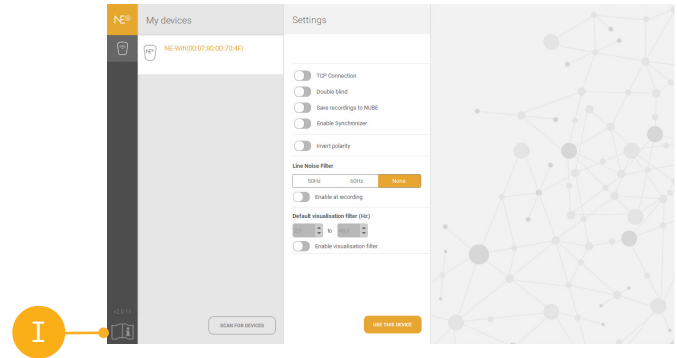
H *Use this Device* button

II.4

How do I access the full instructions for use?

1 Ensure the NIC2 software is connected to the device following the steps in Section II.3.

2 On the bottom of NIC2 left menu, click the Instructions for Use button (I). You will find all relevant instructions to continue your work with the device.



Key:

I Instructions for Use button

