NEURONAUTE®

NEURONAUTE PLUS USER MANUAL

IFU-00122 Rev I

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1. FOREWORD

The **Neuronaute Plus** is a wearable medical device compatible with electrodes.

Warning
United States Federal law restricts medical devices to sale by or on the order of a licensed healthcare practitioner.

1.1 Intended Use

The **Neuronaute Plus** enables the acquisition, recording, storage and transmission of physiological signals in order to analyse potential neurological disorders.

1.2 Indications for Use

The **Neuronaute Plus** is a system intended to acquire, store, archive, and periodically transmit physiological signals from the brain using a full montage array to enable review at a physician's office, hospital, or other remote locations. It allows remote access by users via the **BioSerenity Cloud**.

The **Neuronaute Plus** and its associated software are intended to assist in the diagnosis of neurological disorders. The **Neuronaute Plus** and its components do not provide any diagnostics conclusions or automated alerts of an adverse clinical event about a patient's clinical condition.

The **Neuronaute Plus** is intended to be used by trained healthcare professionals, technicians or patients above 15 years old. In case of a patient below 15 years old, Neuronaute Plus is intended to be used by a care giver.

Adequate training is recommended for proper use of the device.

Neuronaute IceCap 2 electrodes are able to be used on patients weighing at least 10 kg and having a head circumference above 43 cm.

Neuronaute is not intended to replace direct communication with healthcare providers. The system data should not be used alone, but should be used along with all other clinical data and exams to come to a diagnosis.

The **BioSerenity Cloud** allows the display of signals in order to help aid in the diagnosis of physiological disorders through the data collected by recording.

The **BioSerenity Cloud** should allow the analysis and filtering of data in order to aid doctors in diagnosing neurological disorders.

1.3 Intended Patient Population

The device is intended for the following users:

Component	Age of the patient
Neuronaute Plus	All ages
Holding Band	Underbust measurement of at least 70cm.
IceCap	Patients above 18 years old
IceCap 2	Patients weighing at least 10 kg and having a head circumference above 43 cm.

1.4 Intended User Population

The device is intended for the following users:

Device	User
Neuronaute Plus & Holding band	Patients above 15 years old Care giver on patients below 15 years old.
Neuronaute Plus & all accessories	Heatlhcare Professional
Bioserenity Cloud Mobile Application IceCap 2	Heatlhcare Professional

1.5 Scope

The purpose of this manual is to explain the features of **Neuronaute Plus** to the user.

The **Neuronaute Plus** is composed of the following elements:

- Neuronaute Plus core module
- Extender modules
- Holding band
- Battery (x2)
- Battery charger

The **Neuronaute Plus** can be used in combination with:

- Compatible cap or electrodes
- Cloud platform
- Mobile application

1.6 Intended Benefits

The benefits of the device are:

- It enables to increase the number of acts on a same patient and to record more patients.
- Distant diagnostic.
- Data is stored on a non-volatile device, preventing data loss in case of sudden record interruption.

1.7 Document History

The following table shows the document changes history since its creation.

Revision	Date	Description
A	01/04/2022	Initial Creation (IFU 00122 Rev A)
I	13/12/2023	Update and modifications (IFU 00122 Rev I)

1.8 Glossary

App
Refers to the mobile application.

Battery
Rechargeable and removable electronic device.

Cloud
Refers to the applications and services that run on a dedicated Internet platform.

Recorder
Removable electronic card that enables storing and transmitting data to the cloud platform.

1.9 Abbreviations

Abbreviation	Term
BLE	Bluetooth Low Energy
DC	Direct Current
ECG	Electrocardiogram
EEG	Electroencephalogram
EMC	Electromagnetic Compatibility
EMG	Electromyogram
EOG	Electrooculogram
FAQ	Frequently Asked Questions
GND	Ground
IP	Ingress Protection
IPS	Intermittent Photic Stimulation
LED	Light-emitting diode
RF	Radio Frequence

1.10 Symbology

Note
Gives additional information for optimal use of the product.

Warning
Draws attention on important information and / or action: damage to the equipment is possible.

2. INTRODUCTION

2.1 Prerequisites

Using the **Neuronaute Plus** requires:

- Having access to an Internet connection (Wi-Fi)
- Using a device which software / hardware versions are at least:
  - **iOS**
    iOS14 and higher
    iPad Air® (latest version), iPad (5th generation or higher), iPad Pro® (all versions)
  - **Android**
    Android 13
    Xiaomi PAD 6
- Using a healthcare professional account (provided by BioSerenity)

2.2 Contraindications

Do not use the system in any of the following cases:

- Allergy to one of the components of the device: polyamide, polyester, elastane, silicone, any synthetic material.
- Sensory processing disorder having an effect on skin sensitivity.
- Cardiorespiratory disorders which may be increased by compression of the thorax.
- Behavioral problems making the patient excessively agitated or aggressive.
- Mental disorder that is incompatible with using the device.
- Open wound in an area either covered or surrounded by the device.
- Use of the data gathered by the device nor any of its components to establish a brain death diagnosis.
- User strongly contagious.

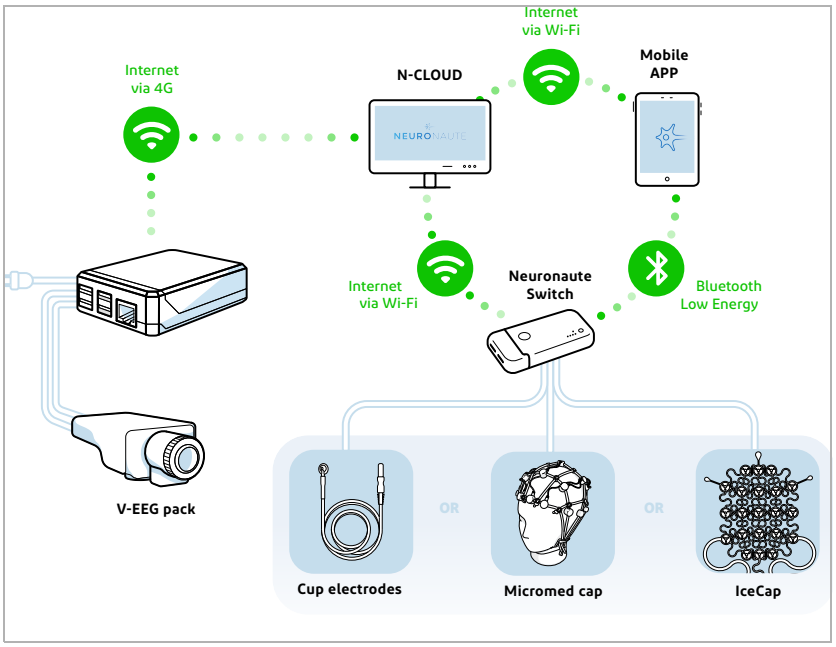
2.3 System Overview

The system is composed of the pieces of equipment listed below.

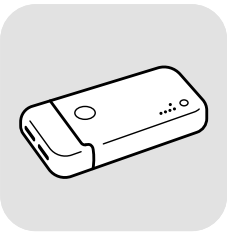
Neuronaute Plus components are connected through Bluetooth and Wi-Fi.

Warning

The use of any unit not recommended in this document could have an unwanted effect on the system.



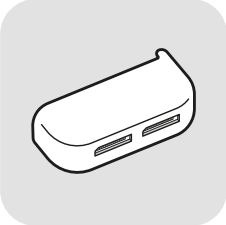
2.3.1 Neuronaute Plus



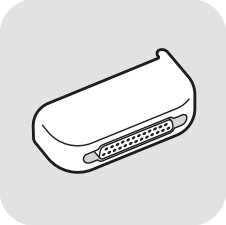
The **Neuronaute Plus** is a device that enables connecting several types of caps to record and transmit data to the cloud platform.

There are 3 different extenders

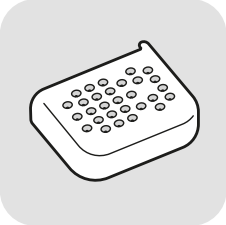
2.3.2 Neuronaute Plus Extenders



IceCap extender



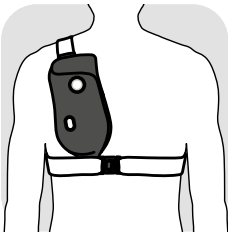
DB 25 extender



Touchproof extender

The extenders are accessories provided with the device. The extenders enable connecting different caps or electrodes to the device.

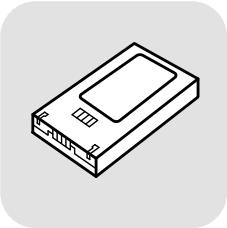
2.3.3 Holding Band (optional)



The holding band is an accessory provided with the device. The holding band enables to wear the device over the clothes.

The holding band is intended for users who have an underbust measurement of at least 70cm.

2.3.4 Neuronaute® Battery

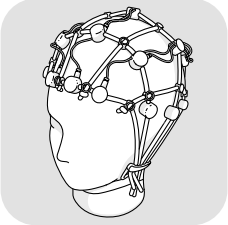


The battery is a removable rechargeable electronic device.

The battery is recharged using a provided charging station.

The battery enables up to 24h of recording. For longer records, a second battery is provided with the system.

2.3.5 Compatible caps / electrodes



Several types of caps can be used with the recorder:

- Neuronaute IceCap / IceCap 2 / IceCap 2 small
- Cup electrodes
- Micromed caps

2.3.6 Neuronaute® Mobile APP

The mobile application is compatible with iOS and Android systems.

The mobile application enables the healthcare professionals to access and manage the prescribed recording sessions.

2.3.7 BioSerenity CLOUD

The cloud is a web-based information system that receives the EEG electrophysiological signals from the recorder through a paired Wi-Fi connection.

The cloud platform enables long-term storage and display of the recorded signals.

2.3.8 Neuronaute® N-DEO

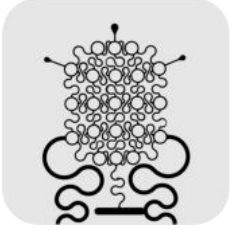
The IP camera enables the visualization of the patient during a recording.

The IP camera provides HD resolution video sequence at 1080p, with advanced night mode and WDR technology.

2.3.9 Neuronaute® N-WAY

The router module enables flexible connectivity for remote monitoring and data transmission to the cloud platform.

2.3.10 Neuronaute® IceCap and IceCap 2 / IceCap 2 Small



The IceCap and IceCap 2 / IceCap 2 small are single use caps which connect to the system using the corresponding module from the **Neuronaute Plus**.

2.3.11 Cup Electrodes

Cup electrodes connect to the system using the dedicated channels of the **Neuronaute Plus**.

BioSerenity recommends the use of EEG cup electrodes approved by the FDA.

3. INSTALLING NEURONAUTE PLUS

3.1 Checking the Device Before Installation

Checking the Device

Before using the system, check the devices:

- Check that the device is correctly cleaned.
- Check that there is no damage on any part of the device.
- Check that the device is not damp, wet or dirty.
- Check that the battery is charged.

Warning

Never use a damaged or degraded device. In case of damaged or degraded device, contact the support.

Warning

Put the system in usage conditions (usage temperature) for an hour before using it.

Checking the patient

Before using the system, verify the patient condition and make sure that the patient has no contraindications.

Warning

If the system is painful to wear, remove the device and contact a healthcare professional.

Checking the Environment

Before using the system, note that the user should:

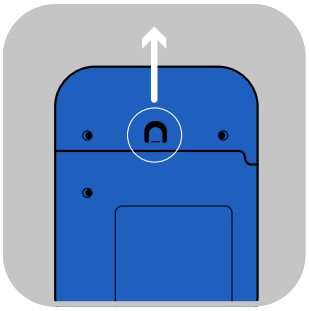
- Keep away from fire or any heat source that may cause damage to the device.
- Keep the device away from any source of water while recording.
- Not smoke near to the device.

3.2 Installing the Neuronaute Plus

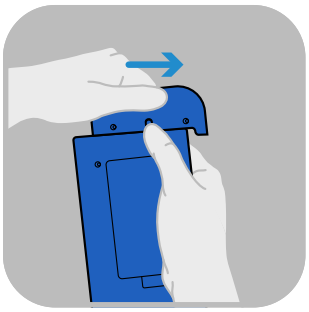
3.2.1 Installing the Extender on the Neuronaute Plus

The extender is a removable piece of the device that can be installed, changed and connected according to the corresponding cap.

To install an extender on the device:



1. If appropriate, remove the extender by pushing on the button located at the rear of the device.



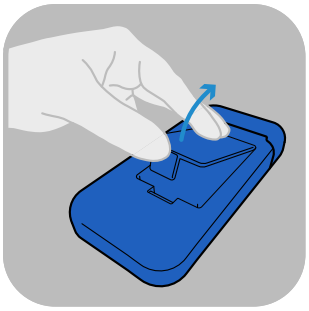
2. While pushing the button, move the extender to the right to remove it.

3. Set the extender to use by moving it to the left of the device.

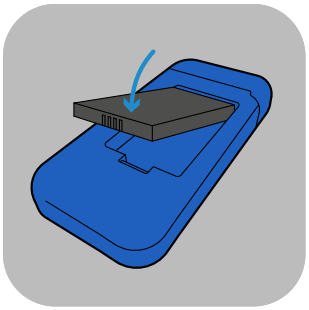
3.2.2 Installing the Neuronaute Plus

Before installing the **Neuronaute Plus**, Check that the corresponding extender is installed according to section “Installing the Extender on the Neuronaute Plus”, page 16.

To install the **Neuronaute Plus**:

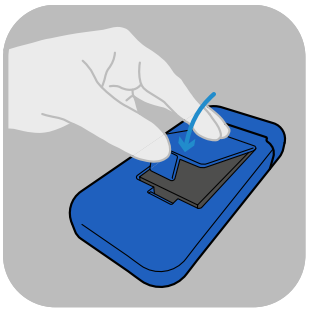


1. Remove the battery cover located on the rear of the device.

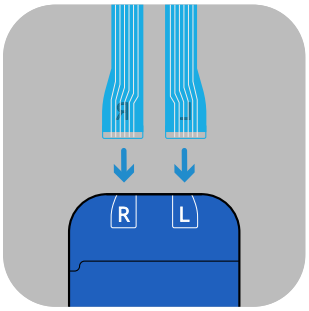


2. Plug a fully charged battery to the device.

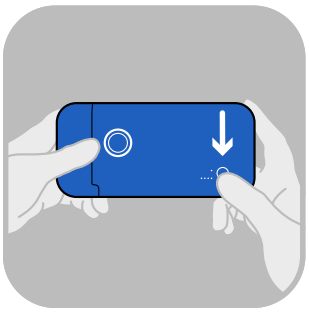
   Note: The record will not start if battery level is under 25%.



3. Close the battery cover.

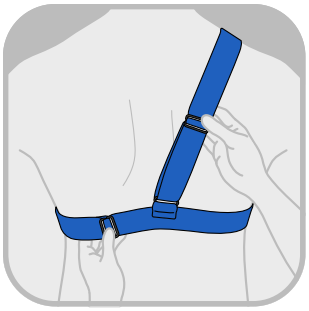


4. Plug the cap or electrodes to the device.
   Refer to 3.3, 7, 3.6.



5. Push the **On** button located on the front of the device to turn it on.
   A led lights up on the device.

6. Put the holding band around the arm and chest of the patient, over the clothes.



7. Close the holding band fastener.
8. If appropriate, adjust the holding band.

9. Put the device in the textile holding band.
10. Fasten the band around the device using the Velcro tape.

Warning
Do not unplug the cap or electrodes during the record.

Warning
Do not unplug the extender during the record.

3.3 Installing the IceCap

The IceCap records:

- 19 EEG channels
- The Oz electrode is used for ground connection.
- The FPz electrode is used as a reference for EEG calculation.

3.3.1 Required Equipment

Before installing the IceCap, make sure that the following components are available:

- IceCap
- Neuronaute Plus
- Battery
- Holding band
- Syringe
- Conductive paste

3.3.2 Installing the IceCap

Before installing the IceCap, make sure that all the components described previously are available and that the patient has no contraindications.

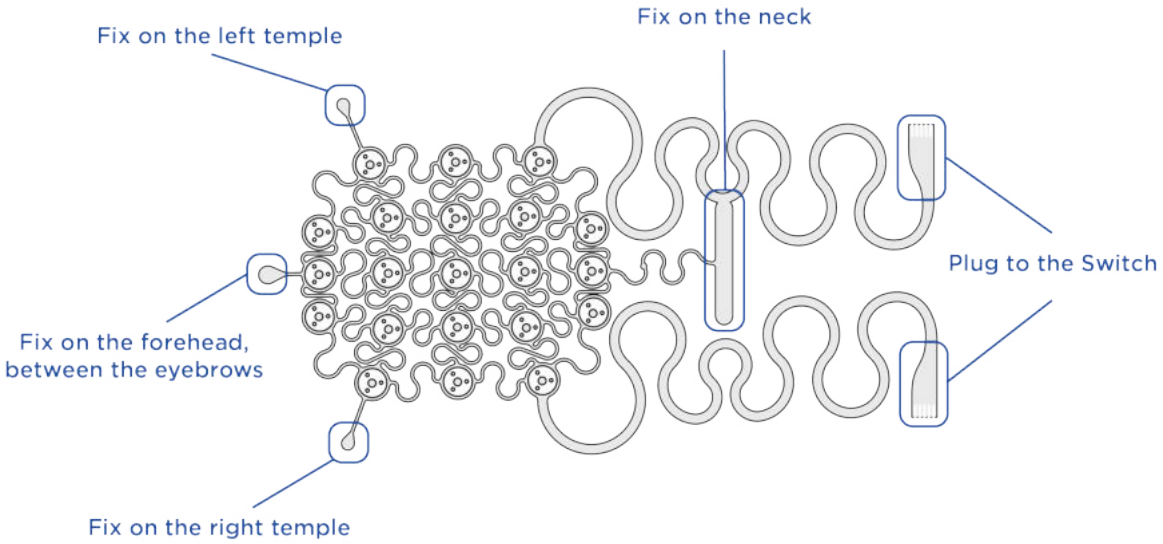
Note
It is recommended to wear gloves while installing the IceCap.

To install the IceCap:

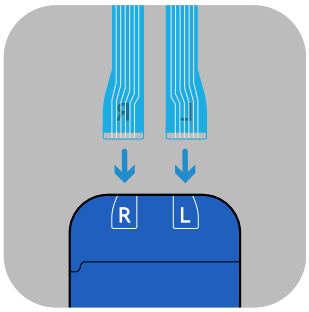
1. Stretch the IceCap and put it on the head of the patient, fixing it on the forehead (between the eyebrows) and on the temples.

2. Stretch the IceCap and fix it behind the head, on the patient's neck.

Warning
Make sure that the conductive side is in contact with patient's skin. Labels shall be on the outer side.



3. Fill the syringe with conductive paste.
4. Put conductive paste in the central hole of each electrode.
5. Remove the hair under each electrode using your fingers or a wooden stick.
6. Plug the IceCap to the **Neuronaute Plus**.



Warning
Make sure that the shape of the connectors corresponds to the shape indicated on the extender.

7. Softly push each electrode to ensure good contact of the conductive paste.

3.4 Installing the IceCap 2 / IceCap 2 Small

The IceCap 2 / IceCap 2 small records:

- 19 EEG channels
- The Oz electrode is used for ground connection.
- The FPz electrode is used as a reference for EEG calculation.

3.4.1 Size Chart

The IceCap 2 exists in two different sizes. Before using the device, make sure to determine the correct size using the size chart below.

To measure the head perimeter of the patient, place a tape measure on the protuberance located in the back the head and on the forehead.

If the patient is between two sizes, choose the inferior one.

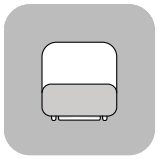
	Minimum head perimeter (cm)	Maximum head perimeter (cm)
IceCap 2 Small	43	53
IceCap 2	53	60

3.4.2 Required Equipment

Before installing the IceCap 2, make sure that the following components are available.

Warning
The conductive paste must be designed for EEG electrodes.

IceCap 2 / IceCap 2 small


IceAdapter

Gel electrode x1

Gloves

Skin preparation gel (mandatory if recording duration > 12h)

Conductive paste

Adhesive cream

Pads

Cups x2

Swabs

Compatible system

3.4.3 Preparing the Installation

Before installing the IceCap 2, make sure that all the components described previously are available and that the patient has no contraindications.

Note
It is recommended to wear gloves while using the IceCap 2.

To prepare the installation:

- Cut 21 pads squares;
- Put some skin preparation gel in a cup;
- Put some conductive paste in a cup.

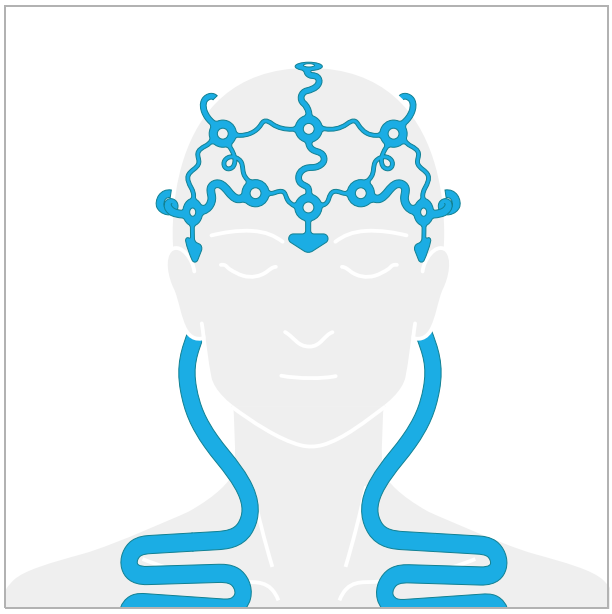
3.4.4 Installing the IceCap 2 / IceCap 2 Small

Before installing the IceCap 2 / IceCap 2 small, make sure that all the components described previously are available and that the patient has no contraindications.

To install the IceCap 2:

1. Stretch the IceCap 2 and put it on the head of the patient:
    - Peel the protective film off from the **Left** and **Right** strips and fix them to the temples.

    - Peel the protective film off from the **Front Nz** strip and fix it to the forehead (between the eyebrows).

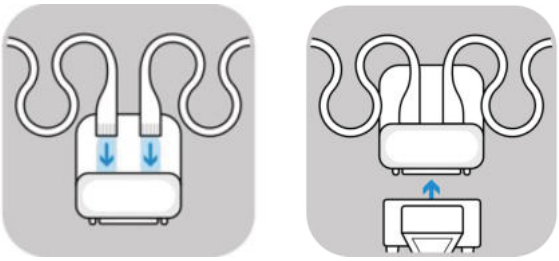


2. Peel the protective film off from the **Back** strip and fix it to the back of the head.

Warning
Fix the connectors to avoid any risk of strangulation.

Warning
Make sure that the conductive side is in contact with patient's skin. Labels shall be on the outer side.

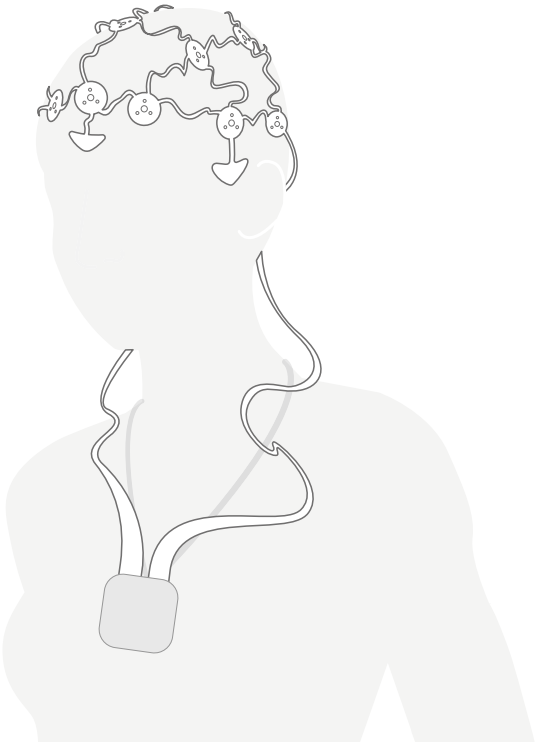
3. Check the electrodes positioning.
4. Using the wooden stick, remove the hair under each electrode and apply some skin preparation gel to the scalp.
5. Using your fingers, apply some conductive paste under each electrode.
6. Plug the IceCap 2 to the IceAdapter.



Warning
Make sure that the L and R marks from the flat cable correspond to the connectors.

7. Using a compatible device, check the impedance. If the values are too high, remove the hair under the corresponding electrodes and softly push the electrodes against the scalp.
8. Apply some adhesive cream on each pad square.

9. Place each pad square on an electrode, with the adhesive cream in contact with the electrode. Softly push the pad to spread the cream.
10. Check the impedance as described in step 8.



3.5 Installing Cup Electrodes

To connect cup electrodes to the **Neuronaute Plus**, connect each cup electrode to the corresponding inputs of the device and set the cup electrodes as described on the manufacturer's documentation.

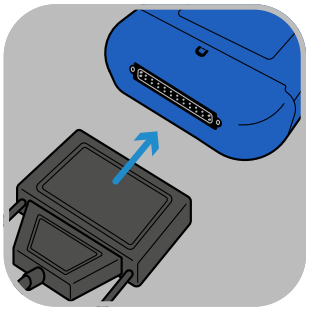
Warning
Cup electrodes must be used under the operating conditions provided by the manufacturer.

3.6 Installing a Micromed Cap

To install a Micromed cap to the **Neuronaute Plus**, refer to the manufacturer's documentation.

To plug the cap to the **Neuronaute Plus**, connect the DB25 cable to the extender.

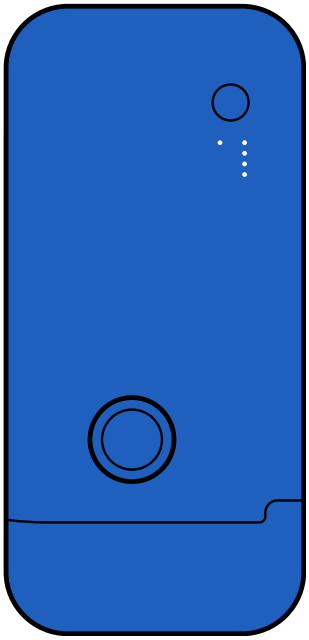
Note
If applicable, screw the 2 screws from the DB25 cable to the extender.



3.7 Neuronaute Plus LED Status

The **Neuronaute Plus** has two sets of LEDs located on its front:

- The LED located on the left gives information on the current record status.
- The LEDs located on the right give information regarding the battery.



3.7.1 Recorder LED

The following table details the different LED display and its corresponding status:

LED Display		Description
	Steady blue	Record ongoing (live streaming off)
	Flashing blue (slow)	Awaiting configuration
	Flashing blue (fast)	Record ongoing Data transfer ongoing
	Steady green	Record ongoing (live streaming on)
	Flashing yellow (fast)	End of record Data transfer ongoing
	Flashing yellow (slow)	End of record Data transfer complete
	Steady purple	Impedance is being displayed
	Red	Error. Contact the support.

3.7.2 Battery LEDs

The following table details the different LED display and its corresponding status:

LED Display		Description
	4 steady LEDs - white	Battery level <75%
	3 steady LEDs - white	Battery level between 50-75%
	2 steady LEDs - white	Battery level between 25-50%
	1 steady LED - white	Battery level <25%
	1 steady LED - red	Battery level <10%
	1 flashing LED - red	Battery level <5%
	4 flashing LEDs - red	No battery, backup power source

Note

Once the battery level drops under 10%, change the battery for a fully charged one.

3.8 Using Neuronaute Plus Battery

3.8.1 Battery autonomy

The battery has a 24h autonomy and must be changed every day.

Warning
Do not use the battery if shows autonomy issues.

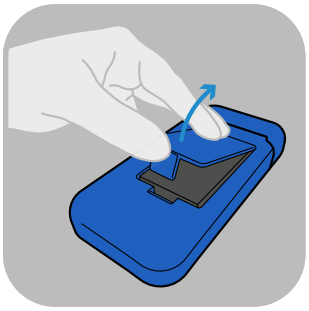
3.8.2 Changing the battery

Warning
To avoid interrupting the signal, the battery must be changed in less than 10 minutes.

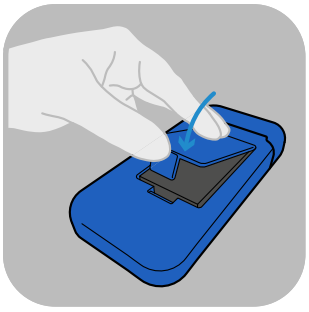
Warning
Do not touch the battery connector pins.

To change the battery:

1. Remove the velcro tape of the holding band.
2. Remove the device from the holding band. Do not remove the cap or electrodes.



3. Remove the battery cover located on the rear of the device.
4. Remove the battery from the device and put it on charge.



5. Plug a charged battery to the device.
6. Close the battery cover.

3.8.3 Charging the Battery

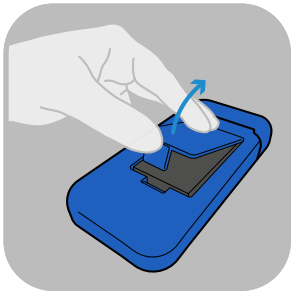
The batteries are charged using a charging station provided with the device.

Note

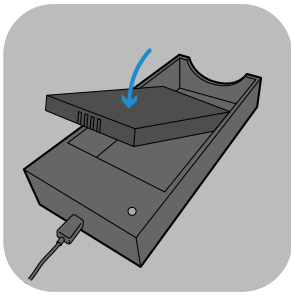
The battery has a 24h autonomy and must be changed every day.
It takes 3 hours to fully charge the battery.

To charge the battery:

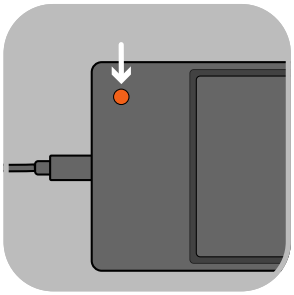
1. Remove the holding band.
2. Remove the device from the holding band.



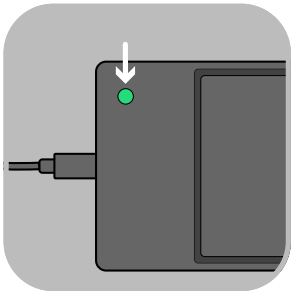
3. Remove the battery cover located on the rear of the device.



4. Plug the battery charger to a power supply.
5. Remove the battery from the device and put it on charge. After a few seconds, the LED flashes orange to indicate that the charge starts.



6. The LED turns to steady orange to indicate that the charge is ongoing.



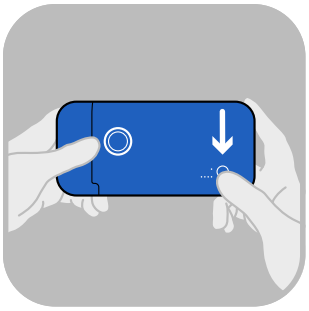
7. Once the battery is charged, the charger's LED turns to steady green.
8. Remove the battery from the charger.

3.9 Turning Off the Neuronaute Plus

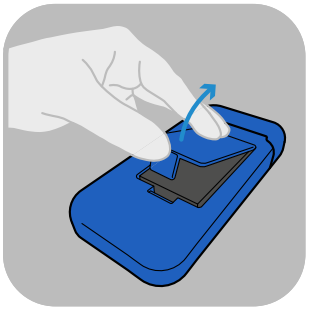
At the end of the recording, the **Neuronaute Plus** must be turned off before starting a new record.

To turn off the **Neuronaute Plus**:

1. Remove the velcro tape of the holding band.
2. Remove the device from the holding band. Do not remove the cap or electrodes.



3. Push the **On/Off** button located on the front of the device to turn it off.



4. Remove the battery cover located on the rear of the device.
5. Remove the battery from the device and put it on charge.

Warning

The **Neuronaute Plus** must only be turned off by a healthcare professional.

Warning

Remove the battery from the **Neuronaute Plus** after each use to prevent damage.

4. BIOSERENITY CLOUD

BioSerenity Cloud is a web-based software for healthcare professionals. It enables the healthcare professional to receive, store and analyze EEG signals.

To access the EEG analysis platform, connect to: neuro.app.bioserenity.com

Note
A Google Chrome web browser is recommended to use the web platform. BioSerenity does not guarantee Cloud performances with other web browsers.

Note
It is recommended to use a 13 inches or larger screen with the device.

4.1 Prerequisites

Before using **BioSerenity Cloud** for the first time, it is necessary to:

- Make sure that a corresponding healthcare professional account exists
- Download the application on a mobile device (refer to “Installing Neuronaute Mobile Application”, page 49).
- Have access to an Internet connection (Wi-Fi)

4.2 Interface Overview

Header

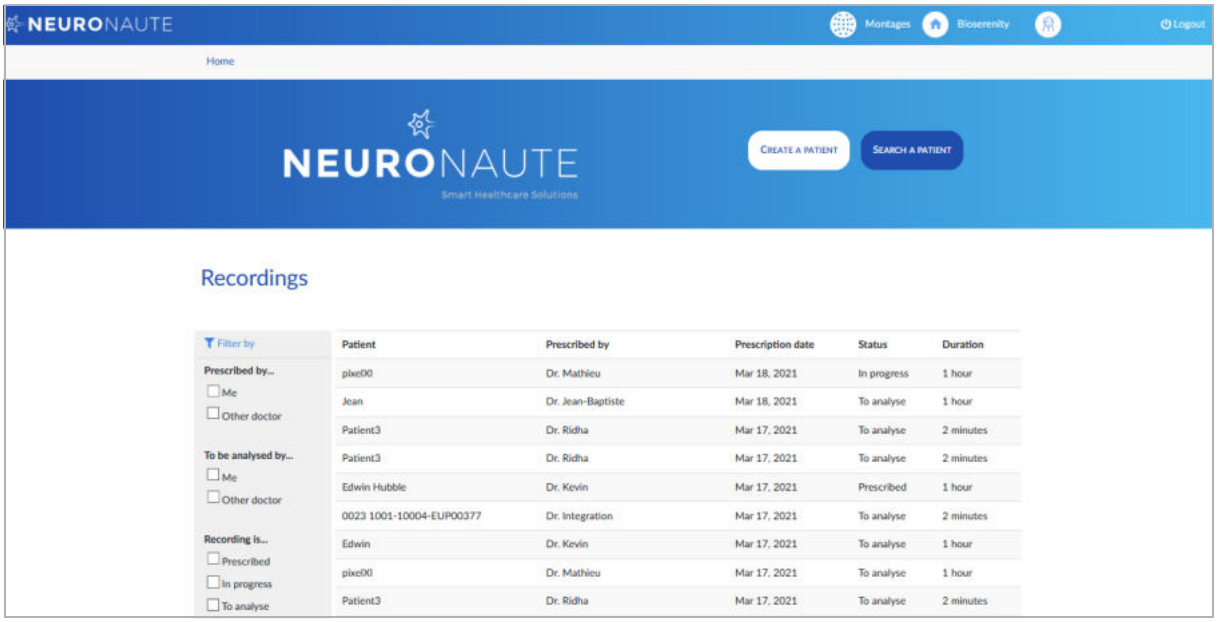
The top part of the interface is called the ribbon. It enables access to the organization and profile settings.

Workspace

The center part of the interface is called the workspace. It displays all information and actions regarding the cloud platform. A navigation tree located in the upper side of the zone shows the current path (example: Home / Patient / Details).

Footer

The bottom part of the interface is called the footer. It displays the legal information and enables access to the support features.


NEURONAUTE
Montages
Bioserenity
Logout
Home
NEURONAUTE
Smart Healthcare Solutions
CREATE A PATIENT
SEARCH A PATIENT
Recordings
Filter by
Prescribed by...
Me
Other doctor
To be analysed by...
Me
Other doctor
Recording is...
Prescribed
In progress
To analyse
Patient
Prescribed by
Prescription date
Status
Duration
pixel0l
Dr. Mathieu
Mar 18, 2021
In progress
1 hour
Jean
Dr. Jean-Baptiste
Mar 18, 2021
To analyse
1 hour
Patient3
Dr. Ridha
Mar 17, 2021
To analyse
2 minutes
Patient3
Dr. Ridha
Mar 17, 2021
To analyse
2 minutes
Edwin Hubble
Dr. Kevin
Mar 17, 2021
Prescribed
1 hour
0023 1001-10004-EUP00377
Dr. Integration
Mar 17, 2021
To analyse
2 minutes
Edwin
Dr. Kevin
Mar 17, 2021
To analyse
1 hour
pixel0l
Dr. Mathieu
Mar 17, 2021
To analyse
1 hour
Patient3
Dr. Ridha
Mar 17, 2021
To analyse
2 minutes

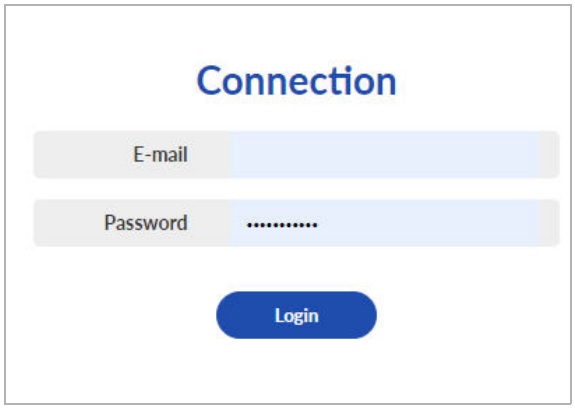
4.3 Connecting to the Cloud Platform

Note
To make sure that your account has been created, you must have received a confirmation email containing a temporary password.

Once a personal account has been created, the cloud platform is accessible.

To connect to the cloud platform:

1. Go to the cloud platform using the link provided by BioSerenity.

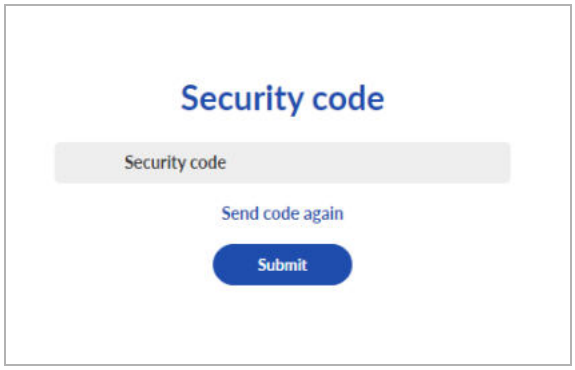


2. Enter the email address and temporary password and click the **Login** button.

3. A security code is required.
    - Click the **E-MAIL** button to receive the security code at the e-mail address used to connect to the cloud platform.
      or
    - Click the **SMS** button to receive the security code at the phone number associated to the account (optional).

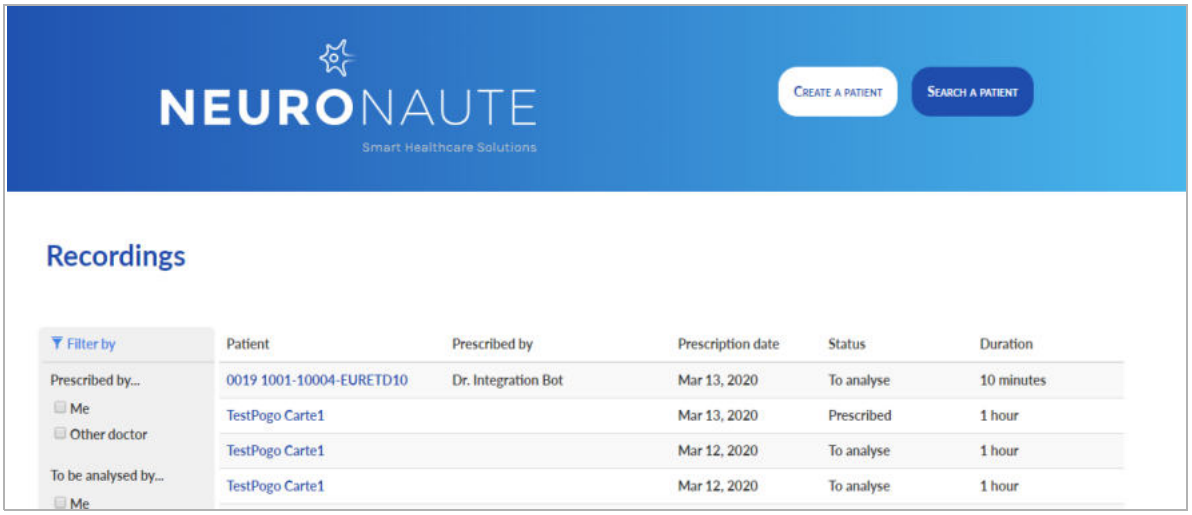
Note
A new security code is required for every connection to the cloud platform.

Note
To send the security code again, click **Send code again**.



4. Enter the security code and click the **Submit** button.

5. Select an organization from the list.
   The homepage appears.



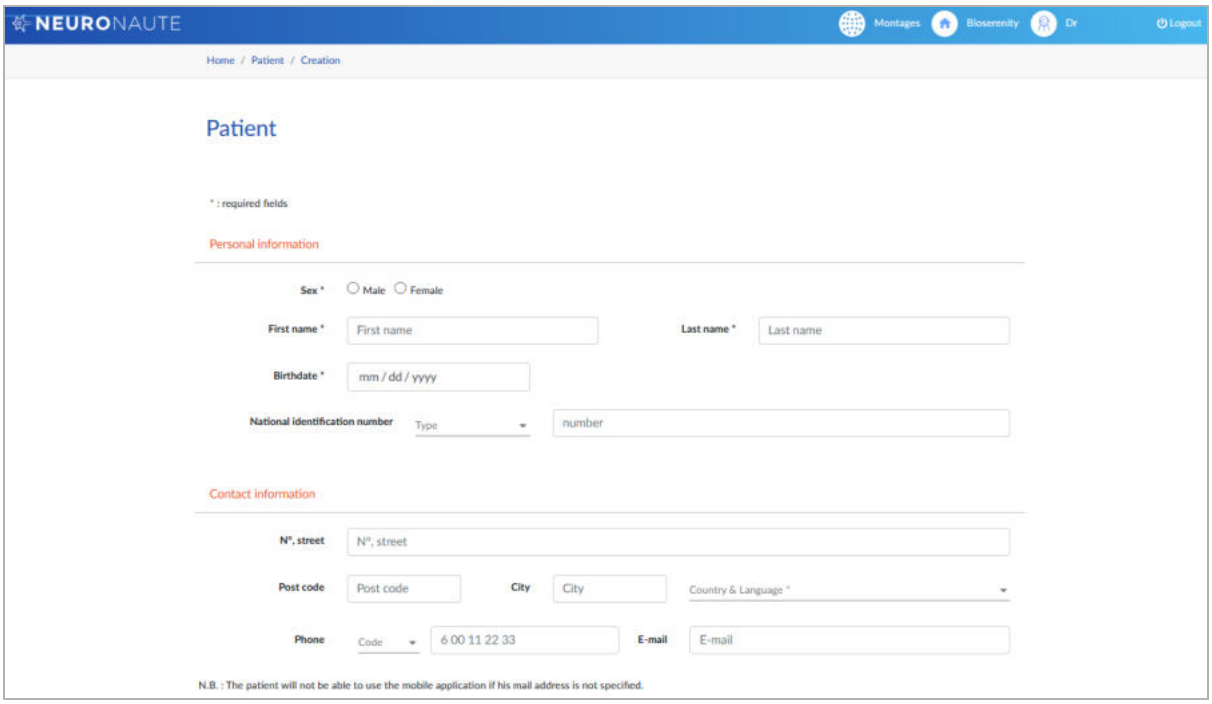
4.4 Managing Patients

4.4.1 Creating a Patient

When creating a patient profile, not all information is mandatory. Yet, the more information is completed, the most optimized the solution will be.

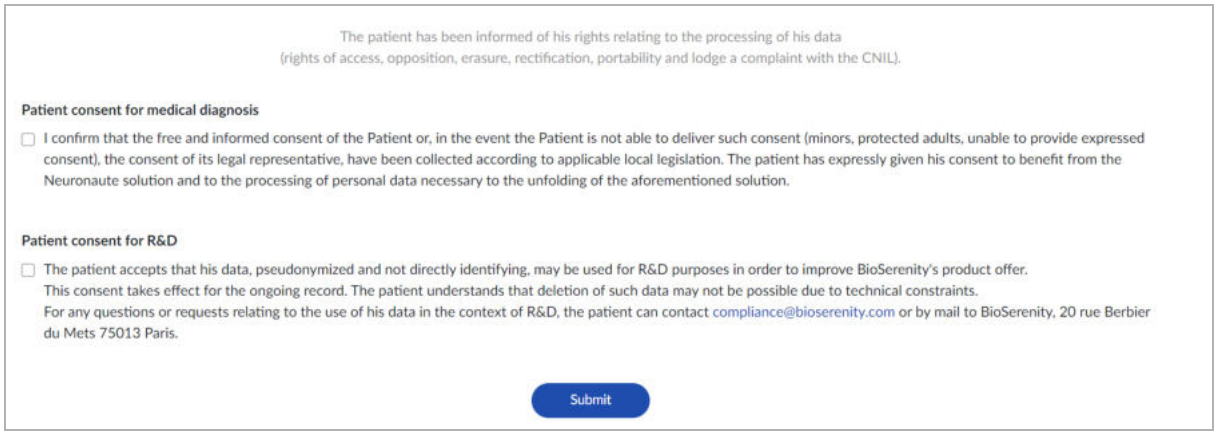
To add a new patient to the database:

1. From the homepage, click the **Create a Patient** button.
   The patient creation window appears.

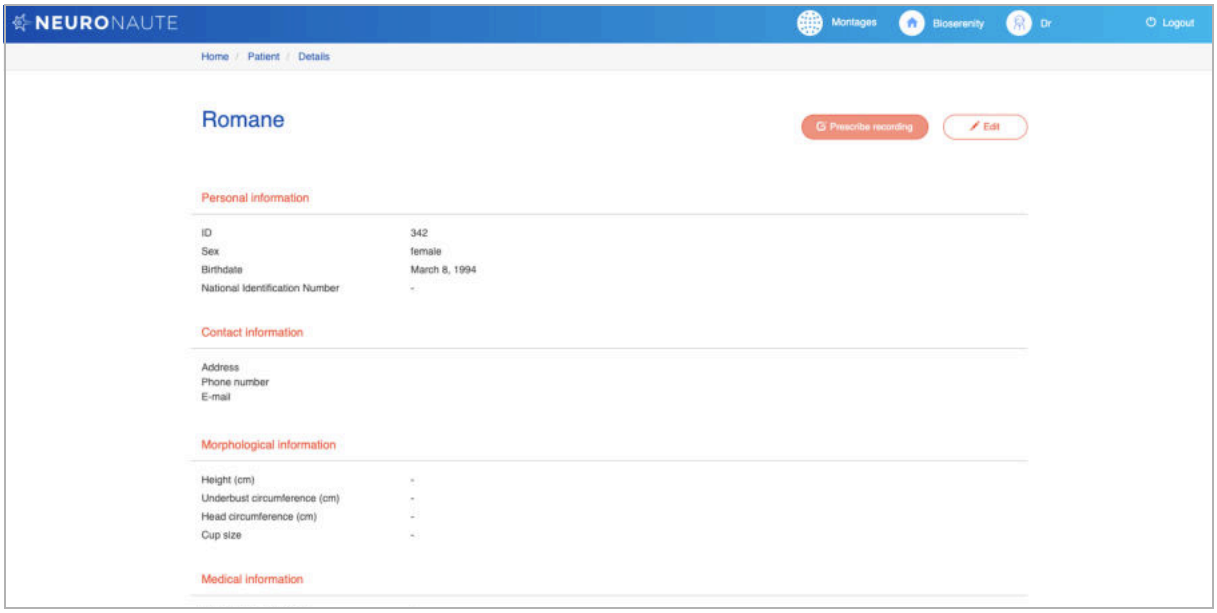


2. Enter the patient personal information.
3. Select a national identification number format and enter the corresponding number.
   The national identification number changes depending on the social security system.

4. Enter the patient additional information.
5. Enter the patient morphological information (not mandatory).
6. Take into account the information regarding the consent of the patient and check the box.



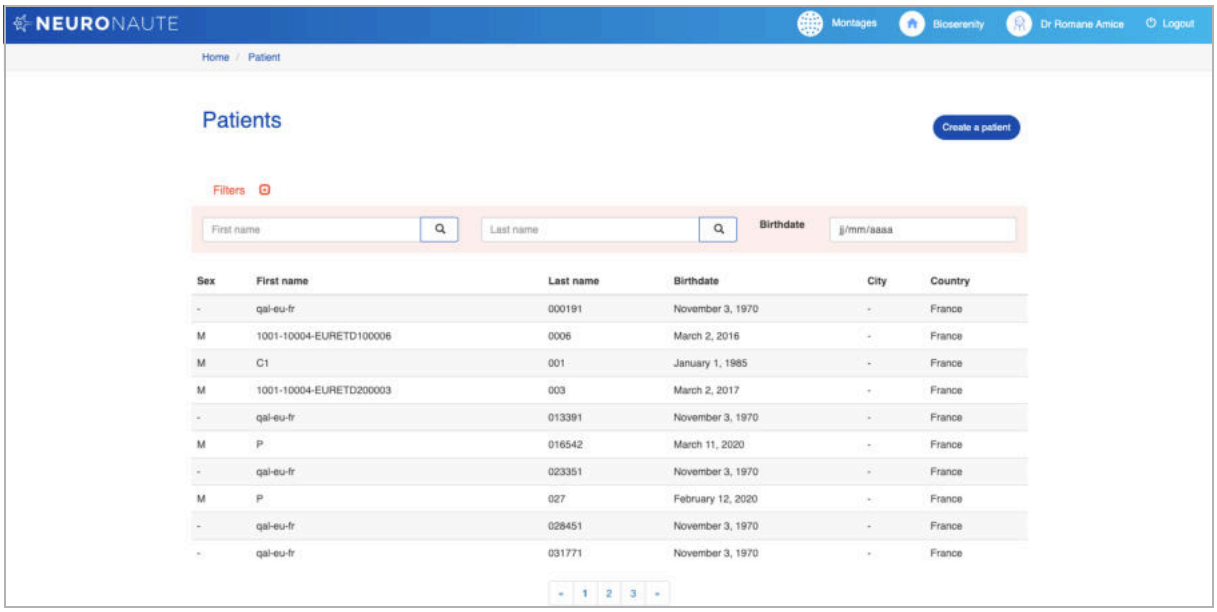
7. Click the **Submit** button to confirm the creation of the profile.
The patient profile appears.



4.4.2 Searching for a Patient

To search for a patient from the database:

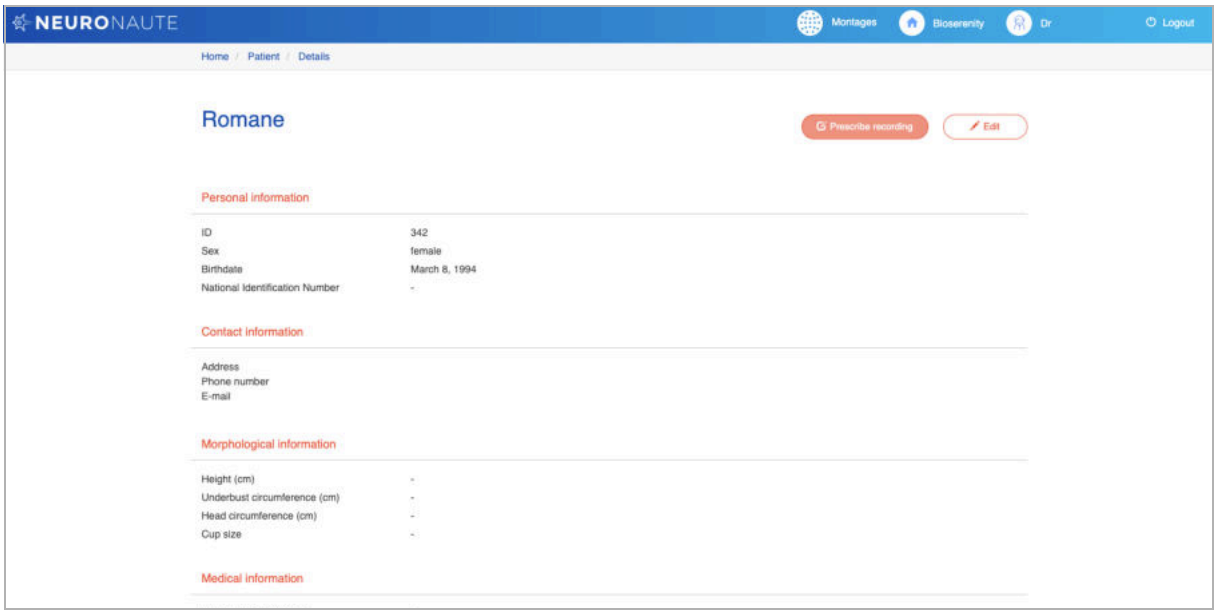
1. From the homepage, click the **Search a Patient** button.
   The patient list window appears.



2. Enter the search criteria to find a patient.
   The list is refreshed automatically.

Note
Use the button to display/hide the search criteria.

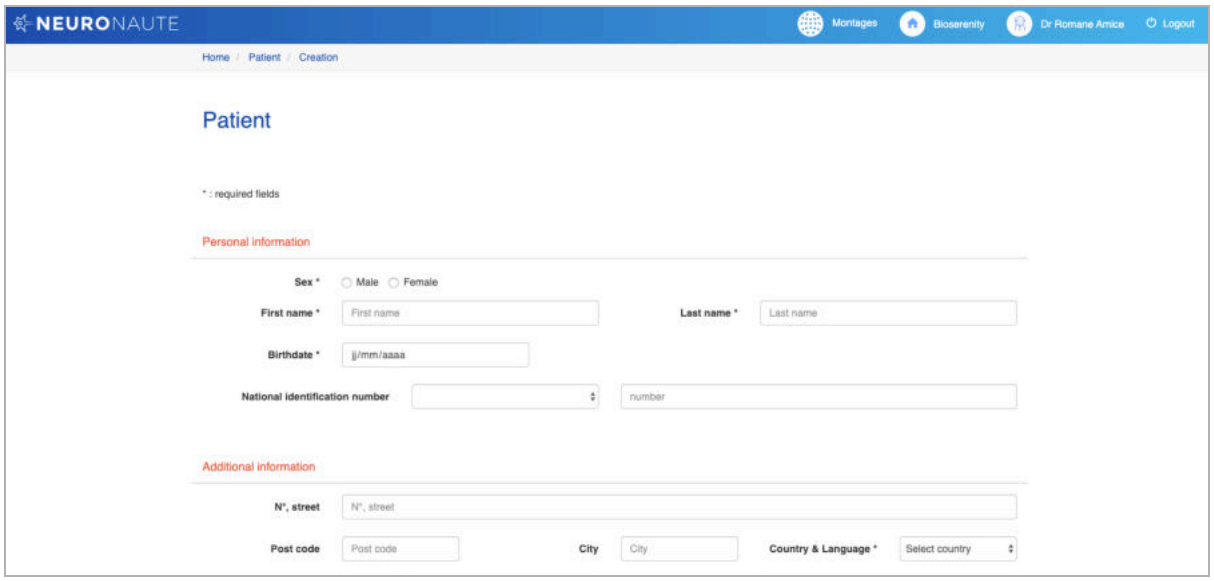
3. Click on the desired patient from the list.
   The patient profile appears.



4.4.3 Editing a Patient Profile

To modify a patient profile:

1. Search for a patient (refer to “Searching for a Patient”, page 39).
2. From the patient profile, click the **Edit** button.
   The patient edition window appears.



3. Edit the patient information (refer to “Creating a Patient”, page 37).
4. Once the patient profile is edited, click the **Submit** button.

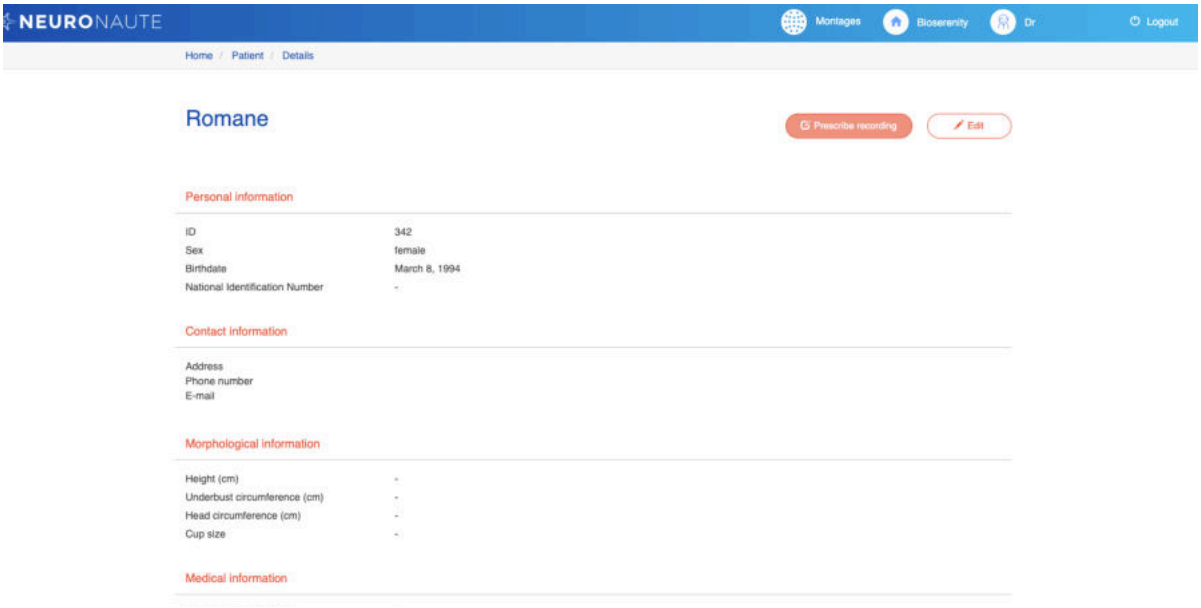
4.5 Managing Records

4.5.1 Prescribing a Record

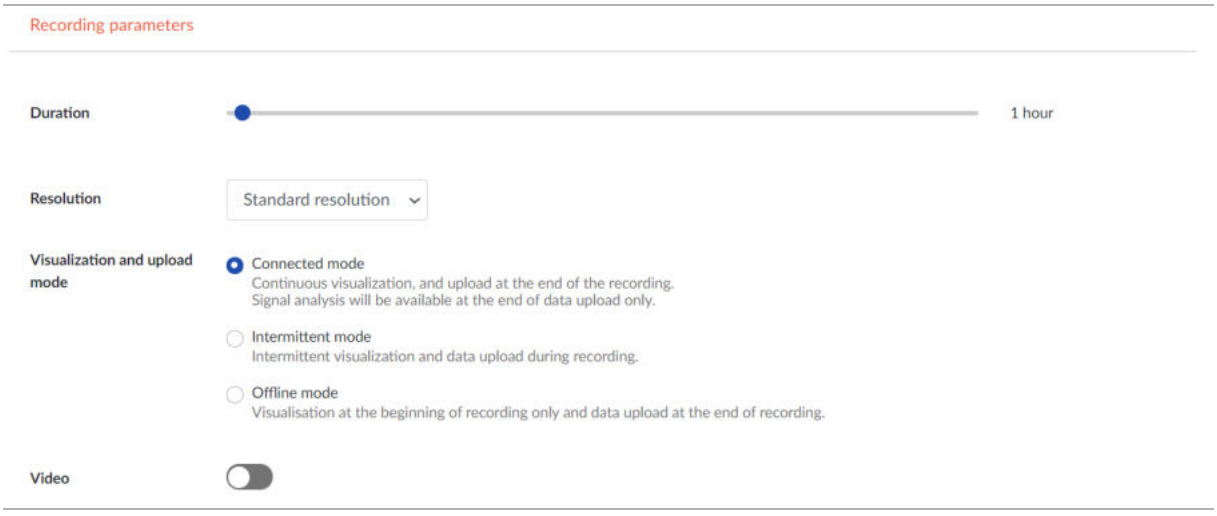
Note
A record can only be started from the mobile application.

To prescribe a record to a patient:

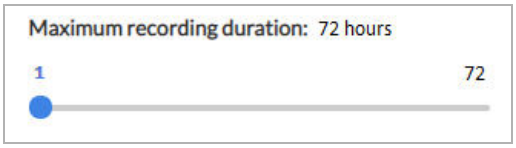
1. From the homepage, click the **Search a Patient** button.
   The patient list appears.
2. Select a patient to display its profile.



3. Click the **Prescribe recording** button.
   The record creation window appears.

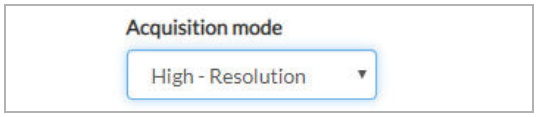


4. Set the duration using the radio buttons.



5. Set the acquisition mode:
   - Standard resolution (*recommended*, sampling frequency is about 250 Hz)
   - High-resolution (sampling frequency is about 500 Hz))

Note
The high-resolution acquisition mode reduces the battery life.

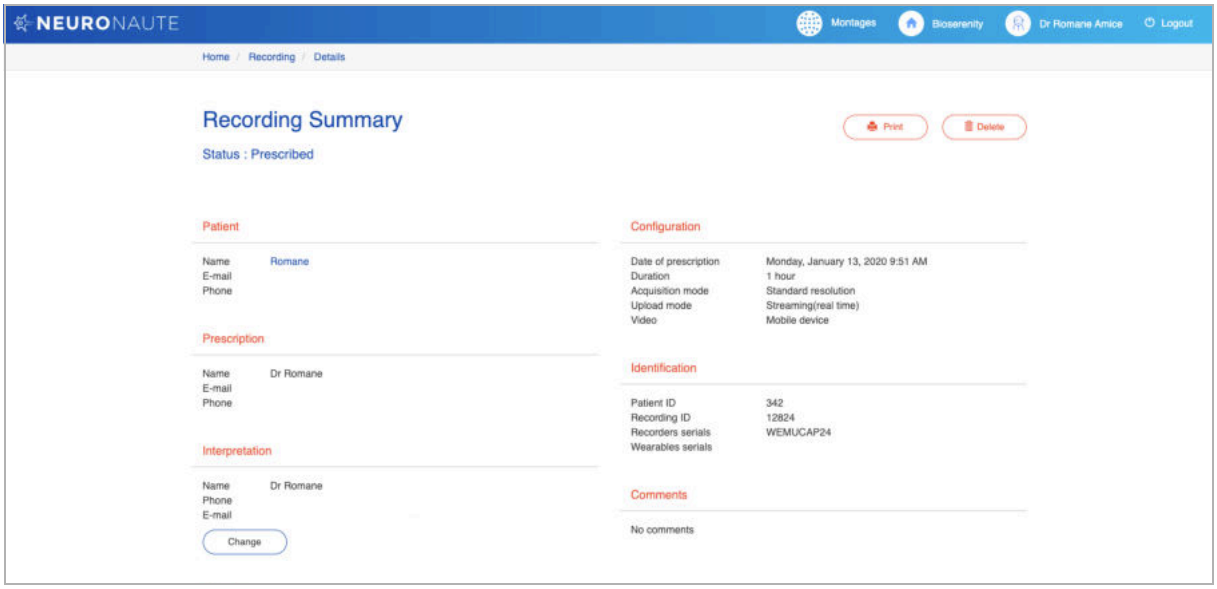


6. Select a visualization and upload mode:
   - **Connected mode**
     Continuous visualization.
     Data upload and signal analysis at the end of the record.
   - **Intermittent mode**
     Intermittent visualization and data upload during recording.
   - **Offline mode**
     Visualization at the beginning of the record
     Data upload and signal analysis at the end of the record.

Note
The live EEG reduces the battery life.

7. Check the corresponding box to enable video display (optional).

8. Click the **Submit** button to prescribe the record.
   The record summary appears.



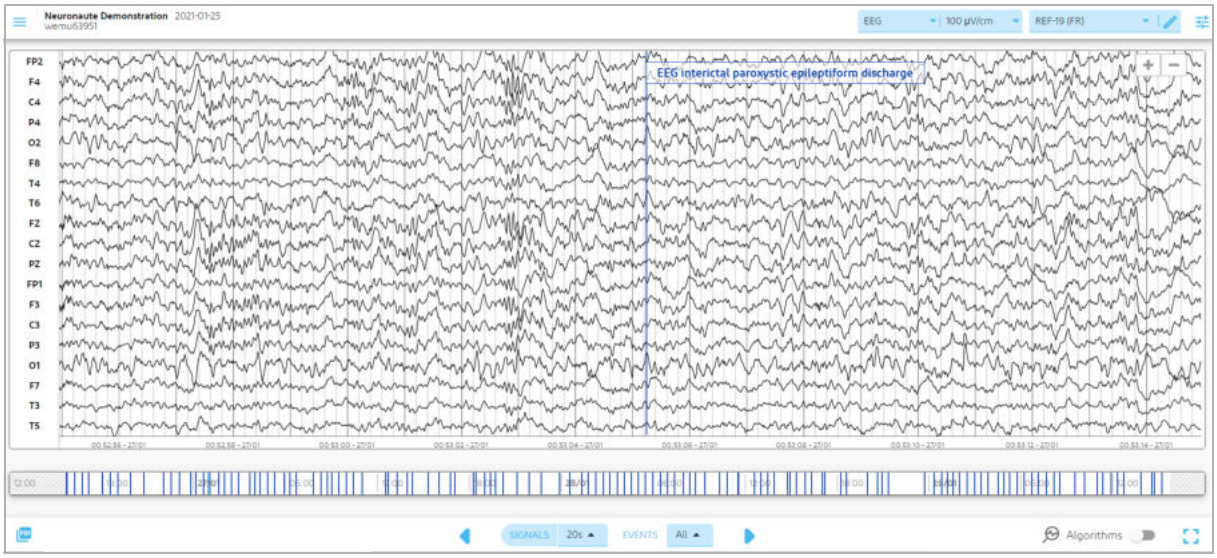
4.5.2 Recording Traces

The recording traces are available from the recording summary. It enables:

- Seeing the record start / end time
- Accessing the analysis platform (refer to “Analysis Platform”, page 44)
- Downloading data as an EDF file

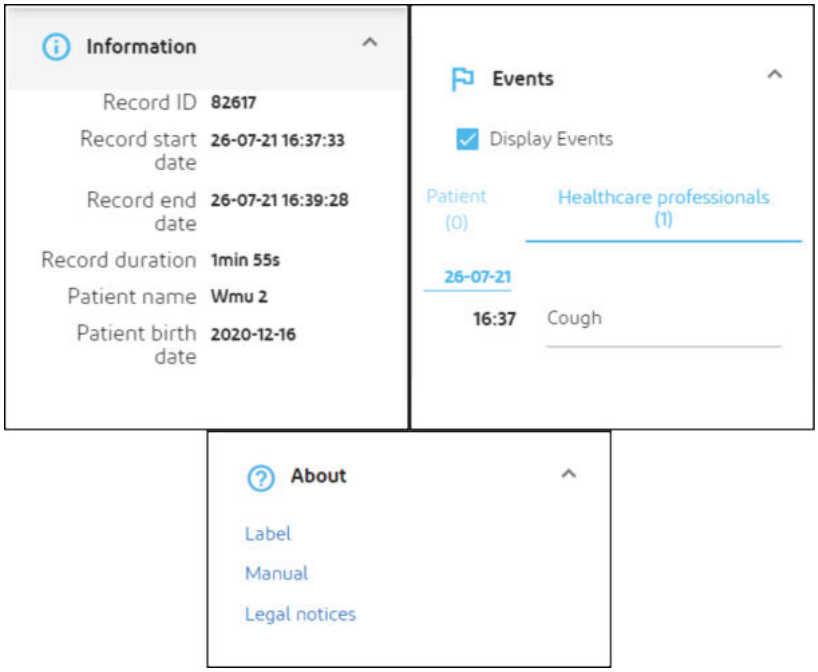
4.6 Analysis Platform

The analysis platform is available from the record summary once the cloud platform receives data from the recorder.



4.6.1 Analysis Platform Menu

The menu located on the left-side of the screen displays information regarding the current EEG analysis.



Information

Identifies the current record and display its Id, start / end date and duration.

Events

Lists the events reported from the mobile application or annotated by the healthcare professional during or after the record.

About

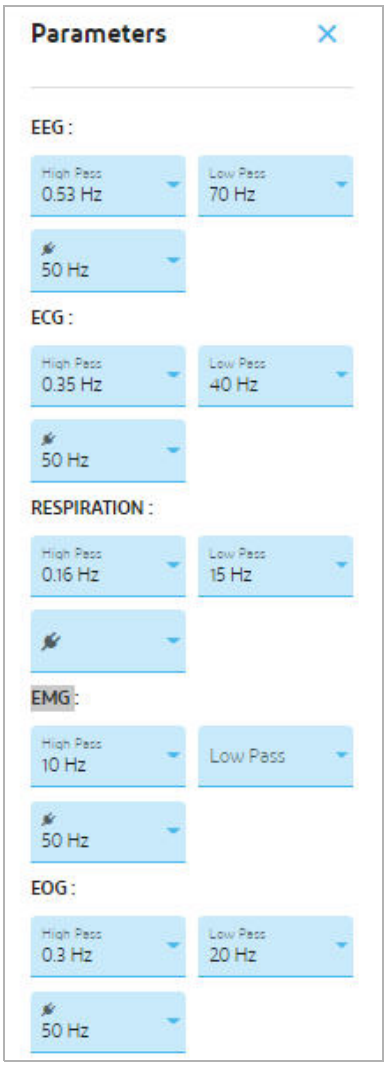
Displays links towards the user manual, product label and legal notices.

Parameters

Configures the grid display (background color, grid and scale configuration, day/night configuration, channels display).

Parameters also enable configuring the filters for the EEG signal display:

- The HP (high-pass) filter passes signals with a frequency higher than the cutoff frequency and attenuate signals with frequencies lower than the cutoff frequency.
- The LP (low-pass) filter passes signals with a frequency lower than the cutoff frequency and attenuate signals with frequencies higher than the cutoff frequency.
- The notch filter attenuates signals with a frequency of 50Hz / 60Hz depending on the power supply frequency.



4.6.2 Analysis Platform Toolbar

The analysis platform ribbon displays:

- Time mark of the record
- PDF export tool
- Analysis time frame
- Manual events display
- Full screen mode

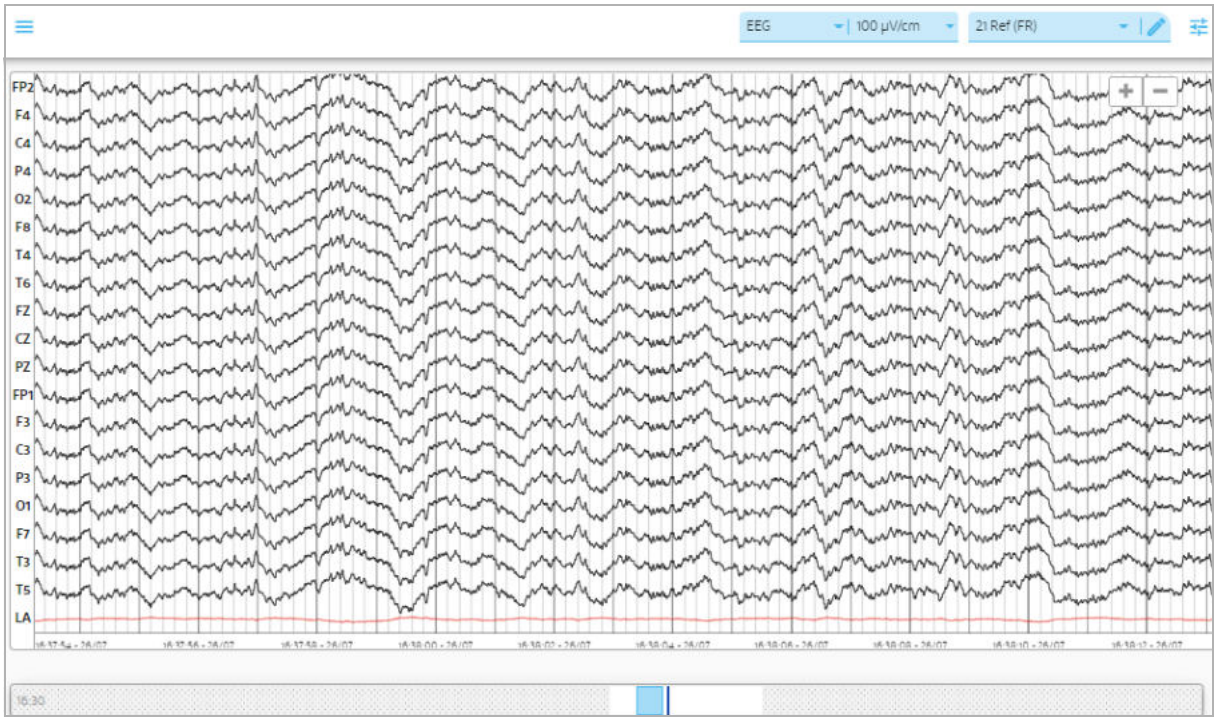
4.6.3 Selecting Gains

Gains can be selected from the menu located in the upper right section of the analysis platform.

Gain selection is applicable for ECG, EEG, EOG, EMG and respiration.

4.6.4 Focusing on an Event

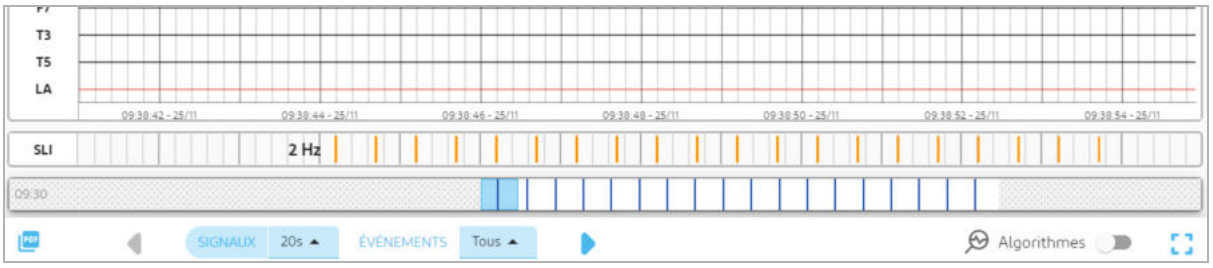
Events from the record display in a dedicated section from the bottom part of the screen. Double-clicking on an event from the bar centers the view on the event.



4.6.5 IPS Protocols Display

The lower section of the screen displays IPS protocols used during the record.

The section displays flash occurrences and frequency (Hz).



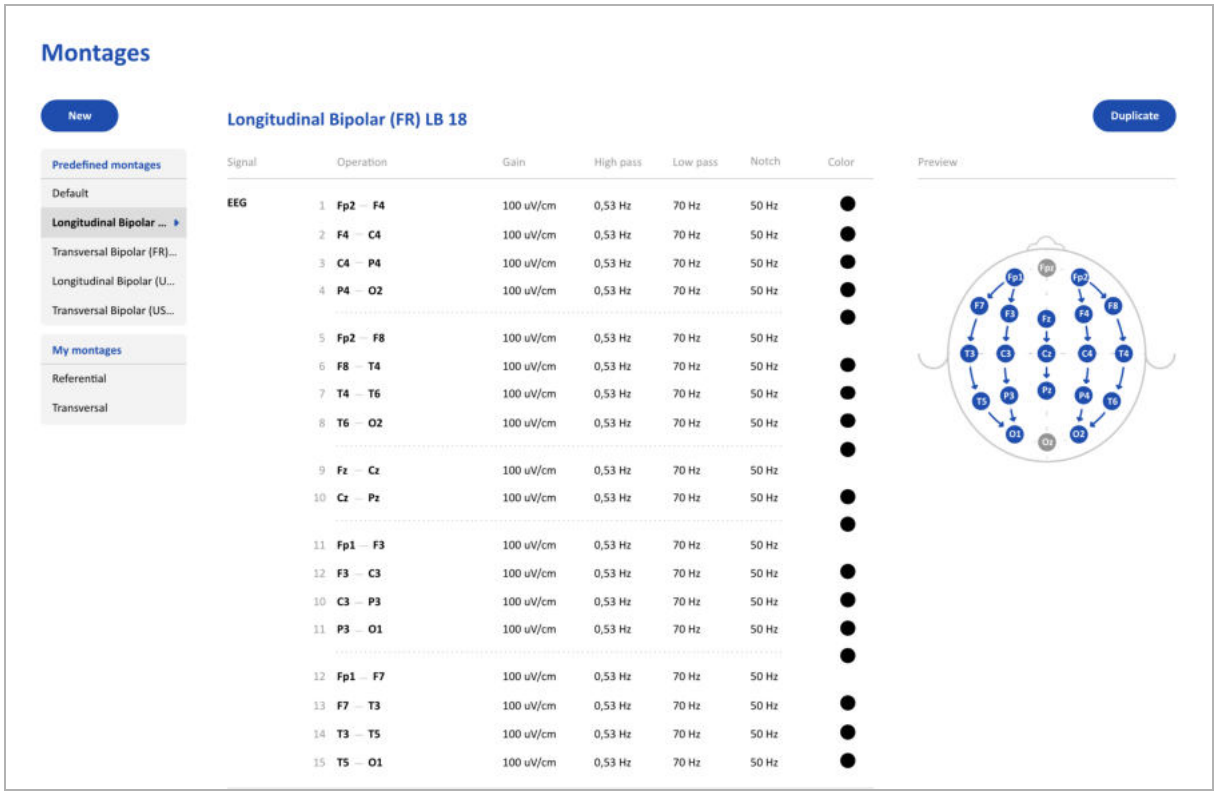
4.7 Creating Montages

A montage is a combination of channels, the results of operations carried out on the signals received from each electrode.

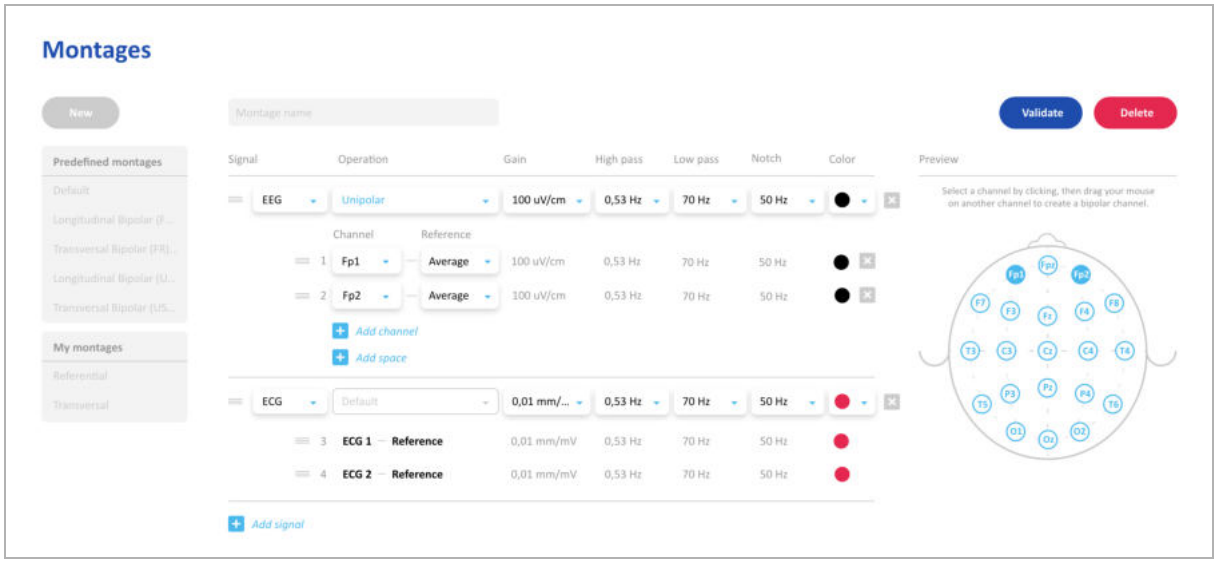
A default montage is available when using **Neuronaute**. The healthcare professional can create customized montages from scratch or from a predefined one.

To create a new montage from scratch:

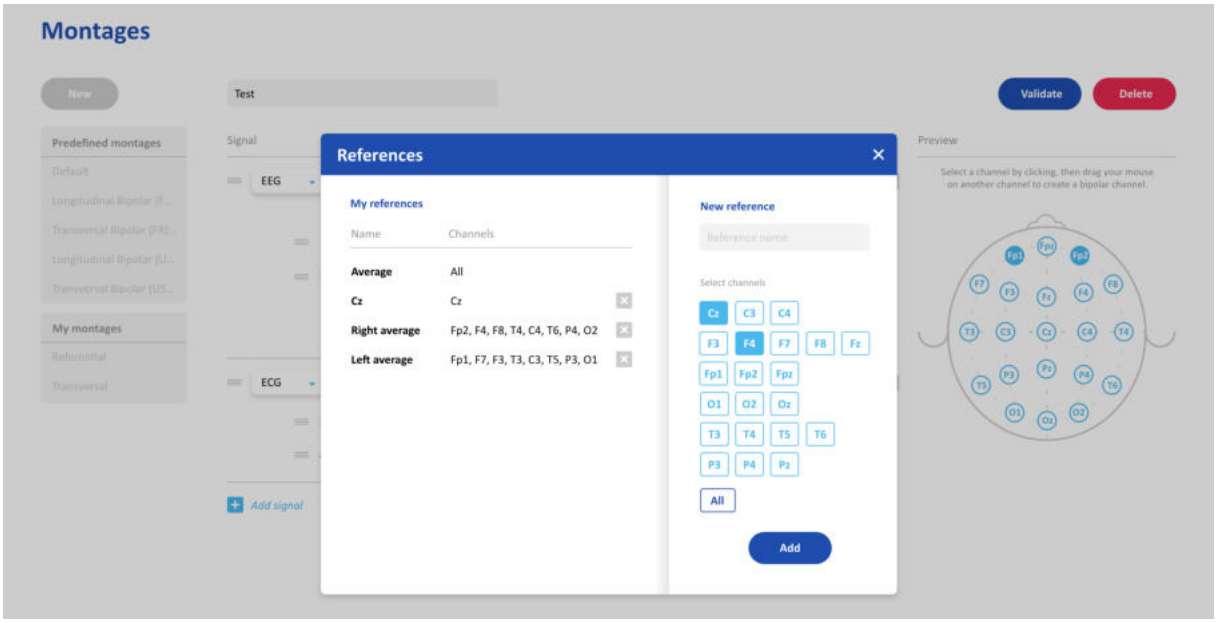
1. From the cloud platform, go to the ribbon and click on the button.
   The montages page appears.



2. From the upper left section of the screen, click on **New**.
   The montage creation page appears.



3. Enter a montage name.
4. If appropriate, select an existing montage and duplicate it to use as a basis for the new montage.
5. From the montage edition window:
    - Select a signal type and edit the associated parameters.
    - Add and organize the EEG channels needed. The schema can also be used to add unipolar (by clinking) and bipolar (by dragging) channels.
    - For each channel, a reference can be selected from a list or created/edited manually.



6. Once the montage is complete, click the **Validate** button.
The montage is added to the montage list.

5. NEURONAUTE MOBILE APPLICATION

Neuronaute mobile application is available for iOS and Android.

Neuronaute mobile application enables the user to:

- Create a patient.
- Prescribe a record.
- Visualize EEG signals during a recording.

Note
Using the mobile application requires an account provided by BioSerenity.

Note
The Android mobile application is intended for use with Neuronaute Plus only.

5.1 Installing Neuronaute Mobile Application

The mobile application requires the use of a mobile device (tablet) with a Bluetooth communication (version 4.0 or higher) and an Internet connection (4G or Wi-Fi).

Note
The Android version of the mobile application requires Wi-Fi.

To install the mobile application:

1. Open a web browser and search for the application.
2. Read and accept the terms of use by checking the corresponding box.
3. Tap on the application icon.

4. Tap on **Install**.
5. Once the installation is complete, the application icon appears on the device interface.

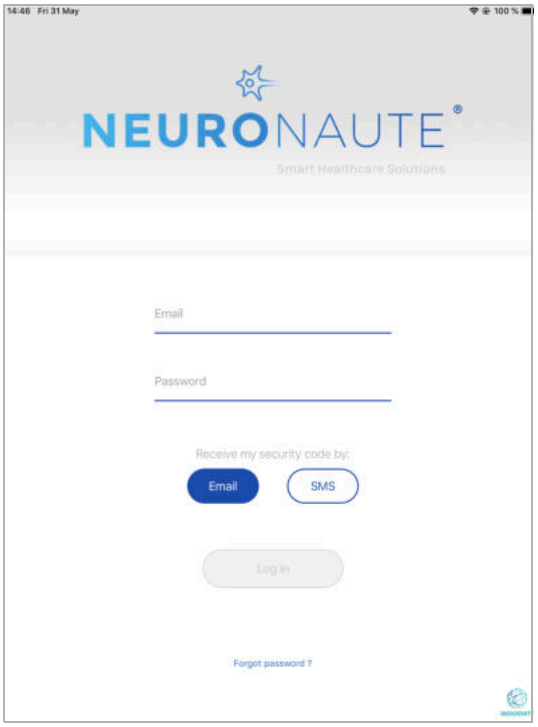
5.2 Connecting to the Mobile Application (iOS Only)

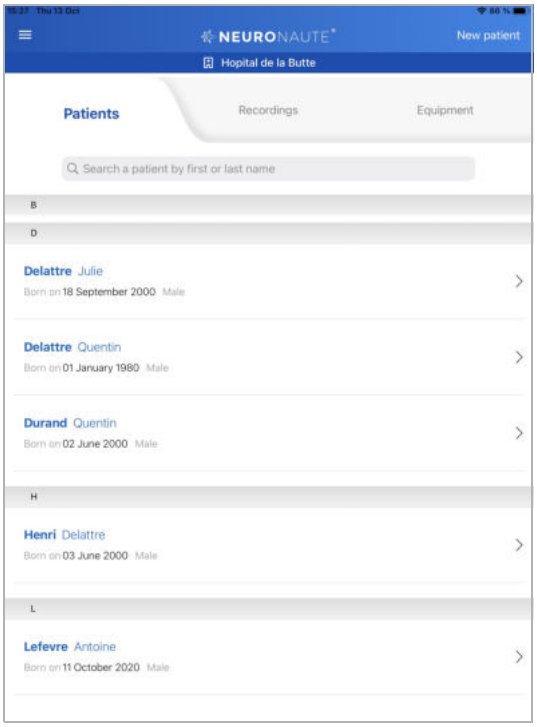
To connect to the mobile application:

1. Enter the email address and password provided by BioSerenity.
2. Select a security code reception mode (e-mail or SMS).
3. Tap **Connect**.
4. Enter the security code.

Note
A new security code is required for every connection to the mobile application.

5. Select an organization and tap **Validate**.
   The homepage appears.
6. Ensure Bluetooth is enabled on the mobile device.





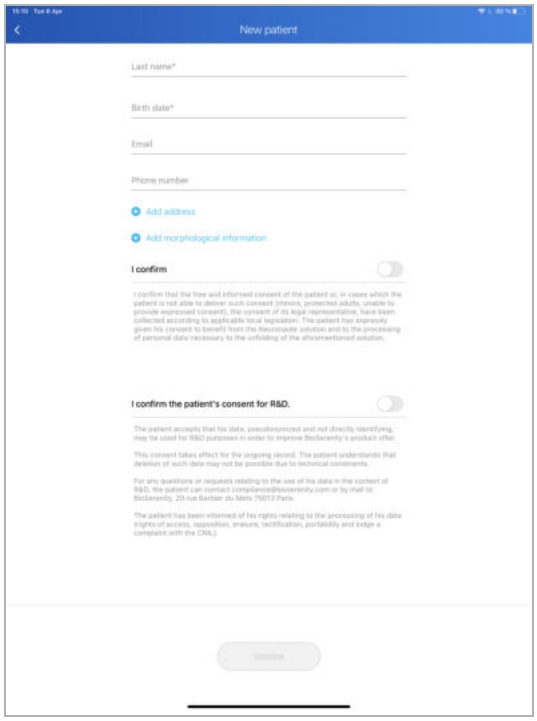
5.3 Creating a Patient (iOS Only)

To create a patient from the mobile application:

1. From the homepage, tap the **New Patient** button located in the upper right section of the screen.
   The patient creation window appears.
2. Enter the patient information.

> **Note**
> *Male / Female*, *First Name*, *Last Name* and *Birthdate* are mandatory.

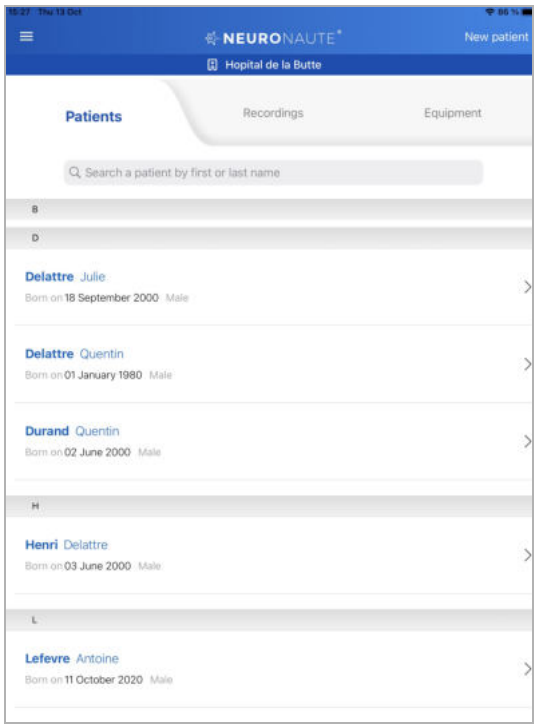
3. Tap **Validate**.
   A confirmation window appears.



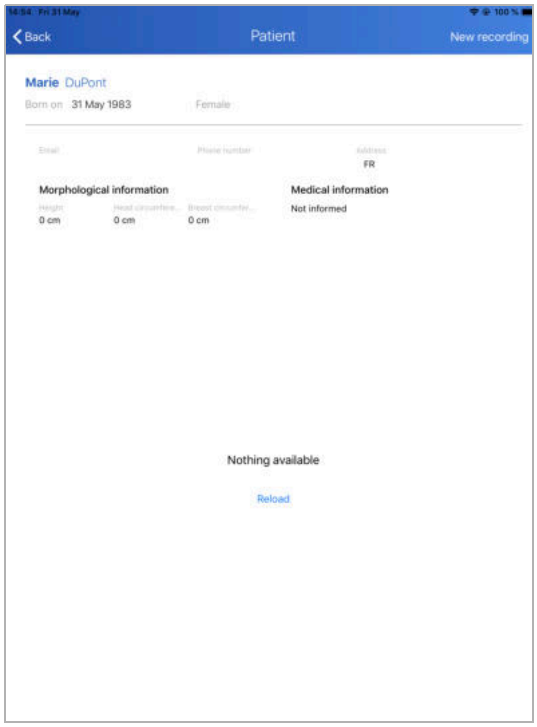
5.4 Prescribing a Record (iOS Only)

To prescribe a record:

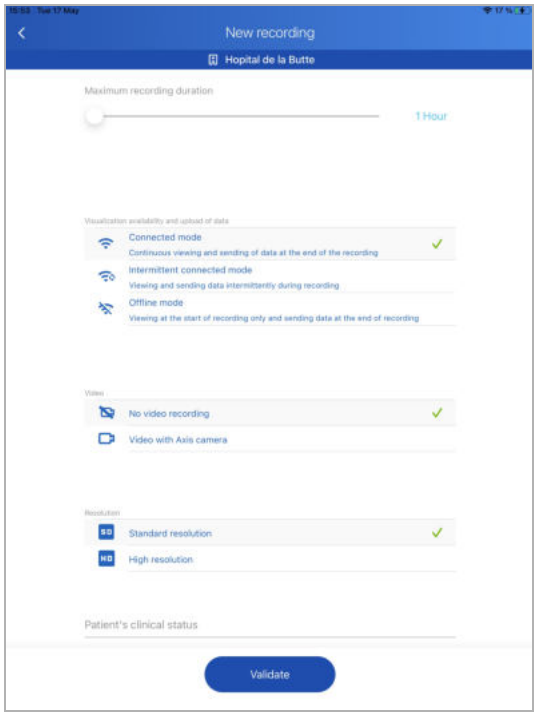
1. From the *Patients* tab, search for a patient using the search bar.



2. Select a patient from the list.
   The patient's information appears.

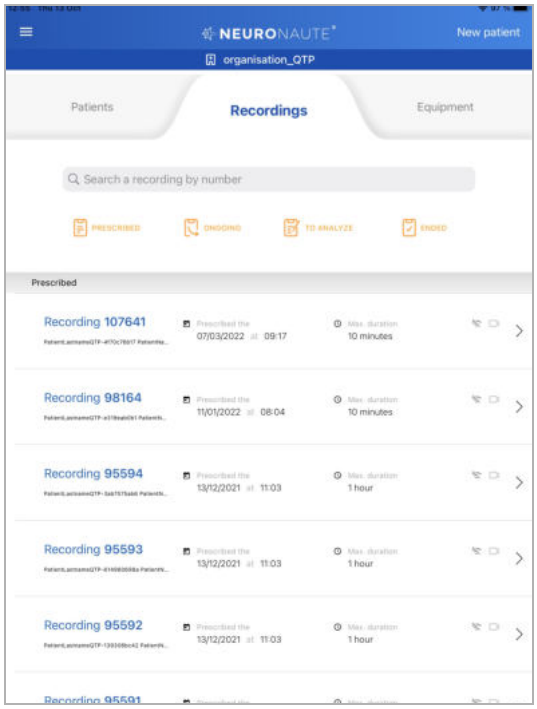


3. Tap the **New recording** button located on the upper right section of the screen. The record creation window appears.



4. The *Maximum recording duration* will automatically end the recording once it reaches this duration. An EEG recording can always be ended manually prior to the maximum duration.
5. Set the visualisation availability:
   - **Connected mode**
     EEG signals displays during the recording, data uploads when recording is finished.
   - **Intermittent connected mode**
     Uploads data during recording, unless currently displaying EEG signals.
   - **Offline mode**
     EEG signals display when starting the record, data upload at the end of the record.
6. Select a video recording mode.

7. Tap **Validate**.
   The recording session is added to the patient profile and to the sessions list.



5.5 Starting a Record (iOS)

Note
If the recorder is not found by the application during the connection:

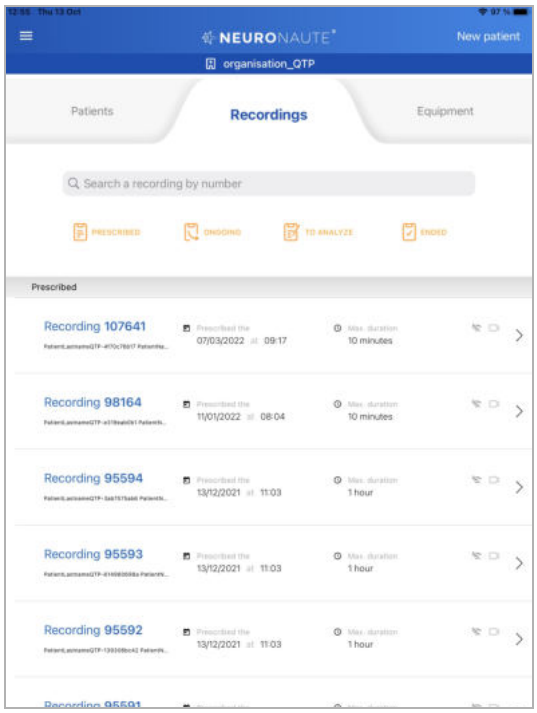
1. Check that the Bluetooth from the device is on.
2. Refresh the devices page.
3. If the problem persists, contact the support.

Note
If the record does not start:

1. Check that the cables connected to the router and camera are properly plugged in.
2. Disconnect and then reconnect the cables connected to the router and camera.
3. If the problem persists, contact the support.

To start a record:

1. From the *Recordings* tab, select a recording session.

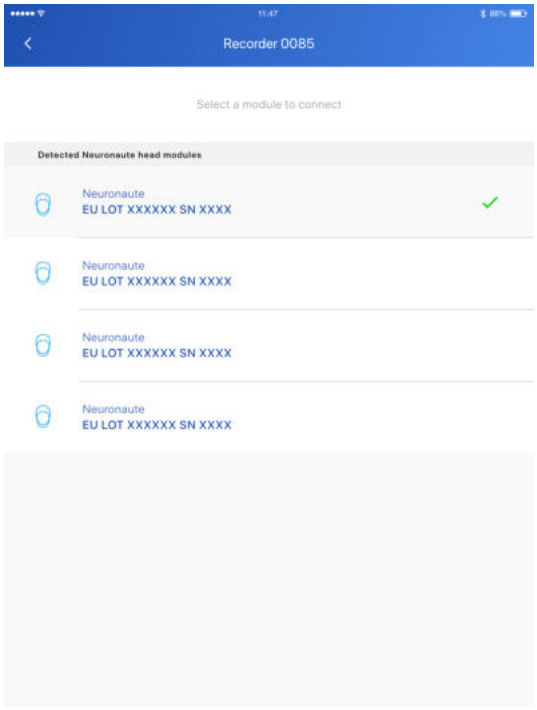


2. In case of EEG video recording, plug the camera into the router and scan the router QR code.

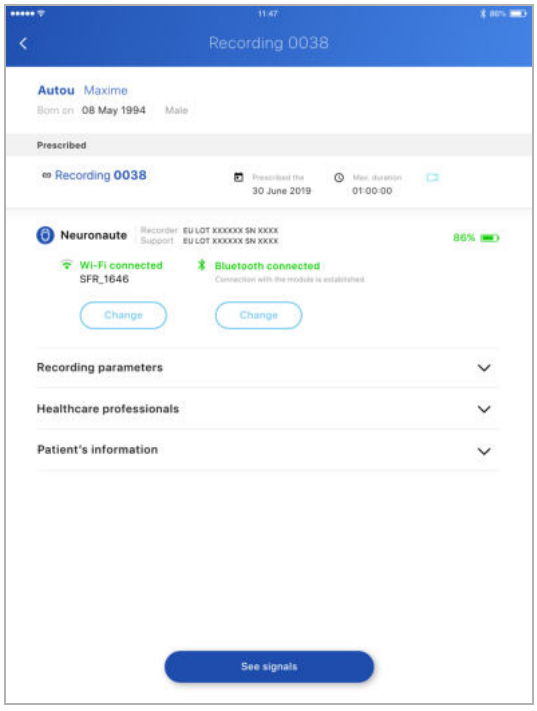
Note
During the recording, the patient should stay within the field of view of the camera.

3. Select a recorder to connect to.
   The recorder information displays in the session.

Note
The recorder must be turned on to appear in the list.
Refer to “Neuronaute Recorder LED Status”, page 43.



4. If no Wi-Fi network has ever been associated with the module, select one from the list. Tap on the Wi-Fi network and enter the password.
5. Once connected to the module, a page summarizes the information regarding the patient, record and connection status (Wi-Fi and Bluetooth).



6. Check the battery level as described in “Starting a Record (Android)”, page 61.
7. Tap **See signals**.
   The EEG signals and video appear.
8. The electrodes impedance display in a dedicated window by clicking the icon located in the bottom-left section of the screen. The color shows the signal quality for each electrode:

- Green : Good signal quality
- Orange : Average signal quality
- Red : Low signal quality
- Grey : No signal

A low signal quality indicates a bad contact between the electrode and the patient skin.

Note
The healthcare professional must check the signal quality before starting a recording. The EEG will not start recording until the record button is pressed.

9. Tap the button located in the lower right section of the screen to start the record.

Note
If no data is available, a red stripe and a warning message appear.

Note
If one or more electrodes disconnect during the recording, the signal will appear flat or noisy.

Note
Once the recording is complete, make sure that the data is uploaded to the Cloud platform (refer to “Neuronaute Recorder LED Status”, page 43).

Note
Real-time data visualization through the mobile application does not aim at establishing a diagnosis. For data analysis, refer to “Recording Traces”, page 54.

5.6 Starting a Record (Android)

Note
If the recorder is not found by the application during the connection:

1. Check that the Bluetooth from the device is on.
2. Refresh the devices page.
3. If the problem persists, contact the support.

Note
If the record does not start:

1. Check that the cables connected to the router and camera are properly plugged in.
2. Disconnect and then reconnect the cables connected to the router and camera.
3. If the problem persists, contact the support.

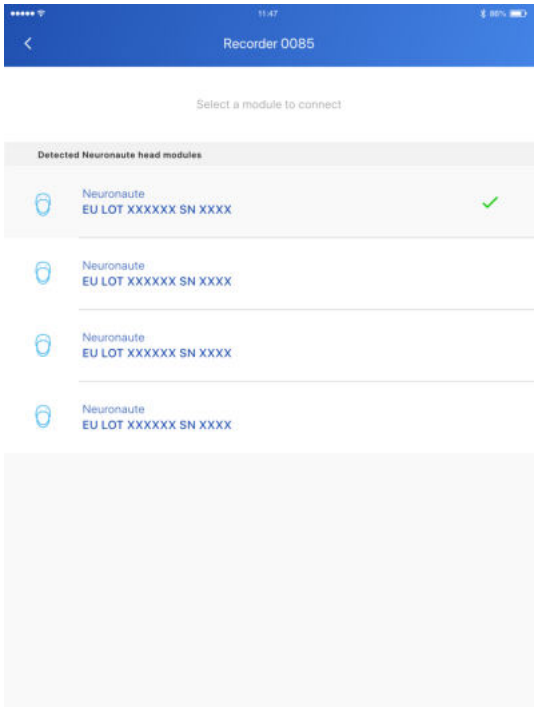
To start a record:

1. From an external electronic medical record (EMR) application, start the record. The Mobile application starts.
2. If appropriate, check the corresponding box to enable video recording.
3. Tap the Finish button.

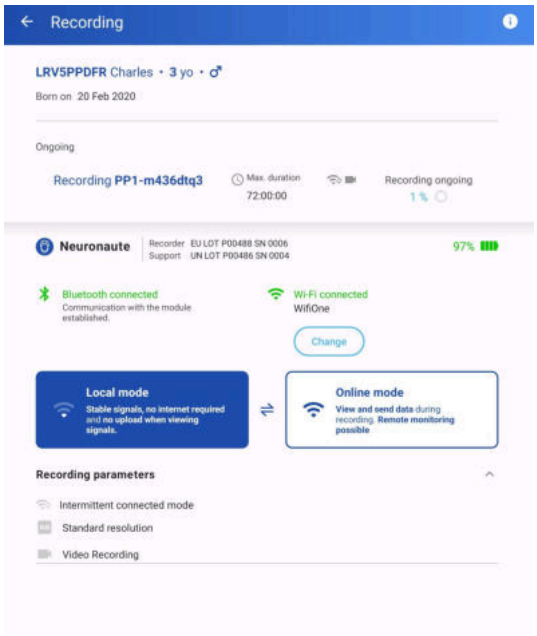
Note
During the recording, the patient should stay within the field of view of the camera.

4. Select a recorder to connect to (Neuronaute Plus only).
   The recorder information displays in the session.

Note
The recorder must be turned on to appear in the list.
Refer to “Neuronaute Recorder LED Status”, page 43.



5. Once connected to the module, a page summarizes the information regarding the patient, record and connection status (Wi-Fi and Bluetooth).



6. Select a recording mode:
    - **Local mode**
      No internet required, data is uploaded at the end of the record.
    - **Online mode**
      Data is uploaded while recording. Enlables video display and remote users.
7. Check the battery level as described in “Starting a Record (Android)”, page 61.
8. Tap **See signals**.
   The EEG signals and video appear.
9. The electrodes impedance display in a dedicated window by clicking the icon located in the bottom-left section of the screen. The color shows the signal quality for each electrode:

- Green : Good signal quality
- Orange : Average signal quality
- Red : Low signal quality
- Grey : No signal

A low signal quality indicates a bad contact between the electrode and the patient skin.

Note
The healthcare professional must check the signal quality before starting a recording. The EEG will not start recording until the record button is pressed.

10. Tap the button located in the lower right section of the screen to start the record.

Note
If no data is available, a red stripe and a warning message appear.

Note
If one or more electrodes disconnect during the recording, the signal will appear flat or noisy.

Note
Once the recording is complete, make sure that the data is uploaded to the Cloud platform (refer to “Neuronaute Recorder LED Status”, page 43).

Note
Real-time data visualization through the mobile application does not aim at establishing a diagnosis. For data analysis, refer to “Recording Traces”, page 54.

5.7 Checking the Battery Level

The battery level indicator is located in the right section of the recording summary.

On top of a percentage indicator, the battery charge is divided in 3 levels:

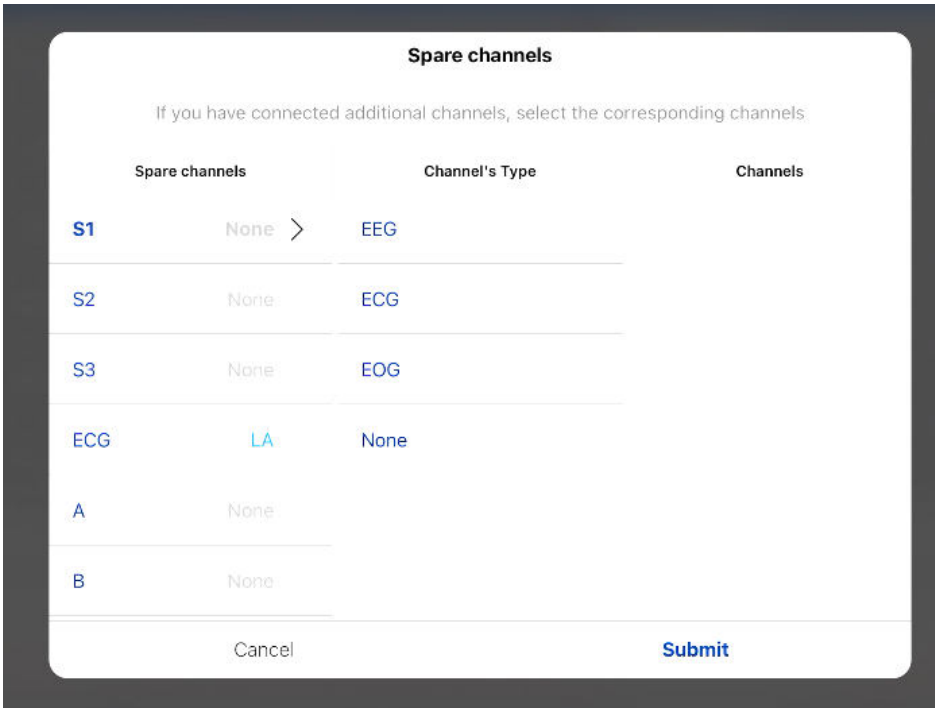
- Green - Battery charged
- Yellow - Moderate charge level, charge the battery soon.
- Red - Low charge level, charge the battery as soon as possible.

5.8 Configuring Additional Channels

When adding or replacing or several electrodes using spare channels, it is necessary to configure the new channels before starting the record.

To configure the new channels:

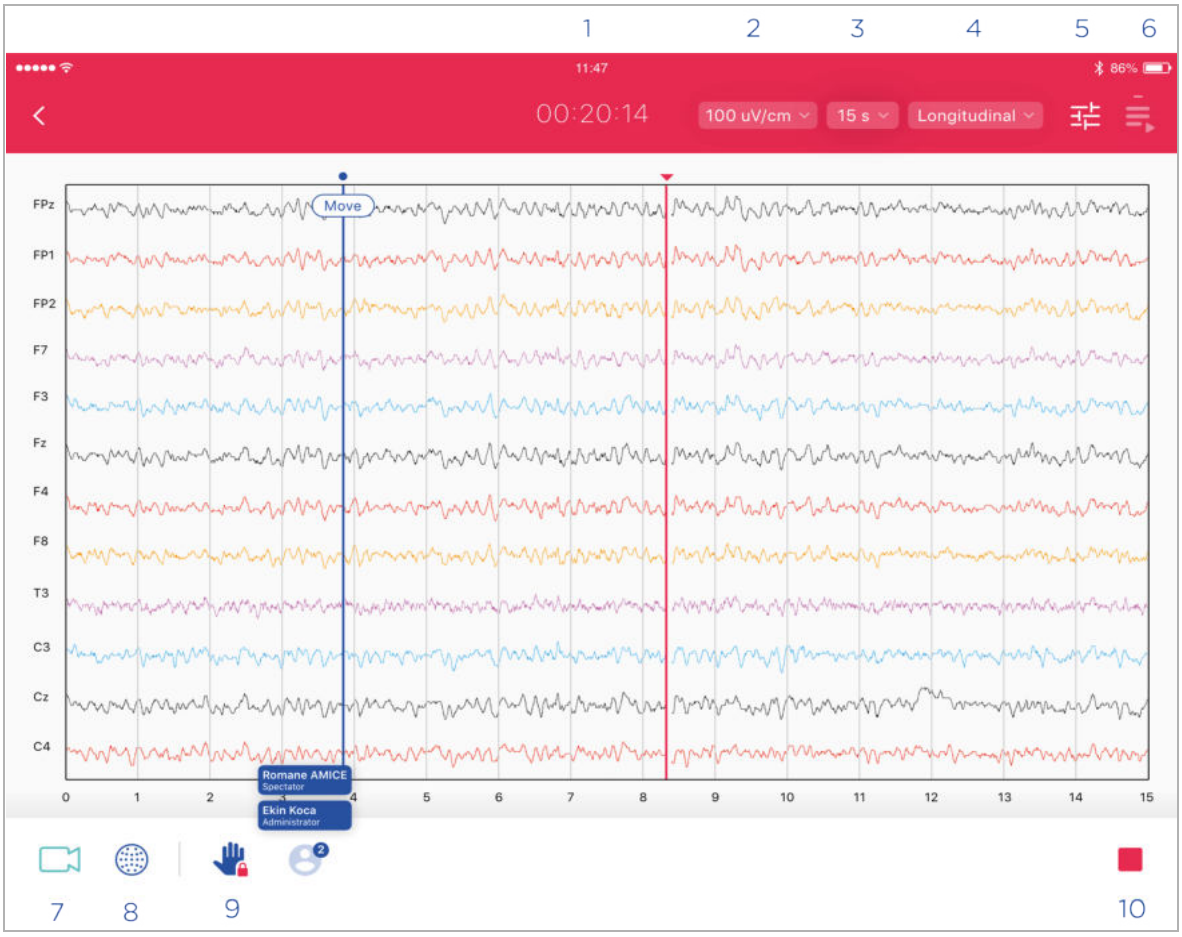
1. From the signals page, tap the button.
   The spare channels page appears.



2. Select the input of the new channel to use and the new channel's type.
3. Tap **Submit**.

5.9 Managing a Recording Session

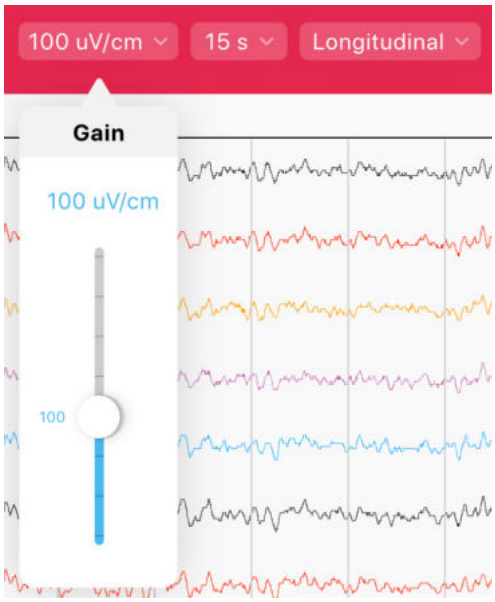
Ongoing records offer several parameters that can be monitored by the healthcare professional.



1	Record duration	**6**	IPS protocols
2	Gain (sensitivity)	**7**	Video display
3	Displayed timeframe	**8**	Impedance display
4	Montages	**9**	Request control
5	Filters	**10**	Start / stop record

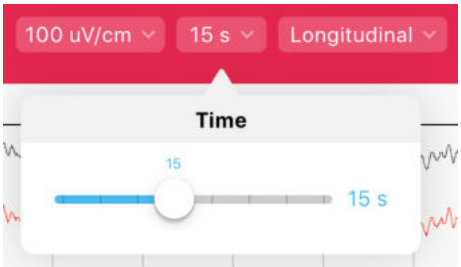
5.9.1 Gain

Drag the gain button to set the desired sensitivity.
The EEG display updates automatically.



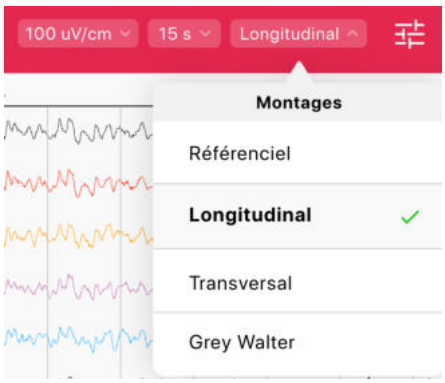
5.9.2 Time Frame

Drag the time button to set the desired time frame to display.
The EEG display updates automatically.



5.9.3 Applied Montage

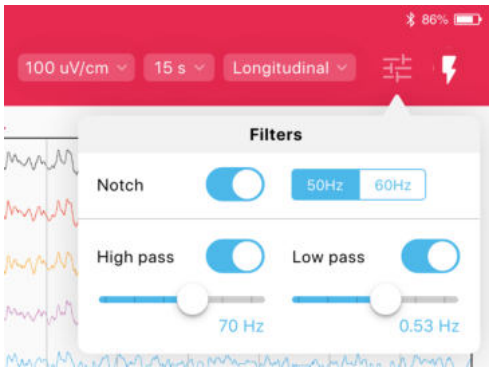
To change the current montage, select a montage from the list (refer to “Creating Montages”, page 61).
The EEG display updates automatically.



5.9.4 Filters

To set the EEG filters:

- The High-pass (LFF) filter passes signals with a frequency higher than the cutoff frequency and attenuate signals with frequencies lower than the cutoff frequency.
- The Low-pass (HFF) filter passes signals with a frequency lower than the cutoff frequency and attenuate signals with frequencies higher than the cutoff frequency.
- The notch filter can be set to 50Hz or 60Hz to attenuate the artifact caused by the power grid in your region.



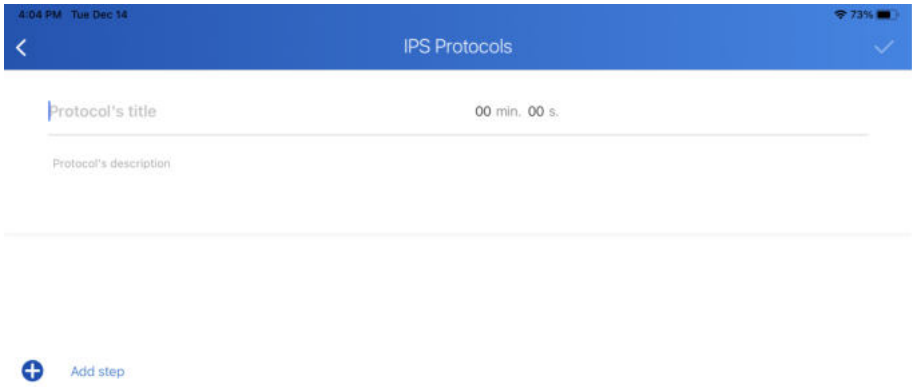
5.9.5 Creating IPS Protocols (iOS only)

IPS protocols are listed from the menu located in the upper left section of the application.

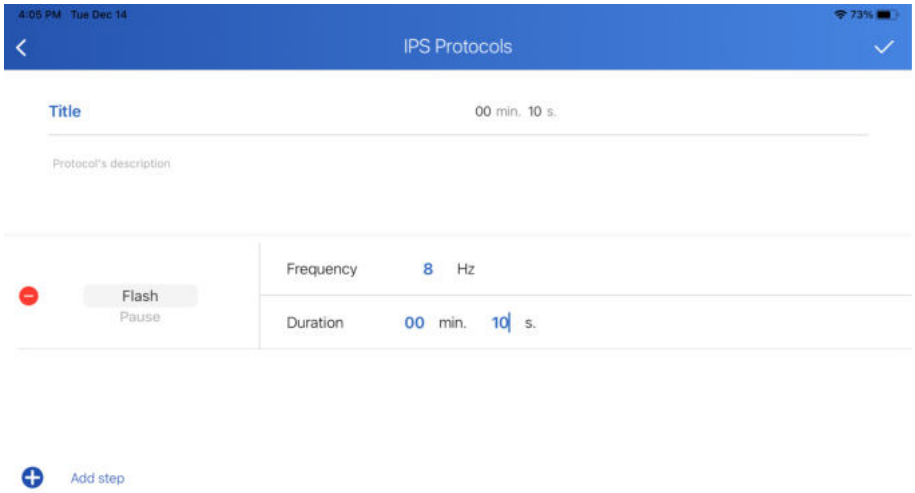
Note
IPS protocols require using a compatible iPad® with an LED flashlight.

To create an IPS protocol:

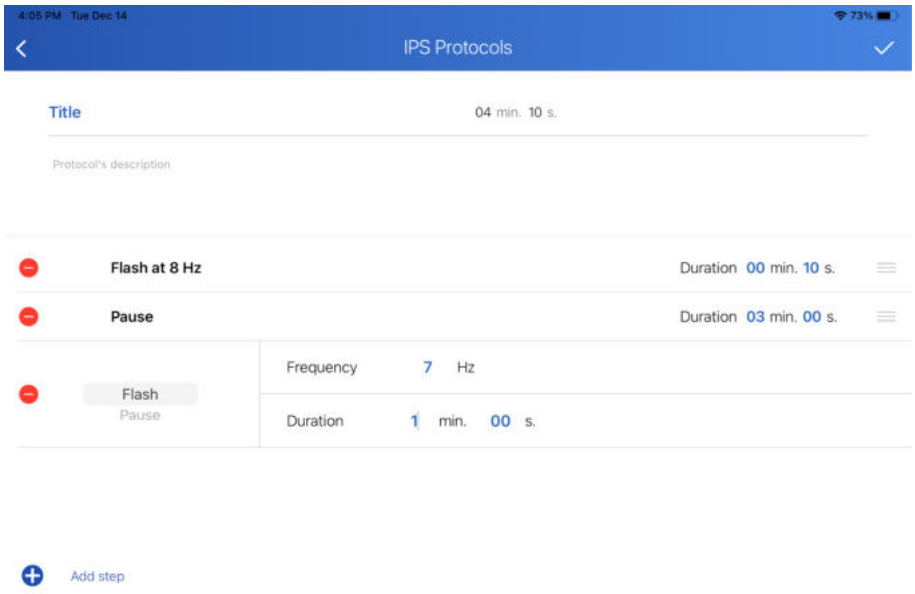
1. From the IPS protocols menu, tap the **+** button located in the upper right section of the screen.
   The IPS protocols creation menu appears.



2. Enter a title and description and tap **Add Step**.



3. Select the type of step and add a frequency and duration.
4. Tap **Validate Step**.
5. If appropriate, add steps until the protocol is complete.

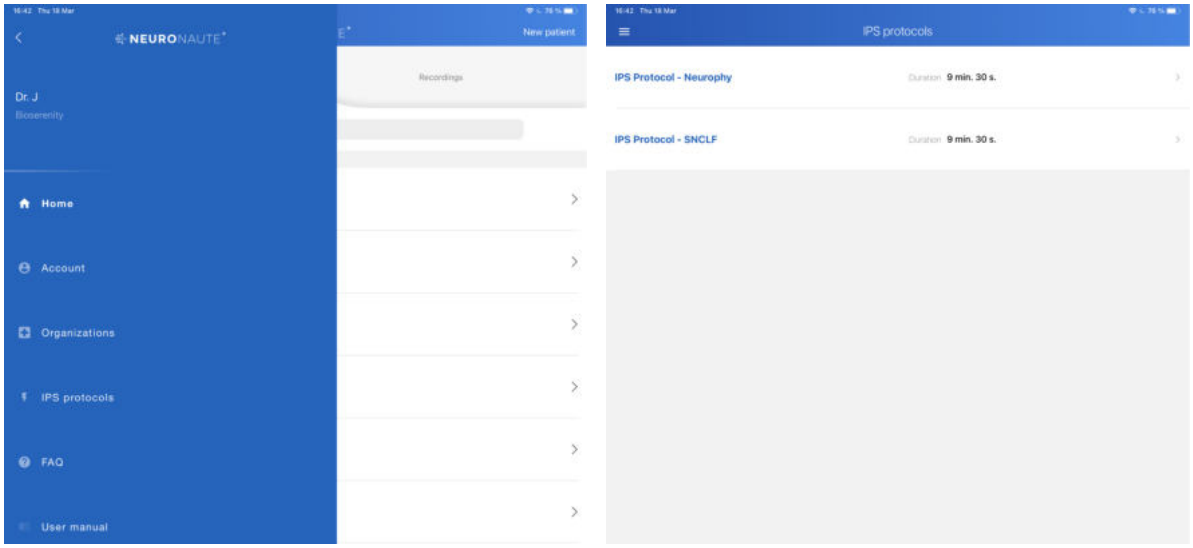


6. Tap ✓ to validate the protocol creation.
   The protocol is added to the list.

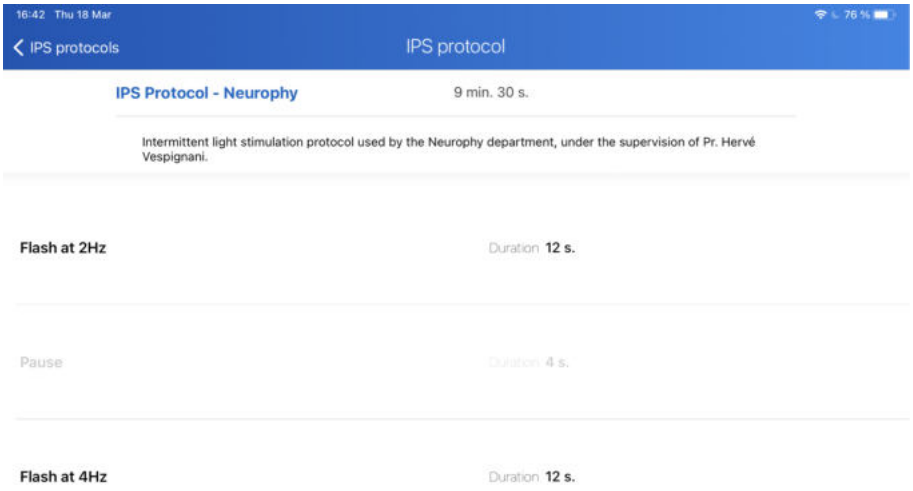
5.9.6 Using IPS Protocols (iOS only)

IPS protocols are listed from the menu located in the upper left section of the application.

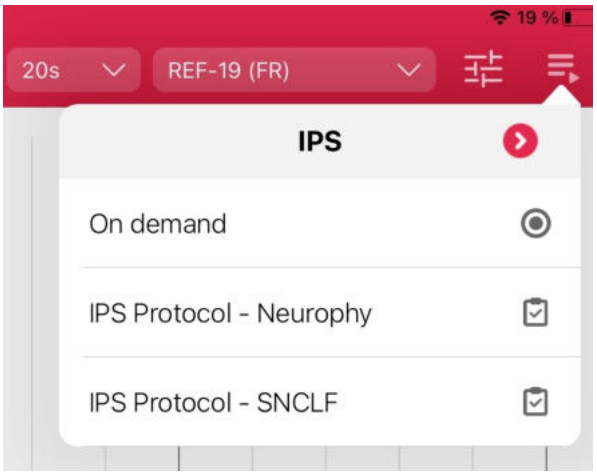
Note
IPS protocols require using a compatible iPad® with an LED flashlight.



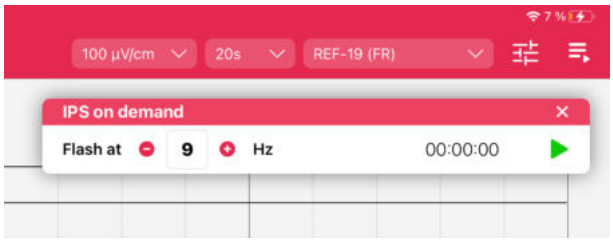
Select a protocol from the list to display the protocol details.



To start an IPS protocol, select an IPS protocol during the recording.
A pop-up indicates when an IPS is ongoing during the recording.

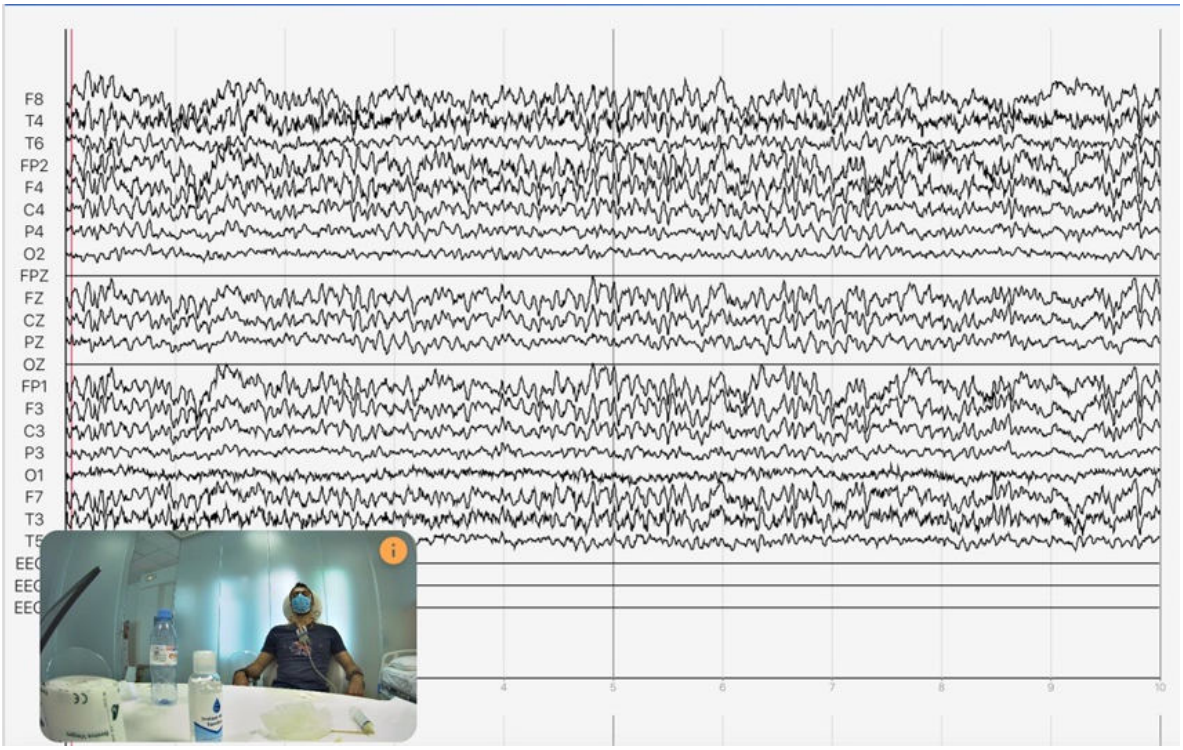


To configure an on-demand IPS frequency, tap **On demand**, set the frequency and tap the **play** button.



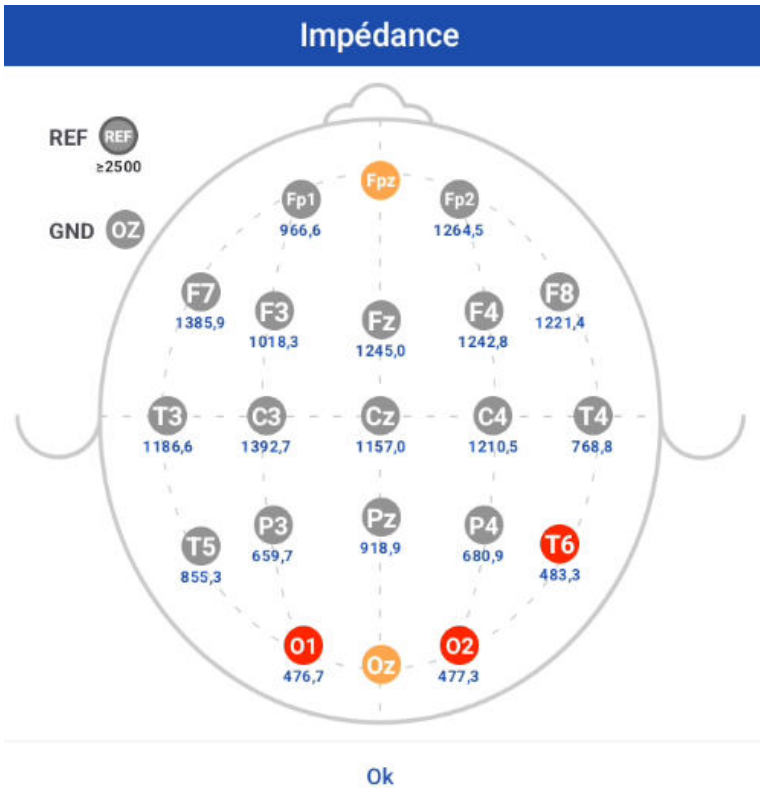
5.9.7 Video Display (Online Mode only)

Click the video icon to display / hide video during the record.



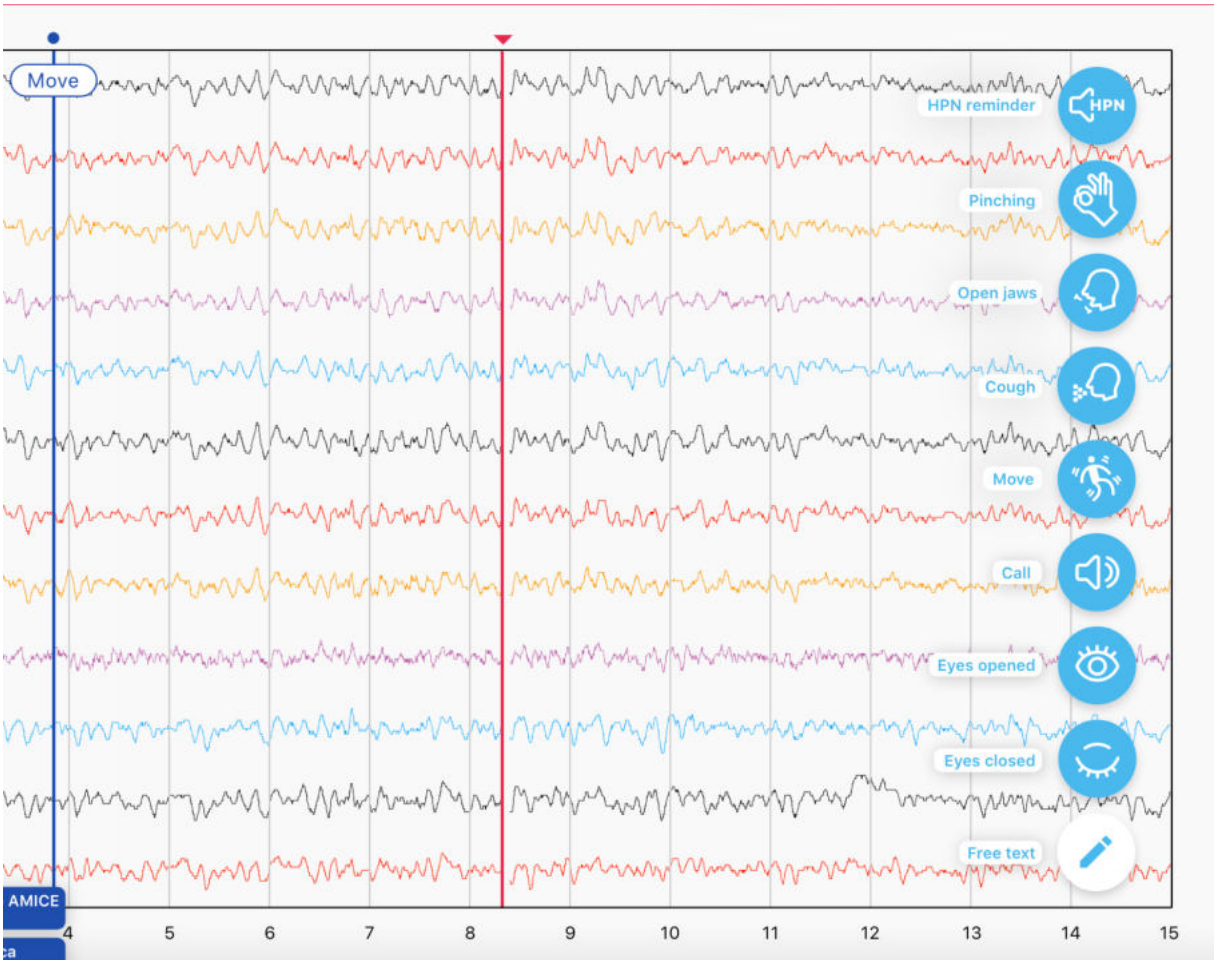
5.9.8 Impedance Display

Click the impedance icon to display the current electrodes impedance during the recording.



5.9.9 Creating Annotations

Tap in the EEG signals window and select the type of annotation to create a new comment. A marker appears on the record showing the type of annotation.



5.9.10 Remote Access for Several Users (Online Mode only)

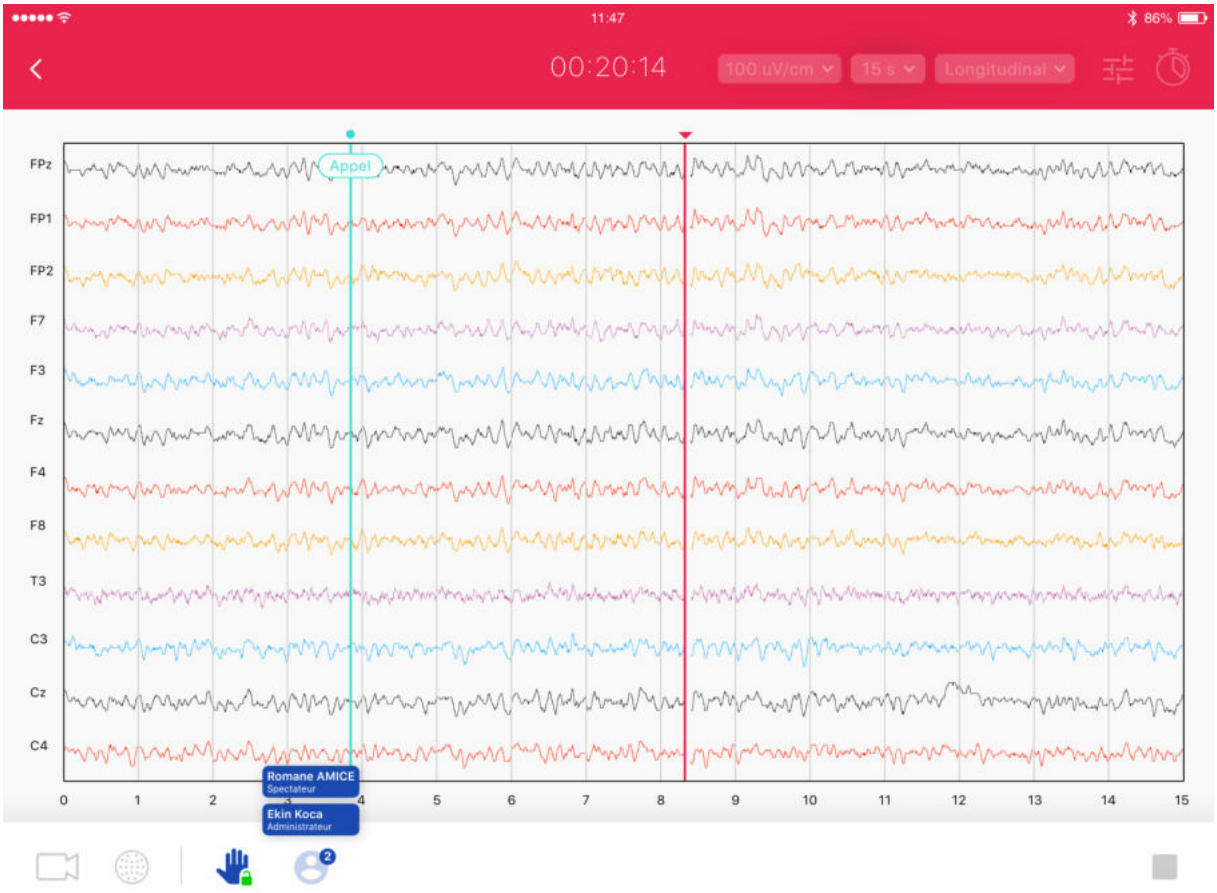
Several users can be connected to the same recording session, while only one master user (local or remote) can control the recording:

- The master can perform all available actions on a record.
- Other users can visualize the record.

Impedance checks are also done remotely, allowing the technologist to remotely check electrode status.

During a record, the master can choose to release control on the record by clicking the icon. The lock icon turns greens when control is released.

Healthcare professionals watching the record are then notified that control is available and can take control on the record by clicking the same icon.



6. MAINTENANCE

6.1 Regular maintenance

The **Neuronaute Plus** does not require any periodic maintenance.

The batteries must be put in complete charge every 3 months.

6.2 Cleaning the Device

The **Neuronaute Plus** and its holding band must be cleaned after each use with disinfectant cleaning wipes.

Warning

After cleaning the device, check that the surface is free of dirt and damage.

Warning

Do not clean the device while using it.

Warning

If there is wear or damage to the device, contact the support.

6.3 Cleaning the EEG Electrodes

The cup electrodes must be cleaned following the manufacturer recommendation.

7. SAFETY INFORMATION

7.1 Operating Conditions

The **Neuronaute** is designed to be used in a controlled medical environment (hospital, doctor's practice, private hospital), in a research environment, or at home.

The following environmental conditions must be met in order to use the product safely:

Characteristics	Environmental conditions
Usage temperature	Between +5 °C and +40 °C
Storage temperature	Between +5 °C and +50 °C
Transportation temperature	Between -25 °C and +70 °C
Relative humidity	Between 5% and 95%
Atmospheric pressure	700 hPa ~ 1060 hPa

7.2 Technical Specifications

Equipment component	Characteristics
Battery	Varta Li-ion EasyPack XL 3.7V | 2400mAh | 8.9Wh VKB: 56456 702 099
Battery weight (g)	49
Battery size (mm)	90 x 44,2 x 27
Battery autonomy if fully charged	24h / 72h
Battery charger	RRC RRC-SCC-EZP 1,5A max out 90-264 VAC input 50/60Hz

Characteristics	Use value
Input noise	<6µVp-p over 0.1-50Hz
Sampling frequency	250Hz or 500Hz
Accuracy of amplitude and rate of variation	≤±20 % of output nominal value or ±10 µV, according to the highest value at rate of variation of 12 mV/s
Input dynamic range and differential offset voltage	≤10% at ±150mV
Frequency response	0.1-60Hz (at -3dB)

Characteristics	Use value
Common mode rejection ratio	≥-80dB at 50hz and 60Hz
Input power	<3,7W
Bluetooth (per module)	Type BLE (Bluetooth Low Energy)
Wi-Fi (per module) type WPA2	A/B/G/N
Battery lifetime	200 cycles / measures

7.3 Safety Information

Warning
The Neuronaute is an electrical device containing type BF applied parts in contact with the patient in accordance with the standard 60601-1.

Warning
Electromedical devices require special precautions regarding EMC (Electro-magnetic Compatibility) and must be installed and operated in accordance with the EMC information provided in section 7.7, page 83.

Warning
The use of accessories, transducers and cables other than those specified (except for transducers and cables sold by the manufacturer of Neuronaute) such as replacement parts for internal components, may cause an increase of EMISSIONS or a reduction of IMMUNITY of the device.

Warning
Portable and mobile RF (Radio Frequency) communication devices may affect ELECTROMEDICAL DEVICES. They must be kept away from the Neuronaute.

Warning
Avoid intense physical activity while using Neuronaute.

Warning
Do not use the system simultaneously with any other medical device that has not been validated along with (see section 2.3, page 10).

Warning
Do not use a modified, damaged or degraded device (packaging damaged, product damaged, corrosion....).

Warning
Do not use the system simultaneously with any other medical device that has not been validated. Do not use with external defibrillator.

Warning
Electrodes conductive parts and associated connectors for applied parts, including the neutral electrode, must not be in contact with other conductive parts, including ground.

7.4 Information on Residual Risks

Warning
Ensure that the name of the patient using the system is carefully filled in so as to reduce the risk of swapping two patients data.

Warning
Use the device on healthy skin only, with no wounds in contact with the device.

Warning
It is recommended to use the device away from any extreme source of heat and cigarettes. Clothing is at risk of igniting if a flame or a burning object goes near.

Warning
The device will be damaged by water: there is a risk of erroneous measurements if the device is considerably damp.

Warning
Do not use the device in case of allergy to one of the components: polyamide, polyester, elastane, any synthetic material.

Warning
Do not use the device nor any of its components to determine brain death.

7.5 Information on Wireless Technology

Neuronaute Wireless technology	WiFi & BLE
Wireless functions	WiFi : Communication with CLOUD BLE : Communication with mobile application
Specific wireless technology	WiFi IEEE 802.11 a/b/g/n Bluetooth 5.0 Low Energy Module

Operating characteristics

Effective RF radiated power output (Wi-Fi module)	2,4GHz = +20dBm 5150MHz to 5250MHz = +23 dBm 5250MHz to 5350MHz = +20 dBm 5470MHz to 5725MHz = +20 dBm
Effective RF radiated power output (BLE module)	2,4GHz = +10dBm
Effective RF radiated operating range	Wi-Fi: up to 30m BLE: up to 10m
Receiving section modulation	Wi-Fi 2.4Ghz: • 802.11b: DSSS • 802.11g: OFDM • 802.11n: MCS Wi-Fi 5Ghz: • 802.11a: OFDM • 802.11n: MCS BLE: (Gaussian Frequency Shift Keying – GFSK)
Receiving section bandwidth	Wi-FI: 2400 to 2483,5MHz, 5150MHz to 5250MHz, 5250MHz to 5350MHz, 5470MHz to 5725MHz BLE: 2400 to 2483,5MHz

Wireless Quality of Service needed for safe and effective operation (QoS) is met by system design and does not depend on wireless network level. The recorder enables full data storage before transmission through Wi-Fi. The data is retained at the sender side until fully acknowledged by the receiver and can be resent if needed.

Recommended wireless security measures: WPA2 wireless encryption for IEEE 802.11 technology).

In case of wireless issue, refer to 5.4, page 68. If the problem persists, contact the support.

Wireless coexistence issues and mitigations (precautions for proximity to other wireless products, and specific recommendations for separation distances): Integrated RF modules are compatible with all required International standards (FCC Part 15C, EN 300 328 V2.2.2, EN 301 489-1 V2.1.1, EN 301 489-17 V3.2.0...).

RF wireless communications information (e.g. FCC rules): FCC PART 15C – BLE FCCID: 2AAQS-ISP1507 – WiFi FCC ID: 2A223-NNPV1.

7.6 Risks Associated with Radio Frequency Transceiver

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

7.7 Information on Electromagnetic Compatibility

Neuronaute essential performance is defined as follows: **Neuronaute** sends EEG signals which are not distorted over 6µVpp and 50µVpp (ECG).

Warning
If the essential performances are not met, the system continues to operate but may transmit inaccurate data to the user.

Basic EMC standad or test method	**Immunity test levels (IEC60601)**	
	Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV contact ± 15 kV air	
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m	
Radiated RF EM fields (IEC 61000-4-3)	3 V/m 80 MHz at 2.7 GHz 80% MA at 1 kHz	10 V/m 80 MHz at 2.7 GHz 80% MA at 1 kHz
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	9 V/m 710 MHz, 745 MHz 780 MHZ, 5240 MHz 5550 MHz, 5785 MHz 27 V/m 385 MHz	28 V/m 450 MHz, 810 MHz 870 MHz, 930 MHz 1720 MHz, 1845 MHz 1970 MHz, 2450 MHz
Conducted disturbances induced by RF fields (IEC 61000-4-6)	3 V 150KHz at 80MHz 6 V in ISM bands between 0.15 MHZ and 80 MHZ 80% MA at 1 KHz	
Electrical fast transients / bursts (IEC 61000-4-4)	± 2 kV 100 KHz repetition frequency	
Surges Line to line (IEC 61000-4-5)	± 0,5 kV, ± 1 kV	
Surges Line to ground (IEC 61000-4-5)	± 0,5 kV, ± 1 kV, ± 2 kV	
Voltage dips (IEC 61000-4-11)	0% U_T; 0,5 cycle A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	0% U_T; 1 cycle 70% U_T ; 25/30 cycles Single phase at 0°	
Voltages interruptions (IEC 61000-4-11)	0% U_T; 250 cycles at 50 Hz 300 cycles at 60 Hz	

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

When operating, the **Neuronaute** emits Bluetooth type radiation in the 2.4Ghz band at levels inferior to 20mW and Wi-Fi type radiation in the 2.4Ghz and 5Ghz band at levels superior to 20mW. It may therefore perturb other devices using radio frequency in these bands. As a result, it is advisable to use it away from devices that may be perturbed by this radiation.

When operating, the **Neuronaute** receives Bluetooth type radiation in the 2.4Ghz band and Wi-Fi type radiation in the 2.4Ghz and 5Ghz band. It may therefore be perturbed by' other devices using radio frequency in these bands. As a result, it is advisable to use it away from devices that may generate radio frequency in these bands.

When operating, the **Neuronaute** emits Bluetooth type radiation in the 2.4Ghz band, modulated in GFSK (Gaussian Frequency Shift Keying).

When operating, the **Neuronaute** emits Wi-Fi type radiation in the 2.4Ghz, modulated in OFDM (Orthogonal Frequency-Division Multiplexing), DSS (Direct Sequence Spread Spectrum), MCS (Modulation Coding Scheme) and in the 5GHz, modulated in OFDM, MCS.

The maximum effective radiated power (WORST) is 100mW.

Manufacturer's directives and declarations - electromagnetic emissions

The Neuronaute is intended to be used in the electromagnetic environment specified below. It is necessary for the client or user of the Neuronaute to make sure that it is used in such an environment.

Emission testing	Conformity	Electromagnetic environment - directives
RF emissions CISPR 11	Group 1	The Neuronaute has to emit electromagnetic energy to carry out the function for which it is intended. Neighbouring electronic devices may be affected.
RF emissions CISPR 11	Class B	The Neuronaute is suitable for use in any premises other than domestic premises and those directly linked to the public network for low-voltage power supply to buildings for domestic use.
Harmonic emissions CEI 61000-3-2	Class A	
Voltage fluctuations / Flicker CEI 61000-3-3	Class A	

7.8 Risks linked to using the device

7.8.1 Risks of Infection and Biocompatibility

The risk of cytotoxicity, irritation or sensitivity are mitigated by:

- Stipulating in this manual not to use this device on an open wound.
- The fact that the risk is the same as the one incurred with any clothing.

7.8.2 Risks Associated with Batteries

In order to limit any potential risk of fire caused by a battery short circuit, the following provisions have been taken:

- The battery is intrinsically safe since it was designed according to the IEC 62133 standards.
- The plastic case protects the device against shock.

Therefore it is possible to consider that the risk is equal to the risk generated by carrying a cellular phone or any other device that uses any rechargeable lithium battery.

8. REGULATORY INFORMATION

8.1 System Life Cycle

8.1.1 Product Lifetime

The components of the system lifetime is estimated in the following list:

- **Neuronaute Plus** is intended to be used up to 200 times.
- The battery is intended to be charged up to 200 times.

Once the lifetime duration of the product is reached, contact the local supplier.

8.1.2 Recycling the Neuronaute Parts

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE) and Directive 2006/66/EC of the European Parliament and Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC governing the recycling of batteries, electrical wire and electronic components.

The electrical wires and other electronic components cannot be discarded along with household waste.

Contact Local Supplier to learn about the return procedures for used batteries in accordance with the legislation in force.

Warning

DO NOT discard any element of the system in household waste without asking the local supplier for return procedures.

Warning

The battery contains hazardous products such as Lithium, which cannot be thrown away with household waste.

Note

Return the device to the manufacturer for recycling.

8.2 Product Symbology

Symbols	Description
	Manufacturer
	Date of manufacture
	Single use
	Use by date
	Serial number
	Catalogue reference
	Batch code
	On / Off
	Do not use if package is damaged
	Keep away from sunlight
	Lower and upper limit of temperature
	Upper and lower limit of humidity
	Warning - Consult the user manual
	Keep dry
	The product must be eliminated in a suitable salvage and recycling structure
	Quantity of product
	Size of the product
	Medical device
	IP rating
	Direct current

Symbols	Description
	Atmospheric pressure limitation
	Type BF applied part
	Operating instructions
Rx only	United States Federal law restricts medical devices to sale by or on the order of a licensed healthcare practitioner.
	Do not expose the device to magnetic resonance environments
	For this country, the 5.15-5.35 GHz is restricted to indoor use.
	Marking on the exterior of the product or on parts of the device, including RF transmitters or involving RF (Radio Frequency) electromagnetic energy for diagnosis or treatment. DEVICES and EM SYSTEMS which include RF transmitters or which intentionally apply RF electromagnetic energy for the diagnosis or treatment must bear the symbol IEC 60417-5140 (2003-04) relating to non-ionizing radiation.

8.2.1 Manufacturer Information

BioSerenity SAS
ICM-iPEPS
47, bd de l'Hôpital
75013 PARIS - France

CE
2797

Neuronaute™ is a trademark of Bioserenity.

Bioserenity Cloud, Neuronaute and Neuronaute Plus are CE marked medical device according to regulation (UE) 2017/745.

8.3 Medical Device Classification

The **Neuronaute system** components are classified as follows:

EU

The **Neuronaute Plus** is a class IIa medical device.

The IceCap / IceCap 2 / IceCap 2 small are class I medical devices.

The cloud platform is a class IIa medical device.

USA

The **Neuronaute Plus** is a class II medical device.

The IceCap / IceCap 2 / IceCap 2 small are class II medical devices.

The cloud platform is a class I medical device.

8.4 Contact

8.4.1 Contact Information

To contact the support services, use the following email address:
support.neuro@bioserenity.com

8.4.2 Internet

The information provided is available and updated on the website:
https://www.bioserenity.com/

8.4.3 FAQ

The FAQ is accessible from the mobile application and at the following link:
https://bioserenity.zendesk.com/hc/en-us

8.4.4 Materiovigilance

Every serious incident related to the device must be notified to the manufacturer and to the competent authority from the user State.

8.4.5 Instructions for Use

The paper version of the instructions for use is available upon request at no additional cost under 7 calendar days. To receive the instructions for use, contact the support.