

nëo™

User Manual



nëo system version 1.2, Product code ES-820
including
nëo monitor version 1.2, Product code: LE-800

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INTENDED USE

The **nëo** monitor is an 8-channel electroencephalograph (EEG) acquisition software. The device is intended to record and display EEG and aEEG signals for monitoring the brain status of neonatal patients (defined as from birth to 28 days post-delivery, and corresponding to a postconceptual age of 24 to 46 weeks). The device is to be used in a hospital environment by qualified clinical practitioners. The device does not provide any diagnostic conclusion about the patient's condition to the user.

nëo[™] is CE marked as a medical device in the EU, according to MDD 93/42/EEC, class IIa, and has received FDA 510(k) clearance in the USA.



waveguard[™] caps are CE marked as medical device in the EU, according to MDD 93/42/EEC, class I, and have received FDA 510(k) clearance in the USA.. Manufactured by eemagine Medical Imaging Solutions GmbH, Berlin, Germany, ISO 13485 certified. ANT Neuro and eemagine are part of the neuromotion group.

For US customers:

Rx only

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DISCLAIMER

This document is written as accurately as possible. However, mistakes are bound to occur, and we reserve the right to make changes to the products, which may render parts of this document invalid.

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1. GENERAL INFORMATION

1.1. About this document

This document serves as the User Manual for nĕo. nĕo consists of the nĕo monitor software, selected components and accessories as required to operate the system. Please note this device is intended to be used by experienced neonatal clinical staff only. This manual assumes that the user has basic knowledge of EEG/aEEG recording and has had no prior training in using our device.

1.2. Intended use

Please refer to the header section of this User Manual (page 2).

1.3. Compatible components with the nĕo monitor

The nĕo monitor software operates on a medical panel PC with a USB connection to the eego amplifier. The software can be used in combination with compatible types of EEG electrodes, and a touchproof adaptor for connecting the electrodes to the amplifier. Components to be used in combination with the nĕo monitor must meet the requirements listed in Table below. The setup as a whole must meet local medical safety regulations.

Compatible items	Requirements
All-in-One PC	<ul style="list-style-type: none">• Compliant with IEC 60950, the EMC Directive 2014/30/EC, the Low Voltage Directive 2014/35/EU, the RoHS Directive 2011/65/EU, the Ecodesign Directive 2009/125/EC, and the Radio Equipment Directive 2014/53/EU where applicable.• Multi-touch capable touch screen with:<ul style="list-style-type: none">a. minimum resolution: 105dpi (dots per inch)b. minimum display size (pixel): 1200 x 800c. minimum display size (dimension): 200mm x 150mm• 2 USB-A ports<ul style="list-style-type: none">a. USB 2.x or USB 3.xb. Minimum data transfer rate: 480 Mbit/s (High Speed)• x64 processor Intel Core i5 or equivalent• 2GB RAM working memory• MS Windows 10 Professional or Enterprise, x64 (English)• Compliance with IEC 60601-1 (depending on local regulation)
EEG amplifier	eego amplifier EE-411 (eemagine Medical Imaging Solutions GmbH)
EEG Adaptor	EEG touchproof adaptor XC-810 (eemagine Medical Imaging Solutions GmbH)

EEG Electrodes	<p>The system should only be used with market-cleared electrodes. Users should read and follow the manufacturer’s instructions for the specific electrodes that are used.</p> <ul style="list-style-type: none"> • CE MDD class I for clinical use with neonatal patients • Gold cup electrodes, Ag/AgCl electrodes, hydrogel sticker-electrodes or subcutaneous steel needle electrodes • Cable length between 30 cm to 150 cm • Compatible with a touchproof connector
EEG caps	<p>waveguard original cap CA-4xx (eemagine Medical Imaging Solutions GmbH)</p> <ul style="list-style-type: none"> • Compatible with eego amplifier EE-411 • Sizes N1, N2, N3, N4, N5, B • CE MDD class I for clinical use with neonatal patients

1.4. Safety warnings

The following warnings and cautions apply to **nëo** and the **nëo** monitor:

- **nëo** and the **nëo** monitor must only be used by trained personnel.
- Compatible components used in combination with **nëo** and the **nëo** monitor may have their own additional warnings and cautions as listed in respective user manuals. Make sure to read and comply with them.
- Non-compliance with warnings and safety regulations may result in severe personal injury to the patient and/or the operator!
- Note that aEEG is known to be subject to common NICU artifacts (e.g. ECG, muscle activity, and high-frequency ventilation) and therefore should always be interpreted with caution and in combination with simultaneously recorded raw EEG signal.
- Ensure that the data are sufficiently free of NICU artifacts by reviewing the EEG quality at the start of the recording, at regular intervals, and whenever the technical environment changes. Failure to do so may result in missing important information during monitoring and subsequent harm of the patient.
- The **nëo** monitor checks for technical abnormalities at regular intervals and displays a warning message in case of high impedance, possible excess of the amplifier’s measurement range, loss of data connection or PC problems. Make sure to check for those warning messages at regular intervals and to attend to the system in case of a warning. Failure to do so may result in missing important information during monitoring and subsequent harm to the patient.
- **nëo** and the **nëo** monitor are not designed to monitor vital processes where variations could result in immediate danger. Other means of vital signs monitoring must be used.



1.4.1. Safety measures

- Do not use **nëo** or the **nëo** monitor with devices not explicitly listed to be compatible.
- Use **nëo** only with compatible electrodes or caps.



- Do not store or operate the system outside the specified environmental conditions for temperature, humidity and air pressure as specified in the datasheet.
- The only power cord that may be used is the original power cord supplied together with the PC. DO NOT replace it with anything else. If any third-party power cord is used then patient safety is not guaranteed.
- Make sure that the wall socket is well earth grounded and complies with standard installation rules.
- Inspect the power cord of the PC on a regular basis for damages. Do not operate the device with a damaged power cord.
- Do not connect active sensors or electrodes to any of the inputs of the amplifier.
- Take care when arranging patient and electrode cables to avoid risks of entanglement or strangulation. Do not pull on the cables when they are connected to the patient.
- Secure the breakout adapter for the electrodes at the incubator. Use the opening for the strap to ensure strain relief if necessary.
- If you operate the system on a medical cart, make sure always to secure the wheels with brakes to avoid an accidental movement of the system and a pull on the electrode cables.
- Reusable electrodes present a potential risk of cross-contamination. Please refer to the documentation that came with your electrodes for instructions on how to prevent this.
- An improperly cleaned breakout adapter presents a potential risk of cross-contamination. Please refer to the documentation that came with the adapter on how to prevent this.
- Do not connect the software and compatible components to a patient undergoing MRI, electro-surgery or defibrillation.
- Do not combine nĕo or the nĕo monitor with other devices without carrying out your own detailed risk analysis involving experts in the field.
- WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- ELECTRICAL SHOCK HAZARD: Do not connect electrode inputs to earth ground. Connecting an earth ground might result in electrocution.
- Conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL/GROUND/REFERENCE ELECTRODE, should not contact other conductive parts including earth.
- The nĕo monitor is not for installation by the customer including IT personnel! It is always to be installed by trained support personnel or distribution representatives of the manufacturer. An integration test with the amplifier and all auxiliary parts is always required during the installation procedure.

1.4.2. Precautionary measures

- The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in APPENDIX B: NĒO TECHNICAL SPECIFICATIONS (EMC); the use of accessories other than specified may result in increased emissions or decreased immunity of the system and result in improper operation.



- The performance of the nēo system was determined to be according to the descriptions in APPENDIX A: ESSENTIAL PARAMETERS. The user can expect distorted signals that are clearly different from EEG signals if degraded due to electromagnetic disturbances.
- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the nēo system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Disposable electrodes that are used for electrophysiological measurements may pose a biohazard. Handle, and when applicable, dispose of these materials in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.

1.4.3. Additional safety warnings

- The nēo system and compatible components are not suitable for use in an environment with an inflammable mixture of anesthetics and air, oxygen or nitrous oxide.
- The nēo system and compatible components are to be kept dry. Clean the all-in-one PC and adapter only with non-aggressive solution suitable for screen cleaning and silicone disinfection as described in this manual.
- Check regularly whether the skin of the patient is irritated by electrode pressure or gel contact.
- If any liquids or moisture penetrate hardware components used with the nēo, turn the device off, remove the plug from the wall socket and have the device checked by the manufacturer.
- Do not expose the nēo system and compatible components to direct sunlight, heat from a source of thermal radiation, excessive amount of dust, moisture, vibration, or mechanical shock.
- Do not wind the cables in loops smaller than 5 cm or bend them sharply, as this may damage the cables.
- Do not use the nēo system when any accompanying part is damaged.
- The nēo system is not defibrillator-proof.
- You may not install additional programs on the PC as this may compromise performance when recording and reviewing data or cause software conflicts.
- Make sure to comply fully with your local cybersecurity guidelines. Please take care of data anonymization or encryption if needed.



1.5. Maintenance

The nēo system requires weekly checks of general cleanliness and sufficient remaining recording time. See section 11 for information on cleaning. The remaining recording time is displayed on the start screen of the nēo monitor, see section 4.1.

The Microsoft Windows Operating system including Windows Defender and virus definitions and the Microsoft SQL server software installed on the PC should be updated with latest Microsoft security patches at least every month or more frequent, according to your local regulations. The update must be performed by a trained technician. Refer to the **nëo** Deployment Guide for details on how to perform the update. If an update to the **nëo** software is recommended or required, you will be contacted by your distributor or by eemagine.

Servicing by authorized service personnel is required every 12 months or more frequent, according to your local regulations. Servicing must be performed by a trained technician. Refer to the **nëo** Deployment Guide for details on how to perform the servicing.

It is strongly recommended that users perform regular backups and ensure that the hard drive of the **nëo** has adequate storage space in monitors database, see section 7.

1.6. System and data protection

After powering up the system, **nëo** will ask for a password to log in. The initial password is “neo” (without quotes). We strongly recommend that a new secure password is set during the deployment of the system at your local institution. Please align with your local IT department for details on PC protection or if you lost the **nëo** system password. Remember to keep the password safe at all times.

nëo monitor protects access to patient data by a security password. The initial password is set to “0000” (without quotes). To change the password, go the Technical setup workflow. We strongly recommend that a new secure password is set prior to the start of the system being put into service. Remember to keep the password safe at all times.

nëo monitor also protects access to the Technical setup by a security password. The initial password is again set to “0000” (without quotes). The password can be changed from within Technical setup workflow. We strongly recommend that a new *secure* password is set prior to the start of the system being put into service. Remember to keep the password safe at all times.

If you need help resetting the Patient data password or the Technical setup password, please contact support with your installation details and proof of eligibility.

If you connect USB storage media for export and backup of data, make sure to use only devices that are virus and malware controlled. Please align with your local IT department for details. Do not disable the virus protection of the **nëo** system PC!

For advanced security, the hard drive of the **nëo** system PC is encrypted using Microsoft’s Bitlocker technology. Do not disable Bitlocker encryption!

Please contact eemagine Medical Imaging Solutions GmbH in case of any security issues, see section 1.7.

1.7. Contact information

For more information and for reporting problems with your nēo, please contact eemagine at:

eemagine Medical Imaging Solutions GmbH




Gubener Str. 47

D-10243 Berlin, Germany

Phone: +49 30 29048404; E-Mail: support@eemagine.com

<http://www.eemagine.com>





2. START COMPUTER

Button	Function
	Turn the unit on/off (hold for 2 seconds)
	Brightness control: brighter
	Brightness control: darker
	Turn display and touch screen on/off (hold for 2 seconds)



After the computer is turned on and credentials are successfully proven, nēo monitor software will automatically launch.

Make sure that the hardware switch on the right flank of the computer is turned on (picture below).

LED	Status	Info
	On	The unit is operating
	Flashing	The unit is in standby mode
	Off	The unit is not connected to the mains
	On	Accessing mass storage



Hardware switch

3. APPLYING ELECTRODES AND CONNECT AMPLIFIER

3.1. Apply electrodes and connect to EEG adapter

Please refer to the user manual of the electrode manufacturer when applying electrodes on your patient.

Plug the touchproof connectors into the according sockets. Do not apply heavy force. It is recommended that colors of the individual electrode cables are matching with the color of the socket.



3.2. Connect adapter or EEG Cap to Nēo

Plug the high-density connector to the compatible socket on the amplifier to connect of the EEG cap or EEG adapter to nēo.



1. High-density connector of EEG adapter or EEG cap
2. EEG Amplifier
3. nēo all-in-one PC

The connector is asymmetric which prevents inserting it in the wrong direction. Please do not apply high force when connecting to the amplifier.

4. EEG/aEEG DATA ACQUISITION

4.1. Select a recording protocol

Turn the PC on and log in. The nēo monitor automatically starts.

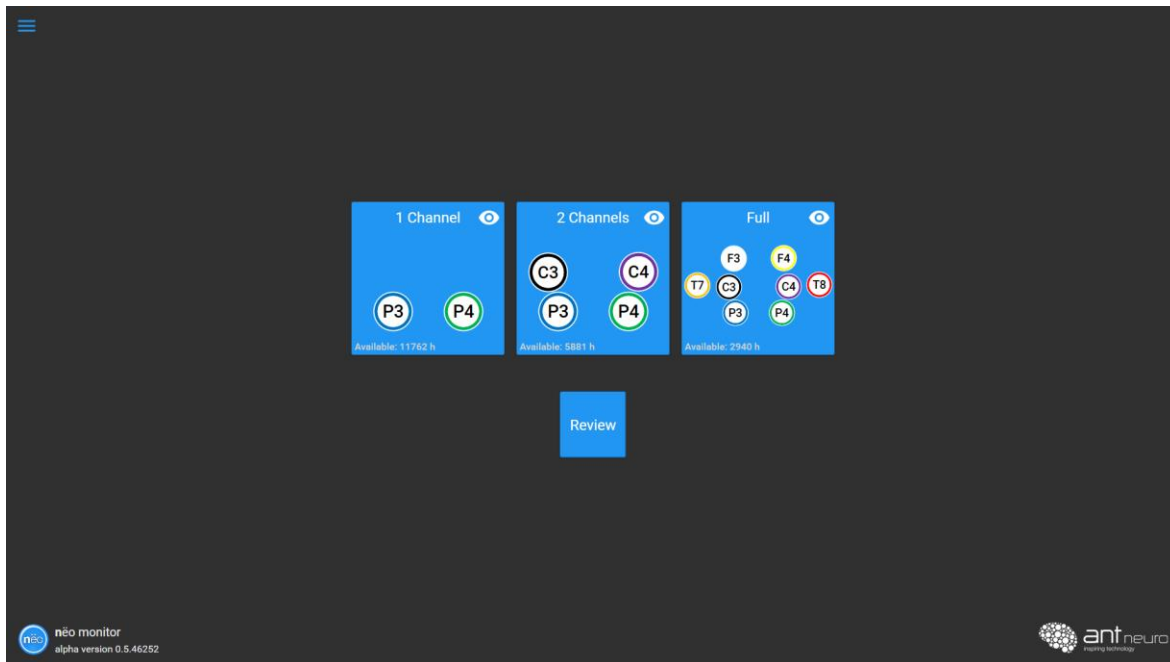
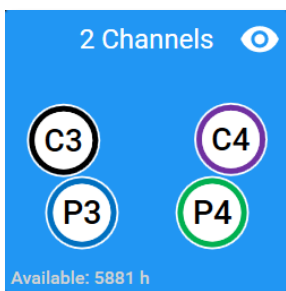



Figure 4-1 Start screen

Select the suitable monitoring protocol by pressing on the corresponding **Protocol** button.



 Assess Information about hardware settings of each protocol (e.g., amplifier type, montage, and sampling rate)

The capacity of remaining hours of recording available on the systems hard drive for the selected protocol is displayed as remaining available recording hours.

4.2. Check impedance values

The *Impedance* screen displays an axial view of the electrode layout. Each electrode is represented by their channel name and impedance value. The impedance value is reflected by the color of the circle. Continue with recording once impedance is sufficiently low.



Figure 4-2 Impedance screen for the Full recording protocol



Start monitoring by pressing the **Signal** button on the bottom right corner.



Pressing the **Start screen** button in the bottom left corner will take you back to the start screen.



The head symbol indicates the direction the patient is facing. The pointy shape is the front.

Please closely follow the respective user manual when applying different type of electrodes.

For the **subcutaneous needle electrodes**, the impedance view shows in binary state whether an electrode is properly inserted.

4.3. Start EEG/aEEG Data Acquisition

By pressing the **Signal** button, you proceed from *Impedance* to *Acquisition* mode, and the recording of EEG/aEEG data starts immediately. Please note that since aEEG is derived from the underlying raw EEG at a regular interval of 15 seconds, no aEEG will be displayed for the first 15 seconds upon starting the recording. The user interface of the *Acquisition* screen is shown in Figure 4-3.

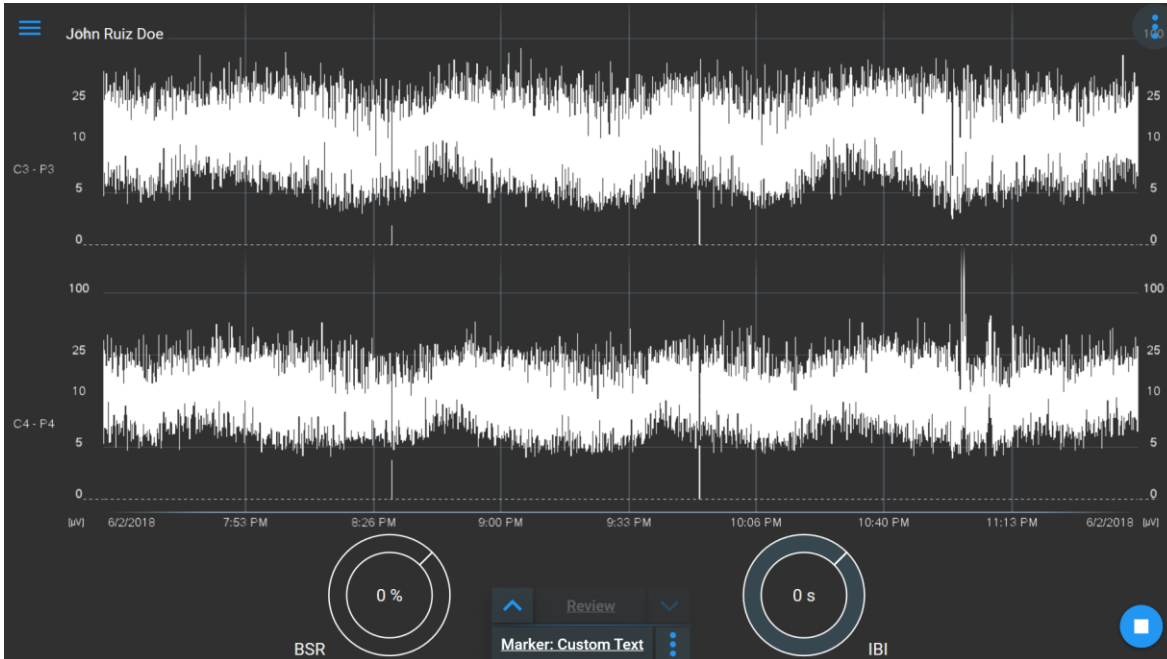


Figure 4-3 User interface of the Acquisition Screen



Pressing the **Patient** button on the bottom right corner will open the patient management menu (refer to Chapter 8). During the patient management view, the EEG/aEEG recording continues in the background. After linking the recording with a patient, the **Patient** button will be replaced by the **Stop** button.



Pressing the **Stop** button in the bottom right corner will end the current monitoring session and exit to the start screen.



Pressing the **Impedance** button will lead back to the impedance screen. After making sure that the impedance values are sufficiently low, you can switch back to the previous data view by pressing the **Signal** button on the bottom right corner. Please note that no data is recorded or computed under *Impedance* mode.

4.4. Bad Signal Quality Warning

For all electrode types, a quality analysis is monitoring the EEG signal for artifacts parallel to the recording. It monitors the powerline hum, drift and flat EEG lines. If bad signal quality is detected the nēo monitor notifies the user with a visual warning (refer to chapter 4.9)

Bad signal quality indicates one of the following possible causes:

- 1) Electrode contact not sufficient
 - a. Check Reference (REF) and Ground (GND) electrode contact and one additional EEG electrode
 - b. Check the rest of electrode positions

- 2) A nearby source of electrical noise
 - a. Check third-party devices that may emitting electrical noise close to the nĕo or electrode cables. Electrical devices such as computer, mobile-phones or other medical devices can be the source of electrical noise.

4.5. EEG and aEEG Views

aEEG view

The aEEG view is the default initial acquisition screen and displays the incoming stream of aEEG data. On the bottom screen Inter Burst Interval (IBI) and Burst Suppression Ratio are displayed. Channel names are shown at the left of each trace.

By default, the aEEG is displayed in semi-transparent mode called “greyscale”. This mode allows a more refined view on the amplitude distribution of the EEG within the 15 second time period of one aEEG sample. To use the traditional opaque aEEG display instead of greyscale mode, switch the display settings in the Technical setup workflow.

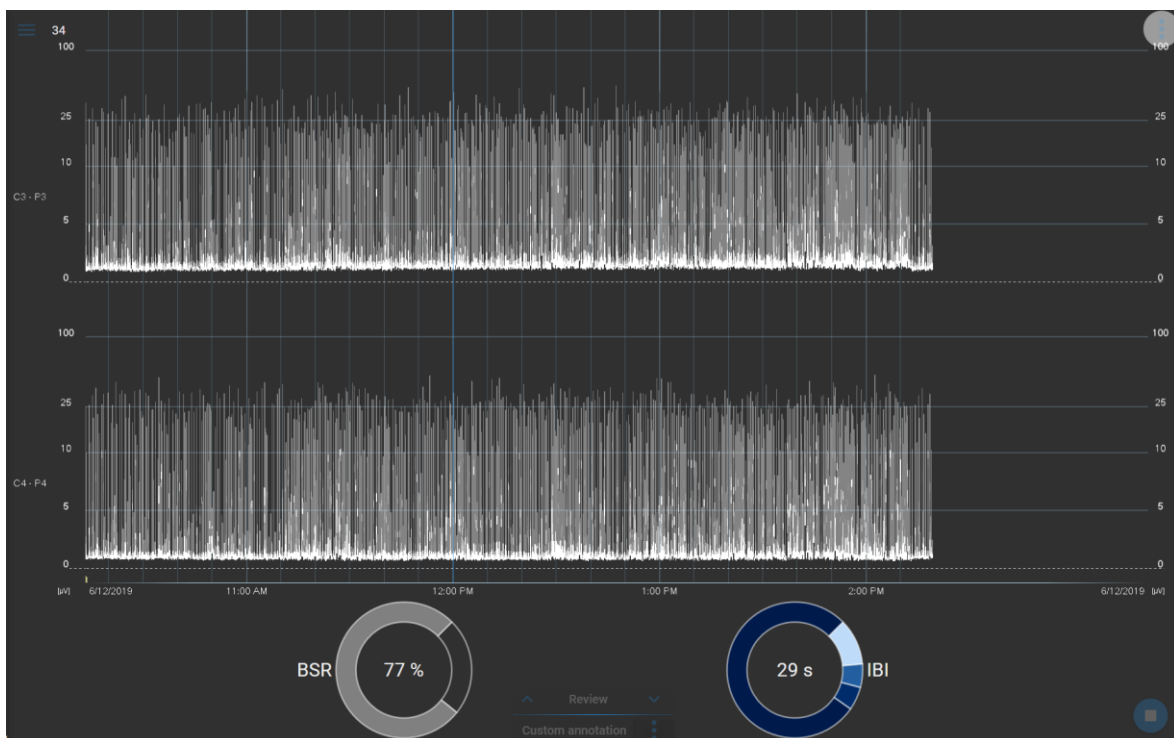


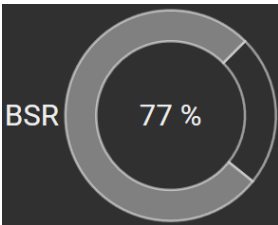
Figure 4-4 aEEG view with visualization of Burst Suppression Ratio and Inter Burst Interval



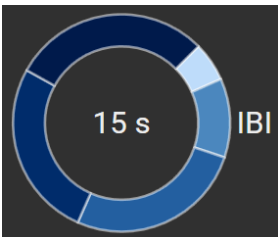
Via the dropdown button in the aEEG window, parameters such as timescale or visible channels can be adjusted. Hiding a channel only affects their visibility, the data is recorded in the background.

The default time axis for aEEG is 6 cm/hour (clinical standard). The aEEG amplitude scaling for 0 – 10 μ V is linear and is logarithmic from 10 – 100 μ V.

The **Burst Suppression Ratio (BSR)** and **Inter Burst Interval (IBI)** are updated every 4 seconds and calculated with the EEG/aEEG recording from the last 10 minutes.



Burst Suppression Ratio (BSR): The BSR is calculated as the percentage of suppression periods. The resulting BSR value is shown in the middle of the circle and indicated by grey shades on the circle. For example, if BSR value for the last 10 minutes is 77%, 77 percent of the circle will be filled with grey color.



Inter Burst Interval (IBI): The average of the IBIs from last 10 minutes is shown in the middle of the circle. In addition, the distribution of all IBIs within these 10 minutes is classified into one of the following categories depending on their length: 2 -5 s, 5 - 10 s, 10 - 20 s, and > 20 s, and displayed in the outer circle.

EEG view

The EEG view can be opened any time during the recording with the EEG UP button:



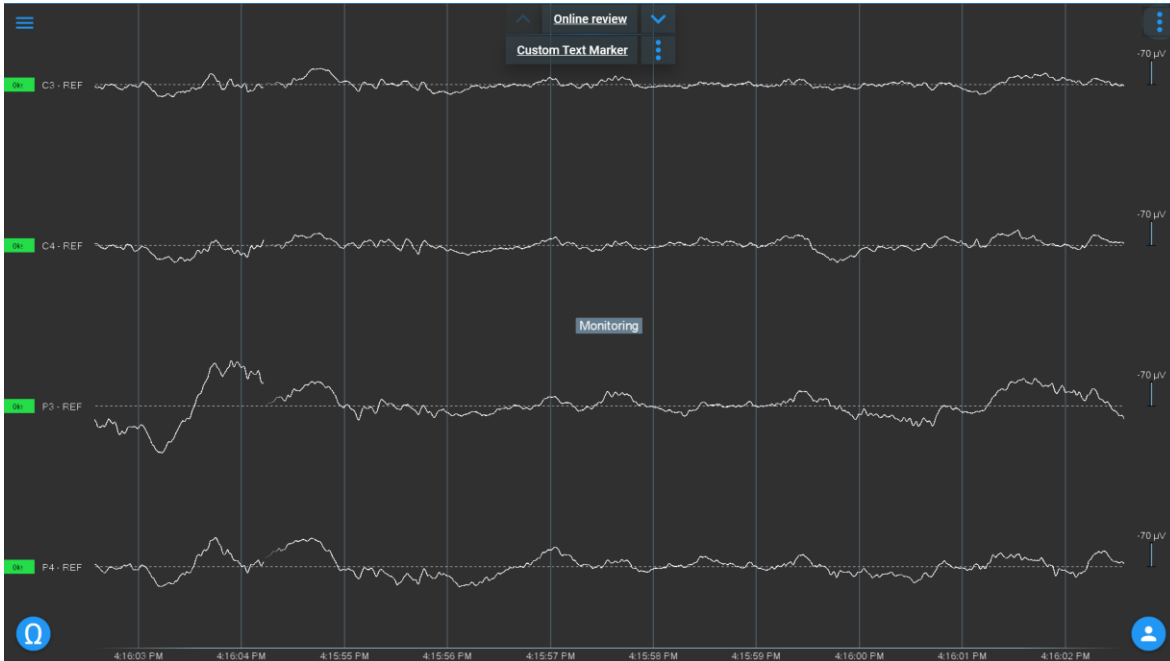
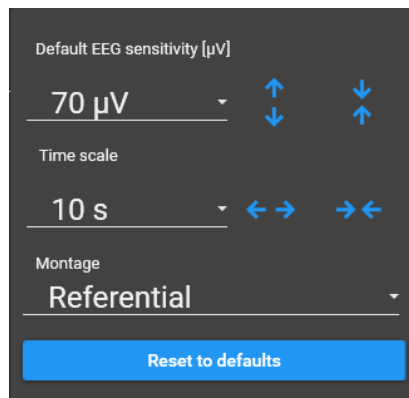


Figure 4-5 EEG view

You can scroll across the EEG channels by panning vertically in the data area, and change the spacing of the channels by pinching vertically in the label area.





Via the dropdown button in the EEG window, parameters such as timescale, EEG sensitivity or montage can be adjusted.



The impedance indicator on the left side of each channel shows the most recent impedance value measured for each electrode.

4.6. aEEG/EEG split-screen

The aEEG and EEG view can be combined in a split-screen and can be triggered by either EEG up  or EEG down  button, depending which view was previously displayed.

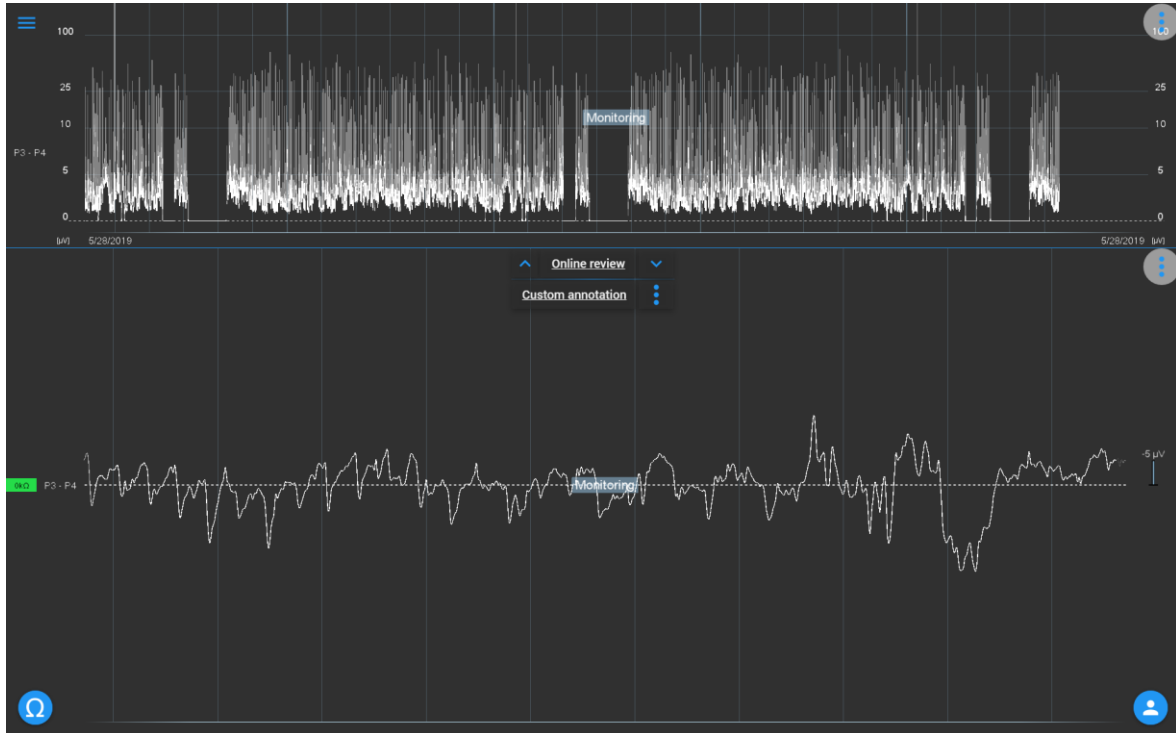
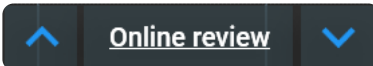


Figure 4-6 EEG and aEEG displayed in a split-screen

4.7. Online review

During a recording, online review is possible at any time.



Push the **Online review** button to switch to aEEG and EEG review, while data is recorded in the background.

Use the **EEG UP** and **EEG Down** buttons to switch between different data views

The Online review has the same functionalities as **Offline Review**, please refer to Chapter 5. However, during the Online review, EEG/aEEG data is recorded in the background.

4.8. Annotations

During a recording, annotations and markers can be set at any time.



Push the **Text Marker** button to insert a custom text annotation.

Use the **Dropdown** button for inserting standard annotations.

Custom Markers are inserted immediately when the button is pressed, while a window is kept open for inserting the custom text.

Standard markers are inserted immediately after the button is pressed.

4.9. Alarms and information messages

The nēo monitor has two types of warning messages:

Non-physiological data detected

Please check the possible causes listed in the user manual!
C3 C4 P3 P4

Alarms:

Attention from clinical staff is required. This includes:

- High electrode impedance
- Amplifier disconnection*
- Non-physiological data detected*
- Bad backup location
- Low disk space
- Too many annotations

Recording started

EEG recording started. Building up data to compute aEEG.

Information:

Informative message to explain the current status of the software. This includes:

- Recording started
- Screenshot exported
- Data exported
- Amplifier connected

You can acknowledge the warning message by tapping on it.

***Amplifier disconnection:** If the USB cable gets disconnected, the software shows the message “Amplifier connection error”. Recording to the current segment will be stopped and resumes automatically as soon as the amplifier becomes available again, which will be indicated by the information message “Amplifier connected”. A special marker will indicate the gap in the recording.

***Non-physiological data detected:** this indicates that the EEG signal is likely out of range of EEG. Multiple causes are possible: very high noise through artifacts, saturated amplifier (the signal sensitivity has to be adjusted in the technical setup) or completely inactive brain signal (refer also to chapter 4.4).

You can switch the message off by tapping on it or tapping on **clear messages** button.

4.10. Select a patient

Once a data acquisition session has started, you can create a new patient or assign the session to an existing patient by pressing the **Patient** button on the bottom right corner. Please refer to Chapter 8. In the patient menu, a new patient can be added, or recording can be assigned to existing patient. A search function enables quick patient matching.

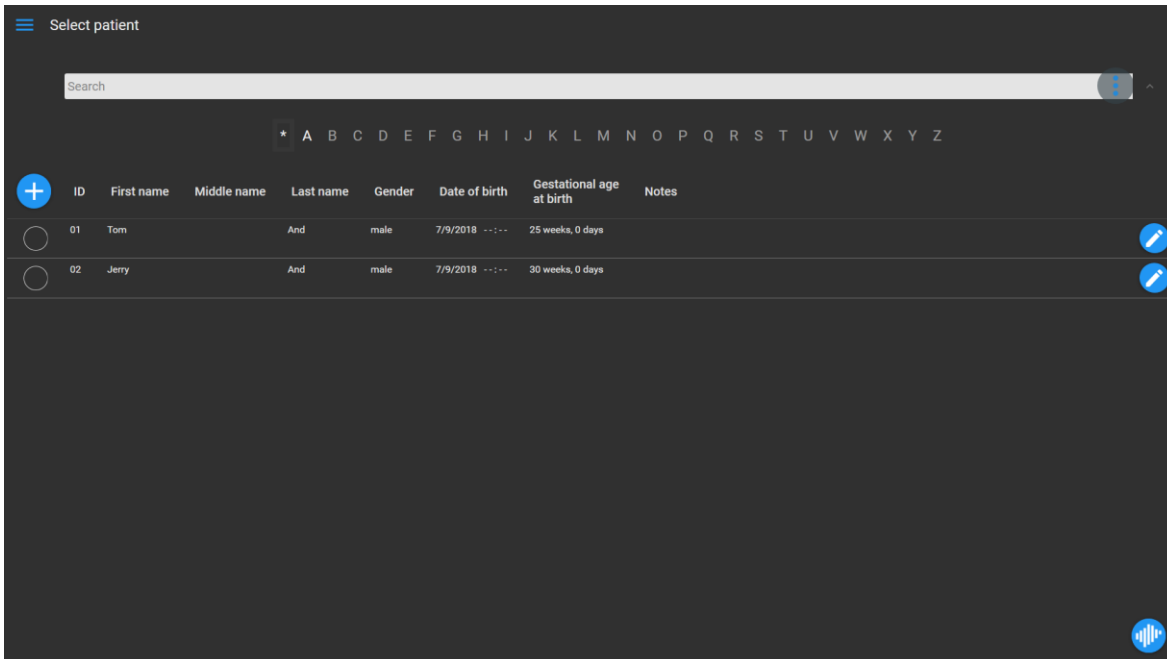


Figure 4-7 Select patient menu



Select search filters.



Add a new patient. A new menu will be opened (Chapter 8).



Edit a patient. A new menu will be opened (Chapter 8).



Return to acquisition.

4.11. Stop EEG/aEEG Data Acquisition



After patient registration, the stop button will appear in the bottom right corner. Pressing the **Stop** button finishes the active monitoring session and exits to the start screen.

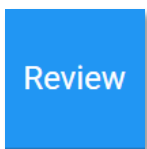
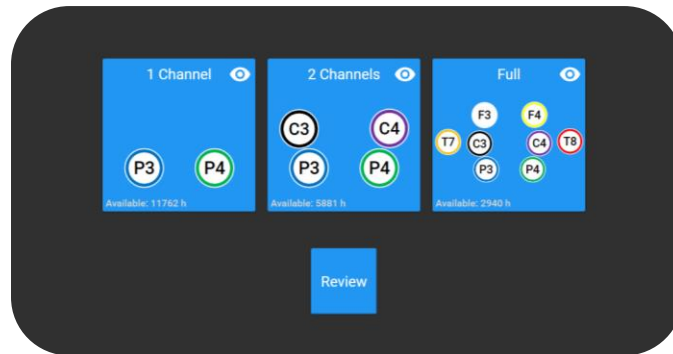
The nēo monitor prevents stopping a data acquisition session before a patient is selected. Although the **Stop** option is always available in the **Options** menu, you will be presented with a reminder that you must select a patient before ending a data acquisition session.

Displayed data in nēo monitor are always saved into the database. In case the software quits unexpectedly during an acquisition session, the recording will be stopped and stored under the name of the selected patient. In case this happens before the patient selection has taken place, you will be presented with a reminder to assign the unsaved session to a patient when the software is started the next time.

5. EEG/aEEG REVIEW

5.1. Start a review session

Using the nēo monitor, you can review all data that is stored in the local database.



Press the **Review** button on the start screen and proceed to the *Patient* selection screen.

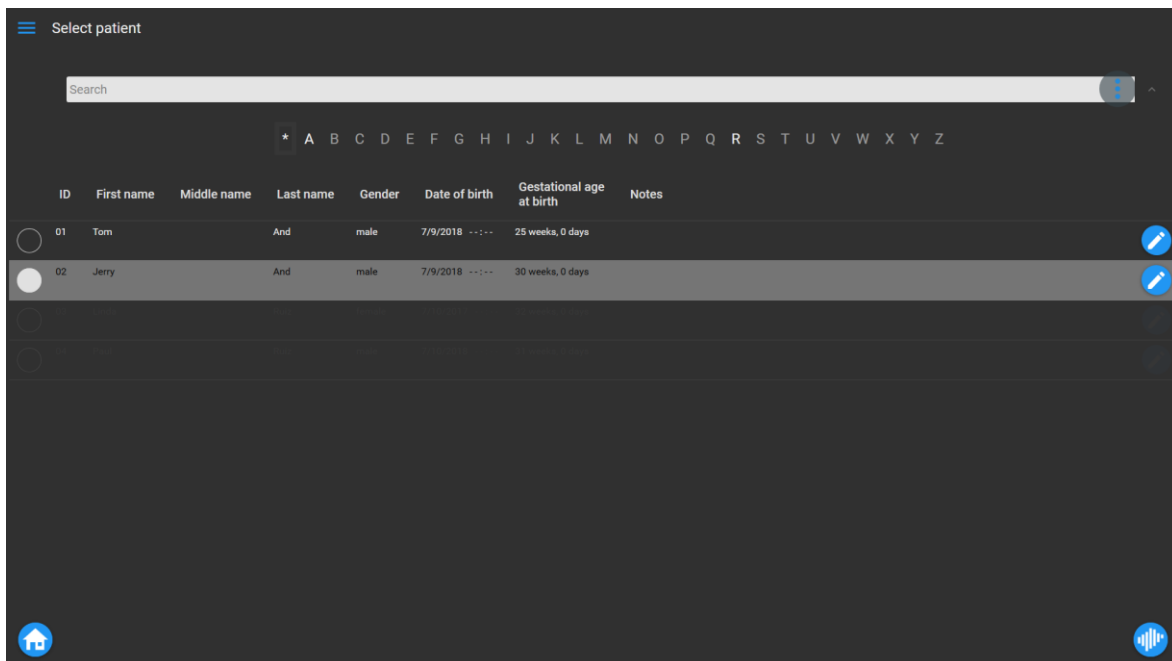


Figure 5-1 Select a patient for review

Tap on the patient whose data you wish to review.



Select search filters.



Edit a patient.



Go to data selection.



Pressing the **Start screen** button in the bottom left corner will take you back to the Protocol selection.

Edit recordings

Tom And

ID: 01
 Date of birth: 7/9/2018 - - - -
 Gender: male
 Gestational age at birth: 25 weeks, 0 days
 Notes:

Recording start	Recording length	Protocol	Sampling frequency
<input checked="" type="radio"/> 7/9/2018 6:10 PM	00h 11min 06s	Full	512
<input type="radio"/> 7/9/2018 5:58 PM	00h 11min 43s	2 Channels	512
<input type="radio"/> 7/9/2018 5:57 PM	00h 00min 15s	2 Channels	512
<input type="radio"/> 7/9/2018 5:39 PM	00h 06min 02s	2 Channels	512
<input type="radio"/> 7/9/2018 4:14 PM	00h 05min 29s	2 Channels	512
<input type="radio"/> 7/9/2018 4:01 PM	00h 00min 22s	2 Channels	512
<input type="radio"/> 7/9/2018 3:53 PM	00h 00min 25s	2 Channels	512
<input type="radio"/> 7/9/2018 3:52 PM	00h 00min 27s	2 Channels	512
<input type="radio"/> 7/9/2018 3:52 PM	00h 00min 22s	2 Channels	512
<input type="radio"/> 7/9/2018 3:51 PM	00h 00min 34s	2 Channels	512
<input type="radio"/> 7/9/2018 3:35 PM	00h 01min 43s	Full	512
<input type="radio"/> 7/9/2018 1:10 PM	00h 05min 29s	2 Channels	512

Figure 5-2 Select a session for review



Return to patient selection.



Open selected data.

5.2. Paging through time

During a review session, recorded aEEG and EEG data, impedances and annotations are shown in their respective displays. A blue vertical line indicates the position of the current time cursor. Impedance on the left side depict the values acquired at the beginning and end of the recording.

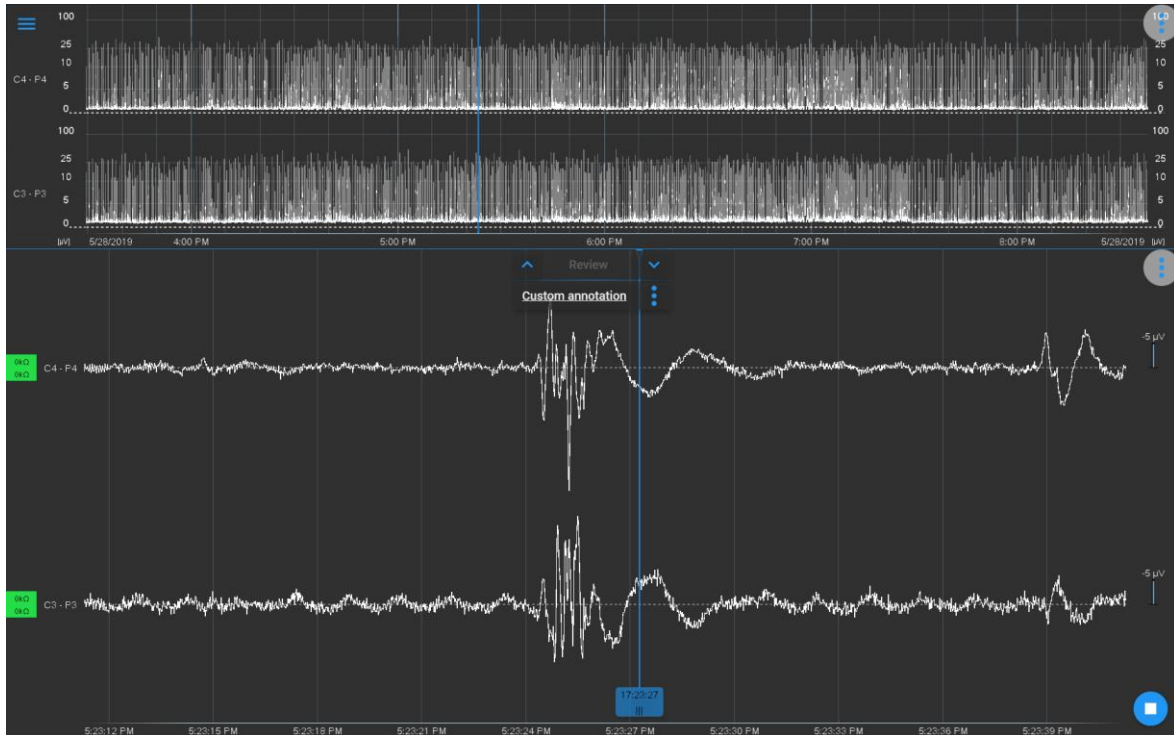


Figure 5-3 Offline review screen



Scroll horizontally in aEEG and EEG view to page through time.
Tap-scroll on the blue time marker to shift its position. Annotations will always be inserted at the current position of the marker.



Tap in aEEG view to jump to a particular time in EEG display.



Pinch or Stretch vertically with two fingers to adjust EEG sensitivity in EEG view.
Pinch or Stretch horizontally with two fingers to adjust time scale in aEEG or EEG view.

5.3. Stop a review session



Pressing the **Stop** button finishes the review and exits to the start screen.

6. QUICK ACCESS NAVIGATOR










While in any view of the nĕo monitor, a quick access navigator can be opened via  in the top left corner.



Figure 5-4 Quick access navigator


The accessible menu points are listed below. The currently active view is displayed in blue.


- | | |
|--|---|
|  aEEG | Displays the aEEG view only. |
|  aEEG & EEG | Displays the aEEG & EEG views in one screen. |
|  EEG | Displays the EEG view only. |
|  Impedance | Activates the Impedance view. |
|  Patients | Activates the Patient Management screen. |
|  Info | Shows the current session information. |
|  Export | Allows the export of the complete EEG and aEEG data including annotations in an importable format. Data are exported onto a USB drive or custom (network) path, depending on the options chosen in the Technical setup workflow. Data are exported as anonymous or with patient name and ID, depending on the options chosen in the Technical setup workflow. |

 **Screenshot** Creates a screenshot of the current view and saves it onto a USB drive or custom (network) path, depending on the options chosen in the Technical setup workflow.

 **Stop** Exits the current recording or review.

further options are only available if the quick access navigator is opened in start screen:


 **Technical setup** Initiate the Technical setup screen. Password inquiry will pop up.

 **Quit** Quit nēo monitor and shut down PC.

7. DATA EXPORT and BACKUP

7.1. EEG/aEEG export

During a monitoring and review session, export functions are available via  in the top left corner.


 **Export** Export complete EEG and aEEG data in an importable format (CNT, EDF+ or ASCII) onto USB or network drive. The name of the exported file is defined by the name of patient, the start and ending time of the data to be exported, and the type of the data (aEEG, raw EEG or filtered EEG).

During monitoring session:

Entire data from the beginning to now will be exported.

During offline review session:

Entire data from the beginning to the end will be exported.

 **Screenshot** Make a screenshot of the current view and save onto USB or network drive.

The Technical setup workflow allows the user to define settings for export location (USB or network drive), data format and data anonymization. Further, it allows customization of the type of EEG data to be exported (filtered and / or raw EEG).

7.2. Database backup

The Technical setup workflow provides the option to back-up the entire database onto an external hard drive, connected to the USB port. The back-up drive needs to be NTFS-formatted. Please make sure that there is sufficient free storage available on the back-up drive. We recommend at least 250 GB for each backup.

8. PATIENT MANAGEMENT

In the **nēo** monitor, each recording is linked to a unique patient. Each patient is entered into the software with a collection of demographic information listed below.

Mandatory information:

- Patient ID: An identification number of the patient defined by the hospital
- First name: One or more first names of the patient
- Last name: The last name (surname or family name) of the patient
- Date of birth: Date of birth of the patient (the date is formatted according to the language settings in the Technical setup workflow)

Optional information:

- Time of birth: Time of birth of the patient (hh:mm)
- Gender: Gender of the patient
- Gestational age at birth: number of weeks and days from the first day of the mother's last menstrual cycle to the birth date
- Notes: Further patient details can be entered into Notes.
- Birth weight: weight of the baby at birth.

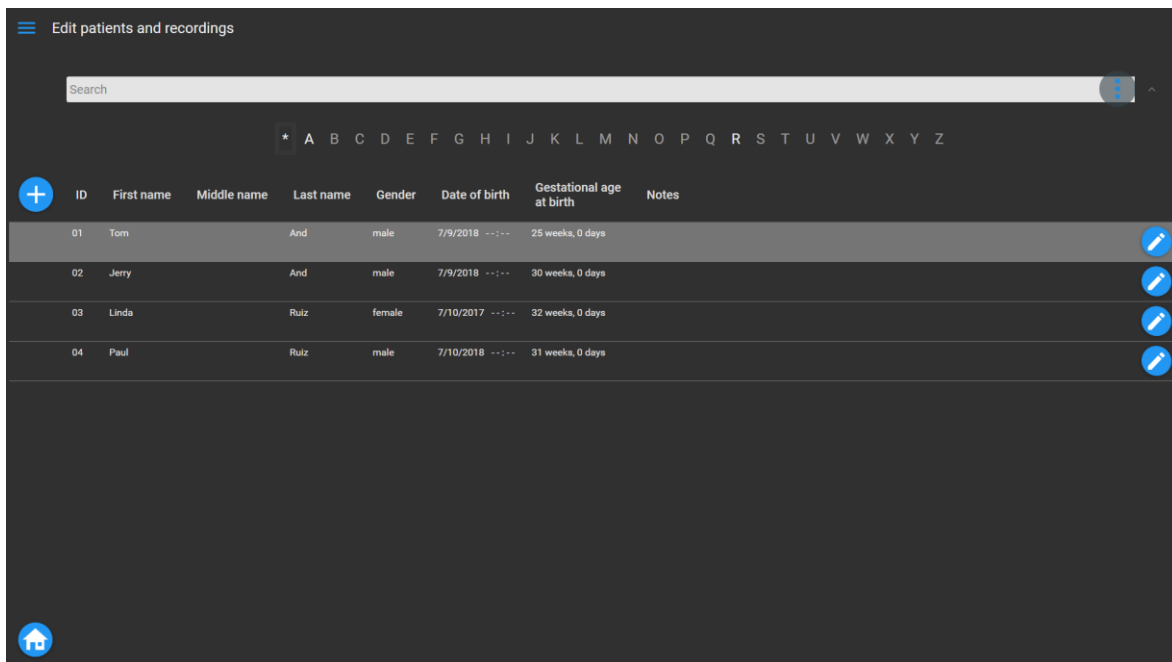


Figure 8-1 Patient selection menu

The patient database is accessible:

1. from the start screen via the quick access navigator in the left top corner.
2. during a recording via the patient button on the right bottom corner.
3. before review mode, right after pressing on the review button in the start screen.

Depending on the entry point to the patient database, different buttons are enabled.



Select search filters. The search field at the top of the screen allows you to search the table. A list of filters is available by pressing the ellipsis button.



Add a new patient.



Edit a patient.



Go to data selection.

Press the **Signal** button on the bottom right corner. You will be directed to a new page, where demographic data of the selected patient is shown on the top, and recording sessions associated with that patient are listed on the bottom.



Pressing the **Start screen** button in the bottom left corner will take you back to the Protocol selection.

The alphabetic bar filters for patients whose first name starts with a particular letter. The * button at the leftmost of the list deactivates this filter.

8.1. Create a new patient or modify an existing patient

Edit patient

ID Gender

First name* Date of birth*

Middle name Gestational age at birth weeks days

Last name*

Notes

Figure 8-2 Patient edit menu




Return to patient selection without saving.



Save patient data and return to patient selection.

After patient selection, the name of the selected patient will be indicated on the top left corner of the *Acquisition* screen.

9. INFO FUNCTION

During a recording with nēo monitor, help can be accessed via  at the top left corner.

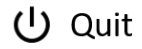


Info

Show current session information (patient information and montage of the protocol).

10. Exit Monitoring and Shut down

Use the quit button from the quick access menu to shut down nĕo. The computer will turn off automatically and remain in standby mode.



Quit

Quit nĕo monitor and shut down PC.

11. CARE AND HYGIENE

The computer unit cannot be sterilized.

If switched on, features of the operating panel or the optional touch screen can be triggered unintentionally, i.e. due to water drops.

Only the wipe disinfectants that are listed below can be used for cleaning the unit.

The active substances in the following table are expected to be harmless for the unit as long as the listed limits are observed. The table does not represent a medical evaluation of the effectiveness of these substances.

Active Substance	Max. Concentration in %	Max. Exposure in Minutes	Example Products
Alcohol	100	360	Bacillof AF Meliseptol
Biguanide	8	360	Incidin Plus
Chlorine, organic or inorganic substances with active chlorine	10	360	Incidin perfekt Optisept
Per-compounds	8	360	Incidin active Terralin PAA
Phenol or phenolic derivatives	6	360	Helipur

The following detergents and agents are unsuitable for cleaning, DO NOT USE PRODUCTS CONTAINING:

- acetone
- citric acid
- cleaning liquids basing on crude oil like petroleum, turpentine or oil

Using cleaning pads, rough sponges and cloths might damage surfaces and sealing material.

APPENDIX A: ESSENTIAL PARAMETERS

a) EEG data recording

During EMC testing the essential performance was monitored based on the criteria below.

- Accuracy of signal reproduction: signal reproduction of a 6Hz triangular signal with 1mVpp is within $\pm 20\%$ of the input signal or $\pm 10 \mu\text{V}$, whichever is greater.
- Input noise: peak to peak input noise voltage under short circuit load condition is below $6\mu\text{Vpp}$ with 50Hz low pass filter applied.
- Frequency response: The output for sine wave signals at 0.5Hz and close to 50Hz (outside notch filter range to suppress 50Hz) is within 71% to 110% of the output obtained for a 5Hz sine wave signal.
- Common mode rejection: Sine wave common mode signal applied with 1Vrms results in less than $100 \mu\text{Vpp}$ signal for frequencies in the range of 50Hz to 60Hz.

b) Accuracy of aEEG computation

At given frequencies, deviation from expected aEEG value is smaller than 2% of input amplitude peak-to-peak voltage or 10% of expected aEEG value (whichever is greater). The following table lists the expected aEEG values and acceptable deviations for sine wave input signals of $100\mu\text{Vpp}$. Note that for sine wave input signals of the given frequencies, the upper and lower value of the expected aEEG are identical.

Frequency (Hz)	Expected aEEG value (μV)	Min (μV)	Max (μV)
2	23	20.7	25.3
10	100	90	110
14	100	90	110
25	14	12	16

APPENDIX B: NĚO TECHNICAL SPECIFICATIONS (EMC)





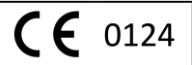








The compliance in the tables below is valid for *nĚo monitor, system ES-820* consisting of:

Part	Cable length (m) (total length must remain < 3 m)
nĚo monitor EEG/aEEG software LE-800	-
ACL All-In-One PC	-
eego amplifier EE-411	0.6
Breakout adaptor XC-810	1.8
Cart XC-820/XC-830	-

Guidance and manufacturer's declaration – electromagnetic emissions		
<i>The nĚo system ES-820 is intended for use in the electromagnetic environment specified below. The customer and/or user of the system should ensure that it is used in such an environment.</i>		
Emission Test Compliance	Compliance	Electromagnetic Environment - guidance
RF Emissions CISPR 11	Group 1	The <i>nĚo system ES-820</i> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The <i>nĚo system ES-820</i> is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration – electromagnetic immunity			
<i>The nĚo system ES-820 has been tested as compliant according to standards as indicated below.</i>			
Immunity Test Standard	Compliance test level	Electromagnetic Environment - guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
Electrical fast transients IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	U _{in} - 100% dips: 10 ms / 3x per phase/ 20s U _{in} - 100% dips: 20 ms / 3x per phase/ 20s U _{in} - 30% dips: 500 ms / 3x per phase/ 20s U _{in} - 100% dips: 5000 ms / 20s	(During and after the test function was as intended) Mains power quality should be that of a typical commercial or hospital environment. (Test of 0 V / 5 s stops function; manual restart OK)	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	
Conducted RF IEC 61000-4-6	3 V rms (0.15 MHz – 80 MHz) 6 V rms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	The use of portable and mobile RF communications equipment can adversely affect the recording; do not use an operating cellular phone within 30 cm (12 inches) of the amplifier, the cables and the electrodes to avoid excessive noise on the signals.	
Radiated RF electromagnetic fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz		
Radiated RF electromagnetic disturbances IEC 61000-4-3	Test freq. (MHz)		Immunity Level (V/m)
	385		27
	450		28
	710-780		9
	810-930	28	
1720-2450	28		
5240-5785	9		

APPENDIX C: EXPLANATION OF SYMBOLS

	Manufacturer symbol: indicated with name, address
	Catalogue number
	Serial number
	Year of manufacture
	Conformité Européenne, CE mark, with number of Notified Body involved in the conformity assessment
	Follow the instructions for use (i.e., this user manual)
	Warning sign: warnings apply
	Special waste disposal regulations apply (EU)
	Safety according to class II electrical equipment (IEC 60601-1) <i>(applicable to eego amplifier)</i>
	Protective earth (ground)
	Applied parts: type BF (IEC 60601-1)
	Applied parts: type CF (IEC 60601-1) <i>(only applicable if on device label)</i>
	MR Unsafe (ASTM F2503-13)
IP20	IP Code (International/Ingress Protection Rating) as defined in international standard IEC 60529. (IP20: protection against fingers or objects < 12mm, not protected from liquids)
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

APPENDIX D: NĚO DATASHEET

Product Name: nĚo
Product Code: ES-820.cc
Product Version: 1



Manufacturer: eemagine Medical Imaging Solutions
Gubener Str. 47
10243 Berlin
Germany



Phone +49 (0)30 2904 8404
Fax +49 (0)30 2904 8405
E-Mail support@eemagine.com
Web www.eemagine.com

Example system label:

REF	ES-820 nĚo system
SN as indicated on product:	INST01514 2019-10-31
	*B195ES8200/\$\$+7INST015147*
	eemagine Medical Imaging Solutions GmbH Gubener Str. 47 10243 Berlin, Germany



OQC passed

for part(s) with SERIAL / LOT number as indicated on product / package

Classification: CE class IIa according to the MDD 93/42/EEC Annex IX
Protecting class I (ME equipment)

Compatibility: **XC-810** Break-out adapter with touch proof sockets
XC-820/XC-830 Medical Cart (Vesa compatible)
XC-821.R Medical Monitor arm for wall norm rails (Vesa compatible)
XC-821.P Medical Monitor arm for poles (Vesa compatible)
XC-822 Medical Table Stand (Vesa compatible)

Description: nēo is an 8-channel electroencephalograph (EEG) acquisition system. The device is intended to record and display EEG and aEEG signals for monitoring the brain status of neonatal patients (defined as from birth to 28 days post-delivery and corresponding to a post-conceptual age of 24 to 46 weeks). The device is to be used in a hospital environment by qualified clinical practitioners.

.cc is the country code for power supply:

As example:

.EU = Europe

.UK = United Kingdoms

.DK = Denmark

.US = United States of America

nēo is compatible with selected accessories and can be connected to mount options with VESA interface.

Specifications:

Touch Screen Monitor	
Weight	4.5 kg
Screen size	15", 16:9 Ratio
Dimensions	385 x 290 x 45 mm
Resolution	1920 x 1080 Pixel Full-HD
Mount	Integrated VESA-100 interface
Data Acquisition	Please see <i>eego amplifier EE-41x EE-43x User Manual</i>
Bipolar channels	6
Referential channels	Max. 8
Sampling Rate	512 Hz
Resolution	24 bit
Input impedance	>1 GΩ
Shielding	Actively shielded inputs
Amplifier size	86 x 100 x 16 mm
Input signal range	150 – 1000 mV _{pp}

Software	Please see <i>nĕo monitor user manual</i>
Operation System	Windows 10 (64bit)
Monitoring features	Real-time EEG aEEG (computed) Continuous Burst-Suppression-Ratio (BSR) Continuous Inter-Burst-Interval (IBI) Impedance Measurement Event-Markers Online-Review mode
Hardware	
Processor	Intel Core™ i5
Working Memory	8 GB
Connectivity	2x USB 3.0
Storage	mSATA 250GB SSD
Graphics	Intel® HD Graphics GT-Series
Operation environment	
Temperature	15°C to 35°C
Relative humidity	15% to 60%, non-condensing
Atmospheric pressure	86 to 106 kPa
Power Supply	
Power supply Unit	Integrated power supply
Power supply voltage	100-240V / 50 / 60 Hz
Power consumption	max. 110 W

Connection to compatible products:

See compatibility list above.

Warning:

Proper use of the **ES-820** depends on carefully reading of all instructions including the **ES-820** descriptions and labels that come with or on the devices. Inaccurate measurements may be caused by incorrect use of the device. Non-compliance with warnings and safety regulations may result in severe personal injury and total loss of equipment.



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