

User Manual

UNEEG™ EpiSight Analyzer

Version number 2.3



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Medical Device

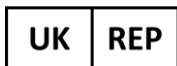


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Caution: Please read paragraphs marked with this symbol carefully as they contain important safety information.



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Warnings and precautions



UNEED™ EpiSight Analyzer is CE-certified as a medical device. If your country requires any other approval for medical devices you must not use UNEED™ EpiSight Analyzer.



The modules from UNEED™ EpiSight Analyzer for the automatic analysis of EEG cannot replace the examination by the physician. As for any other automatic procedure, there can be inaccuracies during the analysis with UNEED™ EpiSight Analyzer. The original EEG still needs to be used for the evaluation and the results of UNEED™ EpiSight Analyzer need to be confirmed based on the unaltered raw EEG trace.



UNEED™ EpiSight Analyzer does not provide any diagnosis or diagnostic recommendation, conclusion or prediction of the patient's state. It remains the responsibility of the physician to decide on the diagnosis or to induce treatment.



The use of the software cannot replace the real-time surveillance by medical staff particularly of the vital functions. The patient's safety remains the responsibility of the medical professional.

The maximum length for continuous EEG recording that can be reviewed and analyzed with the EEG viewer is 15 months. If a recording is longer than 15 months UNEED™ EpiSight Analyzer will stop processing.

For UNEED™ EpiSight Analyzer seizure detection, detection of rhythmic pattern, aEEG, background frequency and sleep analysis the EEG of at least three subcutaneous electrodes must be available.



UNEED™ EpiSight Analyzer seizure detection cannot be used as an alarm system, since there may be a delay of several minutes between the clinical onset of a seizure and the display of the detected pattern. Some EEG-events with epileptic seizures that have an electrographic correlate might be missed. For this reason UNEED™ EpiSight Analyzer can only support but can not replace the qualified expert in the real-time monitoring.



UNEED™ EpiSight Analyzer detection of rhythmic pattern, aEEG, background frequency or sleep analysis included in UNEED™ EpiSight Analyzer should not be used as an alarm system, since the visualization of patterns could be delayed by up to several minutes.

Some events, where patterns defined in the Standardized Critical Care EEG Terminology of the American Clinical Neurophysiology Society are visible in the EEG, might be missed. All measures of UNEED™ EpiSight Analyzer must be evaluated in combination with the original raw EEG and must not be the only basis for a diagnosis, treatment or change of treatment.

Contraindications

There are no known contraindications for the use of UNEED™ EpiSight Analyzer.

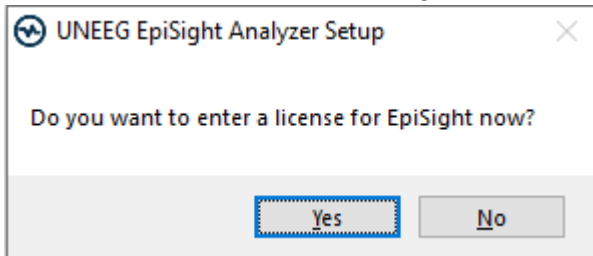
Possible adverse effects

There are no known possible adverse effects when using UNEED™ EpiSight Analyzer.

Quick Start Guide

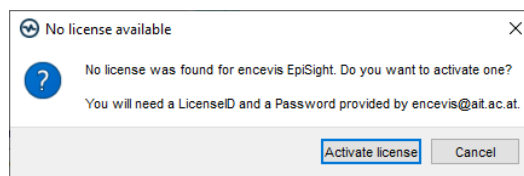
Installation and license activation

1. Download the installer for UNEEG™ EpiSight Analyzer.
2. Start the installer by double-clicking the downloaded executable.
3. The installer will guide you through the installation process.
4. After the installation the following window will pop up:

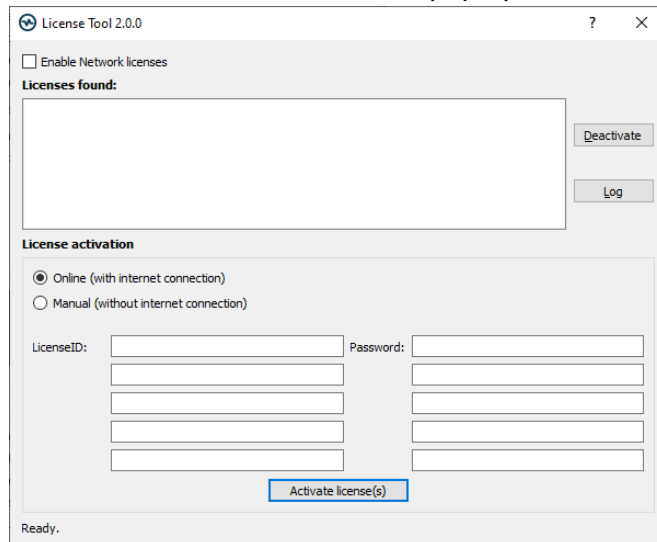


If you click “Yes” you will proceed at step 9.

5. Once the installation has finished, start the EpiSight Analyzer by clicking on the icon on your desktop.
6. You can add new patients to the database and import data.
7. The following steps are just necessary if you have no valid License activated so far. In order to open the patient’s EEG, you will need an active license.
8. Click on “*Open patient*”, the following window will pop up:



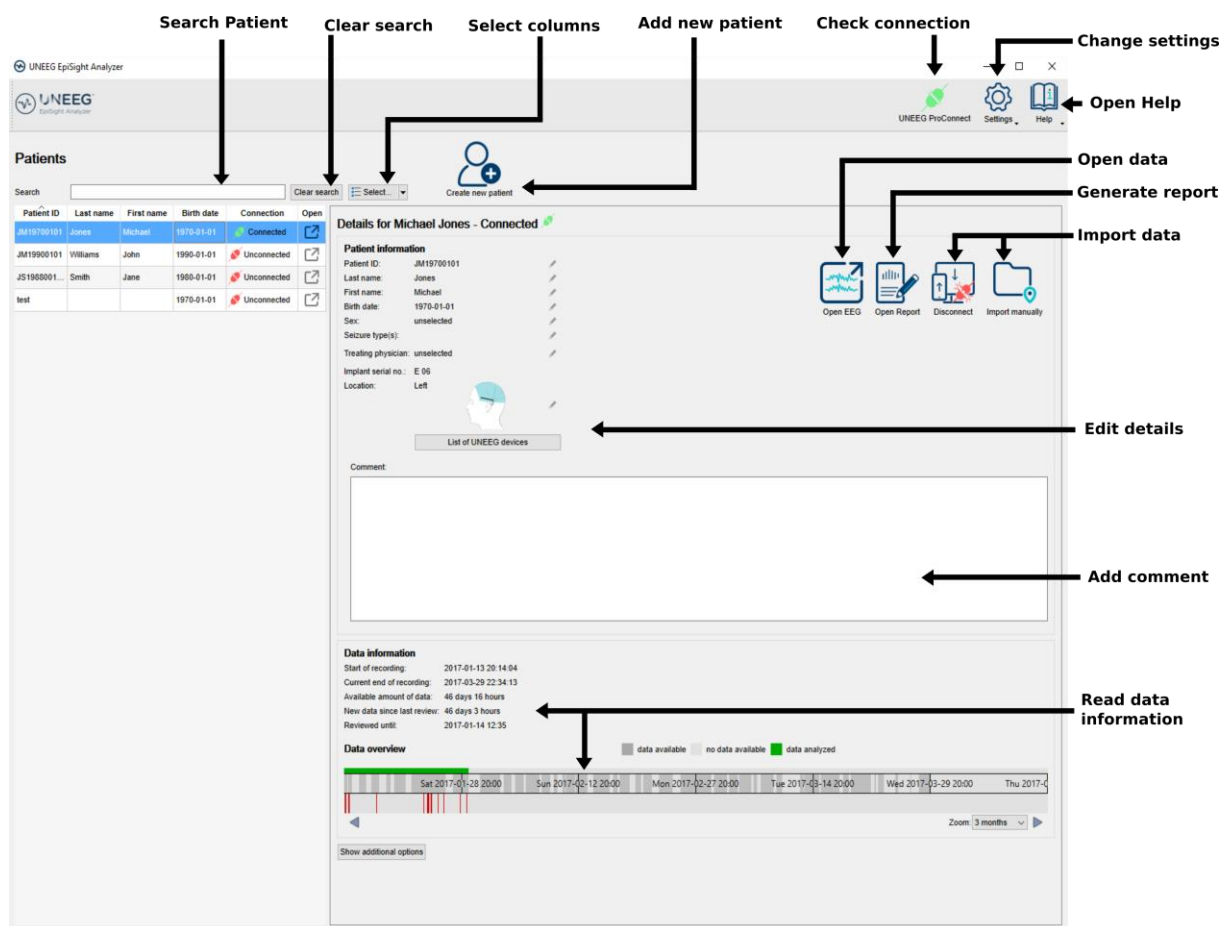
9. Press “*Activate license*”, the License Tool will pop up.



10. If you are connected to the internet, select „*Online*“ as activation mode. Otherwise, select “*Manual*” and contact your distributor in order to get the password for the manual activation.
11. Enter your LicenseID and Password.
12. Press “*Activate license(s)*”.

Patient Database

Starting UNEEG™ EpiSight Analyzer will open the patient database window.

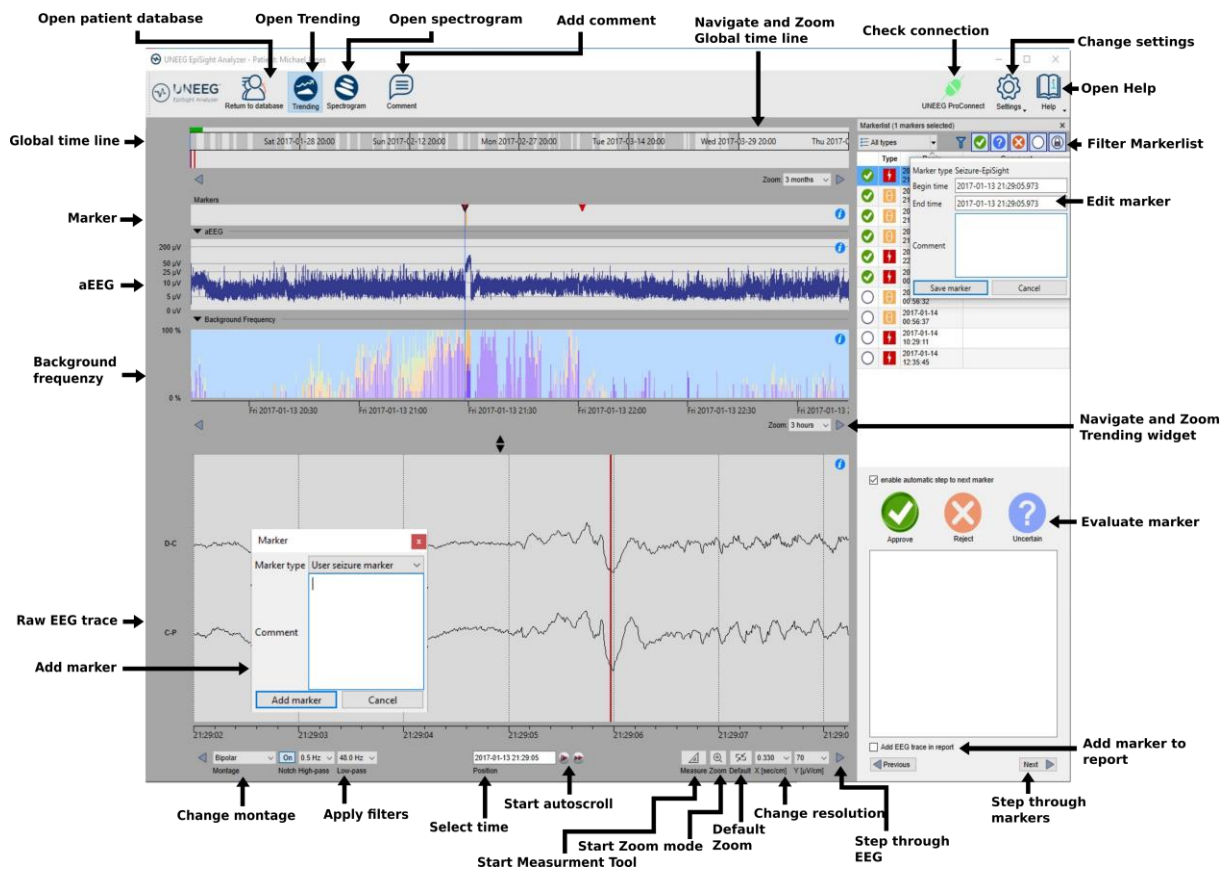


The patient database offers the following functionalities:

- Search for a patient by ID, name or date of birth
- Select the columns shown in the patient list
- Add a new patient
- Edit the patient's information
- Get the information about the EEG data available for each patient
- Open the patient's EEG
- Generate a report
- Connect to UNEEG™ ProConnect
- Import data by connecting to UNEEG™ ProConnect
- Import data manually by selecting a folder
- Change settings
- Open help

Trending

Clicking on “Open patient” will open the trending window.



The trending includes the following functions and traces:

- Global timeline with an overview over all available data
- Zoom in the global timeline and in the analysis windows over a drop-down menu or the mouse wheel
- Seizure and other markers in a trace and in a list on the right side of the window
- Rhythmic pattern markers
- Amplitude-integrated EEG (aEEG)
- Background frequency
- EEG plot synchronized to the traces above
- Change montage
- Apply notch, high-pass and low-pass filters
- Change resolution in time and voltage
- Apply standard zoom
- Start zoom mode
- Start measurement Tool
- Start autoscroll
- Add markers
- Review and edit markers
- Filter marker list by marker type and by status

Spectrogram

Clicking on the icon “Spectrogram” will show the spectrogram traces.

The spectrogram adds the following functionalities:

- Display of the spectrogram of the channels D-C and C-P.
- Get the estimated frequency in the spectrogram trace
- Adjust the color settings by changing the maximum intensity shown.

Report

Clicking on “Report” will open the report window.

The screenshot shows the UNEEG EpiSight Analyzer Report interface. Key elements include:

- Report Section:** Fields for 'Reported by', 'Reference period' (start/end: 2017-01-13 to 2017-02-20), and 'Current period' (start/end: 2017-02-21 to 2017-03-29).
- Patient Information:** Name: Michael Jones, Sex: unselected, Date of birth: 1970-01-01, Age at study time: 47, Treating physician: unselected, Seizure Types: Implant ID: E 06, Location: Left.
- Recording and report summary:**

	Reference period	Current period
Days of recording	39	37
Usage (%)	62%	61%
Electrographic seizures	4	0
Electrographic seizure rate per 24 hours	0.10	0.00
Patient-reported events	0	0
- Seizures over time:** A bar chart showing seizure activity over 24 hours, with a legend for 'Weekend data', 'Weekdays data', 'No data', 'Electrographic seizure', and 'Patient-reported events'.
- Annotations:**
 - 'Automatically generated content' points to the Patient information and summary sections.
 - 'Clear' points to the 'Clear All' button.
 - 'Export to PDF' points to the 'Create PDF' button.
 - 'Fill out' points to the 'Indication for testing', 'Summary of the findings', 'Diagnostic significance', and 'Clinical comments' text areas.
 - 'Copy automatically comment' points to the 'Paste from comment' button.

The report offers the following functionalities:

- Enter additional clinical information including:
 - Indication
 - Summary of the findings
 - Diagnostic significance
 - Clinical comments
- Generate content automatically including:
 - Patient information
 - Statistical information
 - Overview of seizure periods over time
 - Seizure periodicity plots
 - Seizure rate over time
 - Examples of seizures
- Paste the EpiSight comment
- Export to a pdf file

Keyboard shortcuts

The following table shows a summary of keyboard shortcuts available

Modifier	Key	Function
		EEG Plot area
	Arrow left	Scroll EEG-Plot one page to the left
	Arrow right	Scroll EEG-Plot one page to the right
Shift	Arrow left	Scroll EEG-Plot one second to the left
Shift	Arrow right	Scroll EEG-Plot one second to the right
	Home	Scroll EEG-Plot to the beginning of the recording
	End	Scroll EEG-Plot to the end of the recording
Ctrl	+	Zoom one step into the EEG Area
Ctrl	-	Zoom one step out of the EEG Area
Ctrl	0	Zoom EEG Area to default value
Shift	MouseWheel	Zoom at the cursor position in EEG Area
Ctrl	M	Enter measurement mode
	Esc	Exit measurement mode
		Marker List
	Arrow up	Scroll one row up in the marker list
	Arrow down	Scroll one row down in the marker list
Shift	Arrow up	Expand selection with next marker up
Shift	Arrow down	Expand selection with next marker down
Ctrl	A	Select all marker currently visible in the marker list
Ctrl	C	Copy selected marker to the clipboard
	A	Rate selected markers as "approved"
	R	Rate selected markers as "rejected"
	U	Rate selected markers as "uncertain"
		Trending and Spectrogram
Ctrl	S	Show spectrogram
Ctrl	T	Show trending
		Edit Comment
Ctrl	E	Open the comment dialog
Ctrl	Enter	Close patient comment dialog and save comment modifications
	Esc	Close patient comment dialog and discard comment modifications

		Spectrogram and Trending Widget
Ctrl	Arrow left	Scroll spectrogram/trending plot one page to the left
Ctrl	Arrow right	Scroll spectrogram/trending plot one page to the right
Ctrl + Shift	Arrow left	Scroll spectrogram/trending plot 30 seconds to the left
Ctrl + Shift	Arrow right	Scroll spectrogram/trending plot 30 seconds to the right

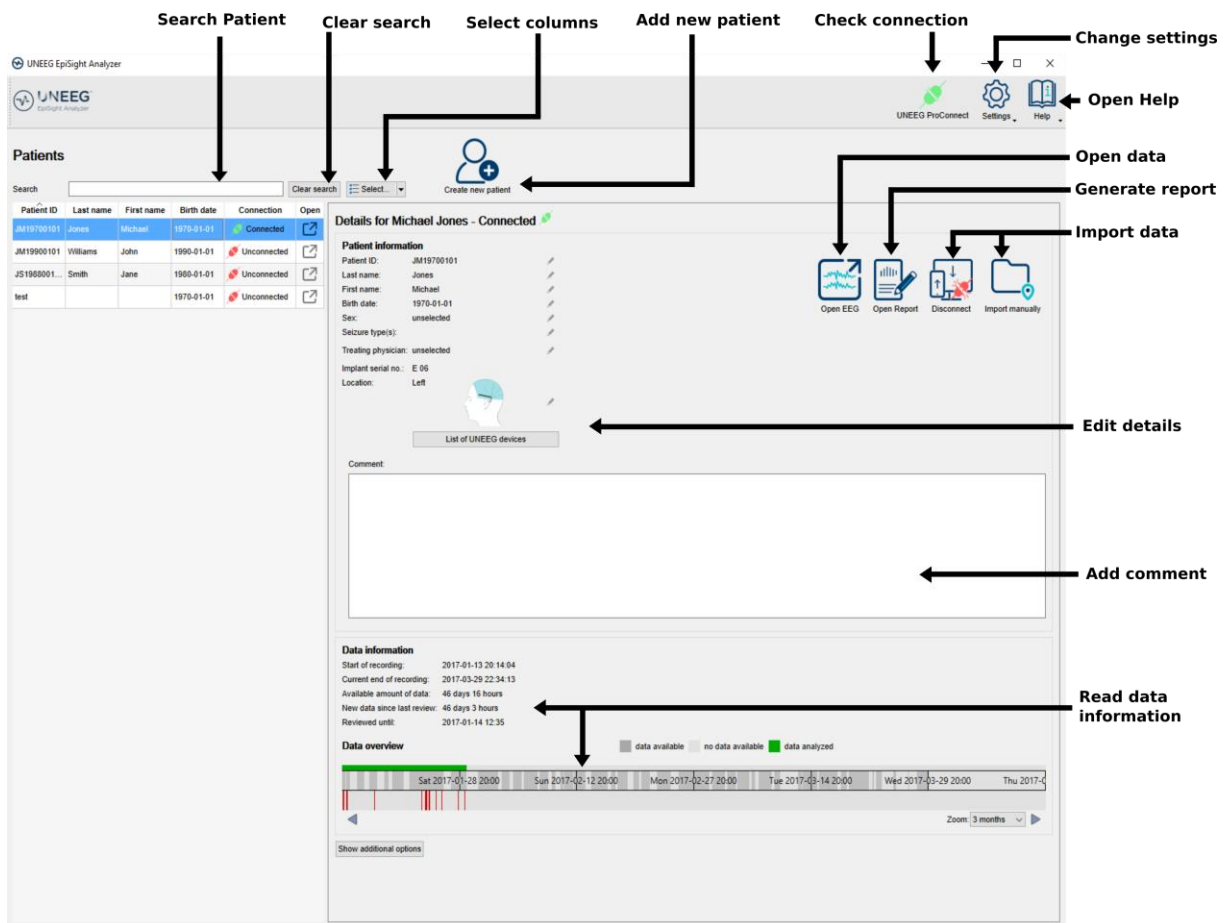
UNEEG™ EpiSight Analyzer

Overview

UNEEG™ EpiSight Analyzer is a software that enables you to review your patients' EEG recorded with a UNEEG SubQ™ 24/7 device. It includes a patient database, an EEG viewer, as well as a series of EEG analysis and reporting tools. The software has several windows that will be described in the following sections.

Patient Database

When you start UNEEG™ EpiSight Analyzer, the patient database window opens.



In the following, the functions of the patient database will be described.

Patient list

In the left panel the list of patients registered in the database is shown.

Search patient

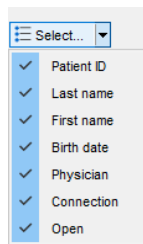
Fill in the search field and the list will be automatically filtered. The filtered results are shown in the patient list.

Clear search

Click on the button "Clear search" and the search results will be cleared. All patients contained in the database will be shown again.

Select fields

You can choose which fields are shown in the patient list by clicking on the drop-down menu “*Select*” as seen below and clicking on the check box on the left of the column name.

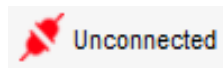


Fields showing patient information

The patient information includes the fields *PatientID*, *Last name*, *First name*, *Birth date* and *Physician*. They can also be seen in the panel “*Details*” and can be edited there.

Field Connection

In this field, the icon shows if you have a connection to the patient’s EEG recording on the ProConnect Server.



The icon is red and says “Unconnected” when the patient entry was newly created, and no pairing was yet performed. The icon is also red when the patient was disconnected over the button “*Disconnect*”.



The icon turns green when you the pairing process was successfully carried out over the button “*Connect*”.

Field Open

In this field, you can see if data is available and clicking on the icon enables you to open the data in the viewer.



The icon is grey when the patient entry was newly created, and no data was yet imported. The data can be imported by starting a pairing process over the button “*Connect*” or by importing the data manually over the button “*Import manually*”.



The icon appears in color after data was imported. Clicking on it will open the available data in the EEG-viewer.

Clicking on the icon is equivalent to double clicking on the whole row or clicking on the button “*Open patient*” in the right panel next to the details of the patient information.

Add a new patient to the database

To add a new patient to the database, click on the field “*Create new patient*”. The following window will pop-up:

Create new patient

Patient ID:

Last name:

First name:

Birth date: 1970-01-01

Sex: unselected

Seizure types: focal generalized unknown

Treating physician: unselected

Implant positioning: Unknown Left Right

Fill out the patient information. You must specify at least a patient ID or first and last name. This information can also be edited later.

Patient and data information

In the right panel of the window the detailed information of the patient selected in the patient list are shown. You will also find buttons to open a patient, start a pairing process to UNEEG™ ProConnect, write a report and import data manually.

Open patient

Clicking on the button “*Open patient*” will open the Viewer with the EEG traces and the analysis of the patient's data.



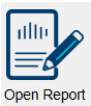
If no data is available, the folder icon “*Open patient*” will be shown in grey. The data can be imported by starting a pairing process over the button “*Connect*” or by importing the data manually over the button “*Import manually*”.



If data is available, the folder icon will be shown in color. Clicking on it will open the available data in the viewer.

The action triggered by “*Open patient*” can also be obtained by clicking on the icon in the field “*Open*” in the patient list or via a double click on the row.

Generate report



Clicking on “*Report*” will lead you to the report window. For more details go to the section *Report*.

Connect/Disconnect

Clicking on “*Connect*” will start the pairing process for the patient.



The icon is grey when no connection is possible to ProConnect. This corresponds to a grey icon of UNEEG™ ProConnect on the upper right corner.



The icon shows a green symbol and says “*Connect*” when you can connect a patient to the UNEEG™ ProConnect. Clicking on the button will trigger the pairing process.



The icon shows a red symbol and says “*Disconnect*” when the connection has already been performed. Clicking on the button will disconnect the patient again.

Please consult the EpiSight Server Admin Tool manual on how to establish the connection between the UNEEG™ EpiSight Analyzer and UNEEG™ ProConnect. To setup UNEEG™ ProConnect consult the UNEEG Medical documentation.

Import manually

Use this option to manually import EEG data that have been stored on your file system.



By clicking on “*Import manually*” you can select a folder where the recorded EEG files are stored. Clicking on “*Select folder*” will start the import of the data. The EpiSight Analyzer will recognize which recordings are new and related to your patient and the respective implant ID. The results of the import will be shown in the area “*Data information*”.



Note that the folder containing your EEG files will appear empty when you select it in the dialog.



The EpiSight Analyzer always needs access to the location of the EDF files to read the EEG.



EpiSight Analyzer will not read new data from the folder automatically. If new EDF files are copied in the folder after import repeat this process to import also the new files.

Update patient information

The patient information can be edited anytime. Every field can be edited individually. Click on the little pencil symbol on the right side of the information. After changing the information press return or click outside the editing field.

Add comment

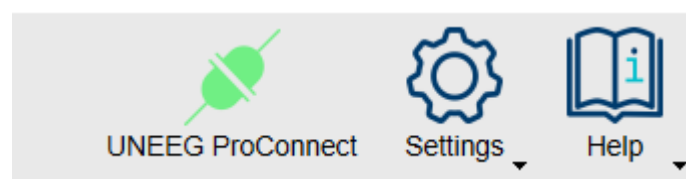
The field comment leaves space to enter additional information. This field can be pasted to the report. See the report section for details.

In the bottom part of the panel, the information about available data of the selected patient is shown. This includes:

- **Start of recording:** The date of the first recorded EEG data
- **Current end of recording:** The date of the last recorded EEG data
- **Available amount of data:** This shows the number of days and hours of recorded EEG data. This number can be much smaller than the total length of the recording as the patient might not have recorded 24hours per day.
- **New data since last review:** Information about the status of the review of the data. This field shows the time span between the date of the last approved marker and the current end of the recording.
- **Reviewed until:** This field shows the date of the last approved marker for this patient
- **Data overview:** The data overview indicates when EEG data is available for the patient. Dark grey areas show time periods with available data. Light grey areas indicates those periods where no EEG data were recorded. A colored bar shows how much of the data has already been analyzed. The latter is green when the analysis is in process and blue when the analysis is done.

Icons in the task bar

In the top right corner, the following icons can be seen:

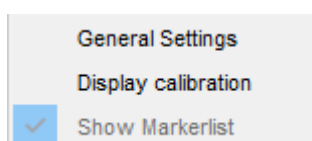


UNEEG ProConnect

This icon is green if the connection to the UNEEG™ ProConnect is active, otherwise it is greyed out. If the icon is unexpectedly grey, consult your IT.

Settings

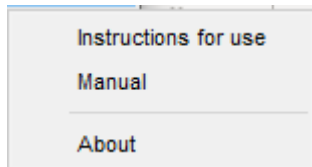
The button “Settings” opens the following menu:



For more details on the settings go to the section [Settings Menu](#).

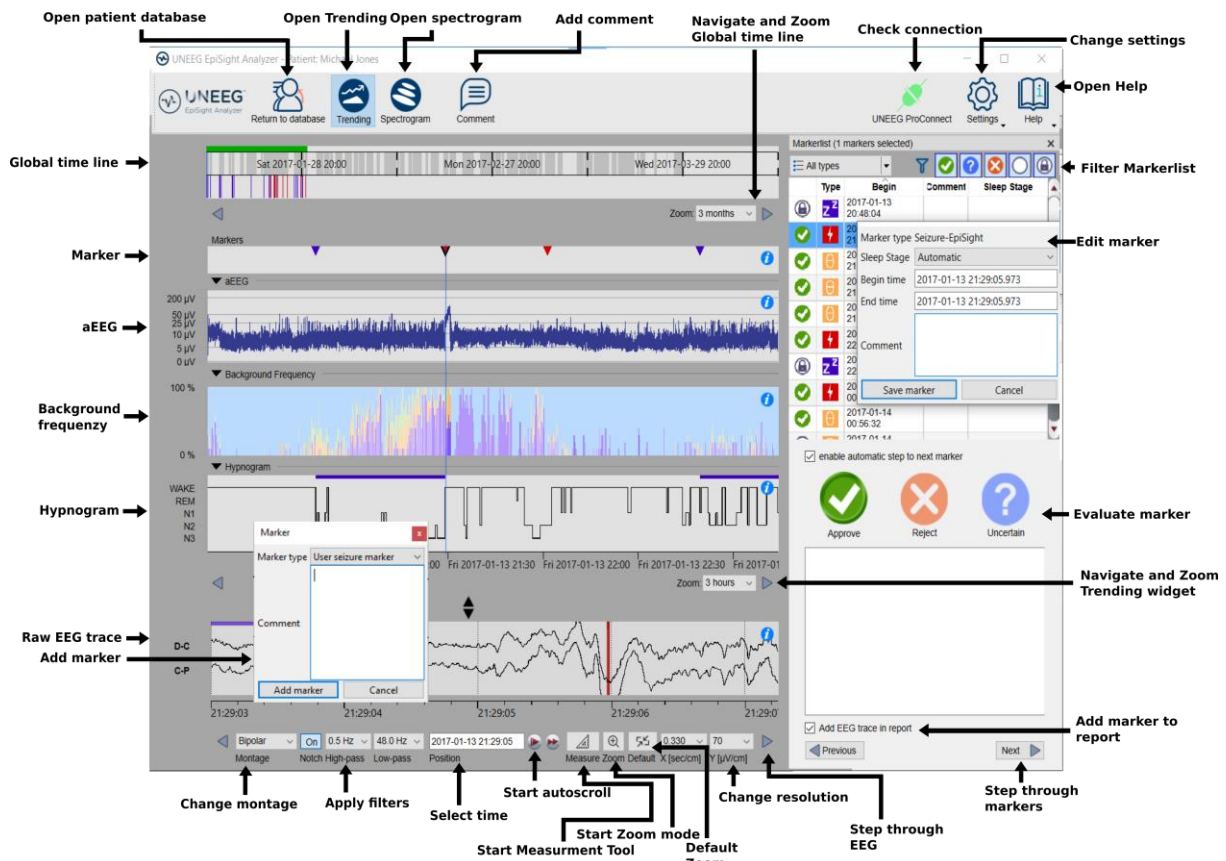
Help

The button “*Help*” opens the following menu and gives access to the documents “Instructions for use”, “User Manual” and opens the window “About”.



EEG-Viewer

Clicking on "Open patient" in the patient database will open the EEG-viewer with the trending traces and the EEG.



In the following, the functions and the traces of the EEG-viewer will be described.

Overview

UNEEG™ EpiSight Analyzer performs automated analysis on the EEG data and shows the EEG in parallel. This includes a seizure detection and classification of epochs related to patterns defined in the ACNS's Standardized Critical Care EEG Terminology. In addition, it shows amplitude-integrated EEG (aEEG), the background frequency and a spectrogram. It provides a condensed graphical representation that helps to assess important information about the state of your patient's brain. The EEG-viewer consists of a global timeline, several trending traces, spectrogram traces, the raw EEG traces and a marker list.

User- and data input

The input to UNEEG™ EpiSight Analyzer is the raw EEG signal only. No video or other data are used by the algorithm. Any settings selected in the Viewer (e.g., filter settings or

montage) are for visualization purposes only. The algorithm does not consider the visualization settings to perform calculations and thus no user input is possible nor needed.

User-defined parameters

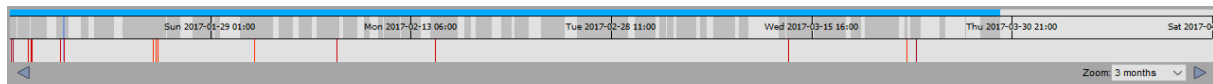
There are no parameters in the algorithm that can be changed by the user.

Outputs to the user

UNEEG™ EpiSight Analyzer makes the results available to the user in form of different types of markers as a function of time. The markers are to be interpreted as epochs in the EEG with a high probability of having certain signal characteristics. The results are presented in a graphical user interface.

Global timeline

The global timeline at the top of the display gives an overview of the complete length of the available EEG and the point in time that is currently shown in the traces below. The global timeline is shown both in the trending and in the spectrogram window.



The top line shows the **progress of the analysis**. It is green during calculation and blue when the calculations are done.

Below the progress line, dark grey areas show **when EEG is available**. Light grey areas indicate periods where no EEG data was recorded.

In the bottom line, vertical bars indicate several types of **marker found in the EEG**. These bars match the time of the entries in the marker list. All marker except pattern markers are shown. You can click on any of these bars to show the corresponding EEG in the EEG plot below (lower panel). For more information on the possible markers, go to the section [Markers](#).

Effect of status filter in the marker list

When you filter the marker list by the rating status “Approved”, “Rejected”, “Uncertain”, or “Locked” only markers with the selected status will appear in the marker line. Filtering can be done by clicking on the icons on the top right corner of the marker list. Note that filtering the marker list by marker type will not have any effect on the markers shown in this trace.

The blue vertical bar shows the **time interval** that is currently shown in the analysis traces. The width of this blue bar is set by the zoom of the analysis traces.

Zooming in the global timeline

The global timeline has several zoom levels from 1 week to 12 months. At startup, the zoom level will be set such that the global timeline always shows the complete EEG. You can change this zoom level by using the drop-down menu “Zoom” on the right corner underneath the global timeline or by using the mouse wheel when the mouse pointer is inside the global timeline.

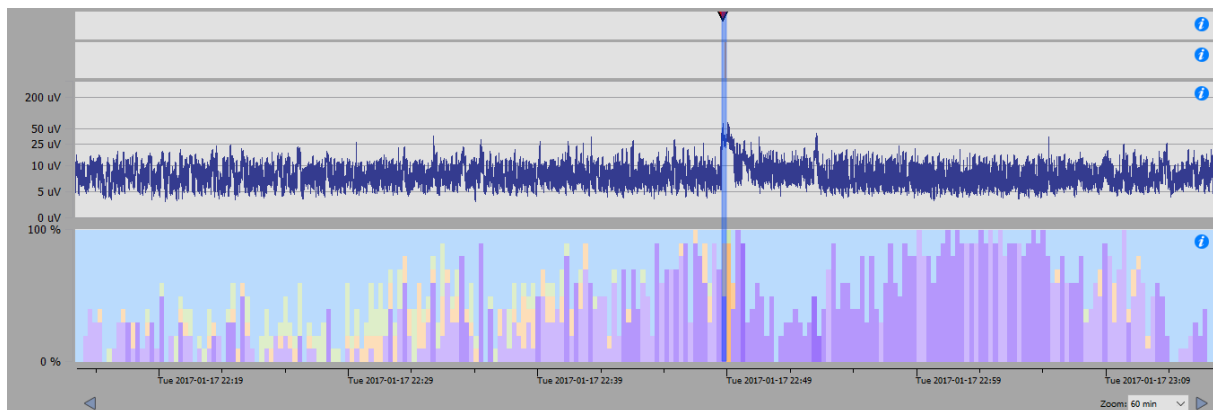
Navigation in time

To navigate in time, click on the global timeline. This will set the trending traces below to this selected time. A blue bar indicates the new selected time window. You can hold and drag the blue bar with the mouse to change its position in time.

Hold and drag your mouse at any place of the global timeline to move the global time. Alternatively, use the arrow buttons underneath the traces to move back and forward in time. The step size is defined in the settings, see section [Page movement](#).




Trending traces

The traces underneath the global timeline are trending traces that are calculated automatically. Each of the traces is described in the following sections.



Seizures and other markers

In the first trace underneath the global timeline, all seizure markers, user-defined markers and file markers are shown as little triangles. These markers can also be found in the [marker list](#). The color of the triangle gives information about the [marker type](#). In principle, the markers that are shown, are those that are automatically detected by the seizure detection.

	Detection of seizure by EpiSight
	User defined marker. In the settings menu the name and the letter can be changed and new marker types can be added.
	Seizure marker inserted by the user

By clicking on a triangle, the corresponding marker in the marker list will be selected and the raw EEG at this time will be shown in the EEG traces below.

Effect of status filter in marker list

When you filter the marker list by the rating status “Approved”, “Rejected”, “Uncertain”, or “Locked” only the markers with the selected status will appear in this marker trace. This can be done by clicking on the icons on the top right corner of the marker list. Note that filtering the marker list by marker type will not have any effect on the markers shown in this trace.

For more information on the seizure detection algorithm go to section [Seizure detection](#) in Annex 1. For more information on the markers and the possible marker types go to section [Markers](#).

Pattern markers

In the second trace underneath the global timeline, vertical bars show all markers that were generated by the rhythmic pattern detection. These markers can also be found in the [marker list](#). The color of the bars gives information about the [marker type](#). There are three different types of pattern markers:

δ	Rhythmic delta activity including sharp waves or spikes
θ	Rhythmic theta activity
α	Rhythmic alpha activity

By clicking on the marker, the marker in the marker list will be selected and the raw EEG at this time will be shown in the EEG traces below.

Effect of status filter in marker list

When you filter the marker list by the rating status “Approved”, “Rejected”, “Uncertain”, or “Locked” only the markers with the selected status will appear in this marker trace. This can be done by clicking on the icons on the top right corner of the marker list. Note that filtering the marker list by marker type will not have any effect on the markers shown in this trace.

For more information on the pattern detection algorithm go to section [Rhythmic pattern detection](#). For more information on the markers and the possible marker types, go to section [Markers](#).

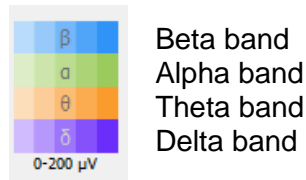
Amplitude-integrated EEG (aEEG)

In the third trace underneath the global timeline, the amplitude-integrated EEG (aEEG) is shown. The aEEG trend displays the amplitude characteristics of a filtered, rectified representation of the EEG signal as a function of time. Time is displayed on the x-axis and the aEEG amplitude measure on the y-axis. The amplitude integrated EEG is shown on a combined linear and logarithmic scale in the range 0μV - 400 μV as defined in [Zhang et al. 2013](#). When you click in the trace, the raw EEG at this point in time is shown in the EEG traces below. The aEEG trend provides a simplified depiction of amplitude characteristics of the EEG signal and is intended to be used in conjunction with other EEG trends and with the original EEG waveforms for a complete and thorough analysis of the EEG.

Background frequency

In the fourth trace underneath the global timeline, the background frequency is shown. The background frequency feature consists of a continuous measure that describes the frequency distribution of the EEG. The relative proportions of the four Berger frequency bands delta (< 4Hz), theta (4-7.5 Hz), alpha (7.5-12.5Hz), and beta (>12.5 Hz) are shown in the range between 0-100% as a function of time. The intensity of the colors corresponds to

the amplitudes in these four frequency bands. The amplitudes for each Berger band, which directly correspond to the power levels in a conventional spectrogram, are indicated by color intensities in the UNEEG™ EpiSight frequency band graph: high amplitudes are indicated by high intensities and vice versa. The color code is the following:



When you click in the trace, the raw EEG at this point in time is shown in the EEG traces below.

Hypnogram

In the fifth trace underneath the global timeline, the hypnogram is shown. The hypnogram feature is a graphic representation of a sleep stage sequence over the whole recording. The sleep stages Wake, REM, N1, N2 and N3 are mentioned in the plot.

Navigation in time

To navigate in time, you can click in any of the traces. This will set the EEG traces underneath to show this selected time. The blue bar indicates the new selected time window. Hold and drag your mouse to move the traces or use the arrow buttons underneath the traces to move back and forward in time. The step size is defined in the settings, see section [Page movement](#).

Zoom

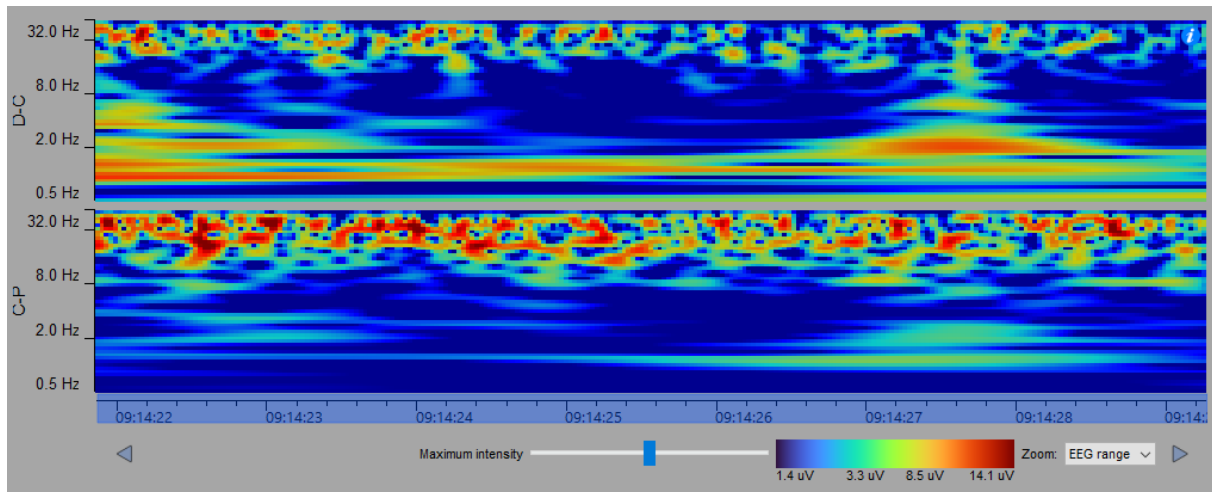
The trending traces have several zoom levels from 15 min to 7 days. At startup the zoom level is 3 hours. You can change this zoom level by using the drop-down menu “Zoom” on the right side underneath the trending traces or by using the mouse wheel when the mouse pointer is inside any of the trending traces.

Adjust height

You can adjust the height of the traces by clicking, holding and dragging the mouse on the two opposite black triangles in the area between the trending traces and the EEG traces.

Spectrogram traces

The spectrogram is shown when you click on the icon “*Spectrogram*” in the tool bar on the top left. The trending traces are then replaced by the spectrogram traces.



The spectrogram describes the distribution of power over the frequency components of the EEG data. The power spectral density is calculated for each channel using Gabor wavelets. The x-axis represents time and the logarithmic y-axis represents the frequency. The value of the power spectral density is shown as a heat map. Cooler colors, as blue and green, show lower power and warmer colors, as yellow, orange and red, show higher power. For each channel of the montage a trace is shown.

By moving the mouse cursor in the traces, you can read the exact time and frequency the mouse is pointing at.

Set maximum intensity

The legend below the spectrogram shows the detailed color map in μV for amplitudes of sinusoidal signals. This mapping can be interactively shifted to achieve optimal contrast for given data. Click, hold and drag the slider “*Maximum intensity*” to the left or to the right.

Navigation in time

To navigate, you click on any of the traces. This will set the EEG traces underneath to show this selected time. The blue bar overlaying the x-axis indicates the new selected time window. Hold and drag your mouse to move the traces or use the arrow buttons underneath the traces to move back and forward in time. The step size is defined in the settings, see section [Page movement](#).

Zoom

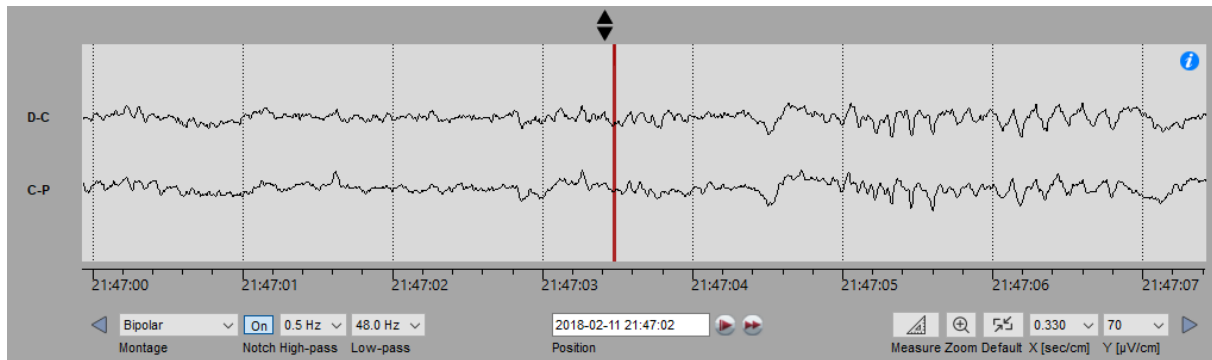
The spectrogram traces have several zoom levels from 15 sec to 10min. At startup the zoom level is 3 minutes. You can change this zoom level by using the drop-down menu “*Zoom*” on the right side underneath the spectrogram traces or by using the mouse wheel when the mouse pointer is inside any of the spectrogram traces.

Adjust the height of the spectrogram

You can adjust the height of the traces by clicking, holding and dragging the mouse on the two opposite triangles in the area between the spectrogram traces and the EEG traces.

EEG traces

In the lower part of the window, the EEG traces are shown. Several controls can be found on the top and underneath that change the visualization of the acquired EEG traces.



Adjust height

You can adjust the height of the traces by clicking, holding and dragging the mouse on the two opposite triangles in the area between the trending traces and the EEG traces.

Navigation in time

Hold and drag your **mouse** to move the traces or use the **arrow buttons** underneath the traces to move back and forward in time. The step size is defined in the settings, see section [Page movement](#). You can also use the left and right **arrows keys** of your keyboard to move back and forward in time. This will move the EEG-trace one screen size to the left or right. When using **SHIFT + arrow key** the EEG trace will move in steps of one second.

To move to a specific point in time you can click in the field "*Position*" under the EEG plot and enter the date and time you want to see the EEG.

Next to "*Position*" field there are auto scroll buttons. By clicking them the EEG plot gets shifted page wise in a time interval defined in the settings or double the speed of the interval. If auto scroll is running it can be stopped by clicking on the button again that now turn into a pause sign.

Montage

You can choose between two possible montages: bipolar (D-C, C-P) or three channels (D-C, C-P, D-P). Because only three electrodes are available, we did not add a possibility to define new montages.

Notch filter

Click on the button "On" / "Off" above the "*Notch*" label to switch on/off the notch filter at 50Hz or 60Hz, depending on your country.

High-pass filter

Click on the drop-down list "*High-pass*" and select the frequency you want for the high-pass filter.

Low-pass filter

Click on the drop-down list "*Low-pass*" and select the frequency you want for the low-pass filter.

Time resolution

Click on the drop-down list "X [sec/cm]" at the right bottom of the viewer and select the new time resolution.

Voltage resolution

Click on the drop-down list "Y [µV/cm]" at the bottom of the viewer and select the new voltage resolution.

Default Zoom

Click on the button and the time and voltage resolution are reset to the predefined default values.

Zooming

Click to activate the zoom mode and change voltage and time resolution of EEG by clicking or using the mouse wheel at a particular position in the EEG. Zoom mode can be canceled by clicking on the button again or pressing the Esc key. If the zoom mode is on, auto scrolling gets disabled.

Measurement Tool

Click to activate measurement mode. In this mode, stats like amplitude and frequency are shown for a selected-rectangle region. Measurement mode can be canceled by clicking on the button again or pressing the Esc key. If the measurement mode is on, auto scrolling is disabled.

Using markers in EpiSight Analyzer

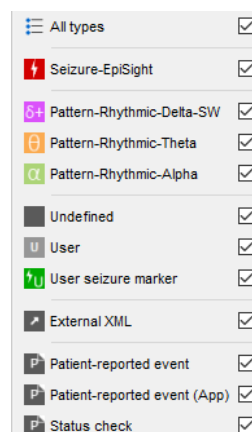
Special EEG events can be marked in the EEG using markers. A marker includes the following information:

- Type (see the different marker types)
- Begin time
- Comment

Markers are saved with the data and can be viewed in the marker list anytime. To distinguish different types of markers, each marker type has its own color and letter that appears as an icon in the marker list. In the EEG traces, markers appear as colored vertical lines. The color of the traces can be defined by the user.

Marker types

All available marker types can be seen by opening the drop-down list “All types”.



Pattern markers

Pattern markers are generated automatically. They can be reviewed, and their status can be changed as described in section [Marker status](#). They cannot be deleted. Their color can be changed in the settings. For more details go to section [Marker types](#).

Sleep markers

Sleep markers are generated automatically. They can be reviewed and edited, and their status is locked as described in section [Marker status](#). Their color can be changed in the settings. For more details go to section [Marker types](#).

Seizure markers

Seizure markers of the type “Seizure-EpiSight” are also generated automatically. They can be reviewed, and their status can be changed as described in section [Marker status](#). They cannot be deleted. Their color can be changed in the settings. For more details go to section [Marker types](#).

User seizure marker

User seizure markers are markers that can be defined by the user. You can add these markers directly in the EEG traces. It is recommended to use this marker if you find additional seizures in the EEG that were not detected by the automatic analysis. The status of a user seizure marker is always locked since they cannot be rated. They can be deleted anytime. Their color can be changed in the settings. For more details go to section [Marker types](#).



User seizure marker is the only user-defined marker type that will be included in the statistical information and the plots in the report section. The number of markers of type “User seizure marker” and approved markers of type “Seizure-EpiSight” will be shown as number of electrographic seizures in the report.

User markers

User markers are markers that can be defined by the user. You can define as many different types of user marker as you need. Section [Marker types](#) describes how to define your own seizure marker type. The status of these user markers is locked as they cannot be rated. They can be deleted anytime.

External marker types

External marker types are markers that are imported from the EEG files. Their type name cannot be changed. The color and the letter can be customized. Their status is locked and they cannot be deleted.

Marker status

The marker status can be used to rate the relevance of a system generated marker. The status can be defined for all automatically generated markers of the type Seizure and Pattern. The default status is empty and can be changed by the user during review.

Markers can have five different types of status:



Empty: This is the default status for Seizure and Pattern markers.



Approve: This status should be selected when the user agrees with the marker.



Reject: This status should be selected when the user disagrees with the marker.



Uncertain: This status should be selected when the user is not sure about the correctness of the marker.



Locked: This status is set by default for all markers other than Seizure and Pattern and cannot be changed.



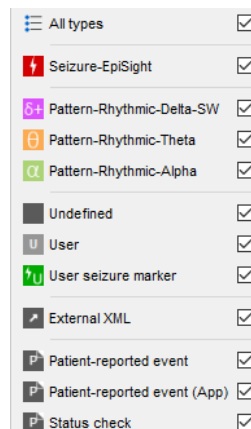
Only marker rated “Approved” will be considered in the report of EpiSight Analyzer. Only these markers will be included in the statistics and the different plots.

Marker list

The marker list is visible at the right side of the screen. It shows all available markers: This can be markers that are already contained in the EEG file, added by the automated analysis or added manually by the user. If you do not see a marker list, go to “*Settings > Show Markerlist*” to show the marker list.

Filter by marker type

All markers have a defined type. These marker types are described in the section [Marker types](#). You can filter the maker list by the type of marker. Select all marker types you want to see in the drop-down list “*All types*”.



Filter by marker status

You can filter the marker list by the status of the markers. Click on the icon of the status you want to show or hide in the marker list.



This filter will also apply on the markers shown in the marker traces of the trending view on the left.

Navigate through the list

Select the marker with the mouse or use the keyboard arrows for going up and down the list.

Sort the list

Click on the title of the column you want to sort by.

Change the fields of a marker

You can edit a marker by double-clicking in the row or right-clicking and selecting “*Edit*” in the context menu of the marker list. Alternatively, you can also edit a marker with a right-click directly on the marker line in the EEG traces and selecting “*Edit marker*” in the context menu.

Delete user markers

You can delete a marker or a selection of markers by right-clicking on a marker and selecting “*Delete selected*” in the context menu. You can select several markers at once by selecting the markers while holding the Ctrl-key. They will then appear selected (colored in blue). Seizure and pattern markers cannot be deleted. They can only be set to state “Rejected”.



Markers will be permanently deleted. There is no possibility to undo this action.

Review markers

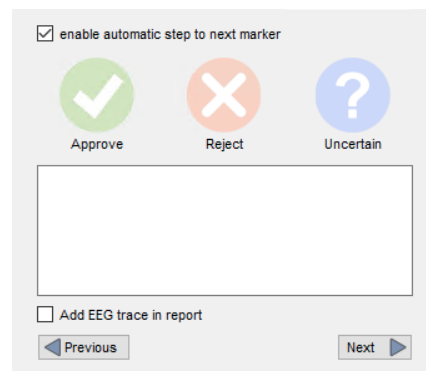
During review, the user has the possibility to rate all automatically generated markers of the type Seizure and Pattern by assigning a status to each item. The different types of status are described in the section [Marker status](#).



Only marker rated “Approved” will be considered in the report of EpiSight Analyzer. Only these markers will be included in the statistics and the different plots.

Rate markers

Markers can be rated by clicking on the icons *Approve*, *Reject* or *Uncertain* that appear on the right bottom corner of the marker list as seen in the picture below. The status can be changed anytime.



Step to the next marker

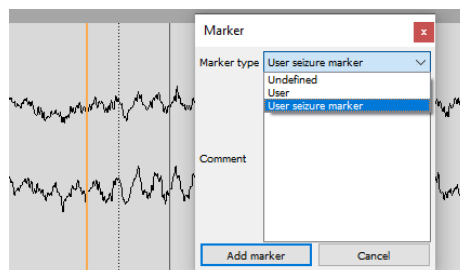
If you check the box “*Enable automatic movement to next marker*”, the next marker in the list will be automatically selected once you clicked on any of the status icons *Approve*, *Reject* or *Uncertain*. If the box is unchecked, you can get to the next marker by selecting it in the marker list or by pressing the buttons “*Next*” or “*Previous*”.

Add seizure example to report

By checking the box “*Add EEG trace in report*”, an image of the EEG around the selected marker is generated and added to the report. The EEG will be shown 10 seconds before and 50 seconds after the marker. For more details, go to the section [Report](#).

Adding a new marker to the EEG

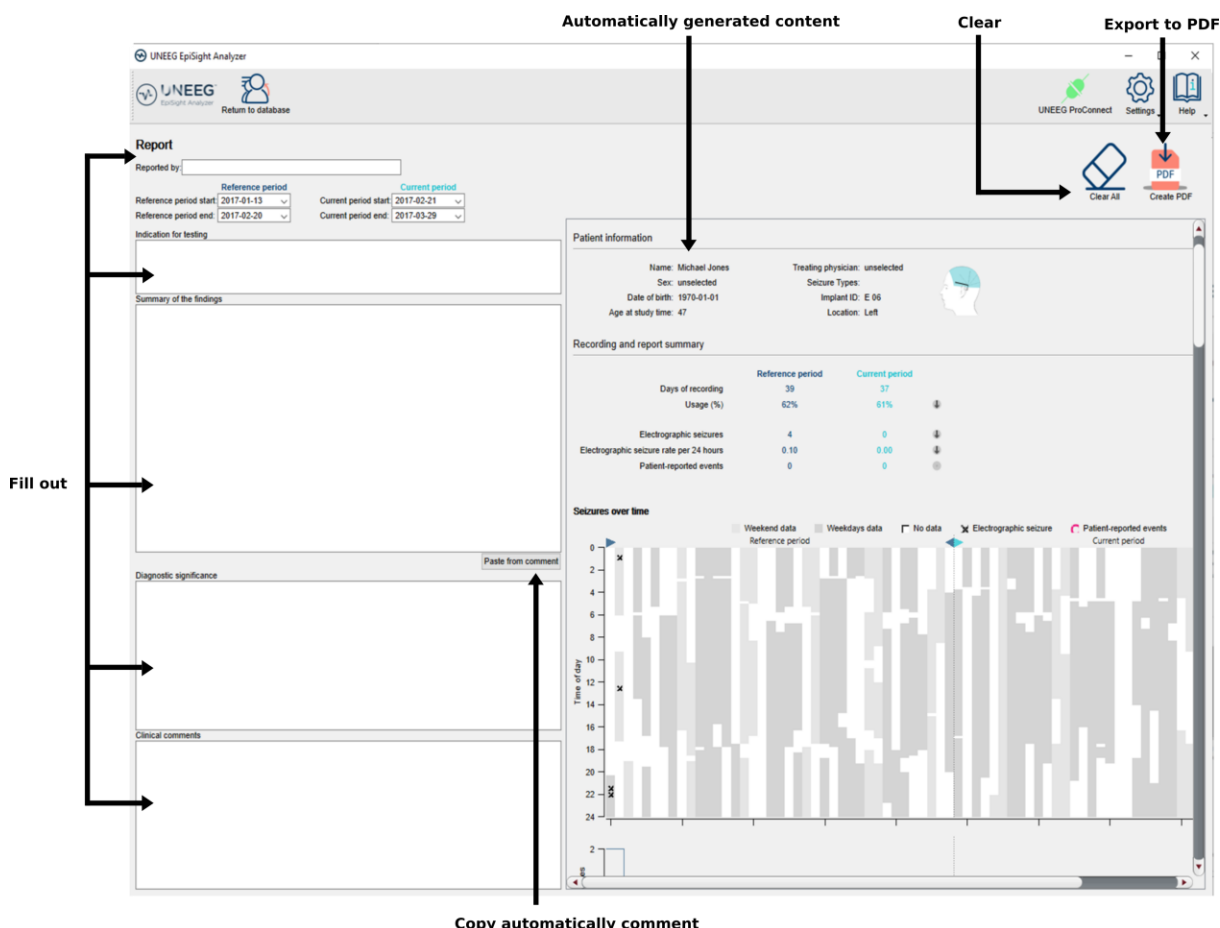
A double-click in the EEG traces will open a marker window as seen below.



Select the marker type you want to insert and optionally write a comment. “*Add marker*” will insert the marker into the system. You can also add a marker by right-clicking on the EEG traces and selecting “*Add marker*”.

Report

Clicking on “**Report**” in the data information window will open the report window of UNEEG™ EpiSight Analyzer. All data entered in the report will be saved automatically when you go back to the patient database



User input to the report

On the left side of the window, you can enter clinical information that you would like to include in the report.

Report by

Enter the author(s) of the report

Reference period and current period

The reference period and the current period are used to generate the information shown on the right side of the window. The current period is the period you are reporting. All seizures in this period will be shown in the plots on the right side of the window. The current period is always shown in light blue.

The reference period is a previous time period that you want to compare the current values against. It is used to calculate the statistical information. The reference period is shown in [dark blue](#).

Indication

The indication can be entered in the corresponding field.

Summary of the findings

The summary of the findings can be entered in the corresponding field. By clicking on the button “*Copy from EpiSight comment*”, all comments previously entered in the patient information screen will be automatically pasted to the summary of findings field.

Diagnostic significance

The diagnostic significance can be entered in the corresponding field.

Clinical comments

The clinical comments can be entered in the corresponding field.

Automatically generated content

The right side of the window shows the content that is generated automatically based on the reference period and current period entered on the left side.

Patient information

The patient information added to the report is the following:

- Date of birth
- Age at study time
- Sex
- Treating physician
- Seizure types
- Implant ID and Location

Statistical information

The statistical information shows the calculated values for the [current](#) period in [light blue](#) and in [dark blue](#) for the [reference](#) period. An arrow shows if the values have increased or decreased compared to the reference period. The values include:

- Hours recorded
- Usage total
- Usage day from 7:00 until 22:00
- Usage night from 22:00 until 7:00
- Number of electrographic seizures
- Electrographic seizure rate per 24 hours
- Electrographic seizure rate per day recorded per 24 hours of recording
- Patient-reported events

Seizure periods

This diagram shows the recorded EEG data and the seizures that occurred in this time period. The x-axis represents days, the y-axis time of day. The left side of the diagram shows the reference period indicated by the two dark blue triangles facing each other. The right side shows the current period indicated by two light blue triangles. The time intervals, where EEG was recorded are plotted in grey for weekdays and yellow for weekends. White indicates time

periods when no data is available. Dark blue crosses show electrographic seizures detected during the reference period. Light blue crosses indicate seizures during the current period. Pink circles depict patient-reported events, i.e. button double pressed events.

Seizure periodicity

The seizure periodicity plot gives an overview of the use of the device and the distribution of electrographic seizures over the day and week. The total number of seizures detected in the reference and current periods are shown above.

The left seizure periodicity plot “*Daily*” shows the average distribution over the day. The dark blue and light blue lines represent the average usage of the device over the day for the reference and the current period, respectively. Time periods when electrographic seizures occurred during the reference and current periods are shown as grey and blue areas, respectively. The radius of the area shows the percentage of the seizures that occurrence in each time period.

The right seizure periodicity plot “*Weekly*” shows the average distribution over a week. The dark blue and light blue lines represent the average usage of the device per day of the week for the reference and the current period, respectively. Time periods when electrographic seizures occurred during the reference and current period area shown as grey and blue areas, respectively. The radius of the area shows the percentage of the seizures that occurrence in each time period.



Only markers rated as approved are counted.



Only markers of type “Seizure-EpiSight” and “User seizure marker” are included in this plot.



Only seizures occurring during the current period are shown.

Seizure rate over time

This diagram shows a histogram giving the number of seizures per day for the reference period in comparison the current period. Reference period and current period are indicated by the two dark blue and light blue triangles facing each other, respectively. The end of weekends are indicated as vertical dashed lines.

Exemplar electrographic seizures

This section contains images of the EEG surrounding a marker for which the “*Add EEG trace in report*” checkbox has been checked as described in the [Add to report](#) section. An image of the EEG and hypnogram data around the marker is generated and added to the report. The EEG will be shown 10 seconds before and 50 seconds after the marker.



Only markers rated as approved and added to the report will be shown.

Clear all

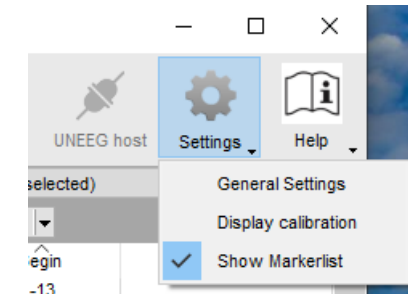
Clicking on the button “*Clear all*” will delete all fields and return the values of the reference and current periods to the default values. For the default settings, the entire time range for which EEG data are available is selected. For the reference period the first half of this period is selected. The current period will cover the second half of the available EEG data.

Create pdf

Clicking on the button “*Create pdf*” will start the export of the report to a pdf file. In a dialog the filename and the path to the file can be chosen.

Settings Menu

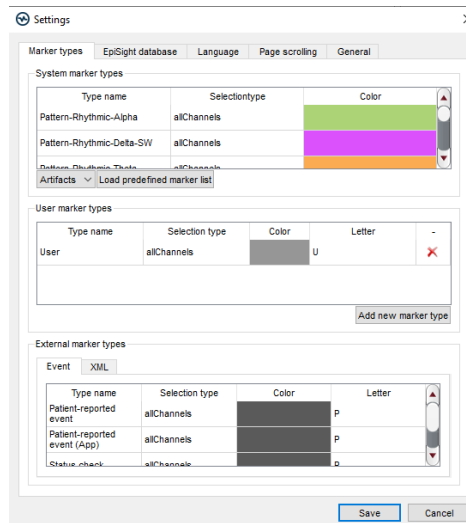
Several settings can be selected in the UNEEG™ EpiSight Analyzer. You open the settings menu by clicking on the settings button in the upper right corner.



General settings

Selecting “**General settings**” leads you to a window with four tabs. The settings apply to all patients and data equally. Please note that changes in the settings will only be applied after restarting EpiSight Analyzer.

Marker types



In this tab, you can see which marker types are available and how to manage them.

System marker types

System marker types are the default marker types. They include:

- [Pattern marker](#)
- [Seizure marker](#)
- [User seizure marker](#)

You can define the color of each marker type by double clicking on the field "Color". The color will be used for the icon in the marker list, in the timelines of the trending area and in

the EEG trace. You cannot rename these marker types or change the letter that appear in the marker list icon.

Additionally there are predefined sets of markers i.e. Artifacts or Sleep, that can be loaded as new System marker types.

User marker types

User marker types are all marker types defined by the user. You can add new marker types by pressing the button "Add new marker type" and define the name, the color and the letter that will appear in the marker list icon. The color will be used for the icon in the marker list, in the timelines of the trending area and in the EEG trace.

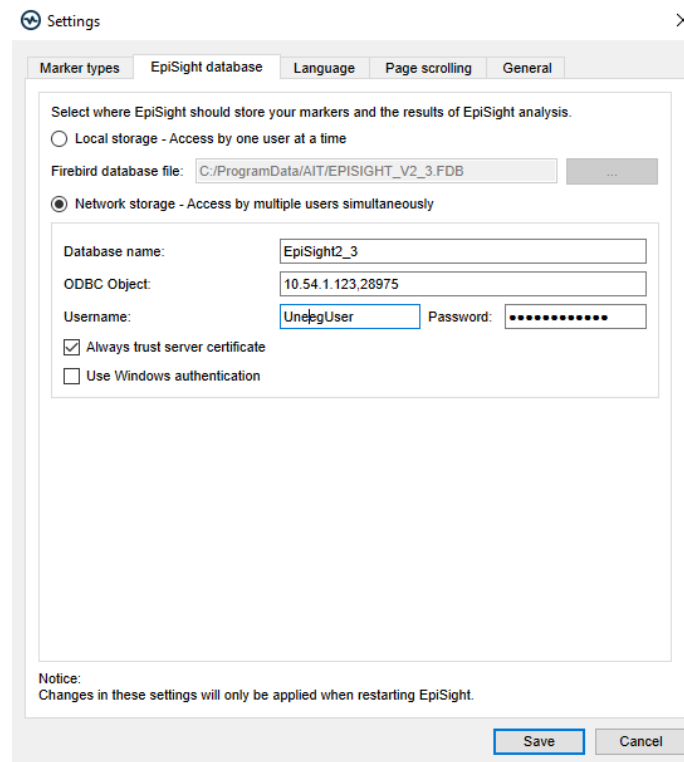
External marker types

External marker types are marker types are included in the EDF files and defined by UNEEG medical products. You cannot add new markers here, but you can change the color and the letter that will appear in the marker list icon. The color will be used for the icon in the marker list, in the timelines of the trending area and in the EEG trace.

EpiSight Analyzer can also read markers defined in an xml file (UNEEDEvents_IMPLANTID.xml) besides the EDF file with the following format:

```
<?xml version="1.0" encoding="utf-8" standalone="yes"?>
<UNEED_Events>
  <Event beginTime="2017-01-01 00:00:01" endTime="2017-01-01 00:00:03"
comment="First comment"> </Event>
  <Event beginTime="2017-01-01 00:01:04" endTime="2017-01-01 00:01:04"
comment="Second comment"> </Event>
</UNEED_Events>
```

EpiSight database



UNEEG™ EpiSight Analyzer stores markers and results of the Analyzer's calculation in a database. You can store this database at several locations:

Local storage - Accessible by one user at a time

This is the best mode, when the results of your review with the UNEEG™ EpiSight Analyzer should only be accessed from your local PC. Only one user at a time can then access the results. You can leave the file name at the default value or select a personalized name.

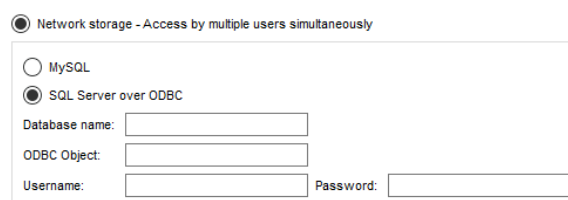
Network storage - Accessible by multiple users simultaneously

This is the best mode, when you want to access the results of your review with UNEEG™ EpiSight Analyzer from several PCs in your network. With this option several users can access the results at the same time. If you want to use this option, you will need a dedicated database server. The database systems supported are MySQL and MS SQL server. Please contact your IT administrator to set up such a database system.



Please make sure that your IT administrator properly secures the database system and always uses SSL certification for all database connections.

To use this network option, you need to specify a database that everybody can access. Your IT administrator will provide you with the necessary information shown in the screenshot below.

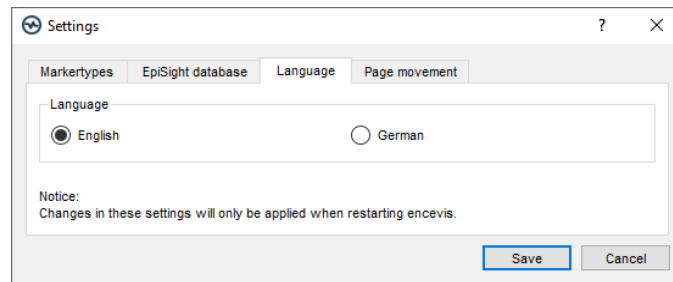


Please note that changes in these settings will only be applied after restarting the software.

If the database you entered has an old database schema or is from an older Firebird database version the DatabaseTool will open. For more information look into the chapter DatabaseTool.

Language

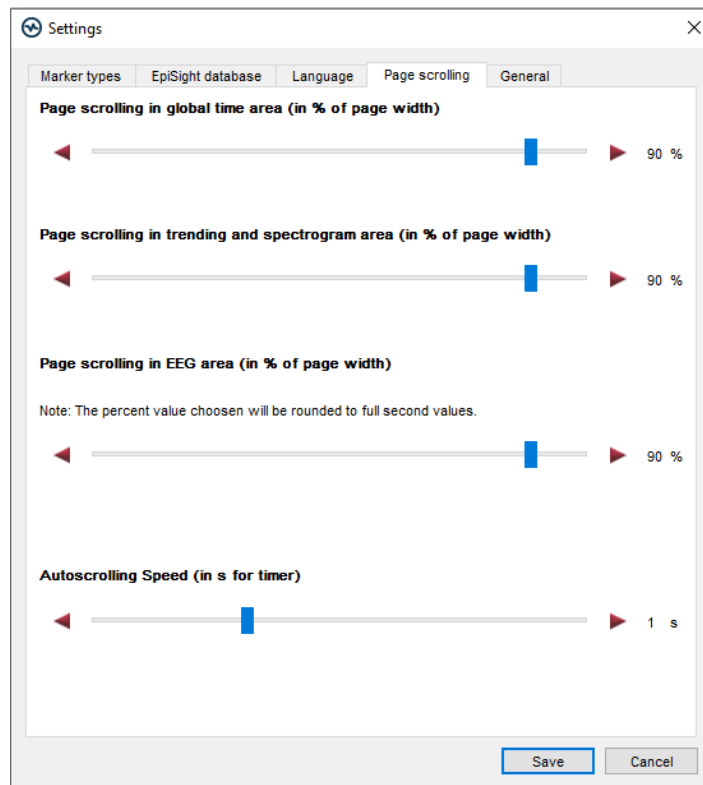
You can select the languages English or German.



Please note that changes in these settings will only be applied after restarting UNEEG™ EpiSight Analyzer.

Page scrolling

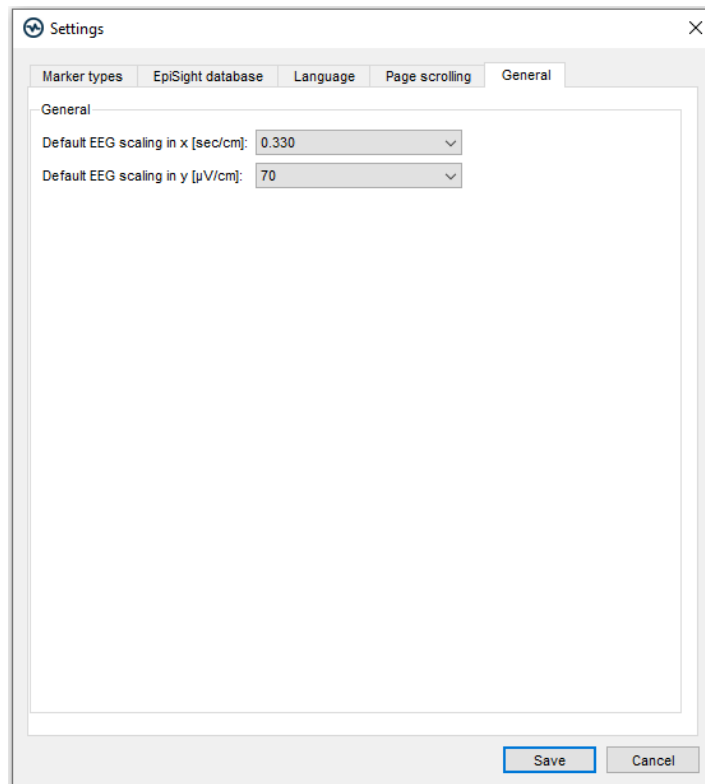
In this tab, you can adjust the scroll steps of the different traces in the EEG-viewer.



Use the sliders to select values between 1% and 100%. The selected percentage of the current window length will then be used as the page feed when moving from one page to the next. Use the slider in the bottom to define the interval speed for autoscrolling.

General Settings

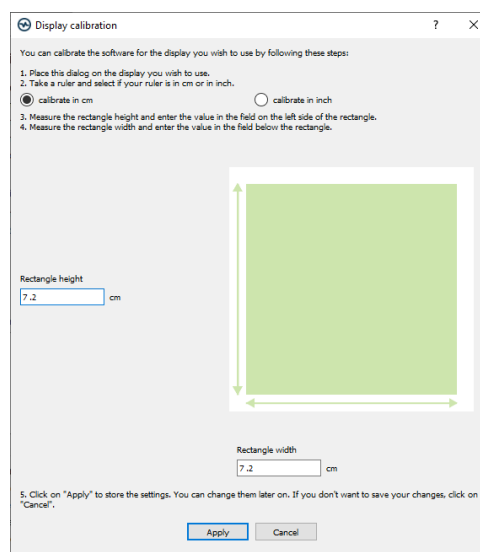
In this tab you can define your default Zoom values.



Use the drop down menus to define the default EEG zoom in time and voltage resolution.

Display calibration

This setting adjusts the visualization to the display that you are using. Selecting “**Display calibration**” opens the following window:



Follow the instructions in the window. Measure the rectangle height and width and enter the values in the corresponding text boxes. Then click on “**Apply**”.

Show marker list

Check the box on the left on of “**Show marker list**” in order to switch on and off the marker list in the trending.

DatabaseTool

Overview

The UNEEG EpiSight Analyzer DatabaseTool, is a small GUI tool which provides an easy way to trigger the transfer of database entries produced by UNEEG EpiSight Analyzer into another database.

The DatabaseTool is also able to configure different databases for the transfer.

The following databases are supported:

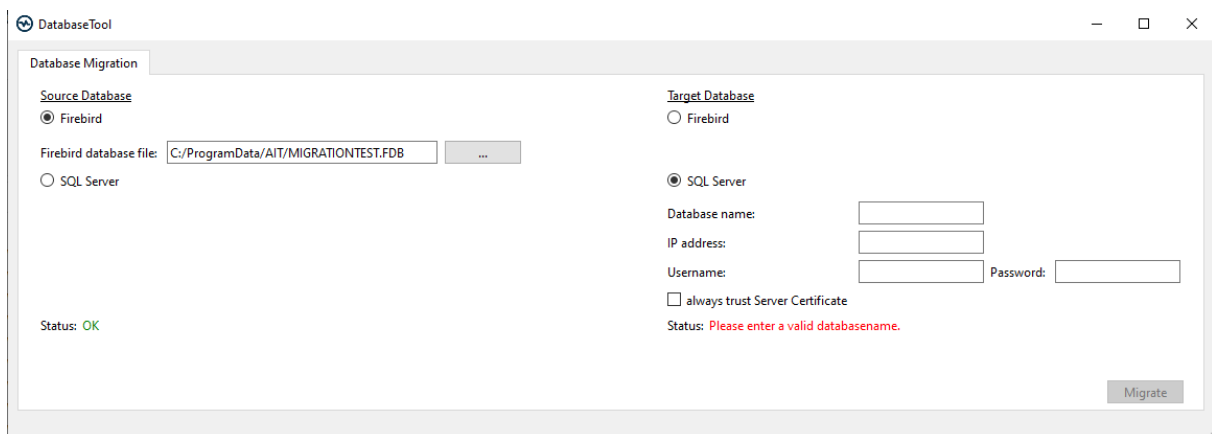
- Firebird Embedded
- MS SQL Server

In chapter „Using the DatabaseTool“ the GUI will be explained very detailed and the different modes the GUI can have are described.

Using the DatabaseTool

The GUI

In general the GUI is split in the area to fill in the source database and to fill in the target database. The User can choose whether the database type is a Firebird or a MS SQL Server database and looks like this:



In case a Firebird database is selected the user can click on the button next to the text field and can browse the database in the file system or insert the path to the .FDB file. When SQL Server is selected the fields Databasename, IP address, Username, Password and trust Server certificate checkbox are shown. In the field IP address it is possible to fill in an ODBC object, an IP Address followed by the Port (e.g. 12.345.678.901,23456) or the computer name also followed by the instance name (e.g. ComputerName\InstanceName). The GUI automatically checks if the inserted databases are valid. The status is shown on the bottom and it indicates the current error or gives an OK.

The fields to enter a source and a target database are the same. It is also possible to transfer the data between different database types. The migration button gets enabled when both, source and target database, are valid.

During the migration the progress is shown in a sperate window. If an error occurs during the migration or the migration was successfully done the user is informed.

Special Mode: Fixed Source Database Mode

When the user of UNEEG EpiSight Analyzer tries to open a database of an older database schema, a message box opens and asks if the database should be migrated to the new schema. If the User want to migrate the database in this case the tool opens but it is not possible to modify the source database. Just a new target has to be inserted and the migration can be triggered. If the migration was successful in this case the tool closes after the migration.

Special Mode: Updating Firebird version Mode

When the user of UNEEG EpiSight Analyzer tries to open a Firebird database of an older Firebird version a messages box opens and asks if the Firebird version should be updated. If the user accepts the update a progress bar will come up and shows the progress of the update. After the update the Tool closes and the database is migrated to the new Firebird version.

UNEEG™ Integration

Connecting to UNEEG™ EpiSight Analyzer – Quick Guide for healthcare professionals

Create a patient profile and set up UNEEG™ MyConnect

The following conditions apply before a patient profile can be created in UNEEG™ EpiSight or UNEEG™ EpiSight Analyzer, and UNEEG™ MyConnect can be set up:

- The patient must have been implanted with a UNEEG™ SubQ.
- UNEEG™ EpiSight (version 1.11 or newer) or UNEEG™ EpiSight Analyzer must be installed on a computer with UNEEG™ ProConnect available (green icon). From now on referred to as the EEG review software.
- UNEEG™ MyConnect (tablet) is available. Consult the separate Quick Guide for setting up UNEEG™ MyConnect.
- The computer has a Wi-Fi connection.
- A recorder is charged and time-stamped using the 24/7 EEG™ SubQ Link programme.

Creating a patient profile in the EEG review software

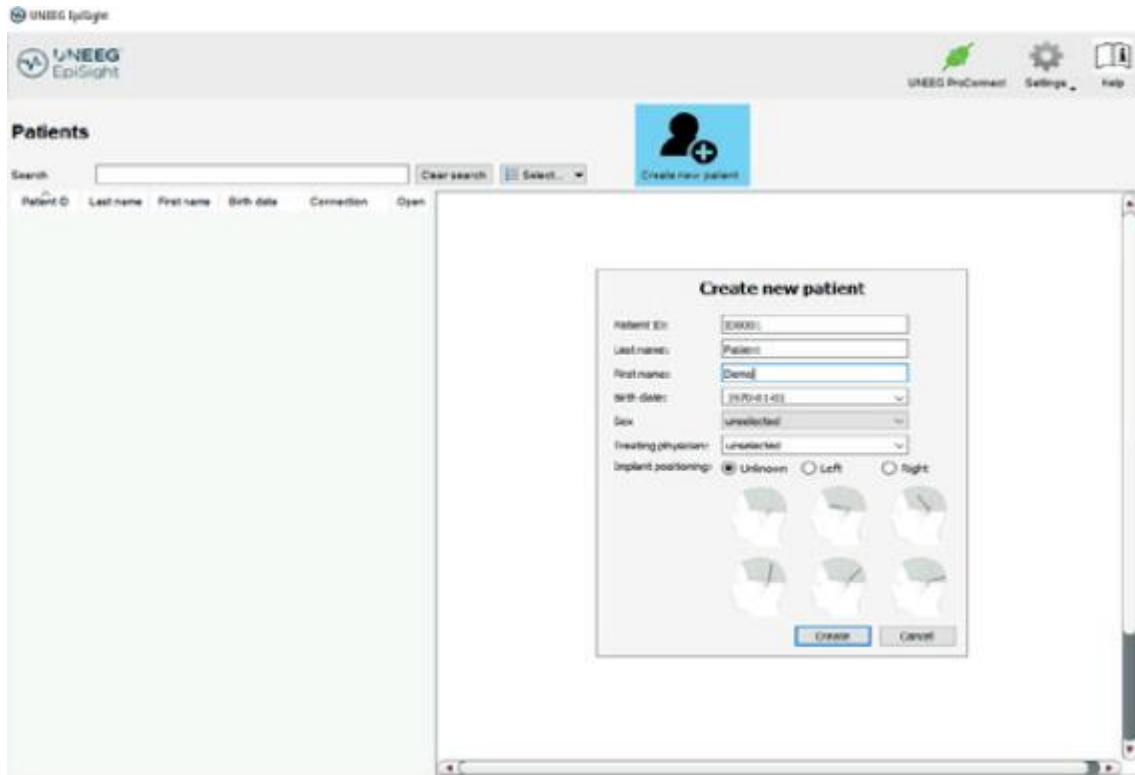
Step 1

- Open the EEG review software.
- The patient database will appear automatically.



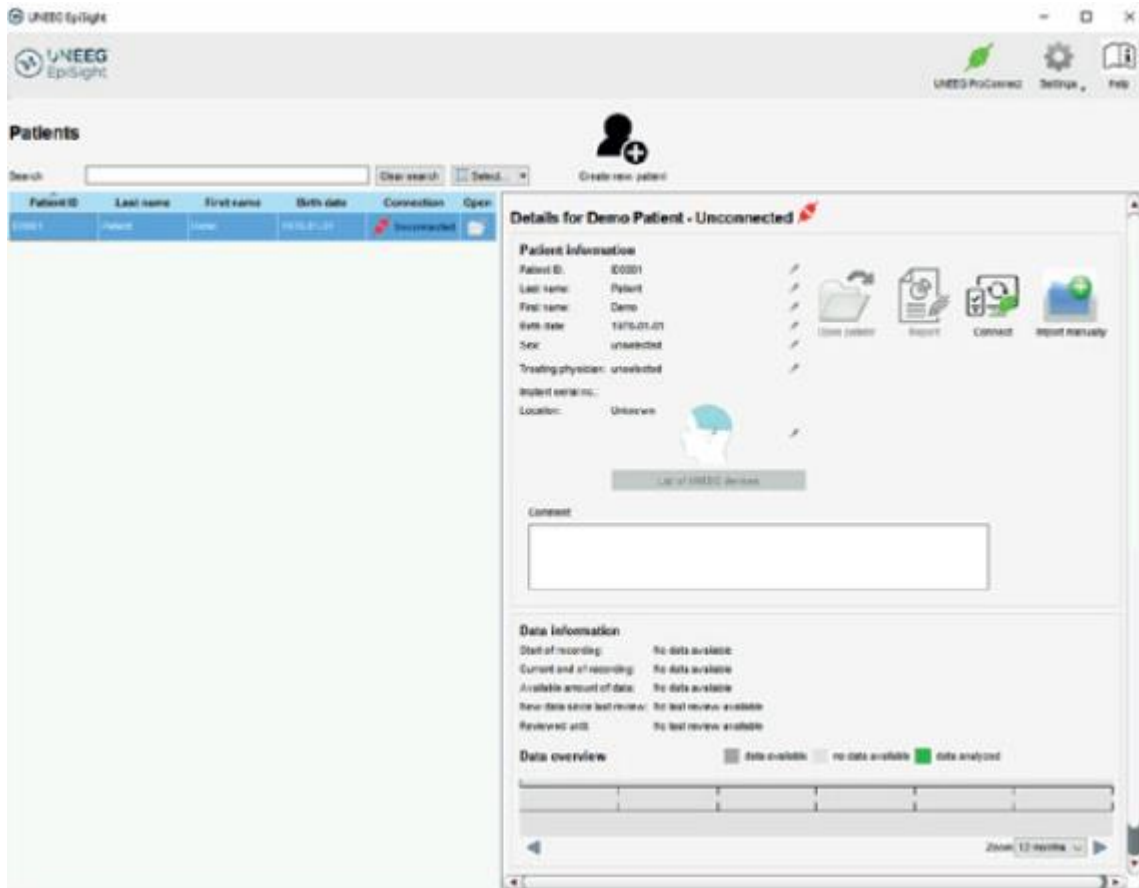
Step 2

- In the patient database, select "Create new patient". A pop-up window will appear.
- Enter the patient details in the pop-up window.
- In order to continue, it is necessary to enter a patient ID or the patient's first and last names.
- Select "Create" to create the patient profile.



Step 3

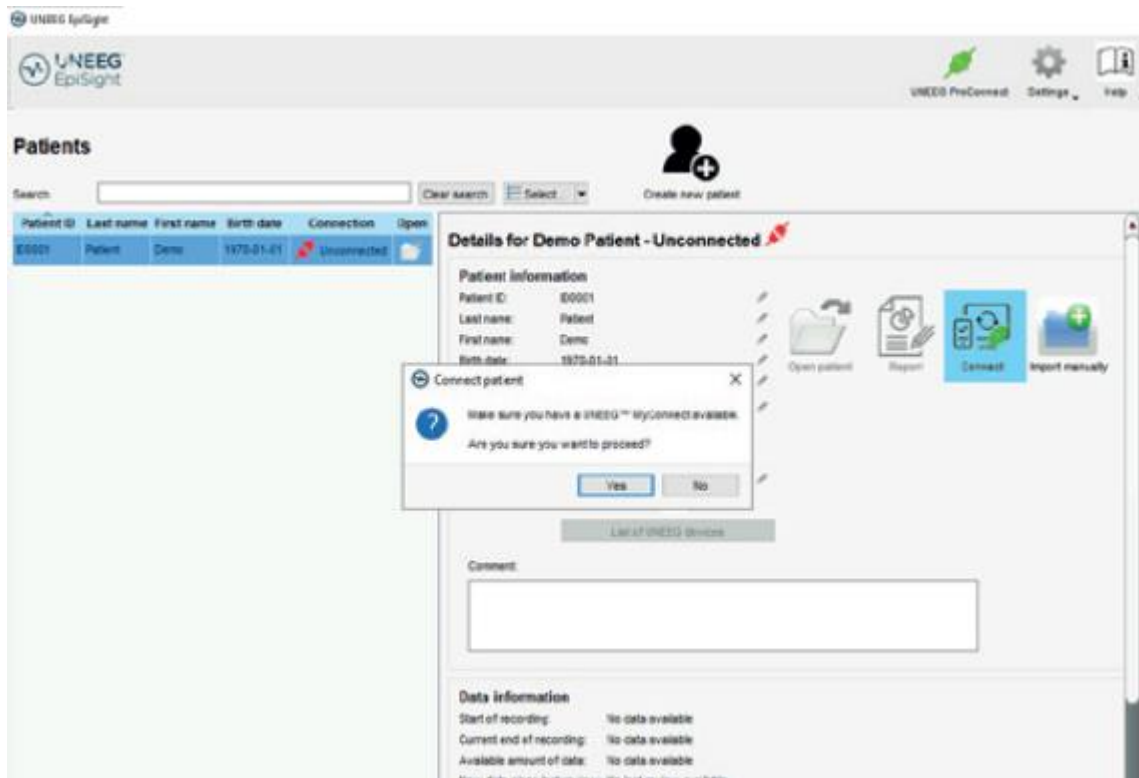
- The patient profile has now been created.
- Note that the implant serial number, data information and data overview appear empty at this stage. You are now ready to set up UNEEG™ MyConnect in the EEG review software.
- Be sure that the computer is connected to the Internet and that the UNEEG™ ProConnect icon in the upper-right corner is green.



Setting up UNEEG™ MyConnect in the EEG review software

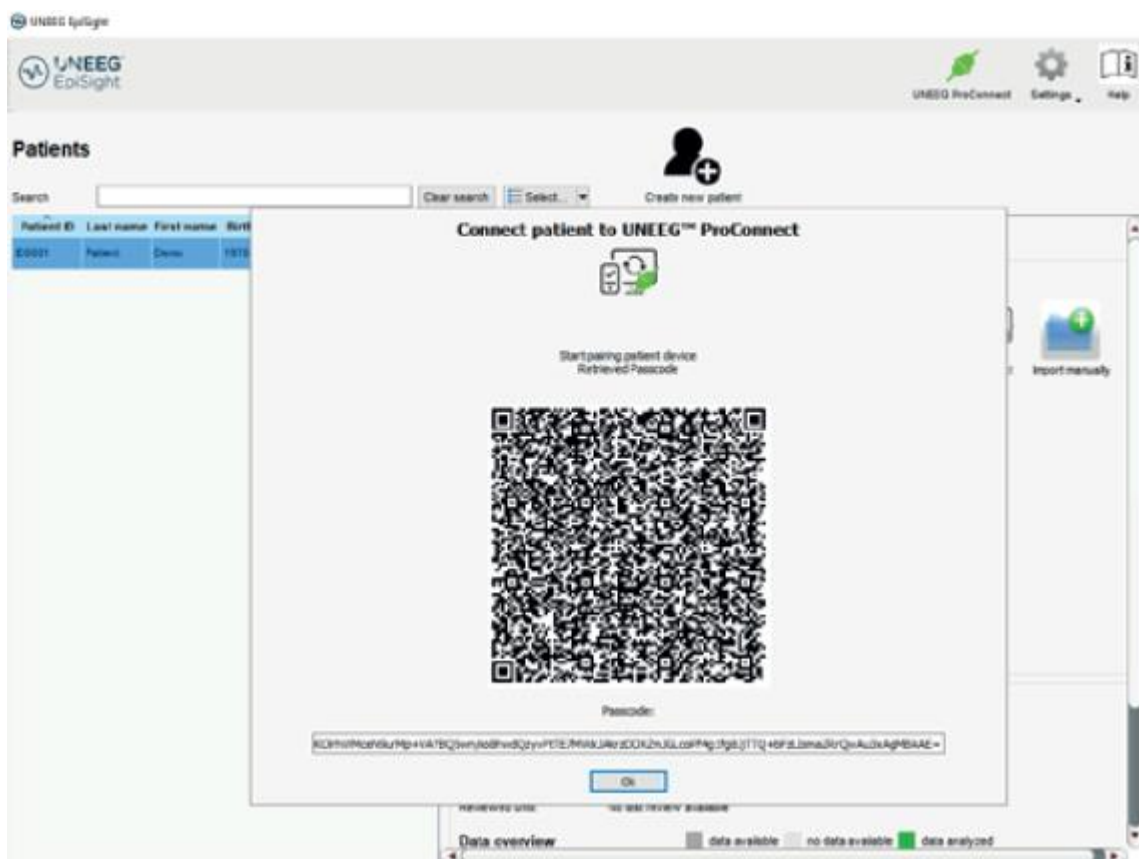
Step 1

- Select the patient profile from the patient list in the EEG review software.
- The selected patient will be highlighted in blue.
- With the patient profile highlighted, select "Connect". A pop-up window will appear.
- Select "Yes" in the pop-up window.
- A second pop-up window displaying a QR code will appear.



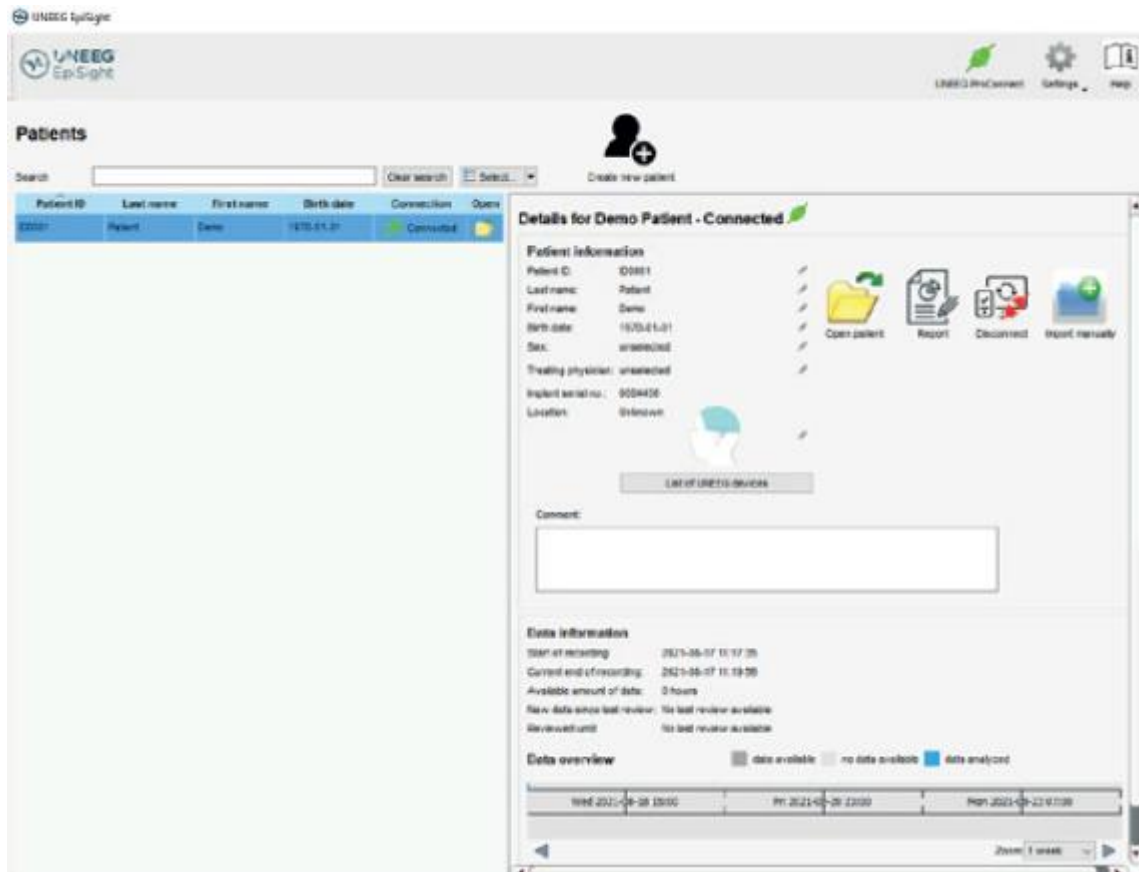
Step 2

- Scan the QR code using the UNEEG™ MyConnect camera.
- To scan the QR code, follow the instructions on the UNEEG™ MyConnect tablet.
- Once the QR code is scanned, press “OK”.






Step 3

- Once the QR code is scanned and the setup in the tablet is finished, the connection status of the patient will change to “Connected” (green icon).
- The implant serial number now displays a 7-digit number, and both the data information and data overview sections should be available.
- The EEG review software can now receive data from UNEEG™ MyConnect.



Troubleshooting

Problem	Possible cause
<p>The “Connect” button is not available.</p> 	<ol style="list-style-type: none"> 1. The computer has no Internet connection. 2. UNEEG™ ProConnect has not been configured. 
Possible solution	
<ol style="list-style-type: none"> 1. Verify your Internet connection. 2. Contact the person with IT responsibility to configure UNEEG™ ProConnect. 	

Problem	Possible cause
<p>The QR code cannot be scanned.</p>	<ol style="list-style-type: none"> 1. There is excessive backlight on the screen displaying the QR code. 2. The screen cursor is placed over the QR code.
	
Possible solution	
<ol style="list-style-type: none"> 1. Reduce the backlight and start again. 2. Move the cursor away from the QR code and try again. 	

Problem	Possible cause
<p>After finishing setup with UNEEG™ MyConnect, neither the implant serial number nor the data information are available in the EEG review software.</p>	<p>Data have not been received in the EEG review software.</p>
Possible solution	
<p>Occasionally, data can take a long time to transfer, depending on the amount of transferred data and network traffic.</p>	
<p>If data have not been received in the EEG review software during the day, contact UNEEG medical.</p>	

Further information can be found in the UNEEG™ EpiSight Analyzer user manual.

Appendix A

Description of the algorithms

UNEEG™ EpiSight Analyzer seizure detection

The UNEEG™ EpiSight Analyzer seizure detection 2.0 is based on a deep neural network model. This model was designed, trained, and deployed using the open-source machine learning platform TensorFlow (www.tensorflow.org). The model consists of a deep stack of convolutional layers and ResNet blocks extracting high level features, a feature pyramid network combining features with different levels of abstraction and scale (Tan et al., 2020), an onset position estimation network creating proposals for potential seizure onset times, and a multi-layer perceptron as a classifier distinguishing seizure EEG from inter-ictal background EEG.

To train this model a training dataset including scalp-EEG from 490 patients of the Temple University Hospital Seizure Detection Corpus (Shah et al., 2018) and sub-scalp EEGs from ten subjects without epilepsy (unpublished data; [clinicaltrials.gov NCT04513743](https://clinicaltrials.gov/NCT04513743)) were used. The scalp-EEGs, recorded at 10-20 electrode positions, were organized in 14 bipolar channel pairs, each of them mimicking “virtual recordings” from three subcutaneously implanted electrodes. For each seizure annotated in the 10-20 EEG recordings the corresponding training goal was set to achieve at least one detection in one of these 14 bipolar channel pairs.

Shah, V., von Weltin, E., Lopez, S., McHugh, J.R., Veloso, L., Golmohammadi, M., Obeid, I., Picone, J., 2018. The Temple University Hospital Seizure Detection Corpus. *Front Neuroinform* 12, 83. <https://doi.org/10.3389/fninf.2018.00083>

Tan, M., Pang, R., Le, Q.V., 2020. EfficientDet: Scalable and Efficient Object Detection. Presented at the Proceedings of the IEEE/CVF Conference on Computer Vision and Pattern Recognition, pp. 10781–10790.

UNEEG™ EpiSight Analyzer rhythmic pattern detection

UNEEG™ EpiSight Analyzer rhythmic pattern detection is based on a computational method, which automatically detects rhythmic EEG patterns in digitized EEG. Three different types of patterns are detected. Rhythmic delta activity including sharp waves and spikes (Rhythmic-Delta-SW) is defined as repeating discharges with uniform morphology without an inter-discharge interval with a frequency up to 4Hz that come with frequent intermixed sharp waves/spikes or a sharply contoured pattern. Polyspike, spike or sharp wave consistently followed by a slow wave in a regularly repeating and alternating pattern are also detected. Rhythmic theta activity (Rhythmic-Theta) is defined as repeating discharges with uniform morphology without an inter-discharge interval with frequencies between 4-7.5Hz. Rhythmic alpha activity (Rhythmic-Alpha) is defined as repeating discharges with uniform morphology without an inter-discharge interval with frequencies between 7.5-12Hz.

At the beginning, EEG segments with artifacts like i.e. excessive amplitudes or artifacts from loose electrodes are removed automatically and are not used for detection. This will avoid false alarms based on measurement problems. Frequencies below 0.4 Hertz and above 70 Hertz are then removed by a finite impulse response filter. The signal in each bipolar channel is divided into segments that represent spikes, waves, or any other discharge item with

durations between 40ms and 1.5s and amplitudes above 20μV. The wave segmentation procedure scans the EEG signal in the time domain for arbitrary peaks with more than 20μV. Each peak is then extended on both sides as long as the waveform lies above two projection lines that start at the borders of the starting peak and have 20% reduced slope value. All resulting wave segments below 40ms and above 1.5s are dropped. These single-channel segments are then combined over all channels. The resulting segments are then marked as spike, sharp wave, or non-spike segment by a spike-detection algorithm. The resulting segments are also used to build groups representing Rhythmic-Delta-SW, Rhythmic-Theta and Rhythmic-Alpha segments as described above. The next step checks if a pattern meets minimal requirements for duration and the number of discharges. Patterns that do not meet these criteria are discarded. Finally, segments of equal pattern type are concatenated to groups with a maximal duration of 30 seconds. More details of the algorithm can be found in [Fürbass et al., “Automatic multimodal detection for long-term seizure documentation in epilepsy”; Clinical Neurophysiology 128 (2017) 1466–1472, May 2017].

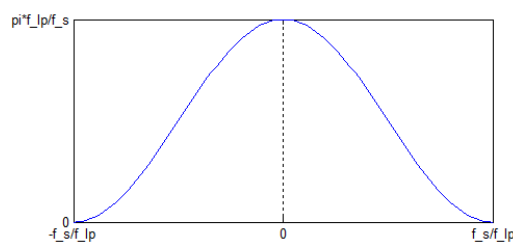
UNEEG™ EpiSight Analyzer aEEG

UNEEG™ EpiSight Analyzer aEEG calculate and visualize a continuous measure that describes the EEG by showing the aEEG as defined in [Zhang, D., Ding, H., 2013. “Calculation of compact amplitude-integrated EEG tracing and upper and lower margins using raw EEG data.” Health (N. Y.) 05, 885–891”, <http://dx.doi.org/10.4236/health.2013.55116>]. The method describes an algorithm to calculate aEEG for single EEG channels.

Channel-wise calculation of aEEG starts by applying the asymmetrical filter to the EEG channel. The frequency response is approximated using a finite impulse response filter that implements the specified 12dB per decade increasing filter response in the range of 2 to 20Hz. The filtered signal is called x_{bp} . Then, the envelope detection of the filtered time series data is implemented by applying a low pass filter h_{lp} to the signal.

$$x_{lp}(t) = (|x_{bp}(t)|) * h_{lp}$$

The filter impulse h_{lp} is a raised cosine window of length $2 f_s / f_{lp}$, where f_s is the sampling frequency, f_{lp} is the cutoff frequency of the lowpass. In our implementation $f_{lp} = 2$. The impulse response is shown in the following figure:



Impulse response of the aEEG

This implementation will result is a smoothed line which will be sub sequentially used as amplitude feature y_{AEEG} . After smoothing, non-overlapping segments of 0.5 seconds are defined, and the maximum and minimum value of each segment is calculated. Then the average value of the maximum and minimum segment values over all channels are calculated respectively resulting in values aEEG_max and aEEG_min. The amplitude-integrated EEG plot of UNEEG™ EpiSight Analyzer visualizes these average values by drawing a line between aEEG_max and aEEG_min as well as connection line between them.

UNEEG™ EpiSight Analyzer background frequency

The UNEEG™ EpiSight Analyzer background frequency feature calculates and visualizes a continuous measure that describes the EEG by showing the frequency distribution of the EEG. The relative proportions of the four Berger frequency bands delta (< 4Hz), theta (4-7.5 Hz), alpha (7.5-12.5Hz), and beta (>12.5 Hz) are shown. The intensity of the colors corresponds to the amplitudes in these four frequency bands.

For the calculation of the frequency band measures, the input signals are divided into segments of three seconds duration. Then the dominant frequency band for each segment is determined, i.e., delta, theta, alpha or beta. The relative frequency of the dominant Berger-bands is calculated within windows of 15 seconds. The amplitude for each Berger frequency band is determined as an average over all segments that have been assigned to that frequency band respectively. The amplitudes for each Berger band, which directly correspond to the power levels in a conventional spectrogram, are indicated by color intensities in the UNEEG™ EpiSight Analyzer frequency band graph: high amplitudes are indicated by high intensities and vice versa.

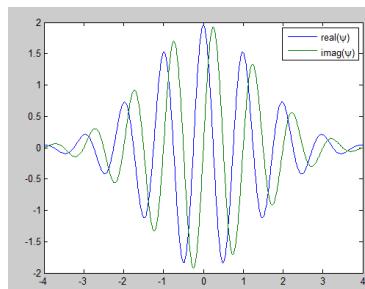
UNEEG™ EpiSight Analyzer spectrogram

The spectrogram calculates a continuous wavelet transform of the input data. This transform is implemented as a bank of FIR filters using different, scaled versions of an analytic Morlet wavelet (or Gabor wavelet)

$$y_k(t, f) = \sum_{\tau = -2\frac{\alpha_{BW}}{f_{max}}}^{2\frac{\alpha_{BW}}{f_{max}}} x_k(t)\psi_f^*(t - \tau).$$

Each of these filters corresponds to a specific frequency f in the resulting time-frequency (TF) representation. The impulse response of the filter for frequency f is defined as

$$\psi_f(t) = \frac{4f}{\alpha_{BW}} \sqrt{\frac{3}{\pi}} e^{2\pi i f t} e^{-\left(\frac{t f}{\alpha_{BW}}\right)^2}.$$



Note that the energy of this wavelet is centred around frequency f and that the scaling is such, that the convolution with a sinusoidal signal of amplitude 1 at frequency f leads to an output signal of constant amplitude 1.

The frequency points f_j used for the analysis are determined with

$$f_j = f_{\min} e^{\frac{j}{N_f-1} \log\left(\frac{f_{\max}}{f_{\min}}\right)}, j = 0, \dots, N_f - 1.$$

The convolution is executed at a sampling rate of $2f_{\max}$, therefore the input signal is initially down-sampled to this rate. After convolution a second down-sampling step with a factor of d is executed. The last step is the calculation of intensities in dB using the equation $y = 20 * \log_{10} x$ dB".

UNEEG™ EpiSight Analyzer sleep

The sleep staging component within the EpiSight Analyzer software is intended to analyze EEG recordings obtained from subcutaneously implanted electrodes of SubQ EEG devices. The primary function of the sleep staging component is the automatic identification of five distinct sleep stages: Wake, Rapid Eye Movement (REM) sleep, and three non-REM stages - N1, N2, and N3. Furthermore, EpiSight calculates the distributions of the amount of sleep stages during nocturnal sleep periods, as well as Nocturnal Sleep Period Time (NSPT), Nocturnal Sleep Time (NST), and the durations of individual sleep stages. These measures can serve for the assessment of an individual's sleep quality and sleep architecture.

EpiSight Analyzer utilizes an artificial neural network trained on extensive EEG data obtained from both scalp and implanted electrodes. This training process involves analyzing EEG data from 1560 subjects over a total recording duration of 18520 hours (about 2 years), resulting in a robust algorithm capable of accurately categorizing sleep stages within 30-second epochs.

Perslev, M., Darkner, S., Kempfner, L. et al. U-Sleep: resilient high-frequency sleep staging. *npj Digit. Med.* 4, 72 (2021). <https://doi.org/10.1038/s41746-021-00440-5>

L. Lechner *et al.*, "Fine-tuning of pre-processing filters enables scalp-EEG based training of subcutaneous EEG models," *2023 IEEE 19th International Conference on Body Sensor Networks (BSN)*, Boston, MA, USA, 2023, pp. 1-4, doi: 10.1109/BSN58485.2023.10331106.