

Quick Start Guide

UNEEG™ EpiSight Analyzer

Version number 2.0



Manufacturer:
AIT - Austrian Institute of Technology GmbH;
Giefinggasse 4; 1210 Vienna; Austria
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Use-by date:
Windows 10: 10/2025



Notified Body:
mdc medical device certification GmbH;
Kriegerstrasse 6; 70191 Stuttgart; Germany



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 and background frequency 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 or background frequency 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 UNEEDG™ EpiSight Analyzer.

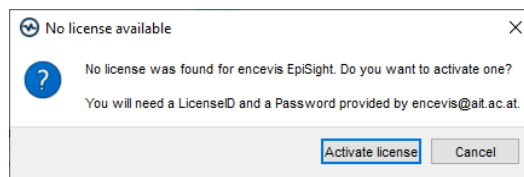
Possible adverse effects

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

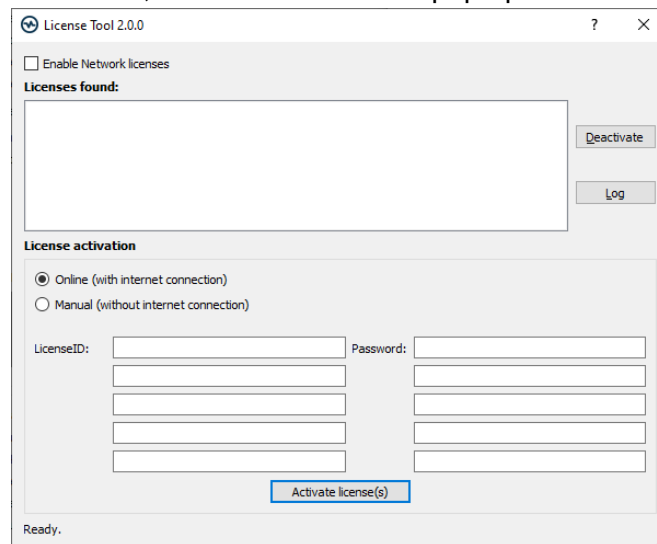
Quick Start Guide

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. Once the installation has finished, start the EpiSight Analyzer by clicking on the icon on your desktop.
5. You can add new patients to the database and import data.
6. In order to open the patient's EEG, you will need an active license.
7. Click on "Open patient", the following window will pop up:



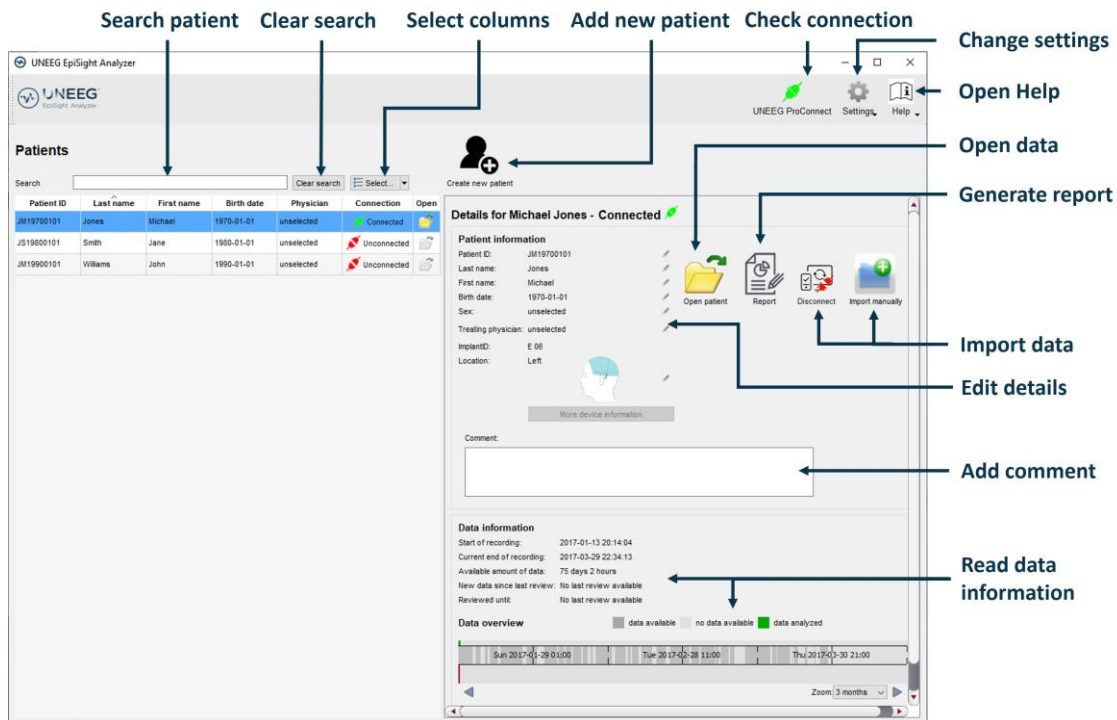
8. Press "Activate license", the License Tool will pop up.



9. 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.
10. Enter your LicenseID and Password.
11. Press "Activate license(s)".

Patient Database

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

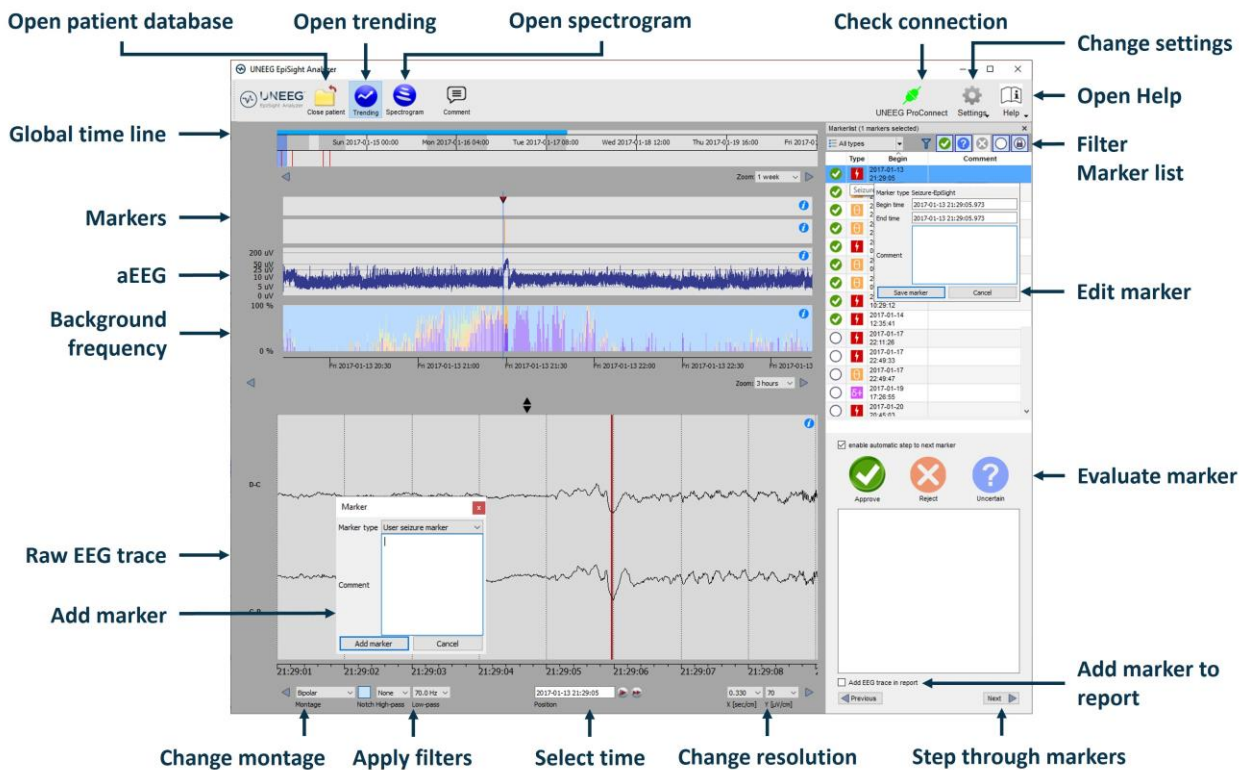


The patient database offers the following functionalities:

- 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.

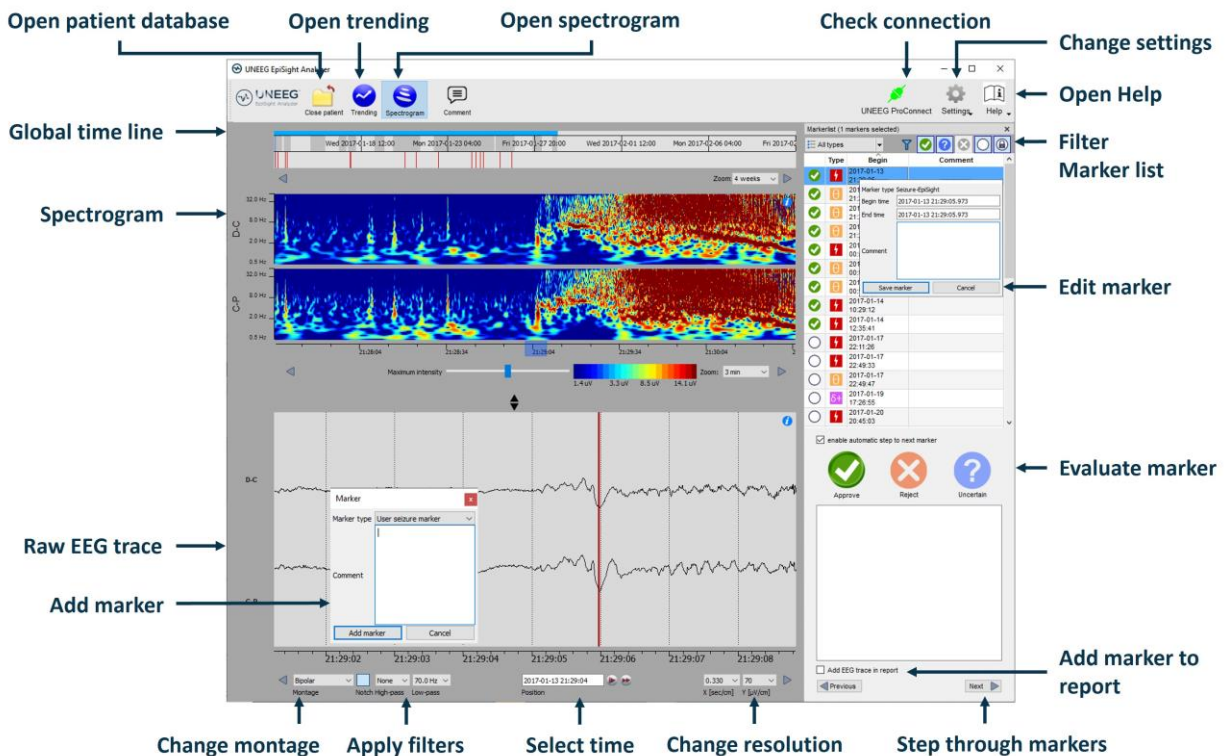


The trending includes the following functions and traces:

- 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
- 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.

Automatically generated content **Clear** **Export to pdf**

Fill out

Copy automatically comment

The report offers the following functionalities:

- Enter additional clinical information including:
 - Indication for testing
 - 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
- Copy 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
		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