

Quick Start Guide

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UNEEG EpiSight



Manufacturer:

AIT - Austrian Institute of Technology GmbH; Giefinggasse 4; 1210 Vienna; Austria

Date of manufacture: 2021



Use-by date:

Windows 10: 10/2025



Notified Body:

DQS Medizinprodukte GmbH; August-Schanz-Straße 2; 60433 Frankfurt am Main; Germany



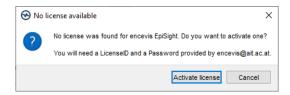
Caution: Please read paragraphs marked with this symbol carefully as they contain important safety information.

Issuing date of this document: 2021-01-18

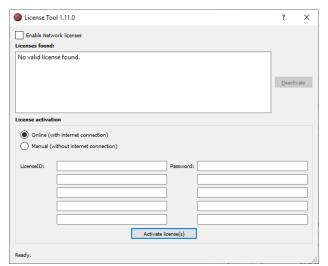


Installation and license activation

- 1. Download UNEEG EpiSight.
- 2. Start the UNEEG EpiSight Installer by double-clicking the downloaded executable.
- 3. The installer will guide you through the installation process.
- 4. Once the installation has finished, start UNEEG EpiSight 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.

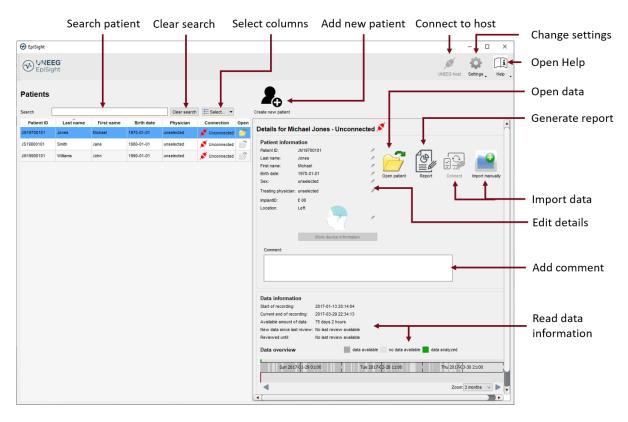


- 9. If you are connected to the internet, select "Online" as activation mode. Otherwise, select "Manual" and contact your distributor in order to get the keys for the manual activation.
- 10. Enter your LicenseID and Password.
- 11. Press "Activate license(s)".



UNEEG EpiSight Patient Database

Starting UNEEG EpiSight will open the patient database window.



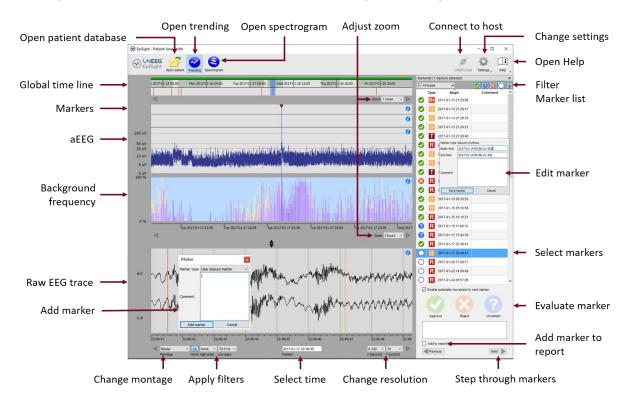
The patient database offers the following functionalities:

- 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
- Import data by connecting to the UNEEG ProConnect
- Import data manually by selecting a folder
- Connect to the UNEEG ProConnect
- Change settings
- Open help



UNEEG EpiSight Trending

Clicking on "Open patient" will open the UNEEG EpiSight Trending window.



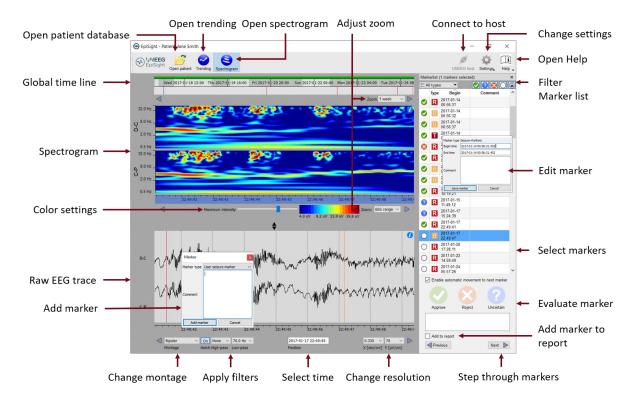
EpiSight EEG-trending includes the following functions and traces:

- 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



UNEEG EpiSight Spectrogram

Clicking on the icon "Spectrogram" will show the spectrogram traces.



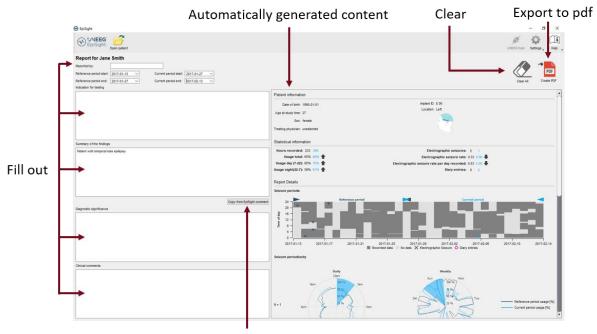
The spectrogram adds the following functionalities:

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



UNEEG EpiSight Report

Clicking on "Report" will open the report window.



Copy automatically comment

The report offers the following functionalities:

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



Keyboard shortcuts

The following table shows a summary of keyboard shortcuts available in UNEEG EpiSight

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	ght 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	А	Select all marker currently visible in the marker list	
Ctrl	С	Copy selected marker to the clipboard	
	А	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	Т	Show trending	
		Edit Comment	
Ctrl	Е	Open the comment dialog	
Ctrl	Enter	Save changes and close comment dialog	
	Esc	Discard changes and close comment dialog	





Warnings and precautions

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This version of UNEEG EpiSight is CE-certified as a medical device. If your country requires any other approval for medical devices you must not use this version of UNEEG EpiSight. Please contact your local distributor to receive a version of UNEEG EpiSight that is not certified as a medical device and can be used outside countries that accept the CE mark.



The modules from UNEEG EpiSight 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 UNEGG EpiSight. The original EEG still needs to be used for the evaluation and the results of UNEGG EpiSight need to be confirmed based on the unaltered raw EEG trace.



UNEEG EpiSight does not provide any diagnosis or diagnostic recommendations or predictions of the patient's state. It remains the responsibility of the physician to decide over 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 one continuous EEG recording that can be analyzed with UNEEG EpiSight is one year. If a recording is longer than one year, UNEEG EpiSight will stop processing.



UNEEG EpiSight 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, UNEGG EpiSight seizure detection can only support but cannot replace the qualified expert in the real-time monitoring.



UNEEG EpiSight detection of rhythmic pattern, aEEG or background frequency must 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 the module UNEEG EpiSight pattern detection 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.