

Quick Start Guide

encevis 1.11

UNEEG EpiSight



Manufacturer:
AIT - Austrian Institute of Technology GmbH;
Giefinggasse 4; 1210 Vienna; Austria
Date of manufacture: 2020



Use-by date:
Windows 10: 10/2025



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

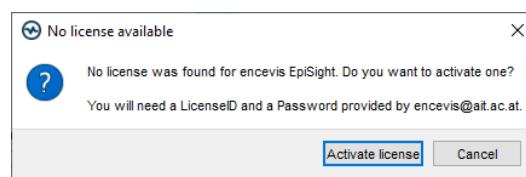


Caution: Please read paragraphs marked with this symbol carefully as they contain important safety information.

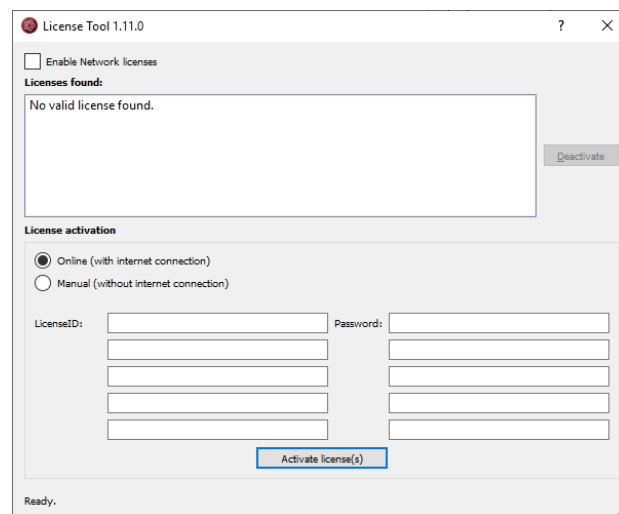
Issuing date of this document:
2020-10-23

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:



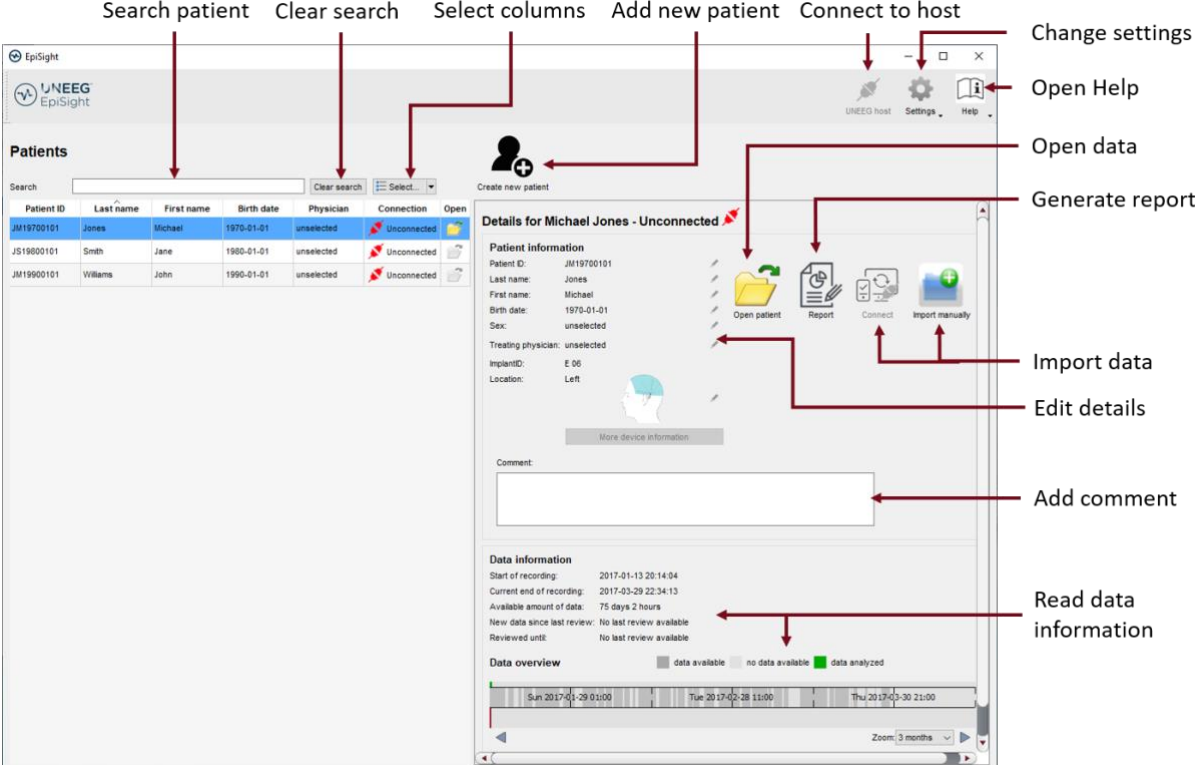
8. Press "Activate license", the License Tool will pop up.



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.



Search patient Clear search Select columns Add new patient Connect to host

Change settings
Open Help
Open data
Generate report
Import data
Edit details
Add comment
Read data information

Patient ID	Last name	First name	Birth date	Physician	Connection	Open
JM19700101	Jones	Michael	1970-01-01	unselected	Unconnected	
JS19900101	Smith	Jane	1990-01-01	unselected	Unconnected	
JM19900101	Williams	John	1990-01-01	unselected	Unconnected	

Details for Michael Jones - Unconnected

Patient information
 Patient ID: JM19700101
 Last name: Jones
 First name: Michael
 Birth date: 1970-01-01
 Sex: unselected
 Treating physician: unselected
 Implant ID: E 98
 Location: Left

Open patient Report Connect Import manually

Comment:

Data information
 Start of recording: 2017-01-13 20:14:04
 Current end of recording: 2017-03-29 22:34:13
 Available amount of data: 75 days 2 hours
 New data since last review: No last review available
 Reviewed until: No last review available

Data overview
 data available no data available data analyzed

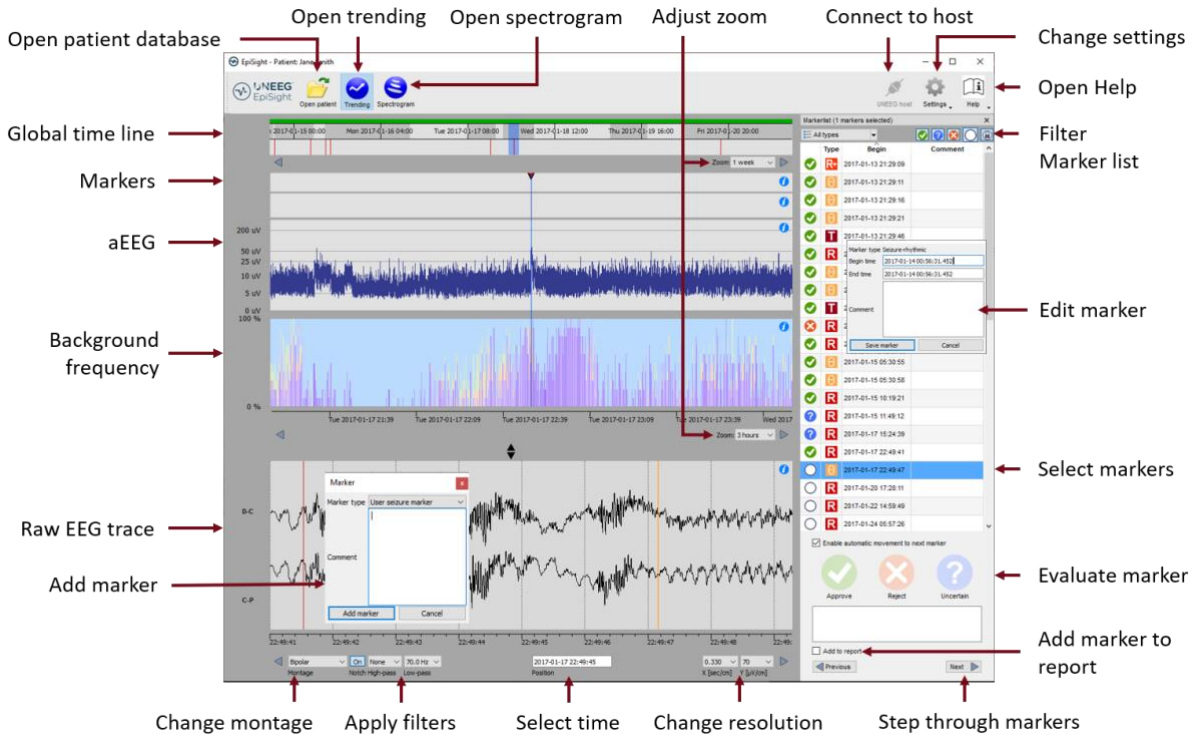
Sun 2017-01-29 01:00 Tue 2017-02-28 11:00 Thu 2017-03-30 21:00
 Zoom: 3 months

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

UNEEG EpiSight Trending

Clicking on “*Open patient*” will open the UNEEG EpiSight Trending window.

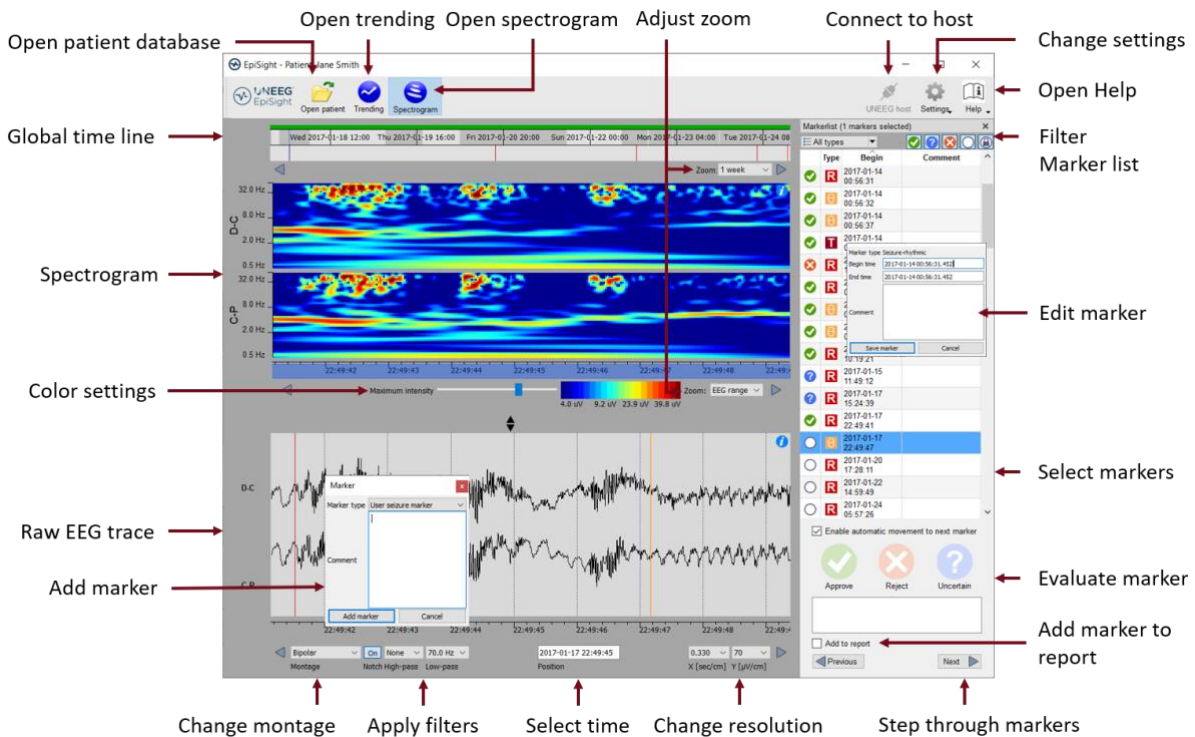


EpiSight EEG-trending includes the following functions and traces:

- 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 screenshot shows the UNEEG EpiSight Spectrogram interface with the following labeled components:

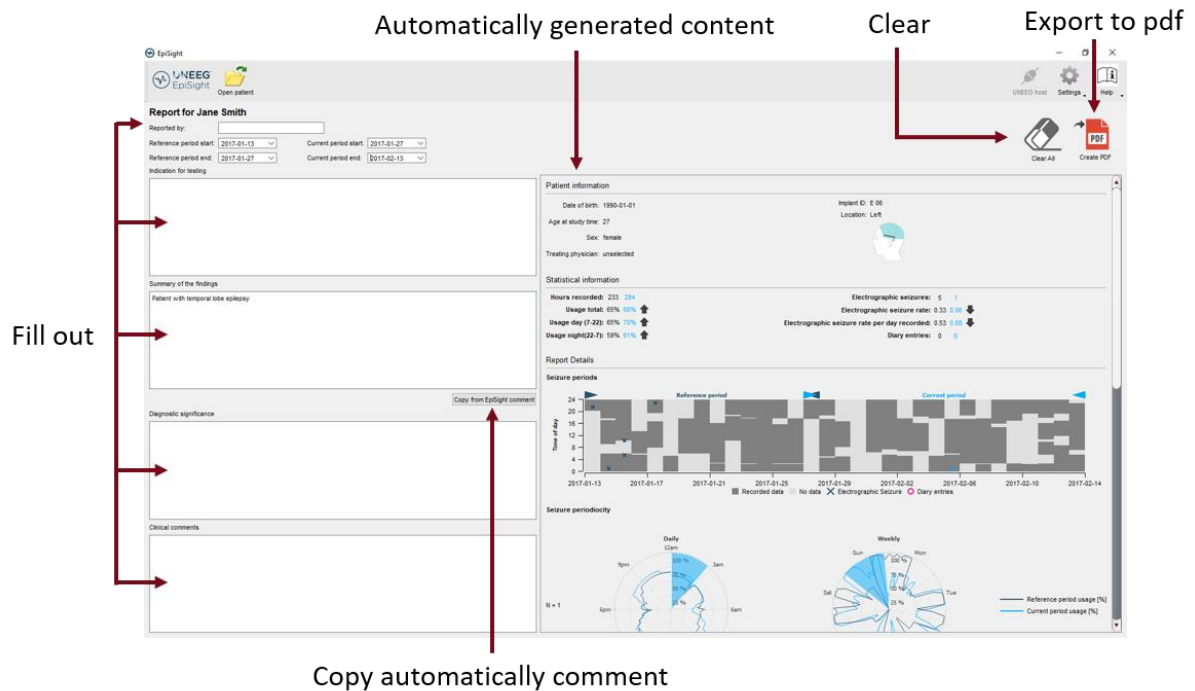
- Open patient database**: Points to the patient name 'EpiSight - Patient Jane Smith'.
- Open trending**: Points to the 'Trending' button.
- Open spectrogram**: Points to the 'Spectrogram' button.
- Adjust zoom**: Points to the 'Zoom: 1 week' dropdown.
- Connect to host**: Points to the 'UNEEG host' connection status.
- Change settings**: Points to the 'Settings' icon.
- Open Help**: Points to the 'Help' icon.
- Global time line**: Points to the top timeline showing dates from Wednesday to Tuesday.
- Filter Marker list**: Points to the 'Filter' icon in the marker list.
- Spectrogram**: Points to the main spectrogram plot showing frequency (0.5 Hz to 32.0 Hz) over time.
- Color settings**: Points to the 'Maximum intensity' slider and color scale (4.0 uV to 36.8 uV).
- Edit marker**: Points to the 'Edit marker' button in the marker list.
- Raw EEG trace**: Points to the 'D.C.' raw EEG trace below the spectrogram.
- Add marker**: Points to the 'Add marker' button in the 'Add marker' dialog box.
- Select markers**: Points to the 'Select markers' button in the marker list.
- Evaluate marker**: Points to the 'Approve', 'Reject', and 'Uncertain' buttons.
- Add marker to report**: Points to the 'Add to report' checkbox.
- Change montage**: Points to the 'Bipolar' dropdown.
- Apply filters**: Points to the 'None', '70.0 Hz', and 'Low-pass' filter options.
- Select time**: Points to the 'Position' field showing '2017-01-17 22:49:45'.
- Change resolution**: Points to the '0.330' and '70' resolution settings.
- Step through markers**: Points to the 'Previous' and 'Next' buttons.

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.











The screenshot shows the UNEEG EpiSight report interface for a patient named Jane Smith. The interface is divided into several sections:

- Header:** Includes the UNEEG EpiSight logo and an 'Open patient' button.
- Form Fields:** Fields for 'Reported by', 'Reference period start/end', and 'Current period start/end'.
- Summary of the findings:** A text area containing the text 'Patient with temporal lobe epilepsy'.
- Diagnostic significance:** A text area with a 'Copy from EpiSight comment' button.
- Clinical comments:** A text area for additional notes.
- Automatically generated content:** A section containing:
 - Patient information:** Date of birth (1990-01-01), Age at study time (27), Sex (female), Treating physician (unselected).
 - Statistical information:** Hours recorded (233 / 284), Usage total (65%), Usage day (7.23%), Usage night (22.7%), Electrophysic seizures (5 / 1), Electrophysic seizure rate (0.33 / 0.06), Electrophysic seizure rate per day recorded (0.53 / 0.06), Diary entries (0 / 5).
 - Report Details:** A 'Seizure periods' heatmap showing seizure activity over time from 2017-01-13 to 2017-02-14. Below it are 'Seizure periodicity' plots for 'Daily' and 'Weekly' cycles.
- Actions:** 'Clear' and 'Export to pdf' buttons are located in the top right corner.

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

Warnings and precautions

	<p>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.</p>
	<p>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 UNEEG EpiSight. The original EEG still needs to be used for the evaluation and the results of UNEEG EpiSight need to be confirmed based on the unaltered raw EEG trace.</p>
	<p>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.</p>
	<p>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.</p>
	<p>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.</p>
	<p>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, UNEEG EpiSight seizure detection can only support but cannot replace the qualified expert in the real-time monitoring.</p>
	<p>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.</p>
	<p>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.</p>