

Quick Start Guide

encevis 1.11

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

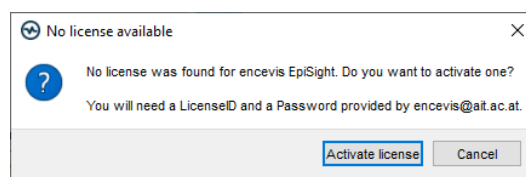


Caution: Please read paragraphs marked with this symbol carefully as they contain important safety information.

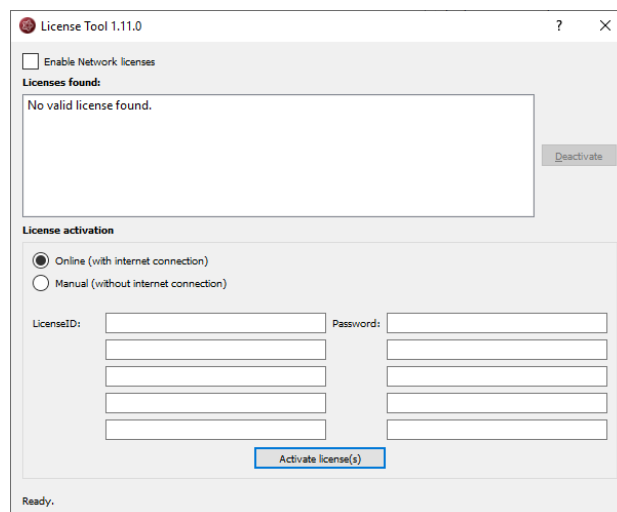
Issuing date of this document:
2021-03-30

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:



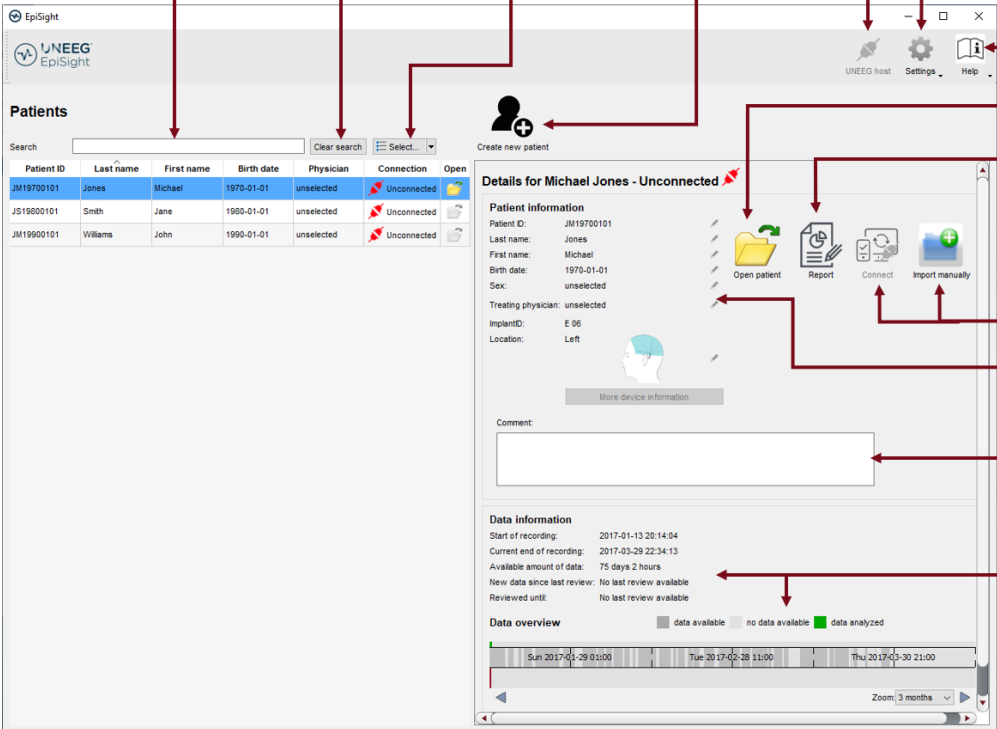
8. Press "Activate license", the License Tool will pop up.



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

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

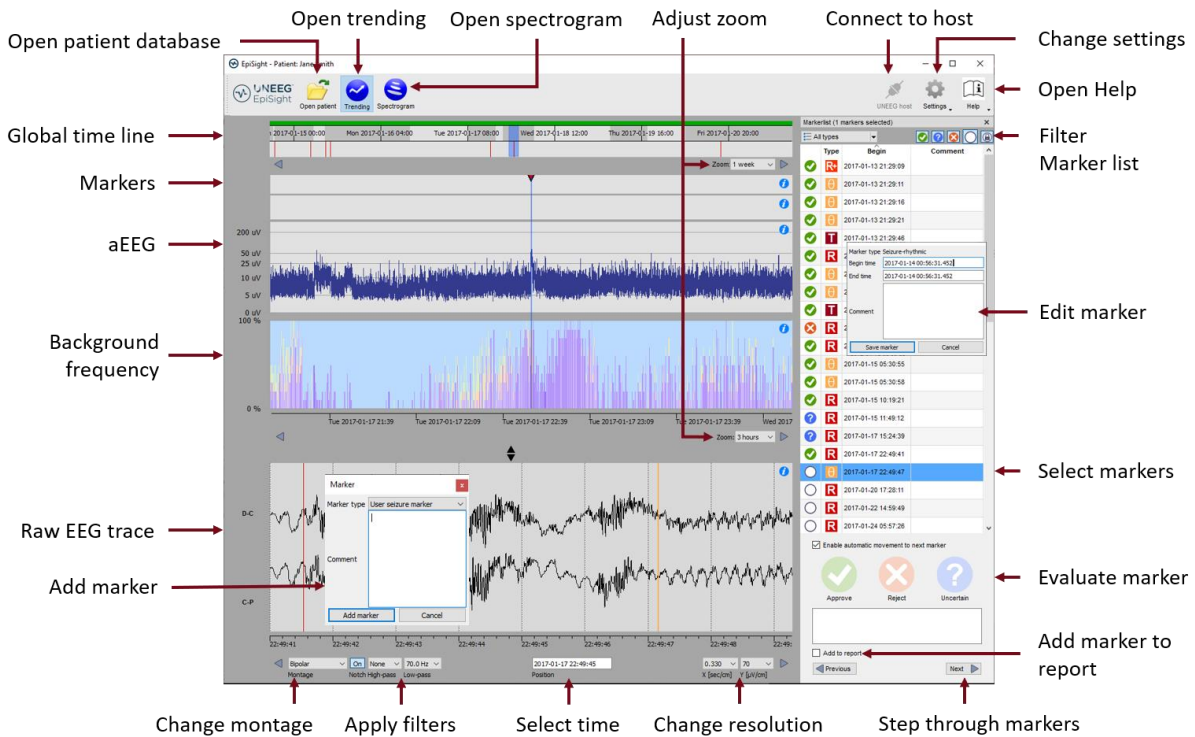
Data overview
 Legend: data available (grey), no data available (white), data analyzed (green)
 Timeline: Sun 2017-01-29 01:00, Tue 2017-02-28 11:00, Thu 2017-03-30 21:00
 Zoom: 3 months

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 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.

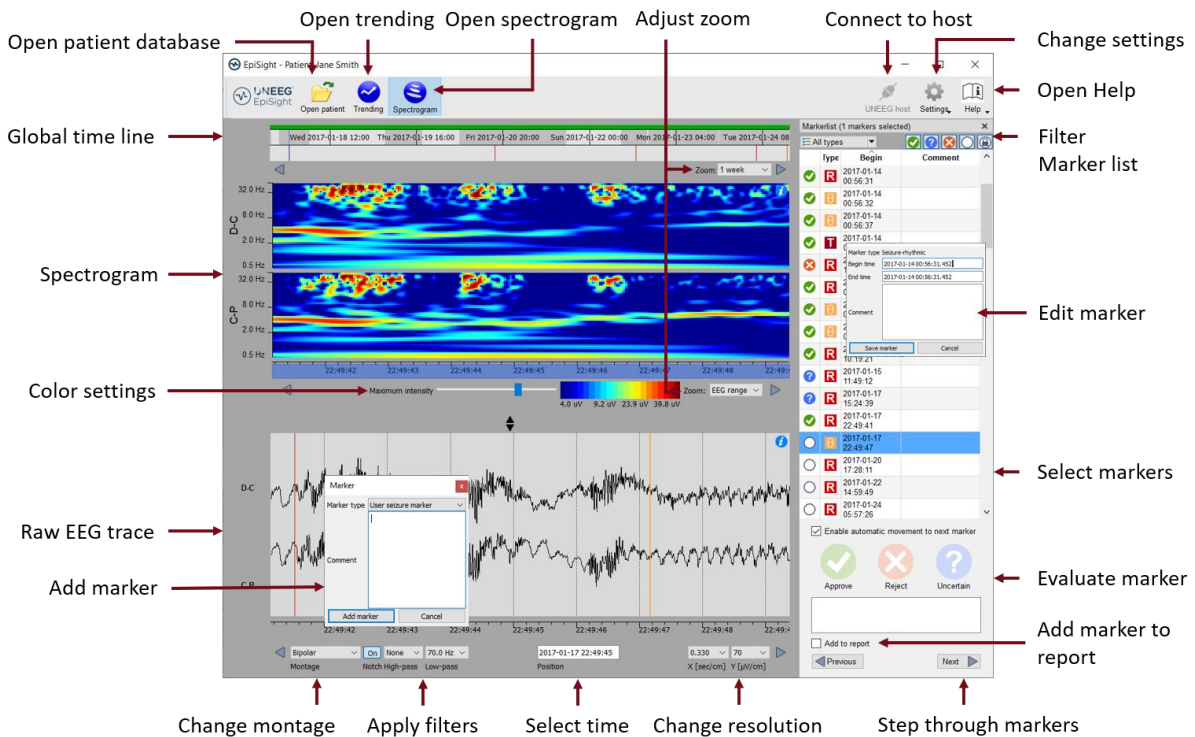


EpiSight EEG-trending includes the following functions and traces:

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

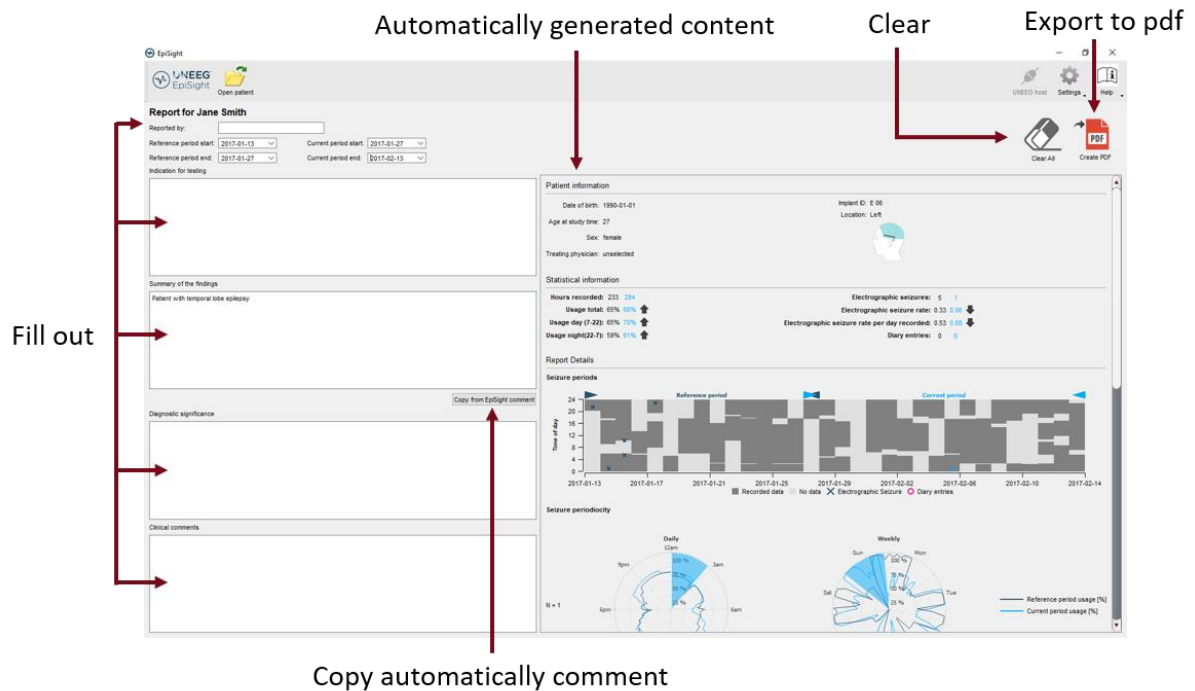
- Open patient database**: Points to the patient selection menu.
- Open trending**: Points to the trending icon.
- Open spectrogram**: Points to the spectrogram icon.
- Adjust zoom**: Points to the zoom control.
- Connect to host**: Points to the host connection button.
- Change settings**: Points to the settings gear icon.
- Open Help**: Points to the help icon.
- Global time line**: Points to the top timeline.
- Filter Marker list**: Points to the filter icon in the marker list.
- Spectrogram**: Points to the main spectrogram display.
- Edit marker**: Points to the edit icon in the marker list.
- Color settings**: Points to the color intensity slider.
- Raw EEG trace**: Points to the raw EEG waveform below the spectrogram.
- Add marker**: Points to the 'Add marker' button in the raw EEG trace.
- Select markers**: Points to the selection icons 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 montage dropdown menu.
- Apply filters**: Points to the filter settings dropdown.
- Select time**: Points to the time selection input.
- Change resolution**: Points to the resolution dropdown.
- 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.



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 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 | 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 | Save changes and close comment dialog |
| | Esc | Discard changes and close comment dialog |

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> |