Quick Start Guide

encevis 1.9

EpiSight

Manufacturer:
AIT - Austrian Institute of Technology GmbH;
Giefinggasse 4; 1210 Vienna; Austria
Date of manufacture: 2019

Use-by date:
Windows 7: 01/2020
Windows 10: 10/2025

CE 0297

Notified Body:
DQS 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.

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Installation

Once you have downloaded encevis EpiSight, start the encevis EpiSight Installer by double-clicking the downloaded executable. The installer will guide you through the installation process.

After the installation has finished, start encevis EpiSight by clicking on the icon on your desktop.
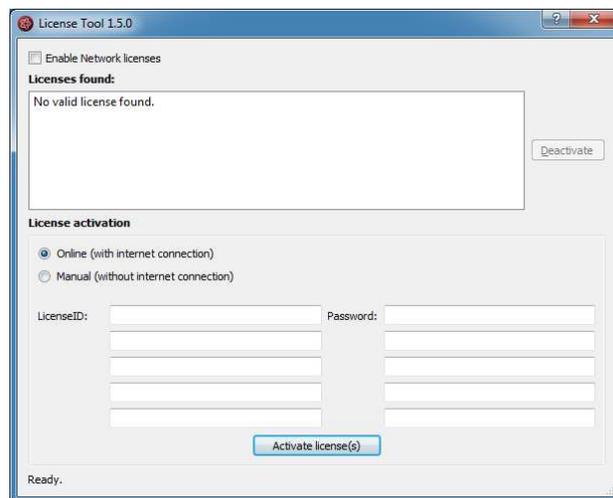
License activation

Encevis EpiSight needs a license to run on your computer. The license will be provided by UNEEG. Please contact your sales person if you did not receive a license key yet.

1. Start encevis EpiSight.
2. Press the button "**Open EEG**", the following window will pop up:
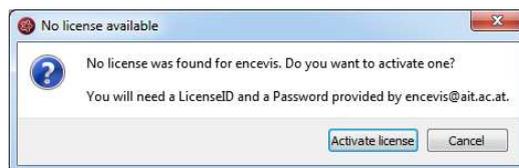
3. Press "**Activate license**", the License Tool will pop up.

4. 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.
5. Enter the LicenseID and Password.
6. Press "Activate license(s)".

Importing new EEG files

Before you can start analyzing EEG data you need to import the data that have been written to your hard drive when using the download tool provided by UNEEG.

Click on the "***Import EEG***" button in the task bar. A dialog will open that allows you to navigate to the directory that contains your EEG files. Once you selected the correct folder[1] press "***Choose Folder***" to start the import.

A dialog will open that indicates the progress of the import. Depending on the number of files and your network connection to your file sever the import can take several minutes. You can cancel the import at any time.

Each EEG file stores the implant ID of the device implanted in the patient. If you import data of a given implant for the first time, encevis EpiSight will ask you for some information about this patient. This includes first name, last name and birth date.
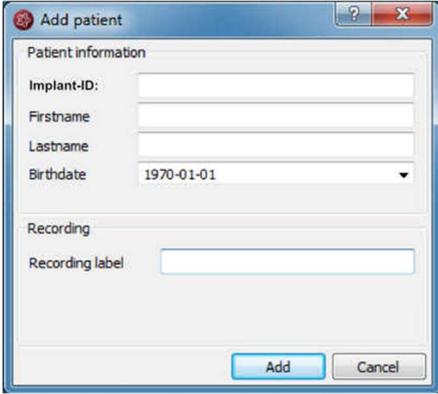

This information will be written to the encevis database and will allow you to find the data of a given patient in you encevis EpiSight patient management.

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[1] Please note that you will not see any EEG files contained in the selected folder. They will however be imported.

Open imported EEG file

You can open an EEG for review by clicking on the "**OpenEEG**" button in the task bar. A new dialog will open that shows all patients that have previously been imported into encevis EpiSight.
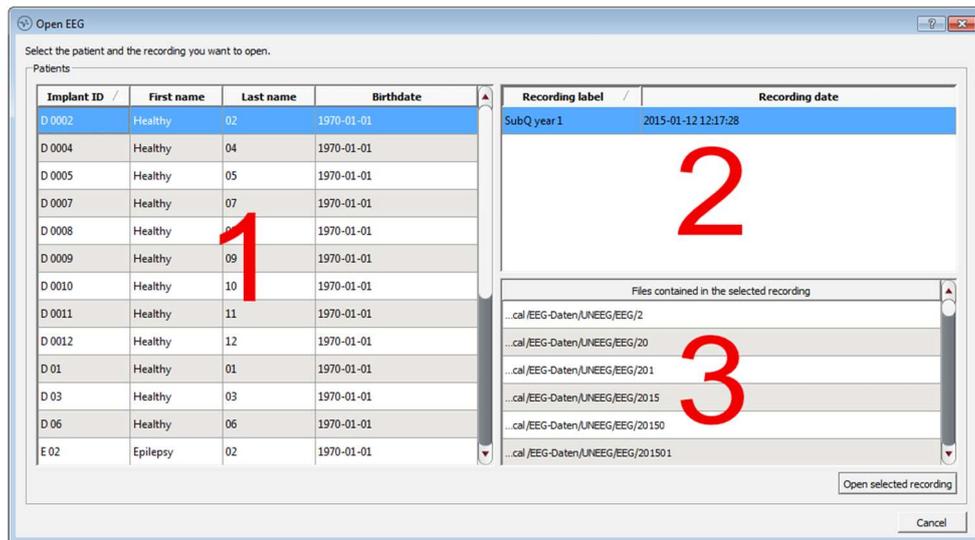
Select the patient you want to review in the left part of the dialog (1 in the previous figure). Once you select a patient, the available data is shown on the right side. The upper part (2 in the previous figure) show the number of years you have data recorded for this patient. The first entry will represent the first year of data, the second entry will represent the second year of data. By default, the first year will be selected. If you want to change this selection click on one of the other entries. In the lower part (3 in the previous figure) all files included in the selected recording period are shown. You do not need to select anything in this table. All files belonging to one period are automatically combined for the review.

Once you selected your recording press "**Open selected recording**" and encevis EpiSight will open all data for the selected patient and period.
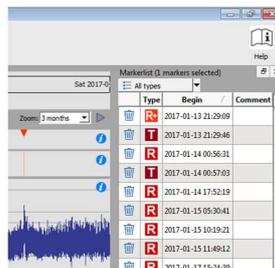
Using encevis EpiSight
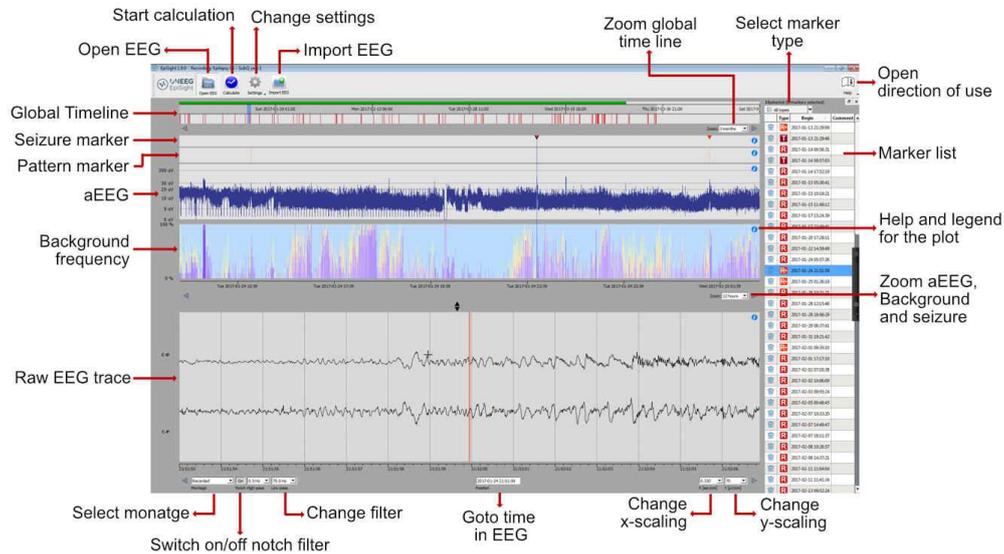
Encevis EpiSight will provide the following main functions:

- Navigate easily through the EEG.
- Switch the montage of the raw EEG
- Change the resolution in time and in voltage.
- Select notch, high-pass and low-pass filters.
- Create, review and change markers for special EEG events.
- Start automatic EEG analysis.
- Select pattern, aEEG or Background frequency events and see the corresponding EEG
- Change EpiSight settings
  - Show deleted marker in the recycling bin
  - Calibrate the display
  - Change patient names and files in "EEG File Management"

Getting help

You can always get additional help for each graph by clicking on the little blue "i" icon on the right side of the plot. In addition, a manual is available by clicking in the icon in the upper right corner of the encevis EpiSight.

Warnings and Precautions

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

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

⚠ encevis 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 encevis EpiSight is one year. If a recording is longer than one year encevis EpiSight will stop processing.

⚠ encevis 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, encevis seizure detection can only support but cannot replace the qualified expert in the real-time monitoring.

⚠ encevis 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 encevis 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.