

Instructions for use

NOT FOR CLINICAL USE

Manufacturer:



AIT - Austrian Institute of Technology GmbH;

Giefinggasse 4; 1210 Vienna; Austria

Date of manufacture: 2025



Serial number:

UNEEG™ EpiSight Analyzer 2.4.0

Issuing date of this document:

2025-03



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



This version of UNEEG™ EpiSight Analyzer is not a medical device. It is intended for research and evaluation, only.



This version of UNEEG™ EpiSight Analyzer must not be used on patients.

1 Who should read this document?

This document is directed to researchers, physicians, medical technicians and nursing staff, who are familiar with the EEG and the interpretation of it. It ensures them a safe use of the system.

2 Who can use UNEEG™ EpiSight Analyzer?

UNEEG™ EpiSight Analyzer is intended to be used by qualified researchers physicians, qualified medical technicians and qualified nursing staff. It is not intended for clinical use.

3 What can UNEEG™ EpiSight Analyzer be used for?

UNEEG™ EpiSight Analyzer aids the qualified user in the analysis and review of EEG data recorded with an electroencephalography device using subcutaneous electrodes. UNEEG EpiSight Analyzer offers a user interface for reviewing EEG recordings. The user interface is optimized to display a low number of electrodes. The EEG viewer can show results of algorithms for the analysis of EEG data. The analysis results are presented in a graphical user interfaces which shall aid the user in the examination of EEG recordings.

3.1 EEG viewer

The EEG viewer is optimized to display EEG signals for a low number of electrodes. It includes frequency filtering of the data, the scaling of the data in x and y direction and the visualization in different montages. Automatic analysis of EEG data is started as soon EEG data has been imported into the the EEG Viewer. The analysis results are presented in the EEG viewer which shall aid the user in the examination of EEG recordings. The analysis includes the seizure detection, detection of rhythmic pattern, background frequency and aEEG.

3.2 Seizure Detection

The UNEEG™ EpiSight Analyzer seizure detection allows the automatic detection of areas in EEG recordings that may correspond to electroencephalographical recognizable epileptic seizures and displays these markings for review.

3.3 Detection of rhythmic pattern

UNEEG™ EpiSight Analyzer pattern detection automatically detects EEG-patterns defined in the Standardized Critical Care EEG Terminology of the American Clinical Neurophysiology Society (Hirsch, L.J., et al., 2013. American Clinical Neurophysiology Society's Standardized Critical Care EEG Terminology: 2012 version. J. Clin. Neurophysiol. 30, 1–27) and graphically presents the results to the user. Additionally, it detects and visualizes rhythmic patterns with frequencies of up to 12Hz. It serves as a support during the examination of EEG-recordings.

3.4 Background frequency

The background frequency in UNEEG™ EpiSight Analyzer analyses the dominant background frequencies of the EEG. These are displayed for the four frequency ranges beta band, alpha band, theta band and delta band.

3.5 aEEG

The aEEG in UNEEG™ EpiSight Analyzer presents the amplitude-integrated EEG according to "Zhang, D., Ding, H., 2013. Calculation of compact amplitude-integrated EEG tracing and upper and lower margins using raw EEG data. Health (N. Y.) 05, 885–891"

3.6 Sleep

The sleep analysis component automatically estimates sleep stages based on the EEG and provides quantitative measures that can be used for the assessment of sleep quality.

3.7 Spectrogram

The UNEEG™ EpiSight Analyzer spectrogram graphically provides the user with a spectrogram for all EEG channels within a defined time range.

4 Life Span

The life span of this version of UNEEG™ EpiSight Analyzer ends on Windows 10 64-bit operating systems on 2025-10-14 (October 14th 2025), on Windows Server 2019 64-bit operation systems on 2025-10-14 (October 14th 2025) and on Windows 11 64-bit operating systems on 2027-10-12 (October 12th 2027). As of this date, no more error corrections will be performed for UNEEG™ EpiSight Analyzer on the named operating system and this version of UNEEG™ EpiSight Analyzer may no longer be used.

5 Are there restrictions of use?



This version of UNEEG™ EpiSight Analyzer is **not** a medical device. It is intended for research and evaluation, only.



This version of UNEEG™ EpiSight Analyzer must **not** be used on patients.

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 UNEEG™ EpiSight Analyzer will stop processing.

For UNEEG™ EpiSight Analyzer seizure detection, detection of rhythmic pattern, aEEG and background frequency the EEG of at least three subcutaneous electrodes must be available.

UNEEG™ EpiSight Analyzer seizure detection may show 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.



UNEEG™ EpiSight Analyzer detection of rhythmic pattern, aEEG or background frequency included in UNEEG™ 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. It can happen that the localization of patterns is not correct.

6 How is UNEEG™ EpiSight Analyzer installed and launched?

UNEEG™ EpiSight Analyzer is delivered with an installation program that guides the user through the installation process and installs the software on the user's PC. The user needs administrator rights to install the software and to license it. The user should therefore contact the IT-department.



When configuring UNEEG™ EpiSight Analyzer with a remote analysis on a second PC it must be ensured that both PCs are running on the same system time. Difference of more than 1,5 minutes might interfere with the UNEEG™ EpiSight Analyzer system.



When using a database server it is the responsibility of the administrator of this database server to ensure that the database is properly secured against unauthorized usage. This includes strong passwords and enabling SSL encryption for accessing the database.

7 How is UNEEG™ EpiSight Analyzer started?

To review and analyze EEG data the program "EpiSight Analyzer.exe" must be started by the user. After the start of "EpiSight Analyzer.exe" the EEG viewer will open.

8 Is additional help for UNEEG™ EpiSight Analyzer available?

Additional help for UNEEG™ EpiSight Analyzer can be found in the electronic help system inside the software under the menu item „Help“. Adobe Acrobat Reader is required for using the help. It can be downloaded directly from the Adobe webpage free of charge (<https://get.adobe.com/reader>).

9 Which EEG-data can UNEEG™ EpiSight Analyzer read?

UNEEG™ EpiSight Analyzer can only read data recorded with the UNEEG 24/7 EEG™ SubQ recorder.

10 Which EEG-systems support UNEEG™ EpiSight Analyzer?

UNEEG™ EpiSight Analyzer shall only be used with the UNEEG 24/7 EEG™ SubQ recorder.

11 Which service and maintenance measures are prescribed?

UNEEG™ EpiSight Analyzer does not require any particular service. The manufacturer has nevertheless the possibility to issue updates in irregular intervals. The manufacturer or the distributor will inform the user about these updates. It is recommended to promptly install these updates. Although the computer hardware is not part of UNEEG™ EpiSight Analyzer it is recommended to service the computer hardware running UNEEG™ EpiSight Analyzer in regular intervals. Particular attention should be given to ensure that sufficient free storage space is available for the operating system to run faultless. The user needs to ensure that the hardware of the computer system fulfills the minimum requirements that are listed in this document.



We strongly recommend that you back up the database used for UNEEG™ EpiSight Analyzer on a daily basis to prevent data loss. If the database is not available, all results are irretrievably lost.

12 Can UNEEG™ EpiSight Analyzer be combined with other products?

UNEEG™ EpiSight Analyzer is a stand-alone EEG analysis software. UNEEG™ EpiSight Analyzer can be used to analyse EEG data recorded with a UNEEG 24/7 EEG™ SubQ recorder and to download data from a UNEEG™ ProConnect system.

13 Which application environment is necessary?

UNEEG™ EpiSight Analyzer is a supplement to an EEG recording device and can be used wherever EEG data are recorded and evaluated. This can be done within a hospital or a doctor's office. Also mobile use on a laptop outside a doctor's office or a hospital is possible. UNEEG™ EpiSight Analyzer can be used wherever the proper use of the required computer hardware is ensured. UNEEG™ EpiSight Analyzer is not intended to be used outside closed rooms.

14 What are the UNEEG™ EpiSight Analyzer system components?

The system is made of the software UNEEG™ EpiSight Analyzer with the functions described above. UNEEG™ EpiSight Server is needed to connect to a UNEEG™ ProConnect system. The LicenseTool licenses UNEEG™ EpiSight Analyzer and is not required for later use. The installer installs and de-installs the system and is not required for later use.

15 How is UNEEG™ EpiSight Analyzer disposed?

UNEEG™ EpiSight Analyzer can be completely removed by the uninstall mechanisms that are provided by the operating system. Alternatively, UNEEG™ EpiSight Analyzer can be removed using the installer. This tool is a component of the UNEEG™ EpiSight Analyzer software.

16 Technical Data

Supported operating systems	Windows 10 64 bit (supported until 2025-10-14) Windows Server 2019 64 bit (supported until 2025-10-14) Windows 11 64 bit (supported until 2027-10-12)
Minimum requirements for Hardware	Intel® i5-3230M, 2.6 GHz Dual Core 4 GB RAM Intel® HD-Grafik 4000 10 GB free hard disk space
Minimum requirements for real-time processing	Intel Core™ i5, CoreQuad 2.8 GHz, 4 GB RAM Intel HD 3000 10 GB free hard disk space
Recommended hardware	Intel Core™ i5, CoreQuad 2.8 GHz, 4 GB RAM Intel HD 3000 40 GB free hard disk space
Minimum resolution requirements	1440 x 900
Allowed biosignals	EEG recorded with the UNEEG 24/7 EEG™ SubQ recorder
Power frequency	50Hz, 60Hz
EEG sampling frequency	100Hz or higher
Type of recording	referential, bipolar

17 How can feedback and problems be reported?

The user can report feedback and problems with UNEEG™ EpiSight Analyzer to the distributor that has provided the software or directly to the manufacturer using the email address encevis@ait.ac.at.

Any serious incidents that occur in relation to the device should be reported directly to the manufacturer using the email address encevis@ait.ac.at and the competent authority of the member state in which the user and/or patient is established.

18 Where are printed versions of the directions of use available?

A printed version of the directions of use is available from the manufacturer.

19 Cyber Security measures important for the safety of UNEEG™ EpiSight Analyzer

Please follow these advises carefully to minimize any security issue due to cyber security:

- Do not enable the guest account on this computer
- Use the database export function for regular backups
- Keep your operating system, firewall and anti-virus software up-to-date
- Do not run this software on Windows operating systems for which the support has been discontinued by Microsoft
- Ensure that access to your computer is restricted to authorized personnel

Errors and omissions excepted