

Instructions for use



Manufacturer:

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

Date of manufacture: 2023



Serial number:

UNEEG™ EpiSight Analyzer 2.0.1



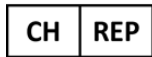
Use-by date:

Windows 10: 2025-10-14



Notified Body:

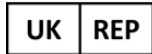
mdc medical device certification GmbH, Kriegerstrasse 6, 70191 Stuttgart, Germany



Representative CH: Arazy Group Swiss GmbH, Bruderholzallee 53

4059 Basel, Schweiz

swiss.ar@arazygroup.com



Representative UK: MEDES LIMITED 5 Beaumont Gate, Shenley Hill, Radlett,

Herfordshire WD7 7AR, England, UK

medes@arazygroup.com



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



(01)09120109830115

Issuing date of this document: 2023-01-26

1 What is the Intended Purpose of UNEEG™ EpiSight Analyzer?

The present medical device enables the evaluation of EEG signals for the qualified user. It provides components to analyze EEG data and provides a component for viewing EEG data and analysis results. The analysis component can operate independently of the component to review EEG data.

The medical device has the following main functions:

- Graphical display of EEG data and application of standard functions such as filter, montages, X- and Y-resolution, or display of video together with the EEG data.
- Automatic detection of seizures in an EEG signal.
- Automatic recognition of patterns in an EEG signal.
- Automatic calculation of quantitative EEG measures.

1.1 Intended User

UNEEG™ EpiSight Analyzer is intended to be used by qualified physicians, qualified medical technicians and qualified nursing staff.

1.2 Patient population

UNEEG™ EpiSight Analyzer can be used on EEG data of adults over the age of 18 years. There are no restrictions on weight, health, gender, or nationality.

1.3 Indication

UNEEG™ EpiSight Analyzer is intended for the review and analysis of EEG recordings made by electroencephalogram (EEG) devices using subcutaneous electrodes and to aid neurologists in the assessment of EEG. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.

UNEEG™ EpiSight Analyzer calculates a set of general measures that are used for the analysis of the EEG during different medical condition. This includes UNEEG EpiSight Analyzer seizure detection component, and quantitative measures intended to analyze the EEG waveform such as frequency bands and rhythmic pattern. These measures can be used for the diagnostics and management of different diseases, such as e.g. epilepsy.

UNEEG™ EpiSight Analyzer does not provide any diagnostic conclusion about the patient's condition to the user.

1.4 Contraindication and unwanted side effects

There are no contraindications or unwanted side effects.

2 What are the main functions of UNEEG™ EpiSight Analyzer?

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.

2.1 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.

2.2 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.

2.3 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.

2.4 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.

2.5 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"

2.6 Spectrogram

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

3 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). 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.

4 Are there restrictions of use?



UNEEG™ EpiSight Analyzer is not intended to be used as a monitoring device. The processing is done offline after the recording finished.



UNEEG™ EpiSight Analyzer is CE-certified as a medical device. If your country requires any other approval for medical devices you must not use UNEEG™ EpiSight Analyzer.



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



UNEEG™ EpiSight Analyzer does not provide any diagnosis or diagnostic recommendation, conclusion or prediction of the patient's state. It remains the responsibility of the physician to decide on 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 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 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 Analyzer can only support but can not replace the qualified expert in the real-time monitoring.



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. All measures of UNEEG™ EpiSight Analyzer 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.

5 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.

6 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.

7 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>).

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

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

9 Which EEG-systems support UNEEG™ EpiSight Analyzer?

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

10 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.

11 Can UNEEG™ EpiSight Analyzer be combined with other medical 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.

12 Which application environment is necessary?

The medical device 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. The medical device 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.

13 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.

14 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.

15 Technical Data

Supported operating systems	Windows 10 64 bit (supported until 2025-10-14)
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
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

16 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.

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

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

18 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