Instructions for use

Manufacturer:
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SN

Serial number:
UNEEG™ EpiSight Analyzer 2.0.1

Use-by date:
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CE 0483

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

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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