



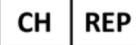
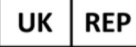




Instructions for use

	Manufacturer: AIT - Austrian Institute of Technology GmbH; Giefinggasse 4; 1210 Vienna; Austria Date of manufacture: 2022
	Serial number: encevis 2.0.3
	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
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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 encevis?

encevis enables the evaluation of EEG signals for the qualified user. It consists of modules for viewing EEG data and several modules, which provide additional analysis functionality. Modules and EEG-viewers can be operated independently of each other. If the EEG Viewer is not used, the transfer of EEG data to the modules is done using a documented interface, which manufacturers of EEG systems can integrate into their systems. encevis is installed and operated on a standard PC. encevis 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 reduction of artifacts in an EEG signal.
- Automatic detection of seizures in an EEG signal.
- Automatic recognition of spikes in an EEG signal.
- EEG source localization and the visualization of the results
- Automatic recognition of patterns in an EEG signal.
- Automatic calculation of quantitative EEG measures.
- Continuous presentation of the detected patterns and quantitative EEG measurements during recording.
- Interface to all modules, which can be integrated by an EEG manufacturer.

1.1 Intended User

encevis should be used by Physicians, medical technicians and nursing staff, who are familiar with the EEG and the interpretation of it.

1.2 Patient population

encevis 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

Encevis can be used wherever EEG data must be displayed and evaluated. This includes in particular neurological wards, epilepsy monitoring units, neurological intensive care units and neurological practices.

encevis calculates a set of general measures that are used for the analysis of the EEG during different medical condition. This includes spike detection component, encevis seizure detection component, and quantitative measures intended to monitor and analyze the EEG waveform such as frequency bands, rhythmic and periodic patterns, burst suppression and heart rate. These measures can be used for the diagnostics and management of different diseases, such as e.g. epilepsy.

encevis 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 encevis?

encevis aids the qualified user in the analysis and review of EEG data recorded with an electroencephalography device using scalp electrodes. encevis offers a user interfaces for reviewing EEG recordings. The EEG viewer can start modules that automatically analyze the EEG. The analysis results are presented in graphical user interfaces which shall aid the user in the examination of EEG recordings. The availability of analysis features and viewers depends on the license installed. The modules can additionally be operated directly by EEG manufacturer via the external interface "AITInterfaceDLL".

2.1 EEG viewer

The EEG viewer is optimized to display EEG signals for up to 256 electrodes. It includes frequency filtering of the data, the scaling of the data in x and y direction, display of video together with the EEG data, the visualization in different montages and artifact reduction. The EEG viewer can also start additional modules that automatically analyze the EEG. The availability of analysis features depends on the installed license.

2.2 Artifact Reduction

The encevis artifact reduction is an analysis module that automatically recognizes and reduces artifacts in the EEG-data which come from EMG, electrode artifacts and optionally from eye movements. encevis artifact reduction can be used in online- and offline mode. The artifact reduction is available in the EEG viewer.

2.3 Seizure Detection

The encevis 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. This can be done online during recording or offline after recording is complete.

2.4 Spike detection

The encevis spike detection is a module for the automatic marking of areas in the EEG that could correspond to spikes or spike-waves. A graphical user interface presents the results to the user. The user interface contains a time line per channel, a list of spike clusters that contain spikes and a list of spikes contained in a selected cluster. In addition, either the EEG or the averaged EEG 0.5 seconds before the spike maximum to 0,5 seconds after spike maximum for all spikes in a selected cluster is shown. Processing can take place online during the recording or offline after the recording.

2.5 Source localization

encevis Source Localization calculates the source of EEG activity and visualizes the results. Individual spikes as well as rhythmic activity can be localized. It serves as a support for the qualified physician and qualified medical-technical assistants (MTA) in the evaluation of EEG recordings. It allows the clinician to quickly and reliably perform a localization of EEG activity. The EEG data should contain at least the full 10/20 configuration of surface electrodes.

2.6 Detection of rhythmic and periodic pattern

encevis 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 in the ICU and EMU. This can take place online during the recording or offline after the recording.

2.7 Background frequency

The background frequency in encevis 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.

2.8 aEEG

The aEEG in encevis 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"

2.9 Burst-Suppression

The burst suppression detection in encevis automatically marks areas in EEG recordings that are burst-suppression patterns according to the definition of "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 displays the results in a graphical user interface.