Directions of Use encevis

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

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SN Serial number:
encevis 1.11.2

Use-by date:
Windows 10: 10/2025

$C \in {}_{0297}$ 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 Who should read this document?

This document is directed to 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 encevis?

encevis is intended to be used by qualified physicians, qualified medical technicians and qualified nursing staff.

3 What can encevis be used for?

encevis aids the qualified user in the analysis and review of EEG data recorded with an electroencephalography device using scalp or subcutaneous electrodes. encevis offers two different user interfaces for reviewing EEG recordings. One EEG viewer is optimized for a multi electrode setup, the other is optimized to display a low number of electrodes. Both EEG viewers 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.

3.1 EEG viewer for multi electrode setup

The EEG viewer for multi-electrode setup 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 to the EEG data, the visualization in different montages and artifact reduction. The EEG viewers can also start additional modules that automatically analyze the EEG. The availability of analysis features depends on the installed license.

3.2 EEG viewer for low-electrode setup

The EEG viewer for low-electrode setup is optimized to display EEG signals for a low number of electrodes only. It includes frequency filtering of the data, the scaling of the data in x and y direction and the visualization in different montages. The EEG viewers can also start an automatic analysis of the EEG signal. 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, spectrogram and aEEG.

3.3 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. It is available in the EEG viewer for multi-electrode setup, only.

3.4 Seizure Detection

The encevis seizure detection allows the automatic detection of areas in EEG recordings that may correspond to electrographically recognizable epileptic seizures and displays these markings for review. This can be done online during recording or offline after recording is complete.

3.5 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. The spike detection can be operated directly by the EEG manufacturer via the external interface "AITInterfaceDLL".

3.6 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. The encevis source location can be operated directly by the EEG manufacturer via the external interface "AITInterfaceDLL".

3.7 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.

3.8 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.

3.9 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"

3.10 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.

3.11 Heart rate

The display of the heart rate in encevis displays the patient's heart rate as long as an ECG measurement was registered in the EEG file. The display of the heart rate in encevis is only intended as an additional information that can help in the interpretation of the EEG and cannot replace the monitoring of the heart by ECG monitors.

3.12 Spectrogram

The encevis spectrogram graphically provides the user with a spectrogram for all or a selected number of EEG channels within a defined time range.

4 Life Span

The life span of this version of encevis ends on Windows 10 64 bit operating systems on 2025-10-14 (October 14th 2025). As of these dates, no more error corrections will be performed for encevis on the named operating systems and this version of encevis may no longer be used.

5 For which patients can encevis be used?

encevis can be used in adults over the age of 18 years. There are no restrictions on weight, health, gender, or nationality. The use in children is not recommended since specificity and sensitivity are not sufficiently defined due to the low amount of available EEG data from children during clinical validation.

6 Are there restrictions of use?

⚠️ 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. If you are located in a country that requires FDA approval for medical devices please contact you local distributor to receive an FDA approved version of encevis. For all other countries please contact your local distributor to receive a version of encevis that is not certified as a medical device and can be used outside countries that accept the CE or FDA 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.