Instructions for use encevis light

NOT FOR CLINICAL USE

Manufacturer:
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Giefinggasse 4; 1210 Vienna; Austria
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encevis 2.1.1

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

This version of encevis is not a medical device. It is intended for research and evaluation, only.

This version of encevis 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 encevis?

encevis light is intended to be used qualified researchers, physicians, qualified medical technicians and qualified nursing staff. It is not intended for clinical use.

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 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" or via the external interface "encevis SeizureICUInterface".

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3.1 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.

3.2 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.

3.3 Detection of Seizures and Status Epilepticus

The encevis seizure detection components allow the automatic detection of areas in EEG recordings that may correspond to electroencephalographical recognizable epileptic seizures and displays these markings for review in form of seizure marker and seizure burden over time. It also identifies patterns that maybe consistent with electrographic status epilepticus as defined in "American Clinical Neurophysiology Society's Standardized Critical Care EEG Terminology: 2021 version. J. Clin. Neurophysiol. 38, 1-29". This can be done online during recording or offline after recording is complete.

3.4 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.

3.5 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. The EEG data should contain at least the full 10/20 configuration of surface electrodes.

3.6 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. This can take place online during the recording or offline after the recording.

3.7 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.

3.8 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"

3.9 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.

3.10 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.

3.11 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.

3.12 External Interface "encevis AITInterface"

The external interface "encevis AITInterface" enables the control of encevis by a software system of an EEG manufacturer. The interface allows to start the modules, to transmit EEG data to the modules, and to receive results at the calling software. This interface allows manufacturers of EEG systems to directly integrate encevis into their recording software. encevis viewer, encevis artifact reduction, and encevis spectrogram can not be controlled by the external AITInterface.

3.13 External Interface „encevis SeizureICUInterface“

The external interface "encevis SeizureICUInterface" allows the "encevis detection of seizures and status epilepticus" to be integrated into a software system of an EEG manufacturer. The interface allows to start the module "encevis detection of seizures and status epilepticus", to transmit EEG data to the module and to receive results at the calling software. This interfacae allows manufacturers of EEG systems to directly integrate the module "encevis detection of seizures and status epilepticus" into their recording software.

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 Are there restrictions of use?



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This version of encevis must **not** be used on patients.

The EEG-data should be recorded at least with the complete 10/20 set of scalp electrodes. For aEEG and background frequency the EEG must be available from at least three scalp electrodes.

The maximum length for on continuous EEG recording with a 10/20 set of scalp electrodes that can be reviewed and analyzed is 10 days. If a recording is longer than 10 days encevis will stop processing.

encevis artifact reduction does not remove all interference and reduces only interference coming from EMG, electrode artifacts or optionally eye artifacts. It can change areas of the EEG that show cerebral activity. encevis artifact reduction works only with electrodes defined in the 10/10 system and additional T1-, T2-, SP1-, and SP2-,electrodes.

encevis 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. Some EEG-events that maybe consistent with electrographic status epilepticus might be missed.

Some EEG-events where spikes occur might not be detected with encevis Spike Detection. The detection of such events with the encevis spike detection cannot replace the analysis by a qualified expert.



encevis detection of rhythmic and periodic pattern, burst suppression, aEEG or any other module included in encevis 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 including Burst Suppression Detection are visible in the EEG, might be missed. It can happen that the localization of patterns is not correct.



The heart rate trace shown in encevis can never replace an ECG monitor. The trace shown in encevis is only intended to provide additional information that can help in the interpretation of the EEG.

encevis source localization may only be used with electrodes defined in the 10/10 electrode system configuration. The use of electrodes other than those included in the 10/10 system may lead to an error message. The results of a source localization are never unambiguous and may differ from the actual position of the source of the EEG activity. The use of a standard head model can lead to deviations in the localization of the EEG activity.

6 How is encevis installed and launched?

encevis 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 encevis with a remote distributor for calculation 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 encevis 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 encevis started?

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

8 Is additional help for encevis available?

Additional help for encevis 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 encevis read?

A list of the supported data formats can be found at http://www.encevis.com/support/dataformats.

10 Which EEG-systems support encevis online?

All encevis modules can be operated online directly from the EEG-devices. For this, the manufacturer of the EEG-device has to integrate the interface to encevis. A list of the manufacturers that have encevis integrated can be found at http://www.encevis.com/support/listOfIntegrations.

11 Which service and maintenance measures are prescribed?

encevis 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 encevis it is recommended to service the computer hardware running encevis 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 encevis on a daily basis to prevent data loss. If the database is lost, all results are irretrievably lost.

12 Can encevis be combined with other products?

encevis is a stand-alone EEG analysis software. Third party EEG manufacturer can interface to encevis. A list of the manufacturers that integrate with encevis can be found at http://www.encevis.com/support/listOfIntegrations. Please contact your EEG vendor or encevis@ait.ac.at for further information.

13 Which application environment is necessary?

encevis 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 encevis can be used wherever the proper use of the required computer hardware is ensured. encevis is not intended to be used outside closed rooms.

14 What are the encevis system components?

The system is made of the software encevis with the functions described above. The software includes additional executables that are required for the online-use of the analysis modules. The LicenseTool licenses encevis 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 encevis disposed?

encevis can be completely removed by the uninstall mechanisms that are provided by the operating system. Alternatively, encevis can be removed using the Installer. This tool is a component of the encevis software.

16 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
Requirements for graphics driver	OpenGL 2.0 or higher
Maximum number of modules running simultaneously (online)	4
Allowed biosignals	EEG, ECG
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 encevis 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 encevis

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