

Directions of Use encevis

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|  | Manufacturer: AIT - Austrian Institute of Technology GmbH; Giefinggasse 4; 1210 Vienna; Austria |
| | Date of manufacture: 2018 |
|  | Serial number: Version 1.7.1 |
|  | Use-by date: 01/2020 |
|  | Notified Body: DQS Medizinprodukte GmbH; August-Schanz-Straße 2; 60433 Frankfurt am Main; Germany |
|  | Caution: Please read paragraphs marked with this symbol carefully as they contain important safety information. |

1 Who should read this document?

This document is directed to physicians, medical technicians and nursing staff, who know about the use of 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?

The encevis EEG-viewer is intended for the review and the analysis of EEG-recordings that were recorded with an electroencephalography device using scalp electrodes. It shall aid the user in the examination of EEG-recordings. This includes the frequency filtering of the data, the scaling of the data in x and y direction and the visualization in different montages. In addition, the encevis EEG-viewer can also start additional modules that automatically analyse the EEG and present the results in form of markers or in the form of modified EEG-curves. All included modules are intended for the support of the user in the examination and monitoring of EEG-recordings.

3.1 Artefact reduction

The encevis artefact reduction PureEEG is an analysis module that automatically recognizes and reduces artefacts in the EEG-data that come from EMG, electrode artefacts and optionally from eye movements.

3.2 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.

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

3.4 Source localization

encevis source localization calculates the source of EEG activity and visualizes the results. Individual spikes or rhythmic activity can be localized. It enables the clinician to quickly perform a localization of the EEG activity in the brain.

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

3.6 Background frequency

The background frequency in encevis analyses the dominant background frequencies of the EEG. These are displayed for the four frequency bands beta band, alpha band, theta band and delta band.

3.7 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"

3.8 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 these graphically.

3.9 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.

3.10 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.

3.11 External Interface AITInterface

The external interface AITInterface enables the control of the encevis by a software system of an external EEG vendor. The interface allows to start the modules, to transfer EEG-data to the modules and to transfer back the results to the calling software. Encevis viewer, encevis Artifact Reduction, and encevis Spectrogram can not be controlled by the external AITInterface.

4 Life Span

The life span of this version of encevis ends on 2020-01-14 (January 14st 2020). From this moment on, there will be no more corrections of errors and this version of encevis should not be used anymore.

5 For which patients can encevis be used?

encevis can be used on the EEG of adults above the age of 18 years. There are no restrictions regarding weight, state of health or gender. The use of encevis with the EEG of children is not recommended, since the clinical validation did not include enough data from children's EEG and therefore the high sensitivity and specificity are not ensured.

6 Are there restrictions of use?



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 staff.

The maximum length for one continuous EEG recording that can be analyzed with encevis is 10 days. If a recording is longer than 10 days encevis will stop processing.

The EEG-data should be available at least with the complete 10/20 set of scalp electrodes.

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

Some EEG-events with epileptic seizures that have an electrographic correlate might be missed. For this reason encevis seizure detection can only support but can not replace the qualified expert in the real-time monitoring.

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 source localization must only be used with electrodes from the 10/10 system. Using electrodes outside the 10/10 system might result in an error message. The results of the source localization are never unequivocal and can differ from the real position of the source of the EEG-activity. Using the standard head model can lead to differences in the localization of the EEG-activity. The source localization with encevis can support but not replace the localization based on the analysis of the original EEG by a qualified expert.



encevis should not be used as an alarm system, since the visualization of patterns could be delayed by up to 1.5 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 (Main Term 1). All measures have to be evaluated in combination with the original raw EEG and must not be the only basis for a diagnosis, treatment or change of treatment.



The heart rate trace shown in encevis can never replace an ECG monitor. The trace shown in encevis is only intended as an additional information that can help in the interpretation of the EEG. It must never be used to monitor the heart function of the patient. It must always be verified based on the original raw ECG trace.

7 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.

8 How is encevis started?

The program encevis.exe must be started by the user. After the start of encevis.exe the EEG-viewer will open.

9 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>).

10 Which EEG-data can encevis read?

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

11 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>.

12 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 fulfils the minimum requirements that are listed in this document.

13 Can encevis be combined with other medical products?

encevis can be used with any certified EEG-system that supports the interface AITInterface. This interface is part of encevis and can be used by other manufacturers of medical products to integrate the modules for the EEG-analysis.

14 Which application environment is necessary?

Encevis is a supplement to an EEG-device and can be used anywhere where EEG-data are recorded. This can take place in a hospital or in doctors' surgeries. A mobile use on a laptop outside doctors' surgeries or a hospital is also possible. The medical product should be used where the proper use of the required computer hardware is ensured. encevis is not intended for the use outside closed spaces.

15 What are the encevis system components?

The system is made of the software encevis with the functions described above. The software includes additionally the AITDistributor and AITPluginManager that are required for the use of the analysis modules. The AITLicenseTool licenses encevis and is not required for later use. The AITMaintenanceTool installs and de-installs the system and is not required for later use.

16 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 AITMaintenanceTool. This tool is a component of the encevis software.

17 Technical Data

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| Supported operating systems | Windows 7 Windows 8 Windows 10 |
| Minimum requirements for Hardware | Intel Atom™ 1.8 GHz Dual Core 2 GB RAM Intel HD 3000 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 1.1 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 |

18 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.

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

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

Errors and omissions excepted