

Directions of Use encevis



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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 encevis PureEEG

The artefact reduction encevis 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 encevis EpiScan

The seizure detection encevis EpiScan is a module for the automatic marking of areas in the EEG that could correspond to epileptic seizures with electrographic correlate. EpiScan makes the results available to the user. This can take place online during the recording or offline after the recording.

3.3 Spike detection encevis EpiSpike

The spike detection encevis EpiSpike 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 EpiSource

encevis EpiSource is a module for the EEG source localization and the visualization of 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 Pattern detection and qEEG encevis NeuroTrend

encevis NeuroTrend is a module for the analysis of EEG-recordings of intensive care patients. It 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. In addition, encevis NeuroTrend calculates and visualizes continuous measures that describe the EEG. This includes the analysis of the frequency distribution and the aEEG (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. doi:10.4236/health.2013.55116).

3.6 External Interface AITInterface

The external interface AITInterface enables the control of the modules encevis EpiScan, encevis EpiSpike, encevis EpiSource und encevis NeuroTrend 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.

4 Life Span

The life span of encevis V1.3 ends on 2019-12-31 (December 31st 2019). From this moment on, there will be no more corrections of errors and encevis V1.3 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 EEG-data should be available at least with the complete 10/20 set of scalp electrodes.

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.

encevis EpiScan cannot be used as an alarm system, since there may be a delay of several minutes between the clinical onset of the seizure and the display of the detected pattern. Some EEG-events with epileptic seizures that have an electrographic correlate might be missed. For this reason encevis EpiScan 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 EpiSpike. The detection of such events with the spike detection encevis EpiSpike cannot replace the analysis by a qualified expert.

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 EpiSource can support but not replace the localization based on the analysis of the original EEG by a qualified expert.

encevis NeuroTrend 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 of the module encevis NeuroTrend 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.

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“.

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

Supported operating systems	Windows 7 Windows 8
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	4
Allowed biosignals	EEG
Power frequency	50Hz, 60Hz
EEG sampling frequency	200Hz or higher
EEG amplifier	All commercially available EEG amplifier PureEEG must not be used in combination with DC-coupled amplifiers.
Type of recording	referential

18 How can feedback und problems be reported?

The user can report feedback and problems with encevis to the distributor that has provided the software.

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