BESA

NEUROSPEC

Research Neurosciences

BESA Epilepsy 2.0

CE-certified software for efficient EEG review and automatic detection of spikes and seizures

international edition

Welcome to BESA Epilepsy 2.0

We recommend reading this document carefully before you are going to install, configure and use the product.

The document covers an introduction to program types, features and licenses. It contains the Safety Instructions and Installation Instructions. Further information about configuration and using the program are available after installation. Please report any suggestions and errors found in the leaflet via email to **feedback@besa.de**.

We strive to bring you the latest methods for advanced EEG analysis in a user-friendly and optimized implementation.

Dr. Tobias Scherg
CEO / General Manager

Table of Contents

Program Types, Features and Licenses

BESA Epilepsy 2.0 is CE-certified software for automatic detection and evaluation of spikes and seizures and it provides tools for efficient EEG review.

The product consists of the following two program types:

BESA Epilepsy 2.0 Detection:

- Required to start detection e.g. by the technician
- Recommended to be installed in monitoring room, best on the PC of the acquisition
- Analyze the EEG
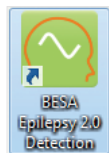
BESA Epilepsy 2.0 Review:

- Required by technician to prepare reports
- Required by physician to do evaluations or finalize prepared reports
- Recommended to be installed in EEG reading room, monitoring room, and physician desk
- Review/evaluate the EEG
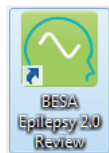
The following **features** are available in the two program types:

Feature	Detection	Review
Automated spike detection	✓	✕
Automated clustering	✓	✕
Automated hyperclustering	✓	✕
Automated seizure detection **New**	✓	✕
EEG review / EEG report **New**	✓	✓
Spike review / Spike report	✕	✓
Seizure review / EEG report **New**	✕	✓

BESA Epilepsy 2.0 provides **4 license schemes**.
Depending on your license the following **features** are enabled:

Feature	Review license	Spike license	Seizure license	Complete license
Automated spike detection	✗	✓	✗	✓
Automated clustering	✗	✓	✗	✓
Automated hyperclustering	✗	✓	✗	✓
Automated seizure detection **New**	✗	✗	✓	✓
EEG review / EEG report **New**	✓	✓	✓	✓
Spike review / Spike report	✗	✓	✗	✓
Seizure review / EEG report **New**	✗	✗	✓	✓

Safety Instructions

Intended Use

- BESA Epilepsy is a medical software product for fast detection, visualization, and evaluation of epileptiform EEG activities recorded non-invasively from the human scalp and stored on computer disk by an independent EEG acquisition system.

- BESA Epilepsy is intended for the Use (MDD 93/42/EEC)

  – For Human Beings
  – and NOT for Animal Beings

- BESA Epilepsy is a software-only product compatible with personal computers running under a Windows operating system.

- BESA Epilepsy is primarily intended to be used as an additional tool for evaluating EEG data recorded during long-term epilepsy monitoring (LTEM), but can also be used for fast EEG review in other settings as specified below.

- BESA Epilepsy does not replace the routine EEG data evaluation as specified by the national and international societies for Clinical Neurophysiology.

- The purpose of BESA Epilepsy is to assist in detecting and evaluating the following epileptiform EEG patterns:

  – Interictal spikes and sharp waves
  – First spike or sharp wave of poly-spikes / sharp waves
  – First spike or sharp wave of generalized discharges
  – Seizures (ictal activity)

- BESA Epilepsy must not be used as monitoring software for vital human functions, for example, in:

  - Intensive care units
  - Neurosurgical units

- BESA Epilepsy should only be used in the following clinical settings:

  - Long-term epilepsy monitoring units, using EEG or video-EEG
  - EEG departments in neurological and psychiatric hospitals
  - Neurological and psychiatric practices that perform EEG examinations

- Surgical decisions must not be based on the evaluation results of BESA Epilepsy alone. All clinical decisions must be based on combining and comparing these results with all available clinical findings, including standard EEG or video-EEG evaluation, neuropsychological examinations, and independent imaging methods.

- BESA Epilepsy must not be used for the following tasks:

  - Detection of very rare events with an occurrence of less than 4 / h
  - Detection of generalized epileptiform patterns with slow onset
  - Localization of a focal irritative zone

- The EEG evaluation on interictal activity in BESA Epilepsy (Spike Review) is based on the spike detection and clustering of at least 4 similar epileptiform spikes or sharp waves within at least one 2 h epoch during the review interval (typically 24 h). Therefore, a routine EEG evaluation (EEG Review) of a period of 2 or 5 minutes at the beginning of each hour of recorded EEG should be performed to double check the existence of focal epileptiform activities. This is especially recommended if no clusters or only a few small clusters are found.

- The EEG evaluation on ictal activity in BESA Epilepsy (Seizure Review) is based on the automatic seizure detection algorithm developed at the Epilepsy Center, Department of Neurology, Universitätsklinikum Erlangen[1]. It is recommended to review the integrated power values in the seizure window in parallel to the EEG data to find ictal activity that might have been missed.

- BESA Epilepsy is intended for EEG evaluation of patients aged more than 2 years in case of a focus on interictal activity (spikes and sharp waves).

- BESA Epilepsy is intended for EEG evaluation of patients aged more than 18 years in case of a focus on the ictal activity (seizures).

---

1 Automatic seizure detection in long-term scalp EEG using an adaptive thresholding technique: a validation study for clinical routine, Rüdiger Hopfengärtner, Burkhard S. Kasper, Wolfgang Graf, Stephanie Gollwitzer, Gernot Kreiselmeyer, Hermann Stefan, Hajo Hamer (Clin Neurophysiol. 2014 Jul; 125(7): 1346-52).

Intended User

- BESA Epilepsy shall not be used by non-experts, users who are not trained in EEG review.

- BESA Epilepsy is only to be used by appropriate trained specialist personnel who also have an understanding of English sufficient to enable them to read the "How To" documents and operate the software

- Users of BESA Epilepsy must consider the national requirements for EEG evaluation independently of the manufacturer's liability

- The BESA GmbH assumes no liability for unauthorized access to this product or unauthorized use. Children, layman and patients shall not use the product

- BESA Epilepsy must not be used as monitoring software for vital human functions, for example, in:

  - Intensive care units
  - Neurosurgical units

Environmental Conditions

- If the product is installed on a PC or notebook within the patient environment, the PC or notebook must either conform to DIN EN IEC 60601-1 medical PC or must be isolated from the patient by means of protection (IEC 60601-1 3rd Edition), for example, using an isolating transformer fixed to the PC or mobile isolating devices for notebooks.

The patient environment is defined as follows:
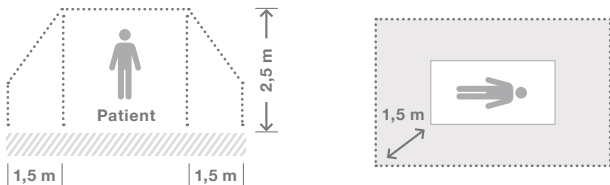
- BESA Epilepsy is intended to be run independently of third-party EEG acquisition and review programs, and supports processing of the following EEG data formats:

  – Alpha-Trace
  – BESA (.besa, .foc)
  – Coherence / Deltamed *
  – Compumedics **
  – EBNeuro **
  – EDF (European Data Format)
  – EGI MFF *

  – Grass-Telefactor / TwinRef
  – Micromed
  – Nicolet Nervus *
  – Nihon Kohden
  – Stellate Harmonie **
  – XLTEK

  * The EEG data format requires reader installation during setup. Check the "Install readers" option at the end of the setup.
  ** The EEG data format requires installation of the corresponding EEG system software.

- BESA Epilepsy requires the EEG data to contain at least 16 scalp electrodes to run spike detection. There is no upper limit to the number of electrodes.

- The seizure detection in BESA Epilepsy was optimized for the subset of electrodes which are the representatives for the

brain activity of the left hemisphere, the right hemispheres and the midline. The quality of the detection depends on the availability of the following channels:

– Left: F11 · FT9 · TP9 · F7 · T7 · P7 · O1 · F3 · C3 · P3
– Right: F12 · FT10 · TP10 · F8 · T8 · P8 · O2 · F4 · C4 · P4
– Midline: Fz · Cz · Pz.

At least one channel of each group must be available.

Installation and De-Installation

• The installation and de-installation of the product must be carried out by the system administrator or an authorized person. This staff bears full responsibility for correct setup of the product within the network.

• Please follow the Installation Instructions being delivered with the product

Product Classification

According to **MDD 93/42/EEC**, Annex IX, rule 10, BESA Epilepsy is a **Class IIa** software product for the detection, visualization, and evaluation of epileptiform activities in human scalp EEG data stored on computer disk.

According to the safety classifications in **DIN EN IEC 62304:2006**, BESA Epilepsy is a **Class A** product (Class A: No injury or damage to health is possible).

The product is non-invasive since it is stand-alone software and does not control any equipment physically connected to the patient. It is designed purely for data analysis. No physical devices are controlled or driven by BESA Epilepsy, nor is any active feedback provided to the patient. Any direct physical damage to the patient, for example, during the EEG recording, can therefore be excluded.

According to **DIN EN IEC 60601-1:2005**, BESA Epilepsy does not affect the possibility of using the computer within the patient environment. BESA Epilepsy does not interfere with other programs or hardware connected to the computer (third-party equipment).

BESA Epilepsy is classified as an "**Analysis unit for long-term EEG data**".

UMDNS code: 16-307
GMDN code: CT112 (software, application program)

Certification

The CE marking certifies that the product fulfills the essential requirements of the Medical Devices Directive **MDD 93/42/EEC**. The number 0197 represents the identification number of the Notified Body.

$C\,E$ 0197

Application Environment

If the product is installed on a PC or notebook within the patient environment, the PC or notebook must either conform to DIN EN IEC 60601-1 medical PC or must be isolated from the patient by means of protection (IEC 60601-1 3rd Edition), for example, using an isolating transformer fixed to the PC or mobile isolating devices for notebooks.

System Requirements

- Operating system: Windows® 8.1, Windows® 7
- CPU: minimum 1 GHz
- RAM: minimum 1 GB
- Display resolution: Minimum 1024 × 768 pixels
- Graphics card: OpenGL 1.1 with 16 MB RAM or more

Disposal Information

The BESA license key and the box must be disposed of according to the national guidelines on environmental protection.

Clinical System Integration

It is recommended to answer the two questions below before you are going to install BESA Epilepsy 2.0.

Where Should I Install BESA Epilepsy?

If you are going to use the product only on a single computer the installation is quite easy. Please run the setup on your computer according the installation instructions in the next chapter.

Where Should I Place the BESA License Key?

If you are going to use the product only on a single computer you connect the BESA license key to a local USB port.

If you are going to integrate the software into a clinical system the images in the next section show the recommended position. Beside this recommendation the dongle can be connected to any computer within the clinical network. In this case it is important that the computer is running 24/7.

Detection　　**Review**　　BESA license key　　Your computer

Examples for Clinical Systems

The EEG system 1 (see image at page 18), e.g. Nihon Kohden, stores the data locally during acquisition and transfers the data after end of recording or after evaluation to the server.

We recommend installing the BESA Epilepsy 2.0 Detection program directly on the acquisition computer for fast access to the data during acquisition. The Detection 1 program can directly analyze the EEG data of the local drive at LTM EEG 1. Detection 2 program analyzes the EEG data of the local drive at LTM EEG 2.

The BESA Epilepsy 2.0 review program can be installed on all computers where the EEG, spike or seizure review is done. In this scenario the physician does the reporting and we install a second copy in the evaluation room.

Note: The license is a floating network license. Using the product at the same time is counted and not the number of installations.

The EEG system 2 (see image at page 19) does not allow installing the BESA Epilepsy 2.0 Detection program directly on the acquisition computer. In this case, you need to choose another computer performing the detections.

The EEG system 3 (see image at page 20), e.g. XLTEK or Nicolet-Nervus, stores the data directly at the server (no local copies). All programs have the same configuration and monitor the server EEG data folder. If you are not allowed to install the detection program at the acquisition unit, please check the **EEG system 4** (see image page 21).

You did not find your system or you still have an idea where to install the programs, please contact our support page at **www.besa.de**.

EEG system 1

Monitoring unit

Station 1

LTM EEG 1

LTM EEG 2

Routine EGG 1

Detection **1**

Detection **2**

Local EEG data
H:\NKT\EEG2100

Local EEG data
H:\NKT\EEG2100

Local EEG data
H:\NKT\EEG2100

Server

BESA
license key

EEG
Server

Server EEG data
\\Server \NKT
**EEG2100 **

BESA Epilepsy
Shared Folder
\\Server \BESA
**Epilepsy Shared **

Physician office

Evaluation room

Review **1**

Review **2**

Physician desk

Evaluation

EEG system 2

Monitoring unit

LTM EEG 1

LTM EEG 2

Station 1

Routine EGG 1

Local EEG data
H:\NKT\EEG2100

Local EEG data
H:\NKT\EEG2100

Local EEG data
H:\NKT\EEG2100

Server

BESA
license key

EEG
Server

Server EEG data
**\\Server \NKT\ EEG2100 **

BESA Epilepsy Shared Folder
**\\Server \BESA Epilepsy Shared **

Physician office

Detection **1**   Review **1**
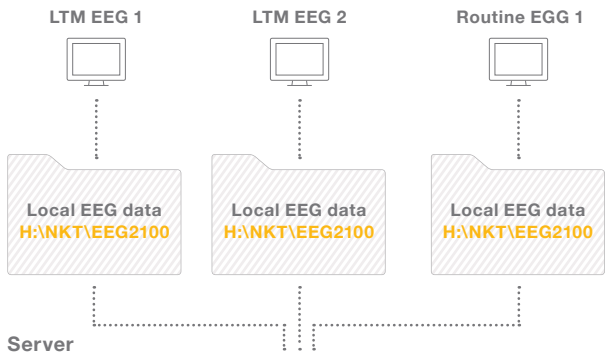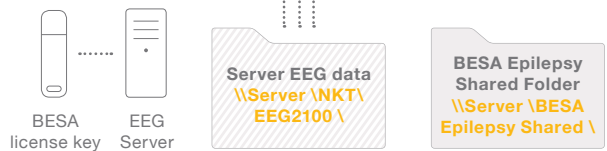
Physician desk

Evaluation room

Detection **2**   Review **2**

Evaluation

EEG system 3

Monitoring unit

Station 1

LTM EEG 1   **LTM EEG 2**   **Routine EGG 1**

Detection **1**   Detection **2**

Server

BESA
license key

EEG
Server

Server EEG data
**\\Server \
EEG Data**

BESA Epilepsy
Shared Folder
**\\Server \BESA
Epilepsy Shared **

Physician office

Evaluation room

Review **1**   Review **2**

Physician desk   **Evaluation**

EEG system 4

Monitoring unit

LTM EEG 1

LTM EEG 2

Station 1

Routine EGG 1

Server

BESA license key

EEG Server

Server EEG data
**\\Server \
EEG Data**

BESA Epilepsy
Shared Folder
**\\Server \BESA
Epilepsy Shared **

Physician office

Detection **1**   Review **1**

Evaluation room

Detection **2**   Review **2**

Physician desk

Evaluation

Installation Instructions

To install **BESA Epilepsy 2.0 March 2016 Patch 8** and **BESA Epilepsy 2.0 March 2016 Examples**, you need to have administrator privileges on your computer. The shown figures are taken from an installation on a computer with the Windows 7 operating system. On other operating systems, the appearance will slightly differ. The instructions start with the program setup, continue with the patch and finally run the tutorial setup.

1. Run the setup file e.g. **BESA_Epilepsy_2.0_March_2016_Setup_Win_x86.exe**.
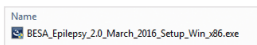
2. The installation wizard starts.
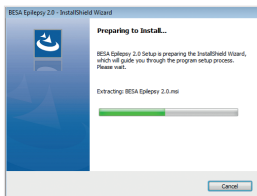
3. The welcome screen is displayed. Press the **Next** button.
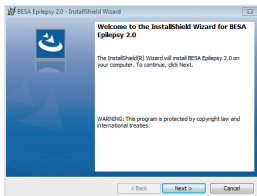
4. Please read the license agreement. If you accept it, select **I accept the terms in the license agreement** and press the **Next** button.

5. The default installation folder of BESA Epilepsy is the **BESA\Epilepsy_2_0** subfolder of your computer **Program Files (x86)** directory. Press the **Next** button to continue.
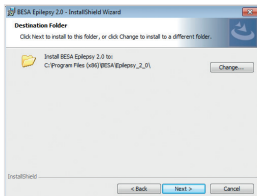
If you would like to install to a different location, press the **Change...** button and specify the desired path.

6. Select the desired setup type. Keep the **Complete** installation for this pre-release and press the **Next** button to continue.
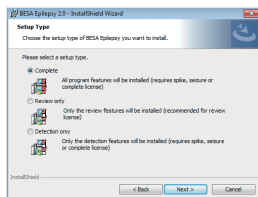
7. BESA Epilepsy is now ready for installation. Press the **Install** button.
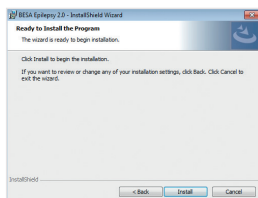
8. BESA Epilepsy is now being installed on your computer.
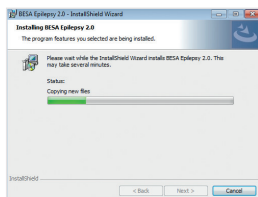
9. Installation of BESA Epilepsy is now complete.

Check the **Install BESA license key drivers** option to install the drivers for the USB license key. If the drivers are already installed, uncheck this option.
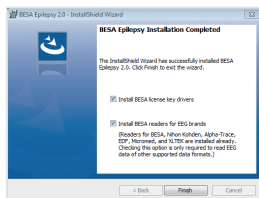
Check the **Install BESA readers for EEG brands** option, if you want to read EEG data of the following data formats:

Coherence/Deltamed, Compumedics, EBNeuro, EGI MFF, Grass-Telefactor/TwinRef, and Stellate Harmonie.

Note for Cadwell and Nicolet-Nervus:
Please skip the reader installation here.

For all other supported data formats (e.g. Nihon Kohden) the readers are already installed and you can uncheck this option.

Press the **Finish** button to proceed with the checked installations or to exit the setup.

10. If the Install **BESA license key drivers** option is checked, the **Sentinel Runtime Installation Wizard** opens. Press the **Next** button to continue. Please follow the on-screen instructions.
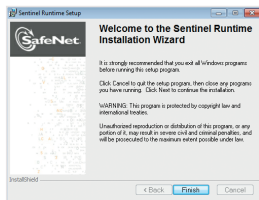
11. The installation of the Sentinel Runtime is now complete. Press the **Finish** button. If you have not checked the **Install readers** option, the BESA Epilepsy setup is now done. Otherwise the setup proceed with the next step.
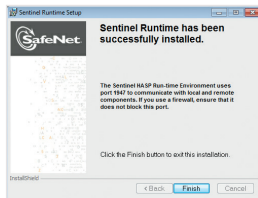
**12.** If the **Install readers** option is checked, the reader installation dialog appears.
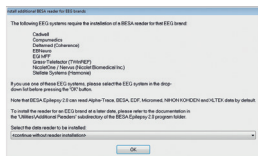
13. Select your data format from the drop-down list and the installation of the reader starts. Please follow the on-screen instructions.
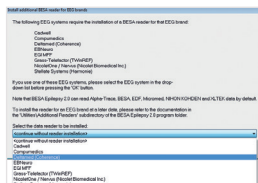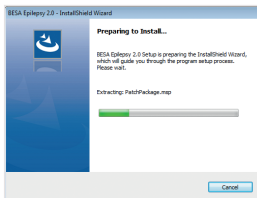
Note: If you want to install additional readers at a later point of time, use the **Install Readers** start menu item in the **BESA → Epilepsy 2.0** start menu group.

The setup installation is complete. Please install the patch to fix some issues with the setup.
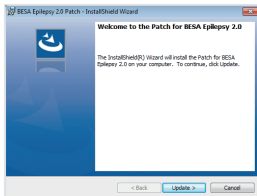
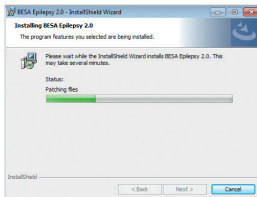14. Run **BESA_Epilepsy_2.0_ March_2016_Patch8_Win_ x86.exe**.
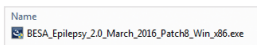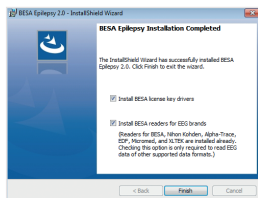

15. The installation wizard starts

16. The welcome screen is displayed. Press the **Update** button.

17. The patch for BESA Epilepsy is now being installed on your computer.

18. Installation of BESA Epilepsy patch is now complete. **Uncheck** both options. Press the **Finish** button to exit the setup. The patch installation is complete.

19. If you like to install BESA Examples data for testing/learning procedures, please run **BESA_Epilepsy_2.0_March_2016_Examples_Win_x86.exe** and follow the on-screen instructions. Otherwise, please proceed with the next step.
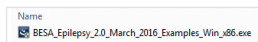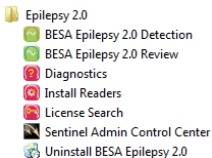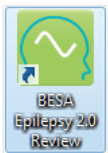

20. Connect the BESA license key (USB key) directly to your computer or a server and wait until Windows completes the configuration of the USB device. If you have trouble with this step, please find more details in the **BESA License Key Manual**.
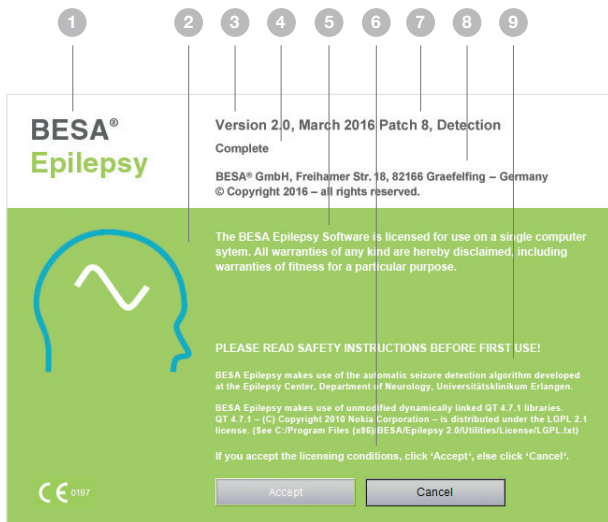
How to Start BESA Epilepsy

Double-click the desktop icons, or click on the start menu group items (image right).

The BESA Epilepsy 2.0 start menu group contains the following items in addition to the program start items:

- **Diagnostics item** allows you to analyze your installation in case of problems with the product.

- **Install Readers** item allows you to install the data readers for the EEG brands Coherence/Deltamed, Compumedics, EB-Neuro, EGI MFF, Grass-Telefactor/TwinRef, Nicolet-Nervus, and Stellate Harmonie. For all other supported data formats (e.g. Nihon Kohden) the readers are already installed.

- **License Search** item allows you to search for your BESA license key.

- **Sentinel Admin Control Center** item allows you to search for and to configure the access to the BESA license key.

- **Uninstall BESA Epilepsy 2.0** item allows uninstalling this product.

The splash screen appears during start up.

BESA®
Epilepsy

Version 2.0, March 2016 Patch 8, Detection
Complete

BESA® GmbH, Freihamer Str. 18, 82166 Graefelfing – Germany
© Copyright 2016 – all rights reserved.

The BESA Epilepsy Software is licensed for use on a single computer sytem. All warranties of any kind are hereby disclaimed, including warranties of fitness for a particular purpose.

PLEASE READ SAFETY INSTRUCTIONS BEFORE FIRST USE!

BESA Epilepsy makes use of the automatic seizure detection algorithm developed at the Epilepsy Center, Department of Neurology, Universitätsklinikum Erlangen.

BESA Epilepsy makes use of unmodified dynamically linked QT 4.7.1 libraries. QT 4.7.1 – (C) Copyright 2010 Nokia Corporation – is distributed under the LGPL 2.1 license. (See C:/Program Files (x86) BESA/Epilepsy 2.0/Utilities/License/LGPL.txt)

If you accept the licensing conditions, click 'Accept', else click 'Cancel'.

[Accept] [Cancel]

CE 0197

1. Program name
2. Program icon
3. Version info
4. License information
5. Safety instructions

6. Startup progress
7. Program type
8. Company information
9. License agreement

Upon success, press the **Accept** button to continue. Press **Cancel** to abort.

If you are using this product for the first time, the database configuration window appears. If you do not know how to proceed, please follow the **How to documents** which introduce the loading of EEG data, detecting and evaluating spikes and seizures.

You are finding the documents in the **C:\Users\Public\ Documents\BESA Epilepsy 2.0\Help** folder or within your started program by doing the following steps. Press the **Cancel** button in the database configuration window and close the database by pressing the **Close DB** button. Select the **Help → Open Documentation Folder (F1)** menu item to open the folder containing the documents.

CE 0197