

# BESA Connectivity 2.0 - Instructions for Use and Intended Use



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## Instructions for Use and Intended Use

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## Description

This document contains the instructions for use and safety instructions, as well as technical description and the intended use and intended user and product classification for the BESA product defined under Product Name.

## Product Name

BESA Connectivity 2.0

The referenced term includes all sub-versions of the product.

# Instructions for Use

This document, and following documents form the complete Instructions for Use for this BESA product:

BESA Connectivity 2.0 - User Manual

BESA Connectivity 2.0 - Update History

BESA License Agreement

BESA Connectivity 2.0 - License Acknowledgements

BESA Product Symbols - Meaning

BESA License Key - Instructions for Use (and within referred documents)

Current and previous versions of documents are available on BESA website: <https://www.besa.de/home/downloads/user-documentation/>

It is mandatory to read the complete Instructions for Use documents, before using the product.

## Manufacturer

BESA GmbH

Freihamer Strasse 18

82166 Graefelfing/Germany

## Life cycle

The life cycle of the product ends on 2028-07-31.

## Safety Instructions and Technical Description

### System Requirements

This BESA product is a stand-alone SW product compatible with personal computers running under the following hardware/OS:

Operating system: Windows® 11 (64bit version, touch not supported)

- CPU: minimum 2.5 GHz, >= 4 cores
- RAM: minimum 8 GB
- Display resolution: minimum Full-HD 1920 x 1080 pixels
- Graphics card: OpenGL 3.3 with 128 MB RAM or more

This BESA product was tested on the following operating system configurations:

- Windows 11 Professional 64bit version 21H2

Please note that changes of the hardware or software platforms (e.g., with patches/updates of antivirus/firewall software, system libraries, firmware, and others) and/or changes to the IT network may result in the possibility of safety and/or security vulnerabilities, and/or reduced functionality of BESA products. It is recommended to use the system combinations as defined within this document.

Please also note that the use of BESA products in an IT-network could result in previously unidentified risks to patients, users or third parties, and that the user is responsible to identify, analyze, evaluate, and control these risks. Any subsequent changes to the IT-network could introduce new risks and require additional analysis.

The BESA License Key is an essential accessory product to BESA products, and shall either be subject to constant supervision, or shall be connected to machines located in areas with access restriction. Failure of the IT-network and/or operating system on which the BESA License Key is used, or failure of the BESA License Key in general, may render BESA products which use the BESA License Key as an accessory product unusable.

## Data Protection

BESA applications offer the possibility to save files that may include „personal data“ as specified in GDPR (Directive 95 /46 EC, General Data Protection Regulation). These files may also include protected health information. Users are strongly advised to inform themselves about applicable regulations. With respect to BESA applications, we especially recommend to not use patient names as part of file names (e.g. for exported data or MRI projects), or to store any data that includes personal data or protected health information on a shared network drive, to which multiple users may have access.

## Use in combination with other products

This BESA product is designed to be used in combination with the following medical device software:

- BESA Research 7.1

This BESA product is designed to be used in combination with the following non-medical software:

- BESA Statistics 2.1

BESA releases are constantly checked with other installations (e.g. MS Office etc.) on the same hardware or software platforms as defined in section System Requirements.

If any incompatibilities are observed, they are documented within the Update History of the product. For further questions and information please use the channels provided on [Home](#) .

## Installation and Un-Installation

The installation and un-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.

This BESA product shall only be installed on PC with password-protected user accounts.

Product updates must also be carried out by the system administrator or an authorized person.

Please note, that in case of any problems during the installation, the setup.exe will trigger a rollback of current changes. In that case, please figure out and eliminate the issue, and run the setup.exe again.

To install the product, please follow these steps:

1. Please download the BESA product from our website:

[Home](#) [BESA Connectivity](#)

2. Run the downloaded setup.exe
3. Please follow the on-screen instructions
4. Towards the end of the installation process, the installation of the BESA License Key setup is triggered, please follow the on-screen instructions, and please refer to “BESA License Key – Instructions for Use” for further information.

Once the installation is complete, proceed with the initial setup as explained in the User Manual.

To un-install the product, please follow these steps:

Un-installation of the product must be carried out by the system administrator or an authorized person. This person bears full responsibility for correct deinstallation of the product within the network.

In the Windows operating system, open “Control Panel > Programs > Uninstall a program”. Search for “BESA Connectivity 2.0”, click on the name and press Uninstall button.

The un-installation wizard will run, uninstalling the program.

### **Exclusions for Use**

Not to be used by children, layman and patients.

### **Contraindication to patients**

N/A

### **Countries and Markets**

This BESA product may be sold globally.

## **Intended Use and Product Classification**

### **Intended Use**

- BESA Connectivity 2.0 is intended for the offline analysis of previously recorded EEG and MEG data files of human beings, and NOT of animal beings.
- BESA Connectivity 2.0 is a stand-alone software product compatible with personal computers running under a Windows operating system.
- BESA Connectivity 2.0 is intended to be run independently of the EEG and MEG acquisition and review programs of other manufacturers.
- BESA Connectivity 2.0 must not be used as monitoring software for vital human functions, for example, in:
  - Intensive care units
  - Neurosurgical units
- BESA Connectivity 2.0 is not for commercial use, e.g. for fee-based analysis services.

### **Intended Purpose**

- The purpose of BESA Connectivity 2.0 is the use as a tool for performing time-frequency analysis and brain connectivity analysis of EEG and MEG data, for research purposes only.
- It is not allowed to use BESA Connectivity 2.0 in a medical environment, or with any intended medical purpose whatsoever.

### **Intended User**

- The intended user is a researcher who is a neuroscience professional with a thorough understanding of the mechanisms underlying the generation of electrophysiological potentials in the human brain. The intended user is expected to be literate in the usage of computer programs in the Windows environment.
  - BESA Connectivity 2.0 is only to be used by appropriate trained specialist personnel who also have an understanding of English sufficient to enable them to read the instructions for use documents and to operate the software.
  - 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 is not liable for the use outside of the rules defined in the instructions for use documents.
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Change History (valid revision number)

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1	Thu, Jul 18, 2024, 15:54:45 PM	>> *Action: approve, VR, Approval: Approved (State: Approval, Thu, Jul 18, 2024, 15:54:36 PM)	None
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Instructions for Use and Intended Use Template	1	Thu, 20 Jun 2024 09:21:07 GMT	None