BESA Statistics 2.1 - Instructions for Use and Intended Use

Documents are subject to workflows, and content shall only be used if the content is approved (indicated by a green ring-symbol)

⊙ Approved, Changed on: February 3rd 2025 at 7:55:45 AM (UTC)

Instructions for 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 Statistics 2.1

The referenced term "BESA Statistics 2.1" includes all sub-versions of the product.

Instructions for Use 🔗

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

BESA Statistics 2.1 - User Manual

BESA Statistics 2.1 - Update History

BESA License Agreement

BESA Product Symbols - Meaning

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

Current and previous versions of documents are available on BESA website:

eIFU Indicator	https://www.besa.de/downloads/user-documentation/

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

At any time during the lifetime of this product, you can request the above-mentioned documents in printed paper form at no additional cost.

Manufacturer 🔗

	BESA GmbH
	Freihamer Strasse 18
	82166 Graefelfing/Germany

Representative inside the European Union 🔗

No	N/A

Life cycle 🔗

The life cycle of the product ends on 2028-12-31.

Incident 🔗

In case of a serious incident or near-incident caused by BESA software, the licensee should directly report to incident@besa.de or follow the guidelines stipulated on the BESA website. (🔗 Incident)

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 64 bit

- CPU: minimum 2 GHz
- 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 Connectivity 2.0

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 .

Application Environment 🔗

Please Note: It is the User's responsibility to ensure the safety of combined medical or medical-&-non-medical-devices particularly installed in the patient environment (whether in institutes, clinics or practitioners' location).

The user of our product has to ensure that such combination fulfil the same safety condition as a single medical device according to IEC 60601-1.

Such combination with any medical device establishes are "in-house medical system" – observe the latest Medical Device Operator Ordinance (e.g. MedBetreiberVerordnung, Germany 2020) or your national Operator Laws.

We recommend you to document / retrace our Software version/updates installed in your facility / network in a MPG-Medizingeräte-Buch (medical facilities book), similar to those needed for hardware.

This BESA product does not affect the possibility of using any medical computer within patient environment.

BESA GmbH is not liable for any use/installation beyond the defined PC network.

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:
   https://www.besa.de/home/downloads/besa-statistics/
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 uninstall the product, please follow these steps:

1. Press the Windows key or select the start icon in the task bar.
2. Choose Settings to open the settings dialog window.
3. Select the entry Apps and scroll down the list of programs until you find the BESA Program you want to uninstall
4. Left-click on the entry and select uninstall to start the uninstallation.
5. Please follow the on-screen instructions.

Exclusions for Use 🔗

Not to be used by children, layman and patients.

Contraindication to patients 🔗

N/A

Manufacture, Transport, Storage and Usage conditions 🔗

Environmental conditions for manufacturing 🔗

N/A

Environmental conditions for Transport, Storage and Usage 🔗

N/A

Countries and Markets 🔗

This BESA product may be sold globally.

Intended Use and Product Classification 🔗

Intended Use 🔗

- BESA Statistics 2.1 is intended for the following use:
  - (a) to find reliable differences between EEG / MEG data of two or more groups / conditions, and
  - (b) to look for reliable correlations between EEG / MEG data and an external factor using a cluster-permutation approach.
- It is not allowed to use BESA Statistics 2.1 directly or indirectly for medical diagnosis and/or treatment of humans. BESA GmbH is not liable for the use of the software beyond the intended research purpose.
- BESA Statistics 2.1 software is licensed for research use only.
- BESA Statistics 2.1 is not for commercial use, e.g., fee-based analysis services.
- BESA Statistics 2.1 is not to be used beyond the scope of the intended use.

Intended Purpose 🔗

- The purpose of BESA Statistics 2.1 is the use as a tool for performing statistical group analysis of EEG and MEG data, for research purposes only.
- It is not allowed to use BESA Statistics 2.1 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 Statistics 2.1 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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Attachments 🔗

None.

∨ Template Change History

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