BESA Statistics 2.1

BESA Statistics provides optimized, user-guided workflows for cross-subject analysis of EEG / MEG data. Cluster permutation statistics ensure robust and reliable results.

Welcome to BESA Statistics

We recommend that you read this document carefully before installing, configuring, and using the product. The document contains firstly the Safety Instructions and general product information.

To familiarize yourself with the usage of BESA Statistics we recommend to carefully read the BESA Statistics 2.1 - User Manual. For further information please refer to the section Instructions for Use within this booklet.

Finally, the section Supported Data Formats lists the input data formats that are supported. BESA Statistics is designed to make using it as easy as possible.

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

Dr. Tobias Scherg
CEO / General Manager

Table of Contents

Safety Instructions [1]

Intended User [1]

The intended user is a neuroscience professional who is knowledgeable in the field of Statistics. He or she 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 appropriately trained specialist personnel who also have an understanding of English sufficient to enable them to read the User Manual and operate the software.

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

System Requirements

BESA Statistics 2.1 is a stand-alone software product compatible with personal computers running under the following hardware/operating system:

Operating system:

Windows® 10 64bit, Touch not supported

CPU:	minimum 2 GHz
RAM:	minimum 8 GB
Display resolution: pixels	minimum 1280x1024
Graphics card: RAM or more	OpenGL 3.3 with 128 MB

Use in combination with other products (1)

The product is allowed to be used in combination with the following software- or hardware-products:
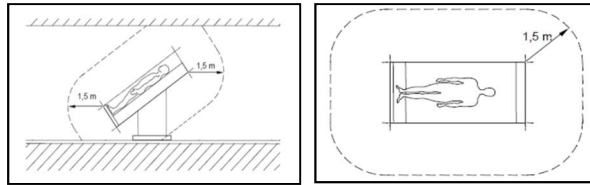
• BESA Research 7.1

Application Environment (1)

a) Definition of Patient Environment

IEC 60601-1-Ed.3.1 - Subclause 3.79 – PATIENT ENVIRONMENT

It is difficult for this standard to define dimensions for the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given below have been justified in practice.

b) 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 fulfils the same safety condition as a single medical device according to IEC 60601-1.

c) Such combination with any non-medical device establishes are "in-house medical system" –observe the latest Medical Device Operator Ordinance (e.g. MedBetreiberVerordnung, Germany 2016) or your national Operator Laws covered by MDD 93/42/EEC.

d) 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.

e) BESA Statistics 2.1 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.

Exclusions for Use [1]

Contraindication to patients

Not applicable.

BESA GmbH is not liable for the use outside of the rules defined in this document.

Intended Use (1)

- 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 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.

Life Cycle (1)

The life cycle of the product is 4 years after release.

Product Classification (1)

According to definitions provided in Regulation (EU) 2017/745; "MDR", BESA Statistics 2.1 is NOT a medical product.

Disposal Information

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

Environmental conditions for Transport, Storage and Usage (1)

Temperature: -20°C to 60°C

Humidity: 30% to 85%

Product Labeling (2)

Product and accessory products are marked by symbols, as described in:

BESA Product Symbols

Installation Instructions

The installation, uninstallation and initial setup of BESA Statistics must be carried out by an administrator or an experienced technician.

BESA Statistics is available as 64-bit program. Please make sure your Windows system supports 64-bit architecture prior to the installation.

1. Please download BESA Statistics 2.1 from our website, https://www.besa.de/downloads/besa-statistics/

2. Run
   BESA_Statistics_2.1_<Month_Year>_Setup_Win_x64.exe

3. Please follow the on-screen instructions.

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

For the installation of the BESA License Key,
please refer to the BESA License Key Manual.

Instructions for Use

Together with this booklet the following documents form the complete Instructions for Use for BESA Statistics 2.1:

BESA Statistics 2.1 - User Manual

BESA License Agreement

BESA License Key Manual

BESA Product Symbols

BESA Statistics 2.1 - Update History

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

Supported Data Formats

BESA Statistics supports the following data formats:

Data type		Data file	Channel file
Sensor level	ERP / ERF	BESA ASCII (*.avr)	BESA channel definition (*.elp)
		BrainVision Analyzer Generic (*.vhdr)	n/a
	TFC ERP / ERF	BESA TFC (*.tfc, *.tfcs)	BESA channel definition (*.elp)
		BrainVision Analyzer Generic (*.vhdr)	n/a
Source level	Source waveforms	BESA swf (*.swf)	Solution file (*.bsa)
	TFC SWF	BESA TFC (*.tfc, *.tfcs)	Solution file (*.bsa)
	Images	BESA source image (*.dat)	n/a
Connectivity		Connectivity data (*.conn)	n/a

See the BESA Statistics 2.1 User Manual for more detailed format descriptions.

References:
(1): BESA Statistics 2.1 - Intended Use+Product Classification
        Revision 002/12.2020; Document ID: 89886
(2): BESA Product Symbols
        Revision 004/06.2020; Document ID: 86227
(3): BESA Statistics 2.1 - User Manual
        Revision 004/12.2020; Document ID: 90175

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