BESA Research 7.1

The most comprehensive signal processing toolbox for EEG / MEG source localization, classic ERP / ERF and brain connectivity analysis

Welcome to BESA Research

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 Research we recommend to carefully work through the BESA Research-Tutorial. For further information please refer to the section Instructions for Use within this booklet.

Finally, the section on Interaction with other BESA Products explains how the different programs are integrated.

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

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Safety Instructions [1)

The referenced term "BESA Research 7.1" includes all sub-versions of the product.

Intended User [1)

The intended user is a physician who is a neuroscience professional with a thorough understanding of the mechanisms underlying the generation of electrophysiological potentials in the human brain. He or she is expected to be literate in the usage of computer programs in the Windows environment.

Results from working with the following module:

• Source Analysis

shall only be used for diagnostic purposes if created by an experienced neurologist with profound knowledge concerning the methods used in said application areas.

BESA Research 7.1 is only to be used by appropriate trained specialist personnel who also have an understanding of English sufficient to enable them to read the Getting Started Guide and operate the software.

Users of BESA Research 7.1 must consider the national requirements for EEG and MEG 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.

System Requirements [1)]

BESA Research 7.1 is a stand-alone SW product compatible with personal computers running under the following hardware / OS:

- Windows® 10   64bit, Touch not supported
- Windows® 7   64bit, Touch not supported
- CPU   minimum 2 GHz
- RAM   minimum 8 GB
- Display resolution   minimum 1280 × 1024 pixels
- Graphics card   OpenGL 2.0 with 16 MB RAM or more

BESA Research 7.1 was tested on the following operating system configurations:

- Windows® 10 Professional 64bit version 2004
- Windows® 10 Professional 64bit version 20H2
- Windows® 7 Professional 64bit Service Pack 1

Please note: 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: 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, orfailure of the BESA License Key in general, may render BESAproducts which use the BESA License Key as an accessory product unusable.

Data Protection [1]

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 [1]

BESA Research 7.1 is designed to be used in combination with the following medical device software:

- BESA MRI 3.0
- BESA Connectivity 1.0

BESA Research 7.1 is designed to be used in combination with the following non-medical software:

- BESA Statistics 2.1
- Matlab Version: any major release between 2006a and 2019b

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.
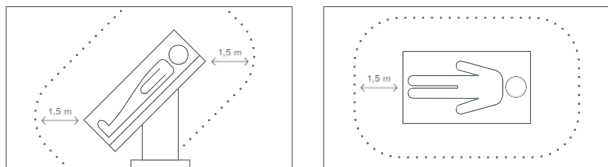
If any incompatibilities are observed, they are documented within the Update History of the product. For further questions and information please contact **info@besa.de**.

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 dimen- sions for the PATIENT ENVIRONMENT given below have beenjustified in practice.

b) **Please Note:** It is the User's responsibility to ensure the safety of combined medical or medical-&-non-medical-devices par- ticularly installed in the patient environment (whether in insti- tutes, 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 an **"in-house medical system"** – observe the latest Medical Device Operator Ordinance (e.g. MedBetreiberVerordnung, Germany 2020) 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 Research 7.1 does not affect the possibility of using any medical computer within patient environment. Our software was tested on the specified IT environment (refer to System Requirements). BESA GmbH is not liable for any use / installation beyond the defined PC network.

Exclusions for Use [1)]

Contraindications to patients: Not applicable.

BESA is not liable for the use outside of the rules definedin this document.

Intended Use [1]

- BESA Research 7.1 is intended for the Use (MDD 93/42/EEC)

    – For Human Beings
    – And NOT for Animal Beings

- BESA Research 7.1 is a software-only product compatible with personal computers running under a Windows operating system.

- The purpose of BESA Research 7.1 is to assist in the analysis of EEG and MEG data by providing tools for the following analysis steps:

    – Raw data review
    – Data pre-processing
    – Artifact rejection and correction
    – Data averaging and ERP analysis
    – 2D and 3D Mapping
    – Source analysis
    – Time-frequency analysis

- BESA Research 7.1 is intended to be used as an additional tool for the clinical evaluation of data for the purpose of analyzing epileptiform EEG and MEG data.

- BESA Research 7.1 does not replace the routine EEG data evaluation as specified by the national and international societies for Clinical Neurophysiology.

- Surgical decisions must not be based solely on the evaluation results of BESA Research 7.1. 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 Research 7.1 is intended to be run independently of the EEG and MEG acquisition and review programs of other manufacturers.

- BESA Research 7.1 must not be used as monitoring software for vital human functions, for example, in:

  – Intensive care units
  – Neurosurgical units

- BESA Research 7.1 is not for commercial use e.g. fee-based analysis services.

- BESA Research 7.1 and its accessory products are not to be used beyond the scope of the intended use.

Life cycle [1)]

The life cycle of the product ends on 2025-05-25.

Product Classification [1)]

BESA Research 7.1 is a medical product according to MDD 93-42-EEC Article 1; Definitions, scope

"medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and / or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

diagnosis, prevention, monitoring, treatment or alleviation of disease	☐ Yes ☒ No
diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap	☐ Yes ☒ No
investigation, replacement or modification of the anatomy or of a physiological process ***)** intended for: investigation of a physiological process	☒ Yes *) ☐ No
'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device	Yes ☐ No ☒

1.1 Duration of application: Short term. Normally intended for continuous use for not more than 30 days.	☒ Yes ☐ No
1.4 Active medical device Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand alone software is considered to be an active medical device.	☒ Yes ☐ No
1.5 Active therapeutical device Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.	☐ Yes ☒ No
1.6 Active device for diagnosis Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities. ***)** intended for: used in combination with other medical devices, to supply information for diagnosing physiological conditions.	☒ Yes *) ☐ No

Product Classification
According to **MDD, Annex IX, III. CLASSIFICATION**

Class I	☐ Yes ☒ No
Class Im	☐ Yes ☒ No
Class IIa	☒ Yes ☐ No
Class IIb	☐ Yes ☒ No
Class III	☐ Yes ☒ No

According to **MDD Annex IX, rule 10 indent 3.**

According to safety classifications in **DIN/ EN IEC 62304:2006+AMD2015**, BESA Research 7.1 is a device of:

The SOFTWARE SYSTEM is software safety class A if:	
the SOFTWARE SYSTEM cannot contribute to a HAZARDOUS SITUATION	☐ Yes ☒ No
the SOFTWARE SYSTEM can contribute to a HAZARDOUS SITUATION which does not result in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM.	☐ Yes ☒ No

The SOFTWARE SYSTEM is software safety class B if:	
the SOFTWARE SYSTEM can contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is non-SERIOUS INJURY.	☒ Yes ☐ No

The SOFTWARE SYSTEM is software safety class C if:	
the SOFTWARE SYSTEM can contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is death or SERIOUS INJURY.	☐ Yes ☒ No

It is a pure data analysis software, no physical devices are being controlled or driven by BESA Research 7.1, nor is any active feedback provided to the patient. Any direct physical damage to the subject can therefore be excluded.

BESA Research 7.1 is a product for analyzing neurophysiological data that may be used in the field of scientific research, and for providing assisting information supporting the diagnosing of disorders in neural processes by analyzing such data.

- UMDNS code: 16-307
- GMDN collective term: CT112
  (Software, application program)

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 Labelling [2]

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

- BESA Product Symbols

Installation Instructions

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

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

- BESA Research 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.

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

1. Please download BESA Research 7.1 from our website, **https://www.besa.de/downloads/besa-research/ besa-research-7-1/**.

Run **BESA_Research_7.1_November_2021_Full_Setup_ Win_x86.exe** for the full setup, or **BESA_Research_7.1_ November_2021_Setup_Win_x86.exe** for the reduced setup without age-appropriate template head models.

2. Please follow the on-screen instructions.

3. Towards the end of the installation process, a dialog window opens to perform the setup of the MATLAB interface. Please follow the on-screen instructions.

   Important note: The corresponding dialog window might open in the background (behind the InstallShield Wizard window). In this case, please bring it to the foreground by selecting the BESA icon from the taskbar.

4. Once the installation is complete, a second setup will open automatically for installing the age-appropriate template head models.

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

Uninstallation   Instructions

The uninstallation of BESA Research must be carried out by an administrator or an experienced technician.

To uninstall BESA Research, please follow the steps below:

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 BESA Research.

4. Left-click on BESA Research and select uninstall to start the uninstallation.

5. Please follow the on-screen instructions.

After successful uninstallation, the entry BESA Research will not be present in the list of installed apps anymore.

To uninstall the batches, scripts etc. of the program please proceed to **C:\Users\Public\Documents\BESA** and delete the folder **Research_7_1** manually.

Please note: other users may have used this directory as well, to make sure that no such data and/or personal settings aredeleted unintentionally.

To uninstall your personal settings of the program please proceed to **C:\Users\<your user name>\Documents\BESA** and delete the folder **Research_7_1** manually.

(In the text above, replace <your user name> with your user name. Also, the drive letter C: provided here may be different on your computer depending on your Windows setup.)

To ensure that the uninstallation is complete please proceed to **C:\Program Files (x86)\BESA** to delete the installation folder **Research_7_1** manually.

To uninstall the BESA License Key drivers, please refer to the BESA License Key booklet, section Uninstallation Instructions.

Microsoft Visual C++ Redistributables are installed alongside BESA Research software. Please make sure that these redistributables are not used by other software packages before uninstallation.
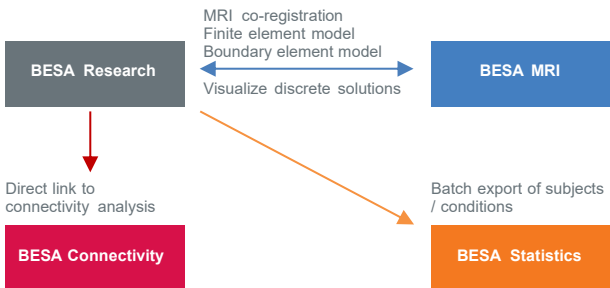
Instructions for Use

Together with this booklet the following documents form the complete Instructions for Use for BESA Research 7.1:

• BESA Research 7.1 - Tutorial
• BESA Research 7.1 - Update History
• BESA Research 7.1 - Reader Documentation
• BESA Research 7.1 - Getting started
• BESA - Quick Guide on 3D Maps
• BESA Research 7.1 - License Acknowledgements
• BESA License Agreement
• BESA License Key Manual
• BESA Product Symbols

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

Interaction With Other BESA Programs

BESA Research integrates with the other BESA Research programs BESA MRI, BESA Connectivity, and BESA Statistics for MRI co-registration and BEM / FEM, brain connectivity analysis, and statistical analysis.

To start **MRI co-registration**, use the menu **File → MRI Coregistration** in the BESA Research main program. After co-registration, the MRI images and – if applicable – the FEM and / or BEM will automatically be available in BESA Research. For **BESA Statistics**, use batch commands to automatically export data in the right format, whether source waveforms, volume images, signal or time-frequency data. If you work with sensor data or discrete sources, add one file that details the channel configuration to the data export folder (either using **File → Save Solution in Source Analysis, or File → Head Surface Points … → Save All Files in Head Coordinates**). Start **BESA Connectivity** directly from the Coherence dialog.

REFERENCES
1) BESA Research 7.1 – Intended Use + Product Classification
   Revision 006/10.2021; Document ID: 86892
2) BESA Product Symbols
   Revision 005/09.2021; Document ID: 86227
3) BESA Research 7.1 – Requirement Specification
   Revision 007/07.2021; Document ID: 86893

CE 0197

The CE marking certifies that this 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.