BESA Connectivity 1.0

The comprehensive toolbox for state-of-the-art brain connectivity analysis in sensor space and source space

Welcome to BESA Connectivity

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 Connectivity we recommend to carefully read the BESA Connectivity - User Manual. For further information please refer to the section Instructions for Use within this booklet.

Finally, the section on Interaction with BESA Research explains how the two programs are integrated. BESA Connectivity 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 Use [1)]

The intended user is a neuroscience professional with a reasonable knowledge concerning frequency data generated in neurophysiological recordings of human brain activity. He or she is expected to be literate in the usage of computer programs in the Windows environment.

BESA Connectivity is only to be used by appropriate 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 Connectivity 1.0 is a stand-alone SW product compatible with personal computers running under the following hardware/OS:

- Windows® 10 – 64bit, Touch not supported
- Windows® 8.1 – 64bit, Touch not supported
- Windows® 7 – 64bit, Touch not supported
- CPU: minimum 2 GHz
- RAM: minimum 4 GB
- Display resolution: minimum 1280 × 1024 pixels
- Graphics card: OpenGL 2.0 with 16 MB RAM or more

Use in combination with other products [1)]

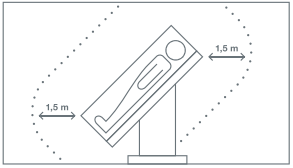
The product is allowed to be used in combination with following software- or hardware-products:

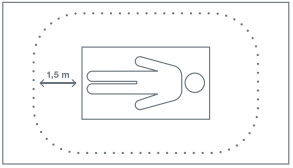
- BESA Research 7.0
- BESA Research 7.1

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 an **"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 Connectivity 1.0 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 is not liable for the use outside of the rules defined in this document.

Intended Use [1)]

- BESA Connectivity 1.0 is intended for the Use (MDD 93/42/EEC)

  – For Human Beings
  – And NOT for Animal Beings

- BESA Connectivity 1.0 is a stand-alone software product compatible with personal computers running under a Windows operating system.

- The purpose of BESA Connectivity 1.0 is to assist in the analysis of EEG and MEG data by providing tools for the following analysis steps:

  – Time-frequency analysis
  – Brain connectivity analysis

- BESA Connectivity 1.0 is intended to be run independently of the EEG and MEG acquisition and review programs of other manufacturers.

- BESA Connectivity software is licensed for research use only. It is not allowed to use the BESA Connectivity software 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.

Life cycle [1)]

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

Product Classification [1)]

BESA Connectivity 1.0 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	☒ 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

MDD 93-42-EEC ANNEX IX CLASSIFICATION CRITERIA

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.	☐ 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 12

According to safety classifications in **DIN/EN IEC 62304:2006+AMD1:2015**, BESA Connectivity 1.0 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 Connectivity 1.0, nor is any active feedback provided to the patient. Any direct physical damage to the subject can therefore be excluded.

BESA Connectivity 1.0 is a product for analyzing neurophysiological data.

- UMDNS code: 17-222 Information System
- GMDN: 17-222 Information System
- 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 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 Connectivity 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 Connectivity 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 Connectivity 1.0 from our website, **https://www.besa.de/downloads/besaconnectivity/**

2. Run **BESA_Connectivity_1_0_November_2019_Setup_Win_x64.exe** and follow the on-screen instructions.

3. 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 Connectivity 1.0:

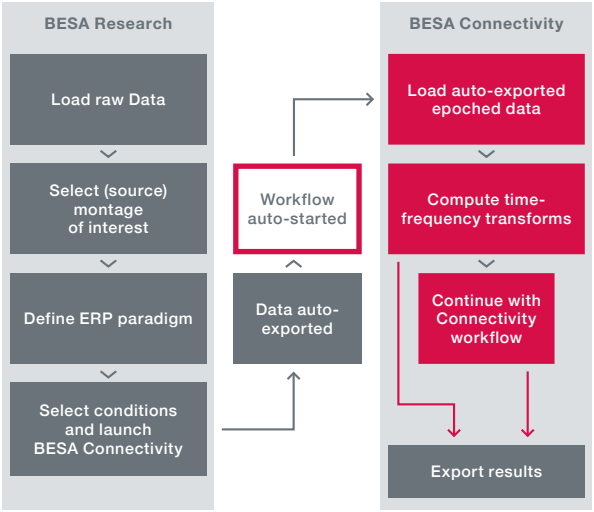
- BESA Connectivity 1.0 - User Manual
- BESA License Agreement
- BESA License Key Manual
- BESA Product Symbols
- BESA Connectivity 1.0 - Update History

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

Interaction with BESA Research

Definition of epoched data for connectivity analysis is performed in the ERP module of BESA Research.

When launching BESA Connectivity, epoched data are auto-saved in the current montage, and the workflow for time-frequency analysis in BESA Connectivity is started.



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REFERENCES

1) BESA Connectivity 1.0 – Intended Use + Product Classification
Revision 004/12.2019; Document ID: 83528
2) BESA Product Symbols
Revision 004/06.2020; Document ID: 86227
3) BESA Connectivity 1.0 – Requirement Specification
Revision 002/10.2019; Document ID: 83529

CE

The CE marking certifies that this product fulfills the essential requirements of the Medical Devices Directive MDD 93/42/EEC.

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