BESA MRI 3.0

Creating individual BEM and 4-layer FEM models made easy: superior source analysis results considering individual anatomy

Welcome to BESA MRI

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 MRI we recommend to carefully read the BESA MRI-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 MRI 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

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Safety Instructions [1)]

Intended User [1)]

- The intended user is a neuroscience professional who is trained in the review of MRI images. He or she is expected to be literate in the usage of computer programs in the Windows environment.

- BESA MRI 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.

- Users who use BESA MRI in combination with BESA Research must consider the national requirements for EEG and MEG evaluation independently of the manufacturer's liability.

- 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 MRI 3.0 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

Use in combination with other products [1)]

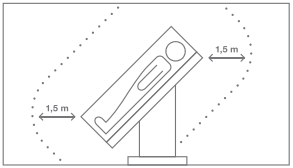
The product is allowed to be used in combination with following software- or hardware-products:

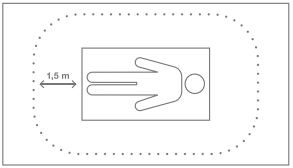
- BESA Research 7.0
- BESA Research 7.1

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 MRI 3.0 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)]

Contraindication to patients: Not applicable.

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

Intended Use [1)]

- BESA MRI 3.0 is intended for the Use (MDD 93/42/EEC)

  – For Human Beings
  – And NOT for Animal Beings

- BESA MRI 3.0 is a stand-alone SW product compatible with personal computers running under a Windows operating system.

- The purpose of BESA MRI 3.0 is to assist in the analysis of EEG and MEG data by providing tools for the following analysis steps:

  – Segmentation of MRI data of human heads
  – Coregistration of EEG and MEG sensor positions with MRI data

- The segmentation component of BESA MRI 3.0 imports digital MRI data, segments and labels different brain and head tissues, transforms the MRI data into ACPC- and Talairach spaces, and renders the scalp and cortical surfaces.

- The coregistration component of BESA MRI 3.0 imports EEG electrode and/or MEG sensor coordinates and fits these to the scalp surface provided by the segmentation component. Optionally, it computes an EEG and/or MEG lead field table for the head tissue segmentation provided by the segmentation component. BESA MRI 3.0 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 MRI 3.0 segmentation requires a patient age of at least 10 years.
- BESA MRI 3.0 alone does not provide any diagnostic conclusion about the subject's condition.
- BESA MRI 3.0 does not replace the routine EEG data evaluation as specified by the national and international societies for Clinical Neurophysiology.
- BESA MRI 3.0 is not for commercial use e.g. fee-based analysis services.
- BESA MRI 3.0 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 MRI 3.0 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 *) 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

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. *) intended for: used in combination with BESA Research 7.x. 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 MRI 3.0 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 MRI 3.0, nor is any active feedback provided to the patient. Any direct physical damage to the subject can therefore be excluded.

BESA MRI 3.0 is a product for analyzing neurophysiological data.

- UMDNS code: 16-307
- GMDN: 35163
- 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 MRI 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 MRI 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 MRI 3.0 from our website, **https://www.besa.de/downloads/besa-mri/**

2. Run **BESA_MRI_3_0_May_2020_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 MRI 3.0:

- BESA MRI 3.0 - User Manual
- BESA MRI 3.0 - MRI Data Recommendations
- BESA License Agreement
- BESA License Key Manual
- BESA Product Symbols
- BESA Update History

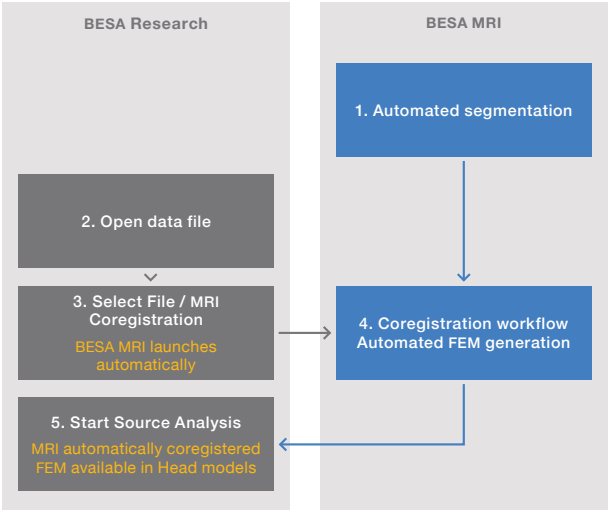
At any time during the lifetime of this product, you can request the above-mentioned documents in printed paper form at no additional cost.

Interaction with BESA Research [3)]

As a result of the segmentation workflow, BESA MRI provides Talairach-transformed MRI data as well as segmented surfaces of brain and head.

Furthermore, as a result of the coregistration workflow, BESA MRI provides coregistration information for these data with a sensor cloud, and individual head models.

All these can be used in BESA Research for source analysis and source imaging. For the smoothest interaction between them, follow the steps below.



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REFERENCES

1) BESA MRI 3.0 – Intended Use + Product Classification
Revision 006/06.2020; Document ID: 86864
2) BESA Product Symbols
Revision 004/06.2020; Document ID: 86227
3) BESA MRI 3.0 – Requirement Specification
Revision 002/08.2019; Document ID: 86865

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.

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