



 **NEUROSPEC**

Research Neurosciences

BESA MRI 2.0

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

international edition



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 Installation Instructions. The Getting Started Guide explains the most important things you need to know to get going; BESA MRI is designed to make using it as easy as possible.

Finally, the section on Interaction with BESA Research explains how the two programs are integrated, and the Quick Reference provides additional information of interest.

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

A handwritten signature in black ink that reads "Tobias Scherg". The signature is written in a cursive, flowing style.

Dr. Tobias Scherg
CEO/General Manager

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Safety Instructions

Intended Use

- BESA MRI is intended for the Use (MDD 93/42/EEC)
 - For Human Beings
 - But NOT for Animal Beings
- BESA MRI is a software-only product compatible with personal computers running under a Windows operating system.
- BESA MRI alone does not provide any diagnostic conclusion about the subject's condition. The analysis results of BESA MRI can be used for diagnosis only when combined with the application BESA Research.
- The segmentation component of BESA MRI 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.
- BESA MRI segmentation requires a patient age of at least 10 years.
- The coregistration component of BESA MRI 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 GmbH is not liable for the use of the software beyond the intended purpose.

Intended User

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

Product Classification

BESA MRI 2.0 is a medical product intended for the use for human beings for the medical purpose of the investigation of a physiological process. According to MDD 93/42/EEC, Annex IX, rule 10, BESA MRI is a Class IIa software product for the preprocessing and segmentation of human scalp MRI data stored on computer disk with the following properties:

1. Duration of application: short term
2. Non-invasive (stand-alone software not controlling any equipment physically connected to the patient).
3. Active medical device since the PC needs electrical supply
4. Used to supply information for detecting and diagnosing physiological conditions.

BESA MRI is analysis software 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 neuroanatomical data. BESA GmbH is not liable for the use of the software beyond the intended purpose.

According to safety classifications in **DIN/EN IEC 62304**, BESA MRI is a **Class A** product (class A: no injury or damage to health is possible): It is designed purely for data analysis. No physical devices are controlled or driven by BESA MRI, nor is any active feedback provided to the patient. Any direct physical damage to the subject can therefore be excluded.

According to UMDNS BESA Research is classified as
“Analysis unit for long-term EEG data”

- UMDNS code: 16-307
- GMDN: 35163
- GMDN collective term: CT112 (Software, application program)

Application Environment

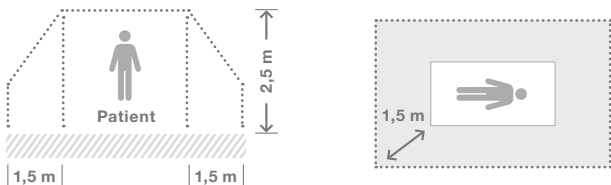
According to **DIN EN IEC 60601-1:2005**, BESA MRI does not affect the possibility of using any computer within patient environment. Other programs or hardware connected to the computer (third party equipment) may not be suitable for use within the patient environment.

If the product is installed on a PC or Notebook within the patient environment, the PC/Notebook must conform either

- a. to DIN EN IEC 60601-1 medical PC or
- b. 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.

Please note: It is User’s responsibility to ensure the safety of combined medical-non-medical-devices (whether in institutes, clinics or practitioners’ location).

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



System Requirements

BESA MRI 2.0 is designed to be used for the following hardware / OS:

- Windows® 10 (Touch not supported)
- Windows® 8.1 (Touch not supported)
- Windows® 7 – 32 bit and 64 bit versions
- Processor: minimum 2 GHz
- RAM: minimum 4 GB
- Display resolution: minimum 1280 × 800 pixels
- Graphics card supporting OpenGL 1.1 with 16 MB RAM or more

Disposal Information

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

Installation Instructions

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

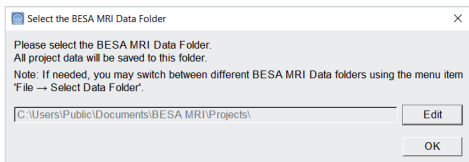
- The BESA GmbH assumes no liability for unauthorized access to this product or unauthorized use. Children, laymen and patients shall not use the product.
 - Product updates must also be carried out by the system administrator or an authorized person.
 - If the product is installed on a PC or Notebook 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 insert the installation USB stick into your computer. Browse to the Setups folder. If you have downloaded BESA MRI 2.0 from our website, browse to the Download folder.
 2. Run **BESA_MRI_2.0_Jan_2017_Setup_Win_x64.exe** for the 64 bit version (recommended), or **BESA_MRI_2.0_Jan_2017_Setup_Win_x86.exe** for the 32 bit version.
 3. Please follow the on-screen instructions.
 4. Once the installation is complete, proceed with the initial setup as explained in the following chapter.

Getting Started

Specifying the BESA MRI Data Folder

As initial configuration step, the BESA MRI Data Folder must be specified (for details see User manual chapter 7.1). This is the folder where BESA MRI stores all project and result data to and reads from (typically on the server).

When starting the program for the first time, the following dialog box appears:

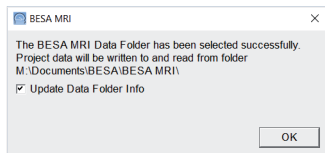


The BESA MRI Data Folder is preselected to All Users on the local PC (shown above for Windows 7). However, it is recommended to create the BESA MRI Data Folder on your server where it is accessible to all users from anywhere in the local network. For more details, see User Manual chapters 6.4.1 and 7.1.

Press the **OK** button if you want to use the preselected local folder in All Users.

Press the **Edit** button to create your BESA MRI Data Folder elsewhere, e.g. on a server.

When the selection is accepted, the following confirmation dialog appears:



Press the **OK** button.

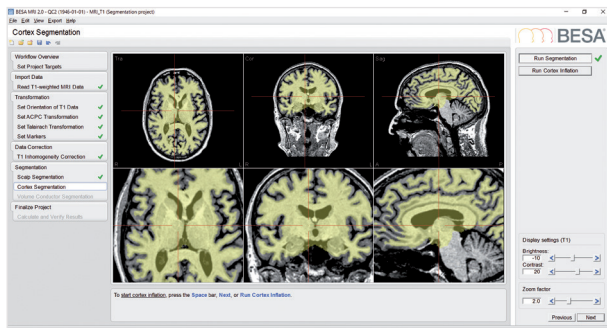
BESA MRI is now configured to start projects.

Notes:

1. The procedure to define the shared BESA MRI Data folder on the server needs to be carried out only once at each PC where you install BESA MRI, i.e. when starting the program for the first time.
2. When switching between BESA MRI Data folders, it is recommended to leave the tick mark on to update all existing projects in the new BESA MRI Data folder (see chapter 7.1).

Workflow Concept and Screen Elements

BESA MRI uses a modern workflow concept that guides you through all the worksteps needed to complete a project, suggests and explains necessary inputs and user actions, and performs many worksteps automatically. At any time, you may interrupt and inspect earlier worksteps or redo them with modified input parameters if required.



A workflow consists of a series of worksteps that have to be done to finalize a project. Each workstep realizes a set of user interactions needed to achieve the workstep-specific result. Some worksteps can be run in automated processing mode with preset parameters, e.g. inhomogeneity correction and segmentation. Thus, only a few user interactions are needed during the initial worksteps.

When pressing the **Next** button or hitting **Space** the next workstep is loaded, proceeding through the workflow steps. The layout of the BESA MRI screen is optimized for this workflow concept. The workflow menu - as shown on the left in the **Workflow Window** - gives an overview over all the worksteps to be done in the selected project (see User Manual chapter 5.1). The workflow menu can be used to switch between the worksteps. For example, you may redo an earlier step with different or advanced parameters and continue with automatic processing of all subsequent steps as defined before.

The current results during a workstep are shown in the **Main Window** in the center. The **Information Window** below provides advice and help for the current workstep. During each workstep a dedicated dialog is shown in the **Interaction Window** on the right to allow for optimized user interaction relevant for the current workstep. The interactions required during a workstep are sequentially aligned from top to bottom of the Window. After completing all interactions, press the **Next** button at the bottom or hit **Space** to proceed to the next workstep. Press the **Previous** button to go back one workstep. After completing the last workstep of the workflow, press the **Finish** button at the bottom of the Interaction Window to save all data created during the project. This allows reloading the full workflow of a project with all worksteps at any time later.

Two workflows are available in BESA MRI:

Project type	Initiate by selecting button
Segmentation	Start New Segmentation
Coregistration	Start New Coregistration

Quick Reference

Supported Data Formats

BESA MRI supports the following data formats:

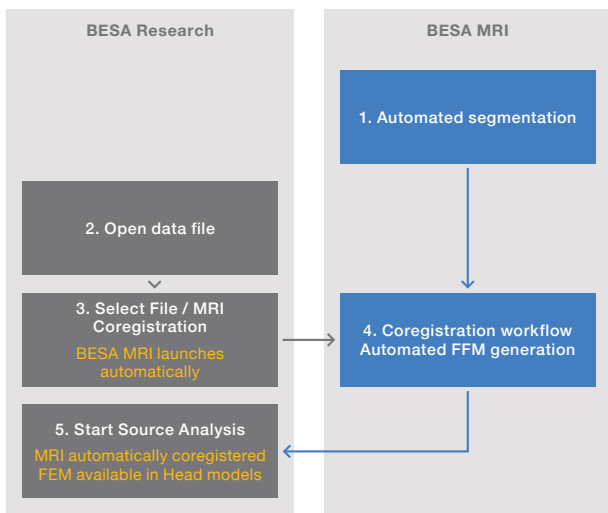
Format	Note
DICOM	<p>If only one scan is in the data folder: Select any DICOM file</p> <p>If several scans are in the data folder:</p> <p>Use file type “DICOM folder”. This will bring up a dialog summarizing the available scans where you can choose</p>
ANALYZE	Select the header (*.hdr) file of the subject’s MRI
NIFTI	Select the NIFTI (*.nii) or the compressed NIFTI (*.nii.gz.) file of the subject’s MRI
BrainVoyager	Select the vmr file. Note that a 1mm isovoxel resolution is assumed.

Interaction with BESA Research

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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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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Document name	BESA MRI 2.0 – Booklet / int. edition
Revision number	001
Revision date	4 April 2017

