



## **Urgent Field Safety Notice**

Note on product usage and software update

regarding

BESA Research 7.1 September 2020

**Graefelfing, 10<sup>th</sup> June 2021**

**Sender:** BESA GmbH, Freihamer Straße 18, 82166 Graefelfing, Germany

**Recipient:** All clinical users of the software BESA Research 7.1 September 2020 who use the software in combination with BESA MRI

**Dear BESA Research customer,**

I am writing to you today to inform you of a software issue in the product BESA Research 7.1. This e-mail is relevant to you if you or someone in your team uses BESA Research for source localization of EEG or MEG data. The affected software version is BESA Research 7.1 September 2020.

### **Problem description**

If individual head models for two different patients are used for source localization in the same session, there is a risk that the wrong head model is used for a patient. The problem occurs in the following scenario:

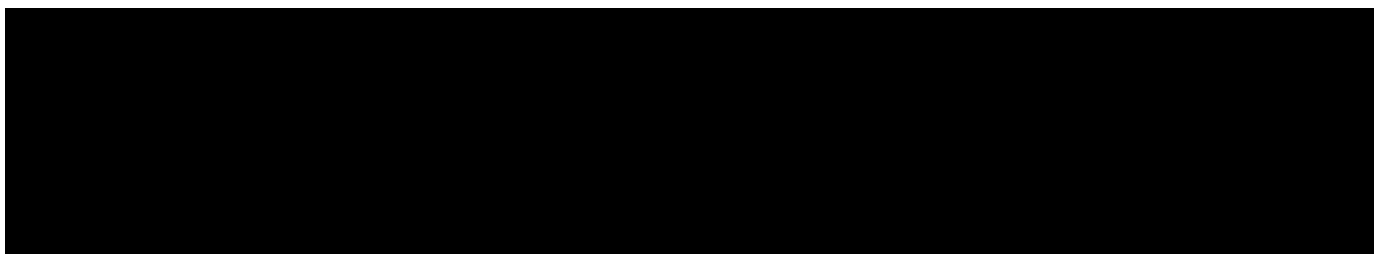
If individual head models were calculated for at least two patients; and a source analysis was done on the first patient with individual head model; then the Source Analysis module is **not** closed before the second patient is opened in the BESA Research software, data for the second patient is then loaded into the Source Analysis module, and the individual head model is selected for the second patient; then, the head model of the first patient is used for source localization, not that of the second patient. If the Source Analysis module is closed before switching to the second patient, the problem does not occur.

### **Hazard**

The potential hazard is a wrong localization of brain activity, e.g. of an interictal epileptic spike. This can lead to a wrong interpretation of the EEG / MEG data.

### **Probability that the problem occurs**

The problem will only occur if the Source Analysis module is not closed before switching to the new patient. It will also only occur if both patients have individual head models associated with them via co-registration done with BESA MRI.





### **Preventing and corrective action**

BESA GmbH has issued a maintenance release that will fix the issue. We urge all customers of BESA Research 7.1 to update their software. Until then, please ensure that the Source Analysis module is closed before switching patients if you work with individual head models. To close the Source Analysis module, you can use the menu entry *File/Exit* or the "x" button at the top right of the Source Analysis window.

### **Transmission of this Field Safety Notice:**

Please also advise any other users of BESA Research in your lab to perform this preventive action when performing source localization. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.

We apologize for the inconvenience this may cause you, and we will notify you as soon as the maintenance release is available.

Please keep this information at least until the measure has been completed.

The appropriate Regulatory Agency has been notified.

### **Contact reference person:**

**Dr. Tobias Scherg**

E: [tobias.scherg@besa.de](mailto:tobias.scherg@besa.de)

T: +49 89 8980 9966

**BESA GmbH**

Freihamer Strasse 18

82166 Graefelfing/Germany