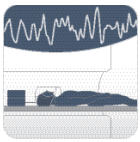

EEG & fMRI

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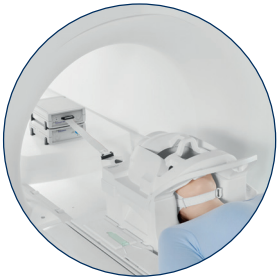
Performing simultaneous EEG-fMRI measurements

Conditions for the safe use of BrainAmp MR amplifiers and accessories in the MR environment



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Contents

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1. About this document

This document describes the essential conditions for the safe use of the BrainAmp MR system in the MR environment. Read these safety instructions carefully to prevent personal injury and damage to property.

1.1 Safety in the MR environment

- Local MR safety rules must be observed at all times.
- The instructions in this document are intended to complement the safety instructions of the scanner manufacturer, they do not replace them.
- It is recommended that all people involved in using the BrainAmp MR / MR plus / ExG MR in an MR environment have previously acquired the status of an MR authorized person or MR operator via the training provided by the local imaging facility.

1.2 Using Brain Products equipment safely in the MR environment

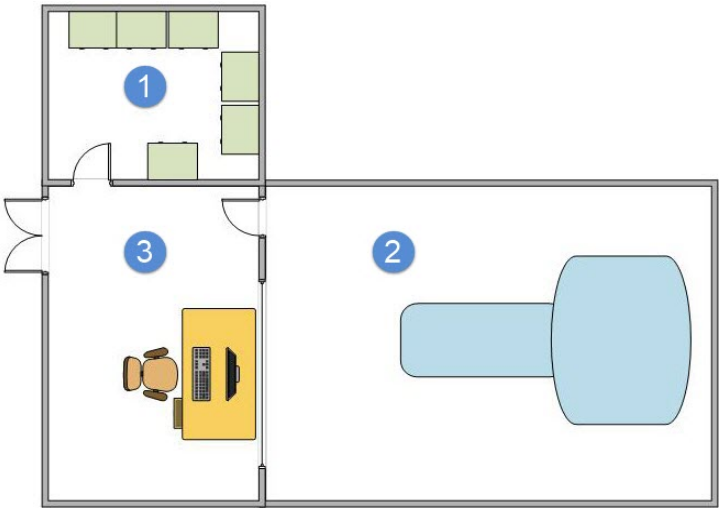
- Initial training on using the BrainAmp MR family of amplifiers in the MR environment will be provided during installation by a Brain Products Certified Distributor or Brain Products Personnel. It is the responsibility of the research organisation to make sure that new personnel are trained in the appropriate use of the BrainAmp MR family of amplifiers in the MR environment.
- These safety instructions are intended for surface EEG and the measurement of peripheral physiology via Brain Products' sensors.
- The instructions provided in this document apply to Brain Products equipment only.
- The use of electrical stimulation equipment, e.g. transcranial electrical stimulation or electrical nerve and muscle stimulation, during simultaneous EEG-fMRI is outside of the intended use of our equipment and is not covered by this document.
- The computer connected to the amplifier should at a minimum fulfill the IEC/EN 62368-1 or IEC/EN 60950-1 safety standard.
- It is assumed that you have the required specialist knowledge in handling the product and accessories. Brain Products does not accept any liability for loss or damage resulting from a failure to follow these safety instructions.
- If you have any questions about the content of this document please contact the Brain Products Technical Support team using the following email address: techsup@brainproducts.com.

2. Terminology

The following provides a guide for terminology used within this manual.

2.1 MR facilities

The image shows an example of a scanner facility layout. The details below provide a recommendation for where to place the various components of the Brain Products EEG system.



1	**Technical room** (cabinets): SyncBox scanner interface
2	**MR scanner room**: BrainCap MR, BrainAmp MR, PowerPack
3	**Control room** (operator): EEG Recording PC, PC-Interface (BUA), SyncBox main unit, TriggerBox

2.2 Definitions from ASTM international standard F2503-13

Term	Description
MR environment	The three dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.
 MR safe	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.
 MR conditional	An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radio frequency fields. Additional conditions, including specific configurations of the item, may be required.
 MR unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

2.3 Terms used in this document

Term	Description
MR authorized person	This person must have passed appropriate local screening for access to the MR environment.
MR operator	An MR authorized person who is also entitled to operate the MRI equipment.
Static magnetic field (B0)	The constant, homogeneous magnetic field of the scanner. It does not change in intensity or direction over time. Measured in Tesla (T).
Radio Frequency (RF) field (B1)	A radio frequency electromagnetic field applied during imaging (e.g. excitation pulses, inversion pulses, etc).
Gradient field	Spatially varying magnetic field used during scanning to manipulate the resonance frequency across an object.
High Field (HF)	MR scanners with a static field strength of up to 3T.
Very High Field (VHF)	MR scanners with a field strength between 3T and 7T.
Ultra high field (UHF)	MR scanners with a static field strength of 7T or higher.
Specific Absorption Rate (SAR)	Measure of the rate at which RF energy is absorbed per unit of tissue mass (W/kg), it can induce heating and can lead to tissue damage.

3. Brain Products MR series of amplifiers and associated equipment

3.1 Product labeling

All components of the MR series of amplifiers carry a label related to their safety properties in the MR environment. ASTM 2503-13 distinguishes three categories regarding the safety properties of items taken into the MR environment. Equipment that is labeled as **MR unsafe** must not enter the MR scanner room. Only use **MR conditional** or **MR safe** equipment in the MR scanner room. The definitions of MR unsafe, MR safe, and MR conditional are provided in the terminology section and are in line with the standard industry definitions.

Please note that all MR conditions specified in this document apply to all items that are labeled as MR conditional. Specific conditions for sequences, coils, field strengths, and positioning of the EEG equipment can be found in the respective sections of this document. If these guidelines are followed, all products labeled as MR conditional can be used safely in the MR environment.

Table 3.1: Labeling of the BrainAmp MR system components in relation to ASTM 2503-13 MR safety categories.

Article name	Article number	MR label
BrainAmp MR amplifier (32 channels)	BP-01830	
BrainAmp MR plus amplifier (32 channels)	BP-01840	

Article name	Article number	MR label
BrainAmp ExG MR amplifier	BP-01836	
PowerPack	BP-02620	
PowerPack Cable	BP-02640	
BrainAmp Connection cable bundled (10 cm)	BP-345-2000	
Ribbon Cable (30 cm)	BP-02400-NN	
Ribbon Cable (100 cm)	BP-02410-NN	
Fibre Optic Cable (20 m)	BP-02310	
ExG Aux Box MR Set	BP-110-4000	

Article name	Article number	MR label
BrainCap MR (32 channels)	BP-330-4000	
USB adapter (BUA 64)	BP-02041	
USB adapter (BUA 128)	BP-02051	
Dual USB adapter	BP-02070	
SyncBox (and associated cables)	BP-02676	
SyncBox scanner interface (and associated cables)	BP-02677	
Signal Tester BrainAmp Standard/DC/MR/MRplus (MR)	BP-210-4010	 (from January 2014)

Article name	Article number	MR label
Signal Tester BrainAmp ExG/ExG (MR)	BP-210-4000	 (from January 2014)
Respiration Belt MR pneumatic sensor	BP-280-0009	
Respiration Belt MR transducer	BP-280-0007	
GSR sensor MR	BP-02810-MR	
3D Acceleration sensor MR	BP-02820	

3.2 Approved EEG caps

Note: General MR safety guidelines should always be adhered to when using any MR-conditional EEG cap in the scanner. These safety instructions apply specifically to the BrainCap MR from revision 3 onwards, since only these comply with contemporary safety standards for field strengths up to 3T. If you are not sure which revision of the BrainCap MR you have, please contact the Brain Products Technical Support team specifying the serial number of your cap. Earlier versions of the BrainCap MR have features that will not be covered in these safety guidelines, please contact the Brain Products Technical Support team if you have questions regarding the safe use of BrainCap MR prior to revision 3.

- Unless otherwise stated all standard BrainCap MRs are designed and approved for field strengths up to 3T.
- For applications in environments ›3T please contact the Brain Products Technical Support team for advice.
- No general approval is provided for custom cap designs. All non-standard BrainCap MR layouts are subject to a liability waiver.

4. Approved scanners

Approved human whole body MR scanners:

Static gradient field

Siemens:	1.5 - 7 T*
Philips:	1.5 - 7 T*
General Electric:	1.5 - 7 T*
Bruker:	up to 4 T*

- If you have a scanner from a manufacturer not listed, please contact the Brain Products Technical Support team.

*** Over 3 Tesla**: Only possible after dedicated setup customization and site specific training by the Brain Products Technical Support team.

5. The importance of head coil features for safe and ergonomic electrophysiological measurements

The choice of the head coil is not only important for the MRI measurements and quality of the images but also for safety. The head coil is the most important determinant of the work space for EEG measurements.

The suitability of a head coil for EEG measurements is determined by considering the presence of appropriate optionsfor straight EEG cable routing and the RF-transmit capabilities.

- EEG optimized head coils provide both transmit capabilities and a cable duct of sufficient diameter to feed EEG cables in line with the Z-axis of the scanner to the amplifier.
- Head coils that do not permit straight EEG cable routing from the cap to an amplifier behind the head are EEG incompatible and should not be used.
- Receive only head coils force the body coil as the RF-transmitter and do not provide the same safety margins as transmit / receive head coils. Therefore restrictions apply to receive only head coils: upper limb EMG, thoracic ECG, and acceleration measurements are not permitted. See figure Figure 5.1 and Figure 5.2 for further information.

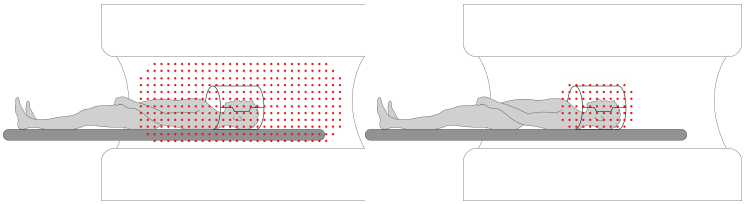


Figure 5.1: Body RF coil

Figure 5.2: Local RF coil

Schematic representation of an RF field in a body transmit coil Figure 5.1 and a head transmit coil Figure 5.2. If a body coil is used as the

RF transmitter coil, the equipment used for recording the EEG and/or peripheral physiology (electrode cap, sensors, cables, amplifier and power supply) are exposed to a considerably stronger and more widespread RF field, Figure 5.1. If a local (head) transmit coil is used, Figure 5.2, only the electrodes and cables are exposed to the RF field. The choice of RF transmitter coil is therefore a crucial factor when setting up a simultaneous EEG-fMRI study.

5.1 Geometry of head coils

Head coils for combined EEG-fMRI recordings must have one of the following characteristics:

- Ducts or openings for the EEG cables in Z axis direction.
- In the absence of a suitable cable duct or opening the coil must consist of a top and bottom part where the coil can be operated without the top part.

Some example of suitable and unsuitable head coils are given below.

Open head coil

An open head coil makes it possible to route the connecting cables between the EEG cap and the amplifier in a straight line, thus preventing any loops.

Example: Siemens 8Ch CP Tx/Rx.

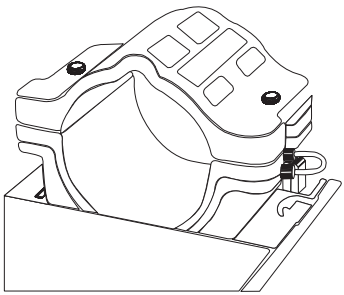


Figure 5.3: Example of an open head coil

Head coil for combined EEG-fMRI with cable duct

This head coil makes it possible to route the connecting cables between the EEG cap and the amplifier in a straight line, thus preventing any loops or curves.

Examples: Philips 32-channel, MR Instruments 32-channel Rx, QED 32-channel TxRx, Siemens Head/Neck 64-channel, GE 48 Channel Head Coil.

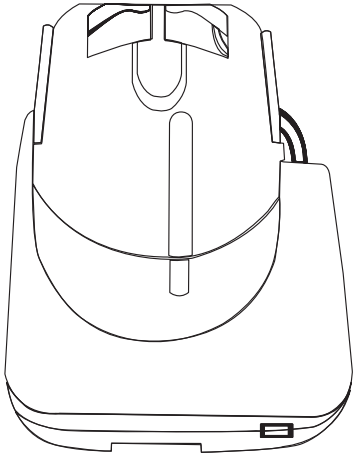


Figure 5.4: Example of a head coil with a cable duct

Head coil with usable side opening

This head coil allows one to route the connecting cables between the EEG cap and the amplifier through the side of the coil. The cables exit at the side of the coil close to the midline and then bend before continuing to the amplifier. Loops are prevented. Models with a side opening are not as well suited to combined measurements as open head coils or head coils that have been specially adapted for EEG recordings. However, they offer an adequate level of safety provided

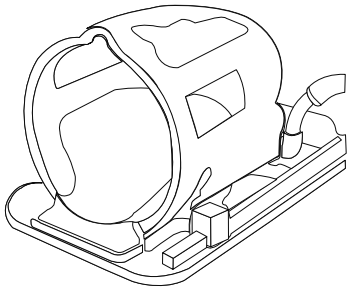


Figure 5.5: Example of a head coil with a usable side opening

that the connecting cables can be led out of the head coil without any loops forming.

Examples: Siemens Invivo 8Ch Rx SENSE, Siemens 12-channel Head Matrix Rx, GE 8-channel, GE 16-channel Head-Neck, Siemens 8-channel SENSE Rx, Siemens mMR Head/Neck, Siemens Head/Neck 20.

Closed head coil

Do not use closed head coils for simultaneous EEG-fMRI recordings. With closed head coils cables cannot be routed in a straight line. Extreme curves or bends will be formed in the cable because the bundled connecting cable must be routed back along the electrode cap inside the coil, exit at the bottom and then be routed back up the outside of the head coil. This also results in the cable being very close to the face of the subject, this is an unacceptable risk.

Examples: Nova Medical Head Coil 32RX, Siemens 32-channel Rx.

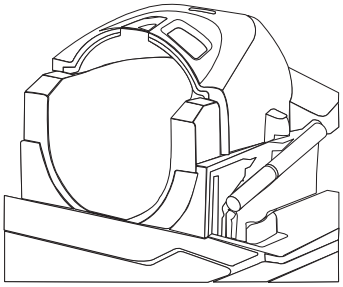


Figure 5.6: Example of a closed head coil

6. Protecting the amplifier from damage

Even though our primary goal is to protect the subject from electrode or cable heating, care has to be taken to protect the EEG equipment from damage due to RF-heating.

The system components that are particularly sensitive to RF-heating include:

- EEG electrode protection resistors
- Protection resistors in the cap connecting box
- The protection circuits at the amplifier input stage.

The mechanisms of RF overload include:

- MR sequences using inappropriate parameters
- Inappropriate setup geometry, e.g. off center or orthogonal cable routing, cable loops
- Electrically un-terminated channels.

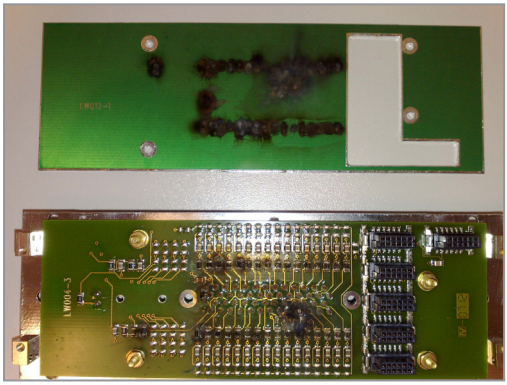


Figure 6.1: Burnt out amplifier board as a result of mishandling. The MR system is very powerful and without due care it is possible to induce high voltages that will damage the amplifier.

6.1 Overloading at the amplifier input by voltages in open channels or high-impedance channels

Electrodes with high impedance act as antennas during scanning and pick up RF energy. The safety circuit at the input is designed to dissipate a certain amount of power, however, when the capacity of the safety circuit is exceeded, the amplifier input is overloaded and damage to the circuit board can occur.

Do the following to prevent damage to the amplifier:

- Minimize the impedances of **all** electrodes.
  - Even the impedance of unused electrodes must be minimised, there should be no electrodes that are not connected to the subject. Deactivating unused channels in the Recorder workspace does not provide protection against voltage overload.
  - Take special care of the ECG and EOG electrodes. These electrodes must not become detached during patient positioning as this will result in high impedance.
- Always check the impedance of all available channels, including the reference electrode and the ground electrode, before starting the scanning session. Remember that clear, visible physiological signals are the most obvious indicator for low impedance electrodes, so be sure to check the signal before starting the scanning session and to monitor the signal during the session.
- Make sure that the ribbon cable is securely attached to the amplifier and the cap connector box.
- If you are using a BrainAmp ExG, when you install the ExG AUX Box make sure that all electrode leads are securely plugged into the appropriate ports to avoid antenna effects.

6.2 Overheating of the amplifier or PowerPack by strong electromagnetic fields and radio-frequency fields

All amplifiers are shielded to protect the sensitive electronic components. If the operating temperature of the amplifier (40 °C) is exceeded, thermal overload protection is triggered and error messages are sent to the recording software. However, this is not a fail-safe mechanism, if overheating continues, it results in irreversible thermal destruction of the amplifier as seen in Figure 6.1.

Observe the following rules to avoid overheating of the amplifier and the PowerPack and to ensure stable operation:

- Use a head coil as the RF transmitter coil where possible.
- Only use allowed sequences with an inherently low specific absorption rate (SAR). Refer to MRI Sequences on page 26 for information on SAR and which sequences are allowed.
- Position the amplifier and cables in accordance with the instructions in Positioning the EEG amplifier on page 37.

7. MRI Sequences

The BrainAmp MR / MR plus system is MR conditional, refer to Definitions from ASTM international standard F2503-13 on page 10 . One of the conditions for safe use is to use only MRI sequences that meet the criteria specified in this chapter.

7.1 Permitted sequences: specification of sequence conditions

We recommend a maximum B1+rms for MRI sequences used for simultaneous EEG. You will find the recommended thresholds in Table 7.1 and this chapter has further information on what B1+rms is and why we use it.

Sequence parameters are just one aspect of our safety recommendations. The B1+rms limits stated in Table 7.1 are for 3 T scanners; furthermore, all other specifications described in the user manual still apply e.g. position of the amplifier, cable routing, and a head coil with an appropriate option for routing the EEG cables. If your setup does not allow for the guidelines in this manual to be followed (e.g. no appropriate head coil available) please contact us to discuss your setup (techsup@brainproducts.com).

Note: The new Standard BrainCap MR (available from April 2020) and the R-Net MR should be connected to the BrainAmp MR (plus) using a 10 cm bundled cable. If a longer cable is used the lower B1+rms threshold of 1µT applies.

Maximum allowed B1+rms values for 3 T and different caps	
Current standard BrainCap MR	Max. B1+rms = 1 µT
New Standard BrainCap MR*	Max. B1+rms = 1.5 µT
R-Net MR	Max. B1+rms = 1.5 µT
* available from April 2020. Please check with Technical Support (techsup@brainproducts.com) if you are not sure whether you have an old or new BrainCap MR (please provide the serial number).	

Table 7.1: Maximum B1+rms values of radio frequency (RF) magnetic field allowed for simultaneous EEG-fMRI using the BrainAmp MR system with different EEG caps by Brain Products. All conditions specified in the user manual must also be met

7.2 What is B1+rms?

In short, B1+rms is a metric used to quantify the amount of radio frequency (RF) magnetic field that is generated by the RF transmit coil for a specific pulse sequence and is expressed in units of µT.

More specifically, it can be defined as a statistical measure of the magnitude of the positive rotating component of the B1-Field. The meaning of each component in this expression is explained in Figure 7.2. If you are interested in learning more, ISMRM.org has some very useful resources. See Literature and Links for a link to a B1+rms video podcast.

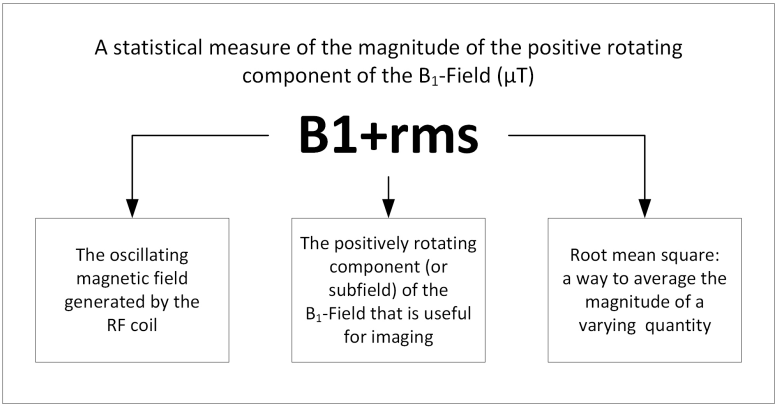


Figure 7.2: Explanation of B1+rms

7.3 Why B1+rms?

Historically we have recommended using low Specific Absorption Rate (SAR) sequences, however, SAR is dependent not only on the imaging parameters but also on the volunteer's weight. B1+rms on the other hand is volunteer independent and is determined by basic MRI parameters. It is a known value based on the pulse sequence parameters, unlike SAR which is an estimated value. Once a sequence has been adjusted to the required B1+rms, it is saved to the scanning protocol and will remain that way as long as relevant parameters are not changed. SAR, on the other hand, will vary from volunteer to volunteer. As such, B1+rms has been recommended as an alternative metric to SAR for limiting the amount of RF power during scanning (for an overview see Faulkner, 2016).

The B1+rms limit that we specify protects the volunteer and the amplifier from excessive RF power while allowing the user more flexibility with their sequence parameters. By specifying a maximum B1+rms for the BrainAmp MR system, the user is free to determine sequence parameters as they see fit, as long as the B1+rms remains below the specified threshold and as long as all other safety guidelines are followed.

It is now mandatory for all scanner manufacturers to display B1+rms at the console (IEC 60601-2-33:2010), so this value should be easily accessible in all new scanners. Consult the documentation from your scanner vendor to find out where this value can be found.

Local experts at your scanning facility will be able to advise you on how to select the most appropriate sequence parameters for your study. The exact parameters to change in order to manipulate B1+rms will vary across scanners, but they are similar to those we consider in relation to reducing SAR. We cannot advise you on how to modify your sequence or provide specific recommendations for any given parameter; however, the technician in charge of your scanner can advise you on how to determine an appropriate scanning protocol for your study.

7.4 Test conditions

Testing for the new B1+rms limits was done under the conditions recommended in this manual. Measurements were done in a Siemens Prisma (3 T) scanner using a Siemens Head/Neck 64 head coil. Temperature measurements were made using a Neoptix Reflex fiber optic temperature thermometer; the positions of the probes were determined by previous measurements using an infrared camera.

Note: The tests were limited to the specific conditions described here, all combinations of manufacturer and head coil could not be individually investigated. However, while the specific parameters affecting the B1+rms may vary between MR system vendors, B1+rms itself is a precise RF exposure metric and the threshold specified here can be applied across 3 T scanner platforms.

7.5 MR sequence abbreviations

Term	Description
fMRI	Functional magnetic resonance imaging
B1+rms	The average effective RF magnetic field generated by the RF transmit coil for a specific pulse sequence
RF	Radio Frequency
SAR	Specific Absorption rate. A measure of the rate at which RF energy is absorbed per unit of tissue mass (W/kg)
EPI	Echo Planar Imaging (used for blood oxygen dependent (BOLD) fMRI)

7.6 Literature and Links

- ISMRM B1+rms video podcast: https://www.youtube.com/watch?v=3L1mImuAt_w
- Faulkner W. (2016) New MRI Safety Labels & Devices. https://www.ismrm.org/smrt/E-Signals/2016FEBRUARY/eSig_5_1_hot_2.htm
- International Electrotechnical Commission. IEC 60601-2-33:2010 + COR1:2012 + A1:2013 + A2:2015 + COR2:2016. Medical electrical equipment. Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.

8. Preparing the Subject

Before starting the measurement, explain to the test subject what they should do if they begin to feel uncomfortable or perceive unexpected sensations during the examination. In line with regular MR procedures, show the test subject how to operate the alarm bell.

8.1 Cap and electrode preparation

- Minimize the impedance at **all** electrodes, there should be no electrodes that are not connected to the subject, this is for safety reasons (refer to Protecting the amplifier from damage on page 23 for further information)
- Make sure there are no loops in connection cables or electrode leads.
- Caps must be used in the exact configuration in which they were supplied. Re-buttoning of electrodes to occupy different sites is not allowed.

8.2 Attaching the ECG cable

On contemporary versions of the BrainCap MR (Series 3), the ECG electrode leaves the cap at the occipital pole. You can only attach the ECG electrode to the back of the test subject. You will achieve the best possible ECG signal quality if you attach the ECG electrode as far down as permitted by the cables, on the back of the test subject along the paravertebral line (see Figure 8.1). Positioning the ECG electrode medially in this manner reduces the amplitude of the scanner artifacts, increases the amplitude of the R peaks and prevents the electrode leads from forming any loops.

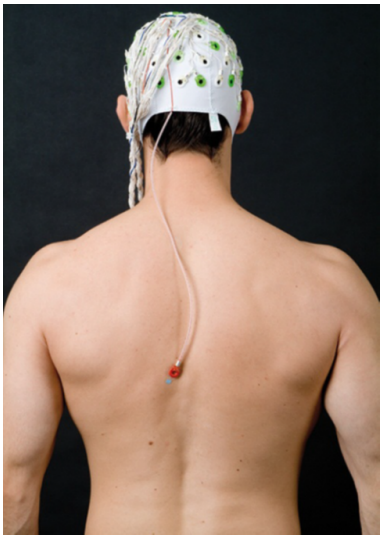


Figure 8.1: Attaching the ECG electrode to the back

Ensure that the electrode leads are not pulled by any movements that may be made by the test subject, as this can cause the electrodes to be moved or dislodged. Make sure that the length of the electrode leads permits some room for such movements while still avoiding loops.

Strong electromagnetic fields and radio frequencies act on electrodes and cables. Therefore, the temperature of electrodes, cables and other equipment can increase during the MR scan. If heating occurs, EEG components that are in direct contact with the subject can cause burns.

- ► Make sure that no electrode cable or other equipment is in contact with the skin of the subject. Drop down electrode cables should be covered by a plastic sleeve.
- ► Make sure that cables cannot move during the experiment, use medical tape to secure cables where necessary

9. Positioning the EEG amplifier

The position of EEG equipment inside the scanner is critical for the safety of the test subject and the data quality.

9.1 Guidelines for positioning the EEG equipment

In an ideal setup:

- all cables run straight and parallel (1).
- sandbags minimize the vibrations on the flat-ribbon cables, connecting boxes, and cap cable bundles (2).
- the EEG equipment is inside the scanner bore (3).
- the EEG amplifier is on the same level as the cable bundle from the EEG cap (4). Platform not supplied.
- the PowerPack (A) is on top of the amplifiers (B).

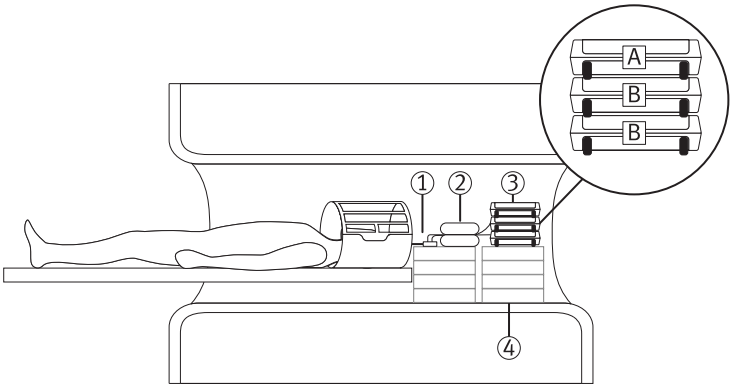


Figure 9.1: Recommended position of the EEG equipment in the scanner

The best position for the EEG equipment is close to the test subject, to avoid unnecessarily long cable.

10. Using the BrainAmp ExG MR for bipolar and sensor data acquisition

The BrainAmp ExG MR is a bipolar amplifier which can be used for peripheral physiology and polygraphic measurements. The BrainAmp ExG MR is part of the BrainAmp MR family of amplifiers and is subject to the same safety guidelines as the BrainAmp MR and BrainAmp MR plus. **As such, the general safety guidelines and restrictions presented in this document also apply to using the ExG amplifier in the MR environment.**

In the MR environment only ever use the BrainAmp ExG MR together with the ExG AUX Box and special MR conditional electrodes and sensors. For bipolar measurements (e.g. EMG, ECG) only use Brain Products MR electrodes / cable sets. For polygraphic signals only use Brain Products MR conditional auxiliary sensors (GSR MR Sensor, 3D Acceleration Sensor MR, Respiration Belt MR). All MR Conditional sensors have been tested for use in MR environments up to 3T.

The general safety rule applies that no cable is permitted to be routed through more than 50 % of the length of the bore of the scanner. In practical terms, when using multiple amplifiers e.g. for EEG and for peripheral physiology, this means that it may be necessary to position amplifiers at the foot end and head end of the bore, e.g. a BrainAmp ExG MR for EMG measurements at the foot end and a BrainAmp MR for EEG measurements at the head end. In this case, each amplifier must be powered from a separate PowerPack; amplifiers at different locations must have their own local PowerPacks.

CAUTION

Under no circumstances should you route the power supply cables through the scanner bore or around the MR scanner.

Special care needs to be taken when positioning electrodes and polygraphic sensors. Specific advice for each type of measurement is provided below.

10.1 Bipolar measurements

EMG

Combined EMG-fMRI measurements are somewhat different to EMG measurements under laboratory conditions. Such measurements require particular care with respect to the choice of suitable electrodes and the routing of the cables. All cable displacement must be avoided. This also applies to respiratory movements that can be transferred to the EMG cables.

EMG signals can be measured at a wide variety of sites on the body. We distinguish between two fundamental application scenarios: EMG measurements on the upper or lower limbs and EMG measurements on the face.

For EMG on the upper or lower limbs only use Brain Products EMG-fMRI electrodes (Multitrode MR electrodes for EMG). The cables have 15 kOhm current-limiting resistors and are bundled in a spiral tube so that they cannot come into direct contact with the test subject. Never use the bipolar EMG-fMRI electrodes for EMG acquisition on the head of the test subject. For EMG on the face we are able to provide custom EMG-fMRI caps for correct, safe routing of cables. Please contact the Brain Products Technical Support team for guidance if you are considering measuring EMG on the face.

We recommend that you do not use a body coil as the RF transmitter coil for combined EMG-fMRI measurements because this limits where you can place the electrodes; they can only be placed outside of the RF field (refer to Figure 5.1 and Figure 5.2 for further information). If a body transmit coil is used EMG measurements are limited to the lower limbs and the extremities of the upper limbs (depending on the length of the scanner bore).

The standard Multitrode MR has a 40 cm lead. Taking into account the alternatives for positioning the amplifier at the foot end of the patient table (see Figure 9.1), the variety of possible positions for the EMG-fMRI electrodes, and the need to route the cables in a straight line, it becomes clear that custom cable lengths may be required for each individual

setup in order to fulfill the safety regulations. This also requires the height of the test subjects / population to be taken into consideration (e.g. children versus adults). For these reasons such applications are considered as customized solutions, as such, they require consultation with the Brain Products Technical Support team and a liability waiver. Please contact the Technical Support Team in advance if you are planning EMG-fMRI studies so we can provide you with suggestions and recommendations for setting up and performing the study safely and successfully. EMG-fMRI studies benefit from extended pilot testing and, where possible, dedicated on site training is recommended.

10.2 Positioning of the amplifier

Position the BrainAmp ExG MR at the foot end of the scanner table, distal to the feet of the test subject.

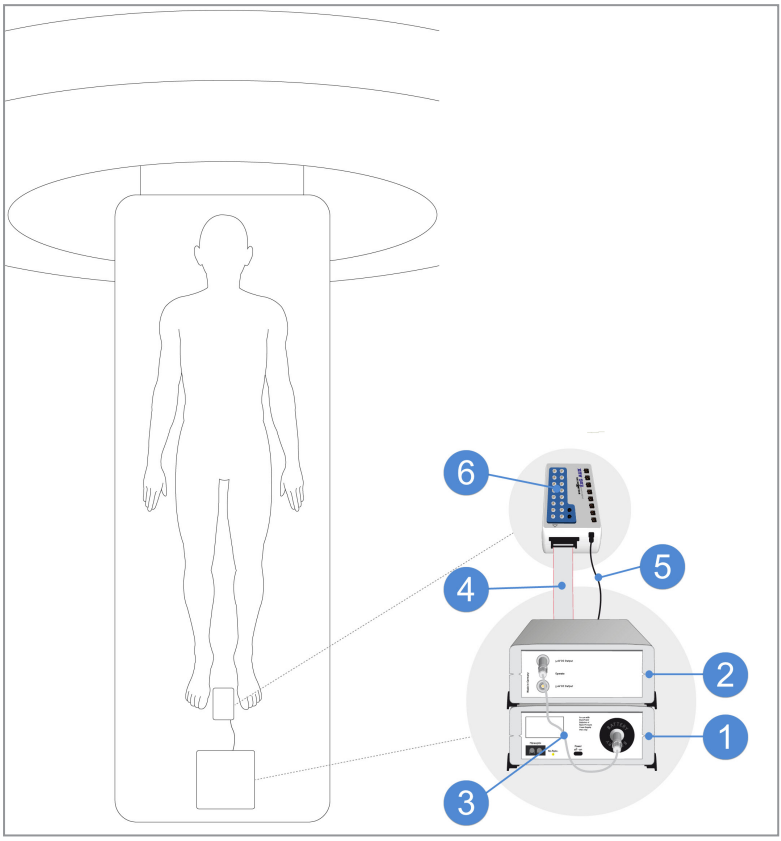


Figure 10.1: Schematic representation of the correct way to position the BrainAmp ExG MR, PowerPack and ExG AUX Box for a combined EMG-fMRI measurement on the limbs. You can also position the ExG AUX Box at the level of the knees so that the 40cm electrode cables can be placed on the lower arm. EMG leads are not shown because the placement is dependent on the individual experimental setup.

Please contact the Brain Products Technical Support team for advice regarding EMG leads.

Pos.	Description
1	BrainAmp ExG MR 16
2	PowerPack
3	PowerPack connecting cable
4	Ribbon cable
5	Power supply cable
6	ExG Aux box

ECG

The standard version of the BrainCap MR is fitted with a drop-down electrode for recording the ECG signal from the subject's back during an EEG-fMRI measurement. However, should you require additional ECG measurements, you can use a BrainAmp ExG MR positioned at the foot end of the scanner bore to record a bipolar ECG measurement. The Brain Products Multitrode MR for EMG can also be used to record ECG. The same safety guidelines regarding electrode placement, lead length and transmit coils apply as for the combined limb EMG-fMRI measurements described in EMG on page 41.

10.3 Polygraphic measurements via the auxiliary channels

All MR sensors are MR conditional and must be used outside of the RF transmit field. Therefore, we recommend that you do not use a body transmit coil for measurements using the auxiliary channels of the BrainAmp ExG MR. If you do choose to use a body transmit coil please be aware that this limits where you are able to place the sensors; you will only be able to use them on the lower limbs and the extremities of the upper limbs. Further details on the RF field when using a body versus head transmit coil can be seen in Figure 5.1 and Figure 5.2.

Guidelines for the safe use of the sensors in the MR environment is provided below. Details on performing a measurement and setting up the Recorder workspace appropriately can be found in the user manual for each sensor.

GSR Sensor MR

The GSR-MR Module is a part of our MR product line and is subject to the same safety regulations and restrictions as all the other components of the BrainAmp MR amplifier system. The GSR module is MR conditional and must be used outside of the RF transmit field.

Use the GSR-MR Module only in combination with the BrainAmp ExG MR amplifier and the ExG AUX Box. These devices offer electrical isolation and can be used in MR scanners.

The GSR electrodes should be applied only to the hand of the subject. The correct position of the GSR electrodes and the appropriate cable routing, to avoid loops, is shown in Figure 10.2.

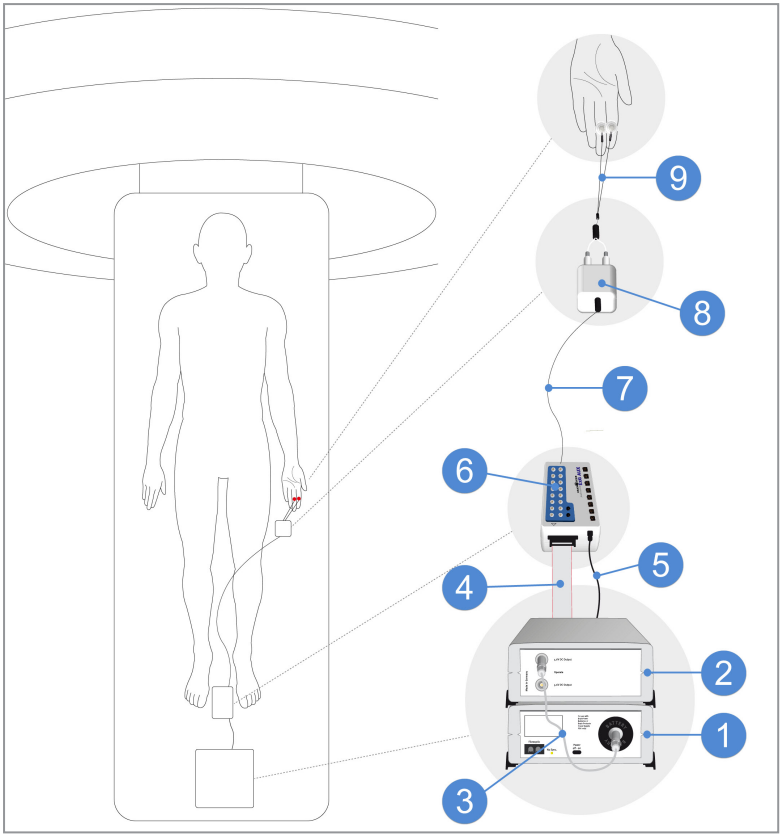


Figure 10.2: Schematic representation of the correct way to position the BrainAmp ExG MR, PowerPack and ExG AUX Box for use with the GSR MR sensor.

Pos.	Description
1	BrainAmp ExG MR 16
2	PowerPack
3	PowerPack connecting cable
4	Ribbon cable

Pos.	Description
5	Power supply cable
6	ExG Aux box
7	5-pin connecting cable
8	GSR-MR Module
9	GSR-MR electrodes

Respiration Belt MR

The Respiration Belt MR is a part of our MR product line and is subject to the same safety regulations and restrictions on use as all the other components of the BrainAmp MR amplifier system.

Use the Respiration Belt MR only in combination with the BrainAmp ExG MR amplifier and the ExG AUX Box.

The transducer is MR conditional. Therefore, always position the transducer outside the RF transmit field. The pneumatic sensor is MR safe. It does not contain ferromagnetic or electrically conductive material, therefore it is safe to use inside the scanner bore.

The correct positioning of the pneumatic sensor and transducer in relation to the ExG Aux Box and BrainAmp ExG MR is shown in Figure 10.3.

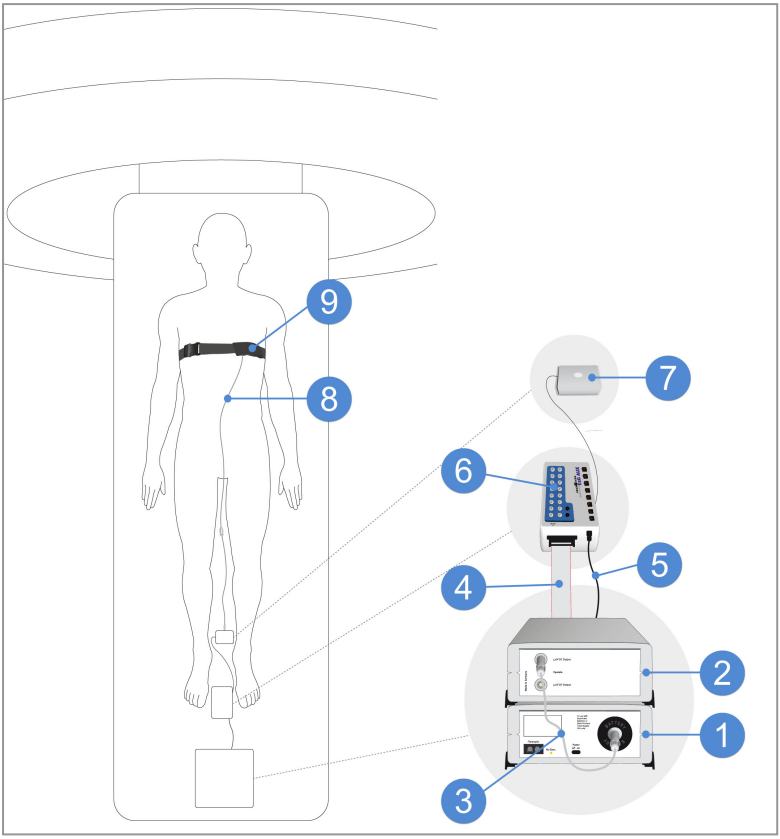


Figure 10.3: Schematic representation of the correct way to position the BrainAmp ExG MR, PowerPack and ExG AUX Box for use with the Respiration Sensor MR

Pos.	Descirption
1	BrainAmp ExG MR 16
2	PowerPack
3	PowerPack connecting cable
4	Ribbon cable

Pos.	Descirption
5	Power supply cable
6	ExG Aux box (MR conditional)
7	Transducer (MR conditional)
8	Extension tube (MR safe)
9	Pneumatic sensor and belt (MR safe)

3D acceleration sensor

The 3D Acceleration Sensor MR is a part of our MR product line and is subject to the same safety regulations and restrictions on use as all the other components of the BrainAmp MR amplifier system.

Use the 3D Acceleration Sensor MR only in combination with the BrainAmp ExG MR amplifier and the ExG AUX Box.

The 3D Acceleration Sensor MR is MR conditional. Therefore, always position the sensor outside the transmit RF field. The correct position of the acceleration sensor in relation to the ExG Aux Box and BrainAmp ExG MR is shown in Figure 10.4.

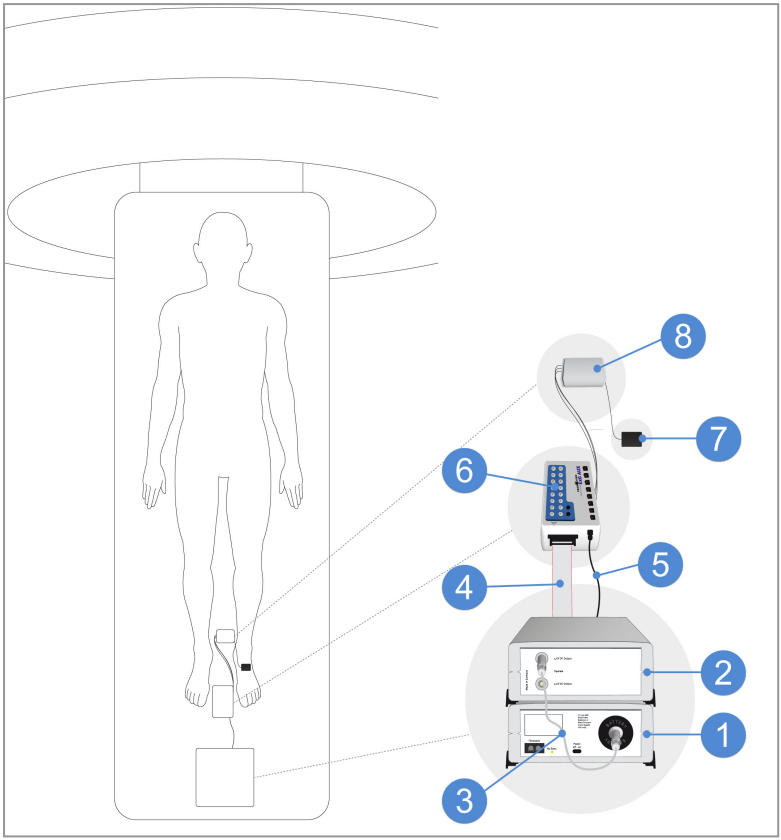


Figure 10.4: Schematic representation of the correct way to position the BrainAmp ExG MR, PowerPack and ExG AUX Box for use with the 3D acceleration sensor MR. The sensor is placed on the foot, however, the sensor can be placed anywhere on the limbs (outside of the RF transmit coil)

Pos.	Desctiption
1	BrainAmp ExG MR 16
2	PowerPack
3	PowerPack connecting cable

Pos.	Desctiption
4	Ribbon cable
5	Power supply cable
6	ExG Aux box (MR conditional)
7	3D sensor module
8	Pre-amplifier

11. Phantom measurements in MR environments

Phantom measurements are useful to assess the impact of the EEG equipment on MR image quality. Special care must be taken if you are to obtain reliable imaging results and avoid damage to the amplifier.

Imaging phantoms as provided by the scanner manufacturer usually have a non-conductive surface. As a result, when you attach the electrode cap to the phantom and connect it to the amplifier, all the electrodes show high impedances. The amplifier can be destroyed by antenna effects if pulse sequences are run with open or high impedance channels, as described in Protecting the amplifier from damage on page 23.

Proceed as follows to avoid destroying the amplifier:

- Before you attach the BrainCap MR, ensure that the entire surface of the phantom is coated with a conductive layer of Abralyte gel.
- After you have attached the BrainCap MR to the fully gel-coated phantom, ensure that the cap fits as tightly as possible to the surface by tightening the chin strap.
- Attach the EOG and ECG electrodes under the edge of the cap.
- Make sure that all electrodes show low impedances. Use impedance mode to check the electrode impedances while you reduce the impedances using a syringe and a further quantity of Abralyt gel, in the same way that you would for measurements with human volunteers.
- Once you have prepared all electrodes in this way, take the phantom into the scanner room and position it and the amplifier in the same way as with a normal measurement.
- We recommend that you check the impedances again before starting the scan.
- All the conditions regarding the setup and position of the amplifiers given in Positioning the EEG amplifier on page 37 also apply for phantom measuremenst.

Please note that in contrast to artifact evaluation, safety testing on imaging phantoms is not reliable.

12. Working with special populations and specific states

While due care and attention is always required for simultaneous EEG-fMRI measurements particular attention/supervision is recommended for populations that may not be able to easily detect or communicate any heating or discomfort during the measurement. This is important for the following special test populations and specific states:

- Children and babies
- Test subjects in a poor state of health
- Uncooperative test subjects
- Test subjects with reduced vigilance (e.g. pharmacological studies)
- Sleep EEG
- Epilepsy
- Sedation.

13. Summary Checklist

Before starting a measurement please check that the following criteria are fulfilled:

1. Route all cables correctly:
   - straight
   - no loops
   - in line with the z axis of the scanner.

2. Only use scanners with the specified field strengths:
   - up to 3T
   - for >3T only with guidance from the Brain Products Technical Support team.

3. Only use permitted head coils:
   - Ideal = cable duct for EEG cable
   - Appropriate = cable routing option at the side or top
   - No-go = completely closed coil
   - Use Transmit-Recieve head coil whenever possible

4. Only use permitted sequences:
   - Single-shot GRE-EPI BOLD sequences
   - Magnetization Prepared Rapid Gradient Echo (Siemens: MP-RAGE, Philips: TFE, General Electric: FSPGR)
   - Spoiled Gradient Echo (Siemens: FLASH, Philips: T1-FFE, General Electric: SPGR).

5. Only use permitted electrode caps:
   - Standard BrainCap MR

- Customised BrainCap MR with Liability Waiver.

6. Minimize the impedance of all electrodes. There should be no open electrodes, so, no electrodes that are not in contact with the subject.

14. Behavior in emergencies

The scanner operator must know how to:

- ► follow the emergency procedures for the facility regarding turning off the scanner
- ► release the scanner table
- ► shut down the amplifier.

The user documentation provided by the scanner manufacturer and local safety regulations also apply without restrictions for combined EEG-fMRI measurements.

Release the test subject from the scanner in an emergency

If you are required to stop the experiment and release the subject from the scanner in an emergency situation please do the following:

1. Stop the scan.
2. Disconnect the electrode cap, sensors and other equipment from the amplifier(s).
3. Move the scanner table out of the bore.
4. Remove the head coil.
5. Help the subject up from the scanner bed and escort them from the room.
6. Remove the cap and sensors from the subject.

Shut down the amplifier

If you must abort the measurement due to a malfunction or fault in the EEG components, proceed as follows:

1. Switch off the amplifier and disconnect amplifier from battery (PowerPack).
2. Disconnect the electrode cap, sensors and other equipment from the amplifier(s).

3. Move the scanner table.
4. Remove the head coil.
5. Help the subject up from the scanner bed and escort them from the room.
6. Remove the cap and sensors from the subject.
7. Check if the amplifier system is working properly and if all the system components are installed correctly. Please refer to the troubleshooting section of the BrainAmp user manual for details of how to test the amplifier.
8. If it is not possible to eliminate the malfunction or if the problem persists, send a detailed description of what has occurred to the Brain Products Technical Support team.

Appendix A Recommended Reading

D. W. Carmichael, J. S. Thornton, R. Rodionov, R. Thornton, A. W. McEvoy, R. J. Ordidge, *et al.*, "Feasibility of simultaneous intracranial EEG-fMRI in humans: a safety study," *Neuroimage*, vol. 49, pp. 379-90, Jan 1 2010.

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Appendix B References

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