



MEG FACILITY

Standard Operating Procedures

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1 Introduction

This document is intended to provide a basic review of good practice in the use of Magneto-encephalography (MEG) and how these should be reflected in the daily running of MEG scans at the MRC Cognition and Brain Sciences Unit and is intended for anyone from the unit or collaborators with members at the unit intending to use this device.

It is based on recommendations made by Elekta-Neuromag (Helsinki), Health Response UK, Lund Eye Tracking Academy (University of Lund, Sweden), and the MRC Cognition and Brain Sciences Unit MEG management committee.

2 MEG Hazards and Safety Procedures

2.1. MEG Dewar

- The Dewar position can be changed between upright and supine only by the MEG Operator.
- The Dewar position can only be changed when no volunteer or other person is placed under the device.
- The chair/bed should be removed prior to the change of Dewar position.
- The green light of the Lifting Mechanism Indicator on the back wall inside the MSR indicates that the Dewar is in its SAFETY POSITION. A volunteer may only be placed under the device when the green 'OK' light is lit and no other light is on.
- Care when positioning the volunteer into the chair is essential. Ensure they do not move backwards too quickly as they might hit their head on the Dewar. Move the chair up using the foot pedal until the volunteer reports that their head is touching the top, be aware that there is a risk of head and neck injury if done too quickly. In the supine position, move/slide the bed with the MEG volunteer on it towards the device slowly.

It is essential to perform these operations slowly, and to obtain continuous feedback from the volunteer about their comfort and well-being. Procedures for changing the position of the MEG system are described in detail in Appendix J: Raising and Lowering the MEG Gantry

2.2 Preparation of volunteers

Risks in the preparation of volunteers relate to the fixing of objects to the body and, in some cases, the use of stimulation materials. These issues must be covered by ethics permissions submitted in ethics proposals by the responsible researcher.

- Attaching electrodes and coils to the scalp and skin: rubbing of the skin surface is required here as well as Microderm tape. This can lead to minor injuries. Always obtain feedback from your volunteer during this procedure. Gloves are available and may be used when attaching electrodes
- The MEG Laboratory includes an electric stimulator. Use of this stimulator must be in accordance with the relevant regulations and covered by a separate ethics proposal.
- EEG electrodes can be attached to the body and should connect with the relevant plugs of the EEG amplification unit found under the right wing when facing the MEG or using the external EEG head box. The ground connection of the pre-amplifier must be used (not external grounding).

2.3 Preparation for experiment: stimulus delivery

It is important to note that stimulus delivery in the machine bears risks, too. These include the risk of causing hearing deficits by very loud acoustic stimuli and the induction of epileptic activity in vulnerable volunteers by bright flickering light (10 Hz). Stimulation with loud noise, bright flickering light and other possible hazards should therefore be avoided. If an experiment requires such stimulation, these hazards should be covered in the ethics application and appropriate measures should be put in place to deal with them.

2.4 Implantable Medical Devices

A volunteer will not be harmed if they come into contact with the MEG with implanted medical devices but it may have a negative effect on the MEG itself. Please inform MEG operators of any suspected implanted devices before allowing the volunteer to enter the MSR. If your study involves volunteers with implanted devices please discuss this with the Lab manager before submitting a proposal to the IIG.

2.5 Monitoring Equipment

2.5.1 The introduction of novel monitoring equipment

The introduction of monitoring equipment into the MSR is not hazardous to any persons close to it but it can affect the quality of the resulting MEG recording.

Only authorised Personnel are allowed to take monitoring and other peripheral equipment into the MSR, even if the item contains no obvious magnetic elements it will still need to be tested to ensure it is MEG safe (see 3.5 Control of equipment).

2.5.2 Volunteer monitoring equipment

The MSR is fitted with a Video camera and an intercom system to enable the researcher and operator to have constant contact with the volunteer throughout the MEG scan.

2.5.3 Oxygen Depletion Alarm

The MSR is monitored by a sophisticated Oxygen Monitoring System. In the unlikely event of Helium evaporation into the MSR, the Oxygen Monitoring System will raise an alarm via the visual beacon and sounder in the MEG room. Please see 2.6.2 Oxygen Warning system for details of the use of this monitoring device and Appendix H: Oxygen Depletion Alarm.

2.6 Cryogenics

There should be no hazards from cryogenics as adequate attention has been paid to the provision of venting directly to the outside of the building of all potential sources of helium following normal boil-off or in the event of a pressure release valve bursting. However for completeness and as a warning, reference is made to some of the potential hazards and the warning systems in place.

The hazards in the use of low temperature liquefied gases for MEG systems are:

- Asphyxiation in oxygen-deficient atmospheres.
- Cold burns, frostbite and hypothermia from the intense cold.
- Over-pressurisation from the large volume expansion of the liquid following evaporation.

2.6.1 Asphyxiation

Evaporation of large amounts of liquid helium and the resulting accumulation of helium gas may produce a locally oxygen-deficient atmosphere, which can cause asphyxia when inhaled. Atmospheres containing less than 18% oxygen are potentially dangerous and entry into atmospheres containing less than 20% is not recommended. Atmospheres containing less than 10% oxygen can result in brain damage and death.

Asphyxia due to oxygen deficiency can occur rapidly and with no warning, even the victim may not be aware.

Typical symptoms of asphyxia are:

- Dizziness
- Drowsiness
- Nausea
- Vomiting
- Excess Salivation
- Diminished Mental Alertness

2.6.2 Oxygen Warning system

If oxygen levels fall dramatically within the MSR during a recording the oxygen monitor inside the MEG lab will sound and the beacon will flash (please see appendix H). The Operator will ask you to exit the building and they will open the MEG lab door and MSR door and direct the volunteer into the garden.

The following steps should therefore be followed immediately:

If there is a volunteer in the MSR room:

If it is safe to do so hit the open button on the MSR and get the volunteer out immediately.

Evacuate the MEG laboratory.

If possible hit the Emergency Power Button (see Appendix B: Power Switches) to isolate the MEG equipment as you leave the room.

If possible leave the main lab door open and open the door to the garden to aid ventilation.

If Medical Assistance is required follow section 4.4 Medical emergencies of this SOP document.

Do not re-enter the room until authorised to do so by the MEG health and safety officer.

If the MSR is empty:

Evacuate the MEG laboratory.

If the MSR door is closed do not open it.

If possible hit the Emergency Power Button to isolate the MEG equipment as you leave the room.

If possible leave the main lab door open and open the door to the garden to aid ventilation.

If Medical Assistance is required follow section 4.4 Medical emergencies of this SOP document.

Do not re-enter the room until authorised to do so by MEG health and safety officer.

In both cases inform at least one of the following people

- MEG lab manager
- Head of MEG/EEG
- Director

2.6.3 Cold Burns, Frostbite and Hypothermia

Liquid helium or even its cold gases can damage the skin producing an effect similar to a heat burn. Unprotected parts of the skin that come into contact with un-insulated items of cold equipment may also stick fast to skin, and be torn on removal.

The cold vapours from liquefied gases may cause frostbite given prolonged or severe exposure to unprotected parts. A symptom is local pain but sometimes no pain is felt or it is short-lived.

Transient exposure to very cold gas produces discomfort in breathing and can provoke an attack of asthma in susceptible people.

2.6.4 Handling Cryogenics

CBSU health and safety procedures

Training authorised by cryogen suppliers, Elekta-Neuromag or CBSU MEG Support Staff must be undertaken before personnel operate and replenish the cryogenics.

Maintenance of the cryogenic plant must have been authorised by the appropriate senior site engineer, physicist or technician to

ensure that it is safe to carry out such work, and those involved must be accompanied by an Authorised Person while in the Controlled Area.

Pipes or metalwork that is not insulated must not be touched by unprotected parts of the body.

In the event of unusual venting, immediately leave the MSR open all of the doors and inform Lab Manager and MEG Support, who will, in turn, contact the Helium supplier.

No unauthorised person, at any time, should operate or tamper with cryogenics, valves, etc.

Hazards related to handling of liquid Helium are dealt with in detail in Appendix I: Helium fill procedure for the MEG unit.

2.7 Other Potential Hazards

2.7.1 Trip hazards

There is a step into the MSR which can be a trip hazard to volunteers and researchers. Be careful when entering and exiting the MSR and ensure you warn volunteers of the hazard.

The projector screen and eye tracker can be trip hazards within the MSR, please be aware when moving around the MSR of these and ensure your volunteer has a clear route to the chair or bed by repositioning these items.

3 Management of the MEG Facility

3.1 Responsibility and Organisation

3.1.1 Key Personnel

CBSU Director

Professor Sue Gathercole
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Telephone: 01223 355 294 x230
Fax: 01223 359 062
Email: sue.gathercole@mrc-cbu.cam.ac.uk

Responsibility: General management of the Cognition and Brain Sciences Unit, including all health and safety related issues.

Head of MEG and EEG

Dr. Friedemann Pulvermüller
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Telephone: 01223 355 294 x670
Fax: 01223 359 062
Email: friedemann.pulvermuller@mrc-cbu.cam.ac.uk

Responsibility: Overseeing research carried out in the MEG laboratory. Authorisation, in agreement with the Lab Manager, of access to the MEG lab. Chairing the MEG Management Committee (MEGMC) that manages the effective use of the MEG facility. Overseeing, in collaboration with the MEG Lab Manager, system operation, Helium refill and system tuning.

Head of MEG

Dr. Yury Shtyrov
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge CB2 7EF
Telephone: 01223 355 294 x832
Fax: 01223 359 062
Email: yury.shtyrov@mrc-cbu.cam.ac.uk

Responsibility: Day-to-day management of MEG laboratory. Authorisation, in agreement with the Head of MEG/EEG, of access to the MEG lab. Liaising with Health and Safety and technical staff in the management of the MEG lab. Overseeing, in collaboration with the Head of MEG/EEG, system operation, Helium refill and system tuning.

MEG Support Coordinator/Health and Safety Coordinator

Mr Gary Chandler

MRC Cognition and Brain Sciences Unit

15 Chaucer Road

Cambridge CB2 7EF

Telephone: 01223 355 294 x411

Fax: 01223 359 062

Email: gary.chandler@mrc-cbu.cam.ac.uk

Responsibility as Support Coordinator: Helium refills, coordinating technical support for the MEG laboratory.

Responsibility as Health and Safety Coordinator: Implementation, supervision and maintenance of general health and safety procedures as required by the UK Health and Safety at Work etc Act 1974.

MEG Operators

There are at present three (designated) MEG Operators, including the holder of a Research Support Postdoctoral Position for MEG.

Email: megadmin@mrc-cbu.cam.ac.uk

Responsibility: Assisting research carried out in the MEG laboratory. Contributing to the administration of the MEG facility. Day-to-day care for the functionality of the MEG facility, including daily Helium readings and system tuning, functionality checks, regular phantom measurements etc. Liaising with suppliers; ordering consumables.

MEG Administrator

Miss Georgina Morrill

MRC Cognition and Brain Sciences Unit

15 Chaucer Road

Cambridge CB2 7EF

Telephone: 01223 355 294 x786

Fax: 01223 359 062

Email: megadmin@mrc-cbu.cam.ac.uk

Responsibility: Administration of the MEG facility. Overseeing MEG bookings. Documentation of MEG usage. Assisting at MEG Meetings. Assisting the Head of MEG/EEG in coordinating MEGMC

meetings. Writing minutes, letters related to MEG lab operation as advised by the MEGMC. Documenting those studies running, registered users etc. Updating SOPs in agreement with the MEG Management Committee

MEG admin email address: megadmin@mrc-cbu.cam.ac.uk
accessed by both MEG admin and Operators

3.1.2 MEG Management Committee (MEGMC)

The MEGMC is responsible for the general running of the MEG lab (including health and safety issues) and shall consist of:-

- The Head of MEG/EEG
- The facility Administrator
- The MEG lab Manager
- A representative of the technical personnel
- The CBSU Health and Safety coordinator
- A representative from Computing
- The Operators

The MEGMC meet once a month, any changes or crucial updates needed between these meetings can be made via chairman's action.

3.1.3 Access for MEG personnel

The MEG and the related equipment are contained within a designated Controlled Area (cf. Appendix A: MEG LAB AREA AND MSR (AUTHORISED STAFF ONLY)). Access to the Controlled Area shall be given only to authorised personnel. Only authorised personnel and Operators will have free access to the Controlled Area.

Unauthorised personnel shall have access only if accompanied by an authorised person or Operator who will take on the full responsibility for the presence of the unauthorised person or persons for the duration of their presence in the Controlled Area.

The Head of MEG shall formally approve certification of a member of staff as an authorised person when the member of staff has satisfactorily completed training in their responsibilities and the safety requirements of MEG equipment.

The MEG Unit shall maintain a list of all authorised personnel together with full details of their training and certification with ready access available to the Authorised Persons and the Operators.

3.2 Controlled Area

3.2.1 Definition of Controlled Area

The controlled area covers two main rooms

The MEG laboratory-

Which contains the Magnetically Shielded Room (MSR), stimuli equipment i.e. Computer, projector, headphone tubes, and the acquisition electronics.

The preparation room-

This contains the Polhemus digitiser, set up computer, laptop for impedance measurement and electrode/HPI application equipment.

3.2.2 Access to the Controlled Area.

Access to the Controlled Area is provided by self-locking doors. The device for operating the locks is:

The MEG laboratory: plastic access card

The Preparation room does not require a key, it will be open unless it is being used by a participant and has been locked from within.

3.3 Access Control

Entry to the MEG laboratory is controlled by access card. Access privileges will be upgraded to include the MEG facility upon completion of the relevant training. Those completing the relevant training and not having a Unit card will be assigned a temporary one whilst they carry out their research at the CBSU.

Lost or mislaid cards must be reported to the CBSU Administrator immediately so that all access privileges on the card can be suspended.

3.3.1 Criteria for authorisation of MEG lab access

The Authorisation for MEG Laboratory access rests with the MEG lab manager and must be endorsed by the Head of MEG and EEG.

An individual shall only be Authorised and granted access after satisfactory completion of the local MEG Authorisation Procedure.

This includes:-

- Studying the current version of the MEG SOP document.
- Attending a MEG laboratory tour given by an MEG Operator or an experienced MEG Researcher.
- Attending a set number of MEG preparations.
- Successfully completing a questionnaire about MEG methods and safety.

To gain authorisation please contact megadmin@mrc-cbu.cam.ac.uk to arrange a lab tour.

MEG Operator status will involve all of the steps above with an extended period of training also covering helium refills, tuning and MEG acquisition settings in the lab under the supervision of each of the Operators and will be granted when all of the operators are satisfied with the capabilities of the trainee Operator.

3.3.2 Responsibilities of Authorised Personnel.

On entering the Controlled Area, all personnel must at all times comply with the CBSU Standard Operating Procedures.

- All unauthorised personnel, which will include visitors, patients and unauthorised staff, shall have access only if accompanied by an authorised Person.
- The authorised person will take on the full responsibility for the presence of the unauthorised person or persons for the duration of their presence in the Controlled Area.
- All authorised personnel who act as volunteers for scanning must conform to the appropriate requirements referred to in the sections about volunteer management (cf. 3.6 Volunteer

management: General considerations and 3.7 Volunteer Management: Scanning).

- Operators, MEG support, MEG lab manager and Head of MEG/EEG only can screen workmen, cleaners, and engineers for entry
- Authorised persons can screen visitors, volunteers and patients for scanning.

MEG Researchers and operators must collaborate in the attachment and digitisation of electrodes and Head Positioning Indicator (HPI) coils; this has important implications for the data that will be analysed.

MEG researchers must set up and control stimulus delivery, initially in collaboration with MEG Support Staff and Operators

3.3.3 Special Categories of Authorised Personnel

MEG Authorised Person

A person who is trained in MEG methods and are familiar with the relevant Health and Safety (H&S) procedures and MEG Standard Operating Procedures (SOPs). An authorised person is allowed free access to the Controlled MEG lab Area.

Types of Authorised person:-

MEG Researcher

A researcher who is leading, or collaborating in, an ongoing MEG study and has completed the MEG Authorisation procedure to the appropriate level (3.3.1 Criteria for authorisation of MEG lab access).

MEG Operator

A person who has been trained to run the MEG device and has completed the MEG Authorisation procedure to the appropriate level (3.3.1 Criteria for authorisation of MEG lab access).

MEG Support or MEG Technical Staff

An authorised person who is technical staff with a specific function in the MEG laboratory (e.g. Helium refill, computer installation).

Access to the MEG facility is restricted to Authorised Persons. All unauthorised people must be accompanied by an Authorised Person.

3.3.4 Required Staffing Levels for Scanning

MEG recordings involving volunteers during Official Opening Hours of the CBSU (9:00-17:30) require that an MEG Operator and an MEG Researcher are present.

MEG recordings involving volunteers outside Official Opening Hours of the CBSU require that an MEG Operator and an MEG Researcher are present.

For phantom recordings the minimum requirement is one MEG Operator.

3.4 Categories of Exposed Persons allowed in the MEG lab

3.4.1 Volunteers

It is not anticipated that any MEG recordings will be used for diagnostic purposes at the MRC Cognition and Brain Sciences Unit. Most studies will require healthy control volunteers selected from a volunteer panel that have been pre-screened for any neurological illnesses as well as any history of head injury, psychiatric disturbance or substance abuse.

However, for some studies it may be desirable to record from 'stable' patients; that is, volunteers who have a neurological history, but who do not require ongoing medical attention and for whom MEG poses no significant risks over and above those that apply to a normal healthy volunteer. Possible groups include stable stroke patients, mild Parkinson's disease and early stage Alzheimer's disease or other types of Dementia. In these and all other cases, patient studies can in principle be conducted in the MEG facility, but always requires prior approval by the Local Ethics Research Committee.

The scanning of healthy volunteers would require prior approval from Cambridge Psychology Research Ethics Committee (CPREC) or Local Research Ethics Committee (LREC). These studies would involve standard cognitive neuroscience paradigms which have been used many times previously under similar circumstances and will be undertaken within the guidelines laid out by the Standard Operating Procedures.

Scanning studies involving patients, drugs or any ethically 'challenging' stimuli would require prior approval from the Local Research Ethics Committee (LREC). These studies would be undertaken within the guidelines laid out by the Standard Operating Procedures.

All volunteers must be screened before entering the MSR (cf. 3.7.2 Screening and Appendix D: MEG SCREENING FORM).

Only MEG Operators or personnel that have been appropriately trained and are experienced in the use of the MEG equipment are allowed to run experiments.

Written informed consent must be obtained from all volunteers.

3.4.2 Staff

Only MEG Authorized Persons shall have free access to the Controlled Area.

Unauthorised staff shall be subject to the procedures for the general public (see below).

3.4.3 General public

All unauthorised personnel, including unauthorised staff and the general public, must seek authority to enter the Controlled Area and be screened for magnetic elements before entering the MSR (cf. 3.7 Volunteer Management: Scanning and Appendix D: MEG SCREENING FORM). They must be accompanied by an MEG Authorised Person at all times when visiting the MEG facility.

3.4.4 Cleaning and maintenance staff

Cleaning and maintenance staff (e.g. estates and engineering staff) requiring access to the Controlled Area may only do so as unauthorised personnel and must undergo screening (cf. 3.7.2 Screening and Appendix D: MEG SCREENING FORM). They may only gain access to the Controlled Area under direct supervision of an Authorised Person. The MEG Support Coordinator will oversee the cleaning of the lab and instruct cleaning personnel appropriately. Lab cleaning is done in conjunction with the Helium refill and maintenance.

In case MEG Support Staff or MEG Operators volunteer for cleaning, the member of staff carrying out the cleaning will ensure that Health and Safety Rules are observed. A request for access of cleaning personnel needs to be made and requires approval of the MEG Lab Manager and Head of MEG/EEG.

3.5 Control of equipment

3.5.1 Equipment policy

Before taking any new equipment into the MSR, whose magnetic properties are not fully known, it must be tested for magnetic artefacts. Note that even non-metallic objects can be magnetic and cause major artefacts (e.g. electro-statically charged cushions).

No specialist equipment can be taken into the Magnetically Shielded Room (MSR) without approval of the Manufacturer or the Head of MEG/EEG and the MEG lab Manager.

Any items taken into the MSR must not be ferromagnetic or electrically charged. If in doubt, please consult the lab manager. Special attention must be paid to metallic tools previously used in strong magnetic fields (e.g. MR facility), as they may be magnetic. Special non-ferromagnetic equipment and non-electrostatic equipment should be used in the MSR exclusively. Here are some examples of pieces of equipment that should not enter the MSR (this list is clearly non-exhaustive):

- Mobile phones,
- Laptop computers,
- Iron tools,
- Power-operated tools
- Keys

3.5.2 Responsibility for Entry of equipment

Control of equipment entering the Magnet Room on a day-to-day basis is the responsibility of the Operator or the Qualified Operator (cf. 3.3 Access Control) responsible for the examination at the time. The opinion of the Lab Manager or Head should be sought whenever in doubt about whether an object can enter the MSR.

3.6 Volunteer management: General considerations

3.6.1 Volunteers

All volunteers must meet the minimum requirement of mobility that is being able to get on to the table or in to the chair unaided. It is the researcher's responsibility to check the volunteer's mobility either by telephone screening or observation.

Members of staff are permitted to be scanned under the supervision of an operator.

The term volunteer shall include:

- Healthy members of the public volunteering for a MEG study.
- 'Stable patients' volunteering for an MEG study.

3.6.2 Prerequisites for MEG Research

For all MEG studies the following prerequisites must be fulfilled:

- Presentation at the IIG
- Ethical approval obtained from the relevant Research Ethics Committee prior to the MEG examination.
- IMC approval by completing the Request for MEG slots form and submitting it to Marion
- Attendance of the CBSU Panel Induction for Volunteer Testing
- Become an MEG researcher (see 3.3.1 Criteria for authorisation of MEG lab access)
- Contacted megadmin@mrc-cbu.cam.ac.uk to request MEG slots
- Run several pilot slots, the first to set up your experimental parameters on the MEG acquisition computer.

Analyse your pilot data before booking your testing slots and volunteers.

3.6.3 Prerequisites for MEG Examination

For all MEG examinations of volunteers the following prerequisites must be fulfilled:

- Written MEG information must be made available to all volunteers before they consent to scanning, as defined in the

study protocol approved by the research ethics committee, information can be found on the MEG wiki.

- Written informed consent must be obtained before the examination (Appendix E: Consent form).
- All volunteers must be screened before entering the MSR (Appendix D: MEG SCREENING FORM, please note completing the form is not a formal requirement as long as the volunteer has been asked about the items listed)

N.B.: The appendices give forms that have been approved previously in the context of specific projects. Each principle researcher conducting a study is responsible for generating a form appropriate as a part of his or her own study. The materials in the appendices can only serve as a starting point here; they need to be adjusted to requirements of specific experimental conditions, task demands, volunteer populations etc.

Volunteers under the age of 18 years:

- All Researchers must be CRB checked as required by law.
- Ethical approval for scanning volunteers must be obtained from the relevant Research Ethics Committee prior to the MEG examination.
- Written MEG information must be made available to the volunteer and their parent/legal guardian before they consent to scanning, as defined in the study protocol approved by the research ethics committee.
- Written informed consent must be obtained before the examination with the volunteer and co-signed by their parent/legal guardian (Appendix E: Consent form).
- The MEG Screening Form (Appendix D: MEG SCREENING FORM) must be completed before the examination either in writing or by verbal means.
- Volunteers aged 16 and over may be exempt from the need for parental/guardian participation in the consent/screening process, where the relevant Research Ethics Committee approves such exemptions within the study protocol.

3.6.4 Responsibility for Volunteers whilst in the Controlled Area.

The responsibility for the safety, health and wellbeing of the volunteer throughout the period that the volunteer is within the Controlled Area will be shared between the researcher and the Operator.

3.6.5 MRC Indemnity Arrangements for Volunteers

Studies sponsored by the MRC:

The MRC provides indemnity where it is the Sponsor or has entered into a written agreement to provide indemnity for all or part of a study:

Negligent Harm. This will be covered by the MRC for MRC sponsored studies involving a member of the CBSU.

Non-negligent Harm. The MRC does not provide cover for non-negligent harm. However, it takes a sympathetic view of non-negligent claims.

A copy of the MRC's indemnity policy statement can be obtained by emailing megadmin@mrc-cbu.cam.ac.uk.

Studies not sponsored by the MRC:

Where the MRC is not the sponsor, then the researcher must provide written confirmation of any insurance or indemnity arrangements made in line with the terms and conditions agreed with their parent organisation. The insurance or indemnity arrangements must be as defined in the LREC/CPREC approval for the study.

Medical Doctors:

Medical doctors are advised to arrange adequate personal insurance against claims for negligent and non-negligent harm. They are advised that even non-remunerated research may be regarded as private practice (non-NHS practice) by some medical insurers.

3.6.6 Pregnant Women

The MEG is a passive receptor therefore the procedure of an MEG recording would not cause any detrimental effect to the well-being of a foetus, but may cause discomfort for someone who is pregnant.

We therefore exclude all women who are pregnant as a general measure of precaution.

3.6.7 Implanted Medical Devices

Implanted medical devices fall into two main categories:

Active implanted medical devices - such as pacemakers, defibrillators, neurostimulators, cochlear implants and drug pumps, where functionality is dependent upon an energy source such as electrical, mechanical or pneumatic power.

Non-active implanted medical devices - which are passive in that they require no power source for their function, for example hip/knee joint replacements, heart valves, aneurysm clips, coronary stents and breast implants.

Both types of implanted medical devices frequently contain metallic components which, while posing no threat to the volunteer during an MEG recording, may cause artefacts which can affect the quality of the recorded data rendering the device incompatible with MEG.

It is recommended to exclude volunteers with implants from MEG recordings.

3.6.8 Metallic Foreign Bodies

Metallic objects such as bullets, pellets, shrapnel, or other types of metallic fragments, older fillings, braces, fixed dental wires, in particular ferromagnetic objects, may be present in the body. Volunteers who are or have been involved in the manufacture of metal products may also carry metal in parts of their body. This may lead to artefacts in the recorded data. The use of such volunteers is therefore not recommended, but, the MEG procedure is not dangerous to the volunteer.

3.6.9 Tattoos, makeup, dyes

All ferromagnetic items must be removed before the volunteer enters the MSR.

I.e. Underwire bras, watches, keys, change, glasses, dentures etc.

Artefacts produced by the volunteer through fixed metallic objects (fillings, and fixed metallic dental work in particular) usually surface in a pre-recording and lead to the exclusion of the volunteer. It is therefore recommended to screen the volunteers prior to experiments, and instruct them accordingly.

3.6.10 Spectacles and Hearing Aids

Spectacles and hearing aids must be removed before entering the MSR. Non magnetic glasses can be provided but there are currently no provisions for those who are hard of hearing.

3.6.11 Tattoos and Makeup

Tattoos may contain iron oxide or other ferromagnetic substances that are magnetic but interference will depend on the type of dye used and where it is on the body.

Volunteers may be asked by the Operator in charge to remove any makeup (makeup remover is provided).

3.6.12 Body Piercings

Metallic body piercings will be magnetic and will disrupt any recording.

All body piercings must therefore be removed before the volunteer enters the Controlled Area

3.6.13 MRI Structural's

For those researchers who require an MRI structural or other MRI scan as well as an MEG recording it is advised that their volunteers undergo the MEG first to avoid magnetic interference and that before coming in for their MEG volunteers are screened using the MRI screening criteria. If this is not possible it is recommended that the MRI scan is NOT done in the 48 hours preceding the MEG recording.

3.7 Volunteer Management: Scanning

3.7.1 Preparation

Identification: The MEG Operator must ensure that the volunteer is correctly identified.

Reassurance and explanation: A suitably trained person (researcher or operator) should describe the procedure to the volunteer, explaining the sights, sounds and experiences to be anticipated, and predicting the likely length of examination. The MEG researcher must ascertain that the stimulation procedures are in place and properly adjusted. The volunteer should be instructed as appropriate for the experiment.

3.7.2 Screening

Before booking in volunteers for a study, volunteers will be pre-screened using the information sheet (cf. Appendix C: Volunteer Information Sheet) that covers major questions in MEG experimenting in order to prevent a wasted MEG time slot, alternatively a suitable 'backup' volunteer can be recruited. The information sheet will mention definite exclusion criteria, such as implanted stimulators, metal implants in the head, and those that may require testing before beginning the study, such as, tattoos, fillings etc.

On arrival to the unit volunteers will be asked to complete a screening form (cf. Appendix D: MEG SCREENING FORM). The Operator and researcher will then prepare the volunteer for the MEG recording. This includes the removal of all ferromagnetic, electronic or electro-statically charged objects from the volunteers body/clothes (e.g. mobile phones, radios, PDAs, music players, watches, credit cards, jewellery, hairpins, body piercings, hearing aids, glasses, metal-containing clothing, shoes, belt, etc). The volunteers will be asked to store these items in one of the lockers provided in the preparation room.

Before entering the MSR, the MEG Operator must ensure that the volunteer has completed the screening form and that he/she has no MEG incompatible items on him/her.

3.7.3 Positioning

Positioning of the volunteer in the machine and changes of gantry position can only be done by an MEG Operator.

Two issues are important here: patient comfort and patient safety. Time taken to ensure that the patient is comfortable will lead to greater patient compliance with the recording and experiment. Importantly, reduced comfort leads to tension and thereby enhanced muscle activity, which constitutes a major source of artefact in non-invasive neurophysiological recordings with MEG or EEG. With regard to patient safety, the prevention of injury is the major concern. Attention must be drawn to the appropriate adjustment of the Dewar and the careful adjustment of the height of the seat, avoiding any pressure exerted onto the volunteer's head.

Placing a volunteer in the MEG always requires continuous monitoring of any possible discomfort, report of pressure felt etc.

General Guidelines for Researchers on assisting able bodied participants into the MEG

Please see the lab manager and/or the Health and Safety officer for a risk assessment of your participant population.

Once the risk assessment has been completed please contact the Operators to gain proper direction before attempting to put anyone into the MSR.

Guidelines for Researchers on assisting participants with poor mobility into the MEG

All studies involving participants with poor mobility are subject to a risk assessment made by the lab manager and/or the health and safety officer.

Participants MUST be able to raise themselves from a seated position to a standing position unaided to participate in any MEG study.

It is the researcher's responsibility to check the participant's mobility either via a social worker/GP or observing without assistance from their partner/spouse.

Once the risk assessment has been completed please contact the Operators to gain proper direction before attempting to put anyone into the MSR.

3.7.4 Comfort

Adequate lighting and ventilation in the MSR interior are important. Care should be taken if pillows, blankets or covers are used to ensure that they are MEG compatible and that heat loss is not inhibited. The MEG operator should regularly attend to and check the proper functioning of the air conditioning system. At all times during experiment the volunteer must be in a position to make contact with the operator and give warning of any discomfort or concern.

3.7.5 Communication

A camera and a two-way intercom are available for communication between the volunteer and the person who is scanning.

The intercom and camera monitor must always be switched on whenever the MSR door is shut with any person inside the MSR.

3.7.6 Maximum Time in the Scanner

The recommended time for a volunteer to be in the scanner is 1.5 hours with an absolute maximum of 2 hours for exceptional circumstances.

3.8 Data management

Published data have to be available for at least 5 years after the publication date. There is therefore a need for data storage. This needs to be done in accordance with Data Protection regulations.

3.8.1 Minimum Data Required

The following is regarded as the minimum data that should be retained from a given volunteer:

- The volunteer's name or reference, sex and age.
- Date of recording.
- Experiment ID.

- The approximate time spent in the MSR.
- This information will be recorded by the MEG operators and stored electronically with the MEG Administrator.

3.8.2 Acquisition Data

Data files storing neurophysiological data and associated information are in electronic form and stored on the volunteer data management system provided by the manufacturer Elekta-Neuromag.

All information stored on the system will never be linked. Never is a person's name stored together with his or her data.

Data is saved using the following format:-

/megdata/cbu/{your test name}/{your volunteer ID}/{date in yymmdd}

I.e. /megdata/cbu/MEGstudy/MEG090001/090909

In the case of the units partners separate secure files have been set up, these are as follows:-

CAMCAN – Cambridge Centre for Ageing and Neuroscience
CSL – Centre for Speech and Language in the Brain
CNE – Centre for Neuroscience in Education
CNBH – Centre for the Neural Basis of Hearing
PCF – Paul Fletcher
GSK – Glaxo Smith Kline

Data is saved using the following format:-

/megdata/cbu/{partners unit}/{your test name}/{your volunteer ID}/{yymmdd}

I.e. /megdata/cbu/CSL/MEGstudy/MEG090001/090909

3.8.3 Data Protection and Confidentiality

The MRC Cognition and Brain Sciences Unit (CBSU) researchers and members of their associated research group will have access to the data. It is possible that the data may be used by external researchers working with the CBSU for a different project with similar ethically approved research protocols, the same standards

of confidentiality will apply. It may also be disclosed to researchers working outside the CBSU who are working in collaboration with researchers scanning within CBSU. If this is the case the non-CBSU person must have signed a Code of Conduct guaranteeing that the data will be kept confidential & secure.

The MRC complies with the requirements of the Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and is committed to upholding the Acts core Data Protection Principles. All enquiries concerning access to data held by the Cognition and Brain Sciences Unit should be addressed to the Freedom of Information Liaison Officer at the Unit in the first instance.

Data files storing neurophysiological data and associated information are in electronic form and stored on the volunteer data management system provided by the manufacturer. All information stored on the system will be linked. Never is a person's name stored together with his or her data. The CBSU volunteer number is used for identification. When the acquisition computer asks for the last and first names for the volunteer, the MEG ID number must be entered instead following the format meg[2 digit year] for surname and a sequential 4 digit number for first name i.e. Meg09 0001. The link between personal information and ID number can only be stored in encrypted format or in locked cabinets. All data acquired and volunteer records should be held in safe keeping for a period that ensures compliance with the current guidance from the Department of Health and the Medical Research Council. It should be in a form from which full details can be retrieved within this period if required.

3.8.4 Abnormal Findings

The Cognition and Brain Sciences Unit is a cognitive neuroscience research unit and does not provide any diagnostic services. This policy should be clearly stated on the volunteer information sheet.

However, all MEG and EEG recordings are screened by CBSU science staff for obviously abnormal neurophysiological activity (spike-wave complexes, local slow wave activity etc.). In the event that a significant abnormality is noticed by the MEG operator in charge that cannot be due to any external interference, this will be brought to the attention of the Lab Manager or Head of EEG/MEG. The issue may be discussed with a

neurologist affiliated with CBSU or with the MEG Management Committee, who will take necessary steps. It may be necessary to exclude such volunteers from this and future studies in which case the reasons for the exclusion will not be fed back to the researcher or the individual concerned.

3.9 Staff training

To avoid accidents, it is essential that all personnel associated with MEG equipment be adequately trained (see also Section 3.3.1 Criteria for authorisation of MEG lab access).

The training of all appropriate categories of staff in terms of their normal duties and those in the event of an emergency is essential before installation and for all new staff subsequent to installation. Regular reviews of the training status as well as updates and refresher training for all staff will be required.

3.10 Accident/Incident Reporting and Investigation

All accidents and near misses, however minor, must be reported to the relevant line manager and recorded.

All accidents and near misses will be investigated by the relevant line manager to establish the root cause and introduce management action to prevent a recurrence.

All notifiable accidents, dangerous occurrences and cases of occupational related ill health, as defined by The Reporting of Injuries, Diseases and Dangerous Occurrences Regulation 1995, must be reported to the Safety Co-ordinator (see 3.1.1 Key Personnel) who will ensure the Director, the local Health and Safety Executive Office and the Health and Safety Section at Head Office are informed.

4 Emergency procedures

4.1 General considerations

An emergency can relate to the well-being of volunteers in the laboratory, to an environmental emergency such as a fire or a threat to a member of staff. Careful consideration must be given to setting up the correct form of training for specialist staff involved in any form of emergency which needs entry into the MEG Laboratory, and the necessary liaison with the appropriate groups both within and outside the establishment.

4.2 Emergency Switches

4.2.1 Location

There are two different types of emergency shutdown switches: The emergency open button for the MSR door and the power isolation button. The location of these switches is shown in the floor plan in Appendix B: Power Switches

4.2.2 MSR Emergency open button

There is one MSR emergency open button located on the right of the MSR door underneath the normal open and close button.

It is designed to release the pressurised air used to close the door and should be used when urgent access into the MSR is required.

4.2.3 Power isolation button

There is one Power isolation button located inside the MEG laboratory to the right of the main door.

The power isolation button cuts power to the lights and the stimulus cabinet.

4.2.4 Location of rescue equipment

An Heartstart FRx Automated External defibrillator, AED, along with an oxygen cylinder and a comprehensive first aid kit is based in the 'Elbow' at the top end of the south wing of the main CBSU building.

In an emergency within the MEG Facility, the AED, along with the oxygen cylinder, will be brought to the MEG Laboratory by one of the AED trained first aiders.

In case of medical emergencies, first aid staff must be contacted, on the internal telephone network, by an 888 call.

4.3 Evacuation and access routes

4.3.1 General Considerations

In the event of the fire alarms sounding the member of staff in charge of the building at that time (e.g. Head of MEG/EEG Qualified Operator, Authorised person)

Will ensure everyone in the laboratory evacuates by a fire escape and makes their way to an assembly point, where they must remain until instructed otherwise.

Check all rooms (including MSR) are empty of people.

Make their way to a meeting point, this may be the garden or, if the route is safe, the front car park.

Escape routes are indicated on the map in Appendix F: West wing lab exit routes.

4.3.2 Access routes for Rescue Vehicles

Turn left into the MRC site from Chaucer Road, once in the front car park turn right and follow the car park to the end where there is a tree and a bike rack in front of you and a gate to your left.

Go through the gate and follow the building around to the left and you will see the glass emergency door, please note the door can only be opened from the inside (cf. Appendix F: West wing lab exit routes for plan showing evacuation and access routes).

4.4 Medical emergencies

4.4.1 General considerations

In the event of a medical emergency (e.g. cardiac arrest), the recording should be terminated immediately. The volunteer should be removed from the MSR

4.4.2 Emergency Procedures (Medical Emergencies)

Operator:-

- terminate the recording
- Check the condition of the volunteer and make an assessment as to whether urgent additional help is needed.
- Escort the volunteer out of the MSR if they are able to move themselves

Call 888 to request the assistance of a CBSU first-aider (during Unit working hours only)

IF THIS IS AN EMERGENCY AND URGENT HELP IS NEEDED:

Call 888 and request the assistance of a CBSU first-aider
Call (9-) 999 out of working hours or when an ambulance is needed

Report our location:

MRC Cognition and Brain Sciences Unit
15 Chaucer Road, Cambridge, CB2 7EF
Emergency Telephone 01223 355294
Switchboard must repeat this back to you!

Report what has happened:

Details of the medical emergency (e.g. suspected cardiac arrest)
Details of the patient (e.g. female approx 25 years old)

DURING UNIT WORKING HOURS: inform Reception by dialing 100 and ask them to send somebody outside to wait for the ambulance and direct them to your location.

OUTSIDE OF UNIT WORKING HOURS: a person should be dispatched to the front car park to direct the ambulance.

Report the incident:

Inform at least one of the following persons

- MEG lab manager
- Head of MEG/EEG
- Director

4.5 Major Equipment Failure

In the event of a power cut remove the participant from the MSR.

The system takes a certain amount of time before electronics can be switched on again. Once power has returned please follow the guidelines in the Manual situated in the MEG lab (pg. 80) for switching on.

4.6 Fire

4.6.1 General Considerations

All fire alarms in the main Unit and the MEG facility are automatically linked to Cambridge Fire Station. Breaking the glass at one of the alarm points will result in the fire brigade making their way to the Unit.

4.6.2 Emergency Procedures (Fire)

ON DISCOVERING A FIRE:

On discovering a fire in the MEG facility:-

- Raise the fire alarm by breaking the glass on one of the fire alarm points.
- Terminate all MEG procedures
- Press the Power isolation button
- Evacuate (see Evacuation below)

ON HEARING THE FIRE ALARM:

- Terminate all MEG procedures
- Evacuate (see Evacuation below)

Evacuation

All occupants must immediately make their way to a fire assembly point.

Staff with volunteers/patients/visitors should escort them to the assembly point.

The MEG Operator will be responsible for checking that the rooms are empty on their way out.

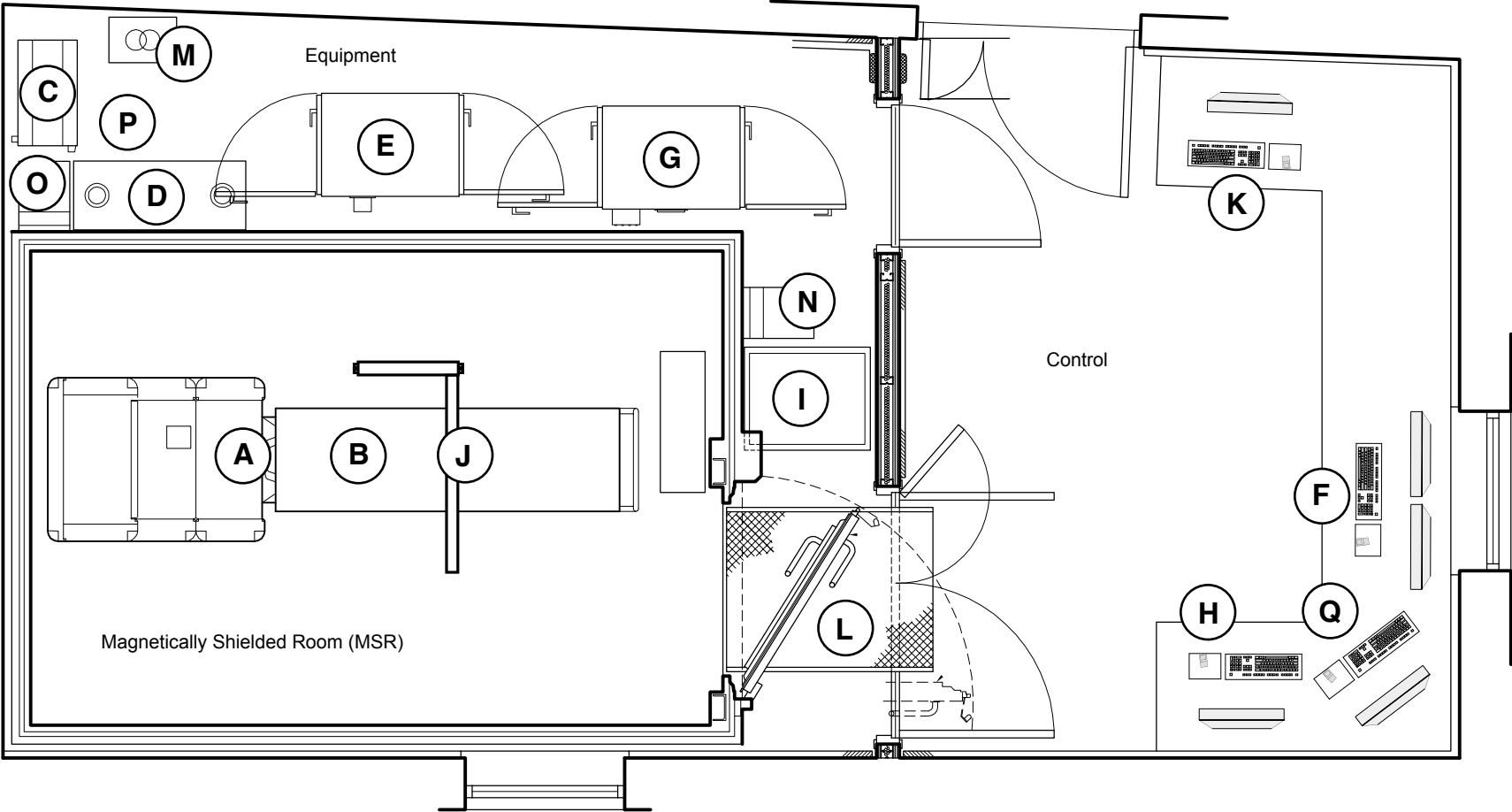
Assemble at the meeting point, meeting points are indicated in Appendix F: West wing lab exit routes. Do not re-enter the building until it has been declared safe by a suitably qualified person.

When reasonable to do so report the incident to at least one of the following: MEG manager, Head of MEG/EEG, Director.

APPENDIX A: MEG LAB AREA AND MSR (AUTHORISED STAFF ONLY)

Rev.	Date	Drawn	Description

N.B. Main electronics and stimulus electronics cabinets will be built as mirror images from standard



Layout Plan

- LEGEND:
- A: Dewar
 - B: Patient bed or chair
 - C: Lifting motor unit
 - D: Electronics feedthrough filter
 - E: Main electronics cabinet
 - F: Data acquisition workstation
 - G: Stimulator cabinet
 - H: Stimulus control
 - I: Video projector
 - J: Back projection screen (movable)
 - K: Analysis workstation
 - L : Ramp 1:8
 - M: Isolation transformers
 - N: Air inlet
 - O: Air outlet
 - P: Helium safety exhaust duct out (Ø100 mm) - connect to duct outside the building
 - Q: Eye Tracker Control

Note: liquid Helium storage t.b.d.

Note		Product Elekta Neuromag	Included in Site plan	Title MRC-CBU MEG Facility Proposal for equipment layout
Date	30.1.2010	Elekta Neuromag Oy		Part/drawing n:o
Drawn	JKn			
Chkd.				
Appr.				

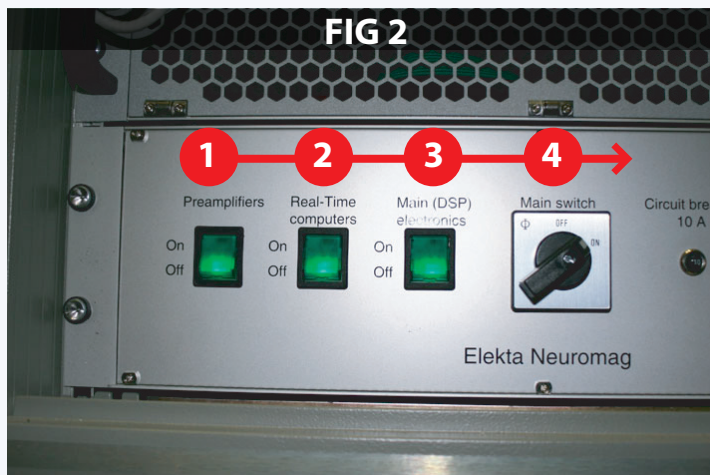
Appendix B: Power Switches

- When removing power or restarting the the system it is important that the following procedure is followed to prevent damage to the system.

Switch location can be found in the rear of the rack (see Fig 1)

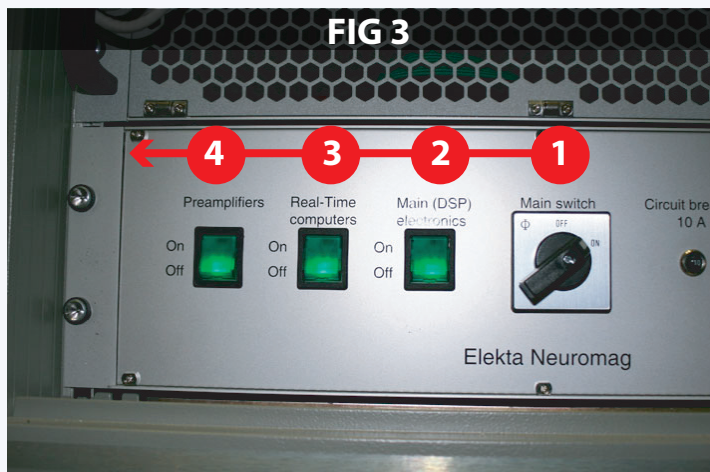
- Switching Power Off - left to right (see Fig 2)**

1. Preamplifiers
2. Real Time Computers
3. Main DSP
4. Main Switch to Off



- Switching Power Back On - right to left (see Fig 3)**

1. Main Switch to ON
2. Main DSP
3. Real Time Computers
4. Preamplifiers



Appendix C: Volunteer Information Sheet

- **Standard information sheet approved by CPREC 10/2006 in the context of a specific ethics approval.**
- **This form needs adjustment to individual experiments and subsequent separate ethics approval.**

General Volunteer Information about MEG experiments

The human Magnetoencephalogram (MEG) records the small changes in magnetic fields at the surface of the head generated by nerve cell activity inside the brain. In the MRC COGNITION AND BRAIN SCIENCES UNIT, we are now using this technique for measuring brain activity related to human perception and cognition.

The experiments address questions about the brain basis of human cognition. We will be happy to explain it to you, in case you are interested, the ideas and hypotheses that motivate the experiments. However, such explanation has to wait until after the experiment, as knowledge about the hypotheses of an experiment may influence the participants' behaviour and strategies. You can withdraw from the experiment whenever you like without giving a particular reason. The following paragraphs are designed to inform you about some general aspects of the methodology.

You are not exposed to external electrical or magnetic fields. The top of your head will simply be positioned within a helmet-like device that can measure the very weak magnetic fields produced as a normal consequence of activity in your brain. Possibly, a handful of sensors will also be attached to your forehead with tape (which should not cause discomfort nor leave any mark), just to measure the precise position of your head relative to the helmet. During a typical experiment, for example, you might be presented with visual words or pictures on a screen in front of you, or hear sounds or words through headphones, and may be asked to press buttons with your fingers according to a simple task. The precise experimental procedures will of course be explained in more detail and you will be given the opportunity to practice and ask questions.

The experimental session typically takes about 1 hour. Preparation time for a simple experiment is usually 15 minutes. However, this can vary depending on the type of experiment, and you will be informed about the specific details before the experiment.

Because the magnetic signals we measure are very weak, we would like to avoid any possible source of recording artefacts. In particular, it is important that muscle activity, eye movements and eye blinks are minimised (though, of course, not completely suppressed). We will therefore ask you to sit or lie as still as possible during the experiment.

We assure you that the data we acquire will be kept confidential. Details of the data storage will be clarified on a different form.

You will be paid for your participation. Payment will be for the entire time spent in the lab (including preparation etc.). The current rate is £10 per hour.

Again, we emphasise that questions about the background of the experiment or the procedures are always welcome. In addition, we would appreciate your feedback about your impression of the experiment.

Appendix D: MEG SCREENING FORM

3.0 MEG SCREENING FORM

MRC Cognition and Brain Sciences Unit



15 Chaucer Road, Cambridge, CB2 7EF Tel: 01223 355294

VOLUNTEER

Date: Study/investigator:

Subject number:

Have you ever had an MRI scan? Yes No

Date: / /

Facility Name & Location:

Are you currently taking or have recently taken any medication? Yes No

Please List:

Please remove **all metallic objects** before you enter the magnetically shielded room including: keys, hair pins, hair bands/clips, jewellery, watch, safety pins, paperclips, money clips, credit cards, coins, pens, belts, metal buttons, & clothing with metal in the material.

Some of the following conditions/items may interfere with the MEG recording. Please check the correct answer for each of the following. If you checked yes, please give more information. E.g. Type of material? How long ago? Where on your body? (Please use diagram)

	Yes	No			Yes	No
Underwire Bra	<input type="checkbox"/>	<input type="checkbox"/>		Artificial limb or joint	<input type="checkbox"/>	<input type="checkbox"/>
Body piercing(s)	<input type="checkbox"/>	<input type="checkbox"/>		Hair dye	<input type="checkbox"/>	<input type="checkbox"/>
Severe Claustrophobia	<input type="checkbox"/>	<input type="checkbox"/>		Tattoo	<input type="checkbox"/>	<input type="checkbox"/>
Hearing aid (Remove before entry)	<input type="checkbox"/>	<input type="checkbox"/>		Tattooed eyeliner or eyebrows	<input type="checkbox"/>	<input type="checkbox"/>
Dentures (Remove before entry)	<input type="checkbox"/>	<input type="checkbox"/>		Asthma or breathing disorders	<input type="checkbox"/>	<input type="checkbox"/>
Fixed metal dental work	<input type="checkbox"/>	<input type="checkbox"/>		Any other metal in or on your body e.g. buttons/zips etc.	<input type="checkbox"/>	<input type="checkbox"/>
Seizures or motion disorders	<input type="checkbox"/>	<input type="checkbox"/>		Wig, toupee, or hair implants	<input type="checkbox"/>	<input type="checkbox"/>

Date:

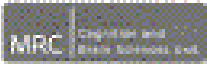
Your Signature /..... /.....

Authorised staff name..... Authorised staff signature.....

Appendix E: Consent form

A standard consent form approved by CPREC 10/2007 for a specific experimental program.

They are available on request from the panel office.
This needs adjustment and ethics approval for use in individual studies.

	MRC Cognitive & Brain Sciences Unit 19 Chaucer Road Cambridge CB2 3EF
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INFORMED CONSENT/RECEIPT FOR TESTING Unit No: 1055

Experiment(s) ID: _____ Test: _____

THIS PART OF THE FORM MUST BE SIGNED BEFORE TESTING BEGINS, NOT AFTER.

The nature of the experiment was explained to me and I agreed to take part.
I understand that I can withdraw from the experiment at any time.

SIGNATURE OF VOLUNTEER: _____ DATE: _____

THIS PART OF THE FORM MUST BE SIGNED AFTER TESTING.

I understand that the data from this testing session will be stored on a computer or on paper, and may contribute to scientific papers and presentations. I agree that the data can be made available anonymously to other researchers, both inside and outside the CBU. This data will not be linked to me as an individual, and my name will not be passed on to anyone outside the CBU, or to anyone in the CBU who is not directly involved in the research project for which this data was collected, without my consent.

SIGNATURE OF VOLUNTEER: _____

I acknowledge receipt of the sum shown, and hereby declare that I am not an employee of the Medical Research Council.

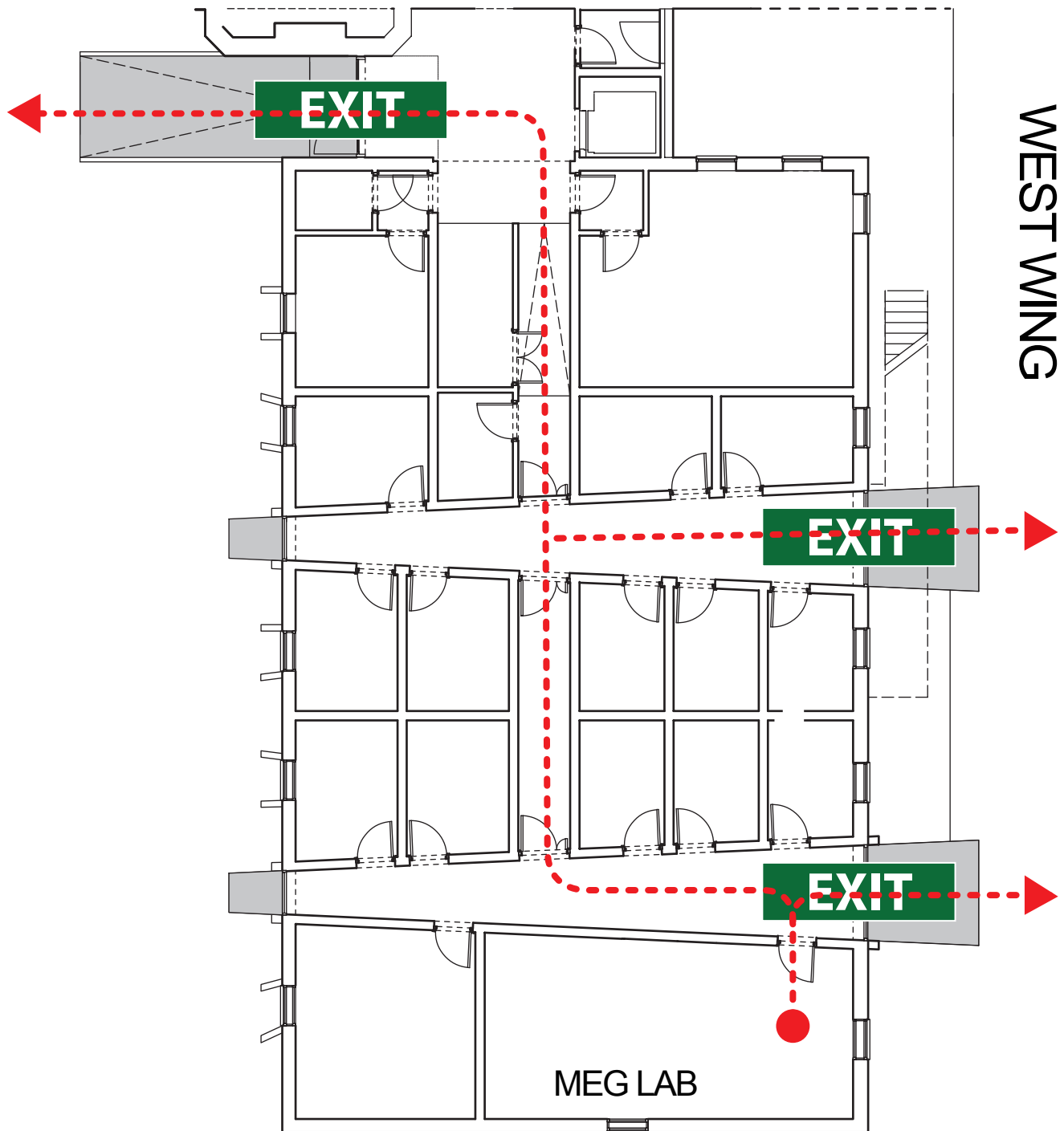
NON-PANEL ☐ PANEL ☐ ID NO: _____ (Please tick as appropriate)

Please PRINT your name and address below

DATE(S) TESTED	NO. OF HOURS	HONORARIUM £10.00 hr	TRAVEL see 1	TOTAL
<small>1 Travel in Cambridge £ 2.00 outside Cambridge £ 7.00</small>			FINAL TOTAL	

SIGNATURE OF VOLUNTEER: _____ DATE: _____

Appendix F: West wing lab exit routes



KEY:

EXIT = EXIT POINTS

 = EXIT ROUTES FROM MEG LAB

Appendix G: Definition of Terms

MEG Authorised Person	A person who is trained in MEG methods and is familiar with the relevant Health and Safety (H&S) procedures and MEG Standard Operating Procedures (SOPs). An authorised person is allowed free access to the Controlled MEG lab Area. Certification of an individual shall only be authorised after satisfactory completion of the MEG Authorisation Procedure (3.3.1 Criteria for authorisation of MEG lab access).
MEG Researcher	An authorised person who is a researcher and is leading, or collaborating in, an ongoing MEG study.
MEG Operator	An authorised person who has been trained to run the MEG device.
MEG Support or MEG Technical Staff	An authorised person who is technical staff with a specific function in the MEG laboratory (e.g. Helium refill, computer installation).
Controlled Area	The controlled area includes the MEG laboratory, MEG preparation room and any additional rooms used exclusively for MEG purposes.
MEG laboratory	Area in the West Wing of the CBSU where MSR and Control Room are situated.
Magnetically Shielded Room (MSR)	Core of the MEG laboratory where the MEG device is situated. The MSR is magnetically and acoustically shielded. Control Room Main room of the MEG laboratory, where computers for stimulation, data acquisition and evaluation are located along with amplifiers and a range of stimulation devices.

Preparation Room	Room close to the MEG laboratory where subjects are prepared for the experiment, verbally instructed and pre-tested.
Non-ferromagnetic or Non-electrostatic	Equipment taken into the MSR must be non-ferromagnetic and without electrostatic charges. Most metals are ferromagnetic, but there are a few, including aluminium, high quality steel, pure gold, that meet this condition.
Official Opening Hours	The Official Opening Hours of the CBSU are: Mon-Thu 9:00-17:30 and Fri 9:00-16:30

Appendix H: Oxygen Depletion Alarm

- At 19% Oxygen the beacon will start flashing. (see Fig 1)
- At 17% Oxygen the Alarm will Sound. (see Fig 1)

In either case the MEG room must be evacuated immediately.

- If there is a subject in the MSR Hit the emergency open on the MSR door and get the subject out immediately. (see Fig 2)
- If the MSR is empty and the door is closed do not open it.
- If possible hit the **RED** Power Isolation Button on leaving the MEG Room. (see Fig 3)
- If possible leave the main lab door open and open the door to the garden to aid ventilation.
- Do not re-enter the Meg Lab until authorised to do so and the Oxygen Monitoring Equipment in room 441 shows the levels are safe. (see Fig 4)

FIG 1**FIG 2****FIG 3****FIG 4**

Appendix I: Helium fill procedure for the MEG:

Note: In the event of an insoluble problem or physical threat to the safety of the operators during this procedure, the Dewar, Gantry and area involved should simply be evacuated. No serious harm can come to the equipment if it is allowed to vent unchecked.

Note: In compliance with the new MRC policy on eye protection, there is a mandatory requirement that the protective visor is worn by the person performing step 14; connection of the syphon tube to the MEG and step 19; removal of the syphon tube from the MEG.

1. Ensure the room is prepared for the fill procedure. The door should be fully opened, the ramp should be in position (*Figure 1a*), the MEG gantry should be in its lowered position (*Figure 1b - see page 3*) (For details on lowering the gantry – see “Raising and lowering the MEG Gantry” instruction sheet.) and the MEG chamber should be free of all obstructions.
2. Ensure you have all the correct equipment to hand. To wit – Two persons who must be present at all times during the fill.

Also:

- Ring seals for both main vent and charging vent,
 - Threaded main vent cap,
 - Ribbed charging vent cap,
 - Two butterfly screw clamps,
 - Spherical pump with tubing and roller valve,
 - Gloves,
 - Transfer pipe,
 - Transfer pipe seal (fitted to the stubby end of the transfer pipe),
 - Transfer pipe attachment assembly (brass screw cap, two rubber washers, metal washer)
 - Cutting implement,
 - Helium storage shed key.
3. Move a full tank of helium out onto the apron in front of the door into the unit. Cut away all ties securing valves and the plastic cover of the main vent.
 4. Mount the ring seals onto the main and charging vents before covering with the Threaded and Ribbed vent caps (*Figures 4a, 4b and 4c*). Fasten both in place with the butterfly screw clamps. Be aware that the Dewar may come with sealing rings permanently fitted in one or both positions, in which case it's unnecessary to use ours. The ribbed cap may already have the pump and tubing attached. This is not a problem and does not need to be removed. (*Figure 4d*)
 5. If not already in position, the two rubber washers, the metal washer and the brass screw connector should be placed along the shaft of the fill pipe. These should ordinarily be there already, however they **must** be present and so should be checked for before proceeding. These four items form the transfer pipe attachment assembly. (*Figure 5*)

FIG.1a



FIG.4a



FIG.4b



FIG.4c



FIG.4d



FIG.5



- **6.** One person (wearing gloves) should support the stubby end of the transfer pipe as the other person introduces the pipe into the main vent through the threaded cap (**Figure 6**). The transfer valve should be closed and the charging vent should be opened. This may result in partial or full inflation of the pump sphere.
- **7.** Once the transfer tube is inserted sufficiently to come into contact with the top of the main vent valve, the transfer pipe attachment assembly should be slid down to the top of the Dewar and tightened finger tight only. The rubber tubing seal on the stubby end of the transfer tube should be removed and the longer end of the transfer pipe should be inserted slowly into the Dewar. (**Figures 7a and 7b**)
- **8.** The sphere pump should be fully inflated at this point and a close eye should be kept on the pressure valve to ensure it doesn't go too high (Above 0.25). If the pressure does climb to unacceptable levels by accident then it will be released via spring-loaded escape valves around the neck of the Dewar. The pressure can be released using the blue roller valve (**Figure 8**) connected to the pump, however care should be taken not to release all the pressure as this is useful for the fill process.
- **9.** As the transfer tube is lowered, a rushing noise should be heard and a shimmer may be seen escaping from the tube's open end. If there is any gas escaping from the neck of the Dewar around the transfer tube, tighten the brass collar down until it stops. Eventually, white mist will begin issuing from the transfer tube (**Figure 9a**). As the tube is lowered still further the rushing will intensify and the sound will deepen until the jet emanating from the nozzle takes on the appearance of a Bunsen-burner flame (**Figure 9b**). At this point, re attach the rubber tubing cap to the end of the stubby end, sealing it. This operation should be performed by someone wearing gloves.
- **10.** With the transfer tube re-capped, continue lowering the tube into the Dewar until it hits the bottom (**Figure 10 - see page 3**). Remember to keep an eye on the pressure gauge at all times.
- **11.** The Dewar can now be wheeled into the MEG chamber. The transfer tube should, at all times, be supported to prevent undue strain from causing stress damage to the tube's internal structures. It should be noted that passing successfully through the door into the building is not a guarantee that the Dewar will fit into the MEG chamber. However, if a Dewar with transfer tube attached will fit into the MEG facility then it should pass through the door of the chamber. No-one entering the MEG chamber should have any metal or electronic items on them.
- **12.** It can be useful to take a helium level reading at this point to give a baseline for the fill. Except under special circumstances, it's unlikely that a fill will take place if the MEG is over 40% full.



- **13.** The Dewar should be wheeled up to the front of the MEG and steadied in place there, with the tubing laid out on the floor with the sphere pump so as to avoid kinks in the piping and things being trapped under wheels and feet (The pressure dial underneath the MEG filler cap should be consulted to ensure the pressure within the MEG is zero before any further actions are taken). One member of the pair should be stationed at the left of the MEG, ready to extract the gantry fill-plug and control the pressure-release valve while the other will be inserting the hose.
 - **14.** The team-member on the left (looking at the unit) should loosen the gantry plug until it can be pulled out easily. It should be left in place until ready. The filler should remove the tubing from the tip of the transfer tube and watch the vapour issue forth (**Figure 14a**). When the stream has, once again, assumed the form of a Bunsen flame the filler should signal the valve operator to remove the plug. The filler will now, rapidly, bring the transfer tube in and insert it into the fill tube (**Figure 14b**). This will now be screwed securely into place. It should be noted that these larger plugs and tubes should never be attached too securely and should be screwed only to finger tightness.
- NOTE: FACE PROTECTION VISOR MUST BE WORN FOR STEP 14**
- **15.** While fitting the transfer tube, the person conducting the operation should keep an eye on the gantry pressure indicator. The optimal pressure is between 0.07 and 0.9. If the pressure appears to be increasing above this then the filler should notify the valve controller to open his release valve and release some of the gaseous Helium. The pressure should not be permitted to rise above 0.9. (**Figure 15**)
 - **16.** With everything fitted together, the internal pressure within the gantry should begin to fall towards zero. At this point one of the personnel should begin pumping the spherical pump. This agitates the liquid helium and causes it to begin to flow. Pressure within the Dewar should be pumped to around .5, however it may not be possible to bring the pressure up this high. Once the pressure within the gantry begins climbing to around 0.08, the pumping may be discontinued and the siphoning action of the cryogenic fluid will maintain the process.
 - **17.** Sometimes the siphoning operation may be reluctant to continue as expected. In these cases it may be necessary to pump the system more vigorously and in the face of higher back-pressure. In this case, it's vital to have someone weighing in excess of 75Kg to perform the pumping as any lower weight will be insufficient to compress the pump. If the siphoning operation is functioning optimally, the unit should fill at a rate of approximately 10% per 5 minutes. This will rapidly drop to nothing as the liquid helium is exhausted. The best way to judge this is from the MEG control console as the meter on the side of the MEG is less accurate.



- **18.** As the supply of available liquid Helium in the Dewar comes to an end, pressure within the Gantry will either maintain at a constant level or decrease rapidly. At the same time, the transfer-rate will drop to zero. At this point, only gaseous Helium remains in the Dewar and further pumping is pointless. If the pressure within the Dewar and the Gantry are individually or collectively high then the pressure must be released via the control valve on the side of the unit or the pump/tube valve on the Dewar.
- **19.** The pressure dial underneath the MEG filler cap should be consulted to ensure the pressure within the MEG is zero before any further action is taken. One of the team should unscrew the transfer tube from the Gantry fitting and remove and re-cap it. Simultaneously, the other member of the team should re-insert the Gantry plug.

NOTE: FACE PROTECTION VISOR MUST BE WORN FOR STEP 19

- **20.** Open the travelling valve, close all other valves and wheel the unit back outside.
- **21.** Vent any pressure that has accumulated while the Dewar was being transported by opening the roller-valve and unfasten the brass coupling that is holding the transfer tube into the Dewar. Be certain whoever does this is wearing cryo-gloves.
- **22.** Once the fitting is completely unscrewed, extract the transfer tube out of the top of the tank, again with the second member of the team supporting the stubby end of the tube. The rubber washers and coupling should be left stuck to the rod body. Once the tube is fully exposed, store it inside next to the radiator. Close the main valve on the top of the Dewar, remove all the fittings you added at the beginning of the process and move Dewar back into the Helium storage shed.

Other notes:

- *Anyone handling or coming into close proximity with liquid Helium must wear gloves to protect their skin from accidental exposure and cold burns.*
- *The individual controlling the end of the transfer tube that inserts into the Gantry must wear the protective visor in case of splashback.*
- *At 0.14 Bar, the primary safety cap on the Gantry will blow. A pressure release valve activates at 0.1 Bar however care should be taken when filling the gantry to ensure that the pressure does not spike when connecting the transfer tube. This can be difficult because of the necessity of wearing gloves, tightening the attachment on the hose and the clouds of vapour produced by the liquid Helium.*
- *The pressure dial underneath the MEG filler cap should be consulted to ensure the pressure within the MEG is zero before any actions are taken as this can cause a blowback.*
- *The pressure release vent on the side of the Gantry must never be opened when there is no pressure within the Gantry as this can allow air to enter the Gantry and taint the liquid Helium supply.*

Appendix J: RAISING AND LOWERING THE MEG GANTRY:

RAISING THE GANTRY

1 Stand everyone clear of the moving parts of the system. No-one should be laying in the unit at this time. (Figure 1)

2 The indicator light on the rear of the unit should be showing green (OK). (Figure 2)

3 Depress the 'Up' key to the rear of the unit. The yellow (Tension) indicator should illuminate and the unit should begin to rotate upwards. (Figures 3 and 4)

4 Continue to depress the 'Up' button until the yellow (Limit) light illuminates in addition to the yellow (Tension) light. (Figure 5)

5 Tap the 'Down' button until the yellow (Limit) light extinguishes and the yellow (Tension) light is replaced by the green (OK) light. (Figure 6)

6 The gantry is now in position for scanning of seated patients. (Figure 8)

LOWERING THE GANTRY

1 Stand everyone clear of the moving parts of the system. No-one should be sitting in the unit at this time. (Figure 8)

2 The indicator light on the rear of the unit should be showing green (OK). (Figure 2)

3 Depress the 'Up' key to the rear of the unit. The yellow (Tension) indicator should illuminate and the unit should begin to rotate upwards. Almost instantly, the yellow (Limit) light should illuminate. At this point, release the 'Up' key. (Figures 3, 4 and 5)

4 Depress the green latch lever on the rear of the MEG. (Figure 7)

5 Keep the latch lever depressed as you also depress the 'Down' button on the rear of the MEG. The yellow (Limit) light should go out but the yellow (Tension) light will remain lit. (Figures 6 and 4)

6 The MEG gantry should begin to rotate downwards until it finally reaches its fully lowered position. As it reaches the supine position, the yellow (Tension) light will go out and the green (OK) light will illuminate. (Figures 1 and 2)

CAUTION.....



If, at any point during the procedures, the red (Fault) light should illuminate. If possible, lower the gantry to the supine position and report the fault to Elekta.

CAUTION.....



Never attempt to scan with the gantry in any position other than in the fully up and locked position (resting on the latch) or the fully down position (resting on the stops). The green ok LED must be on in either position.

CAUTION.....



Raising the gantry from the supine to seated positions will cause the helium level meter to under-read by approximately 20%. Helium readings should only be taken in the supine position.

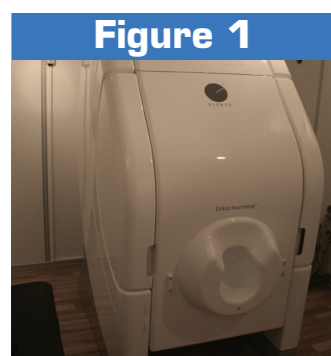


Figure 1

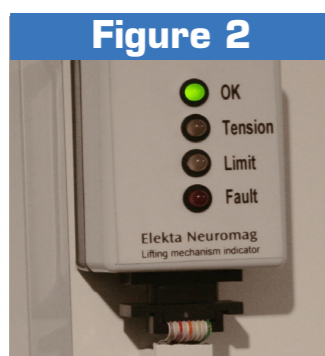


Figure 2

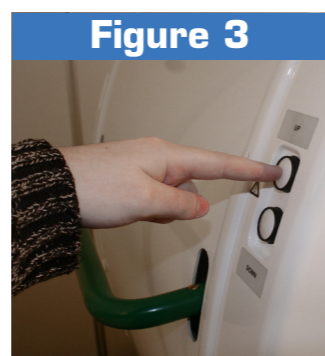


Figure 3

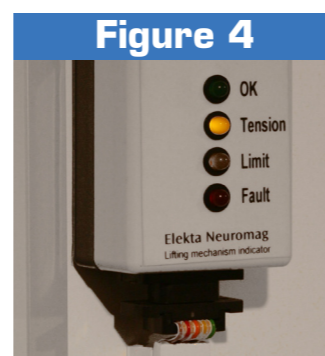


Figure 4

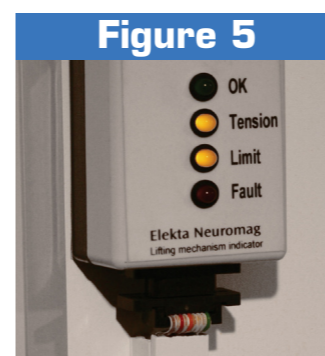


Figure 5

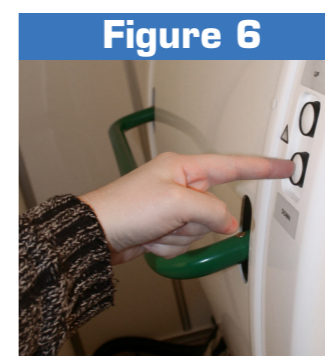


Figure 6

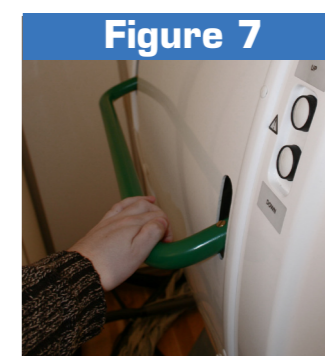


Figure 7

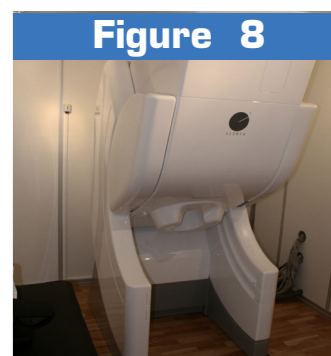


Figure 8