

Title: SOPs for 7T MRI Scanning

Doc. No.: MR\_S **NUMBER** **TBC**

## Standard Operator Procedures for 7T MRI Scanning

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### ISSUE / REVIEW HISTORY

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## A. Introduction

The Wolfson Brain Imaging Centre have recently installed a Siemens Terra 7T MRI scanner. At the time of writing in 2018, there are only five 7T MRI scanners in the UK, and approximately one hundred in the world. 7T MRI has proved itself to be a valuable tool for physics development and neuroimaging research in volunteers. A number of sites are now increasingly also performing research studies using 7T MRI in patient groups, including Cambridge. There are practical and technical differences between MRI scanning at 7T compared to scanning with a conventional clinical 3T. This document therefore describes a set of rules that apply specifically to 7T MRI scanning at the Wolfson Brain Imaging Centre.

In summary:

- A.1. 7T MRI scanning must only be performed by an approved 7T Scan Operator (defined in Section B below); or under their direct, in-person supervision during training.
- A.2. Specific training (Sections C and G) must be completed successfully to become a 7T scan operator.
- A.3. 7T MRI scans must be performed with an appropriate number of trained personnel for the category of subject or phantom. (Section D)
- A.4. 7T MRI scans on patients must comply with additional rules. (Section E)
- A.5. Anyone entering the 7T controlled area must have been satisfactorily screened according to the 7T safety screening policy (defined in Section F).
- A.6. Any incidental finding during a 7T MRI scan must be managed in accordance with the WBIC incidental findings policy.
- A.7. 7T MRI scanning must comply with the WBIC Standard Operating Procedures (available from <https://universityofcambridgecloud.sharepoint.com/sites/WBIC/SOPs>), except where the general-purpose SOPs conflict with the specific 7T MRI provisions in this document.

## B. 7T scan operators

Due to the cutting-edge nature of 7T MRI technology, the workflow for 7T MRI scanning is less well developed than for 3T MRI. Only a limited set of pulse sequences are provided with the scanner by the vendor; most pulse sequences must be implemented by the research team or obtained from collaborating sites. 7T MRI studies often involve additional calibration steps not required for 3T MRI. We anticipate that a significant amount of MR physics development work will take place on the WBIC 7T MRI scanner. Some of these studies will need substantial blocks of time on the scanner for setup, measurement, and returning the system to



# UNIVERSITY OF CAMBRIDGE

## Wolfson Brain Imaging Centre

**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

normal operation. It is therefore imperative that appropriately trained staff and students are able to operate the scanner independently.

Training to run the 7T MRI scanner requires successful completion of the 7T Scanner Operator Training Programme and Final Assessment. This includes demonstration of enough experience to be confident and competent in all aspects of MR safety and data acquisition that are relevant to the project being undertaken. One of the staff assessors listed at the end of the scanner operator training record must sign the assessor sheet to certify completion of training. Under no circumstances should an operator carry out a scan unsupervised unless they have successfully completed the appropriate training and assessment. Operators must adhere to the safe working practices of WBIC at all times, as described in this document and the WBIC Standard Operating Procedures (<https://universityofcambridgecloud.sharepoint.com/sites/WBIC/SOPs>).

- B.1. 7T MRI scanning must only be performed by an approved 7T scan operator (defined below); or under the direct, in-person supervision of an approved 7T scan operator (e.g. during training or for academic collaborators).
- B.2. A 7T Scan Operator is someone who:
  - B.2.1. Is a member of staff, a graduate student, or the holder of an official academic visitor agreement at the University of Cambridge, or an employee of the scanner manufacturer (Siemens).
  - B.2.2. Has attended the WBIC safety course, and passed the test.
  - B.2.3. Has read and understood this document and the WBIC Standard Operating Procedures relevant for MRI scanning (<https://universityofcambridgecloud.sharepoint.com/sites/WBIC/SOPs>).
  - B.2.4. Has performed 20 7T MRI scans (observed and then under the direct supervision of an existing 7T scan operator), or who can demonstrate equivalent previous experience.
  - B.2.5. Has had their Scanner Operator Training Record (see Section G below) signed by one of the named staff assessors.
- B.3. 7T Scan Operators may be approved to run only a limited category of scans (e.g. only phantoms, only volunteers, only participants in a named study).
- B.4. Before signing the Scanner Operator Training Record (see Section G below), a named staff assessor must be satisfied that the operator has sufficient knowledge of the scanner, understanding of the risks and appropriate training in dealing with emergency situations to be able to scan safely for the studies they are authorised to scan for.
- B.5. The Head of 7T MRI Physics will hold the list of currently approved 7T Scan Operators.
- B.6. Approval as a 7T Scan Operator is not a right. It may be withdrawn by the Director of the WBIC.



## C. 7T scan operator training procedure

- C.1. All 7T scan operators are required to complete the operator training programme and pass the final assessment. The training typically involves a period of training and the completion of 20 scans (observed and then supervised). The final assessment involves practical demonstrations and a question-and-answer session with a named staff assessor (see Section G below). Training may differ depending on the intended scan operator category.
- C.2. Operator Trainees will be required to complete the Scanner Operator Training Record to record their development. Under specific circumstances, it may be possible to accelerate the training programme for individuals with extensive experience of the MRI environment and clinical MRI equipment. Such cases will be dealt with on an individual basis and at the discretion of the named staff assessors. The relevant previous experience should be recorded on the log sheet.
- C.3. Operator trainees will be given a copy of the Scanner Operator Training Record and the information necessary to answer the questions during the training phase. During the final assessment, knowledge will be assessed by an approved assessor at a mutually convenient time. The decision about whether an operator is ready to be signed off will be made by the assessor.
- C.4. Operator trainees will be required to attend an emergency evacuation demonstration session and be confident in the safe and rapid evacuation of subjects from the scanner. It is the responsibility of the trainee to keep this training up to date subsequently.
- C.5. Depending on the type of study being undertaken operators may be required to undertake additional specific training; this will be recorded on the Scanner Operator Training Record.
- C.6. Emergency evacuation procedures, life support training and magnet safety training should all be kept up to date.
- C.7. To ensure all operators are up to date with software / hardware upgrades, any operator who has not scanned at least once in any six month period should arrange a brief supervised session before resuming scanning unsupervised. Any operator who has not scanned in the last 12 months will be required to demonstrate competence before resuming scanning unsupervised.
- C.8. Requests to move between operator categories should be addressed to the named staff assessors who will evaluate requests on a case by case basis. Operators who are found to be scanning protocols without the appropriate operator status may have their operator license rescinded with immediate effect.
- C.9. Operator status may be rescinded if individuals do not comply with these requirements.**



## D. Minimum attendance requirements for 7T MRI

*The following conventions are used in this section:*

**7T Scan Operator** – this is defined in detail in Section B and Section C above.

**Attendant** – a person who has attended the WBIC in-house safety training course and is familiar with the MRI scanning suite and procedures.

**Clinical Attendant** – a person whose job it is to look after the clinical care of a patient. This may be a doctor, nurse, psychiatrist/psychologist, or radiographer who has attended the WBIC in-house safety training course.

- D.1. For healthy volunteers minimum staff levels are one 7T Scan Operator and one Attendant.
- D.2. For patients not requiring special monitoring or other care minimum staff levels are one 7T Scan Operator and one Clinical Attendant.
- D.3. For patients requiring full monitoring minimum levels of staffing are one 7T Scan Operator and two Clinical Attendants.
- D.4. For scanning phantoms after hours two people should be present to ensure safety – one 7T Scan Operator and one Attendant. If a second person cannot be found for a phantom experiment a telephone contact should be made regularly with a member of the physics staff, and entry into the magnet room should be limited (prior arrangement required).
- D.5. For Drug Studies and Well Out Patient studies, it is acceptable to have a clinician available on a bleep on site but not necessarily in the control room.

The list of trained staff is available on the WBIC website, along with details of approved WBIC radiographers and 7T scan operators. (<https://www.wbic.cam.ac.uk/facilities/7t-terra/scanops>)

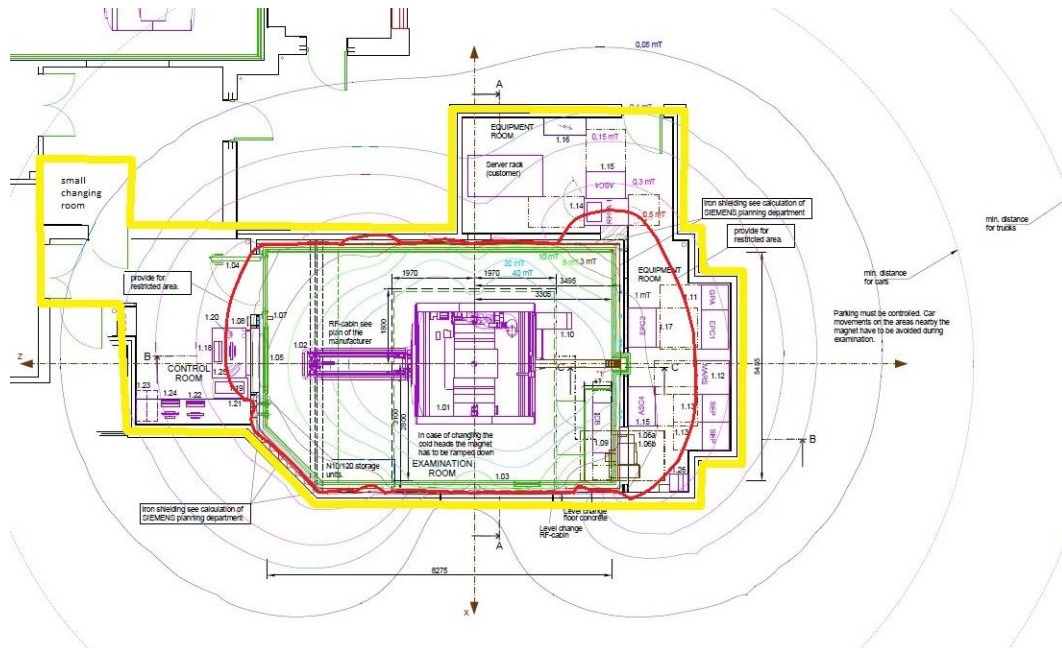
## E. 7T MRI scans on patients

- E.1. 7T MRI scans that are intended to inform a treatment/clinical management decision ("clinical scans") must be performed by a 7T scan operator who is also an HCPC registered radiographer.
- E.2. 7T MRI scans for research purposes where the participant is a well patient ("research scans on patients") will usually be performed by a 7T scan operator who is also an HCPC registered radiographer. However, the Superintendant Radiographer at her/his sole discretion may waive this requirement to permit specific patient groups to be scanned by specified 7T scan operators. For example, this might apply to stable out-patient populations returning for repeat research scans.

## F. 7T safety screening policy

### F.1. Controlled area

MRI is a well-established medical imaging modality. Many thousands of subjects have an MRI scan each year without incident at centres across the world. MRI does not expose the subject to ionising radiation. However, there are certain risks in the scanner environment, such as the risk of impact by ferromagnetic projectiles, adverse interactions with implanted medical devices (pacemakers, surgical implants, etc), and the risk of burns from radiofrequency- or gradient-induced heating. To minimise these risks, it is required that all people entering the controlled area at the WBIC 7T MRI scanner are appropriately trained and supervised.



**Figure 1:** Diagram showing the controlled area around the WBIC 7T MRI scanner in yellow, and within that the 5 Gauss line in red. Regulations for access to the controlled area are described below. Note that the controlled area includes the technical room at the back of the 7T and the WBIC roof.

### F.2. Responsibilities

WBIC radiographers are responsible for the oversight of safety screening and ensuring that best practice is followed in the controlled areas.

WBIC physicists are responsible for advising the radiographers on safety concerns associated with MRI scans.

All safety incidents should be reported to the WBIC Safety Officer (currently Guy Williams). Reports will be reviewed by the WBIC safety committee, who will report to the WBIC Operations Committee and to the University Safety committees.



**F.3. Initial screening at the time of recruitment (for research participants)**

Research participants should be given a preliminary screening prior to their attendance for a scan. The safety screening forms are available at <https://universityofcambridgecloud.sharepoint.com/sites/WBIC/SOPs>. The questions can be put to potential subjects over the phone prior to recruiting them to a study. The completed safety screening forms should be submitted to the WBIC 7T Radiographic team 7 days before the scheduled scan so that any potential safety concerns can be identified, with enough time to take further advice as required before the subject attends for their scan.

**F.4. On the day of the scan (all scan subjects)**

The scan operator carrying out a scan is responsible for the safety and well-being of the subject at all times. This person will have been trained in all relevant procedures. Subjects will be formally screened outside the controlled area using the appropriate screening form. An appropriately trained person must go through this form in person with the subject prior to the subject entering the control room. A new safety screening form and personal interview must be completed each time a subject is scanned, even if the subject has been scanned before.

An answer of “yes” to any question on the screening form does not automatically mean that it is unsafe for the subject to enter the controlled area. However, it will mean that further questions will need to be asked of the subject. Operators will write on the screening form a summary of the answers to additional questions that they have asked and why they believe it is safe to scan the subject, or state that they consider it unsafe.

All forms must be signed by the subject and countersigned by an appropriately trained person.

If there are any concerns as to whether it is safe to scan a subject, advice should be sought from the WBIC 7T Radiographic team. If there is any doubt as to the safety of scanning a particular subject then that individual should not be allowed into the controlled area and should not be scanned. **The scanner operator has the authority to postpone or cancel a scan due to safety concerns.**

**Healthy volunteers:**

Upon arrival all volunteers should be screened in the reception of the Wolfson Brain Imaging Centre and if any doubts are raised the scan should not commence. The person scanning that subject should double check that screening has been performed and that the volunteer has placed his/her belongings (including watches, jewellery etc) in one of the lockers provided. Locker keys should not be taken into the magnet room as the ring is magnetic. If a private area is required for screening, please use the WBIC Reporting room.

If volunteers undergo another scan they must be rescreened at that point.





# UNIVERSITY OF CAMBRIDGE

## Wolfson Brain Imaging Centre

Title: SOPs for 7T MRI Scanning

Doc. No.: MR\_S **NUMBER** **TBC**

### **Patients**

Patients should be screened as volunteers where possible, along with a review of their clinical EPIC notes where available. Other sources of information about the suitability of the patient for an MRI examination can be gained from their relatives, by visual inspection of the patient and discussion with clinicians. All equipment and probes that are attached to the patient should be MRI safe/conditionally safe or rendered so. Devices should be labelled as MRI safe/MRI conditionally safe. No other item should enter the scanner room. If you are unsure of the MRI safety of a device, advice may be sought from others (e.g. a physicist, MRIS etc.). If any doubt remains, the scan should not take place.

The utmost care must be taken when screening unconscious patients. The above rules apply but obviously the patient cannot give any information. The clinician in charge of the patient (who should be familiar with MRI safety issues) must provide assistance, but if the person conducting the scan feels there is any doubt over the patient's suitability the scan must not go ahead.

If patients undergo another scan they must be re-screened at that point.

#### **F.5. Before entering the magnet room**

Please request all subjects use one of the designated changing rooms and change into scrubs provided. Please remember it is the responsibility of the person taking the subject into the magnet room (i.e. beyond the 5G line in Figure 1) to ensure that a thorough secondary screen is performed and that the subject is magnet safe. Use the Metal Detector Wand to ensure no undisclosed metals are present before entering the scanner room. Safety should be the primary concern at all times.

#### **F.6. Reviewing the MRI safety screening forms**

The MRI safety screening forms are a tool to help the operator ensure that a subject is safe to enter the controlled area. It is essential that the questions on the form represent the current best practice in screening subjects. As such the forms are reviewed regularly and updated to reflect changes in best practice. Operators should ensure that they are using the most up to date version of the form.

#### **F.7. MRI screening of scan operators, staff, students, and visitors**

Everyone should complete an MRI screening form prior to entering the MRI suite – preferably when they first start work at WBIC and annually afterwards. This form is very comprehensive but special attention should be made to previous occupations (are they potentially hazardous e.g. metal work) and previous medical history (metallic implants etc). Female staff should also be aware of the pregnancy question. Although there are no known health risks to the baby or mother by working in this environment, steps to minimize exposure to static and radiofrequency magnetic fields are regarded as a wise precaution. This form should be renewed once a year or when circumstances change.





**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

Everyone must remove metallic items from their person on entering the MRI suite (watches, coins, keys, credit cards, phone, jewellery, pens, hairgrips/clips etc).

Staff from other departments (gardeners, electricians etc.) should be screened and warned of the effects of magnetic fields on their tools even if they are not entering the magnet room. All planned works will provide the Superintendent Radiographer with a set of RAMS before arriving on site. Permission should be sought from the WBIC before external contactors are permitted to enter any of the controlled areas around the WBIC. If “hot works” are required, a “hot works” permit should be requested from the main Addenbrooke’s Estates Department.

Please take extreme care with clinical staff. Globally, busy and preoccupied clinical staff have often been the cause of accidents in MRI facilities.

### **F.8. Short-term visitors not entering beyond the 5G line**

Visitors on a tour of the MRI unit should be accompanied by WBIC staff member or scan operator. Visitors do not need to complete full safety screening if they will not enter beyond the 5G line and are under direct supervision at all times. The scanner door should not be opened during a scan acquisition. A good view of the system can usually be seen through the viewing window when the lights are on.

Note that it is not advisable for visitors with pacemakers to enter the imaging suites even for a visit.

**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

## G.APPENDIX: 7T scan operator training record

### *WBIC 7T MRI SCANNER OPERATOR TRAINING RECORD*

NAME	
PI / SUPERVISOR	
DEPARTMENT	

<p><b>DETAILS OF TRAINING REQUIRED FOR SCAN OPERATORS</b></p> <p>(It is the responsibility of operators to keep this training up to date, operators may be asked to produce evidence of their training at any time while working in WBIC)</p>	
DATE OF WBIC BUILDING INDUCTION	
DATE OF MAGNET SAFETY TRAINING (Must be refreshed annually)	
DATE Basic Life Support Training	
Date of Manual Handling training to include lateral transfer.	
DATE OF 7T MRI EVACUATION TRAINING	
CUH Fire training and evacuation	

**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

DATE OF COMPLETION OF GOOD CLINICAL PRACTICE TRAINING (FOR CLINICAL FELLOWS)	
Competency sign off for participant safety screening	
Competency sign off for use of the metal detector	
Competency sign off for use of the RIS	



**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

**LOG SHEET – SUPERVISED SCANNING**

	DATE	SUBJECT RIS CODE (e.g. 12345)	ROLE (observed / supervised)	ASSESSOR INITIALS
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				



### 7T MRI SCANNER OPERATOR ASSESSMENT

GENERAL	COMPLETE (tick ✓)
Where are the keys to enter the magnet room?	
What is the WBIC policy on taking any new equipment into the scanner room?	
SCANNER OPERATION	COMPLETE (tick ✓)
How do you switch on and boot up the system in combined mode?	
How do you switch off the system?	
How do you switch on and boot up the system in parallel transmit mode?	
How do you enter the participant / patient details into the RIS?	
How do you enter the participant / patient details onto the scanner console?	
What do you check if the scanner won't work / stops?	
How do you re-boot separate components of the system?	
How do you do an error save log?	
How do you contact the magnet service team?	
How do you check the helium level? What is the action level?	
How do you check if the cold head is running? Where is the control?	
How do you trouble-shoot if the image quality is poor?	
How do you check the temperature and humidity? What are the required limits?	
How is data archived and retrieved?	
How do you charge the Bluetooth gating devices?	
How would you record a failed scan? and what further steps do you need to take?	

**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

INSIDE THE SCANNER ROOM	COMPLETE (tick ✓)
What do all the controls on the magnet bore do?	
How do you safely attach the imaging coils?	
What to do if a coil is not recognised on the scanner? (Troubleshooting coil plugs.)	
Where do you attach the table ancillaries e.g. headphones?	
How do you use the physiological monitoring equipment?	
Where is the patient alarm?	
How do you turn off the patient alarm?	
How to turn on/off patient comfort	
How do you use the table movement stop button?	
How do you re-set the table after the stop button has been pressed?	
How do you manually move the table?	

EMERGENCY SITUATION	COMPLETE (tick ✓)
Where are the quench buttons?	
Where are the electrical stop buttons?	
When do you use the quench buttons?	
When do you use the electrical stop buttons?	
What do you do if you need help in an emergency?	

**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

THE FOLLOWING IS FOR NEURO GROUPS\*

How do you turn the projector on and off?	
How do you set up the stim PC for your paradigm?	
How do you connect peripheral devices for your experiment e.g. button boxes?	
How do you check your devices are working correctly?	
How do you use the syringe driver?	
How to position equipment safely in the scanner room.	
What are the guidelines for the administration of gadolinium based contrast agents?	

\*Please note that you are only required to complete those assessments listed above that relate to your protocol/s. However, if at any point you wish to operate additional equipment etc. You must complete the appropriate training and gain signed approval from an approved assessor.





# UNIVERSITY OF CAMBRIDGE

## Wolfson Brain Imaging Centre

**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

### SCANNER OPERATOR ASSESSMENT – PRACTICAL

Screening	COMPLETE (tick ✓)
Did the scan operator introduce himself or herself to the person to be scanned?	
Did the scan operator explain their role in the session?	
Was the screening done in a private area and outside of the controlled area?	
Was the importance of screening explained?	
Was it explained why the person to be scanned needed to be screened at each and every visit?	
When screening was each question asked individually and responses sought to each individual question?	
Were the responses explored and documented adequately?	
Were the personal belongings of the person to be scanned placed in an appropriate place (e.g. locker)?	
Was a secondary screening completed just before entering the magnet room?	
Using the registration system	COMPLETE (tick ✓)
Were the details of the person to be scanned entered correctly?	
Positioning	COMPLETE (tick ✓)
Was the person to be scanned made comfortable?	
Was physiological monitoring / recording equipment fitted correctly and explained (if relevant)?	
Was the squeeze ball given to the person to be scanned and its use explained?	
Was positioning achieved to prevent skin – skin, skin – coil and skin – cable contact?	

**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

During the scan	COMPLETE (tick ✓)
Did the scanner operator check that the person to be scanned could hear them over the intercom?	
Was the person to be scanned adequately informed about the procedure that is going to take place?	

Post Scan	COMPLETE (tick ✓)
Was the person warned about the table still being elevated?	
Was the person warned about potential dizziness after lying down?	
Was the room left ready for the next scan?	
Was the screening form completed fully and filed appropriately?	



# UNIVERSITY OF CAMBRIDGE

## Wolfson Brain Imaging Centre

**Title:** SOPs for 7T MRI Scanning

**Doc. No.:** MR\_S **NUMBER** **TBC**

**PREVIOUS SCANNING EXPERIENCE (if relevant)**

Date	Institute	Scanner Make / Model	Field Strength	Approx. no. of human scans	Category of scans / patient groups

**OTHER RELEVANT TRAINING**

Details of training / name of course	Date

**ASSESSOR SIGN OFF**

OPERATOR CATEGORY (phantom/volunteer/patient)	SIGNATURE	DATE

**APPROVED ASSESSORS**

The Superintendant Radiographer (for Radiographer staff/graduate students/visitors).

The Head of 7T MRI Physics (for MR physics staff/graduate students/visitors).