

SAFETY PLAN

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**Center for Biomedical Imaging
Boston University School of Medicine
650 Albany Street
Boston, MA 02118**

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Manufacturer contacts:

**Philips Medical Systems, 1-800-722-9377;
Site number for the MRI scanner (3T Intera): 103808**

1. Introduction

The Center for Biomedical Imaging (CBI) is located in the **basement** of the “Evans Biomedical Research Center” (so called “X”-building) on the Boston University School of Medicine Campus. The street address is 650 Albany Street, Boston, MA 02118.

Directions to the MRI facility: Once inside lobby of the X-building, take the **third most** elevator (freighter elevator) from the entrance. This is the only elevator that will provide access to the CBI. Inside the elevator, press the button **BR** (*basement rear*). The door will open directly to the receptionist area of CBI.

1.1. Magnetic Resonance Imaging (MRI)

Magnetic resonance imaging (MRI) is a new technique that allows doctors and investigators to see inside the human body in remarkable detail without using x-rays. Instead, MRI uses a powerful magnet, radio waves and a sophisticated computer system. The **strong magnet** needed for MRI scans (about **60,000 times stronger** than the earth’s natural magnetic field!), care and special recursions will need to be taken both for normal operation as well as in emergency cases.

2. Operator's Checklist for the 3T System

The purpose of this document is to provide a list of key tasks that operators of the 3T system will need to know to operate the scanner. This list can be used as both a catalog of skills which need to be learned, as well as a check-off list for testing of skills. This checklist will be used for certifying completion of training and is signed by both the trainer and the trainee.

Checklist

- ☐ Obtaining of consent
- ☐ Safety screening of subject. Also obtain weight and Date of Birth.
- ☐ Research subject to place belongings and metal objects into locker.
- ☐ Escorting subject to scanner following transport indicator signals.
- ☐ Final screen and pat down prior to entering magnet room.
- ☐ Familiarizing subjects with the scanner and its operation. This would include showing them the table, the surrounding magnet, and expected sounds during the scan and methods for communication including the intercom and the squeeze ball.
- ☐ Positioning of subject. This includes the insertion of earplugs, use of headphones, use of knee and other pads and having subject positioned on the table.
- ☐ Landmarking of subject using the laser system.
- ☐ Moving the subject to the magnet isocenter.
- ☐ Adjusting light, airflow, sound volume for subject comfort. Check on subject comfort prior to leaving magnet room and closing door.
- ☐ Check intercom communication system.
- ☐ Volunteer registration into scanner database.

- ☐ Selecting desired protocol and running the localizer.
- ☐ Running the anatomical sequence.
- ☐ Running an fMRI sequence including positioning, slice orientation.
- ☐ Removing subject from the magnet.
- ☐ Escorting subject from 3T scanner to reception area.
- ☐ Archiving of data. To CD-ROM or to DICOM receiver.
- ☐ Clean up of magnet room and console room. Leave it the same or better.
- ☐ Make entry in paper scanner log sheet as to scanner status.
- ☐ Marking time on web scheduler as used. Use of web based scheduling system including scheduling a session, canceling a session, and marking a session time as used.

Certification Date: _____

Examiner Name: _____

Examiner Signature: _____

Examinee Name: _____

3. Volunteer check list

Subject Name: _____

For staff only:

Session #:

Operator name and #

IRB #:

BU Safety Screening Form

1. Do you have a problem with claustrophobia (fear of closed spaces?)
No _____ A little _____ Pretty much _____ Severe _____
2. Do you have a heart pacemaker or defibrillator or other implanted devices? If yes, describe.
No _____ Yes _____
3. Have you ever had an operation? If yes, Investigator to fill out Page 2.
No _____ Yes _____
4. Have you ever been injured by metallic foreign body which was not removed?
No _____ Yes _____
5. Do you wear braces on your teeth, or do you have false teeth or removable bridgework? Do you have any unremovable body piercings?
No _____ Yes _____
6. Do you have any tatoos? If yes, describe their location.
No _____ Yes _____
7. (Females only): Is there any possibility that you are pregnant?
No _____ Yes _____
8. Please list medications you took today or are taking regularly.
(try to include the name of the medicine, dose, how often, and time of last dose).
9. Have you ever had any previous studies (MRI, CT or other)? If yes circle on list.
No _____ Yes _____
10. Do you have a breathing disorder or movement disorder? If yes describe.
No _____ Yes _____
11. Weight: (lbs) _____ Birthdate: ____/____/____

Signature of Person Completing Page 1

Date: / /

Investigator to complete if Item #3 on Page 1 is Yes.

Some of the following items may be hazardous to your safety and some can interfere with the MRI examination. Please check the correct answer for each of the following. Do you have any of the following:

- ☐ Yes ☐ No Cardiac pacemaker
- ☐ Yes ☐ No Implanted cardiac defibrillator
- ☐ Yes ☐ No Aneurysm clip(s)
- ☐ Yes ☐ No Carotid artery vascular clamp
- ☐ Yes ☐ No Neurostimulator
- ☐ Yes ☐ No Insulin or infusion pump
- ☐ Yes ☐ No Implanted drug infusion device
- ☐ Yes ☐ No Bone growth/fusion stimulator
- ☐ Yes ☐ No Cochlear, otologic, or ear implant
- ☐ Yes ☐ No Any type of prosthesis (eye, penile, etc.)
- ☐ Yes ☐ No Heart valve prosthesis
- ☐ Yes ☐ No Artificial limb or joint
- ☐ Yes ☐ No Electrodes (on body, head, or brain)
- ☐ Yes ☐ No Intravascular stents, filters, or coils
- ☐ Yes ☐ No Shunt (spinal or intraventricular)
- ☐ Yes ☐ No Vascular access port and/or catheter
- ☐ Yes ☐ No Swan-Ganz catheter
- ☐ Yes ☐ No Any implant held in place by a magnet
- ☐ Yes ☐ No Transdermal delivery system (Nitro)
- ☐ Yes ☐ No IUD or diaphragm
- ☐ Yes ☐ No Tattooed makeup (eyeliner, lips, etc)
- ☐ Yes ☐ No Body piercing(s)
- ☐ Yes ☐ No Any metal fragments
- ☐ Yes ☐ No Internal pacing wires
- ☐ Yes ☐ No Aortic clip
- ☐ Yes ☐ No Metal or wire mesh implants
- ☐ Yes ☐ No Wire sutures or surgical staples
- ☐ Yes ☐ No Harrington rods (spine)
- ☐ Yes ☐ No Metal rods in bones
- ☐ Yes ☐ No Joint replacement _____
- ☐ Yes ☐ No Bone/joint pin, screw, nail, wire, plate
- ☐ Yes ☐ No Hearing aid **(Remove before MRI)**
- ☐ Yes ☐ No Dentures **(Remove before MRI)**

NOTE: YOU ARE REQUIRED TO WEAR EARPLUGS OR EARPHONES DURING THE MRI EXAMINATION.

Date: / /

Signature of Investigator Completing Page 2

4. Potential risks of MRI

(1) Magnetic Field in the MRI (subject environment). The MRI scanner, which operates at the magnetic field of 3 Tesla, has been approved for clinical use by the FDA, following several years of data collection regarding the effect of magnetic field on human subjects. There is no evidence of any adverse effect of strong magnetic fields on either humans or non-human subjects.

(2) Metallic objects carried into the MRI room. Volunteers will be advised several times to leave any metallic object they have in lockers located away from the MRI scanner. Before they enter the scanner room, the investigator will make sure that the subjects do not carry any metallic object.

(3) Other energies, such as radiofrequency pulses, or rapid changes in the field strength. As in (1), the effects of radiofrequency pulses and magnetic field gradients have been assessed by the FDA evaluating years of accumulated data. The clinical scanner in use sets very conservative limits on the strength of radiofrequency pulses as well as the magnetic field gradients used, and all methods used in the experiment are used in standard clinical imaging protocols.

(4) Displacement of Implanted metallic devices and unknown risks posed to fetuses: these populations are excluded from the possibility to participate in the study.

(5) Acoustic noise: noise will be reduced to FDA acceptable levels. If at any given moment the subject feels discomfort due to excessive noise (or for any other reason), the subject will signal to the investigator by squeezing a squeeze-ball that produces an audible signal, and the subject will be promptly removed from the scanner.

5. Non-MR personnel (anyone not explicitly approved to enter the MRI room)

- A. No person shall enter the room without permission of the technologist.
- B. The technologist will question each person as to the presence of a cardiac pacemaker, cerebral aneurysm clips, or other surgically implanted metal devices.
- C. The person shall be asked to remove jewelry, hairpins, and all loose objects in their pockets.
- D. Every person should be made fully aware of the danger of taking any metal object into the room.
 - 1. That the magnet is on at all times.
 - 2. The dangers involved to themselves and the equipment if these safety guidelines are ignored.
 - 3. The expense of the repairs.

6. Housekeeping

The Center for Biomedical Imaging should be cleaned accordingly to normal hospital procedures, **except for the magnet room itself**. The MRI room will be cleaned by the **Center for Biomedical Imaging personnel** approved for entering the MRI room.

7. Emergency Procedures

Emergency types:

Several types of emergency situations can arise in the context of MRI scanning. Types include:

1. Spontaneous medical emergencies occurring during an MRI examination: heart attack, seizure, loss of consciousness, allergic reaction to contrast agent, and any other emerging medical situation in which the volunteer requires medical assistance.

Procedure: Volunteer must be removed from the MRI scanning room immediately and as fast as possible. All medical treatments including resuscitation attempts if necessary **must be administered outside the MRI scanning room.**

2. Accidental medical emergencies caused by an accident in the MRI environment: projectile accidents, burns, electrical shocks, and any other accident caused by equipment failure or malfunction.

Procedure: Volunteer or any other wounded person(s) must be removed from the MRI scanning room immediately and as fast as possible. All medical treatments including resuscitation attempts if necessary must be administered **outside the MRI scanning room.** Should any person become attached to the magnet or trapped between the magnet and a foreign metallic object (e.g. gas tank, metallic table, stretcher, etc.) one MRI technologist must remain in the room to provide assistance to the trapped individual while a second MRI technologist must proceed to de-energize (i.e. quench) the magnet **immediately** by pressing the red EMERGENCY STOP red button located in the control room. If a second technologist is not available, the magnet must be de-energized (quenched) first and the MRI technologist should immediately run into the magnet room to support the released metallic object and to assist the individual. In all cases, remove from the MRI room the previously trapped individual before providing any medical treatment.

3. Equipment related emergencies including metallic objects adhering to the magnet structure, fires, smoke or gases in the room.

Procedure: 3a) In case of a metallic object adhering to the magnet structure, MRI physicist should be alerted immediately.

Do not attempt to release the object by force, as serious damage to the magnet will result. Evacuate the MRI room. Do not allow any untrained person(s) inside the magnet room.

Do not de-energize the magnet before assessing the possible hazards resulting from the release of the object to the ground. For example a bottle of oxygen could break and ignite if dropped to the ground. Similarly, hazardous materials could be accidentally released to the environment.

3b) In the very unlikely event that cryogen gases being released directly in the MRI scanning room **all persons** must evacuate the MRI scanning room **as fast as possible** and then **close the door** so that these cryogen gases remain contained. Evacuate the area and alert security and the MRI physicist.

3c) In case of fire in **any** of the rooms associated with the MRI scanner, the magnet must be de-energized (quenched) immediately to prevent projectile accidents and injuries to the fire department personnel.

4. Security related emergencies including suspicious packages in the MRI room or vicinity and belligerent or armed individuals in the MRI environment.

Procedure: Do not de-energize (quench) the magnet under any circumstances.

MRI technologist should abandon their posts and leave the area as soon as possible. Security personnel and the MRI physicist must be alerted immediately.

8. Magnetic Safety

MR imaging systems are provided with a **magnet emergency stop button**, which should be used only under the following conditions:

- A. Forces due to the magnetic field that are causing volunteer or personnel injury, requiring an **IMMEDIATE SHUTDOWN** of the magnetic field.
- B. Fire or other unexpected occurrence that demands immediate action and entry to the examination room by emergency personnel.
- C. Any other situation that would require an immediate relief from the magnetic field effect as an alternative to the normal, controlled "ramp-down" of the magnetic field.

9. Emergency procedures

ALL medical emergencies **MUST** be managed **outside** of the MRI scan room. This is to eliminate the risk of accidentally introducing dangerous, magnetic projectiles (i.e., oxygen tanks) that could severely injure someone.

1. On entry into the scan room, make sure the only people following you are people you are certain can be trusted with entering the scan environment.
2. If someone else is with you, have the close the door to the scan room.
3. Pull the volunteer out of the scan tunnel.
4. Un-dock the table and remove the volunteer from the scan room.
5. **CLOSE THE SCAN ROOM DOOR!** Everything that is needed to manage a code is outside of the scan room. There should be no reason for anyone to go into the scan room.

10. Manufacturer (Philips Medical Systems) recommendation for emergency procedures

Philips Medical Systems December

2.3 Emergency procedures



Electronic or other metallic emergency equipment must not be brought into the examination room.

A procedure must be established for rapid removal of the patient from the examination room in the event of an emergency.

In addition, precautions should be taken and an appropriate plan should be established for use of emergency equipment **outside** the examination room, especially for the following classes of patients:

- patients at risk of cardiac arrest,
- patients predisposed to seizures or claustrophobic reactions,
- patients who are heavily sedated, confused, or unconscious,
- patients with whom no reliable communication can be maintained.

The system is also equipped with a red TableTop Release button (TTR) on each side of the patient support. Pressing one of the TTR buttons will release the tabletop and allow the Operator to move the tabletop out of the magnet and remove the patient even in the event of power failure. To re-enable motorized movement, press the TTR button again. When a TTR button has been pressed to release the table the led of the Manual mode button will flash.

TTR button



There are Gyroscan NT systems without a TTR button. For these systems the following different instruction is valid:

Note that pressing the table emergency stop button, this is the pink manual mode button, will stop all motor movements and will free the table top so that it can be moved manually.

See also section 2.9 in this chapter.

15 December

11. Magnet shutdown (manufacturer information)

2.9 MECHANICAL SAFETY

2.8.2 Magnet EMERGENCY STOP button



Philips Gyroscan MR systems are provided with a magnet EMERGENCY STOP button for IMMEDIATE SHUTDOWN OF THE MAGNETIC FIELD.

The button is marked: **EMERGENCY STOP** operation of this switch will de-energize the magnet.

The button should be used under the following conditions:

- Forces due to the magnetic field that are causing patient or personnel injury, requiring an IMMEDIATE SHUTDOWN of the magnetic field.
- Fire or some other unexpected event that demands immediate action and entry into the examination room by emergency personnel.
- Any other situation that requires immediate shutdown of the magnetic field as opposed to the normal, controlled ramp-down of the magnetic field.



The superconductive magnet can only be restarted by a service engineer and the procedure takes about a day to complete and is very expensive.

12. Fire emergency (manufacturer information)

2.10 Fire safety

In the event of a fire in the examination room, press the magnet EMERGENCY STOP button to rapidly shutdown of the magnetic field before bringing fire-extinguishers into the examination room.

All operators of this medical electrical equipment should be fully aware of and trained in the use of fire extinguishers and other fire-fighting equipment, and in local fire procedures.



For electrical or chemical fires only use extinguishers that are specifically labelled as suitable. Using water or other liquids on an electrical fire can lead to serious or fatal injury.

If it is safe to do so, attempt to isolate the equipment from electrical and other supplies before attempting to fight a fire. This will reduce the risk of electric shocks.

Use of electrical equipment in an environment for which it was not designed can lead to fire or explosion.

Fire regulations for the type of medical area being used should be fully applied, observed and enforced. Fire extinguishers should be provided for both electrical and non-electrical fires.

13. Explosion safety (manufacturer information)

2.5 Explosion safety

This equipment must not be used in the presence of explosive gases or vapours, such as certain anesthetic gases. Use of electrical equipment in an environment for which it was not designed can lead to fire or explosion.



Flammable or potentially explosive disinfecting sprays must not be used, since the resultant vapour could ignite, causing fatal or other serious personal injury and/or damage to equipment.

14. Electrical safety (manufacturer information)

2.4 Electrical safety

The Philips Gyroscan NT MR system may be operated on a permanent 24-hour basis without adversely affecting its safety or performance.

Do not allow water or other liquids to enter the equipment as they may cause short-circuits or corrosion. There is no danger from urine passed by the patient.



- ***Do not remove covers or cables from the equipment. High electrical voltages are present within the equipment. Removing covers or cables could lead to serious or fatal personal injury.***
- ***Covers, cables or components should only be removed by qualified and authorised service personnel. In this context, qualified means those legally permitted to work on this type of medical electrical equipment in the jurisdiction(s) in which the equipment is being used, and authorised means those authorised by the user of the equipment.***

Only use the Gyroscan NT in rooms or areas that comply with all applicable law (or regulations having the force of law) concerning electrical safety for this type of equipment.

15. RF energy safety (manufacturer information)

2.6 RF energy and safety

The scan procedures always involve the emission of RF energy. This can heat the patient and hence is of concern. The RF energy deposited in the patient is expressed in terms of the Specific Absorption Rate (SAR). This is the radio frequency (RF) power absorbed by the patient per unit mass (W/kg). The predicted SAR is calculated for each scan procedure with an accuracy of ± 1 dB.

Information on the expected SAR for a scan is displayed to the operator on the Info page as:

SAR (W/kg) / SAR level: .. / ..

and in the scan overview as:

SAR: ..

The system recognises three SAR levels, as prescribed in IEC 60601-2-33:

Level 0 (or normal operating mode)

SAR limits:

Less than or equal to 1.5 W/kg*

Safety measures:

Routine monitoring.

Level I (or first level controlled operating mode)

SAR limits:

Greater than 1.5 W/kg* but less than 4 W/kg*

Safety measures:

In addition to routine monitoring, particular caution must be exercised for patients who are sensitive to temperature increases or to RF energy, e.g.:

- Patients at risk of cardiac arrest
- Patients susceptible to seizures, or claustrophobic reactions
- Decompensated cardiac patients, febrile patients, and patients with impaired ability to perspire
- Patients who are unconscious, heavily sedated, or confused, and with whom no reliable communication can be maintained.
- Patients with fever, reduced thermal regulatory capabilities or increased sensitivity to raised body temperature.
- Patients who are thermally insulated. (e.g. in a gypsum cast)

When the predicted SAR exceeds 1.5 W/kg the following warning message is displayed on the bottom line:

**High SAR level in scan(s) <number(s)>, Monitoring is required.
Press cancel or proceed.**

If the patient's condition cannot be monitored, or the risk is too high, the scan parameters must be changed to give a SAR in level 0. If the predicted SAR is acceptable, enter the scan name and start the scan by clicking Proceed.

Level II (second level controlled operating mode)

SAR limits:

Greater than 4W/kg*

The system is adjusted to generate a maximum SAR of 4 W/kg, so scanning in level II is impossible.



The SAR thresholds are only valid for room temperatures not greater than 24°C and relative humidities not greater than 60%, as specified in the system installation procedures. If these conditions are exceeded, e.g. if the patient is warmed by means of a heated blanket, the SAR must not be greater than 1.5W/kg and patient's condition must

16. Liquid Helium Safety (manufacturer information)

2.12 Safety with liquid helium



- *Under no circumstances should a container be brought into the magnet area unless it is known to be made of non-magnetic material or the magnet is not energised. It is extremely dangerous to patient, personnel and equipment to bring any magnetic or ferrous metal objects into the examination room. Special non-magnetic containers are available from liquid gas suppliers and must always be specified and appropriately labeled.*
- *Under no circumstances should liquid helium be transferred into the magnet prior to installation of the helium venting system.*



Filling with liquid helium.

- *Filling with liquid helium should be carried out by trained and authorized persons. See section 17.4: Topping up the liquid helium*
- *Liquid helium is extremely cold and can freeze human tissues. Always use protective gloves. Injuries caused by freezing must be washed with water and treated as burns.*
- *There is danger of suffocation as the helium will dilute the oxygen in the air. Always ensure that the examination room and the storage room for liquid gases are well ventilated.*
- *If liquid helium is accidentally released in the examination room, accumulation of liquid oxygen may occur, resulting in a potential fire hazard due to spontaneous ignition.*

17. Helium Gas Safety (manufacturer information)

2.13 Safety with helium gas

Properties of helium gas:

- Odourless
- Non-flammable
- Non poisonous
- On evaporation a cold mist is formed. Helium gas rises in air.

High concentrations of helium gas in the examination room can lead to suffocation, as it dilutes the oxygen in the air.

Under normal operating conditions a small amount of helium gas is evaporated by the boil-off of the liquid helium in the magnet.

A large amount of helium gas is evaporated when the magnet EMERGENCY STOP button is used for immediate shutdown of the magnetic field, or during a spontaneous magnetic field shutdown.

Gyrosan MR systems are equipped with a helium venting system, which vents the helium gas from the magnet to the outside of the building under normal operation and emergency switch off conditions.



In the event of a failure of the venting system (e.g. venting system is blocked) and shutdown of the magnetic field, a high concentration of helium gas could build up in the examination room forming clouds of cold mist. Open the door of the examination room.

The patient and personnel must be evacuated from the examination room immediately if this occurs.

An oxygen detector with audible alarm may be used as a warning device. Do not switch-off the air conditioning or air circulation in the room if helium has leaked into the examination room (this is an automatic procedure triggered by a smoke detection alarm for detection of fire) but maintain air circulation and ventilation.

18. Acoustic Noise Safety (manufacturer information)

2.14 Acoustic noise protection

Earplugs, head phones or some other form of ear protection must be worn during scanning. Noise levels may be high enough to cause discomfort to the patient. Ear protectors ensure maximum comfort for the patient which is, in turn, important for good image quality.



Only use ear protectors that contain no metal parts.

The sound level at the control panel must comply with local regulations; there may be local regulations concerning exposure to noise at work.