

Human Subjects

University of Minnesota
Center for Magnetic Resonance Research



Safety & Policy Manual

Last Updated on November 2011; also available online at:
<http://www.cmrr.umn.edu/safety>

Emergency Information

for

Center for Magnetic Resonance Research

Dial 911 for
Police, Fire, and Life Threatening Emergencies
(Meet Responders at Front Door and Communicate Dangers of Facility, Do Not Allow them to Enter the Magnet Room without being Screened and Briefed)

Building: 180	Department: Radiology	College: Medical School
Address: 2021 6 th St SE Minneapolis, MN 55455		

Paging for CMRR Assistance (Emergency Use Only)

Dial: **3-8085** and communicate need for assistance

Medical Emergencies

1. Dial **911**
2. Remove subject from scanner and/or magnet room if possible (MR Safe wheelchair and gurney located in CTSI patient prep area)
 - a. **If and Only If** emergency involves a ferrous object pinning someone against the magnet initiate magnet quench
3. Administer CPR if required (AED's located near copier on "classic" side and outside of 3T on the "new" side)
4. **Meet responding personnel at front door, escort them to subject, and communicate dangers of facility**

Fire

1. Dial **911**
2. Remove subject/personnel from scanner and/or magnet room
3. If feasible perform electrical shutdown of magnet
4. If deemed safe/appropriate attempt to extinguish fire using **blue and white fire extinguisher Only**
5. **Meet responding personnel at front door and communicate dangers of facility**

Contact Information

Name	Office	For help with ...	Email
Jeremy Kulesa	5-8847	Safety incidents	kulesa@cmrr.umn.edu
Peter Anderson Gregor Adriany	5-9583	Scanner hardware problems	peter@cmrr.umn.edu gregor@cmrr.umn.edu
John Strupp	6-0361	Software and Host Computer problems and questions	strupp@cmrr.umn.edu

Contents

1	General Information	4
1.1	Terms and definitions	4
1.2	Reporting of Safety Incidents or Near-Incidents	4
1.3	Handling a Medical Emergency.....	4
1.4	Contact Information.....	5
1.5	Tours and Training Exercises	5
2	Safety in the MR Environment.....	5
2.1	MR Hazards	6
2.2	Metal Screening	6
2.3	Special Hazards	7
2.3.1	Laser Light Localizer	7
2.3.2	Phantom Leaks	7
2.3.3	Echo planar (fMRI) Imaging.....	8
2.3.4	Medical Gases.....	8
2.4	Ear Plugs and Headphones	8
2.5	ECG, Pulse and Respiratory Monitoring	8
2.6	MR Compatible Wheelchair	8
3	Safety Policies	8
3.1	Supervision of subjects and guests	8
3.2	The Two-Person rule	9
3.3	Door Security.....	9
3.3.1	Door Failures	9
3.4	Accurate Entry of Subject Weight, Age and Sex.....	9
3.5	Temperature Control.....	9
3.6	Pregnancy	10
3.7	Children	10
3.8	Transport Light System.....	10
3.9	Obese Patients.....	10
4	Safety Procedures	11
4.1	Performing an Emergency Magnet Quench.....	11
4.2	Performing an Emergency Electrical Shutdown	11
4.3	Performing a Routine Electrical Shutdown	12
5	Handling Medical Emergencies and Subject Problems	12
5.1	Medical Emergencies.....	12
5.1.1	Procedure for removing subject from scanner room	13
5.2	Subject Squeeze Bulb	13
5.3	Subject Tingling or Muscle Twitch	14
5.4	Perspiration and Increased Pulse	14
5.5	Incidental Findings – Abnormal Looking Scans.....	15
6	Handling Facility Emergencies	15
6.1	Fire Emergencies	15
6.2	Audible Alarms.....	16
6.3	Non-Fire Facility Emergencies.....	16
7.	Using the CMRR paging system	17

1 General Information

When properly used, Magnetic Resonance Imaging technology provides a safe and powerful tool for medical diagnostics and research. However, the powerful MRI systems at the CMRR could pose a serious risk if used incorrectly. Therefore, it is crucial that all users of the human research systems learn the safety procedures described in this manual.

1.1 Terms and definitions

1.1.1 Authorized Personnel

Authorized personnel are people who have successfully completed the Magnet Specific Operator Certification process (for more details on operator certification, see “Magnet Specific Operator Training” on the CMRR safety webpage, <http://www.cmrr.umn.edu/safety>). To minimize risks to subjects and other members of the research team, only authorized personnel are allowed unaccompanied access to the MR scanner room. Subjects, their guests, or research personnel who have not been safety trained are not permitted to enter the MRI scanner room unaccompanied.

1.1.2 Rooms in the scanner suite

The **control room** is where monitors, keyboards, and mice of the console host computer and stimulation computers reside. The **scanner room** is the room with the actual MRI scanner. The **RF equipment room** is where the console and computers reside.

1.1.3 Research and Standard Mode for scanner gradient operation

By default, after power up or reset the gradient units are in **Research Mode**, which sets higher limits for peripheral nerve stimulation (resulting from fast switching of imaging gradients). This mode lasts for 2 hours after each gradient reset. Some studies may require more conservative **Standard Mode** for operation with sensitive patients.

1.1.4 Safety Incidents and Near-Incidents

For the purposes of this document, a safety incident is defined as an incident in which a person is injured or equipment is damaged (e.g. a magnetic object becomes a projectile and hits someone, or a subject is burned by RF heating during an experiment). A near-incident is a situation in which a person could have been harmed, or equipment narrowly avoided being damaged.

1.2 Reporting of Safety Incidents or Near-Incidents

All incidents must be reported to Jeremy Kulesa (kulesa@cmrr.umn.edu), no more than 24 hours after the incident. When appropriate, such events must also be reported to the University of Minnesota IRB. All near-incidents (e.g. hair clips flying into the scanner, subject reports of peripheral nerve stimulation) should also be reported to the Safety Officer and Peter Anderson or Gregor Adriany.

1.3 Handling a Medical Emergency

If you believe that a study participant or anyone else in the building has a medical emergency and needs immediate assistance, **call 911**. You should review the safety procedures in this manual (beginning on page 11) regularly so that you do not need to take unfamiliar actions in a panic situation.

If you need assistance while you wait for emergency personnel to arrive (e.g. getting the subject out of the scanner, sending someone to wait at the front door while you perform CPR), you can call the front desk (6-2001) or you can use the CMRR paging system (instructions on last page) to call for help. The protocol for this is to announce “**Code Blue, and then list the magnet,**” which will let people know that there is a medical emergency at the scanner suite, and anybody who is available should go to offer assistance.

1.4 Contact Information

Contact information for magnet hardware and software as well safety related questions and incidents are listed below. If you have any questions or need help while scanning please do not hesitate to contact the individuals below for assistance.

Name	Office	For help with ...	Email
Jeremy Kulesa	5-8847	Safety incidents	kulesa@cmrr.umn.edu
Peter Anderson Gregor Adriany	5-9583	Scanner hardware problems	peter@cmrr.umn.edu gregor@cmrr.umn.edu
John Strupp	6-0361	VnmrJ Software and Host Computer Problems and questions	strupp@cmrr.umn.edu

1.5 Tours and Training Exercises

Tours or training exercises that would involve having several unauthorized personnel (personnel without safety training) present in the scanner, control or equipment rooms for more than a few minutes must be authorized in advance. If you would like to arrange for a tour please contact Deb Morgan, Jeremy Kulesa, or Kathleen Dockter.

If you are going to be stopping by just briefly, please look at the schedule in advance and call the person who will be running the study to ask if it is OK to drop in. For some subject groups, it is not appropriate to just drop in. At the very least, call back to the console room to get clearance before taking your group back.

2 Safety in the MR Environment

There are no areas in the MR suites that can be considered completely safe. Many objects in the scanner control room, and equipment rooms are **NOT MR COMPATIBLE** and may become projectiles in the MR scanner rooms. **Never** move any object from these rooms into the MR scanner room unless you are **absolutely certain** that the object is MR safe. Similarly, some objects in the MR scanner room may only be safe when kept at a distance from the MR scanner. Only personnel explicitly authorized to do so should move objects that are labeled “Not MR safe”, or that are of unknown construction.

The most likely cause of injury or equipment damage comes from personnel who are unfamiliar with the equipment and its hazards. Personnel working in the facility must be constantly vigilant of who is entering the console and scan room areas. This means that, while you are scanning or using the scanner suite, you are responsible to verify that everyone who enters the room does so safely (e.g. without carrying magnetic objects). Especially in emergency situations, you must ensure that no unauthorized persons enter the scanner room, and that all authorized personnel have adequately checked themselves for possible hazards such as projectiles.

2.1 MR Hazards

The main hazards of the MR environment are:

- **Projectiles**

The “projectile effect” occurs when heavy or sharp ferromagnetic objects are hurled into the instrument. Even seemingly innocuous objects, such as hand tools or paperclips can cause serious injury.

- **Electronic Devices**

Electronic devices such as implanted pacemakers, cochlear implants, or brain stimulation devices could malfunction in or near the scanner. For example, certain cardiac pacemakers can be damaged by exposure to magnetic fields, causing direct hazards to subjects. Under no circumstances should persons with pacemakers enter the MRI scanner room (or even leave the lobby area).

- **Dangerous Voltages**

As in many laboratories, the MRI lab contains wiring and circuitry that operate at dangerous voltages. Under no circumstances should users touch any exposed wiring, or any exposed terminals in the equipment cabinets. If you observe any exposed wiring, please inform Peter Anderson or Gregor Adriany immediately.

- **Induced Electrical Currents**

During scanning, the magnetic field will be rapidly changed. This switching can induce electrical currents within the body that cause nerve or muscle stimulation. The scanner will ensure that these effects are within FDA limits. On some scanning sequences however, the participant may feel muscle twitches or tingling (see section 5.3 beginning on page 14 for additional details).

- **Suffocation**

In extreme cases, the imaging magnet may release large volumes of helium gas (which is colorless and odorless) that can rapidly force all air out of the scan room. Normally, the helium gas would be vented through the roof. However, there is a small but significant risk that the venting system could fail.

- **RF Heating**

Improper scanner operation could result in excessive heating of the subject due to radio-frequency (RF) energy being deposited in the tissue. Even normal scanning causes tissues to warm a little bit, and non-ferromagnetic implants or devices (such as permanent retainers) can heat up, even though they are considered MR compatible. The RF monitor screen displays the time averaged dose of RF energy delivered to the coil, and will shut down your sequence if they exceed the limits entered by the operator which must adhere to the FDA's Specific Absorption Rate (SAR) guidelines. It is important that you always accurately set limits for your coil and anatomy prior to scanning and observe all FDA limitations:

- (1) Averaged over the whole body, 4-W/kg for 15 minutes.*
- (2) Averaged over the head, 3-W/kg for 10 minutes.*
- (3) Averaged over the head or torso per gram of tissue, 8-W/kg for 5 minutes.*
- (4) Averaged over the extremities per gram of tissue, 12-W/kg for 5 minutes.*

2.2 Screening

Any subject preparing to enter an MR scanner room must complete a screening form, and this form must be reviewed thoroughly by the responsible investigator before access to the scanner room is granted. Persons who are safety certified at the scanner are not required to complete a screening form for themselves but are responsible for verifying that they are safe to enter the scanner room. **A new screening form must be completed by subjects for each day**

that they are to be scanned (an example of a screening form may be found at www.cmrr.umn.edu/safety).

If there are any doubts regarding the screening responses, do not allow the individual to enter the scanner room. The fact that the individual has been scanned in an MR scanner previously (even at the CMRR) is never a sufficient basis upon which to conclude that the subject can enter the scanner room safely, since risks vary according to magnetic field strength. Dental fillings and orthodontic braces do not constitute significant risks (though the latter may produce unacceptable artifacts) and do not preclude scanning. Subjects with tattoos or permanent eyeliner should be advised of the small risk of local redness or irritation, but may be scanned. Tattoos present a possible risk of metal contamination. Thus, potential participants with tattoos may be precluded from study participation.

Some subjects may have metal in their body of which they are unaware (e.g. metal workers with small splinters—particularly dangerous near the eye—or military/law enforcement personnel with shrapnel). Subjects should be asked whether they have any risk of shrapnel or metal splinters in their body.

Some implanted metal devices have been established as safe for MR scanning. **It is the responsibility of the primary investigator to verify beyond any doubt that a given medical device is MRI safe.** *Reference Manual for Magnetic Resonance Safety, Implants, and Devices* (by Shellock) is one source for information. Even if you are certain that the implanted metal does not constitute a risk, do not allow the individual into the scanner room unless you have obtained explicit authorization from a qualified medical professional to do so. Qualified individuals (e.g., neuro-radiologists or neurosurgeons) may request blanket authorization to assume responsibility for such authorizations for their own research protocols. Silver, gold and platinum jewelry is not ferromagnetic. Nonetheless, subjects should remove jewelry before going in the scanner since these metals can still conduct electricity and therefore pose a risk for burns in the presence of time-varying magnetic fields. Jewelry that forms large loops is particularly hazardous.

If something comes up in the screening process and you are not sure if it is safe to scan them consult the PI, as ultimately it is their decision. If the PI is not available you may consult with other CMRR faculty, but always err on the side of caution if a consensus cannot be reached and cancel the subject.

2.3 Special Hazards

In addition to the general and metal-based hazards present in an MR environment, there are also several special hazards relating to the equipment and/or the scanning process (or type of scan) itself.

2.3.1 Laser Light Localizer

In the scanner, a laser is available for “landmarking” the patient’s position in the scanner. Subjects should be instructed to keep their eyes closed while the laser light is turned on to avoid eye injury. If the laser light appears as a spot rather than as crosshairs, it should be turned off immediately, and Peter Anderson or Gregor Adriany staff should be notified that it is in need of repair.

2.3.2 Phantom Leaks

The MR phantoms are used to calibrate the scanners and test sequences. These are sealed and should not show any evidence of leakage. The contents of MR phantoms are potentially hazardous. If a phantom develops a leak, protective clothing (gloves, lab coat, goggles and, if the contents have become aerosolized, a face mask) should be worn while cleaning the leak. The contents should be disposed of as hazardous materials (i.e., not simply poured down the drain).

2.3.3 Echo planar (fMRI) Imaging

Echo planar imaging, used in fMRI, DTI and ASL utilizes rapidly changing gradients and is associated with higher voltages than many other MR imaging sequences. The risk of peripheral nerve stimulation is increased with echo planar. This risk can be reduced by choosing a phase-encoding direction that is oriented anterior-posterior when this is an option.

2.3.4 Medical Gases

Medical oxygen is not available in the scan room. Please note that the medical crash cart brought by the emergency team will include oxygen but their oxygen tank is **NOT MR COMPATIBLE** and is an extreme safety hazard. **NEVER ALLOW AN OXYGEN TANK INTO THE SCANNER ROOM UNLESS YOU ARE CERTAIN IT IS EXPLICITLY MR SAFE!!**

2.4 Ear Plugs and Headphones

Anyone in the scanner room while the scanner is in operation must be provided with and must use hearing protection in the form of earplugs and/or headphones to avoid hearing injury from the acoustic noise generated by the scanner.

2.5 ECG, Pulse and Respiratory Monitoring

Some investigators may use devices for ECG, pulse, or respiratory monitoring. These may be used for acquisition of gated scan images or for monitoring purposes. Only specially designed electrodes can be safely used for monitoring and must be used in strict accordance with the manufacturer's guidelines. These devices must be properly placed and shielded to prevent risk of burns to the subject. If you need to perform physiologic monitoring, you must first obtain special training on the proper use of the monitoring equipment.

Note that the magnetic field alters the contours of the electrocardiogram. If a patient requires the use of a defibrillator (defibrillation should NEVER be performed in the scanner room), monitoring electrodes applied for use in the scanner should be removed first to avoid electrical burns.

2.6 MR Compatible Wheelchair

MR compatible wheelchairs are available are located behind the nurses desk in research patient prep area, the 3T analysis room, the lobby, and near the lockers in the old lobby. The wheelchairs are vital pieces of safety equipment and **should not be removed from the building under any circumstances** other than for evacuation of a non-ambulatory person from the building in the event of an emergency. The MR compatible wheelchair should not be used to pick up or deliver a patient. Such patients should be brought to the CMRR using standard transport equipment and then transferred to the MR compatible wheelchair.

3 Safety Policies

3.1 Supervision of subjects and guests

Subjects, any guests that may accompany them (family members, friends), and unauthorized personnel (research staff without safety training) must be accompanied at all times.

During normal work days, investigators may inquire with front desk staff whether they are willing to supervise subjects while they wait for a scan to start, or guests who must wait in the lobby during scanning sessions (e.g. minors or pregnant family members). The front desk staff have many other duties and are not generally available to supervise research participants.

3.2 The Two-Person rule

Solo scanning of subjects is not acceptable. It is the responsibility of the primary investigator to ensure that, in addition to the operator running the scanner, a second person is available during the entirety of every scanning session. The second person is not required to be in the scanner suite throughout the session, but must be in the building and available to respond to a **Code Blue** page at any time. The recommended best practice is to schedule two people from your own research team for every experiment.

Under no circumstances may you leave a subject in the scanner without a certified operator in the console room. If there is a computer or equipment malfunction during a study, call for assistance or have your second research team member help. If you cannot reach one of the designated personnel, call the front desk to have them paged (phone numbers are posted by the phone). If your second research team member is not in the room, do not use the paging system yourself during normal business hours – call the front desk and ask that your colleague be paged. If there is no answer at the front desk, then follow the instructions at the back of this manual to use the paging system to call for assistance.

3.3 Door Security

All magnets are in secure suites located in the CMRR. You must complete CMRR safety training to gain unaccompanied access to the suites, which is controlled by a card reader on the door. **Access doors to the scanner rooms should never be propped or left open nor should any other door leading into or within the CMRR.**

3.3.1 Scanner Door Failures

You should not scan if the door to the scanner room does not properly seal since your data will potentially be contaminated. In the event of a door malfunction, it is possible that you will be unable to open the door, and if you are inside the scanner room, you may find yourself trapped. You should never close the scanner door from the inside unless someone is on the outside to provide assistance. To help maintain room humidity, you should leave the door mostly closed but not all the way shut when you are in the scanner room alone.

3.4 Accurate Setting for SAR monitoring

Accurate information must be provided to ensure that FDA limits for energy deposition are not exceeded. Weights should be correct to within five pounds. Incorrect information should **never** be entered in an effort to get the scanner to conduct a study that it otherwise would not perform because FDA limits would be exceeded.

3.5 Temperature Control

In regulating energy deposition in the subject's body in accordance with FDA guidelines, the scanners assume that the ambient temperature in the room does not exceed 75° and that the relative humidity does not exceed 60%. Consequently, the thermostat is never set for a room temperature higher than 75°, and the scanner room is generally cold. Blankets and sheets are

available for patient comfort if needed; these are located in the cabinets in the magnet rooms and control rooms.

3.6 Pregnancy

Although there is no evidence that participation in an MR study by a pregnant woman would be harmful to her fetus, federal guidelines for the use of MRI in clinical settings recommend that MRI studies be delayed until after the pregnancy when possible. Consequently, it is **CMRR policy** that:

1. Pregnant women may not undergo MR studies unless the study itself is specifically designed to investigate pregnancy with IRB approval.

2. Except for members of the research team, women who are pregnant (including a pregnant parent or spouse of a research subject) are not allowed into the scanner suite at any time. They should wait in the lobby, accompanied by a member of the research team.

3. Pregnant members of the research team are allowed in the scanner room (e.g., for positioning a subject), but must not remain in the scanner room while the scanner is in operation.

It is not CMRR policy to require pregnancy testing for research subjects. A negative answer on a screening questionnaire is considered sufficient.

3.7 Children

Children (under age 18) may only enter the scan rooms as participants in an IRB approved research study of children. Children not involved in the research study (e.g., the child or sibling or a research subject) may not enter the scan room and may only be present in the control room if under direct adult supervision. The scanner room door must be kept closed whenever children are present.

All safety precautions applicable to adult subjects are applicable and, if anything, more important in children. Careful metal screening, accurate entry of age, sex and weight, and use of the "Standard Mode" scanning option are important steps in minimizing risks to this population. All subjects should be given the squeeze ball, but this is particularly important for children.

3.8 Transport Light System

If the lights are illuminated it is against CMRR policy to allow patients or volunteers to utilize the hallway. Using and obeying the lights also ensures that patients/volunteers are not exposed to research animals and that our research animals are not exposed to disease by personnel not wearing protective equipment. In some cases researchers will also be asked to vacate the corridors so that certain animals can be transported. Please make every effort to clear the corridors if asked to do so.

3.9 Obese Subjects

Subjects weighing more than 400 pounds should not be scanned. This is the weight limit for the MR compatible wheelchair that might be needed to transfer the patient off the table during an emergency. The scanner beds are designed to support weights up to 440 pounds. Even subjects weighing substantially less than 400 pounds should never be allowed to sit at the distal end of the scanner bed, since it is not designed to support the full weight of a large subject applied at full mechanical advantage.

4 Safety Procedures

4.1 Performing an Emergency Magnet Quench

The scanner's magnetic field is always on, regardless of whether you are scanning or not. In emergency situations, it is possible to turn off this magnetic field (a process referred to as "quenching". **Users of the magnets should quench them only if the magnetic field itself poses an immediate risk of serious injury or major property damage.** Two such circumstances are:

1. A metal object is lodged in the scanner in a way that poses an immediate serious threat to a person (e.g., a person is pinned to the magnet by a metal object that is causing internal injuries).

2. Fire personnel determine that there is **no other alternative** to entering the room with axes or other heavy gear when fighting a fire.

In the absence of a major emergency, **facility users should never quench the magnet by themselves**, even if they are convinced that a magnet quench will ultimately be necessary. Call personnel listed in Section 1.4 to assist with the quench.

The location of the quench buttons for each system are covered in the CMRR Safety Training presentation and are reviewed during the Magnet Specific Operator Training. It is imperative that operators know and memorize the location of these buttons prior to scanning any subjects.

Magnet Quench Procedure

1. When the magnet is quenched, the helium in the scanner boils off rapidly. To minimize the chance of asphyxiation in the event that the helium is improperly vented you should remove yourself and the subject from the scanner room before quenching the magnet.

Caution: Helium vent ducts become dangerously cold during a quench. Do not touch them!

2. Make sure the door to the scanner room is wide open before quenching the magnet (for rapid egress and to avoid pressure build-up in the scanner room).

3. Locate and press the QUENCH BUTTON in the control room or scanner room. Lift the Plexiglas cover and press the button. The magnetic field will fall to a safe level within 20 seconds.

4. If emergency medical assistance is needed, call 911 and request medical assistance as detailed on page 12 of this manual.

5. Notify Peter Anderson, Gregor Adriany, and Jeramy Kulesa staff that you have quenched the magnet.

4.2 Performing an Emergency Electrical Shutdown

The following events should prompt an emergency electrical shutdown:

1. You see smoke or fire coming from the scanner, equipment room or console.
2. Flooding has carried, or is threatening to carry, water into electrical equipment.

Please note that electrical shutdowns do not turn off the magnetic field—the magnet is always on unless the magnet has been quenched!

Emergency Electrical Shutdown Procedure

1. Locate and press one of the large red electrical shutdown buttons in the scanner room or control room. **Make sure that it is the electrical shutdown button, not the quench button.**
2. Electrical shutdown immediately stops all power to the scanner, the scanner equipment and the console computers. It does not turn off the lights. Also, power to other equipment may not be interrupted, so be aware that electrical or fire hazards may still be present.
3. In the case of fire or medical emergency, call 911.
4. Remove your subject from the scanner room. The scanner bed motors will have been powered down, so simply pull the bed out of the gantry.
5. Notify Peter Anderson, Gregor Adriany, and Jeramy Kulesa that you have performed an Emergency Electrical shutdown.

4.3 Performing a Routine Electrical Shutdown

A routine electrical shutdown requires 3-5 minutes to complete. You should initiate a routine electrical shutdown if you believe that a situation is developing that might predispose the equipment to damage. Situations that would warrant a routine electrical shutdown may include:

1. Receiving notice that an electrical outage in the building is likely.
2. Development of a minor water leak that is not expected to flood electrical equipment before a routine shutdown can be completed.
3. Alarms indicating that the magnet has quenched or that helium is low.
4. Error messages indicating that correction of a problem requires a reboot of the system.
5. Failure of the scanner bed to respond to its controls

Per the manufacturer's updated recommendations, the routine electrical shutdown should NOT be routinely performed at the end of the day. The scanner should be left in operational status.

5 Handling Medical Emergencies and Subject Problems

5.1 Medical Emergencies

If you believe that a participant or anyone else in the facility has a medical emergency and needs immediate assistance, **call 911**.

The following procedures are designed on the assumption that a physician or nurse is not immediately available in the MR laboratory at the time of the emergency. If a physician or nurse is present, the medical recommendations may be adjusted as deemed medically appropriate for the

subject's condition. However, **all non-medical aspects of these guidelines, particularly those relating to removing a person from the magnet or the scanner room, must be followed** to avoid unnecessary injury to the subject or personnel.

1. If (**and only if**) the medical emergency involves the subject being pinned to the magnet by a metal object held in place by the magnetic field, quench the magnet following the magnet quench procedure described on page 11 of this manual.

2. Call 911. Describe the event. Give the location as:

Center for Magnetic Resonance Research
Address: 2021 6th St SE
Building #: 180

3. Send someone to open the front door of the Center for Magnetic Resonance Research so that emergency personnel will be able to enter when they arrive, if the emergency is during normal business hours call the front desk (6-2001) and have them page **Code Blue, 4T, 3T, etc.** after hours and on weekends use the paging system to page **Code Blue, 4T, 3T, etc..**

4. If the emergency involves a subject in the magnet then remove the subject from the magnet room as described in the next section.

5. Provide medical assistance in accordance with your training and experience while awaiting arrival of the paramedics. Should you need it, the Automatic External Defibrillators (A.E.D.) are located on the wall in the copy/mail room (1-208A) in the "old" CMRR main lobby and on the corridor wall outside of the new 3T.

5.1.1 Procedure for removing subject from scanner room

As discussed above, there are several situations where it is important to remove the participant from the scanner (e.g. magnet quench, code blue, etc). **Under no circumstances should emergency personnel untrained in MR safety enter the scan room.** For this reason it is also important for users of the facility to know how to remove the scanning bed from the main scanner. In case of an emergency the manual release for the table may have to be used. The procedures for each magnet will be covered in the Magnet Specific Operator Training.

5.2 Subject Squeeze Bulb

The scanner is equipped with a squeeze bulb that allows the subject to set off an audible alarm to attract the operator's attention. The squeeze bulb should be made available to subjects unless some alternative method of constant monitoring (e.g., another person in the scanner room) is in effect. Use of the squeeze bulb or some comparable form of continuous subject monitoring is mandatory if you are operating the scanner in "Level 1" mode, which has an increased risk of peripheral nerve stimulation or subject heating due to RF energy deposition. Level 1 mode is not appropriate for children, elderly subjects or subjects with any known medical condition (e.g. diabetes, fever).

The squeeze bulb plugs into a connector at the foot of the bed. You can verify that the squeeze bulb is connected by noting that the squeeze bulb LED lights up when you press the talk button on the intercom. If the subject squeezes the squeeze bulb, a continuous audible alarm is emitted via the intercom and the intercom squeeze bulb LED lights up. **All subjects should be given the squeeze bulb to use during all scans.**

In the event that a subject presses the squeeze bulb alarm the following steps should be taken:

Squeeze Bulb Alarm Procedure

1. If a scan is running when the squeeze ball is activated, press the “STOP” button on the console using the mouse. Alternatively, you may press the “STOP” button on the intercom to stop the scan immediately.
2. Press the intercom talk button to stop the audible alarm.
3. While holding down on the intercom talk button, speak to the subject to determine why the squeeze bulb was pressed. Make sure that the volume is turned up so that you can hear the subject’s response.
4. If necessary, enter the room to further investigate and/or correct the problem.

5.3 Subject Tingling or Muscle Twitch

Tingling or muscle twitches are potential physiologic effects of time varying magnetic fields. Such effects are particularly likely to occur with echo-planar imaging in fMRI studies. To minimize the likelihood of such peripheral nerve stimulation, operate the scanner in “Standard Mode”. In this mode, only 1% of subjects should experience such effects. However, the scanner may not run certain pulse sequences or parameter sets in “Standard Mode”. If you operate in the default “Research” operating mode, up to 50% of subjects may experience magneto stimulation with certain pulse sequences.

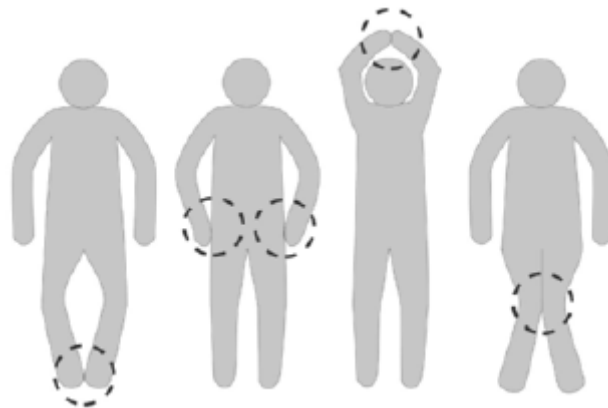


Figure 8 Illustrated are some subject positioning loops that may predispose them to peripheral nerve stimulation or burns by creating a circular current path. Subjects should be instructed not to clasp their hands at any point; feet and legs should be separated by sheets or clothing.

Complaints of tingling or muscle twitches should prompt re-screening for any metal objects that might have been previously overlooked and verification that subject positioning does not form potential loops. For echo planar imaging, selecting a phase encoding direction that is anterior-posterior (when this is an option) should reduce the likelihood of magneto stimulation. Note that the sensory input associated with magneto stimulation will pose an unwanted confound in fMRI studies.

5.4 Perspiration and Increased Pulse

Perspiration and an increased pulse rate may result from energy deposition in the body during scanning. Energy deposition in the body is carefully regulated by the scanner in

accordance with FDA guidelines. If your subject develops these symptoms, you should verify that the SAR limits are correct for the anatomy and coil you are using. For subjects who have medical conditions such as fever, diabetes, pregnancy, or cardiovascular disease that can impair thermal regulation, it may be advantageous to use even lower SAR limits. Children or elderly subjects (over 65) are also at increased risk of overheating.

5.5 Incidental Findings – Abnormal Looking Scans

In the event that a researcher sees something in a scan that raises questions, there is a system in place for requesting scan reviews by a radiologist. The appropriate procedure is documented at <http://www.cmrr.umn.edu/internal/HumanSubjects.shtml> and summarized here:

- 1) Include in your consent form the approved text found at the CMRR's Human Subjects Research page (URL above).
- 2) There are two stages to submitting the scan for review
 - a. Create a review request via the web-based interface at <https://www.cmrr.umn.edu/scanreviews2/>. Select your protocol in the menu that appears after you click on User, click "Select 4T, 3T, 7T, etc. Project" button, then at the bottom of the next page, click "New review for this project."
 - b. After filling out the required information on the online form, from transfer the appropriate scans from the scanner console to the Radiology DICOM server: From the Patient Browser, select Transfer -> Send to ... Radio_RV0041. The Event # from the scheduler needs to be the Patient ID, entered during patient registration. If you did not enter the Event # as the Patient ID, and the data are still on the scanner, you can Edit → History to fill in the Patient ID form on the subject's record.
- 3) The review should be complete within a few weeks. When the review is complete, you can see the results by clicking on the "Read Completed Reviews" in the User section of the Scan Review website.
- 4) The project is charged \$50 per reading.

6 Handling Facility Emergencies

6.1 Fire Emergencies

In case of a fire emergency:

1. Call 911 and give the location as:

Center for Magnetic Resonance Research
Address: 2021 6th St SE
Building: 180

2. If smoke or fire is coming from the scanner, equipment room or console, perform an emergency electrical shutdown as described elsewhere in this manual.
3. If you are scanning and smoke or fire is NOT coming from the scanner, equipment room or console, stop the scan and release the bed.
4. If you determine that it is necessary or appropriate to attempt to extinguish a fire in the scanner room yourself (e.g., if your subject is on fire), **use the blue and white MR**

compatible fire extinguishers located in the RF Equipment rooms next to the scanner suites.

NEVER BRING A STANDARD RED FIRE EXTINGUISHER FROM ELSEWHERE IN THE BUILDING INTO THE SCANNER ROOM.

5. Remove the subject from the scanner and escort the subject out of the building.
6. When emergency personnel arrive at the building, you or another qualified person should meet them outside the front door to **explain the risks of the magnetic environments. Don't assume that this has been taken care of.**
7. Do not return to the building until advised by fire personnel that it is safe to do so.
8. Contact Peter Anderson, Gregor Adriany, and Jeramy Kulesa to advise them that there was a fire in the building.

6.2 Audible Alarms

You should never scan while an audible scanner-related alarm is sounding. If you cannot identify and correct the underlying problem, your study should be discontinued. If an audible alarm is sounding, investigate the following possibilities:

1. The alarm might be the building fire alarm. This extremely loud alarm is audible throughout the building, is associated with flashing lights in the hallways, and would be difficult to mistake for a scanner related alarm. Even if you suspect that the fire alarm has been triggered accidentally, you **MUST** do the following:
 - a. If you are scanning, stop the scan immediately and remove the subject from the scanner.
 - b. Accompany the subject out of the building via the nearest accessible exit.
 - c. Do not reenter the building until told that it is safe to do so by fire personnel
2. The alarm might have been triggered by someone squeezing the squeeze bulb. Look to see if the squeeze bulb LED on the intercom is lit. If it is, see the separate section regarding the squeeze bulb. You will be able to continue your study if this is the source of the alarm.
3. The helium level might be low or the magnet might have quenched as a result of someone pressing the quench button notify appropriate staff of the problem and send your subject home.

6.3 Non-Fire Facility Emergencies

In the event of a non-fire emergency , such as an unscheduled power shutdown, a water leak, or an earthquake or other natural disaster, the following general guidelines should be followed:

1. Remove the subject from the scanner. Except in the case of immediate threat (water rushing under the door or smoke coming from the room next door), it is best to leave the scanner powered on and use the electronic table controls to remove the subject from the scanner.
2. Perform a routine electrical shutdown, or if circumstances such as a rapid flooding threaten to reach the equipment before a routine shutdown could be completed, perform an

emergency electrical shutdown. Both shutdown procedures are described elsewhere in this manual.

3. If appropriate, evacuate the building and do not return until advised to do so.
4. Notify Peter Anderson, Gregor Adriany, and Jeramy Kulesa of the emergency.

7. Using the CMRR paging system

There are only two situations under which you should use the paging system:

- 1) in case of emergency, when you need to call a second person to assist with removing the subject from the scanner and waiting for emergency personnel.
- 2) on the evening or weekend, when you need help with a computer or equipment failure and the second person helping you scan is not in the room with you.

To page:

- 1) Pick up the handset and dial 3-8085
- 2) After you hear one ring, press **1**.
- 3) Talk.
- 4) Hang up.

Acknowledgments and version-tracking

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The original version, dated August 6, 2008, was compiled by Cheryl Olman with help from Bryon Mueller, Casey Tuck and the 3T Policy Committee.

This version, dated Nov. 2011, was amended to include general safety policies and procedures for scanning human subjects at all scanners. Please contact Jeramy by email (kulesa@cmrr.umn.edu) with questions or concerns about the content of this manual.