GENERAL INFORMATION

- 1. Before anyone (i.e., staff, subject, visitor) enters the magnet room, a screening form must be completed by the subject and reviewed by the investigators or the technologists who will be performing the MRI exam.
- 2. Before entering the magnet room, all pockets are to be emptied of: watches, pagers, wallets, pens, pencils, hair clips, jewelry, keys, coins, and any other possible projectiles.
- 3. It is recommended that the person being scanned change into MR-compatible clothing.

Pajama bottoms and gowns are provided for this purpose.

4. The magnet room door should be kept closed at all times except when entering or exiting the room.

Keeping the door shut tight will reduce RF noise during imaging.

- 5. All persons scanned must wear ear protection. If they decline, the exam must be canceled.
- 6. Never scan with an unplugged surface (or body) coil in the bore of the magnet.
- 7. Use of any research equipment, coils, or supplies not supplied by the MRI facility must be approved by an MR Steering Committee or appropriate official.
- 8. All investigators and technologists must clean up after themselves. Return all equipment to its proper place. The room should be kept neat and tidy. Do not lay coils or phantoms on the floors.
- 9. Please report all malfunctioning or damaged equipment to the technologist(s) immediately.
- 10. All studies should be archived immediately after the exam is complete. Data may remain on the system for up to 7 days (or some agreed upon time) unless disk space becomes critical, in which case, the oldest studies will be removed first. If a study requires extra time on the disks, log it in the "DO NOT REMOVE" logbooks, which are located in each control room.
- 11. A physician must be available to cover MR exams where patients are being scanned or a contrast agent is being administered. For normal volunteers, no medical coverage is necessary, however, the investigators and technologists must be familiar with code procedures and calling 911 if a medical emergency should arise.
- 12. Investigators and technologists should never leave their subjects unattended in the magnet. If the investigator or technologist must leave the MR area, then he/she must get another qualified person to cover.
- 13. Subjects should never be left lying on the scan table outside of the magnet. Due to the lack of side rails on the table, there is a risk of the subject falling off the table.

MRI ORIENTATION AND TRAINING PROGRAM

To ensure a safe and knowledgeable working environment, all potential MRI operators must complete formal training as outlined below. Upon satisfactory completion of this orientation program, only those deemed "Qualified Operators" by the MRI Steering Committee will be assigned a 1 year safety certificate.

Each MRI operator will complete an orientation in the MR facility via a walk-through and demonstration of the equipment and safety procedures. All orientation sessions will be supervised and documented on the form found on the facing page. The orientation and training will include:

> Nursing procedures Screening/safety Consent forms Monitoring equipment Emergencies Code procedures

Scanning procedures Coil selection/setup Positioning Pulse sequence selection Imaging options selection Scanner startup/shutdown Record keeping/documentation Archiving/deletion of data

Filming procedures (if applicable) Processor startup/shutdown Laser camera startup/shutdown Filming software Developing films.

MR Safety Guide

A3.2

Supplement 11

| ТОРІС | REVIEWED BY | DATE |
|--|----------------------------------|--------------|
| Nursing procedures | | |
| Screening/safety | | |
| Review screening form | | |
| Review consent form | | |
| Review permission form | | |
| Monitoring equipment | | |
| ECG (electrocardiogram) | | |
| Blood pressure | | |
| Pulse oximeter | | |
| • Emergencies | | |
| Code procedures | | |
| ТОРІС | REVIEWED BY | DATE |
| Scanning procedures | | |
| Coil selection/set up | | |
| Positioning | | |
| Pulse sequence selection | | |
| Imaging options selection | | |
| Scanner startup/shutdown | | |
| Record keeping/documentation | | |
| Archiving/deletion of data | | |
| ТОРІС | REVIEWED BY | DATE |
| Filming procedures | | |
| Processor startup/shutdown | | |
| Laser camera startup/shutdown | | |
| Filming software | | |
| Developing films | | |
| Documentation o | of Approval | |
| is approved to op (Investigator's name) | perate the (Name and location | n of magnet) |
| Approval given by | Date: | |

MRI SAFETY STUDY GUIDE

Section I: The Magnetic Environment

Magnetic field

It is important to remember when working around a superconducting magnet that the magnetic field is always on. Under normal working conditions, the field is never turned off. Therefore, it is important to be aware of safety issues regarding ferrous objects that can act as projectiles and watching out for patients who may have contraindicated devices implanted in their bodies.

There are two units used to describe magnetic field strength. They are Tesla and Gauss: 1 Tesla equals 10,000 Gauss. The strength of the magnetic fields of a 1.5T (15,000 Gauss) system is ~30,000 times that of the earth's magnetic field. The 5-Gauss line defines the area at which the magnetic field becomes dangerous to patients with cardiac pacemakers. For many 1.5T systems the 5-Gauss line is located at the foot of each scan table as well as at the same distance from the back of the magnet.

Keep doors closed

The doors leading to the magnet room should be closed at all times except when entering or exiting the room. This will prevent people who do not belong in the room from wandering into the room. This also can dramatically reduce RF noise appearing in the images (the room is not properly RF screened).

Consent and screening procedures

Consent forms

Every research patient will need to sign a consent form. Research often involves the use of non-FDA (Food and Drug Administration)-approved MRI sequences on patients and volunteers. These sequences are important to the advancement of the science of MRI. The research patients and volunteers must be informed that these non-approved sequences are being performed and consent must be given. Copies of the consent forms for patients and volunteers to sign <u>every time they have a research exam</u> should be readily available. In addition, the consent form must be signed by the Principal Investigator or his/her designee. Only one consent form is needed per exam, but the research patient must sign a new consent form every time he/she returns for another exam. Offer the volunteer or signee a copy of the consent form. See the MRI research technologists or the scanning investigator for a copy of the consent form.

Screening forms

As stated earlier, the magnets have a very strong magnetic field surrounding them, which has the potential to attract certain types of metal. The magnetic field can also interfere with the normal operation of electronic devices. For these reasons, a detailed health history for every person that enters the magnet room is necessary. This includes all staff members, investigators, patients, and volunteers. The repercussions associated with a patient, volunteer, or staff member being injured because of negligence on the part of the scanning investigator could be severe and could cause clinical scanning or research to be halted at this facility.

Screening forms have been designed and must be completed by every person entering the magnet room. Examples of the screening forms can be found in *APPENDIX 1*. In the event that a staff member has an accident or surgery where a metallic foreign object or electronic device is implanted into their body, the staff member would be restricted from going into the magnet room until the metallic/electronic object can be cleared for safety purposes.

It is up to the staff member to be aware of such circumstances and to report any such events to their direct supervisor.

From this point on, patients and volunteers will be referred to as "subjects." However, it should be noted that the word "patient" refers to any person scanned in the clinical or research facility who is under the care of a physician; that physician being one who is an investigator in the clinical or research study.

Subjects who return for other MRI exams must fill out a new screening form for each visit. Every screening form must be signed by the subject and the investigator or technologist who is performing the scan.

Keep in mind that all subjects who are providing information regarding their health history must be conscious and coherent. Any gaps in memory or lack of information about a surgical procedure is grounds for canceling the subject, unless a family member can provide a detailed history. If there is ever any question about the past health history of a subject regarding metal in their body, it is required that the MRI exam be put on hold until the question can be investigated thoroughly.

An in-depth explanation of contraindications to MRI will follow in the next section.

Section II: Contraindications for MRI

There are several types of contraindications that would prevent a subject from having an MRI scan. Metallic implants and foreign bodies as well as the physical condition of the subject will be discussed in this section. All subjects are required to remove any clothing that has metal on it. Gowns and pajama bottoms are provided for the subject to change into. All **subjects and staff members** must empty their pockets of any loose metallic objects (e.g., hair pins, safety pins, coins, keys, ID badges, wallets, credit cards, banking cards, lighters, pocket knives, scissors, stethoscopes, hemostats, etc.) before entering the magnet room.

Surgical implants

There are hundreds of metallic implants that can be surgically placed into a person's body for various reasons. Some of these implants are ferrous and may be attracted to the magnetic field. Some may be electronic in nature, in which case, the magnetic field can interrupt the normal operations of the device. By placing an electronic device in the magnetic field, a current may be induced in the conducting wires of the device, which could possibly burn the patient. There are many metallic implants that are non-ferrous and may be compatible for MRI such as orthopedic screws, rods, and plates. It is suggested that a waiting period of at least 2 weeks after surgery is necessary for the tissues around the implant to take hold of it to prevent any potential movement of the implant. Although the 2-week period is generally observed, in some more emergent instances, a subject with a non-ferrous implant may be scanned as soon as 1 day after the implant is in place. There are also some ferrous implants (e.g., heart valves, venous blood clot filters) that are compatible for MRI. Typically, the waiting period for these implants is between 2 and 6 weeks. The bottom line is that the waiting period decision should be left to a radiologist who is familiar with the implant and its magnetic properties. To prevent injury to the subject, it is extremely important that the scanning investigator be familiar with the difference between compatible and contraindicated implants and devices.

MR Safety Guide

Accidental metallic foreign bodies

Occasionally, a subject may have been injured by a piece of metal that punctured his/her body in some way, shape, or form. Common causes of this type of injury are bullets, buckshot, pellets, or BBs. Other frequent causes are metal slivers that fly off by those who grind, sand, or cut metal. These metal slivers often fly into the eyes, hands, or face (and it is likely that the people working in these areas are completely unaware because these metal slivers are so fine). Also, people who have been involved in wartime activity may have pieces of shrapnel or other metal fragments in their body. Any of these circumstances must be investigated thoroughly to prevent injury to the subject.

Checklist of tested implants, devices, and metallic foreign bodies

There is a small handbook entitled "Pocket Guide to MR Procedures and Metallic Objects: Update" (Shellock, 2001). This book lists hundreds of surgical implants and metallic foreign bodies that have been tested by leading MRI safety authorities in magnetic environments for evidence of deflection and torquing of the metallic objects. This book should be used to investigate any questionable implant or foreign body.

Procedure to clear metallic implants and foreign bodies

The subject should list all of his/her surgical or accident history on the screening form. In addition to this, the investigator should requestion the subject about his/her history even if the subject has written that he/she has not had any surgery. It is not uncommon for a subject to conceal or forget about a procedure or accident that may have happened some time ago. He/she also may be uncomfortable about writing it down for others to see. Further questioning the subject and explaining the importance of honesty can sometimes provide additional information to the investigator.

If the subject has had a surgical implant or an accident involving metal, find out the following information:

- 1. What was the procedure? What was the nature of the accident?
- 2. What kind of implant is it? What does it do? What is it used for?
- 3. When was the procedure done? What year?
- 4. Do you know for sure that it is metal?
- 5. Who was the doctor/surgeon who performed the procedure? Is he or she still in practice?
- 6. At what hospital was the procedure performed?
- 7. If it was an accident, did you have any X-rays done at that time and was the metal removed?

Once all of the answers to these questions are obtained, proceed with the following:

- 1. Provide the above information to the MRI technologist. The technologists have been educated as to what may or may not be scanned and in many instances will be able to assist.
- 2. If the technologist does not know of the implant or thinks the subject may have to be canceled, the principal investigator and a radiologist must be consulted to obtain more information. If the subject does not know if the implant is metal, the radiologist may suggest X-rays be done to rule out metal. X-rays may not be performed without the permission of the principal investigator.

- 3. If the radiologist does not know of the implant, contact the surgeon who placed the implant and request a copy of the operating room report, which should describe the model and name of the implant. Attach this report to the screening form of the subject for permanent documentation.
- 4. The final responsibility of canceling or proceeding with the exam lies with the principal investigator, who should make an informed decision based on the information provided by the MRI technologists and radiologists.
- 5. If the subject is cleared, a written permission signed by the principal investigator for the subject to undergo the MRI exam must be provided to the MRI research staff. Attach this permission form to the screening form of the subject for permanent documentation.

IMPORTANT NOTE: Any person (subject or staff) who has a history of working with metal as an occupation or hobby should have X-rays of their orbits to rule out any metallic foreign body before they enter the magnet room. A case of a patient being blinded by a metal sliver piercing the optic nerve was a former metal worker who had no knowledge of a piece of metal existing in his eyes. Typically, if metal workers get a sliver of metal in their eyes, it is removed in an emergency room by a physician. However, without X-rays, there is no way of knowing if the entire piece of metal was removed. Usually, X-rays will be ordered at the time the metal is taken out. If a copy of the report from those X-rays can be obtained and the subject has no more metal in his/her eyes since the time of the X-rays, then use the original X-ray report to clear the subject for the MRI exam.

Emergency removal of the subject from the MRI scanner

If the investigator has placed a subject in the scanner and upon looking at the first set of images notices a metallic artifact present, the investigator must follow the proper procedure for removing the subject from the scanner and the magnet room.

- 1. Inform the subject that he or she is going to be removed from the magnet. Instruct him/her to remain perfectly still and to not sit up at any time.
- 2. Pull the table out of the scanner very slowly.
- 3. Move a gurney into the magnet room and place it next to the table.
- 4. Have the subject slide, without sitting up, onto the gurney.
- 5. Slowly pull the gurney straight away from the magnet without turning.
- 6. Once the doorway is reached, slowly turn the gurney and move it out through the doorway.
- 7. Once the subject is safely outside of the room, he/she may sit up.

NOTE: This procedure should also be used if the subject informs the technologist of a contraindicated metallic implant in his/her body after already being placed in the magnet (or if being taken out for any other reason as well, e.g., he/she pushes the button or squeezes the ball requesting to come out).

Pregnant subjects

It is the policy of the MRI department to not scan any pregnant subjects for research purposes. In the clinical environment, pregnant patients are only scanned in emergency situations. With this in mind, and realizing that research is not done on an emergency basis, pregnant subjects must wait until after they give birth in order to participate in a research project.

MR Safety Guide

If a subject believes she may be pregnant, it is up to the principal investigator to decide if the subject should undergo a pregnancy test. If the principal investigator deems the pregnancy test necessary, all arrangements and financial responsibility will be taken care of by the principal investigator or his/her designee.

If the pregnancy test is negative and the subject is to undergo the MRI, a copy of the pregnancy test report will be needed to attach to the screening form of the subject for permanent documentation.

Contrast agents used in subjects who are breastfeeding

In the case where a subject is breastfeeding her child, the mother must be informed that her breastmilk must be expressed with a breast pump and thrown away for 48 hr following the injection of gadolinium contrast agent. It is important that she be aware of this in order to store enough milk to feed the child during the 48 hr after the contrast agent injection.

Pregnant staff

It is the policy of the MRI department that all pregnant staff members be restricted from the magnet room when radiofrequency pulses are on. Any pregnant ancillary staff member (e.g., nurses, coordinators, assistants) who does not need to be in the magnet room should stay out of the room unless there is an emergency with a subject. Pregnant staff members, such as MRI technologists, who must enter the room on a regular basis should only stay in the room as long as necessary, i.e., positioning subjects, emergencies, etc. The goal is to keep the pregnant staff member out of the magnet room as much as possible unless it is part of the job description to be in the room or if there is an emergency with the subject. If an MRI staff member is pregnant, she should inform her supervisor immediately. Ancillary staff members should let the MRI technologists know if they are pregnant.

Radiofrequency and specific absorption rate

MRI employs radiofrequency (RF) pulses to disturb the alignment of protons in the nucleus of hydrogen atoms in the body. These RF pulses deposit heat into the tissues of the body. This heat deposition is termed specific absorption rate (SAR). SAR is measured in watts per kilogram and is a function of several variables, including: (1) the type of RF pulse used (90° or 180°); (2) the number of RF pulses in a sequence; (3) the pulse width; (4) the T_R ; (5) the weight of the patient; and (6) the type of coil used. The FDA and IEC (International Electrotechnical Commission) have developed guidelines to regulate the acceptable amount of deposited heat. Currently all manufacturers of MRI equipment are permitted to submit their pulsing sequences to the FDA for SAR review.

Conditions in the examination room

The examination room should have an ambient temperature of $21^{\circ}C \pm 3^{\circ}C$ with a relative humidity of 50% to 70%.

Specific absorption rates

- 1. The FDA (*http://www.fda.gov/cdrh/ode/magdev.html*) does not require an approval of an investigational device exemption (IDE) if the field strength is not >4 Tesla or if SAR is less than or equal to:
 - a. 4 W/kg averaged over the whole body for any period of 15 min; or
 - b. 3 W/kg averaged over the head for any period of 10 min; or
 - c. 8 W/kg in any gram of tissue in the head or torso, or 12 W/kg in any gram of tissue in the extremities, for any period of 5 min.

- 2. IEC 60601-2-33 normal mode; i.e., when the field strength is ≤2 Tesla (see IEC 60601-2-33 Medical Electrical Equipment—Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis, 2002, 2nd Ed., International Electrotechnical Commission). The SAR are limited to:
 - a. 2 W/kg averaged over the whole body for any period of 6 min; or
 - b. 3.2 W/kg averaged over the head for any period of 6 min; or
 - c. 10 W/kg in any gram of tissue in the head or trunk, or 20 W/kg in any gram of tissue in the extremities, for any period of 6 min; or
 - d. three times the appropriate long-term SAR level for any period of 10 sec.
- 3. IEC 60601-2-33 first controlled mode; i.e., when the field strength is >2 Tesla but is not >4 Tesla. The SAR are limited to:
 - a. 4 W/kg averaged over the whole body for any period of 6 min; or
 - b. 3.2 W/kg averaged over the head for any period of 6 min; or
 - c. 10 W/kg in any gram of tissue in the head or trunk, or 20 W/kg in any gram of tissue in the extremities, for any period of 6 min; or
 - d. three times the appropriate long-term SAR level for any period of 10 sec.

Acoustic noise

- 1. The FDA regulates the peak unweighted sound pressure level to be not >140 dB or the A-weighted r.m.s. sound pressure level to be not >99 dBA with hearing protection in place.
- 2. IEC 60601-2-33 regulates that the peak unweighted sound pressure level is <140 dB.

NOTE: It should be noted that subjects with thermoregulatory illnesses such as a fever, or diseases in which the patient is unable to sweat, may be compromised by heat deposition in MRI. Extreme care should be taken with these subjects to keep them cool during the exam. Choose sequences that do not result in high amounts of heat deposition. The eyes are also particularly susceptible to heat deposition.

Section III: Emergency Procedures

CPR requirements

It is a common requirement of MRI departments that all investigators, technologists, students, or other staff who will be conducting MRI experiments on humans are certified in cardiopulmonary resuscitation (CPR).

Crash carts

There is usually one crash cart located in any MRI area.

Calling 911

In order to get emergency help, call 911 and follow the instructions of the dispatcher. Tell them the address right away. Remember to speak clearly and slowly so there is no misinterpretation of information. Some sites may have their own internal procedures.

Code procedures

In order to know the status of the subject at all times, it is strongly recommended that the pulse oximeter be placed on the finger of every subject that goes into the magnet. This will provide the heart rate and oxygen saturation for the subject while he/she is in the scanner. If the subject should become unresponsive, begin the code procedure as listed below.

- 1. Immediately remove the subject from the bore of the magnet.
- 2. Try to arouse the subject by shaking him/her gently.
- 3. If there is no response, feel for a pulse at the carotid artery in the neck. At the same time, listen for breathing near his/her mouth and nose while looking at his/her chest to determine breathing.
- 4. If the subject is not breathing or does not have a pulse, call **911** immediately, also call security.
- 5. Return to the subject immediately and begin rescue breathing and/or CPR appropriate to the condition of the patient.
- 6. If more than one investigator is present, have him/her call **911** and security for help and then round up as many medical personnel as possible.
- 7. The second person should also bring the stretcher into the magnet room to enable transport of the subject out of the room. Make sure the stretcher is made of aluminum, which is MR compatible.
- 8. DO NOT BRING THE CRASH CART INTO THE MAGNET ROOM.
- 9. If the subject is transported outside of the magnet room, proceed to the holding area and bring the crash cart. The crash cart is equipped with an ambu bag that may be used to breathe the patient if trained to do so.
- 10. Once emergency personnel arrive, <u>DO NOT</u> let them into the magnet room. Secure the subject out of the magnet room without endangering any personnel who have not been cleared to enter the room. Among other items, paramedics always have stethoscopes, scissors, and hemostats on them, which will turn into deadly projectiles if brought near the magnet. In addition, their health history is unknown and they may have contraindicated implants in them.
- 11. Inform the emergency personnel of the incident and stay close by to assist them with any questions they may have or items they may need.
- 12. After the subject is taken away by the paramedics, fill out an incident report.

Quench

The term "quench" is used to describe the rapid boil off of the cryogens that keep the magnet cooled and in a superconducting state. Cryogens are supercooled liquid helium and nitrogen. Without cryogens, the magnet loses its magnetic field. Usually a quench is undesirable and is due to a malfunction within the system. In rare instances, a quench may be necessary to free someone from the magnet if they have been accidentally struck by a projectile ferrous object and pinned to the magnet. In each control room, there are boxes on the wall that enclose quench buttons that should be pushed in the event that the magnetic field must be manually run down.

When a quench occurs, either spontaneously or manually, evacuate from the magnet room immediately to avoid being overcome by helium gas, should the room not vent properly. If manual quenching of the magnet is to be done, make sure the door to the scan room is left open to avoid a vacuum forming, which may seal the door shut. If the magnet quenches spontaneously, and the door does not open, break the window between the control room and the magnet room in order to get the subject and possibly yourself out of the room. Remember to stay low so that helium or nitrogen is not breathed in.

MR Safety Guide

Projectile injury

If a subject or staff member becomes pinned to the magnet by a ferromagnetic object, evaluate the situation quickly before taking any action. If the person is unconscious, bleeding profusely, at risk of losing a limb or extremity, or in severe pain, manually quench the magnet to bring down the field in order to release the object and the person. If the person is responsive and able to communicate his/her well being, leave him/her in the position until a service engineer can respond and ramp the magnet down slowly to avoid a full quench. If the latter is chosen, and the person then loses consciousness, or his/her condition worsens, immediately quench the magnet manually. Keep in mind that the cryogens are expensive to replace, so evaluate the situation carefully but never put cost above the life or well being of the subject.

Once released, secure the subject out of the room and call 911 for emergency medical help.

Responsible parties

Any time a patient is scanned, or any contrast agent is administered to a human in the MRI area, a physician must be available to cover in the event of a medical emergency. If the principal investigator is not a medical doctor, arrangements must be made to have a medical doctor available to respond for emergency purposes. If a designee of the principal investigator is present with the subject, the designee must know how to reach the principal investigator, or a medically responsible party, immediately in the case of an emergency. This also means when a subject is scanned, the responsible physician may not be out of town without arranging for medical coverage in the event of an emergency. The MRI technologists will assume that these arrangements have been made before the subject is scanned and will not be responsible for medical treatment of the patient other than proper emergency procedures in the event of an emergency or adverse event.

Section IV: The Scanner and Related Equipment

Bringing computers up and shutting computers down

Bringing the MRI computer up, or booting the computer, is a fairly simple procedure. Make sure that the information from the local service representative for the specific system is available.

From this point on, in order to use the scanners, the scan time on the research magnets must be pre-approved.

Table controls and table stop buttons

Each of the magnets is equipped with a table that moves into and out of the scanner by using the plasma controls on the front of the magnet gantry. Each scanner should have buttons or pedals on the scan table or around the magnet in order to manually release the scan table. For example, in the Siemens Vision, there are two orange arrows that indicate "up/down" and "in/out." On both sides of each table are red table release buttons. Normal position for the buttons is in the "out" position. To remove the table rapidly, push one of the red buttons "in" to release the table. The table may then be pulled out of the magnet bore manually.

Stereo/headphones/earplugs

All subjects are required to wear ear protection while undergoing an MRI exam. Earplugs will be provided. Headphones are also provided, which hook into the stereo system so the subject may enjoy music during the exam. The headphones are also part of the noise cancellation system that helps drown out the knocking noise of the gradients. For the high-field systems, if the subject refuses all hearing protection, the scan cannot be performed.

Communicating with the subject while in the scanner

It is important to maintain voice contact with the subject throughout the exam. The researcher or the technologist should routinely establish contact between each sequence. Speak to the subject while depressing the "speaking" button on the keyboard. In order to hear the subject, the "hearing" button on the keyboard must be depressed.

Patient alarm

Every subject should be given the patient alarm ball to hold in his/her hand during the exam. The subject should be instructed to squeeze the ball if:

- a. he/she needs to speak with the investigator or technologist in between sequences;
- b. he/she wants to come out of the scanner immediately;
- c. something is hurting.

Because the scanner cannot be put in a pause mode, stopping a scan to speak to the subject will require one to start the scan over again from the beginning. For this reason, it is wise to advise the subject to squeeze the ball only in situations of pain, injury, or claustrophobia. If the investigator or technologist is communicating with the subject routinely between sequences, the subject will be less likely to squeeze the ball in the middle of a sequence to ask a non-emergent question.

In vivo monitoring system

With an in vivo system, one may be able to do the following:

- 1. obtain an ECG trace from the subject;
- 2. obtain blood oxygen saturation percentages from the subject;
- 3. obtain blood pressures from the subject.

ECG and cardiac gating

Currently, there are several types of studies where cardiac gating is desirable. Cardiac gating functions to allow imaging in areas of the body where there is considerable motion. For example, when imaging the heart, cardiac gating is used to instruct the computer to image all of the slices at the same point in the heart cycle every time the heart beats. This gives the appearance that the heart motion is frozen resulting in images with the appearance of little or no motion artifact.

Special attention must be given when attaching the electrode and leads to the chest of a subject. Because the lead wires are placed in a magnetic field, it is possible to induce an undesirable current in those wires, which may burn the subject. It is imperative that the lead wires and the main ECG cable have no loops in them when placed on the subject. The main cable should not touch the sides of the magnet or the skin of the subject as it is run out of the magnet bore. The cable should be run straight out of the bore with no loops and should not cross over the body of the subject at any point. If the cable must be obtained from the left side of the subject to the plug-in port on the right side of the table, run the cable down the left side of the subject, and then across the foot of the table. A washcloth, sheet, or towel must be placed between the skin and any wire that makes contact with the skin.

Blood pressure monitor

The blood pressure monitor is able to measure the blood pressure of the subject noninvasively at prescribed intervals throughout the exam. The researcher may set a time interval at which the monitor will automatically inflate the cuff on the arm of the subject while in the scanner. An updated blood-pressure reading is displayed with each measurement interval.

MR Safety Guide

The blood-pressure cuff may be placed on either arm but care should be taken not to place it on an arm that has an i.v. placed in it. Also, it is not uncommon for women who have undergone a mastectomy to have poor lymph circulation in the arm on the side of the mastectomy. Because of this, these subjects cannot usually withstand pressure placed on the arm of the same side as the mastectomy. For example, if the woman has had her right breast removed, place the blood-pressure cuff on her left arm. If she has had both breasts removed, ask her on which arm she would prefer to have the cuff placed.

Blood oxygen saturation monitor (pulse oximeter)

The pulse oximeter, when placed on the fingertip of the subject, will display the heart rate of the subject and percentage of oxygen in the blood. The pulse oximeter may be placed on any finger of the subject, however, the index or middle finger has been found to work the best. Place a piece of adhesive tape around the clip when it is on the finger to hold it securely in place.

The corrugated cable running from the finger clip to the pulse oximeter contains fragile fiber optic wires. It is important that this cable is not stepped on or crushed; be careful with it. Damage to the fiber optics or a break in the corrugated cover could cause the pulse oximeter to malfunction or produce RF artifacts.

NOTE: For safety purposes, it is strongly recommended that the pulse oximeter be placed on all subjects who are having an MRI exam. If the subject should fall asleep in the scanner and become unresponsive when the investigator or technologist attempts to speak to him/her, the investigator or technologist will know whether or not the subject is well or in distress based on the readouts from the pulse oximeter. This will save the investigator or technologist from having to stop the experiment to go into the magnet room to check on the subject. Also, if the subject should have heart failure or breathing difficulty, the investigator or technologist will know immediately based on the pulse oximeter readout.

Removing subjects from the MRI scanner

If a subject requests to be removed from the magnet at any time, the investigator or technologist should do so promptly. Whether due to pain, illness, or claustrophobia, the investigator or technologist must never keep the subject in the MRI scanner against his/her will. If a subject asks to be brought out, communicate with him/her to determine the problem. Ask the subject if he/she can continue, if not, remove the subject immediately.

Starting/stopping a scan

To start a scan, simply click on the "measurement" (or its equivalent) button on the control screen. To stop a scan, click on the "stop" (or its equivalent) button on the control screen.

Oxygen/suction/room air supplies

Some MRI facilities are equipped with oxygen, suction, and room air channels. These may be mounted on a wall or hung from a ceiling to the left of the scanner. Oxygen is marked by the green hose or regulator, suction is white, and room air is yellow.

Section V: Data Acquisition and Management

Responsibility for acquired data, archiving, and deletion of data

All investigators and technologists are responsible for the data acquired. Data must be archived immediately after the exam is complete in order to prevent loss by removal off the MRI system disks.



Data may stay on the MRI system disks for up to 7 days. It is requested that if the investigator or technologist does not need the data or is finished processing it, then it should be removed. If the disks become full and deletion is necessary, the oldest studies will be removed first.

If an investigator or technologist needs his/her data to stay on the disks for longer than 7 days, he/she should fill out the "DO NOT REMOVE" logbooks, which reside in each scan control room. Also, if an investigator or technologist restores a study to the MRI system, he/she should log this in the "DO NOT REMOVE" logbook so that the study is not removed before the data is used.

Investigators or technologists may only remove one's own data. All other MRI data may only be removed from the system disks by the MRI chief technologists.

MRI OPERATOR EXAM

Name:

Date:

Department:

- 1. Mr. Jones is feeling a little claustrophobic during his exam and would like his wife to sit with him during his MRI exam. Mrs. Jones had a pacemaker implanted 5 years ago, therefore, it is permissible to allow her into the room as long as she stays at least 10 feet from the front of the magnet.
 - a. True
 - b. False
- 2. For subject safety purposes, which of the following items are contraindicated for an MRI scan.
 - a. Orthodontic braces
 - b. Orthopedic screws in the ankle placed 6 months ago
 - c. Aneurysm clips
 - d. Pacer wires (no pacemaker) left in the chest after open heart surgery 3 years ago
 - e. c and d only
 - f. All of the above
- 3. You walk into the scan room and find a maintenance employee pinned to the magnet by a floor buffer. He is unresponsive but has a weak pulse. You immediately ...
 - a. Throw cold water on him
 - b. Use smelling salts to try to rouse him
 - c. Call his supervisor and tell him that the maintenance employee is sleeping on the job
 - d. Call for help then attempt to free the employee; if unsuccessful, press the quench button to eliminate the magnetic field
- 4. While scanning a subject for a heart study, he suddenly complains of a stinging, burning sensation at the location of one of the electrodes placed on his chest for cardiac gating. You
 - a. Tell him to remain quiet until the sequence has finished
 - b. Turn the radio up louder so that you cannot hear his complaint
 - c. Tell him the stinging will subside in a few hours
 - d. Immediately remove him from the magnet and inspect the area of the leads for loose or crossed wires
- 5. When positioning the ECG monitoring cable on a subject for a heart study, it is OK to run the cable across the subject's body to plug it into the connector box.
 - a. True
 - b. False

- 6. You have just positioned a subject inside of the magnet for a knee scan when she suddenly remembers she had a brain aneurysm repaired 10 years ago. You ...
 - a. Rapidly pull the table out of the scanner, immediately lower it, and rush her out of the room as fast as possible
 - b. Continue with the exam because you are not scanning her head
 - c. Call 911
 - d. Very slowly, pull the table out of the scanner and then have the subject slowly slide onto a stretcher so that you can slowly cross her through the magnetic field lines and out of the room
- 7. Which of the following represent the current FDA recommendations regarding specific absorption rates for an MR scanner that does not have a field strength >4 Tesla?
 - a. Not to exceed 4 W/kg averaged over the whole body for any period of 15 min
 - b. Not to exceed 3 W/kg averaged over the head for any period of 10 min
 - c. Not to exceed 8 W/kg in any gram of tissue in the head or torso, or 12 W/kg in any gram of tissue in the extremities, for any period of 5 min
 - d. All of the above
- 8. If a subject is unresponsive when you try to communicate with him in between scanning sequences, you should ...
 - a. Continue with the scan and assume that he is sleeping
 - b. Call 911
 - c. Defibrillate him
 - d. Pull him out of the scanner or at the very least go into the room to see if he is O.K.
- 9. To avoid the confusion that a patient is well or not, it is a good idea to use the pulse oximeter on everyone that is placed into the magnet.
 - a. True
 - b. False
- 10. Your subject has informed you that he has worked as a metal grinder for 10 years but he has never had any metal shavings fly into his eyes.
 - a. Proceed with the scan since he has never had any metallic foreign bodies in his eyes
 - b. Do not proceed with the scan and at the discretion of the principle investigator, send the subject for X-rays of his orbital area to rule out possible metallic foreign bodies
- 11. Your subject has informed you that she had a metal sliver enter her eye 10 years ago but that the doctor got it all out. You ...
 - a. Proceed with the scan since the metal sliver was removed
 - b. Do not proceed with the scan and at the discretion of the principle investigator, send the subject for X-rays of the orbital area to rule out possible metallic foreign body

- 12. While performing a brain MRI on a 24-year-old woman, she begins to complain of some stinging around her eyelids. Upon examining her you find out that she has permanent tattoo eyeliner. You ...
 - a. Terminate the exam, take her out of the scanner, apply cold compresses to her eyes, and seek the proper medical attention
 - b. Take her out of the scanner, apply ice-cold compresses to her eyes to lower the temperature in the area, and then continue with the scan if she feels up to it
 - c. Inform the subject to shut her eyes and the pain will go away
- 13. Your subject has had a heart attack while undergoing an MRI exam. You ...
 - a. Call 911 and immediately bring the crash cart into the magnet room to begin resuscitation measures
 - b. Call 911 and bring the subject out of the room on a stretcher to begin resuscitation measures
 - c. Call a hospital code team and bring the subject out of the room on a stretcher to begin resuscitation measures
 - d. Call a hospital code team and immediately bring the crash cart into the magnet room to begin resuscitation measures
- 14. During the middle of a measurement, you hear the subject attempting to speak to you but you can not hear her clearly. You ...
 - a. Ignore her and continue the measurement
 - b. Stop the measurement and speak to her
 - c. Stop the measurement and yell at her for interrupting
 - d. Terminate the entire exam
- 15. Your subject tells you she had surgery 20 years ago on her brain but she can not remember exactly what it was for. You ...
 - a. Proceed with the scan because she seems credible
 - b. Cancel the scan for today until further investigation into the matter can occur
 - c. Tell the subject of the risks involved due to her lack of history and allow her to decide if she wants to have the MRI
 - d. Proceed with the test only after having the subject signs a waiver that releases us from responsibility of injury
- 16. Which of the following are contraindicated for an MRI exam?
 - a. Cardiac pacemaker
 - b. Swan-Ganz catheter
 - c. Aneurysm clips
 - d. All of the above
- 17. It is acceptable to loop an insulated surface coil cable around a subject's arm or leg to help keep the cable from getting caught in the table.
 - a. True
 - b. False

- 18. Cryogens are ...
 - a. Industrial-strength cleaners
 - b. Sedatives
 - c. Liquefied gases used to cool a superconducting magnet and that are deadly to breathe
 - d. Sewer gases
- 19. A quench is ...
 - a. A relief of thirst for a hardworking technologist
 - b. A rain cloud that occurs inside of the magnet room due to overuse of the magnet by physicists
 - c. A rapid, usually undesired, release of the cryogens, which causes a rapid decline of the magnetic field
 - d. The German word for magnet
- 20. The first thing that you should do if a quench occurs is ...
 - a. Call 911
 - b. Call the service engineers
 - c. Immediately remove the subject from the scanner
 - d. Call the EPA (Environmental Protection Agency)
- 21. If during a quench the cryogens do not vent out of the room properly, a vacuum may form, making it difficult to open the door of the magnet room to get the subject out. If you are unable to open the door, you should ...
 - a. Sit and wait
 - b. Use a blow torch to burn through the door
 - c. Break the window between the control room and the magnet room
 - d. Panic
- 22. If your subject becomes short of breath while in the MR scanner, you should immediately grab the oxygen tank off of the crash cart and administer oxygen.
 - a. True
 - b. False
- 23. It is acceptable to let someone go into the magnet without emptying their pockets of metal objects if they are only going to be in there for <30 min.
 - a. True
 - b. False
- 24. Which of the following objects are approved for entry into the MR scanner room?
 - a. Stethoscope
 - b. Hemostats
 - c. Employee I.D. badges
 - d. Small paper clips and coins
 - e. None of the above

- 25. The system stop key will cut power to ...
 - a. All computer cabinets except for the gradient chiller cabinet
 - b. The lights
 - c. The fire alarms
 - d. The automatic sprinklers
- 26. If you get a message that the gradient chiller system is malfunctioning, you should immediately ...
 - a. Continue to scan because the chiller is on automatic controls
 - b. Run from the room screaming
 - c. Stop scanning to avoid overheating the gradient coils
 - d. Call 911
- 27. If the subject sets off the patient alarm during the scan you should ...
 - a. Page the MRI technologists
 - b. Tell the subject to be patient
 - c. Communicate with the subject to check on his/her status
 - d. Turn off the alarm and keep scanning
- 28. Which of the following are contraindications for MRI?
 - a. Cochlear implants
 - b. Neurostimulators
 - c. Patient-controlled anesthesia devices
 - d. All of the above
- 29. Pregnant women should never be scanned in our research facility.
 - a. True
 - b. False
- 30. Pregnant staff members are not permitted to enter the magnet room.
 - a. True
 - b. False
- 31. Which of the following is the correct method of investigating a metallic implant in a subject?
 - a. Take the subject's word that his/her implant is non-ferrous.
 - b. Call the surgeon responsible for placing the implant and get a detailed written operating room dictation explaining where the implant was placed, what it is, what it is made of, the manufacturer, and the model name and number
 - c. Ask the subject's family member
 - d. Call a physician referral service

- 32. Any time a patient is scanned for research purposes, a medical doctor or other qualified medical personnel associated with the study must be present or in the near vicinity, and available at all times.
 - a. True
 - b. False
- 33. An in vivo MR–compatible monitoring system is capable of measuring which of the following?
 - a. ECG and heart rate
 - b. Blood pressure
 - c. Blood oxygen saturation
 - d. All of the above
- 34. It is acceptable to leave a subject lying on the scan table outside of the magnet bore while you leave the room.
 - a. True
 - b. False
- 35. All subjects undergoing an MRI should be given ear protection in the form of earplugs with or without the noise cancellation headphones.
 - a. True
 - b. False
- 36. Every person that enters the magnet room should have completed a screening form regarding metal in the body.
 - a. True
 - b. False
- 37. It is mandatory that subjects remove all metal, metal jewelry, clothing with metal on it, and pocket contents before having an MRI scan.
 - a. True
 - b. False
- 38. Metallic objects in the body will produce artifacts on the images that look like ...
 - a. A black signal void with bright edges
 - b. A green streak
 - c. A line through the image
 - d. Pink swirls
- 39. If caught in the magnet room during a quench, where should you place your body to avoid inhalation of the cryogens?

d. Pressed up against the window between the scan room and the control room

- a. On top of the scan table
- b. Perpendicular to the main magnetic field
- c. As close to the floor as possible

- 40. The simplest way to stop a scan is to ...
 - a. Click the mouse on the "stop" (or its equivalent) button on the menu of the scan console
 - b. Quench the magnet
 - c. Turn the key off
 - d. Speak the word "stop" into the microphone
- 41. Which of the following is the correct reason to shut the MRI system down (not the magnetic field)?
 - a. Building utilities are to be shut off
 - b. The scanner applications have locked up
 - c. No one is going to be using the system for several hours
 - d. All of the above
- 42. When should the doors to the magnet rooms be shut?
 - a. When measurements are running
 - b. Whenever the system is not in use
 - c. Whenever there is the potential that someone not associated with the study will wander into the room
 - d. All of the above
- 43. If anyone asks you to take them into the magnet room to look at it, what do you do?
 - a. Take them right into the magnet room
 - b. Insist that they empty their pockets and then take them into the magnet room
 - c. Tell them absolutely not, under any circumstances, will you let them into the magnet room
 - d. Screen them for metal in their bodies as if they were patients, and if they are cleared, have them remove all loose metal from hair, pockets, and clothing, and then take them into the magnet room
- 44. All subjects must complete consent forms of some type before having MRI scans in the research facility.
 - a. True
 - b. False
- 45. A volunteer had an MRI scan 6 months ago and they are now participating in the research program again. What documents do they need to complete?
 - a. None, the ones they completed before are still good
 - b. Screening form only
 - c. Consent form only
 - d. Consent and screening forms

- 46. Under normal circumstances, when the MRI scan is not an emergency, how long must subjects who have had non-ferrous metal, e.g., orthopedic screws or plates, surgically implanted wait before undergoing an MRI scan?
 - a. 2 to 6 weeks
 - b. 5 years
 - c. 1 year
 - d. Forever
- 47. How long must subjects who have had ferrous metal devices that are not contraindicated for MRI, i.e., heart valves, venous blood clot filters, surgically implanted wait before undergoing an MRI scan?
 - a. 2 to 6 weeks
 - b. 5 years
 - c. 1 year
 - d. Forever
- 48. After completing a scan, you should ...
 - a. Leave the room clean and tidy
 - b. Leave the room as you found it
 - c. Leave the phantoms on the floor
 - d. Call the technologists to clean up the room
- 49. Ferromagnetic objects are dangerous to take near the magnet because ...
 - a. They can become projectiles and harm the subject
 - b. They will burn the subject
 - c. They become very heavy
 - d. There are too many north poles and the subject gets dizzy
- 50. The leads for cardiac gating must be handled as follows:
 - a. Wound together and routed down the center of the magnet
 - b. Run in parallel across the subject's chest
 - c. Placed on the shin of the subject
 - d. Coiled in a loop and placed across the subject's chest
 - e. None of the above
- 51. Echo-planar imaging and other sequences can be quite loud. You should ...
 - a. Tell the subject to grin and bear it
 - b. Have the subject cup his hands over his ears
 - c. Use earplugs with or without earphones to dampen the sound
 - d. Have the subject sing during the scan to dampen the sound

- 52. Consent forms must be signed by all subjects when non-FDA sequences are used.
 - a. True
 - b. False
- 53. While scanning a subject for a heart study, he suddenly complains of chest pain. You ...
 - a. Tell him to remain quiet until the sequence is finished
 - b. Ignore his complaints
 - c. Immediately remove him from the scanner, get him out of the room, and call 911
 - d. Give him a drink of water and put him back into the scanner to continue the exam
- 54. If ferrous devices and devices containing motors or questionable ferrous parts are needed in the magnet room, they should be secured when brought into the magnet room.
 - a. True
 - b. False
- 55. The 5-Gauss line is ...
 - a. A pixel line in the matrix
 - b. The magnetic field line territory at which the magnetic field can become harmful
 - c. A catheter inserted into the femoral artery
 - d. A geometric theorem
- 56. Where is the 5-Gauss line located in most MR facilities?
 - a. At the front door of the building
 - b. In the street in front of the building
 - c. Between the foot of the table and the RF window/screen, which is between the control room and the magnet room
 - d. At the opening of the magnet bore
- 57. When a subject is in the bore of the magnet, it is okay for the investigator or technologist to leave the control room ...
 - a. To check the weather outside
 - b. Whenever he/she feels like it
 - c. When he/she wants to get himself/herself a soda
 - d. If, and only if, he/she gets someone else to monitor the subject while gone
- 58. Potential subjects who have magnetically controlled artificial body parts or prostheses, such as artificial limbs or eyes, can not undergo an MRI exam.
 - a. True
 - b. False

- 59. Which of the following sequences tend to have the worst problems with RF power deposition?
 - a. Low flip angle RF spoiled gradient echo sequences
 - b. Spin echo, FLAIR (fluid attenuated inversion recovery), and turbo-spin echo sequences
 - c. TRUE FISP (true fast imaging with steady state free precession) sequences
 - d. Both b and c



Supplement 10

ANSWERS TO THE EXAM

| 1. b | 21. c | 41. d |
|-------|-------|-------|
| 2. e | 22. b | 42. d |
| 3. d | 23. b | 43. d |
| 4. d | 24. e | 44. a |
| 5. b | 25. a | 45. d |
| 6. d | 26. c | 46. a |
| 7. d | 27. с | 47. a |
| 8. d | 28. d | 48. a |
| 9. a | 29. a | 49. a |
| 10. b | 30. b | 50. b |
| 11. b | 31. b | 51. c |
| 12. a | 32. a | 52. a |
| 13. b | 33. d | 53. c |
| 14. b | 34. b | 54. a |
| 15. b | 35. a | 55. b |
| 16. d | 36. a | 56. c |
| 17. b | 37. a | 57. d |
| 18. c | 38. a | 58. a |
| 19. c | 39. c | 59. d |
| 20. c | 40. a | |
| | | |

ACKNOWLEDGEMENT

The authors would like to thank Professor E. Mark Haacke for his original input and continuing contributions, and Dr. Yu-Chung N. Cheng for his review of the material.

Contributed by Glenn Jay Foster Washington University St Louis, Missouri